Service Contract "Study on the Impact of (other than REACH/CLP) European Chemical/Waste Regulations on the Defence Sector"

Final report

20.ISE.OP.020

25 January 2021

REACHLAW
COMPLIANCE. SUSTAINABILITY.

milieu
Law & Policy Consulting

This Final Report has been drafted by Lucille Labayle, Julia Lietzmann and Lise Oulès of Milieu Consulting SRL, and Tim Becker of REACHLaw Ltd. (Article 9 WFD/SCIP Database work package) under Contract No 20.ISE.OP.020.

Milieu Consulting SRL, Chaussée de Charleroi 112, B-1060 Brussels, tel.: +32 2 506 1000; e-mail: julia.lietzmann@milieu.be; web address: www.milieu.be.

TABLE OF CONTENTS

FIGURES

TABLES

ABBREVIATIONS USED

AIA	Aerospace Industries Association
AIAD	Italian Industries Federation for Aerospace, Defence and Security
A&D	Aerospace & Defence
AF	Armed Forces
ASD	Aerospace and Defence Industries Association of Europe
B2B	Business to Business
BOM	Bill of Materials
BPC	Biocidal Product Committee
BPR	Biocidal Products Regulation (Regulation (EU) 528/2012)
CARACAL	Competent Authorities for REACH and CLP
CBI	Confidential Business Information
CFCs	chlorofluorocarbons
CJEU	Court of Justice of the European Union
CLP	Classification, Labelling and Packaging (Regulation (EC) No 1272/2008)
CMR	Carcinogenic, mutagenic and toxic for reproduction substances
CN	Combined Nomenclature (Annex I to Council Regulation (EEC) No 2658/87) on the tariff and statistical nomenclature and on the Common Customs Tariff
CoC	EDA Code of Conduct on REACH Defence Exemptions (March 2015)
CoP	Conference of Parties [to the Stockholm Convention]
COTS	Commercial Off-The-Shelf
CSS	Chemicals Strategy for Sustainability
DG CLIMA	Directorate-General for Climate Action
DG DEFIS	Directorate-General for Defence Industry and Space
DG ENV	Directorate-General for the Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DTIB	Defence Technological and Industrial Base
ECHA	European Chemicals Agency
EC	European Commission
EDA	European Defence Agency
EDEM	European Defence Equipment Market
EDTIB	European Defence Technological and Industrial Base
EEA	European Economic Area
EEA	European Environment Agency
EEE	Electrical and electronic equipment
ESA	European Space Agency
ETC/CME	European Topic Centre on Climate Change Mitigation and Energy
EU	European Union, comprising all EU Member States (currently 27)
EUPCS	European Product Categorization System. EuPCS webpage
EURITS	European Union for Responsible Incineration and Treatment of Special Waste
F-gas	Fluorinated Greenhouse Gas (Regulation (EU) No 517/2014)
GWP	Global Warming Potential
HCFC	Hydrochlorofluorocarbon
HFO	Hydrofluoroolefin
FMS	Foreign Military Sales
FMV	Swedish Defence Materiel Administration
Fn	Footnote
Hazmat	Hazardous Materials
IPR	Intellectual Property Rights
ITAR	The International Traffic in Arms Regulations (US)

IUCLID	International Uniform Chemical Information Database
LOI	Letter of Intent Framework Agreement Treaty of 27 July 2000 between France, Germany, Italy, Spain, Sweden and UK
MoD	Ministry of Defence
MoE	Ministry of Environment
MRO	Maintenance, Repair and Overhaul
MS	Member State
MSCA	Member State Competent Authority
NDIA	National Defence Industry Association
NEA	National Enforcement Authority
NGO	Non-governmental organisation
ODS	Ozone depleting substances
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
O5A	« Once an article, always an article »
OR	Only Representative (REACH Article 8)
PACT	Public Activities Coordination Tool
PBT	Persistent, Bioaccumulative, Toxic substance
PEG	Partner Expert Group
PFC	Perfluorocarbon
PIC	Prior Informed Consent Regulation (Regulation (EU) 649/2012)
pMS	(EDA) Participating Member State, 26 EU Member States (all except Denmark)
POPs	Persistent Organic Pollutants (Regulation (EU) No 2019/1021)
POPRC	POPs Review Committee
PPPR	Plant Protection Products Regulation
R&D	Research and Development
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
REFIT	Regulatory Fitness and Performance Programme
RMOA	Risk Management Option Analysis
RoHS	Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (Directive 2011/65/EU)
SAF	Swedish Armed Forces
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SDS	Safety Data Sheets
SEAC	Socio-Economic Assessment Committee
SME	Small and Medium-sized Enterprise
SSN	Simplified SCIP Notification
SVHC	Substance of Very High Concern
S2S	System to System
TARIC	TARif Intégré Communautaire; The integrated Tariff of the European Union database
TFEU	Treaty on the Functioning of the European Union
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
vPvB	Very persistent and very bioaccumulative substance
WFD	Waste Framework Directive (Directive 2008/98/EC, as revised by Directive (EU) 2018/851)
w/w	Weight by weight

EXECUTIVE SUMMARY

The 'Study on the Impact of (other than REACH/CLP) European Chemical/Waste Regulations on the Defence Sector' commissioned by the European Defence Agency in May 2020 provides detailed information on the implementation of selected EU chemicals and waste legislation and its impact on the defence sector, as well recommendations to tackle identified issues.

In a first part the study focuses on the following five pieces of EU chemicals and waste legislation[1] that are of concern for the defence sector:

- **Biocidal Products Regulation** (Regulation (EU) 528/2012),
- **Persistent Organic Pollutants Regulation** (Regulation (EU) 2019/1021),
- **Ozone Depleting Substances Regulation** (Regulation (EC) No 1005/2009),
- **Fluorinated Gases Regulation** (Regulation (EU) No 517/2014),
- **Restriction of the use of certain hazardous substances in electrical and electronic equipment** (Directive 2011/65/EU).

It explains the scope of and processes under the regulations, their interactions with REACH and CLP Regulations and among each other, and analyses their impacts on the defence sector.

In a second part, the study analyses the implementation of Article 9(1)(i) and (2) of the **Waste Framework Directive** (Directive 2008/98/EC).

The study builds upon the work carried out by REACHLaw in 2016 for the European Defence Agency (EDA) on the *'Impact of REACH and CLP European Chemical Regulations on the Defence Sector'*[2]. This previous study mostly focused on the impacts of REACH[3] and CLP[4] and looked briefly at the impacts of some other pieces of chemicals and waste legislation. The present study took this work as a starting point and provides a more in-depth overview of the impacts of selected pieces of chemicals' legislation other than REACH and CLP, and selected pieces of waste legislation on defence stakeholders[5].

The work on the Waste Framework Directive is a new component compared to the 2016 study, as the revision of the Directive that the study focuses on (i.e., the creation of the SCIP database) was introduced in 2018.

Methodology

The methodology for this seven-months study is based on a combined set of tools, namely documentary review, legal analysis, and stakeholder consultation.

The consultation aimed to gather input from main stakeholder groups implementing and/or affected by all six regulations/directives covered by the study. Questionnaires have been designed for each stakeholder group, namely:

- European institutions/agencies,
- National Ministries of Defence (MoDs),
- Member States' competent authorities responsible for the implementation of the regulations covered by the study (MSCAs),
- EU and national defence industry associations and their members,
- EU/international industry associations.

Thirty entities have provided information through the questionnaire. The stakeholder consultation has been complemented by interviews (via e-mail and telephone). The information provided through the questionnaires, together with (limited) literature sources and interviews, provided the evidence base for the study.

Key findings and recommendations

The following key findings and recommendations have been identified in the study (per regulation/directive within the scope of the study).

Biocidal Products Regulation

Requirements

Regulation (EU) 528/2012[6] (Biocidal Products Regulation – BPR) sets rules for the **approval of active substances in biocidal products** at EU level, the **authorisation of biocidal products** at Member State or EU level and the placing on the market of articles treated with biocidal products. It ensures that all biocidal substances and products undergo a risk assessment for toxicity to humans and the environment before they can be made available on the market.

Biocidal active substances are approved at EU level by the European Commission - following an evaluation carried out by a Member State Competent Authority (MSCAs) and the opinion of ECHA's Biocidal Products Committee (BPC)[7] - for a maximum period of ten years (or five or seven years if the substance presents specific concerns). Biocidal products are authorised at national level by Member States' Competent Authorities, with a possibility to use the mutual recognition process for authorisation in several Member States. Biocidal products can also be authorised at EU level through Union authorisations. Authorisations are granted for ten years – or five if the product contains substances of concern.

Article 2(8) of the BPR provides for the possibility that Member States **exempt specific uses of certain biocidal products, on their own or in a treated article, where necessary, in defence applications**. The exemption is not automatically granted but requires a decision on a case-by-case basis from the authority responsible for granting the exemption in the Member States (i.e., Ministry of defence (MoD) and/or MSCA), following an assessment that the exemption is necessary/linked with interests of defence. MoDs generally consider the Article 2(8) defence exemption as a last resort to be used only if complying with the BPR would impede the use of a critical product in defence applications.

There are **other derogation mechanisms** (not specific to defence) in the BPR that may enable Member States to temporarily authorise biocidal products that do not fulfil the conditions for authorisation. Article 55(1) of the BPR allows MSCAs to authorise, for 180 days, a biocidal product if such a measure is necessary to contain a danger to public health, animal health or the environment. Article 55(2) provides for a provisional authorisation, granted by MSCAs and the Commission, for three years, for a biocidal product containing a new active substance, before the approval process of the active substance is completed. A derogation for essential uses was introduced by Article 5 of Regulation (EC) No 1451/2007[8] (no longer in force) and maintained by Article 22 of Regulation (EU) No 1062/2014[9], for biocidal products containing a substance from the Review Programme which has not been approved or for which no approval dossier was submitted. The derogation allows to extend the deadline for removing the biocidal product from the market. This mechanism was used extending the use of copper for the prevention of biofouling in the pipework and waterway system of ships.

Impacts

The BPR is **consistent** with the REACH and CLP Regulations and with the other regulations covered by the study. The BPR uses definitions from the REACH Regulation and classifications under CLP to

define risk management measures (exclusion and substitution criteria). Synergies with the POPs Regulation exist as the PBT assessment under the BPR can support the identification of new POPs.

In relation to the defence sector, consulted stakeholders observed the **reduced availability of certain biocidal products** (such as insect repellents for textiles, antifouling products, or preservatives) and treated articles. Stakeholders reported that the reduced availability of products could lead to **reduced performance, reliability, or longevity of defence equipment**, and may raise issues for the maintenance of legacy equipment still in use. The unavailability of substances sometimes results from suppliers not applying for approval of active substances and/or authorisation of biocidal products because of lack of awareness of processes and deadlines (application starts late, only when the imminent threat to the product is understood) or lack of capacity (dossier submission is considered costly by suppliers of biocidal products).

Requirements of the BPR related to the **transfer of information on biocidal used in treated articles** in the supply chain are currently not fully implemented and this prevents defence industries from fully tracking biocidal uses in articles and ensuring compliance with the BPR and national procurement provisions requiring information on biocidal products used in procured equipment. This is more of a concern when suppliers are located outside the EU, as they are less aware of BPR requirements. Consequently, monitoring costs were reported to be significant for defence industries.

The Article 2(8) **defence exemption has barely been used**, in particular as it is considered by MoDs as a last resort. The defence exemption mechanism is considered as complex by defence industries as each exemption is only valid in one Member State. In addition, the **process for requesting an exemption at national level is not always clear** to defence industries – i.e. which institution to contact, which information to provide and in which format. The effectiveness of the exemption mechanism might also be limited, in particular as it only applies to defence applications and cannot be used to secure the use of a dual use substance in civil applications. As a result, the defence exemption does not prevent the risk of commercial obsolescence.

Recommendations

Recommendations to tackle these issues address:

- the impacts of the BPR on the availability of biocidal products for the defence sector by proposing discussing those impacts, as well as possible collective actions at EDA level;
- the low level of information in the supply chain on biocidal products used in treated articles by promoting awareness raising towards suppliers on the requirements of Article 58 of the BPR (labelling and communication obligations for treated articles); and
- the shortcomings of the defence exemption mechanism by proposing to provide easily accessible information to industry on the procedure to request a defence exemption at national level, and harmonise the implementation of the exemptions for defence across Member States.

POPs Regulation

Requirements

Regulation (EU) 2019/1021[10] on Persistent Organic Pollutants (POPs Regulation) is the main EU instrument implementing the Stockholm Convention and the UNECE POPs Protocol. It regulates the production, **placing on the market and use of POPs**, the management of stockpiles and wastes and measures to reduce releases of unintentionally produced POPs.

Annex I to the Regulation currently lists **29 banned POPs**, including pesticides and industrial chemicals. It includes exemptions for specific uses, reflecting the specific exemptions included in the

Annexes to the Convention. As a rule, the exemptions expire after five years but may be extended for another five years. Although there is no exemption mechanism specific to defence or military equipment, exemptions for defence/military uses may be granted in the Annexes to the Convention and in the POPs Regulation, as has been the case for decaBDE in civil and military aircrafts. Similar exemptions might be adopted in the future, in particular as other PFAS substances are likely to be listed in the Annexes to the Convention.

Regulation (EU) 2019/1021 (which repealed Regulation (EC) No 850/2004 – previous POPs Regulation) assigned new responsibilities to ECHA, including providing scientific support for the identification of new POPs and organising consultations on proposals for the inclusion of new POPs and on the risk profile and risk management evaluation prepared by the POP Review Committee of the Stockholm Convention. New POP candidates are identified through activities carried out under other legislation, Persistent, Bioaccumulative, Toxic (PBT)/very Persistent, very Bioaccumulative (vPvB) substances assessment in regulatory processes (especially Substances of Very High Concern (SVHC)[11] and Restriction) under REACH, PBT assessment in the BPR and Plant Protection Products Regulation (PPPR).

Proposals for new POPs are discussed with Member States at the Competent Authorities expert group and within the Council. These discussions, as well as the consultations organised by ECHA, provide **early opportunities for MoDs and defence industries to raise defence related issues** with regards to the inclusion of new POPs in the Convention and may propose specific exemptions for defence uses where necessary. As there are no possibilities for derogations once amendments to the Convention have been adopted, it is critical to manage potential impacts of the inclusion of a substance as early as possible in the regulatory process to ensure that appropriate exemptions can be proposed and negotiated at the POP Review Committee.

Impacts

The POPs Regulation is **consistent** with REACH and CLP. The Common Understanding paper[12] on the interaction between REACH and the POPs Regulation published by the Commission in 2014, identifies cases of potential overlaps between the two Regulations and explains agreed standard practice in those cases. The general rule in case a new POP is already restricted under REACH is that the entry in REACH Annex XVII is deleted. When the new POP is subject to authorisation requirements under REACH, and a conflict arise with the authorisations granted under REACH, a case-by-case analysis should determine whether to refuse or remove authorisations or temporarily delay the implementation of the amendment to the Convention through the POPs Regulation (by notifying the EU's non-acceptance of the amendment to the Convention to the Secretary General of the Convention). This last solution was used only in one case (Hexabromocyclododecane (HBCDD)). The POPs Regulation is also consistent with the other regulations covered by the study.

The POPs Regulation had until now **little impact on the availability of substances for defence equipment** because most substances listed in Annex I to the POPs Regulation have already been substituted. However, the inclusion of **PFOA** in the POPs Regulation had an **impact on the availability of surface treatments available for textiles** (for water and oil repellency and non-flammable properties). Inclusion of other **PFAS** substances in the Stockholm Convention is expected, following their inclusion in Annex XVII to REACH, which might impact the availability of substances meeting military standards for fire extinguishing equipment, military personal protection equipment and textiles. The substitution of long chain PFAS, such as PFOA, by short chain PFAS is therefore only a short-term solution and alternatives need to be secured when possible. Concerns were also expressed in relation to the potential inclusion of Octamethylcyclotetrasiloxane (D4), which has several uses, including naval paints. Impacts of potential future inclusion of substances in the Stockholm Convention and POPs Regulation need to be further assessed by MoDs.

According to the defence industry, **knowledge** of the POPs Regulation in the supply chain,

particularly in SMEs, is quite **low**, which creates problems and delays for defence industries in tracing POPs in defence equipment, as they mainly rely on information provided by suppliers. It remains difficult to constrain suppliers outside the EU to track and substitute POPs, even though the Stockholm Convention is an international Convention. Consequently, **monitoring costs** are significant for defence industries.

Recommendations

Recommendations therefore address the impacts of the POPs Regulation on the availability of substances for the defence sector by proposing discussing those impacts, as well as possible collective actions at EDA level. They also suggest ways to anticipate and manage earlier in the legislative process the possible impacts of the POPs Regulation by:

- Making use of the consultations organised by ECHA to flag necessary exemptions early on,
- Exploiting synergies with the restriction process under REACH where relevant to discuss relevant exemptions before the substance is nominated as a POP and send a signal to industry that the substance will eventually have to be substituted, and
- If considered feasible after informal discussion with the Commission the creation of a cooperation mechanism through which EDA would be informed by the Commission before the draft proposal of new substances proposed for inclusion in the Annexes of the Convention.

Ozone Regulation

Requirements

Regulation (EC) 1005/2009[13] on substances that deplete the ozone layer (the Ozone Regulation) supports the implementation of the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer but goes beyond by setting a higher level of ambition for the EU, establishing stricter phase-out schedules and covering a wider range of substances. Also, while the provisions of the Protocol for licensing system focus on the import and export of substances, the Regulation's licensing system also covers products and equipment containing or relying on those substances.

The Ozone Regulation defines a number of measures and requirements for Member States to regulate the use of ozone-depleting substances, in order to replace them with more climate-friendly alternatives. The Regulation aims for **controlling, monitoring and reporting** on the production, use, trade and handling of **ozone depleting substances (ODS)** and products relying on them, while ensuring the enforcement of ODS policies. **The controlled substances (alone or in a mixture, and virgin or recycled) are listed in Annex I to the Regulation and cover Chlorofluorocarbons (CFCs), Halons (1211, 1301, 2402), Carbon tetrachloride (CTC), 1,1,1- Trichloroethane (TCA), Methyl Bromide (MB), Hydrochlorofluorocarbon (HCFCs), Bromochloromethane (BCM)**. Furthermore, five additional 'new' substances are considered in Annex II, namely Dibromodifluoromethane (halon 1202), methyl chloride (MC), Bromoethane (ethyl bromide), trifluoroiodomethane (trifluoromethyl iodide), and 1-Bromopropane (n-propyl bromide). Article 13 of the Ozone Regulation provides for exemptions of 'critical uses' of halons (including military uses) which are permitted for a limited period. Annex VI to the Ozone Regulation specifies these critical uses along with progressive decommissioning dates. There are other derogation mechanisms (not specific to defence) defined in Chapter III of the Regulation.

Impacts

It is considered that there is consistency between the Ozone Regulation and the CLP Regulation that

are linked through the labelling requirements required for various ODS exempted from prohibition. Regarding REACH, ozone-depleting substances placed on the market generally fall under REACH and thus require registration and evaluation processes. It is noted that an exchange of information, as well as control mechanisms for substances, would enhance the coherence between the two Regulations. Some substances with ozone-depleting potential, such as very short-lived substances (VSLS), may already be restricted under REACH, while they might not be currently covered by the existing regime of the Ozone Regulation. It is noted that the Impact Assessment currently carried out aims at tackling this issue. The main interactions with other EU chemicals Regulations focus on the F-gas Regulation. The consultation carried out for this study showed that defence industries struggle with differentiating between the two. Some of the new substances identified may present characteristics that could qualify them to be regulated by both Regulations. Also, the reduction of ODS emissions fostered by the Montreal Protocol globally and the Ozone Regulation at the European level has led to the introduction of fluorinated gases (F-gases) as substitutes for ODS in sectors such as refrigeration and air conditioning applications. This becomes problematic when these F-gases subsequently are phased-down under the F-gas Regulation.

Overall, it appears that **requests for derogations from defence stakeholders have been limited**. However, the above-mentioned exemption under Article 13(1) of the Ozone Regulation concerning **critical uses of halons is of specific relevance for the defence sector**. According to the stakeholders consulted, halons, which are classified as "Ozone 1 (H420 – Hazardous to the Ozone Layer)" represent the most difficult group of substances to find workable alternatives for in the aerospace and defence industry. Therefore, the **time-limited exemptions granted under Article 13 are regularly used by stakeholders** and are considered to allow more flexibility than REACH authorisations, allowing stakeholders to have more time to search replacements. Most MoDs consulted have stated to comply with the requirements of the Ozone Regulation given the specific provisions provided for military uses. They only make use of halons when these cannot be replaced and try to work on the development of substitutes to the extent possible without jeopardizing the operability of the equipment and the safety of the personnel.

As far as MoDs are concerned, difficulties to manage the impacts of the Ozone Regulation mostly relate to the need to adapt their organisation to comply with the phase-out of certain substances and train their workforce to handle new substances for military uses. On the other hand, defence industry stakeholders highlighted difficulties for downstream users to identify restricted substances. The source of confusion regarding substance identification may then stem from the need to clarify which substances are specifically covered by the Annexes, underlining for instance that although the Ozone Regulation covers HCFCs, this does not concern all HCFCs.

During the consultation, several challenges to overcome in the coming years have been highlighted. First the risk of **unavailability of substances** represents an issue especially for products and equipment relying on controlled substances which have a long lifetime. Refilling those products or equipment may become more and more difficult. The **search for alternatives** may be complex as some alternatives have **not yet proven to meet minimum standards for use in military equipment**. However, it is noted that one positive impact of the Ozone Regulation identified was that the phase-out of substances **incentivised research for alternatives** and pushed discussions at the international level to introduce globally applicable phase-out dates. As a consequence, with the exception of aircraft fuel tank inerting, a majority of new design now integrate suitable alternatives (such as F-gases). There remains a challenge for existing systems still in operation.

Finally, all the stakeholders consulted identified several potential additional costs in relation to the implementation of the Regulation. **Logistics and administrative costs** are expected to reorganise and adapt the defence sector to the provisions of the Regulation. Further investments in R&D would also be necessary to search for innovative solutions and reduce the burden of alternative substances. The retrofitting of old equipment to comply with the Regulation will also lead to further spending as

substitutes may be more expensive than ODS. MoDs highlighted that there will also be **procurement costs regarding controlled substances as civil applications will decrease** along with the availability of these substances.

Recommendations

The recommendations developed in this study address:

- the **lack of awareness and information** among the defence sector concerning the nomination of substances for phase-down or phase-out under the Ozone Regulation making the Ozone Regulation part of a tool similar to the PACT tool of ECHA;
- the issue of **regrettable substitution** by a plea for streamlining the phase-out processes under the Ozone regulation and the F-gas Regulation (see below section on F-gas Regulation);
- the challenges linked to the phase out of ODS and the further costs foreseen by **providing strong incentives to pursue research and innovation** to find viable alternative substances which meet military standards.

F-gas Regulation

Requirements

Regulation (EU) No 517/2014[14] (F-gas Regulation) aims for the protection of the environment and the fight against climate change by reducing the emission of the **fluorinated greenhouse gases**, F-gases, by two thirds compared with 2014 levels by 2030. In accordance with the objectives of the Kyoto Protocol, it constitutes a pillar of the European Union's action against F-gases. With this Regulation, the European Union played a proactive role on the international stage and supported talks on actions on F-gases under Montreal Protocol on Substances that Deplete the Ozone Layer, which culminated with the adoption of the Kigali Amendment, which entered into force on 1 January 2019, and added HFCs to the list of controlled substances under the Montreal Protocol.

Pursuant to Article 2, the fluorinated greenhouse gases covered are **Hydrofluorocarbons (HFCs), Perfluorocarbons (PFCs), and Sulphur hexafluoride (SF6)**. These are all listed in Annex I to the Regulation, as well as Annex II for the other F-gases subject to reporting in accordance with Article 19. It is noted that the reduction in the use of F-gases relies on the notion of Global Warming Potential (GWP) which corresponds to the climatic warming potential of a greenhouse gas relative to that of carbon dioxide (Article 2). Annexes I, III, IV and V to the Regulation provide the specific GWP values allowed for each substance or mixture.

The use of F-gases **in military equipment benefits from several exemptions**, such as exemptions from the ban on uses of F-gases from January 2020 (Article 13(3)), and exemptions from bans on products containing F-gases are listed in Annex III to the Regulation Article 11(1). Article 11(3) provides that competent authorities are allowed to send a request to the Commission for a temporary exemption (up to four years) regarding the placing on the market of products and equipment relevant for Annex III if the authorities manage to prove that safe alternatives present a disproportionate cost or that none are yet available yet. Finally, pursuant to Article 15(2)(d) exemptions from the quota system established for placing on the market may concern uses in military equipment, too.

Overall, the implementation of exemption mechanisms can **vary across Member States**. Some MoD do use specific exemptions to meet the military standards set for the equipment and their functioning, while others try to avoid the activation of the exemption mechanism by decreasing the use of F-gases. However, most stakeholders noted that some military uses are very difficult to handle

such as refrigeration application or fire protection systems. In this case the use of F-gases can be authorised under the scope of the Regulation.

Impacts

None of the stakeholders interviewed underlined any inconsistencies with the REACH or CLP Regulations or any other EU chemicals regulation, except with the Ozone Regulation. The objective of the Ozone Regulation is to replace chlorofluorocarbon (CFC), hydrochlorofluorocarbon (HCFC) and halons with substances with a limited ozone-depleting potential since 2000. One of the solutions found was to substitute the regulated substances with hydrofluorocarbons (HFC) for refrigeration and as fire extinguishing agents. However, the F-gas Regulation requires the phase-out of HFCs in production and in maintenance (from 2020). Consequently, HFCs are now being replaced by hydrofluoroolefins (HFO). However, concerns were raised by the consulted stakeholders regarding the **technical performance characteristics of HFOs that may not fit within the design margins**, such as electric consumption or refrigeration power in terms of volume and mass or safety characteristics of the substances being phased out.

Further challenges regarding **regrettable substitution** were identified regarding the substitution of F-gases with a high GWP-value with other F-gases with a lower GWP-value, as this was the case for R 404a[15] (3921 GWP) which was replaced by R 134a[16] (1430 GWP). These substitutions can thus only constitute a temporary solution and a more sustainable alternative should be pursued. This represents a challenge particularly for fire protection applications for which military specifications ensure the safety of people inside vehicles.

In addition to the risk of potential substitutions between the Ozone Regulation and the F-gas Regulation, most of the consulted industry stakeholders agreed on the fact that the difficulty to find appropriate alternatives represented the main challenge of the F-gas Regulation. The main concern is that **some substitutes known to date are very flammable** and may not meet the existing standards for use in military applications. Moving away from F-gases with a high global warming potential, due to them being gradually phased out, is proving very difficult for the defence industry because F-gases with a low global warming potential are flammable, which is unacceptable in most air, maritime and land defence platforms. Existing legacy equipment is not going to be supported in the future if F-gases become obsolete and new equipment with non-F-gas alternatives are a fire hazard in a combat zone, according to some consulted stakeholders. Reformulation may lead to less effective refrigerants which may result in a use of larger volumes of refrigerants to gain the same effect and meet minimum standards for use in military applications. Furthermore, commercial obsolescence is also expected. Already some F-gases are beginning to disappear from the market. As these substances will no longer be used for civil applications, they will most likely become more expensive to purchase for use in military applications.

Finally, the implementation of the Regulation may entail some **potential additional costs** for the defence sector. There should be further **administrative costs** to ensure the supervision of regulatory changes, the implementation of provisions or the inventory and reporting obligations for specific substances. Consequently, an increase in the resources needed in terms of **manpower** (and the need for certified personnel) as well as **IT tools** to track substances is expected. There may also be some potentially higher costs to ensure the remodelling and redesign of old equipment. In fact, some MoDs underlined that reformulation could pose a problem, especially for refrigeration applications and fire protection systems. Lastly, **R&D** to identify alternative substances will also involve costs, which in turn may result in higher prices of the new substances than the currently available substances.

Recommendations

The recommendations developed in this study focus on the same measures proposed in relation to

the Ozone Regulation, hence:

- **increasing the level and timeliness of information** among the defence sector on legislative processes,
- providing **incentives to pursue research and innovation** to anticipate the phase-down of F-gases,
- as well as requiring the **mandatory identification of F-gases** in equipment by suppliers.

RoHS Directive

Requirements

Directive 2011/65/EU[17] provides for the restriction of the use of certain hazardous substances in **electrical and electronic equipment (EEE)**. EEE placed on the market must not contain the following substances in concentrations exceeding the limits provided in Annex II to RoHS: **lead, mercury, cadmium, hexavalent chromium, PBB, PBDE, and four phthalates (DEHP, BBP, DBP and DIBP)**.

Several groups of EEE are excluded from the scope of the RoHS Directive, including '*necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes*'. Other groups of EEE excluded from the scope of RoHS are also relevant to the defence sector, such as equipment designed to be sent into space, parts of non-scope equipment, large-scale fixed installations, means of transport for persons or goods, except two-wheeled electric vehicles, and non-road mobile machinery made available exclusively for professional use. However, in several Member States, the general approach followed in procurement is to require 'voluntary' compliance with the RoHS Directive whenever possible, even for equipment excluded from the scope of RoHS, and to require suppliers to report on the use of the Article 2(4) exemption. In addition, exemptions – i.e., temporary permissions for placing EEE containing certain restricted substances on the market – can also be granted for certain applications upon request from industry. Those exemptions are listed in Annex III and IV to the Directive.

According to Article 6(1) of the RoHS Directive, the list of substances restricted in EEE in Annex II to RoHS must be periodically reviewed by the Commission, on its own initiative or following the submission of a proposal for inclusion of a substance by a Member State. The first review was done in 2012-2014, the second in 2018-2020. The 2018 Substance review covered seven substances, two of which have been recommended for inclusion in Annex II to RoHS – Medium Chain Chlorinated Paraffins and Tetrabromobisphenol-A. Further assessment or increased scrutiny are recommended for some of the other substances.

Impacts

The **scope of the REACH Regulation and the RoHS Directive can partially overlap** since REACH applies to all substances, including in mixtures and articles, which means it also applies to substances in EEE which are covered by the RoHS Directive. Potential overlaps between the REACH Regulation and the RoHS Directive might occur when risk management measures are taken under REACH or RoHS for substances that are already regulated under one of the two. The **Common Understanding paper**[18], published by the Commission in 2014, identifies cases of potential overlaps between the two and outlines the agreed standard practice in those cases. A possibility highlighted by the paper to deal with overlaps is to exclude or remove EEE from the scope of REACH restrictions if the substance is included in Annex II to RoHS, or to exempt from the REACH authorisation requirement uses covered under the RoHS Directive. However, this approach assumes that RoHS provides the same level of protection as REACH, which can be challenged based on the fact that the RoHS Directive does not control the use of a substance in the manufacturing process of EEE or at the workplace (it only

restricts the substance in the end product) and that several categories of EEE are excluded from the scope of RoHS. In general, the study found that the Common Understanding paper does not provide guidance on interactions between RoHS and REACH Annex XIV and Annex XVII with regards to EEE that are excluded from the scope of RoHS, such as military equipment. Consulted MoDs pointed at potential inconsistencies between REACH and RoHS for defence/military EEE excluded from the scope of RoHS.

Both MoDs and defence industries did not report significant impacts on defence equipment due to the use of the scope exclusion. However, the RoHS Directive can **negatively impact the availability of equipment necessary for the defence sector**, in spite of the scope exclusion, because the defence industry relies significantly on civil equipment and Commercial Off-The-Shelf (COTS) electronic components, which must be compliant with RoHS. This has reduced the availability of certain components (e.g., components coated with tin-lead solder alloy) and the **suitability of some components for defence applications**, resulting in **higher costs** for defence industries (e.g., higher costs of components specifically transformed for defence use, costs of stockpiling those components).

In addition, the defence sector might be affected by the upcoming inclusion of substances in Annex II to RoHS, such as Tetrabromobisphenol-A (TBBP-A) and Medium Chain Chlorinated Paraffins (MCCP), recommended for inclusion by the 2018 substance review[19], and other substances not recommended for inclusion but that are under increased scrutiny, such as diantimony trioxide (ATO). However, the concrete impacts still need to be fully assessed by the defence industry and MoDs.

The defence industries indicated that the scope exclusion remains critical for some uses for which proven alternatives are lacking, to meet defence safety requirements. However, it was also reported that the scope exclusion slowed down the uptake of suitable alternatives – for example suitable lead-free soldering alternatives for some uses – and perpetuated obsolete uses, which could be at risk of being impacted by REACH (as lead has been added to the Candidate List).

Recommendations

The recommendations developed in this study address the interactions between REACH and RoHS by proposing

- a **revision of the Common Understanding paper** issued by the Commission, to provide adequate guidance in relation to categories of EEEs excluded from the scope of RoHS;
- the drafting of **additional guidance** from the Commission about the differences in concentration values between REACH and RoHS.

They also address the impacts of the RoHS Directive on the availability of substances for the defence sector by proposing discussing those impacts, as well as possible collective actions at EDA level.

Recommendations finally address means to **foster substitution of restricted substances** in defence uses for which alternatives suitable for the defence sector exist by proposing to:

- harmonise national approaches towards requiring voluntary compliance with RoHS for EEE excluded from the scope of the Directive;
- raise awareness of alternatives to lead soldering and other uses of restricted substances under RoHS for which suitable alternatives exist.

General recommendations for BPR, POPs, Ozone, F-gas, RoHS

The following recommendations have been developed applying to all the above-mentioned five regulations:

- Exchange of good practices in relation to procurement requirements;
- Monitoring of substances used in defence applications;
- Raising awareness on commonalities and differences as well as interactions between the different chemicals/waste regulations.
- Addressees of these recommendations are EDA and MoDs.

The priority of the recommendations is determined as a function of their implementation feasibility (difficulty) vs. the expected benefit (impact) for the European defence sector, as illustrated in an indicative way in the figure below.

Figure 1 - Recommendations for BPR, POPs, Ozone, F-gas, RoHS

WFD Article 9 / SCIP database

Requirements

The Waste Framework Directive 2008/98/EC (WFD), as revised by Directive (EU) 2018/851 which entered into force in July 2018, mandates the European Chemicals Agency (ECHA) to establish a database with information on articles containing Substances of Very High Concern (SVHCs)on the Candidate List established under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This database is named 'SCIP' (Substances of Concern In Products) database. EU Member States must ensure that any supplier of an article containing such SVHC(s) in a concentration above 0.1% weight by weight (w/w) provides the information pursuant to Article 33(1) of REACH to ECHA from 5 January 2021 – the so-called "**SCIP notification**". The SCIP database aims to ensure that the information about the presence of SVHCs is available throughout the whole lifecycle of products and materials, including at the waste stage. It was due to be established by 5 January 2020; the final database (SCIP v1.0) enabling the submission of SCIP notifications was launched on 28 October 2020, i.e., about two months in advance of the entry into application date of the SCIP notification requirement, subject to national transposition.

Article 9 WFD refers to Article 33(1) of REACH but the way SCIP is implemented at the EU level could potentially be interpreted as **going beyond the WFD/REACH legal text** in several aspects. This applies in particular to the **articles covered** (e.g., articles imported for own (final) use could be covered), and the **data to be provided**, especially category information, the product breakdown structure and related identifiers for complex object components to locate the SVHC(s). ECHA also requires information to be submitted via a specific format and is planning to publish the data submitted to the SCIP database on its website. With regards to the defence sector, the Commission (DG ENV) has clarified that a Member State may provide a specific exemption referring to Article 2(3) REACH or have recourse to Article 346(1)(a) of the Treaty on the Functioning of the European Union ("essential interests of its security").

The national transposition of Article 9(1)(i) WFD on SCIP notification is still pending in a number of Member States, in spite of the expiry of the transposition deadline on 5 July 2020. The analysis of national provisions in the area of defence shows that there are three different types of clauses: (1) Automatic exclusion from SCIP; (2) Case-by-case exemption upon request (cf. REACH Article 2(3)); (3) Upfront SCIP notification waiver.

Potential impacts

The study identifies potential impacts on MoDs from implementation of WFD Article 9 on SCIP in relation to the **setup and management of defence exemption processes** (where applicable), **potential security risks for MoDs in complex scenarios** and the possible existence of a SCIP notification duty for MoDs in some Member States consulted.

A survey conducted by the Aerospace and Defence Industries Association of Europe (ASD) amongst its membership in 2020 anticipates strong negative impacts on the aerospace and defence sector. It is estimated that more than 1 million notifications (comprising both civil and military business) will be submitted by the sector to the SCIP database in 2021. Notifications per company are expected to span from below 100 up to 200,000 per annum. The expected number of product declaration levels according to the SCIP requirements varies in average from 2 to 7 levels, with a typical value of 4 and a maximum of 12 (e.g., for the most complex objects like aircraft or armoured vehicles). It is expected, therefore, that not only SMEs will struggle with the **large scale and complexity of notifications** they need to make.

As a consequence, the defence industry (as reported by ASD) plans to analyse the national legal implementations of WFD Article 9 in respect of defence exemptions as a first priority. For remaining

notification obligations, the defence-sensitive / classified information and/or confidential business information (CBI) shall be protected in any case, notably through highly aggregated notifications.

As the provisions governing implementation of SCIP in the area of defence are to be implemented separately in each EU Member State, defence industry stakeholders consulted have expressed unanimously that their **harmonisation is of utmost importance** as supply chains are mostly transnational today and the industries involved cannot, or hardly, manage non-harmonised exemptions. According to anecdotal evidence from the defence industry consultation, precautionary SCIP notifications are envisaged for military products sold in the EU as of January 2021, unless there is a clear exemption.

Asked about the potential benefits of SCIP requirements from their perspective, defence industry stakeholders do support the overall intent of the circular economy, but have serious concerns linked to the SCIP database "one-size-fits-all" design and implementation. Defence products are not manufactured with the intention of being conventionally recycled, and they have bespoke instructions that determine how they should be disposed of.

For United States (US) military hardware supplied to the EU, the SCIP reporting requirements are found by the Aerospace Industries Association of America (AIA) to directly conflict with the requirement to safeguard product and technical information governed by the International Traffic in Arms Regulations (ITAR), to which the US defence industries are legally bound. The associated security risks may possibly pre-empt compliance with SCIP reporting requirements. According to AIA, therefore, the ability to provide US defence products to EU Member States could be impacted if defence exemptions cannot be secured.

The SCIP requirements / related views have been evolving during the study and are still evolving at EU (Commission and ECHA) and national levels (Member State transposition, including on defence-related provisions). SCIP notifications with view to the entry into application date for the notification duty as from 5 January 2021 according to WFD Article 9(1)(i) – subject to national transposition – have only started. Therefore, it is still very unclear how the system will finally work. Hence, the final impacts and implementation strategies of MoDs and the defence industry are still widely unclear or to be elaborated. The present SCIP analysis has been an important first step of a long process.

Recommendations

Recommendations within the realm of the study are primarily addressed to MoDs and/or EDA:

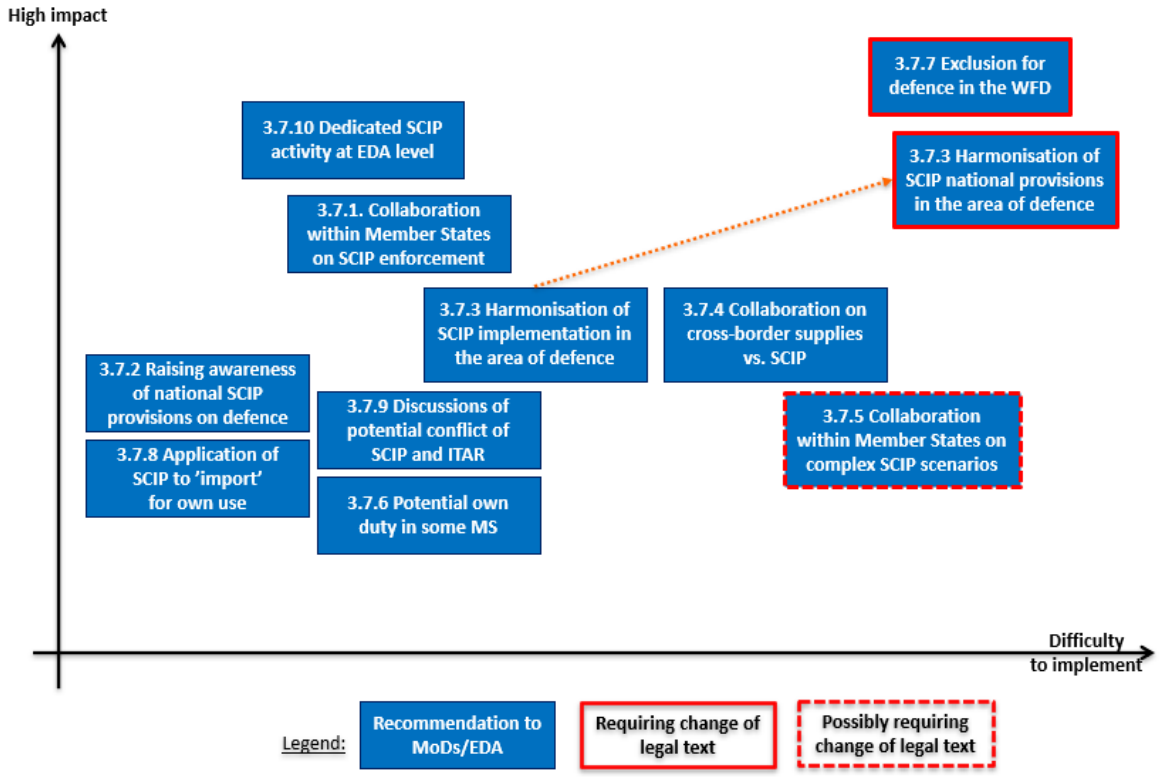
- Given the expected large scale and complexity of SCIP notification for defence (and related) industries and potential security risks for MoDs, **awareness raising with national enforcement authorities on specificities of defence products** with regards to SCIP is proposed.
- It is suggested to raise awareness of SCIP related provisions by adding to the **EDA website** information on national provisions governing SCIP implementation in the area of defence, including but not limited to defence exemption clauses, procedures and number of decisions.
- EDA with MoDs may consider possibilities to **harmonise the application of national provisions governing SCIP implementation in the area of defence**, including SCIP defence exemptions, where the Member State provisions are similar (e.g., a new EDA Code of Conduct to address WFD Article 9/SCIP database). If harmonisation within the existing national provisions cannot be achieved, possibilities to harmonise the legal provisions governing SCIP in the area of defence across Member States could be discussed.
- Collaboration between Member States is proposed in relation to **cross-border supplies**. It may result, for example, in 1) a joint exemption process for SCIP (where similar provisions exist), and 2) recognition of exemptions in the Member State of origin.
- In cases of complex SCIP scenarios, in Member States where a security risk for an MoD is

identified the MoD could enter discussions with the MSCA to obtain an **exemption from the SCIP notification**.

- Where applicable, MoDs are advised to identify actual cases where a **SCIP notification duty on their MoD/Armed Forces** is deemed to exist, and subsequently assess the use of SCIP defence exemptions.
- Follow up with the Commission (DG ENV) to obtain a **legal clarification** on whether SCIP notification based on WFD Article 9(1)(i) also applies to **'import' for own (final) use** is recommended.
- Together with MSCAs and the national defence industries, MoDs may assess further the necessity to propose to the Commission an **exclusion for defence from** the **SCIP** notification requirement **in the WFD legal text**.
- The **potential conflict of SCIP and ITAR requirements** for US military hardware could be discussed on a contract-by-contract basis between the MoDs concerned and their contractors. However, a discussion on possible solutions between EDA/MoDs and AIA should also be considered.
- The setup of a **dedicated SCIP activity at the EDA level** is recommended. As part of it the EDA, together with MoDs and in consultation with defence industry, EC and ECHA as appropriate, would further assess and elaborate solutions to mitigate the impacts of the evolving SCIP requirements for defence-related cases in the future, taking into account further experience gained in the meantime.

The priority of the recommendations is determined as a function of their implementation feasibility (difficulty) vs. the expected benefit (impact) for the European defence sector, as illustrated in an indicative way in the figure below.

Figure 2 - Recommendations SCIP



Recommendations addressing the **collaboration** on and **harmonisation** of SCIP implementation in the area of defence across different Member States and alleviation of possible adverse impacts to the defence industry are considered to be of the highest priority. At the same time, these recommendations contribute to the vital protection of **confidentiality** and avoidance of any supply disruptions in the defence sector due to SCIP. The recommendations addressing certain **legal issues** are also important to this end.

1 INTRODUCTION

1.1 CONTEXT AND OBJECTIVES OF THE STUDY

The 'Study on the Impact of (other than REACH/CLP) European Chemical/Waste Regulations on the Defence Sector' commissioned by the European Defence Agency in May 2020 provides detailed information on the implementation of selected EU chemicals and waste legislation and its impact on the defence sector, as well as recommendations to tackle identified issues.

In a first part the study focuses on the following five pieces of EU chemicals and waste legislation[1] that are of concern for the defence sector:

- Biocidal Products Regulation (Regulation (EU) 528/2012),
- Persistent Organic Pollutants Regulation (Regulation (EU) 2019/1021),
- Ozone Depleting Substances Regulation (Regulation (EC) No 1005/2009),
- Fluorinated Gases Regulation (Regulation (EU) No 517/2014),
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS),

It explains the scope of and processes under the regulations, their interactions with REACH and CLP and among each other, and analyses their impacts on the defence sector.

In a second part, the study analyses the implementation of Article 9(1)(i) and (2) of the Waste Framework Directive (Directive 2008/98/EC).

The study builds upon the work carried out by REACHLaw in 2016 for the European Defence Agency (EDA) on the 'Impact of REACH and CLP European Chemical Regulations on the Defence Sector'[2]. This previous study mostly focused on the impacts of REACH and CLP and looked briefly at the impacts of some other pieces of chemicals and waste legislation. The present study took this work as a starting point and provides a more in-depth overview of the impacts of selected pieces of chemicals' legislation other than REACH and CLP, and selected pieces of waste legislation on defence stakeholders[3].

The work on the Waste Framework Directive is a new component compared to the 2016 study, as the revision of the Directive that the study focuses on (i.e., the creation of the SCIP database) was introduced in 2018.

1.2 METHODOLOGY

1.2.1 Description of the Work Packages

The work was structured around the following six Work Packages, as set out in a management plan that was agreed between EDA and the contractor during the inception phase of the project:

[1] For simplicity reasons the five pieces of legislation are referred to as 'regulations' although they also include the RoHS Directive.

[2] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector. The study's final report is publicly available at https://www.eda.europa.eu/docs/default-source/documents/eda-reach-study-final-report-2016-december-16-p.pdf (Last accessed 02.10.220).

[3] The term "defence stakeholders" in this instance and throughout the study report has the meaning of "MoDs/Armed Forces and EU defence industry".

Table 1: Overview of Work Packages

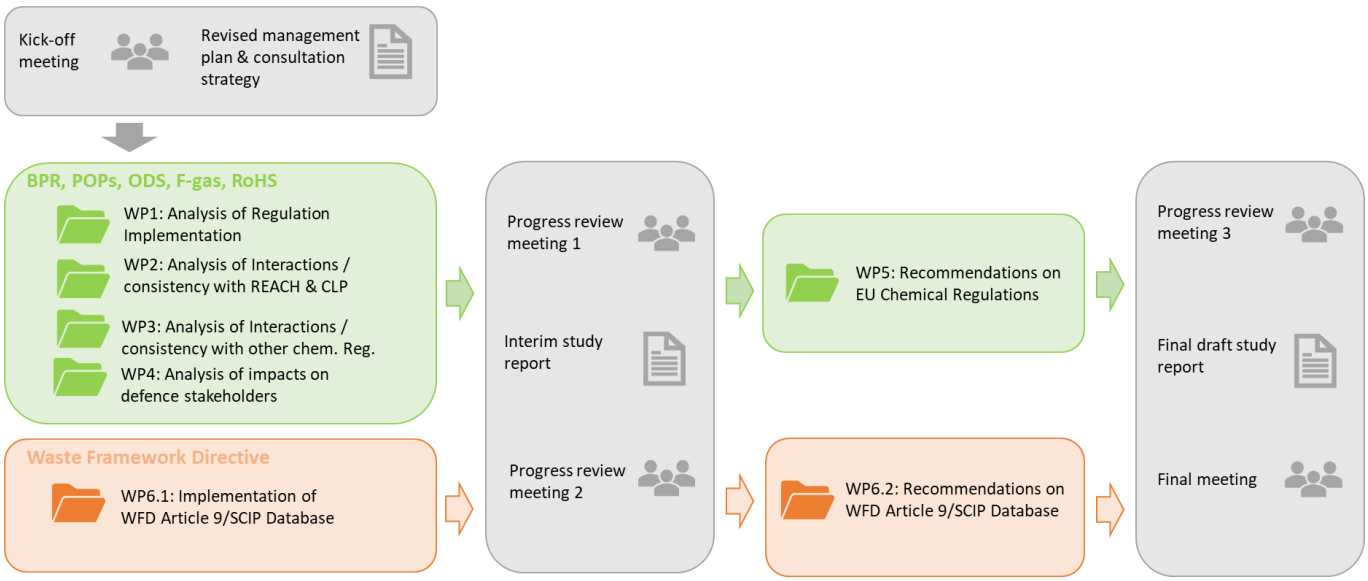
Legislation	Work Packages	Objectives
BPR POPs Regulation Ozone Regulation F-gas Regulation RoHS Directive	Work Package 1	▪ Provide the EDA with an overview of the implementation of the five selected pieces of EU chemical legislation – BPR, POPs Regulation, ODS Regulation, F-gas Regulation and the RoHS Directive. ▪ Provide an overview of the legal framework at international, EU and national levels (i.e. international agreements underpinning EU legislation, EU legislation and transposing measures in Member States in the case of the RoHS Directive). ▪ Include full mapping of the stakeholders involved in the implementation of the five pieces of legislation at EU and national level, and an overview of the past, ongoing and/or future initiatives – i.e. REFIT initiatives, proposals for amendments etc. ▪ Include full mapping of the substances impacted by the five pieces of legislation of the processes foreseen in each of them to further regulate substances – either already regulated substances or new ones.
	Work Package 2	Analyse the interactions between the five selected regulations and the REACH and CLP Regulations, to identify where there are inconsistencies, overlaps, gaps or conflicts.
	Work Package 3	Analyse the interactions between the five selected regulations with each other, to identify where there are inconsistencies, overlaps, gaps or conflicts.
	Work Package 4	▪ Gather information on how the different regulations are implemented by defence stakeholders, if there are exemptions[4] for defence in the regulations/directives, how defence stakeholders are using these exemptions, and the extent to which national authorities – Ministries of Defence – can ensure that their prerogatives are respected. ▪ Identify the main impacts on the defence sector and national Ministries of Defence and the potential undesired regulatory outcomes, such as regrettable substitutions.
	Work Package 5	▪ Develop recommendations based on the work carried out in Work Packages 1 to 4, and in particular, on the identification of the impacts of the five selected pieces of EU chemical legislation – BPR, POPs Regulation, ODS Regulation, F-gas Regulation, RoHS Directive, on MoDs and the defence industry: ▪ At EU level: to improve consistency with REACH/CLP and the other chemical/waste regulations and mitigate the impacts of inconsistencies/conflicts on MoDs and the defence industry; ▪ At EDA / national Ministries of Defence level, to mitigate impacts of the selected chemical/waste regulations to MoDs and defence industry and increase harmonisation in the implementation of the regulations across Member States.
Waste Framework Directive / SCIP	Work Package 6	Take stock and elaborate on the implementation and impacts of WFD Article 9 and SCIP Database.
	Work	▪ Analyse ECHA's implementation of SCIP notification and database, as

[4] Exemption can be defined, based on the 2016 EDA study as 'any exception from the application of standard requirements of the legislation in question for certain cases foreseen in the legal text, be it in full, with respect to specific requirements, or subject to a case-by-case decision by an authority. However, for the purpose of RoHS Article 2(4) the term "disapplication" as the common denomination by some MoDs is used for lit. (a) and "exclusion" for the other cases listed'. The term "exclusion" (from the scope) is also used where military products or uses are taken out of the scope of the legislation or specific requirement automatically fully or partly (without the need to grant case-by-case exemptions).

Legislation	Work Packages	Objectives
database	Package 6.1	well as national transposition rules in the 26 EDA participating Member States, including defence aspects. ■ Analyse impacts of WFD Article 9 and SCIP Database on MoDs and the defence industry.
	Work Package 6.2	■ Develop recommendations based on the work carried out in Work Package 6.1: ■ Recommendations towards the EDA and national MoDs, and in consultation with the defence industry (as needed), on the implementation of WFD (Article 9), including on the mitigation of related impacts especially for MoDs; ■ Recommendations to the defence industry as necessary on the implementation of WFD (Article 9) and mitigation of impacts. The need for such recommendations through this study will also rely heavily on the outcome of the consultation with industry, especially ASD.

The figure below provides an overview of the main tasks and project milestones.

Figure 1: Overview of project tasks and main deliverables



The methodology for this 7-months study is based on a combined set of tools, namely documentary review, legal analysis, and stakeholder consultation.

1.2.2 Documentary review

The study relied on a variety of sources, such as articles and studies, documents published by EU institutions or national governments, documents or position papers from industry, trade journals or market studies. There was almost no scientific literature available on the impact of the regulations on the defence sector. The list of sources is presented in the **Bibliography**.

1.2.3 Legal analysis

The different Work Packages include, as a starting point, a review and analysis of the legal text of the

different regulations. In particular, Work Package 1 includes a full mapping of the substances impacted by the five pieces of legislation or by the processes foreseen in each of them to further regulate substances – either already regulated substances or new ones. Work Packages 2 and 3 review the legal texts to identify the interactions between the different pieces of legislation. The contractor looked in particular for cross-references and defence related elements, including exemptions as applicable. This also includes a mapping of provisions restricting or prohibiting the production, placing on the market and use of substances in the regulations to identify similarities and differences that might lead to overlaps or conflicts in a way one substance can be regulated under different regulations. Work Package 4 includes a review of the defence related elements, including defence exemptions, as applicable, in the various pieces of legislation. Attention is paid to the scope of the exemptions, including, in particular, whether they cover dual use. Finally, the contractor considered relevant EU case law in the study.

1.2.4 Stakeholder consultation

A stakeholder consultation has been carried out which was based on a Consultation Strategy agreed between EDA and the contractor during the inception phase. A list of all consulted stakeholders is provided in Annex I to this report.

Questionnaire

The consultation aimed to gather input from main stakeholder groups implementing and/or affected by all six regulations/directives covered by the study. Questionnaires have been designed for each stakeholder group, namely:

- European institutions/agencies;
- National Ministries of Defence (MoDs)[5];
- National competent authorities responsible for the implementation of the regulations covered by the study (MSCAs)[6];
- EU and National Defence Industry Associations (NDIAs)[7] and their members (focusing on all six regulations/directives);
- EU/international industry associations (CEFIC, Critical Raw Materials Alliance, International Antimony Association, the International Lead Association, Eurometaux, CII, the European Recycling Industries' Confederation (EuRIC AISBL), SME United, and Enterprise Europe Network).

The full list of stakeholders contacted is provided in Annex I to this report.

Questionnaires were divided into two main parts corresponding to the two components of the study: the first part covers the five following regulations/directives: BPR, POPs Regulation, ODS Regulation, F-gas Regulation, and the RoHS Directive. This part included a first set of questions concerning the implementation and impacts of the five regulations/directives and a second set of questions related to interactions between those regulations/directives with REACH/CLP and with each other, and their

[5] While during the inception phase, all EDA pMS MoDs were invited by EDA to participate in/contribute to the study consultation, seven (7) MoDs (France, Germany, Italy, Netherlands, Romania, Spain, and Sweden) eventually expressed interest and participated. When reference to MoDs is made in the study (e.g. on consultation outcome) this is meant to reflect the specific MoDs mentioned only.

[6] The exact MSCAs that were targeted for consultation were chosen in coordination with EDA and the MoDs that expressed interest to participate to the study consultation.

[7] The exact NDIAs that were targeted for consultation (further to consultation with NDIAs as members of ASD) were chosen in coordination with EDA and the MoDs that expressed interest to participate to the study consultation.

regulatory consistency. The second part covered Article 9 of the revised Waste Framework Directive and the implementation of the SCIP database.

Questionnaires were submitted for consultation with EDA and Member States' experts on 3 June 2020, and subsequently revised. The consultation was launched by e-mail on 17 June 2020. The deadline for responding to the consultation was set to 17 July 2020 for EU institutions and MoDs, and 31 July 2020 for ASD, NDIAs and defence industries. Reminders were sent between the launch of the stakeholder consultation and October 2020.

Thirty entities provided the filled-in questionnaire. They are indicated in the table below:

Table 2: Completed questionnaires received

Stakeholder groups	Responses received
European Commission	DG ENV B.2 Sustainable Chemicals
ECHA	ECHA Dir. B/Exposure and Supply Chain Unit WFD/SCIP ECHA Hazard Assessment III
MoDs	France, Germany, Italy, Netherlands, Romania, Spain, Sweden
MSCAs	France (BPR, POPs, ODS, F-gas), Germany (BPR, POPs, ODS, F-gas), Netherlands (POPs, ODS, F-gas), Romania (POPs, ODS, F-gas, RoHS), Sweden (BPR, POPs, ODS, F-gas, RoHS, WFD/SCIP)
EU aerospace and defence association	ASD
NDIAs[8]	ROMARM (Romania), SOFF (Swedish Security and Defence Industry Association)
Other EU/international industrial stakeholders	EuRIC AISBL (sent a position paper regarding SCIP), Etienne Lacroix Group, RUAG Ammotec, Rheinmetall, Enegothech, CMR Alliance.
Non-EU/US Industry Association	AIA[9]

The stakeholder consultation has been complemented by interviews (via e-mail and telephone). The information provided through the questionnaires, together with literature sources and interviews, provided a solid evidence base for the study.

Interviews

For WP 1-5, the contractor considered telephone interviews with the Commission and ECHA more effective than sending questionnaires. First contacts were made in the first week of September 2020 to arrange interviews. An interview was carried out with DG CLIMA.A.2 Climate Finance, Mainstreaming, Montreal Protocol on 6 October 2020. An interview with DG ENV.B.3 has been carried out on 16 November 2020 concerning the RoHS Directive.

For WP 6, an interview was conducted with SMEunited represented by its Austrian member Wirtschaftskammer Österreich (WKÖ) on 1 September 2020.

[8] A few NDIAs indicated that they would not respond individually but had contributed to the response of ASD or agreed with it (GIFAS – French Aerospace Industries Association, BDSV - Federation of German Security and Defence Industries and BDLI - German Aerospace Industries Association).

[9] The US Aerospace Industries Association expressed unsolicited interest to/provided input/questionnaire response, without being a study targeted stakeholder. Following consultation with EDA, the AIA input was accepted by the contractor and considered in the study report.

External events relevant for the study

On 9 July 2020, following prior coordination between EDA, the Commission and ECHA, the contractor participated as an observer in the Joint Meeting of the Expert Groups on Waste and CARACAL – Open Session on SCIP. Prior to the meeting, the contractor submitted a written question to the meeting participants dd. 30 June 2020 concerning the applicability of the SCIP notification to 'import' for own (final) use. Answers or comments on contractor's question were not received during the meeting. The contractor provided a meeting summary for EDA and MoD REACH experts dated 10 July 2020.

Comments on the draft final report

In addition to MoDs (which were given the opportunity to comment on all deliverables), the draft final report (not including the sections related to recommendations which were under development at the time) was sent on 17 November 2020 to the Commission (namely DG CLIMA, DG DEFIS, DG Environment, DG GROW, DG SANTE), ECHA, and ASD for review. They were given until 30 November 2020 to provide informal comments at working level on the draft final report, if/as they considered necessary, to be considered by the contractor when finalising the study final report. Informal feedback was indeed received from DG CLIMA on the sections related to the Ozone and F-gas Regulations, DG Environment on the section related to the WFD/SCIP database, DG SANTE on the section related to the BPR, ECHA on the sections related to the BPR, POPs Regulation, and WFD/SCIP database, and ASD on the sections related to the RoHS Directive and the WFD/SCIP database. These useful informal comments were incorporated by the contractor to the extent possible, in the study final report.

1.2.5 Project meetings

Five project meetings have been held. The following table presents the meetings and topics.

Table 3: Project meetings

Meeting	Timing	Place	Agenda	Deliverables
Kick-off meeting	Month 0 – 25 May 2020	Virtual meeting through Webex	▪ Project organisation ▪ Management Plan ▪ Consultation Strategy	▪ Draft Management Plan ▪ Draft Consultation Strategy ▪ Presentation
Progress Meeting 1	Month 1 –25 June 2020	Virtual meeting through Webex	▪ Progress WP 1, 2, 3, 4 and 6.1.	▪ Progress report ▪ Presentation ▪ Final Management Plan ▪ Final Consultation Strategy
Progress Meeting 2	Month 4 – 30 September 2020	EDA (Brussels) and through Webex (MoDs, REACH Law)	▪ Progress WP 1, 2, 3, 4 and 6.1. ▪ Initial considerations and work Plan WP5 and 6.2	▪ Progress report ▪ Initial considerations and work Plan WP5 and 6.2 ▪ Presentation
Progress Meeting 3	Month 5 – 27 October 2020	Virtual meeting through Webex	▪ Final results WP 1, 2, 3, 4 and 6.1. ▪ Progress on WP5 and 6.1	▪ Draft Interim study report ▪ Outline of WP5 and WP6.2 Presentation
Final meeting	Month 6 – 23 November 2020	Virtual meeting through Webex	▪ Draft final results on all WPs	▪ Draft final study report ▪ Presentation of the draft final study

Because of the COVID-19 pandemic, all meetings have been organised online, through Webex. During

the Second Progress Meeting, EDA and part of contractor's team met and conducted the meeting physically, at EDA premises, while facilitating in parallel an online meeting for remote attendees. The MoD representatives participated in all meetings through Webex.

1.2.6 Glossary and list of substances

A **glossary** of terms used in the study is provided in Annex I to this report; as well as a **list of substances** referred to in this report in Annex IX.

2 IMPACTS OF SELECTED CHEMICALS AND WASTE REGULATIONS ON DEFENCE STAKEHOLDERS

2.1 BIOCIDAL PRODUCTS REGULATION (REGULATION (EU) 528/2012)

The Biocidal Products Regulation sets rules for the **approval of active substances** in biocidal products at EU level, the **authorisation of biocidal products** at Member State or EU level and the placing on the market of articles treated with biocidal products. It ensures that all biocidal substances and products undergo a risk assessment for toxicity to humans and the environment before they can be made available on the market. The Regulation, which was adopted in 2012 and entered into force in 2013, replaced the 1998 Biocidal Products Directive. The Regulation applies in the European Economic Area (EEA) (i.e., EU Member States and Iceland, Liechtenstein and Norway) and in Switzerland (on the basis of a Mutual Recognition Agreement with the European Union)

Biocidal active substances, for which an application for approval has been submitted, are approved at EU level by the European Commission - following an initial assessment carried out by a Member State Competent Authority and the opinion of ECHA's Biocidal Products Committee - for a limited period of time. Biocidal products are authorised at national level by Member States' Competent Authorities, through mutual recognition of national authorisations, or through Union authorisation by the Commission at EU level. The BPR also contains rules for phasing out substances of concern and replacing them with safer alternatives (exclusion criteria listed in Article 5(1) and substitution criteria listed in Article 10 of the BPR – see section 2.1.1.5). Scientific criteria for the determination of endocrine-disrupting properties were established and are applicable since June 2018[10].

2.1.1 Implementation of the Regulation

2.1.1.1 Scope of the Regulation

The BPR applies to biocidal products[11], which fall into one of the 22 product types listed in Annex V to the Regulation (*'Biocidal product-types and their descriptions as referred to in Article 2(1)'*), and to treated articles[12]. Product types are grouped into four main groups:

- Disinfectants,
- Preservatives,
- Pest control, and
- Other biocidal products.

The list of the 22 product types is available in Annex III to this report.

Article 2(2) excludes from the scope of the BPR any biocidal products or treated articles that would fall under other EU legislation such as medicinal products for human and veterinary use, food and

[10] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.

[11] A substance or mixture which perform a biocidal function, i.e. *'destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action'* as defined in Article 3(1) of the BPR. A treated article that has mainly a biocidal function is considered as a biocidal product.

[12] Treated article - substances, mixtures or articles which have been treated with, or intentionally incorporates, one or more biocidal products but does not perform in itself a biocidal function (Article 3(1)(l)).

feeds, food additives, toys, medical devices, cosmetic products, and pesticides.

As active substances are approved for a specific product type (listed above), different applications for approval must be submitted for each product type – as a result, one substance can be approved for one product type and not approved for another product type. The list of active substances for which an application for approval has been submitted by product type is available on ECHA's website[13], as well as information on approved active substances and biocidal products authorised on the EU market[14]. In addition, ECHA publishes the list of the respective substance and product suppliers, in accordance with Article 95 of the BPR. Since 1 September 2015, a biocidal product cannot be made available on the EU market unless the substance supplier or the product supplier is included in the Article 95 list for the product type(s) for which the substance is approved or under review (Article 95(2)). This list is also available on ECHA's website[15].

Treated articles can only be placed on the market if they are treated with biocidal products containing active substances approved in the EU.

2.1.1.2 Exemptions, transitional measures and derogations

Defence exemption

Article 2(8) of the BPR provides for the possibility that Member States exempt specific uses of certain biocidal products, on their own or in a treated article, where necessary, in defence applications. More specifically, Article 2(8) of the BPR states the following: "*Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.*"

The exemption is **not automatically granted** but requires a decision on a case-by-case basis from the authority responsible for granting the exemption in the Member States (following an assessment that the exemption is necessary/linked with interests of defence).

The table below summarises the procedure for granting an exemption in consulted Member States (i.e., which authority receives the exemption request, which authority assesses the interest of defence, which authority grants the exemption, and whether the procedure is formal – established by law – or informal – not established by law). The exemption is often granted by the MoD (FR, DE, ES, SE), sometimes in consultation or jointly with the MSCA (FR, SE), or in one case by the MSCA (NL,). Romania is not included in the table below as the national law does not provide for the possibility of granting defence exemptions. Italy is currently revising their BPR procedures and is therefore also not included in the table.

[13] Information on biocides: https://echa.europa.eu/fr/information-on-chemicals/biocidal-active-substances (Last accessed on 01.10.2020).
ECHA > Information on Chemicals > Biocidal Products Regulation > Biocidal Active Substances.
[14] Information on biocides: https://echa.europa.eu/information-on-chemicals/biocidal-products
ECHA > Information on Chemicals > Biocidal Products Regulation > Biocidal Products.
[15] Information on biocides: https://echa.europa.eu/information-on-chemicals/active-substance-suppliers
ECHA > Information on Chemicals > Biocidal Products Regulation > List of active substances and suppliers.

Table 4: Authorities involved in the process of granting BPR defence exemptions according to Article 2(8)

Member State	Authority receiving the defence exemption request	Authority identifying the interests of defence	Authority granting the defence exemption	Formal / informal procedure
France	To be determined by Decree (likely MoD)	MoD	MoD jointly with the MSCA (Ministry of Ecological Transition)	Formal procedure – Decree being drafted, not yet adopted
Germany	Procurement agency (BAAINBw)	Bundeswehr Responsible Authority for Hazardous Substances at BAIUDBw	MoD	Informal procedure
Netherlands	MoD	MoD	MSCA (Ministry of Environment) in consultation with Board for the Authorisation of Plant Protection Products	Informal (MSCA uses EDA REACH CoC as point of reference)
Spain	MoD	MoD	MoD	Informal procedure
Sweden	Department of Defence Inspector	Department of Defence Inspector	Department of Defence Inspector in consultation with the MSCA (Swedish Chemicals Agency)	Formal procedure (SFS 2014:425, chapter 3, paragraph 6)

Germany, Netherlands and Spain have indicated that the procedure is informal (e.g., internal guidelines/procedure). France and Sweden have procedures established by law. In France, a ministerial decree is being drafted to describe the procedure for applying, evaluating and granting a defence exemption. According to the French MSCA, the process will closely follow the procedure implemented under the REACH Regulation.

No exemptions have been granted under Article 2(8) of the BPR in most Member States covered by the study (FR, DE, ES, IT, RO, SE) so far. One exemption was granted in the Netherlands for a substance. In Germany, applications for exemptions have been received from contractors. These are currently reviewed by the Federal Office for Infrastructure, Environmental Protection and Services (BAIUDBw). Defence industries that returned the questionnaire also indicated that they had not requested an exemption under Article 2(8) of the BPR.

Five MoDs indicated that the exemption mechanism under the BPR (Article 2(8)) should only be used as a **last resort**, when complying with the BPR is not possible. Several MoDs indicated that the granting of an exemption in their countries, requires an application from the contractor justifying the request. Three MoDs indicated that compliance with the BPR is required in **procurement contracts** for both biocidal products and treated articles. For instance, in Sweden, suppliers are required to provide information on biocide uses and safe handling of products, based on a specific criteria document (available in Annex IV to this report). In the Netherlands, the MoD maintains the List of Banned and Restricted Substances (LBRS), including biocides, which is part of procurement requirements. This list is available in Annex V to this report.

Derogations under Article 55 of the BPR

Article 55(1) of the BPR allows Member States' competent authorities to authorise, for a period not exceeding **180 days**, a biocidal product that does not fulfil the conditions for authorisation under the BPR (Article 17 and 19), *'for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a **danger to public health, animal health or the environment which cannot be contained by other means'***. Article 55(1) can be applied to all biocidal products. In cases where the active substance is a new active substance (i.e., was not present on the EU market before 14 May 2000, as further defined in Article 3(1)(e) of the BPR), Article 55(2) on transitional authorisations can apply (see below).

The derogation under Article 55(1) can only be granted by a Member State for application in the national territory. The competent authority must inform other competent authorities and the Commission of the derogation, its duration and justification. The competent authority may request the Commission to **extend the derogation for a period not exceeding 550 days**. The Commission decides, by means of an implementing act, whether the extension can be granted. Article 55(1) derogation may be used by MSCAs, including for defence uses in emergency situations, only if the above-mentioned conditions are met.

Article 55(2) provides that a **provisional authorisation** can be granted by MSCAs and the Commission, for a period not exceeding **three years**, to a **biocidal product containing a new active substance, before the approval process of the active substance is completed**. The provisional authorisation applies in cases where the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, ECHA, consider that the biocidal product meets the conditions for granting an authorisation (Article 19 of the BPR). If after the three-year period the approval process of the active substance is still not completed, the provisional authorisation can be extended for one year maximum if there are good reasons to believe that the active substance will be approved. In such cases, other competent authorities and the Commission should be informed of the extension. Article 55(2) is likely to be used by MoDs in more cases than Article 55(1), which is only applicable for emergency situations related to imminent dangers to public health, animal health, or the environment.

Transitional measures

Article 89(2) of the BPR allows Member States to continue to apply their national system or practice of making available and use of biocidal products containing an active substance included in the Review Programme for a given product-type for up to three years after the date of its approval. In case of non-approval of the active substance, national rules can only apply until one year after the non-approval decision.

Derogations for essential uses

Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC (Biocidal Products Directive), which is no longer in force, provided that biocidal products containing active substances from the first phase of the Review Programme that had not been approved or for which no approval dossier was submitted, could not be placed on the market. Member States could, however, apply, according to Article 5 of Regulation (EC) No 1451/2007, for a **derogation to obtain an extension of the deadline for removing the biocidal products containing the non-approved active substance** in cases *'where they considered that an active substance was essential for them for reasons of health, safety or protection of cultural heritage or was critical for the functioning of society, and for which there no technically available and economically feasible alternatives or substitutes that were acceptable from the standpoint of*

environment and health'.

Article 5 of Regulation (EC) No 1451/2007[16] was used for extending the **use of copper in marine growth prevention systems**. Following Commission Decision 2012/78/EU, no complete dossier was submitted for the approval of copper as an active substance, and biocidal products containing copper could not be placed on the market for use in product-types 2, 5 or 11 after the transitional period (February 2013). Several Member States therefore submitted applications to the Commission to allow the placing on the market of biocidal products containing copper for a number of uses, including for Product-type 11 for 'the prevention of biofouling of the water inlet/pumps and throughout the entire pipework and waterway system of a ship'. Those derogations were granted by Commission Decision 2014/395/EU and 2014/459/EU[17] providing that these Member States may allow the placing on the market and the use of biocidal products containing Copper for the uses specified in the Decision.

Eventually, dossiers for the approval of copper for the product-types relevant to those uses were submitted and validated as complete by the evaluating Member State by 31 December 2014 at the latest, in which case, Member States could continue to allow the placing on the market of the biocidal products until the deadlines provided for in Article 89(2) of the BPR. The examination of these dossier is still on-going to date.

Commission Delegated Regulation (EU) No 1062/2014[18] on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in the BPR, which repealed Regulation (EC) No 1451/2007, maintained the **possibility for derogations for essential uses** (Article 22 of Commission Delegated Regulation (EU) No 1062/2014). No such derogation for essential use has been applied under Commission Delegated Regulation (EU) No 1062/2014. Member States can apply for a derogation to transitional measures referred to in Article 89(2) of the BPR, within 18 months of the date of a decision not to approve an existing active substance, for the same reasons as under Regulation (EC) No 1451/2007. The requesting MSCA should submit a reasoned application to ECHA through the register, and, as under Regulation (EC) No 1451/2007, the Commission is responsible for granting the derogation. If the derogation is granted, Member States should:

- Ensure that continued use is limited to the conditions of the derogation;
- Impose appropriate risk mitigation measures;
- Ensure that alternatives are being sought, or that an application for approval of the active substance is being prepared for submission in accordance with Article 7 in due time before the expiry of the derogation.

2.1.1.3 Governance

European Commission

DG SANTE, Unit E.4 is the competent unit in the Commission for the implementation of the BPR. It

[16] Commission Regulation (EC) No 1451/2007of 4 December 2007on the second phase of the 10-year work programme referred to in Article 16(2) of Directive98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12.2007, p.3-65.

[17] Commission Decision 2014/395/EU of 24 June 2014 concerning the placing on the market for essential use of biocidal products containing copper, OJ L 186, 26.6.2014, p.103-107. Commission Decision of 10 July 2014 concerning the placing on the market for essential use of biocidal products containing copper

[18] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014, p. 1–34.

has in particular the following responsibilities:

- Propose decisions for the approval, non-approval of active substances and renewal or not of approval;
- Propose decisions for Union authorisations of biocidal products;
- Propose decisions in relation with Member States' requests for derogation or extension of derogations under Article 55(1) of the BPR, or essential uses in application of Commission Delegated Regulation (EU) No 1062/2014;
- Propose delegated acts on amendments to Annex I to the Regulation ('*List of substances referred to in Article 25(a)'*)– i.e., amendments to the list of substances eligible for the simplified authorisation procedure (see section 2.1.1.5 below);
- Propose delegated Acts to specify certain provisions of the Regulation and adapt Annexes II (*'information requirements for active substances'*), III ('*information requirements for biocidal products) and IV (general rules for the adaptation of the data requirements'*) to the BPR to scientific and technical progress;
- Prepare a report on implementation of the Regulation every five years from 2015 (Article 65(3)); and
- Organise expert group meetings with Member States Competent Authorities to facilitate the implementation of the BPR.

ECHA

In the implementation of the BPR, ECHA:

- Organises the application process for approval of active substances and renewal of approval, for Union authorisation of biocidal products, for simplified authorisations of biocidal products, for inclusion of substances in Annex I to the BPR. This means ECHA receives applications, checks that applications have been submitted in the right format and accepts applications, collects applicants' fees as set in Regulation (EU) No 564/2013, and ensures that process is happening within deadlines;
- Coordinates the evaluation processes of approval of active substances and renewal of approval, of Union authorisation of biocidal products, of simplified authorisations of biocidal products, of inclusion of substances in Annex I to the BPR;
- Manages consultations for substances that are candidates for substitution;
- Manages dossier submission for national authorisation and mutual recognition (see 2.1.1.5);
- Provides the secretariat of the Coordination Group where issues relating to the authorisation process are discussed among Member States;
- Maintains the Register for Biocidal Products (R4BP)[19], an IT system used for all the operations listed above;
- Provides the Secretariat for the Biocidal Products Committee, which provides an opinion on the evaluation of active substances carried out by evaluating Member States, Union authorisations of biocidal products and inclusion of substances into Annex I to the BPR ;

[19] Register for Biocidal Products: https://r4bp.echa.europa.eu/r4bp-web-industry/index.xhtml (Last accessed on 06.11.2020).

- Is responsible for assessing technical equivalence of active substances[20];
- Assists applicants regarding data sharing and assists in data sharing disputes;
- Provides technical and scientific support to the Commission upon request;
- Publishes the list of active substances for which a dossier has been submitted and the respective substance and product suppliers (see 2.1.1.1) – the 'Article 95 list'; and
- Provides secretariat for the Forum for Exchange of Information on Enforcement which includes a subgroup on BPR (Forum Biocidal Products Regulation Subgroup (BPRS)).

The Biocidal Products Committee (BPC)

The BPC is composed of experts appointed by Member States for a period of three years. At the time when this report was finalised, almost all Member States have appointed a member (with the exception of Bulgaria and Poland). EEA countries can also appoint members, who have the same rights as other members, except the right to vote. Norway and Switzerland have appointed members in the BPC[21]. Applicants for the approval of a biocidal substance or the authorisation of a biocidal product can also participate in BPC meetings as observers when their specific case is addressed by the Committee or its working group[22]. Accredited Stakeholders Organisations, including mainly industrial organisation and NGOs, can also participate as observers to those meetings. The BPC has four permanent working groups (on efficacy, analytical methods and physico-chemical properties, human health and environment) and four ad-hoc working groups (on human exposure, assessment of residue transfer to food, environmental exposure and microorganisms). The BPC prepares in particular the opinion of ECHA on the approval of active substances and Union authorisations of biocidal products, which serve as a basis for Commission decisions.

Forum for Exchange of Information on Enforcement – Biocidal Products Regulation Subgroup (BPRS)[23]

The Forum for Exchange of Information on Enforcement is a network of authorities responsible for the enforcement of REACH, CLP, Prior Informed Consent (PIC) Regulation[24], POPs Regulation and BPR in the EU, Norway, Iceland and Liechtenstein. In 2017, a specific subgroup for the enforcement of the BPR was created. The subgroup coordinates joint enforcement projects, including coordinated inspection campaigns, training for inspectors and exchanges of best practices on enforcement. The first BPR-EN-FORCE (BEF) project (modelled on the REACH-EN-FORCE (REF) projects) on treated

[20] The purpose of technical equivalence is to determine the similarity with regard to the chemical composition and hazard profile of substances produced from a source different to the reference source or when there has been a change to the manufacturing process compared to the substance of the reference source in respect of which the initial risk assessment was carried out. It should be assessed by ECHA in the context of biocidal product authorisation when there has been a change with regard to the source of the active substance. See ECHA's website: https://echa.europa.eu/regulations/biocidal-products-regulation/technical-equivalence (Last accessed on 06.11.2020).

[21] Members of the Biocidal Products Committee: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/members-of-the-biocidal-products-committee (Last accessed on 01.10.2020)
ECHA > About Us > Who we are > Biocidal Products Committee > List of BPC members with their CVs and Declarations of interest.

[22] ECHA (2013) Rules of procedure for the Biocidal Products Committee, Article 6(7): https://echa.europa.eu/documents/10162/4221979/bpc_procedure_rules_en.pdf/4462dc96-b5ed-414b-b000-6dc5dbc799e7 (Last accessed on 01.10.2020)
ECHA > About Us > Who we are > Biocidal Products Committee > Rules of procedure of the BPC.

[23] The BPRS does not have a specific webpage but members, work programme, meetings etc. are available on the Forum's webpage: https://echa.europa.eu/about-us/who-we-are/enforcement-forum (Last accessed on 04.11.2020).
ECHA > About Us > Who we are > Enforcement Forum.

[24] Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, OJ L 201, 27.7.2012, p. 60–106.

articles started in 2018[25]. The priorities identified in the 2019-2023 Work Programme are the launch of an enforcement project focusing on active substances used in biocidal products (second BEF project), and tackling new and emerging issues in relation to the BPR with pilot project activities[26].

Member States' competent authorities

The list of national competent authorities[27] for the BPR is publicly available on EU CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens)[28]. These are mostly Ministries of Health or Environment, and in some cases the Ministry of Agriculture or the chemicals' agency. In addition, all Members States have set up a helpdesk on the BPR, which provides information and advice to industry.

One expert group and one Committee are assisting the Commission in the implementation of the Regulation:

- **The Competent Authorities for Biocidal Products**[29], which includes Member States' representatives, as well as industry representatives and NGOs as observers. This expert group is consulted by the Commission on delegated acts and deals with implementation issues. The Aerospace and Defence Industries Association of Europe (ASD) is an observer in this group;
- **The Standing Committee on Biocidal Products**[30] is composed of Member States' representatives (and representatives of Norway and Switzerland who participate but do not have the right to vote). It delivers opinions on Commission Implementing Decisions (e.g., approval/non approval/renewal of active substances, postponement of expiry dates etc.) and Implementing Regulations (e.g., Union authorisations).

2.1.1.4 Evaluation and review of the Regulation

The BPR was not formally evaluated (as a single Regulation) since its adoption. It was, however, in the scope of the Fitness check on the most relevant chemicals' legislation (excluding REACH), carried out in 2015-2019. The BPR is also in the scope of the Fitness Check on Endocrine Disruptors that should be completed in 2020. There is currently no planned review of the Regulation.

The recently published Commission's Chemicals Strategy for Sustainability[31] proposed follow ups

[25] Forum enforcement projects: https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects (Last accessed on 09.11.2020). ECHA > About Us > Who we are > Enforcement Forum > Forum enforcement projects.

[26] Forum Work Programme 2019-2023, p.12. Available at: https://echa.europa.eu/documents/10162/13577/forum_work_programme_2019-2023_en.pdf/f8add1f0-f25e-abfc-fb0d-5ad66c717a6e (Last accessed on 09.11.2020).

[27] List of BPR national competent authorities: https://ec.europa.eu/health/biocides/regulation_en (Last accessed on 01.10.2020)
Home >Live, work, travel in the EU > Health Policy (under 'Health') > Public Health > Biocides > Regulation > Competent authorities.

[28] https://circabc.europa.eu/ui/welcome

[29] Competent Authorities for Biocidal Products: https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3125 (Last accessed on 01.10.2020)
European Commission > Register of Commission expert groups and other similar entities > Group Details (Biocides - E03125).

[30] Standing Committee on Biocidal Products: https://ec.europa.eu/transparency/comitology-register/screen/committees/C13900/consult
European Commission > Comitology register > Search for Committees > Standing Committee on Biocidal Products.

[31] Communication from European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment, COM(2020) 667 final, 14.10.2020.

regarding endocrine disruptors, which might affect their considerations in the BPR. The Strategy proposes to establish legally binding hazard identification of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation, including the BPR. The Strategy also aims to ban endocrine disruptors in consumer products and increase workers' protection.

2.1.1.5 Regulatory evolution of substances

The BPR requires two rounds of decision-making, one for the approval of substances at EU level and one for the authorisation of products at Member State level or EU level for certain biocidal products.

Approval of biocidal substances

Companies intending to put **active substances** on the market are required to apply for approval of an active substance with ECHA. The application is assessed by the evaluating Member State competent authority, before being sent to the Biocidal Products Committee that provides an opinion, which serves as a basis for the final decision taken by the European Commission. Approvals for active substances can be granted for a maximum period of ten years, or a maximum period of seven years if the substance presents specific concerns (candidates for substitution), or even shorter when the active substance meets the exclusion criteria set out in Article 5(1) of the BPR. After this period, an application for the renewal of the approval must be submitted to ECHA by companies and the approval process takes place again. The Commission can decide to undertake an early review of an approved substance in case there are indications that the substance no longer satisfies the approval conditions. This may lead to amendments to the conditions of approval or to the cancellation of an approval. In case of non-renewal or cancellation of approval, biocidal products containing the active substances concerned must be removed from the market within 360 days of the decision (i.e., 180 days for making available on the market and additional 180 days for the use of existing stocks as per Article 52 of the BPR).

Substances that were **already on the market in biocidal products before May 2000** are progressively evaluated according to the Review Programme, established first under the Biocidal Products Directive (Directive 98/8/EC) and which continues under the BPR. The rules for the implementation of the Review Programme are detailed in Regulation (EU) No 1062/2014, which repealed Regulation (EC) No 1451/2007, including derogations for essential uses (see 2.1.1.2). The approval process is the same as the process for new substances. The **review programme is to be completed in 2024**.

The risk assessment for approval of active substances covers both human health and environmental impacts and requires the assessment of cumulative and synergistic effects on the environment.

The BPR foresees that active substances falling under certain hazard classifications or properties cannot normally be approved. Active substances which have been classified as carcinogenic, mutagenic or toxic for reproduction 1A or 1B according to the CLP Regulation, active substances with endocrine-disrupting properties and active substances which meet the criteria for being PBT or vPvB under REACH cannot be approved (Article 5(1)). Derogations are foreseen in the following cases (Article 5(2)):

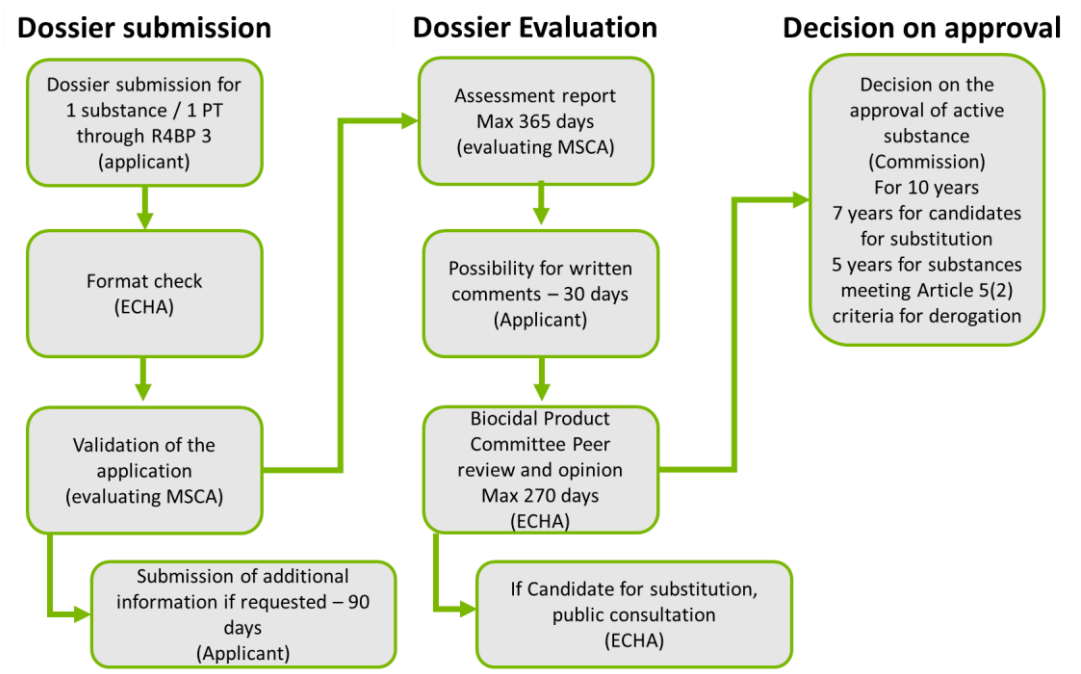
- *The risk to humans, animals or the environment from exposure to the active substance in a biocidal product* […] *is negligible,*
- *It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment*, or
- *Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance*.

Based on these derogation possibilities, these substances can be approved for an initial maximum period of five years, subject to appropriate mitigation measures.

In addition, substances that meet certain hazard criteria listed in Article 10(1) of the BPR are considered as **candidates for substitution**[32]. These substances are **approved for a period** of seven years according to Article 10(4) and application for the authorisation of products containing these substances must undergo a **comparative assessment** – i.e., they can be authorised, according to Article 23(3) of the BPR, only if:

- *For the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages, and*
- *The chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.*

Figure 2: Procedure for the approval of active substances



[32] Candidates for substitution are substances which:

- Meet at least one of the exclusion criteria listed in Article 5(1) (i.e. substances meeting criteria for classification as CMR 1A and 1B, meeting PBT/vPvB criteria, substances with endocrine-disrupting properties) but might be approved according to the conditions laid down in Article 5(2).);
- Meet the criteria to be classified as respiratory sensitiser according to CLP;
- Acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;
- Meet two of the criteria for being PBT in accordance with Annex XIII to REACH;
- Present reasons for concern such as high potential of risk to groundwater, even with very restrictive risk management measures;
- Contain a significant proportion of non-active isomers or impurities.

Authorisation of products

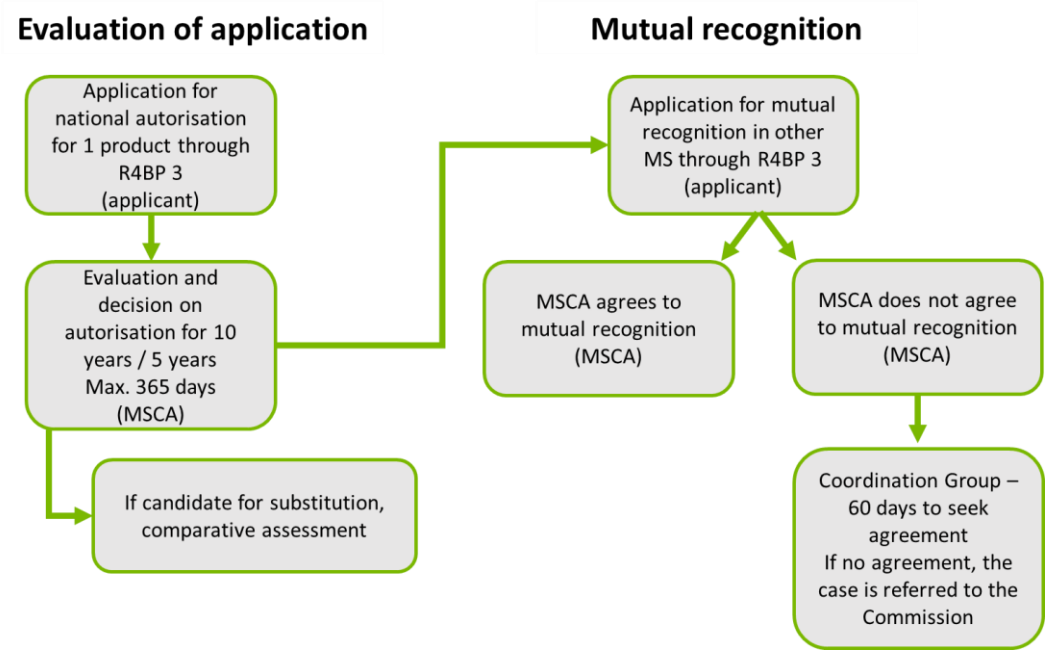
Companies intending to place **biocidal products** (containing approved substances) on the market must **apply for authorisation through national level authorisation**, with a possibility to use the mutual recognition process for authorisation in several Member States, or **Union authorisation**, which allows companies to place their products on the market in all Member States without having to request national authorisations. Requests for Union authorisations follow a similar process as active substances (application to ECHA, evaluation by a national competent authority, opinion of the BPC and final decision by the Commission). There is also a simplified authorisation procedure for biocidal products, which:

- Contains only active substances listed in Annex I to the Regulation (i.e. substances considered as not harmful);
- Do not contain any substance of concern;
- Do not contain any nanomaterials;
- Are considered sufficiently effective;
- Handling and intended use do not require personal protective equipment (Article 25 of the BPR).

If all the above conditions are met, the applicant can submit an application for simplified authorisation to ECHA, which is reviewed by the evaluating MSCA. When a simplified authorisation is granted, the biocidal product can be made available on the market in all Member States without the need for mutual recognition, if the authorisation holder notifies Member States before placing the product on the market (Article 27 of the BPR).

Authorisations may be granted for a single biocidal product or a biocidal product family. **The maximum duration of an authorisation is ten years** (Article 17 of the BPR), and a maximum duration of 5 years when the product contains active substances that are candidates for substitution (see Footnote 32).

Figure 3: Process of national authorisation of biocidal products



2.1.2 Interactions with REACH and CLP

2.1.2.1 Interactions with REACH

Definitions

The **BPR relies on a number of definitions from the REACH Regulation**. Definitions of *'substance'*, *'mixture'*, *'article'*, 'product and process-orientated research and development' and 'scientific research and development' from REACH are used in the BPR (Article 3(2)).

However, the definition of 'treated article' used in the BPR differs from the definition of 'article' in REACH. In the BPR a 'treated article' can be a 'substance', 'mixture' or an 'article' (within the meaning of REACH[33]) treated with a biocidal product. In addition, the term 'product' does not exist in REACH, and under the BPR, a product can similarly be a substance, mixture or article. During the consultation carried out for this study, several MoDs and defence industry stakeholders commented on the confusion created by these differences.

Exemption from REACH Registration

Active substances used in biocidal products that were already approved under Directive 98/8/EC (Biocidal Products Directive) and which are under evaluation in the Review Programme (Regulation (EU) No 1062/2014), i.e., existing active substances, are 'regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product' under REACH (Article 15(2) of REACH). This Article of the REACH Regulation does not apply to new active substances. It is, however, completed by Article 57 of the BPR, which provides that active substances authorised for placing on the market under the BPR are 'regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product' (Article 57 of the BPR). These two Articles, one under REACH and one under BPR, ensure that the substance approved under the BPR does not have to be registered under REACH to be placed on the market. However, if such a substance is manufactured or imported for any use other than in biocidal products, the registration obligation under REACH applies.

Risk management measures based on REACH

Active substances which meet the criteria for PBT or vPvB or identified as endocrine disruptors cannot be approved (Article 5 BPR).

Active substances that meet two of the criteria for being PBT in accordance with REACH are considered as candidates for substitution (Article 10 BPR).

Biocidal products cannot be authorised for use by the general public if they consist of, contain or generate, a substance that meets the criteria for being PBT or vPvB or if they have endocrine-disrupting properties (Article 19(4) BPR).

Communication in the supply chain

Safety Data Sheets (SDS) are required for active substances and biocidal products in accordance with Article 31 of REACH (Article 70 of the BPR). For substances that are considered as registered (see above) no Chemical Safety Report (CSR) is required according to Article 14 of REACH and therefore an exposure scenario does not need to be attached to the SDS[34].

[33] According to Article 3(3) of REACH, an 'article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'.

[34] ECHA, Q&As BPR, 'Is a safety data sheet required for active substances and biocidal products according to the BPR?' ID: 0908: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/biocidalproductsregulation (last accessed 02.10.2020). ECHA > Support > Q&As > Browse by topic > Biocidal Products Regulation.

Communication in the supply chain is also needed for an effective application of the provisions on treated articles specified in Article 58 of the BPR. Article 58(3) and (4) of the BPR requires that the label of treated articles contains a statement that the treated article incorporates biocidal products, and information on the biocidal properties attributed to the treated article and any relevant instructions for use, including any precautions to be taken to handle the treated article. In addition, Article 58(5) requires the supplier of a treated article to provide consumers with, upon request, information on the biocidal treatment of the treated article, within 45 days, and free of charge. The provisions of Article 58(3) and (4) are similar to the provisions of Article 33(1) of the REACH Regulation, and those of Article 58(5) to those of Article 33(2) of REACH, although the scope of Article 58 of the BPR is broader, as Article 33 of REACH only covers information about SVHCs[35] in articles.

2.1.2.2 Interactions with CLP

Application of CLP to active substances and biocidal products

The **provisions of CLP apply to active substances and biocidal products regulated by the BPR**, which means that active substances and biocidal products must be classified and labelled according to the CLP Regulation (Article 69(1) of the BPR). Labelling requirements imposed by the BPR (Article 69(2) of the BPR) and requirements for advertisement for biocidal products (Article 72 of the BPR) are supplementary to the provisions of the CLP Regulation related to labelling (Title III – Articles 17 to 34 of CLP, with the exception of Article 30 of CLP as the supplier of a biocidal product should update the label in accordance with the BPR) and advertising (Article 48 of CLP). In addition to fulfilling CLP requirements, biocidal products must not bear labels that are likely to mislead the user on the risks of the product (e.g., 'non-toxic'), and must clearly display information such as:

- Information on the authorisation holder, and the authorisation number,
- The identity of every active substance and its concentration in metric units, as well as nanomaterials contained in the product, if any,
- The uses for which the biocidal product is authorised and instructions for use, as well as instructions for safe disposal,
- Potential adverse effects and users for which the product may be restricted, and where applicable, specific dangers to the environment (e.g., non-target organisms and water contamination) (Article 69 of the BPR).

According to Article 36(2) of the CLP Regulation, active substances in the meaning of the BPR are subject to harmonised classification and labelling, which means that all hazard classifications and labelling elements are to be harmonised. ECHA's introductory guidance on CLP recalls that this is different from other substances, as per Article 36(1) of CLP, 'for which only the classification and labelling elements for CMRs and respiratory sensitisers will normally be harmonised while other classifications and the related labelling elements will only be harmonised on a case-by-case basis if justification is provided demonstrating the need for such action' at EU level[36]. For biocides (and

[35] SVHCs are substances which meet criteria listed in Article 57 of the REACH Regulation: substances which meet the criteria for classifications as carcinogens, mutagens or toxic for reproduction 1A and 1B (CMR) as per the CLP Regulation, substances meeting persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) criteria as per REACH Annex XIII, and substances that are considered on a case by case basis to present the same level of concern as CMR or PBT/vPvB.

[36] ECHA (2019) Introductory Guidance on the CLP Regulation. Version 3.0, Section 22, p.80. Last accessed on 01.10.2020, https://www.echa.europa.eu/documents/10162/23036412/clp_introductory_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027.
ECHA > Support > Guidance > Guidance documents > Guidance on CLP > Introductory Guidance on CLP.

pesticides), only MSCAs can propose harmonised classifications for active substances under the BPR, unlike for industrial chemicals, where manufacturers, importers and downstream users of a substance can also submit a CLH dossier to ECHA[37]. This difference is justified by the necessity to coordinate the evaluation of the active substance with the harmonised classification process – i.e., the MSCA in charge of evaluating the active substance should submit a CLH dossier for the active substance in parallel[38] – because the approval of the active substance depends on certain cases on the harmonised classification – i.e., some substances cannot be approved under the BPR based on their classification (see paragraph below).

Risk management measures based on CLP classification

- Active substances which have been classified as carcinogenic, mutagenic or toxic for reproduction 1A or 1B cannot be approved (Article 5(1)(a)(b)(c) BPR) unless the derogation possibilities described above are met.
- Active substances that meet the criteria to be classified as a respiratory sensitiser in accordance with CLP are considered as candidates for substitution (Article 10 BPR).
- Biocidal products cannot be authorised for use by the general public if they meet the classification criteria of CLP for: acute oral toxicity category 1, 2 or 3, acute dermal toxicity category 1, 2 or 3, acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3, acute inhalation toxicity (vapours) category 1 or 2, specific target organ toxicity by single or repeated exposure category 1, a category 1A or 1B carcinogen, a category 1A or 1B mutagen, or toxic for reproduction category 1A or 1B, if it meets the criteria for being PBT or vPvB in accordance with Annex XIII to REACH[39] (Article 19(4) BPR). However, Article 19(5) provides the possibility to derogate of this under certain circumstances.

2.1.3 Interactions with other chemicals' regulations/directives

2.1.3.1 BPR and POPs Regulation

There are no exemptions in the POPs Regulation for biocidal active substances. Article 2(3) of the BPR indicates that the BPR applies without prejudice to the POPs Regulation.

The **BPR contributes to the substitution of substances exhibiting POP or PBT characteristics** in biocidal products. A substance which meets the criteria for being a persistent organic pollutant (POP), set out in paragraph 1 of Annex D to the Stockholm Convention[40] (or which meets the PBT or vPvB criteria under REACH) is considered as a substance of concern under the BPR (Article 3(1)(f)), and therefore, for example, cannot be eligible for simplified authorisation.

In addition, all biocidal active substances undergo a formal PBT assessment as part of the approval

[37] ECHA, Harmonised classification and labelling (CLH): https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling (Last accessed on 01.10.2020).
ECHA > Legislation > CLP > Harmonised classification and labelling (CLH).

[38] ECHA (2014) Guidance on the preparation of dossiers for harmonised classification and labelling Version 2.0, Section 7.1, p. 37. Available at: https://echa.europa.eu/documents/10162/23036412/clh_en.pdf/36b11f14-01a0-4474-be46-e48dd9b27849 (Last accessed on 09.11.2020).

[39] Criteria ofr the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances.

[40] The Stockholm Convention on Persistent Organic Pollutants is the international instrument governing the placing on the market and use of POPs. Annex D to the Convention defines criteria for persistence, bioaccumulation, potential for long-range environmental transport, and adverse effect of the substance. Evidence of these criteria should be submitted when a Party proposes a new substance for inclusion in the Annexes to the Convention. More information is available in section 2.2 on the POPs Regulation.

process. Substances exhibiting PBT characteristics cannot be approved as biocidal active substance unless the derogation criteria are met as set out in Article 5(2) – see Section 2.1.1.1). However, Article 5 only mentions substances meeting PBT or vPvB criteria as not being eligible for approval under the BPR – the reference to the POPs Regulation and to the Convention is only present in Article 3(1).

No issues have been raised by stakeholders consulted for this study on the interface between the two Regulations.

2.1.3.2 BPR and Ozone Regulation

There are no substances regulated both by the BPR and the Ozone Regulation. No issues have been raised by stakeholders on the interface between the two Regulations.

2.1.3.3 BPR and F-gas Regulation

Although there are no provisions preventing it, there are no active substances regulated both by the BPR and the F-gas Regulation. Co-formulants present in biocidal products must also comply with the provisions of the F-gas Regulation. No issues have been raised by stakeholders on the interface between the two Regulations.

2.1.3.4 BPR and RoHS Directive

There are no exemptions in the RoHS Directive for biocidal active substances. However, there are currently no biocidal active substances regulated by RoHS. No issues have been raised by stakeholders on the interface between the two regulations.

2.1.4 Impacts on the defence sector

2.1.4.1 Availability of products

During the stakeholder consultation, four MoDs reported that the BPR had a **negative impact on the availability of biocidal products for defence applications**, either because of non-approval or non-renewal of approvals of active substances or authorisations of biocidal products. Two MoDs indicated that the BPR had a **negative impact on the availability of treated articles** and has led or could lead in the future to problematic reformulations – either leading to the article not meeting minimum standards for use in defence applications or leading to reduced performance, reliability or longevity of the article. One MoD reported that no issues with biocidal products or treated articles' availability had been observed.

The main issues raised by MoDs and ASD concerned:

- **Insect repellents for textiles** (i.e., tents and soldiers' clothes): three MoDs mentioned pyrethroids and in particular the insect repellent Permethrin (EC no.: 258-067-9, CAS no.: 52645-53-1), used in areas of operations with a high presence of disease-transmitting insects. Permethrin is approved for use as wood preservative (PT8) and as an insecticide/acaricide (PT18) but not as a repellent (PT19). One MoD expressed the view that since the biocidal product is not meant to be used in the EU but only in international operations, the treated textiles could be handled (but not used) in the EU before being shipped and used outside the EU, without requiring a defence exemption;
- **Insect repellent for the skin:** one MoD referred to the active substance Icaridine (EC no.: 423-

210-8; CAS no.: 119515-38-7). The substance has however recently been approved[41] for use as a repellent and attractant biocidal products (Product-type 19) for a period of ten years from 1 February 2022 to 31 January 2032, and therefore the issue should be solved;

- **Organotin antifouling coatings**, i.e., anti-fouling in the naval sector, the main component of which, Tributyltin (TBT), was banned in 2008 by the International Convention on the Control of Harmful Anti-fouling Systems on Ships, and in the EU by Regulation (EC) No 782/2003 on the prohibition of organotin compounds on ships. The Convention and the EU Regulation, however, do not apply to warships. One MoD yet stated that compliance with the Regulation was required also for warships. Those antifouling products have been mainly substituted by antifouling products using copper (EC no. 231-159-6, CAS no. 7440-50-8), or Full Release Coatings (FRC) solutions which contain octamethylcyclotetrasiloxane (D4)[42]. Those solutions are, however, not likely to be long lasting solutions, as an EU proposal for inclusion in the Stockholm Convention is pending for D4 (see 2.2.1.6);
- **Marine growth prevention systems** (MGPSs) for seawater pipework (using copper). As mentioned in section 2.1.1.2, a derogation to the transitional measures (through Article 5 of Regulation (EC) No 1451/2007) was used in 2014 for extending the use of copper in marine growth prevention systems. According to one MoD, this solution was found at the last moment, when the naval industry found out that the biocidal product they used was not authorised and applied for the derogation. The evaluation of an application for the approval of copper in preservatives for liquid-cooling and processing systems (Product-type 11) – one of the uses concerned by the derogation – is ongoing. According to ASD, approval of copper is necessary for antifouling products as marine growth on the hull of a naval vessel significantly reduces its speed and manoeuvrability and increases its fuel consumption;
- **Preservatives** (anti-microbial in the aerospace sector): one MoD referred to the active substance N-(3-aminopropyl)-N-dodécylpropane-1,3-diamine (EC no.: 219-145-8; CAS no.: 2372-82-9), for which applications for approvals are under review as preservatives for products during storage (PT6), wood preservatives (PT8), preservatives for liquid-cooling and processing systems (PT11) and working or cutting fluid preservatives (PT13).

As mentioned above, unavailability of substances can be caused by suppliers not applying for approval of active substances and authorisation of biocidal products or by suppliers applying later, only when they realise the imminent threat for the product. One MoD mentioned that cases of obsolescence due to non-submission of a dossier for approval could happen in the near future because suppliers are SMEs that might not have the capacity to submit dossiers. A recent example was mentioned by ASD and one MoD concerning fuel treatment in aircraft. Following a recommendation from EASA[43] identifying security issues with using the product in aerospace applications, including multi engine loss of thrust control, the manufacturer of the biocidal product Kathon™ FP 1.5 Biocide removed the product from the market for those applications. The only available alternative for the aerospace industry was a biocidal product (Biobor JF), which contains two active substances that have not been notified as active substances in Regulation (EC) 1451/2007 on the second phase of the work programme. Products containing these substances therefore

[41] Commission Implementing Regulation (EU) 2020/1086 of 23 July 2020 approving Icaridin as an existing active substance for use in biocidal products of product-type 19, OJ L 239, 24.7.2020, p. 9–11.
[42] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.106.
[43] EASA Safety Information Bulletin No 2020-06 of 20 March 2020 on the use of DuPont Kathon™ FP 1.5 Biocide. Available at: https://ad.easa.europa.eu/ad/2020-06 (Last accessed 02.10.2020).

cannot be marketed since 2006 and are not eligible for authorisation under the BPR[44]. Several MSCAs granted Article 55(1) derogations to ensure immediate supply of the product[45]. This solution is, however, temporary (maximum 180 days). One MoD indicated that an application for an extension of the derogation (550 days) had been submitted to the Commission. To ensure the continued use of the product, the manufacturer would need to submit a dossier for the approval of the two active substances contained in the product (the process takes approximately two years), or MoDs and MSCAs of Member States where the product is needed would need to grant a defence exemption.

According to ASD, the **BPR is reducing the number of available active substances and biocidal products on the EU market**, which reduces purchasing options and leads to higher prices. ASD also mentioned that the reduction of the number of available substances might lead to resistance of pests to the active substance (caused by repeated treatments with the same substance), which would reduce the effectiveness of biocidal products. ASD also expects that some preservatives will not be approved because of their CLP classification.

2.1.4.2 Costs linked to the BPR

Main costs linked to the implementation of the BPR identified by stakeholders were:

- **Costs of the submission of dossiers** was raised by defence industry stakeholders; they consider it as an expensive process that might discourage suppliers to submit an application, especially considering the overall low volumes of biocidal products needed in defence products. This issue was already raised in the 2016 EDA study and was also raised in one of the studies supporting the Fitness Check on non-REACH chemicals' legislation[46]. Interviews conducted with industry stakeholders (all sectors) during the Fitness Check confirmed that the BPR regulatory processes are considered costly and time-consuming by industry and that some producers consider the process not affordable;
- **Increased prices** of biocidal products or treated articles due to reduced competition between suppliers;
- **Costs of tracing biocides in treated articles**: defence industry stakeholders mentioned this as a specifically difficult and costly exercise (see below – communication in the supply chain), because this information is less accessible than information available on SDS. Costs are mostly related to IT tools, which according to industry stakeholders are not always up to date to track biocides, or to trace information on labels;
- **Costs of regulatory monitoring**: this type of cost was mentioned both by defence industry stakeholders and one MoD and consists of administrative costs related to monitoring of regulatory changes and for MoDs, the tracing of biocidal products used through contract clauses to anticipate upcoming issues.

[44] BAUA – Federal Office for Chemicals (2020) General decision on authorisation of the biocidal product "Biobor JF" for preventive antimicrobial treatment of fuel systems of temporarily decommissioned planes by professional users due to a danger to public health, 07/04/2020. Available at: https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/EN/Biozide/general_decision_jet-fuel.pdf?__blob=publicationFile&v=3 (Last accessed 02.10.2020).

[45] See above Section 0 'derogations'.

[46] Amec Foster Wheeler (2017) Study supporting the Fitness Check on the most relevant chemicals' legislation, final report, p.83 (first paragraph). Available at: https://op.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1 (last accessed on 02.10.2020).

2.1.4.3 Communication in the supply chain

ASD and other defence industries reported that it was **difficult for the defence industry to obtain information on biocidal products used in treated articles from their suppliers.** As biocidal products are often used two or three levels upstream in the supply chain, defence industries are quite dependent on the information provided by suppliers. However, defence industries have indicated that provisions of Article 58 of the BPR on the labelling and transmission of information on treated articles are not fully implemented in the supply chain; as a result, biocidal products used to treat articles are difficult to trace for defence industries.

This problem is, however, not specific to the defence sector. A market survey carried out by KEMI in 2016 on consumer products in Sweden showed that the use of biocidal products to treat articles was widespread, and that in most cases, rules related to the labelling of treated articles were not respected. In addition, in most cases, suppliers of treated articles lacked the necessary knowledge to inform customers, or were not aware of their information duties[47].

For substances and mixtures, defence industries usually receive the information through the SDS identifying the substances used, and therefore biocidal products used in mixtures are more visible to defence industries.

ASD indicated that **imports from outside the EU of treated articles are of particular concern** as non-EU suppliers may use non authorised products Non-EU suppliers may fail to inform importers because of their lack of knowledge of BPR requirements. It has happened that defence industries have to destroy imported treated articles, when they are not compliant with the BPR.

Two MoDs indicated that they **require information on biocidal products** contained in treated articles through **procurement contract clauses**, both to ensure that the treated articles are compliant with the BPR and to map uses of biocidal products in treated articles to anticipate potential impacts from upcoming regulatory changes on the availability of treated articles. One of these MoDs, Sweden, uses specific information requirements available in Annex IV to this report.

2.1.4.4 Duration of approvals

Two MoDs raised the issue of "inadequacy" of regulatory timeframes with the longevity of defence equipment. As defence products have a long service life (several decades), the timeframes of approvals of active substances (i.e., not exceeding ten years) are not aligned with the typical service life of defence products, which might become problematic when performing service and maintenance of the equipment.

2.1.4.5 Challenges and limitations of the defence exemption mechanism

Several MoDs reported **challenges in the use of the defence exemption**. In particular, two MoDs indicated that granting an exemption is a complex procedure, which might lead to avoiding using it whenever possible. Another MoD added that a case-by-case exemption, as in the BPR, leads to high administrative burden and reduced legal certainty (as it is left to each Member State) compared to an exemption mechanism that is automatically applicable to the defence sector, such as the exemption mechanism of the RoHS Directive.

ASD and another defence industry stakeholder indicated that the process for submitting BPR

[47] KEMI (2016) Market survey on articles treated with biocides, PM 6/16, p.7. Available at: https://www.kemi.se/en/publications/pms/2016/pm-6-16-market-survey-on-articles-treated-with-biocides (Last accessed on 02.10.2020).

exemption requests is not very well known by defence industry stakeholders (i.e., what is the procedure, who to contact). According to ASD, the exemption mechanism in the BPR is also burdensome for defence industries. As defence industries often operate in several EU Member States, if they need a defence exemption, they will have to go through several exemption processes in all Member States where the product is sold, which leads to additional costs (for applying and justifying the exemption) and potential delays as processes in each Member State might happen on different timelines.

One MoD indicated that the **effectiveness of the exemption mechanism** might be limited for the defence sector, in particular as it only applies to defence applications and cannot be used to secure the use of a **dual use substance** in civil applications. As a result, if the substance is withdrawn from the civil market, it will likely become unavailable for the defence sector. The MoD mentioned that this limitation was particularly relevant in relation to the BPR as none of the identified biocides used in the defence application is specific to the defence sector, therefore there is a risk of discontinuation of production.

ASD and another defence industry, mentioned the same issue of commercial obsolescence. As the **defence sector is a marginal market for suppliers of biocidal products**, there are risks that, even if a defence exemption is granted, it will not prevent suppliers from discontinuing their production of specific biocidal products or treated articles.

2.1.5 Summary

Regulation (EU) 528/2012[48] (Biocidal Products Regulation – BPR) sets rules for the **approval of active substances in biocidal products** at EU level, the **authorisation of biocidal products** at Member State or EU level and the placing on the market of articles treated with biocidal products. It ensures that all biocidal substances and products undergo a risk assessment for toxicity to humans and the environment before they can be made available on the market.

Biocidal active substances are approved at EU level by the European Commission - following an evaluation carried out by a Member State Competent Authority (MSCAs) and the opinion of ECHA's Biocidal Products Committee (BPC)[49] - for a maximum period of ten years (or five or seven years if the substance presents specific concerns). Biocidal products are authorised at national level by Member States' Competent Authorities, with a possibility to use the mutual recognition process for authorisation in several Member States. Biocidal products can also be authorised at EU level through Union authorisations. Authorisations are granted for ten years – or five if the product contains substances of concern.

Article 2(8) of the BPR provides for the possibility that Member States **exempt specific uses of certain biocidal products, on their own or in a treated article, where necessary, in defence applications**. The exemption is not automatically granted but requires a decision on a case-by-case basis from the authority responsible for granting the exemption in the Member States (i.e., Ministry of defence (MoD) and/or MSCA), following an assessment that the exemption is necessary/linked with interests of defence. MoDs generally consider the Article 2(8) defence exemption as a last resort to be used only if complying with the BPR would impede the use of a critical product in defence applications.

There are **other derogation mechanisms** (not specific to defence) in the BPR that may enable

[48] Regulation (EU) 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123.
[49] Biocidal Products Committee: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee (last accessed on 08.12.2020).

Member States to temporarily authorise biocidal products that do not fulfil the conditions for authorisation. Article 55(1) of the BPR allows MSCAs to authorise, for 180 days, a biocidal product if such a measure is necessary to contain a danger to public health, animal health or the environment. Article 55(2) provides for a provisional authorisation, granted by MSCAs and the Commission, for three years, for a biocidal product containing a new active substance, before the approval process of the active substance is completed. A derogation for essential uses was introduced by Article 5 of Regulation (EC) No 1451/2007[50] (no longer in force) and maintained by Article 22 of Regulation (EU) No 1062/2014[51], for biocidal products containing a substance from the Review Programme which has not been approved or for which no approval dossier was submitted. The derogation allows to extend the deadline for removing the biocidal product from the market. This mechanism was used extending the use of copper for the prevention of biofouling in the pipework and waterway system of ships.

The BPR is **consistent** with the REACH and CLP Regulations and with the other regulations covered by the study. The BPR uses definitions from the REACH Regulation and classifications under CLP to define risk management measures (exclusion and substitution criteria). Synergies with the POPs Regulation exist as the PBT assessment under the BPR can support the identification of new POPs.

In relation to the defence sector, consulted stakeholders observed the **reduced availability of certain biocidal products** (such as insect repellents for textiles, antifouling products, or preservatives) and treated articles. Stakeholders reported that the reduced availability of products could lead to **reduced performance, reliability, or longevity of defence equipment**, and may raise issues for the maintenance of legacy equipment still in use. The unavailability of substances sometimes results from suppliers not applying for approval of active substances and/or authorisation of biocidal products because of lack of awareness of processes and deadlines (application starts late, only when the imminent threat to the product is understood) or lack of capacity (dossier submission is considered costly by suppliers of biocidal products).

Requirements of the BPR related to the **transfer of information on biocidal used in treated articles** in the supply chain are currently not fully implemented and this prevents defence industries from fully tracking biocidal uses in articles and ensuring compliance with the BPR and national procurement provisions requiring information on biocidal products used in procured equipment. This is more of a concern when suppliers are located outside the EU, as they are less aware of BPR requirements. Consequently, monitoring costs were reported to be significant for defence industries.

The Article 2(8) **defence exemption has barely been used**, in particular as it is considered by MoDs as a last resort. The defence exemption mechanism is considered as complex by defence industries as each exemption is only valid in one Member State. In addition, the **process for requesting an exemption at national level is not always clear** to defence industries – i.e., which institution to contact, which information to provide and in which format. The effectiveness of the exemption mechanism might also be limited, in particular as it only applies to defence applications and cannot be used to secure the use of a dual use substance in civil applications. As a result, the defence exemption does not prevent the risk of commercial obsolescence.

2.2 POPS REGULATION (REGULATION (EU) NO 2019/1021)

Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs Regulation) is the main instrument

[50] Commission Regulation (EC) No 1451/2007of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12.2007, p.3-65.

[51] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014, p. 1–34.

implementing the Stockholm Convention and the UNECE POPs Protocol. The Regulation entered into force on 15 July 2019, and repealed the previous POPs Regulation, Regulation (EC) No 850/2004. It is applicable in all Member States (including those which are not Parties to the UNECE POP Protocol[52]).

The POPs Regulation regulates the production, placing on the market and use of POPs, the management of stockpiles and waste and measures to reduce releases of unintentionally produced POPs. It also contains provisions requiring the setting up of emission inventories for unintentionally produced POPs, national and European Union implementation plans and monitoring and information exchange mechanisms[53].

2.2.1 Implementation of the Regulation

2.2.1.1 International legal basis

Regulation (EU) No 2019/1021 **implements the Stockholm Convention on Persistent Organic Pollutants** and the **1998 UNECE Protocol to the 1979 UNECE Convention on Long-Range Trans-boundary Air Pollution (CLRTAP) on Persistent Organic Pollutants**. The EU, along with all EU Member States, is Party to both instruments, the Convention since 2004 and the Protocol since 1998.

The Stockholm Convention on POPs was adopted in 2001 and **entered into force in 2004**.

The Stockholm Convention requires Parties to:

- **Prohibit and/or take the legal and administrative measures** necessary to **eliminate the production, use, import and export of chemicals listed in Annex A** – *'Elimination'* to the Convention (Article 3(1)(a));
- **Restrict the production and use of the chemicals listed in Annex B** – *'Restriction'* to the Convention (Article 3(1)(b));
- Make sure that the chemicals listed in Annex A and B to the Convention are only imported or exported for permitted or exempted uses or for the purpose of environmentally sound disposal (Article 3(2)). Article 3(1) and (2) does not apply to quantities of a chemical to be used for laboratory-scale research or as a reference standard;
- Take measures to regulate with the aim of **preventing the production and use of new chemicals and pesticides which**, taking into consideration criteria in paragraph 1 of Annex D to the Stockholm Convention (*'Information requirements and screening criteria'*), **exhibit the characteristics of persistent organic pollutants** (Article 3(3));
- Take into consideration within assessment schemes for pesticides and chemicals in use, the criteria in paragraph 1 of Annex D to the Convention when conducting assessments of pesticides and chemicals currently in use (Article 3(4));
- **Reduce the total releases derived from anthropogenic sources** of each of the **chemicals listed in Annex C** – *'Unintentional production'* to the Convention (Article 5);
- Develop appropriate strategies for identifying stockpiles, products and articles consisting of,

[52] Only Malta is not Party to the UNECE POPs Protocol.

[53] European Commission, European Union Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants, SWD(2018) 495 final/2, 21.1.2019, p. 15. Available at: http://www.pops.int/Implementation/NationalImplementationPlans/NIPTransmission/tabid/253/Default.aspx (Last accessed on 08.10.2020).
Stockholm Convention > Implementation > National Implementation Plans > NIP Transmission > Addressing COP 7 amendments > European Union.

containing or contaminated with a chemical listed in Annex A, B or C to the Convention; manage stockpiles in a safe, efficient and environmentally sound manner; take appropriate measures to ensure that waste products and articles containing chemicals listed in Annexes A, B or C to the Convention are handled, collected, transported and stored in an environmentally friendly manner; dispose of waste products and articles containing chemicals listed in Annexes A, B or C to the Convention in a way that destroys or irreversibly transforms the POP content (Article 6);

- Develop and implement a plan for the implementation of its obligations under the Convention (Article 7).

The **UNECE Protocol, adopted in 1998**, **bans or severely restricts the production and use of a list of 16 POPs** comprising 11 pesticides, two industrial chemicals and three unintentional by-products. The Protocol also lays down rules for dealing with waste of banned substances and requires Parties to reduce their emissions of dioxins, furans, polycyclic aromatic hydrocarbons (PAHs) and hexachlorobenzene (HCB) below their levels in 1990 (or an alternative year between 1985 and 1995). It also sets specific emission limit values for the incineration of municipal, hazardous and medical waste[54].

In 2009, amendments to the Protocol were adopted to include seven additional substances; however, these amendments have not yet entered into force, as the ratification of two thirds of the Parties has not been obtained[55]. These amendments were ratified by the EU in 2016.

Main bodies of the Stockholm Convention

The main bodies operating under the Convention are the Conference of the Parties (CoP) and the POPs Review Committee (POPRC).

The CoP is the governing body of the Convention and is composed of representatives of governments of the 184 countries that have accepted, ratified or acceded to it. The list of Parties to the Convention is available on the Convention's website[56]. Most parties, like the EU, adopt all amendments to the Convention when they enter into force. Some Parties have, however, added a declaration upon ratification, acceptance, approval or accession stating that any amendment to Annex A, B, or C to the Convention enters into force only upon the deposit of the country's instruments of ratification, meaning that those countries have to formally adopt each of the amendments. The countries are presented in Table 5 below.

[54] European Commission, European Union Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants, SWD(2018) 495 final/2, 21.1.2019, p. 6.

[55] UNECE, Protocol on Persistent Organic Pollutants (POPs): http://www.unece.org/env/lrtap/pops_h1.html (Last accessed on 08.10.2020).
UNECE > Environmental Policy > Conventions and Protocols > The air Convention and its Protocols > Protocols.

[56] Status of ratification: http://chm.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx (Last accessed on 10.11.2020). Stockholm Convention > Countries > Status of Ratifications > Parties and Signatories.

Table 5: Parties to the Convention which decided to ratify each amendment to the Convention

Parties to the Convention	
▪ Argentina	▪ Korea
▪ Australia	▪ Mauritius
▪ Bahrain	▪ Micronesia
▪ Bangladesh	▪ Moldova
▪ Botswana	▪ Russia
▪ Canada	▪ Uzbekistan
▪ China	▪ Vanuatu
▪ Guatemala	▪ Venezuela
▪ India	

Most of those countries have not adopted all the amendments to the Convention; some countries such as Australia, have not adopted any. The list of amendments to the Convention and their date of adoption is available on the Convention's website[57].

The **Conference of the Parties**:

- **Adopts the amendments to the Annexes to the Convention**, based on the POPRC recommendations (see 2.2.1.6);
- DecidesDecides whether to extend the expiry date of a specific exemption listed in Annex A or B to the Convention (see 2.2.1.3);
- Adopts the Work Programme and the budget of the Convention.

CoP Meetings are held every two years.

The POPRC is a subsidiary body established under the CoP at its first meeting. The POPRC reviews the chemicals proposed for inclusion in the Annexes to the Convention. The POPRC consists of 31 experts from all regions of the world. There are currently eight experts from African states, eight from Asian and Pacific States, five from Latin American and Caribbean States, three from Central and Eastern European States and seven from Western European and other States[58]. Members of the Committee are government-designated experts in chemical assessment or management, who are confirmed by the CoP. Each member serves a four-year term that can be renewed once.

The POPRC is responsible for the **technical and scientific review of proposals for inclusion of new POPs in the Convention**, including:

- Examining proposals sent to the Secretariat of the Convention, evaluates whether screening criteria listed in Annex D to the Convention are met, and if so, decides whether the proposal should proceed (see 2.2.1.6);
- Developing the risk profile of substances considered for inclusion in the Convention, and based on it, decides whether the proposal should proceed further (see 2.2.1.6);
- Developing the risk management evaluation of substances considered for inclusion in the Convention (see 2.2.1.6);

[57] Amendments to Annexes to the Stockholm Convention: http://chm.pops.int/Countries/StatusofRatifications/Amendmentstoannexes/tabid/3486/Default.aspx (Last accessed on 10.11.2020) Stockholm Convention > Countries > Status of Ratifications > Amendments to annexes.
[58] POPRC Members: http://chm.pops.int/TheConvention/POPsReviewCommittee/Membership/tabid/2808/Default.aspx (Last accessed on 09.10.2020).

- Making recommendations for listing the substance in Annex A, B, and/or C to the Convention, which have to be adopted by the CoP (see 2.2.1.6);
- Reviewing the information provided by Parties to the Secretariat in view of registering specific exemptions listed in Annex A or B to the Convention (production, use, control measures, etc.), as well as information provided by Parties that have registered specific exemptions on progress made towards relying on alternatives for a given substance. The analysis of the POPRC is used by the CoP to review entries in the exemption register and decide on requests made by Parties to extend the validity of specific exemptions (see 2.2.1.3).

Identification of POPs

As required by the Stockholm Convention, Parties must take measures to prevent the production and use of new chemicals and pesticides which exhibit the characteristics of persistent organic pollutants. This requirement is reflected in Article 3(3) of the POPs Regulation.

Under the Convention, **persistent organic pollutants are identified based on characteristics and screening criteria listed in Annex D to the Convention** ('Information requirements and screening criteria'). When proposing a new substance for inclusion in the Annexes to the Convention, parties should provide evidence related to the following characteristics.

Table 6: Characteristics and screening criteria listed in Annex D to the Stockholm Convention

Screening criteria	Details / evidence to be provided
Persistence	(i) The half-life of the chemical in water is greater than two months, or its half-life in soil is greater than six months, or its half-life in sediment is greater than six months; or (ii) The chemical is otherwise sufficiently persistent to justify its consideration within the scope of this Convention.
Bioaccumulation	(i) The bio-concentration factor or bio-accumulation factor in aquatic species for the chemical is greater than 5,000 or, in the absence of such data, that the log Kow is greater than 5; or (ii) The chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity; or (iii) The bioaccumulation potential of the chemical is sufficient to justify its consideration within the scope of this Convention, as shown by monitoring data in biota.
Long range transport	The chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days. This can be evidenced by measured levels of the chemical in locations distant from the sources of its release; monitoring data; environmental fate properties and/or model results.
Adverse effects	Adverse effects to human health or to the environment, as shown by toxicity and ecotoxicity data, justifies consideration of the chemical within the scope of this Convention

2.2.1.2 Scope of the Regulation

Article 15 of the POPs Regulation empowers the Commission to **adopt delegated acts to amend**

Annexes I[59], II[60] and III[61] to the POPs Regulation to adapt them to changes to the list of substances set out in the Annexes to the Convention or the Protocol.

Article 3 of the POPs Regulation:

- Prohibits the manufacturing, placing on the market and use of substances listed in Annex I to the Regulation (corresponding to Annex A to the Convention), and,
- Restricts manufacturing, placing on the market and use of substances listed in Annex II to the Regulation (corresponding to Annex B to the Convention)[62].

Article 6 of the POPs Regulation requires Member States to draw up action plans to eliminate the total release of substances listed in Annex III to the Regulation (corresponding to Annex C to the Convention).

In addition, Article 3(3) requires that Member States and the Commission take appropriate measures to prevent the manufacturing, placing on the market and use of substances that exhibit characteristics of POPs, taking into account the characteristics and criteria set out in Annex D to the Convention (there is no corresponding criteria in the POPs Regulation). This should be done, according to Article 3(3) through *'the assessment and authorisation schemes for existing and new substances under the relevant Union legislation'*.

As per Article 22(3)(b) of the Convention, if a Party to the Convention is **unable to accept an amendment of one of the Annexes to the Convention**, the party can submit a **notification of non-acceptance** to the Secretary General of the UN within one year from the date of communication to the Parties of the adoption of the amendment. The notification can be withdrawn by the Party at any time. In the absence of such notification, the amendment enters into force and must be implemented in the EU[63]. This opt-out mechanism has been used by the EU in one case (HBCDD) to delay the inclusion of a substance in the POPs Regulation (see Table 14).

Table 7 lists the substances included in the Stockholm Convention, the UNECE POPs Protocol and the POPs Regulation. There are currently 29 POPs listed in Annex I to the Regulation, which comprise pesticides and industrial chemicals.

Table 7: POPs listed in the Stockholm Convention, the UNECE POPs Protocol and the POPs Regulation[64]

Substance	EC number	CAS number	Listed in Convention	Listed in Protocol	Listed in POPs Reg
Intentionally produced POPs					
Aldrin	206-215-8	309-00-2	Annex A	Yes	Yes
Chlordane	200-349-0	57-74-9	Annex A	Yes	Yes

[59] Part A 'Substances listed in the Convention and in the Protocol as well as substances listed only in the Convention' ; Part B 'Substances listed only in the Protocol'.

[60] 'List of substances subject to restrictions'.

[61] 'List of substances subject to release reduction provisions'.

[62] Annex II to the Regulation currently does not contain any substances. The two substances listed in Annex B to the Convention, DDT and PFOS, are listed in Annex I to the POPs Regulation.

[63] European Commission (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding. Available at : https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en (Last accessed on 08.10.2020).
European Commission > Departments and executive agencies > Internal Market, Industry, Entrepreneurship and SMEs > Business and industry > Business and industry by sector > Chemicals > REACH > Relationships with other legislation.

[64] Based on 'Table 1: Overview on POPs regulated at international level' in the European Union Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants, SWD(2018) 495 final/2, 21.1.2019, p.9, and updated with the latest developments.

Substance	EC number	CAS number	Listed in Convention	Listed in Protocol	Listed in POPs Reg
Chlordecone	205-601-3	143-50-0	Annex A	Yes	Yes
Decabromodiphenyl ether (c-decaBDE)	4-604-9	1163-19-5	Annex A	No	Yes
Dicofol	204-082-0	115-32-2, 10606-46-9	Annex A	No	Yes[65]
Dieldrin ()	200-484-5	60-57-1	Annex A	Yes	Yes
Endosulfan	204-079-	959-98-8, 33213-65-9, 115-29-7, 1031-07-8	Annex A	No	Yes
Endrin	200-775-7	72-20-8	Annex A	Yes	Yes
Heptachlor	200-962-3	76-44-8	Annex A	Yes	Yes
Hexabromobiphenyl (HBB)	EC no. 52-994-2	36355-01-8	Annex A	Yes	Yes
Hexabromocyclododecane (HBCDD)	247-148-4, 221-695-9	25637-99-4, 3194-55-6	Annex A	No	Yes
Hexabromodiphenyl ether	253-058-6 and others	36483-60-0 and others	Annex A	Yes	Yes
Heptabromodiphenyl ether	273-031-2 and others	68928-80-3 and others			
Hexachlorobenzene (HCB)	204-273-9	118-74-1	Annex A	Yes	Yes
HCBD – hexachlorobutadiene	201-765-5	87-68-3	Annex A	Yes	Yes
Alpha hexachlorocyclo-hexane	206-270-8	319-84-6	Annex A	Yes Hexachlorocyclohexanes (HCH;EC no. 210-168-9; CAS no. 608-731), including lindane (EC no. 200-401-2; CAS no. 58-89-9)	Yes (all isomers including gamma HCH found in lindane)
Beta hexachlorocyclo-hexane(	206-271-3	319-85-7	Annex A		
Lindane	200-401-2	58-89-9	Annex A		
Mirex	19-196-6	2385-85-5	Annex A	Yes	Yes
Pentachlorobenzene	210-172-0	608-93-5	Annex A	Yes	Yes

[65] Commission Delegated Regulation (EU) 2020/1204 of 9 June 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of dicofol OJ L 270, 18.8.2020, p. 4–6. The delegated Regulation entered into force on 7 September 2020.

Substance	EC number	CAS number	Listed in Convention	Listed in Protocol	Listed in POPs Reg
Pentachlorophenol (PCP)	201-778-6 and others	87-86-5	Annex A	No	Yes
Polychlorinated biphenyls (PCB)	215-648-1 and others; CAS no.	1336-36-3 and others	Annex A	Yes	Yes
PCN –polychlorinated naphthalenes	274-864-4 and others; CAS no.	70776-03-3 and others	Annex A	Yes	Yes
Perfluorooctanoic acid (PFOA) ()	206-397-9 and others	335-67-1	Annex A	No	Yes[66]
SCCPs – short chain chlorinated paraffins ()	287-476-5	85535-84-8	Annex A	Yes	Yes
Tetrabromodiphenyl ether	254-787-2 and others	40088-47-9 and others	Annex A	Yes	Yes
Pentabromodiphenyl ether	251-084-2 and others	32534-81-9 and others			
Toxaphene	32-283-3	8001-35-2	Annex A	Yes	Yes
DDT	200-024-3	50-29-3	Annex B	Yes	Yes
Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride (PFOS)	217-179-8 220-527-1 249-644-6 249-415-0 274-460-8 260-375-3 223-980-3 250-665-8 216-887-4 246-262-1 206-200-6 and others	1763-23-1 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8 4151-50-2 31506-32-8 1691-99-2 24448-09-7 307-35-7 and others	Annex B	Yes	Yes
Unintentionally produced POPs					
Hexachlorobenzene (HCB)	204-273-9	118-74-1	Annex C	Yes	Yes
HCBD – hexachlorobutadiene	201-765-5	87-68-3	Annex C	Yes	Yes
Pentachlorobenzene	210-172-0	608-93-5	Annex C	Yes	Yes
Polychlorinated Biphenyls (PCBs)	215-648-1 and others	1336-36-3 and others	Annex C	Yes	Yes

[66] Commission Delegated Regulation (EU) 2020/784 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188 I/1, 15.6.2020. The Delegated Regulation entered into force on 4 July 2020.

Substance	EC number	CAS number	Listed in Convention	Listed in Protocol	Listed in POPs Reg
Polychlorinated dibenzo-p-dioxins (PCDD)	217-122-7	1746-01-6	Annex C	Yes	Yes
Polychlorinated dibenzofurans (PCDF)	N/A	N/A	Annex C	Yes	
PCN – polychlorinated napthalenes	274-864-4 and others	70776-03-3 and others	Annex C	Yes	Yes
Polycyclic aromatic hydrocarbons (PAHs)	205-916-6 and others	207-08-9 and others	No	Yes	Yes

2.2.1.3 Exemptions for specific uses

Annex I to the POPs Regulation includes **exemptions for specific uses of listed substances**. These exemptions reflect the exemptions included in the Annexes to the Convention. It may happen that the EU implements the amendment to the Annexes to the Convention more strictly in the POPs Regulation (i.e. that not all exemptions listed in the Annex to the Convention are included in Annex I to the POPs Regulation), in cases where there is already a restriction in the REACH Regulation for certain uses (in this case the entry in the POPs Regulation will reflect both the Convention and the existing restriction) or based on a risk analysis done under REACH in an Annex XV dossier, confirmed by the opinions of the RAC and SEAC[67].

Although there is **no exemption mechanism specific to defence or military equipment** (as in the BPR or the RoHS Directive), exemptions for defence/military equipment can be granted in the Annexes to the Convention and in the POPs Regulation. This has been the case for the use of decabromodiphenyl ether (decaBDE) – for civil and military aircrafts. Similar exemptions might be adopted in the future, in particular as other PFAS substances are likely to be listed in the Annexes to the Convention.

Exemptions for specific uses listed in Annex A or B to the Convention **expire five years after the date of entry into force of the decision to include the substance**, unless an earlier date is decided by a Party (Article 4(4) of the Stockholm Convention). The CoP, upon request from a Party, can decide to **extend the expiry date of a specific exemption** for a period of up to five years (Article 4(7) of the Stockholm Convention). For the specific exemptions to be applied by a Party, the Party must first register for those specific exemptions by returning to the Secretariat the forms for notifications of specific exemptions[68]. Registers of specific exemptions for chemicals listed in Annex A and B to the Convention[69] were established in accordance with Article 4 of the Stockholm Convention, listing the Parties that registered for specific exemptions and their expiration dates for each Party. A Party may withdraw at any time an entry from the Register for a specific exemption, by notifying the Secretariat. Specific exemptions included in Annex I to the POPs Regulation are those that the EU has registered.

[67] European Commission (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding, p.2.

[68] Specific Exemptions and Acceptable Purposes: http://chm.pops.int/Procedures/Exemptionsandacceptablepurposes/tabid/4646/Default.aspx (Last accessed on 10.11.2020) Stockholm Convention > Procedures > Exemptions and acceptable purposes.

[69] Registers of Specific Exemptions for chemicals listed in Annex A to the Convention: http://chm.pops.int/Implementation/Exemptions/SpecificExemptions/ChemicalslistedinAnnexA/tabid/4643/Default.aspx (Last accessed on 10.11.2020) Stockholm Convention > Implementation > Exemptions > Specific Exemptions > Register of Specific Exemptions for chemicals listed in Annex A.

2.2.1.4 Recent amendments to the Regulation

A recast of the Regulation was carried out in 2018 and the new POPs Regulation was adopted in 2019. The recast mainly aimed to:

- Assign **new responsibilities to ECHA and to the Forum** for Exchange of Information on Enforcement (see 2.2.1.5);
- **Align definitions with other legislation, in particular REACH** (i.e. definitions of *'placing on the market', 'substance', 'article',* were amended, definitions of *'manufacturing'* and *'use'* were added, and the term *'preparation'* was replaced by *'mixture'*) and the Waste Framework Directive (i.e. definitions of *'waste', 'disposal'* and *'recovery'* were amended). The definition of *'closed-system, site-limited intermediate'* was also added to the Regulation;
- Adapt the POPs Regulation with regards to Comitology. Article 16 of the previous POPs Regulation (Regulation (EC) No 850/2004) indicated that the comitology committee responsible for the Regulation had its legal bases in Article 29 of the Dangerous Substances Directive (67/548/EEC), which was repealed by the CLP Regulation. As a result, the comitology committee established by the Directive ceased to exist. Article 20 of Regulation (EU) 2019/1021 provides for the new Committee procedure (see 2.2.1.5);
- Update the Annexes to the Regulation to comply with the Stockholm Convention;
- Adapt provisions on reporting and monitoring, with a view to simplify monitoring and introducing new responsibilities for ECHA, in particular producing a regularly updated Union overview of the implementation of the Regulation.

2.2.1.5 Governance

European Commission

The European Commission (DG Environment, unit B2 Sustainable chemicals) is responsible for policy work under the POPs Regulation, in particular:

- The preparation of proposals to the Council for the listing of a substance in the Annexes of the Convention;
- The adoption of delegated acts to amend Annex I, II and III to the Regulation, pursuant to the listing of a substance in the Annexes to the Convention;
- The review and update of Annexes IV[70] and V[71] to the Regulation (concentration limits for POPs in waste).

The Commission also ensures the representation of the European Union in the Convention and maintains and updates, as appropriate, the plan for the implementation of Union obligations under the Convention. Article 7 of the Stockholm Convention requires all Parties to report on the measures taken to implement the Convention. This requirement is reflected in Article 9 of the POPs Regulation, which requires Member States to prepare and update their national implementation plan and the Commission, supported by ECHA to maintain and update the Union Implementation Plan. The Union Implementation Plan aims to:

- Review the existing Union level measures related to POPs;
- Assess their efficiency and sufficiency in meeting the obligations of the Stockholm Convention;

[70] 'List of substances subject to waste management provisions set out in Article 7'.
[71] 'Waste management'.

- Identify needs for further Union level measures;
- Establish a plan for implementing the further measures;
- Identify and strengthen links and potential synergies between POPs management, other environmental policies and other policy fields; and
- Increase awareness on POPs and their control measures.

The first plan was developed in 2007 (SEC(2007) 341) and was updated a first time in 2014 (SWD(2014) 172 final). The current (third) Plan was adopted in 2019 (SWD(2018) 495 final/2). The development of the fourth implementation plan is ongoing to reflect new policy developments (i.e. further addition of new POPs to the Convention and the EU regulation) and scientific and technological developments (i.e. where new research furthers the elimination of POPs)[72].

ECHA

Regulation (EU) No 2019/1021 gave new responsibilities to ECHA including:

- Supporting the identification of new POPs and the technical preparation of dossiers. These tasks are considered as the highest priority for ECHA. In practice these tasks include drafting the various POP dossiers on behalf of the Commission and presenting the cases to the POP Review Committee (POPRC). ECHA also provides general scientific support for the identification of new candidate POPs, for example, by identifying potential new POP candidates and by collaborating with countries (both EU and non-EU) who draft proposals and dossiers;
- Publishing a notice that a proposal for the listing of a substance will be prepared by the Commission and manage consultations in the EU for new POP proposals and for the risk profile and risk management evaluation stages of the process under the Stockholm Convention;
- Supporting the Commission's work in the Stockholm Convention's POPs Review Committee;
- Supporting the Commission in maintaining the Union implementation plan;
- Compiling and making available information from reporting obligations;
- Providing information on POPs in the Agency's chemical database and maintaining relevant sections of the website. Information on POPs, such as inventories on new and existing POP substances as well as general information regarding the regulation have already been incorporated on the website. ECHA uses its communication channels to inform on POP related developments and its helpdesk to answer enquiries from stakeholders;
- Supporting the Commission in establishing monitoring programmes and mechanisms for the regular provision of comparable monitoring data on the presence of substances as listed in Part A of Annex III to the Regulation in the environment;
- Managing the reception, registration and storage of national monitoring and reporting data, for whichIT systems are being developed and publish the Member States' national reports as well as the Union Overview report;
- Providing secretariat for the Forum for Exchange of Information on Enforcement, which will support enforcement activities related to the POPs Regulation;
- Providing technical assistance upon request to MSCAs and members of the Forum.

[72] DG Environment, Persistant Organic Pollutants (POPs) : https://ec.europa.eu/environment/chemicals/international_conventions/index_en.htm (Last accessed on 09.11.2020). European Commission > Environment > Chemicals > Persistant Organic Pollutants (POPs).

ECHA and the Commission coordinate the POP work through close collaboration and regular contact, for example, by regular monthly teleconferences and ad-hoc meetings. In addition, ECHA participates in the meetings of the Commission expert group on POPs.

Forum for Exchange of Information on enforcement

Specific activities for POPs may be undertaken as part of Forum enforcement projects, for example the planned REACH-EN-FORCE 10 (REF-10) on substances in articles will include POP substances (e.g. SCCP). REF-10 will run during the period 2021-2023[73].

Council

The Council is involved in the process for identifying and listing new POPs in the Annexes to the Convention. Based on the proposal made by the Commission to submit to the Convention a formal EU proposal to include a substance in the Annexes to the Convention, the Council adopts a decision on the submission of the proposal, on behalf of the Union.

The Council is also involved in the preparation of the EU position for the CoP meeting. Based on Commission proposals, the Council adopts Council decisions on the position to be taken, on behalf of the European Union, on the proposals for amendments to the Annexes to the Convention.

Member States' competent authorities

As per Article 19 of the POPs Regulation, Member States must designate a competent authority or authorities responsible for the administrative tasks and enforcement of the Regulation. In most countries, the designated competent authority is the Ministry responsible for environment, sometimes supported by the environmental agency. The list of MSCAs is provided in Annex VI to this report.

The Commission expert group 'Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)' (E01656)[74], gathering representatives of MSCAs, assists the Commission in the preparation of delegated acts, of risk profiles of substances, supports the Commission in the nomination of chemicals for listing in the Annexes to the Convention, and on other issues related to the implementation of the POPs Regulation (Union Implementation Plan, waste related issues, monitoring and reporting etc.).

In addition, as per Article 20 of the POPs Regulation, two Member State Committees are assisting the Commission in the implementation of the Regulation, the REACH Committee[75], established by Article 133 of the REACH Regulation, and for all waste-related issues, the Committee for the adaptation to scientific and technical progress and implementation[76] established by the Waste Framework Directive.

[73] Information provided by the Commission and ECHA as part of the stakeholder consultation, carried out for this study.

[74] See Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs) (E01656): https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1656&news=1 (Last accessed 09.10.2020). European Commission > Register of Commission expert groups and other similar entities > Group Details.

[75] Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (C34200). More information for the Committee can be accessed through a search of the Comitology Register (using the number of the Committee) https://ec.europa.eu/transparency/comitology-register/screen/committees?lang=en (last accessed on 09.10.2020). European Commission > Comitology Register > Search for Committee.

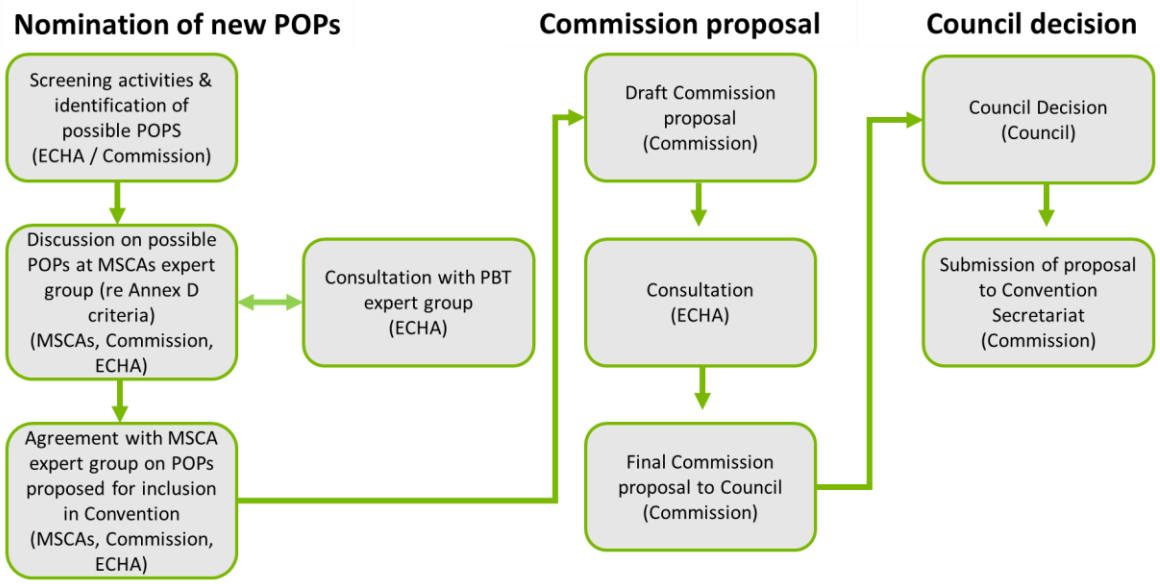
[76] The Committee for the adaptation to scientific and technical progress and implementation of Directive 2008/98/EC on waste (C37000): https://ec.europa.eu/transparency/comitology-register/screen/committees?lang=en (last accessed on 09.10.2020). European Commission > Comitology Register > Search for Committee.

2.2.1.6 Regulatory Evolution of substances

EU procedure to identify new POPs and submit a proposal for inclusion in the Convention

The process for identifying and nominating new POPs for inclusion in the Convention at EU level has been significantly revised by the 2019 recast of the POPs Regulation. Where only the Commission and the Council were involved before, **ECHA now has a supporting role in the process of identifying new POPs and managing consultations** (which are a new step in the procedure).

Figure 4: EU procedure for identification and proposal for inclusion of new POPs in the Convention



There is no specific ECHA process to identify substances that meet the criteria in Annex D to the Convention, but substances which meet the characteristics and criteria listed in Annex D to the Convention may be identified based on **available data and risk assessment activities carried out under REACH** (registration data, SVHC identification, PBT assessment), **the BPR and the Plant Protection Products Regulation (PPPR)**[77]. ECHA and the Commission have undertaken some **screening activities** for potential new POP candidates. Substances with PBT/vPvB properties and undergoing REACH regulatory processes (especially SVHC and Restriction) may be likely candidates, as are active substances used in biocidal products and also active substances used in plant protection products (for which EFSA has undertaken reviews), which are in the process of approval or renewal of the approval under the BPR and PPPR, respectively. Member States, through the Competent Authorities expert group, are also encouraged to provide available data at national level to identify substances which meet the POPs criteria (Annex D to the Convention) and provide evidence for the proposal[78]. The **potential new POP candidates are discussed with the Competent Authorities expert group**, in particular regarding the fulfilment of the screening criteria listed in Annex D to the Convention. A substance may, on the basis of the discussion, be prioritised for nomination to the Stockholm Convention. If there is a **general agreement among the MSCAs** to proceed with preparing the proposal, the **Commission drafts the proposal with the support of ECHA and MSCAs**. Discussion

[77]Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1–50.

[78] Summary record of the 21st Meeting of the CAs on Regulation (EU) 2019/1021 on POPs, 26 November 2019. Available at: https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17912 (Last accessed on 09.10.2020)

on the likely fulfilment of the screening criteria may also held in the **PBT Expert Group.**

The **scientific dossier** in accordance with Annex D to the Convention, intended to accompany an EU proposal to the Convention Secretariat **is open to consultation**, managed by ECHA. Submitted comments (excluding confidential information) are published on ECHA's website. The consultation on the draft proposal for the listing of Chlorpyrifos in the Convention is ongoing[79]. ECHA also organises consultations on the draft risk profile and the draft risk management evaluation prepared by the POPRC (see Table 9), in parallel to the calls for information launched by the POPRC (as this was done for Methoxychlor and Dechlorane Plus[80]).

The EU proposal takes the form of a Commission proposal for a Council Decision on the submission of a proposal for the listing of a substance in the Annexes to the Convention, submitted by the Commission to the Council. The **Council then adopts the Council Decision**, giving the Commission the mandate to submit a proposal for the listing of a substance in the Convention on behalf of the EU to the Secretariat of the Convention, together with the scientific dossier.

The table below lists the substances the EU intends to propose for listing in the Convention with the status of the proposal.

Table 8: Substances for which a proposal for inclusion in the Convention is ongoing at EU level

Substance	EC/CAS number	Status
Chlorpyrifos	EC no. 220-864-4; CAS no 2921-88-2	Draft Proposal published, consultation ended on 09/12/2020 [81]
Octamethylcyclotetrasiloxane (D4)	EC no. 209-136-7; CAS no 556-67-2	Proposal under development (Council decision pending)[82]

Other substances are considered by EU institutions and Member States for the development of a proposal, as shown by the discussions at the Competent Authorities expert group[83], such as:

- Quinoxyfen (EC no. 602-997-3; CAS no. 124495-18-7),
- Medium-chain chlorinated paraffins (MCCPs) (EC no. 287-477-0; CAS no. 85535-85-9),
- Long-chain chlorinated paraffins (LCCPs) (EC no. 264-150-0; CAS no. 63449-39-8), and
- Phthalates, including DEHP (EC no. 204-211-0; CAS no. 117-81-7).

[79] ECHA, Proposals for new POPs: https://echa.europa.eu/proposals-for-new-pop-s (Last accessed on 09.11.2020). ECHA > Consultations > Proposals for new POPs.
[80] ECHA, Previous consultations on proposals for new POPs: https://echa.europa.eu/previous-proposals-for-new-pop-s (Last accessed on 09.11.2010). ECHA > Consultations > Proposals for new POPs > Previous consultations on proposals for new POPs.
[81] According to the Commission and ECHA, the submission of a proposal for a Council Decision to the Council may take place this year.
[82] The Commission submitted a proposal for a Council Decision on the submission, on behalf of the European Union, of a proposal for the listing of D4 in Annex A, B and/or C to the Stockholm Convention in March 2016 (under the previous POPs Regulation – before ECHA had a role in the nomination of new POPs). The Council Decision is still pending.
[83] Summary record of the 21st Meeting of the CAs on Regulation (EU) 2019/1021 on POPs, 26 November 2019, point 18. Available at: https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17912 (Last accessed on 09.10.2020).

Procedure for including new POPs in the Annexes to the Convention

The procedure includes the following steps, which takes at least three and a half years[84].

Table 9: Procedure for listing a new POP under the Stockholm Convention[85]

Steps in the procedure	Authority/stakeholder responsible
1. Drafting and submission of the proposal	
Any party to the Convention can propose new substances for inclusion in the Annexes to the Convention. The proposal must provide evidence that the substance fulfils the screening criteria listed in Annex D to the Convention.	Parties to the Stockholm Convention
The Secretariat of the Convention checks that the proposal contains information required by Annex D to the Convention and forwards it to the POPRC.	Secretariat of the Stockholm Convention
2. Assessment of the proposal	
Screening criteria	
The POPRC reviews the proposal and applies the screening criteria specified in Annex D to the Convention (see 2.2.1.1).	POPRC
Risk assessment	
If the POPRC concludes that the criteria are met, it launches an information collection on further hazards, risks, uses and exposures, as listed in Annex E to the Convention ('Information requirements for the risk profile').	POPRC
Based on information provided by the Parties and observers, the POPRC drafts a risk profile, including information required in Annex E to the Convention: ■ Sources, including production data, including quantity and location; uses and releases, such as discharges, losses and emissions ■ Hazard assessment for the endpoint or endpoints of concern, including a consideration of toxicological interactions involving multiple chemicals ■ Environmental fate, including data and information on the chemical and physical properties of a chemical as well as its persistence and how they are linked to its environmental transport, transfer within and between environmental compartments, degradation and transformation to other chemicals ■ A determination of the bio-concentration factor or bio-accumulation factor, based on measured values ■ Monitoring data ■ Exposure in local areas and, in particular, as a result of long-range environmental transport ■ National and international risk evaluations, assessments or profiles and labelling information and hazard classifications, as available ■ Status of the chemical under international conventions	POPRC
Based on the risk profile, the POPRC decides whether global action is needed on the substance.	POPRC
3. Risk management	
If the POPRC decides to go forward with the proposal, it launches a call for	POPRC

[84] European Commission (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding.

[85] Table based on the overviews of the procedure provided on the Stockholm Convention's website: http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx (Last accessed on 09.10.2020) [Stockholm Convention > The Convention > POPs Review Committee > Overview and Mandate] and ECHA's website: https://echa.europa.eu/proposals-for-new-pops (Last accessed on 09.10.2020) [ECHA > Legislation > POPs > Proposals for new POPs].

Steps in the procedure	Authority/stakeholder responsible
information related to risk management solutions, alternatives, socio-economic considerations and existing risk management measures, as specified in Annex F to the Convention ('Information on socio-economic considerations')	
Based on the information provided by the Parties and observers, the POPRC develops a risk management evaluation, including the information required in Annex F to the Convention: ■ Efficacy and efficiency of possible control measures in meeting risk reduction goals (including technical feasibility, costs including environmental and health costs) ■ Alternatives (including technical feasibility, costs including environmental and health costs, efficacy, risks, availability and accessibility) ■ Positive and/or negative impacts on society of implementing possible control measures (such as health, agriculture, biodiversity, economic aspects, sustainable development, social costs) ■ Waste and disposal implications (including technical feasibility and costs) ■ Access to information and public education ■ Status of control and monitoring capacity ■ Any national or regional control actions taken, including information on alternatives, and other relevant risk management information	POPRC
The POPRC assesses the information and makes a recommendation to the CoP regarding the inclusion of the substance in the Convention.	POPRC
4. Decision on the inclusion of the substance in the Annexes to the Convention	
The CoP decides, based on the recommendation from the POPRC, on the inclusion of the substance in Annex A, B and/or C to the Convention and specifies the control measures and the exempted uses. Amendments to the Convention must be adopted by a consensus of all parties. If no agreement is reached, a three-quarter majority might, as a last resort, adopt the amendments. Amendments to the Protocol must be adopted by a consensus of the parties.	Conference of Parties to the Stockholm Convention

As mentioned in section 2.2.1.5, the EU prepares a **common position for the meetings of the POPRC and CoP**, which includes the EU's position on the inclusion of new substances in the Annexes to the Convention. Those positions are **discussed with Member States at the Commission expert group and the Council**.

The substances presented in the Table below are currently under review for inclusion in the Convention.

Table 10: Status of the procedure for substances proposed for listing under the Convention[86]

Substance	EC/CAS number	Status of review
Dechlorane plus	EC no. 236-948-9; CAS no. 13560-89-9	Risk profile under development
Methoxychlor	EC no. 200-779-9 ; CAS no. 72-43-5	Risk profile under development
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	EC no. 247-384-8; CAS no. 25973-55-1	Proposal submitted to the Convention
Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds	EC no. 206-587-1 (and others); CAS no. 355-46-4 (and others)	Recommended by POPRC for inclusion in Annex A to the Convention without specific exemptions[87]

Implementation of amendments to the Annexes to the Convention in the POPs Regulation

Following inclusion in the Annexes to the Convention, the substance is added to the annexes to the Regulation with the **adoption of a delegated act**. The Commission adopts the delegated act, after consulting the Competent Authorities expert group for the POPs Regulation. Delegated acts are notified to the Council and Parliament, which have two months to provide any objection to the entry into force of the delegated act.

2.2.2 Interactions with REACH and CLP

2.2.2.1 Interactions with REACH

Definitions

The **recast of the POPs Regulation in 2019** provided the opportunity to **align the terminology used in the POPs Regulation with that of the REACH Regulation**. The definitions of 'placing on the market', 'substance', 'article', that were already in the POPs Regulation were amended to cross-reference the definitions of REACH (Article 2(1), (2), and (3) of the POPs Regulation), definitions of 'manufacturing' and 'use' were added and cross reference REACH (Article 2(5) and (6) of the POPs Regulation), and the term 'preparation' was replaced by 'mixture' to use the same terminology as in REACH (Article 2(4) of the POPs Regulation).

POPs and PBT identification

The REACH Regulation also **includes a process for identifying substances that present POPs characteristics, i.e., persistence and bioaccumulation**. As part of the REACH registration process, all substances registered for which a Chemical Safety Assessment is required (i.e., substances manufactured or imported in volumes above 10 tonnes per year) must be screened for persistent, bioaccumulative and/or toxic (PBT) or very persistent and very bioaccumulative substance (vPvB) properties. If a substance is considered a PBT or vPvB, registrants must identify, implement and communicate through their supply chain risk management measures and operational conditions to

[86] Substances under review are listed on the Stockholm Convention's website: http://chm.pops.int/TheConvention/ThePOPs/ChemicalsProposedforListing/tabid/2510/Default.aspx (last accessed on 09.10.2020) [Stockholm Convention > The Convention > The POPs > Chemicals Proposed for Listing] and ECHA's website: https://echa.europa.eu/list-of-substances-proposed-as-pops (last accessed on 09.10.2020) [ECHA > Information on Chemicals > POPs Regulation > List of substances proposed as POPs].

[87] Decision of POPRC -15/1: http://chm.pops.int/TheConvention/ThePOPs/ChemicalsProposedforListing/tabid/2510/Default.aspx (last accessed on 09.10.2020) Stockholm Convention > The Convention > The POPs > Chemicals Proposed for Listing.

reduce the releases and exposures to the substance. Following the PBT assessment, the substance might be identified as an SVHC, as per Article 59 of REACH, and placed on the Candidate List, and later might be made subject to the authorisation regime.

Criteria to identify PBT / vPvB substances are laid down in **Annex XIII to REACH**. They **differ slightly from the screening criteria included in Annex D to the Convention**, in particular as they distinguish between PBT and vPvBs (which have stricter persistence and bioaccumulation criteria). Both sets of criteria focus on the same properties – persistence, bioaccumulation. Toxicity is not a clear-cut criterion in the Convention, but Annex D to the Convention refers to it in the criterion related to *'adverse effects'* (and requests the provision of '*evidence of adverse effects to human health or to the environment*' / or '*toxicity or ecotoxicity data indicate the potential for damage to human health or to the environment*'). The REACH Regulation, however, provides for a clear toxicity criterion for PBT substances but does not include toxicity as a criterion for vPvB substances, as highlighted in a study from the Dutch National Institute for Public Health and the Environment from 2011[88]. Contrary to POPs under the Convention, there is no criterion linked to long range transport potential for PBT and vPvB. The table below presents the criteria laid down in the Stockholm Convention and REACH Annex XVII (PBT and vPvB criteria). Those criteria are not cumulative – they do not all need to be fulfilled for the assessment of persistence, bioaccumulation and toxicity. The criteria for identification of POP, PBT and vPvB substances are presented in Table 11 below.

[88] RIVM (2011) Identifying potential POP and PBT substances. Development of a new Persistence/ Bioaccumulation-score. RIVM Report 601356001/2011. Available at: https://www.rivm.nl/bibliotheek/rapporten/601356001.pdf (Last accessed on 09.10.2020).

Table 11: Criteria for the identification of POPs, PBT and vPvBs (based on RIVM, 2011)

Criterion	Annex D Stockholm Convention	PBT (REACH Annex XIII)	vPvB (REACH Annex XIII)
Persistence	Half-life (t1/2) in water > 2 months t1/2 in soil > 6 months t1/2 in sediment > 6 months Evidence that the chemical is sufficiently persistent to justify inclusion in the Convention	t1/2 in marine water > 60 days, t1/2 in fresh or estuarine water > 40 days t1/2 in marine sediment > 180 days, t1/2 in fresh or estuarine water sediment > 120 days t1/2 in soil > 120 days	t1/2 in marine, fresh or estuarine water > 60 days t1/2 in marine, fresh or estuarine water sediment > 180 days t1/2 in soil > 180 days
Bioaccumulation	Bio-concentration factor or bio-accumulation factor in aquatic species > 5,000 or, in the absence of such data, that the log Kow is greater than 5 Evidence of other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity; Monitoring data in biota indicating that the bio-accumulation potential is sufficient to justify inclusion in the Convention	Bioconcentration factor in aquatic species > 2 000	Bioconcentration factor in aquatic species > 5 000
Long range transport potential	t1/2 in air > 2 days Measured levels in remote areas or via migratory species, air or water	No criterion	No criterion
Toxicity	Reasons for concern Evidence of adverse effects Toxicity or ecotoxicity data that indicate the potential for damage	Long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms < 0,01 mg/l Classified as carcinogenic 1A or 1B, or mutagenic 1A or 1B or toxic for reproduction 1A, 1B, or 2 Chronic toxicity indicated by classification specific target organ toxicity after repeated exposure (STOT RE category 1 or 2)	No criterion

Registration under REACH and PBT assessments are one of the main sources of information for identifying substances meeting criteria listed in Annex D to the Convention, which can be candidates for inclusion in the Convention[89].

[89] European Commission, European Union Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants, SWD(2018) 495 final/2, 21.1.2019, p. 71.

Interactions in risk management measures

The main objective of the Stockholm Convention, and thus the POPs Regulation, is to eliminate the production and use of intentionally produced POPs and encourage their substitution. Elimination and substitution of hazardous substances are also key objectives of the REACH Regulation. As the REACH Regulation aims to control SVHC, which include PBT and vPvB, **the scope of the REACH Regulation and the POPs Regulation may partially overlap**. **Potential overlaps might occur when risk management measures are taken under REACH or the POPs Regulation for substances that are already regulated under one of the two regulations**. A Common Understanding paper[90] on the interaction between REACH and the POPs Regulation was adopted by the Commission. This paper identifies cases of potential overlaps between the two Regulations and explains agreed standard practice in those cases. The Common Understanding paper has been developed at a time when Regulation (EC) No 850/2004 (previous POPs Regulation) was still in force. The Commission will analyse whether the Common Understanding paper needs to be revised following the recast of the POPs Regulation. It is, however, likely that the main elements of the paper are still valid and that only minor adjustments may be needed[91].

The following tables summarise those cases and actions recommended by the paper, first with regards to Annex XVII[92] restrictions, then with regards to Annex XIV[93] authorisations under REACH.

With regards to REACH Annex XVII restrictions, the paper covers the following three scenarios:

Table 12: Interactions between REACH Annex XVII restriction and inclusion in Annex I to POPs Regulation.

Scenario in CU Paper	Status of REACH Restriction	Status of inclusion POPs Convention / Regulation	Conditions	Action recommended
1	Under consideration	In force	A. Full ban of a substance under POPs Regulation (no exemptions for specific use)	Risk to human health and environment already adequately controlled; conditions for the preparation of a proposal for a restriction laid down in Article 69 of REACH are not met.
			B. Exemptions for specific uses in Convention and the EU wants to implement the Convention more strictly	Stricter rules would be included in the POPs Regulation, based on risk analysis done under REACH.
2	In force	Under consideration	A. Amendments to the Annexes to the Convention are consistent with REACH Annex XVII (i.e. restricted uses under REACH are covered by the ban in the	Annexes to the POPs Regulation are amended to implement the amendments to the Annexes to the Convention; the entry in REACH Annex XVII concerning the substance is removed.

[90] European Commission (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding.
[91] Information provided by the Commission as part of the stakeholder consultation.
[92] 'Restrictions on the manufacture, placing, on the market and use of certain dangerous substances mixture and articles'.
[93] 'List of substances subject to autorisation'.

Scenario in CU Paper	Status of REACH Restriction	Status of inclusion POPs Convention / Regulation	Conditions	Action recommended
			Convention)	
			B. Amendments to the Annexes to the Convention are not consistent with REACH Annex XVII: exempted uses in the Annexes to the Convention are restricted in REACH Annex XVII	Annexes to the POPs Regulation are amended to implement the amendments to the Annexes to the Convention; the entry in REACH Annex XVII concerning the substance is removed. The entry in the POPs Regulation will implement the Convention more strictly (exempted uses in the Convention will not be exempted in the POPs Regulation to reflect the REACH restriction).
			C. Amendments to the Annexes to the Convention are not consistent with REACH Annex XVII: uses benefitting from a derogation in REACH Annex XVII are restricted by the Annexes to the Convention.	The Convention and the POPs Regulation prevails over the REACH Regulation. Derogations provided for in REACH Annex XVII can apply only until the entry into force of the amendments to the Convention.
3	Under consideration	Under consideration	The inclusion in the Annexes to the Convention is proposed before or soon after the restriction procedure has been initiated	Pursue the restriction procedure as it normally takes less time than the process for listing a substance in the Annexes to the Convention, and because it will support the development of the EU position for the Convention negotiations. In addition, the outcome of the procedure under the Convention could be that POPs criteria are not met and the risk would not be properly managed if the restriction is not pursued.

According to the Commission, the legal coherence between REACH Annex XVII and the POPs Regulation will be improved in the future by ensuring that amendments to REACH Annex XVII are done in a more timely manner after the listing of a new chemical in the POPs Regulation[94].

With regards to Annex XIV authorisations, the paper covers the following three scenarios:

[94] Information provided by the Commission and ECHA as part of the stakeholder consultation carried out for the study.

Table 13: Interactions between REACH Annex XIV authorisation requirements and inclusion in Annex I to POPs Regulation.

Scenario in CU Paper	Status of REACH Authorisation	Status of inclusion POPs Convention / Regulation	Conditions	Action recommended
1	Under consideration	In force	A. Full ban of a substance under POPs Regulation (no exemptions for specific use)	The substance might not be included in Annex XIV to REACH.
			B. There are exempted uses in the Convention and POPs Regulation	If the substance was to be included in Annex XIV to REACH, authorisation might only be granted to exempted uses under the Convention and POPs Regulation. However, risks related to exempted uses can be addressed through the POPs Regulation (adaptation to technical progress). Superimposing REACH authorisation requirements should be properly justified.
2	In force	Under consideration	A. The listing in the POP Convention is adopted before the sunset date…	
			1. And the one-year deadline to opt out from an amendment to the Convention expires before the sunset date or the date of decision on the application	Two options: Implement the amendment to the Annexes to the Convention, refuse/withdraw authorisations based on Article 61(6) of REACH, and remove the entry in Annex XIV to REACH [95].
				Opt out of the amendment to the Annexes to the Convention until the sunset date.
			2. And the one-year deadline to opt out from an amendment to the Convention expires after the sunset date and the date of decision on the application	Three possibilities: If no authorisations are requested or can be granted, the amendment to the Convention can be implemented immediately.
				If authorisations requested are in line with exempted uses in the Convention, the amendment can be implemented immediately, and the authorisations granted.
				If authorisations requested are for uses that are not exempted in the Convention, there are two options, implement the amendment to the

[95] According to Article 61(6) of REACH: 'If a use of a substance is subsequently prohibited or otherwise restricted in the POPs Regulation, the Commission shall withdraw the authorisation for that use'.

Scenario in CU Paper	Status of REACH Authorisation	Status of inclusion POPs Convention / Regulation	Conditions	Action recommended
				Convention and refuse authorisations, or grant the authorisations and opt out within the one-year deadline.
			B. The listing in the POP Convention is adopted after the sunset date…	
			1. And the Convention does not exempt any uses	Two options: Implement the amendment to the Annexes to the Convention, withdraw already granted authorisations and remove authorisation requirements.
				Opt out of the amendment to the Annexes to the Convention within the one-year deadline.
			2. And the Convention does exempt some uses	If authorisations granted are in line with exempted uses, the amendment to the Convention can be implemented in the POPs Regulation
				If authorisations granted are not in line with exempted uses, there are two options: implementing the amendment and withdrawing authorisations or opting out withing the one-year deadline.
3	Under consideration	Under consideration	A. Inclusion in Annex XIV to REACH is considered when a proposal for listing in the Convention has been submitted	Too late to introduce authorisation requirements under REACH (as the authorisation procedure takes roughly as much time as listing in the Convention).
				An alternative is to introduce a restriction procedure instead, pending inclusion in the Convention as the restriction procedure is quicker and will manage the risk in the meantime.
			B. Authorisation procedure under REACH terminated when listing in Convention is proposed	Possibility to go through the authorisation procedure pending inclusion in the Convention.

The table below lists examples of substances covered by the POPs Regulation for which the various scenarios identified above have been applied.

Table 14: Status of POPs in REACH and applicable common understanding (CU) paper scenario

Substance	Status in POPs Regulation	Status in REACH	Common Understanding paper scenario
Perfluorooctanoic acid (PFOA) (EC no. 206-397-9 and others; CAS no. 335-67-1)	Annex I to POPs Regulation (2019)	Entry 68 in Annex XVII to REACH (2017)	Restriction 2B – the entry in REACH Annex XVII will be deleted[96]. However, the entry in Annex I to the POPs Regulation establishes a limit value (for PFOA, its salts and PFOA-related compounds) occurring as an unintentional trace contaminant in substances, mixtures and articles, which does not exist in the Convention but reflects the restriction previously established in REACH (0,025 mg/kg for PFOA including its salts, and at 1 mg/kg for the individual PFOA-related compounds or a combination of those compounds) [97]. Restriction 2C – Derogations granted in Annex XVII to REACH which are not among the specific exemptions in Annex A to the Convention could apply until 3 December 2020 (date of entry into force of the amendment of Annex A to the Convention)[98].
Decabromodiphenyl ether (c-decaBDE) (EC no. 4-604-9; CAS no. 1163-19-5)	Annex I to POPs Regulation (2017)	Entry 67 in Annex XVII to REACH (2017)	Restriction 2A – the entry in REACH Annex XVII will be deleted; exempted uses in the final Convention decision were in line with exemptions previously established in REACH Annex XVII. Authorisation 3A – c-decaBDE was considered for Annex XIV to REACH when proposal for inclusion in Convention is submitted. The EU went for Annex XVII instead[99] to manage risks until inclusion in the Convention.
Hexabromocyclododecane (HBCDD) (EC no. 247-148-4, 221-695-9; CAS no. 25637-99-4, 3194-	Annex I to POPs Regulation	Entry 03 Annex XIV to REACH	Authorisation 2A1: Listing in Convention adopted before the sunset date (November 2013) and the 1-year deadline

[96] The technical amendment to REACH Annex XVII to remove the entries for PFOA, and decaBDE and Pentachlorophenol (PCP) is currently in process for adoption by the Commission and is expected to come into force later this year. The REACH committee has already expressed a favourable opinion for its adoption.

[97] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188 I/1, 15.6.2020.

[98] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188 I/1, 15.6.2020.

[99] Commission Delegated Regulation (EU) 2017/227 of 9 February 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(pentabromophenyl)ether, OJ L 35/6, 10.2.2017.

Substance	Status in POPs Regulation	Status in REACH	Common Understanding paper scenario
55-6)	(2013)	(sunset date August 2015)	for implementation expiring before the sunset date (November 2014). The EU decided to opt out and notified the Secretary General of the Convention on 19 August 2015 that the Union did not accept the amendment of Annex A to the Convention. 13 companies were granted authorisations in January 2016 for two specific applications for uses in expanded polystyrene[100]. On 22 April 2016, the European Union notified the Secretary-General of its withdrawal of the notification of non-acceptance of the amendment. REACH Authorisations granted had to be limited to the scope of the specific exemption in Annex A to the Convention (i.e., use of HBCDD only in expanded polystyrene and extruded polystyrene in buildings). As no authorisations had been requested for extruded polystyrene, this exemption was removed from Annex I to the POPs Regulation[101].
Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride (PFOS) (EC no. 217-179-8 and others; CAS no. 1763-23-1 and others)	Annex I to POPs Regulation (2010)	(Former) Entry 53 in Annex XVII to REACH (2009)	Restriction 2B – the entry in REACH Annex XVII was deleted in 2011. Exempted uses in the REACH restrictions were carried over in Annex I to the POPs Regulation. However, the REACH restriction contained fewer exempted uses than the Convention decisions. Annex I to the POPs Regulation only contains exemptions previously included in the REACH restriction[102].

Among substances proposed (or intended to be proposed by the EU) for inclusion in the Annexes to the Convention, some are already regulated under REACH. Table 15 below shows their status under REACH and the possible scenarios that could be applicable, based on the Common Understanding paper.

[100] Authorisations granted for two uses of HBCDD: https://echa.europa.eu/view-article/-/journal_content/title/authorisations-granted-for-two-uses-of-hbcdd (Last accessed on 09.10.2020).
[101] Commission Regulation (EU) 2016/293 of 1 March 2016 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, OJ L 55, 2.3.2016, p. 4–8.
[102] Commission Regulation (EU) 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III, OJ L 223/29, 25.8.2010.

Table 15: Substances proposed for inclusion in the Annexes to the Convention, their status in Annex XIV and XVII to the REACH Regulation and potentially applicable common understanding (CU) paper scenario

Substance	Status in REACH	Potential Common Understanding paper scenario
Dechlorane plus (EC no. 236-948-9 ; CAS no. 13560-89-9)	▪ Restriction proposal ongoing ▪ Candidate List of SVHC for Authorisation (2018)	Authorisation 3A - initially considered for Annex XIV to REACH when proposal for inclusion in Convention submitted. Restriction proposed instead to manage risk until inclusion in Convention and POPs Regulation.
Methoxychlor (EC no. 200-779-9 ; CAS no. 72-43-5)	Not registered under REACH	
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) (EC no. 247-384-8; CAS no. 25973-55-1)	REACH Annex XIV Entry 51 (last application date May 2022; sunset date November 2023)	Depends when amendments to Annex A to the Convention are adopted – potentially 2A1/2.
Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds (EC no. 206-587-1 (and others); CAS no. 355-46-4 (and others))	Restriction proposal ongoing[103] Candidate List of SVHC for Authorisation (2017)	Authorisation 3A - initially considered for Annex XIV to REACH when proposal for inclusion in Convention submitted. Restriction proposed instead to manage risk until inclusion in Convention and POPs Regulation.
Chlorpyrifos (EC no. 220-864-4; CAS no 2921-88-2)	Not registered under REACH	
Octamethylcyclotetrasiloxane (D4) (EC no. 209-136-7; CAS no 556-67-2)	▪ Candidate List of SVHC for Authorisation (2018) / Recommendation for inclusion in Annex XIV to REACH (2020) ▪ REACH Annex XVII Entry 70 (2018)	Authorisation 3B – possibility to go through with the authorisation process (if sufficiently advanced to be adopted before amendment to Annex A to the Convention).

During the stakeholder consultation, one MoD mentioned that the restriction process for POP candidate substances is seen as a preliminary listing in the Convention, and that restricting the substance in REACH first could be a useful process as the strategies implemented by the defence industry to mitigate the impact of the REACH Regulation have been of great value also to mitigate the impacts of other chemical regulations, such as the POPs Regulation. Another MoD indicated that, when the substance is first restricted under REACH, research and development activities are launched to find alternatives, which proves useful once the substance is included in the Convention. The restriction is perceived in these cases as a warning for the industry that the substance might be prohibited by the POPs Regulation, which allows solutions to be searched for ahead of the listing in the Convention.

Another opportunity provided by the adoption of a REACH restriction prior to the listing of the

[103] RAC's opinion was adopted 13 March 2020 and SEAC's opinion was adopted 11 June 2020: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1827f87da (Last accessed on 02.12.2020)

substance in the Convention, according to one MoD, is that it allows for a discussion of exemptions that are necessary for defence use, early in the regulatory process – even though the REACH Regulation allows for defence exemption. If these exemptions are discussed at this early stage, they could be more easily fed into the proposal for inclusion of the substance in the Convention (if the EU is the submitter) and/or in the work of the POPRC and final decision of the CoP.

2.2.2.2 Interactions with CLP

There are no direct references to CLP in the provisions of the POPs Regulation. However, when certain uses of POPs listed in Annex I to the Regulation are exempted from prohibition, they must comply with CLP when placed on the market. Annex I to the POPs Regulation might also provide for mandatory labelling requirements for certain allowed uses of certain listed substances (i.e., make sure that the POP present in the product is identifiable), to be applied in addition to the requirements of the CLP Regulation. There are currently two substances for which such requirements have been included in Annex I to the POPs Regulation (debaBDE and hexabromocyclododecane) [104].

2.2.3 Interactions with other chemicals' regulations/directives

2.2.3.1 POPs Regulation and BPR

See section 2.1.3.1 'BPR and POPs Regulation'.

2.2.3.2 POPs Regulation and Ozone Regulation

There are no substances regulated both by the POPs Regulation and the Ozone Regulation. No issues have been raised by stakeholders on the interface between those regulations.

2.2.3.3 POPs Regulation and F-gas Regulation

There are no substances regulated both by the POPs Regulation and the F-gas Regulation. No issues have been raised by stakeholders on the interface between those regulations.

2.2.3.4 POPs Regulation and RoHS Directive

Inclusion in Annex II to RoHS *('Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials'*) is not based on specific hazard properties defined in other chemicals' legislation (such as REACH, CLP or POPs Regulations); however, substances or groups of substances meeting POPs criteria may be included in Annex II to RoHS based on the recommendations of the substance review (see section 2.5.1.5).

Several substances banned by the POPs Regulation belong to groups of substances restricted in electrical and electronic equipment (EEE) under the RoHS Directive:

- **PBDEs:** Pentabromodiphenyl ether (EC no. 251-084-2; CAS no. 32534-81-9), Tetrabromodiphenyl ether (EC no. 254-787-2; CAS no. 40088-47-9) Hexabromodiphenyl ether (EC no. 253-058-6; CAS no. 36483-60-0), Heptabromodiphenyl ether (EC no. 273-031-2; CAS no. 68928-80-3) and decabromodiphenyl ether (EC no. 214-604-9; CAS no. 1163-19-5), all regulated under the POPs

[104] Without prejudice to the application of other Union provisions on the classification, packaging and labelling of substances and mixtures, articles in which decaBDE is used must be identifiable by labelling or other means throughout its life cycle; and expanded polystyrene placed on the market after 23 March 2016 in which hexabromocyclododecane was used must be identifiable by labelling or other means throughout its life cycle.

Regulation belong to the group of polybrominated diphenyl ethers (PBDEs), restricted by the RoHS Directive. For all these substances, the entry in the POPs Regulation contains a derogation, which allows for the placing on the market and use of those substances in electrical and electronic equipment falling within the scope of the RoHS Directive. Those derogations are not present in the Convention, they have been introduced in the POPs Regulation by a Corrigendum in June 2019[105]. Although no explanation is provided, it is assumed that the correction mainly aimed to manage the interactions between the POPs Regulation and the RoHS Directive. In this case, the limit value provided by the RoHS Directive (0,1% by weight in homogenous material) would apply for EEE instead of that of the POPs Regulation for those substances (equal to or below 10 mg/kg or 0,001 % by weight);

- **PBBs (RoHS) and HBB (POP):** The flame retardant Hexabromobiphenyl (HBB, EC no. 52-994-2; CAS no. 36355-01-8) banned by the POPs Regulation belongs to the wider group of polybrominated biphenyls (PBBs)[106], restricted by RoHS. However, the entry for HBB in the POPs Regulation does not contain any derogation for EEE. Therefore, the POPs Regulation prevails over the RoHS Directive for the specific substance HBB (which is then banned from being placed on the market and used), while the RoHS Directive applies to other substances in the PBB group.

No issues have been raised by stakeholders on the interface between those regulations.

2.2.4 Impacts on the defence sector

2.2.4.1 Availability of substances

Four MoDs indicated that the POPs Regulation had until now **little or no impact on the availability of substances for defence equipment**, because most substances listed in Annex I to the POPs Regulation have already been substituted in the defence sector and more largely in Europe, and alternatives meeting the minimum standards for use in defence applications have been available in most cases. However, concerns were expressed – by MoDs and defence industry stakeholders – in relation to substances recently included in Annex I to the Regulation – in particular **PFOA** – and to potential future inclusion of new substances in Annex A to the Convention.

Regarding PFOA, one MoD explained that the POPs Regulation did have an impact on the availability of surface treatments available for textiles (for water and oil repellency and non-flammable properties). Substitution of long chain PFAS, such as PFOA, is mostly ensured by the use of short chain PFAS, which entails a risk of obsolescence, according to two MoDs, as short chain PFAS, used in defence applications, might be included in the Annexes to the Convention in the future, following their inclusion in Annex XVII to REACH. This might impact the availability of substances meeting military standards for **fire extinguishing equipment, military personal protection equipment and textiles**, as, at least for personal protection equipment, non-fluorinated substances do not display the same level of performance and reliability as PFAS substances and do not meet military standards. MoDs indicated that they had to further assess the impacts of future restrictions of PFAS substances. The wide use of PFAS, in particular for personal protection equipment, is, however, of concern as it might make substitution more difficult.

Two MoDs mentioned the **substitution of long chain PFAS by short chain PFAS as a possible case of regrettable substitution**, as it is expected that restrictions under REACH or inclusion in the POPs

[105] Corrigendum to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 179 of 9.6.2020 p.4-6.

[106] Persistent Organic Pollutants Review Committee (2006) Risk profile on hexabromobiphenyl: http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx
Stockholm Convention > The Convention > The POPs > The New POPs > Hexabromobiphenyl.

Regulation would occur also for short chain PFAS (as short chain PFAS are suspected to pose risks for human health and the environment). Such a substitution would only shift the problem to short chain PFAS. However, in practice, such substitution might be necessary for the cases where alternatives to PFAS do not meet military standards.

Defence industries have indicated that the inclusion in Annex I to the POPs Regulation could lead to **sudden unavailability of substances and disruptions in the supply chain**, which have an impact on the production and put pressure on R&D and resources. The impact is significant since no addition of exemptions is possible once the substance is included in the POPs Regulation and since the Regulation also bans imports and exports of the substances. One defence industry mentioned as an example that the inclusion of PFOA in the POPs Regulation had a knock-on effect on the availability of PTFE, a polymer used in several pyrotechnic compositions, in which PFOA is present as unintended impurities at low levels (below the 0,025 mg/kg threshold established by the POPs Regulation). The lack of supplies of specific qualities led the defence industry to qualify other suppliers outside the EU.

One MoD also expressed concerns in relation to the availability of Octamethylcyclotetrasiloxane (D4), which the EU is currently considering proposing for inclusion in the Convention. One of the uses of the substance is in **naval paints** and the listing as POPs could impact their availability.

Finally, one MoD mentioned that the unavailability of substances following the inclusion in the POPs Regulation may cause uncertainty on how to qualify existing articles containing the substance – as articles already in use before the date when the Regulation became applicable to that substance (Article 4(2) of POPs Regulation) and therefore still be allowed for use, or as stockpile and therefore be managed as waste (Article 5 of POPs Regulation).

2.2.4.2 Costs linked to the POPs Regulation

Defence industry stakeholders and some MoDs reported that the POPs Regulation had an impact on the following costs:

- **Increased procurement costs** (one MoD, ASD and two other defence industries): one MoD mentioned a case where the redesign of defence equipment following the listing of a substance in the POPs Regulation led to increased procurement costs.
- **Increased research and development costs for the substitution of listed substances** (one MoD, ASD and two other defence industries): One MoD mentioned that this was especially the case when there was no previous restriction under REACH, because R&D activities are then usually minimal and efforts to substitute the substance in the timeframe imposed by the POPs Regulation might be extensive. One defence industry mentioned the substitution of polychlorinated naphthalene a particularly long and costly substitution process as a new substance had to be developed with a chemical manufacturer.
- **Regulatory monitoring costs**: one MoD and ASD mentioned that monitoring regulatory activities and anticipating upcoming restrictions increased human resource needs. One MoD anticipates that costs will continue to increase because of the ongoing and upcoming restrictions of PFAS.
- **Costs of tracing uses of POPs in defence applications**: ASD and another defence industry indicated that human resources dedicated to identifying uses of POPs has increased, as well as costs of updating IT tools to track POP substances.

2.2.4.3 Communication in the supply chain

Defence industry stakeholders reported that the **knowledge of the POPs Regulation** in the supply chain, particularly in SMEs, **is quite low**, which creates problems and delays for defence industries in tracing POPs in defence equipment, as defence industries mainly rely on information provided by

suppliers. When part of the supply chain is outside the EU, the awareness can be even lower, and it might be more difficult, even though the Stockholm Convention is an international instrument, to require suppliers to trace POPs, and if necessary, to substitute banned substances. It may happen that defence industries only become aware of the presence of a POP in an article, when the supplier changes the design or production of the article, following the restriction of the substance.

One defence industry also indicated that **most defence industries do not track POPs** in their systems yet. In addition, one defence industry mentioned that to ascertain the presence and concentration of POPs in articles (for example flame retardants added to polymers like HBCDD), it might be necessary to send samples for analysis, but that testing of POPs in articles is very complex. For several POPs, there are no standardised or accredited testing methods available on the market, which may result in testing results that are less reliable and dependent on how the test has been carried out at each laboratory. The complexity of the analyses depends on several parameters, such as representative samples, extraction with an appropriate solvent to release the substance from the sample matrix and a high-resolution analytical instrument. In addition, those tests are often very expensive which limits the number of samples that can be tested.

Defence industry stakeholders also reported that tracking POPs was sometimes made difficult when **a wide family of substances is concerned** for which CAS numbers of all substances have not been identified. Stakeholders noted that this also happens in REACH processes.

2.2.4.4 Anticipating and managing impacts of the POPs Regulation

Several MoDs indicated that compliance with the POPs Regulation is managed through **contract clauses**. The French MoD requires suppliers to confirm compliance and provide information on POPs uses if those are permitted by the POPs Regulation. The Swedish MoD uses a special criteria document that bans substances classified as vPvB and/or as PBT (see Annex VII to this report), and the Dutch MoD maintains the List of Banned and Restricted Substances (LBRS) (see Annex V to this report), which is part of the procurement requirements.

Two MoDs underlined the necessity to manage potential impacts of the POPs Regulation **as early as possible in the legislative process** to ensure that appropriate exemptions can be proposed and negotiated at the POP Review Committee, as was done for DecaBDE. Exemptions for military aircrafts – provided in the REACH Annex XVII restriction – were not initially identified by the POPRC as necessary but were included in the final amendment to the Convention, thanks to different actions including the intervention of an MoD, ASD and EDA[107]. Until now, stakeholders were essentially made aware of substances intended to be proposed by the EU for inclusion in the Convention with the release of a proposal for a Council decision. Following the recast of the POPs Regulation, ECHA will now publish a **notice that a proposal for the listing of a substance will be prepared by the Commission**, and the scientific dossier in accordance with Annex D to the Convention that is intended to accompany an EU proposal will be put to **consultation by ECHA**. This should give more notice to stakeholders to anticipate the development of an EU proposal for inclusion of a substance in the Convention. An option proposed by one MoD to increase early stakeholder awareness would be to **strengthen cooperation between the Commission and the EDA** and ensure that the **Commission communicates to EDA** about substances proposed as POPs in advance of draft Council decisions, so that MoDs have sufficient time to assess the potential impacts.

[107] Following initial input from defence industry/ASD, EDA intervened on this issue by writing a formal EDA letter to ECHA and an EDA letter to the Commission, highlighting the potential impact to defence, and by reporting on the issue to Member States (to inform them of the main developments and encourage them to consider follow-up actions) and to defence industries/EDA pMS NDIAs (to raise their awareness on the issue).

As described in section 2.2.2.1, the adoption of a REACH restriction prior to the inclusion of a substance in the Annexes to the Convention supports the early discussion at EU level of necessary defence exemptions to be negotiated at the level of the Convention and encourages the industry to launch substitution activities and define mitigation strategies. This might be possible when no concrete action has been taken yet under REACH, for instance when the substance is on the Candidate List, but the authorisation process has not started.

2.2.4.5 Input from the Aerospace Industries Association of America

AIA raised the issue of substances being assessed under multiple regulatory frameworks (for instance REACH and POPs Regulation), and explained that the uncertainty about the policy choices that will be made (i.e., under which regulation the substance will be restricted) creates significant challenges for the industry to prepare for future regulation of a substance.

2.2.5 Summary

Regulation (EU) 2019/1021[108] on Persistent Organic Pollutants (POPs Regulation) is the main EU instrument implementing the Stockholm Convention and the UNECE POPs Protocol. It regulates the production, **placing on the market and use of POPs**, the management of stockpiles and wastes and measures to reduce releases of unintentionally produced POPs.

Annex I to the Regulation currently lists **29 banned POPs**, including pesticides and industrial chemicals. It includes exemptions for specific uses, reflecting the specific exemptions included in the Annexes to the Convention. As a rule, the exemptions expire after five years but may be extended for another five years. Although there is no exemption mechanism specific to defence or military equipment, exemptions for defence/military uses may be granted in the Annexes to the Convention and in the POPs Regulation, as has been the case for decaBDE in civil and military aircrafts. Similar exemptions might be adopted in the future, in particular as other PFAS substances are likely to be listed in the Annexes to the Convention.

Regulation (EU) 2019/1021 (which repealed Regulation (EC) No 850/2004 – previous POPs Regulation) assigned new responsibilities to ECHA, including providing scientific support for the identification of new POPs and organising consultations on proposals for the inclusion of new POPs and on the risk profile and risk management evaluation prepared by the POP Review Committee of the Stockholm Convention. New POP candidates are identified though activities carried out under other legislation, Persistent, Bioaccumulative, Toxic (PBT)/very Persistent, very Bioaccumulative (vPvB) substances assessment in regulatory processes (especially Substances of Very High Concern (SVHC)[109] and Restriction) under REACH, PBT assessment in the BPR and Plant Protection Products Regulation (PPPR).

Proposals for new POPs are discussed with Member States at the Competent Authorities expert group and within the Council. These discussions, as well as the consultations organised by ECHA, provide **early opportunities for MoDs and defence industries to raise defence related issues** with regards to the inclusion of new POPs in the Convention and propose specific exemptions for defence uses where necessary. As there are no possibilities for derogations once amendments to the

[108] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77.

[109] SVHCs are substances which meet criteria listed in Article 57 of the REACH Regulation: substances which meet the criteria for classifications as carcinogens, mutagens or toxic for reproduction 1A and 1B (CMR) as per the CLP Regulation, substances meeting persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) criteria as per REACH Annex XIII, and substances that are considered on a case by case basis to present the same level of concern as CMR or PBT/vPvB.

Convention have been adopted, it is critical to manage potential impacts of the inclusion of a substance as early as possible in the regulatory process to ensure that appropriate exemptions can be proposed and negotiated at the POP Review Committee.

The POPs Regulation is **consistent** with REACH and CLP. The Common Understanding paper[110] on the interaction between REACH and the POPs Regulation published by the Commission in 2014, identifies cases of potential overlaps between the two Regulations and explains agreed standard practice in those cases. The general rule in case a new POP is already restricted under REACH is that the entry in REACH Annex XVII is deleted. When the new POP is subject to authorisation requirements under REACH, and a conflict arise with the authorisations granted under REACH, a case-by-case analysis should determine whether to refuse or remove authorisations or temporarily delay the implementation of the amendment to the Convention through the POPs Regulation (by notifying the EU's non-acceptance of the amendment to the Convention to the Secretary General of the Convention). This last solution was used only in one case (Hexabromocyclododecane (HBCDD)). The POPs Regulation is also consistent with the other regulations covered by the study.

The POPs Regulation had until now **little impact on the availability of substances for defence equipment** because most substances listed in Annex I to the POPs Regulation have already been substituted. However, the inclusion of **PFOA** in the POPs Regulation had an **impact on the availability of surface treatments available for textiles** (for water and oil repellency and non-flammable properties). Inclusion of other **PFAS** substances in the Stockholm Convention is expected, following their inclusion in Annex XVII to REACH, which might impact the availability of substances meeting military standards for fire extinguishing equipment, military personal protection equipment and textiles. The substitution of long chain PFAS, such as PFOA, by short chain PFAS is therefore only a short-term solution and alternatives need to be secured. Concerns were also expressed in relation to the potential inclusion of Octamethylcyclotetrasiloxane (D4), which has several uses, including naval paints. Impacts of potential future inclusion of substances in the Stockholm Convention and POPs Regulation need to be further assessed by MoDs.

According to the defence industry, **knowledge** of the POPs Regulation in the supply chain, particularly in SMEs, is quite **low**, which creates problems and delays for defence industries in tracing POPs in defence equipment, as they mainly rely on information provided by suppliers. It remains difficult to constrain suppliers outside the EU to track and substitute POPs, even though the Stockholm Convention is an international Convention. Consequently, **monitoring costs** are significant for defence industries.

2.3 OZONE REGULATION (REGULATION (EC) NO 1005/2009)

Regulation (EC) 1005/2009 on substances that deplete the ozone layer (the Ozone Regulation) supports the implementation of the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer. The Regulation entered into force in 2010, and repealed the previous Ozone Regulation, Regulation (EC) 2037/2000. The Regulation is binding in its entirety and applicable in all Member States[111].

[110] European Commission (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding: https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en (Last accessed on 08.2020).
[111] Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

2.3.1 Implementation of the Regulation

The general objective of the Regulation is to **comply with the Montreal Protocol**, while setting a **higher level of ambition for the EU** in areas where it is technically and economically possible regarding the protection and recovery of the ozone layer and the use of ozone-depleting substances (ODS). To achieve this, the Regulation aims for controlling, monitoring and reporting on the production, use, trade and handling of ODS and products relying on them, while ensuring the enforcement of ODS policies[112].

The review of the ODS in 2008 led to the repeal of Regulation (EC) 2037/2000 and the publication of Regulation (EC) 1005/2009. Overall, **the new Regulation aimed to bring clarification to reduce the administrative burden and streamline reporting requirements** while also updating the regime of exemptions, to specify the prohibition of HCFCs in 2020 to comply with the Montreal Protocol, and finally to address issues linked to ODS contained in products and equipment as well as new substances which were not previously included[113].

To **ensure the highest environmental protection possible**, the Regulation establishes several specific mechanisms, the main one being the **prohibition of the production, placing on the market and use** of ODS, including in products and equipment (Chapter II of the Regulation). In addition, the Regulation includes **general exemptions for some uses** reflecting the state of technology at the time of the drafting of the Ozone Regulation. It also allows for **Commission Decisions authorising case-specific derogations from a prohibition**, based on a justified request from a Member State (Chapter III). Measures are also defined to regulate the trade of ODS (Chapter IV) through licensing requirements and quota limitations, and the control of emissions (Chapter V) through technical requirements for leakage, destruction and recovery. Finally, reporting requirements are also established by Member States and by undertakings, with national inspection obligations.

2.3.1.1 International legal basis

As highlighted above, one of the general goals of the Regulation is **to fulfil the obligations of the Montreal Protocol on Substances that Deplete the Ozone Layer** while also setting a higher level of ambition for the European Union. In accordance with the provisions of the Vienna Convention for the Protection of the Ozone Layer from 1985, the Montreal Protocol, adopted in 1987, was the **first agreement to introduce binding goals regarding the reduction of chlorofluorocarbons (CFCs**). There are currently 198 Parties to the Protocol[114]. Over time, several amendments completed the Protocol to include new chemicals to control. Today, ten groups of halogenated hydrocarbons (referred to as 'controlled substances') are covered by the Protocol as presented in Table 16 below[115].

[112] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.6. Available at: https://ec.europa.eu/clima/events/evaluation-ozone-regulation_en (Last accessed on 12.10.2020)
European Commission > Energy, Climate change, Environment > Climate Action > Events.

[113] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.10.

[114] It is noted that on the 16th of September 2009, the Vienna Convention together with the Montreal Protocol achieved universal participation by 196 parties, becoming the first set of treaties in the history of the United Nations to reach such milestone.

[115] It is noted that the Kigali Amendment added hydrfluorocarbons (HFCs) to the groups of controlled substances.

Table 16: List of controlled substances as listed in the Montreal Protocol

Substance	EC number	CAS number
Chlorofluorocarbons (CFCs) which encompass two controlled substances groups under the Montreal Protocol (Group I on Chlorofluorocarbons and Group II on other fully halogenated CFC)	N/R	N/R
Halons: halon 1211 (Bromochlorodifluoromethane) halon 1301 (Bromotrifluoromethane) halon 2402 (Dibromotetrafluoroethane)	 EC/List no.: 206-537-9 EC/List no.: 200-887-6 EC/List no.: 247-042-8	 CAS no.: 353-59-3 CAS no.: 75-63-8 CAS no.: 25497-30-7
Carbon tetrachloride (CTC)	EC/List no.: 200-262-8	CAS no.: 71-55-6
1,1,1- trichloroethane (TCA)	EC/List no.: 200-756-3	CAS no.: 71-55-6
Methyl bromide (MB)	EC/List no.: 200-813-2	CAS no.: 74-83-9
Hydrobromofluorocarbons (HBFCs)	N/R	N/R
Hydrochlorofluorocarbons (HCFCs)	N/R	N/R
Bromochloromethane (BCM)	EC/List no.: 200-826-3	CAS no.: 74-97-5
Hydrofluorocarbons (HFCs)[116]	N/R	N/R

The main obligations for Parties to the Montreal Protocol are **to plan a gradual phase-out of the production and consumption of the controlled substances** listed above based on a specified time schedule, the reporting of the production, use, import and export of these substances, and the creation of a licensing system for import and export[117].

In 2010, **the Ozone Regulation went beyond the Protocol in setting a stricter phase-out schedule for HCFCs** but since 2020 the phase-out for virgin HCFCs is obligatory for all developed countries However, it was decided to allow maintaining minor production in developed countries until 2030 (up to 0.5% of baseline levels) for serving refrigeration and air-conditioning equipment. Furthermore, the Ozone Regulation is also phasing out the use of non-virgin HCFCs. Finally, while the provisions of the Protocol for a licensing system focuses on the import and export of substances, the Regulation's licensing system also covers products and equipment containing or relying on those substances[118].

Regulation (EU) No 517/2014 on fluorinated greenhouse gases ensures the EU's compliance with the obligations of the Montreal Protocol related to HFCs. See Chapter 2.4.

2.3.1.2 Scope of the Regulation

Article 2 defines the scope of the Ozone Regulation, which should **cover controlled substances listed in Annex I** to the Regulation (alone or in a mixture, and virgin or recycled), **new ones listed in Annex II** to the Ozone Regulation, and products and equipment containing or relying on Annex I substances.

[116] It is noted that HFCs are not ozone-depleting substances themselves and are used as alternatives to ODS. HFCs are greenhouse gases which can have high or very high global warming potentials (GWPs). They are covered by the F-gas Regulation.

[117] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.3.

[118] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, pp105-106.

Furthermore, **Chapter III of the Regulation defines provisions regarding the exemptions[119] and derogations**[120] linked to the prohibitions cited above. Some of the exempted uses that are specified in the Regulation are namely:

- **feedstock uses** (Article 7), understood as any controlled or new substance undergoing chemical transformation in a process in which it is entirely converted from its original composition
- **process agent uses** (Article 8), understood as chemical process agents in the applications listed in Annex III to the Regulation 'Processes in which controlled substances are used as process agents as referred to in Article 3(12)'
- **essential laboratory and analytical uses** for controlled substances other than hydrochlorofluorocarbons (Article 10)
- **remaining uses of HCFCs** (Article 11)
- **pre-shipment, or non-quarantine applications** applied no more than 21 days prior to export to meet the official requirements of the importing/exporting country, and quarantine uses, understood as treatments to prevent the introduction, establishment or spread of quarantine pests or to ensure their official control. This was allowed until 18 March 2010. Now only emergency uses of methyl bromide may be authorized by the Commission upon request from a Member State (Article 12).

It is noted that pursuant to Article 11, reclaimed and recycled hyrochlorofluorocarbons could be placed on the market and used for the maintenance or servicing of existing refrigeration, air-conditioning and heat pump equipment until 31 December 2014. Furthermore, HCFCs cannot be produced nor placed on the market for repackaging and subsequent export after 31 December 2019.

Critical uses of halons (including military uses) are also permitted for a limited period (Article 13). Annex VI of the Ozone Regulation specifies these critical uses along with progressive decommissioning dates[121].

During the consultation, DG CLIMA further specified that **Member States may request the Commission to grant derogations to them in the cases specified by the Regulation**. If the derogation is accepted, a Commission Implementing Decision defines the conditions under which the Commission grants the exemption/derogation to the Member State, in addition to the already existing obligations set out in the Ozone Regulation. The **additional conditions are set on a case-by-case basis**, with reporting being a common practice. The concerned Member State must abide by these conditions to ensure compliance with the decision.

The same list of ODS that are controlled substances as in the Montreal Protocol is available in Annex I to the Regulation 'Controlled substances' (see Table 18 below). In addition, contrary to the previous Ozone Regulation, the current Regulation covers new substances which are not included in the Montreal Protocol[122]. These are listed in Annex II to the Regulation 'New substances' (Table 17) and are subject to some of the reporting requirements under Article 27.

[119] In the context of ODS policies, exemptions can be understood as the possibility to use ODS for some specific exempted uses identified in the Regulation. Source: Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009, p.25.

[120] In the context of ODS policies, derogations can be understood as the possibility to apply for a temporary permission to use a certain controlled substance for a specific use for a defined period of time by a specific undertaking. Source: Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009, p.25.

[121] The cut-off dates were added to Annex VI by Regulation (EU) 744/2010 amending Regulation (EU) 1005/2009.

[122] Regulation (EC) No 2037/2000 of the European Parliament and on the Council of 29 June 2000 on substances that deplete the ozone layer.

Table 17: List of new substances as included in Annex II to the Regulation

Substance	EC number	CAS number
Dibromodifluoromethane (halon-1202)	EC/List no.: 200-885-5	CAS no.: 75-61-6
1-Bromopropane (n-propyl bromide)	EC/List no.: 203-445-0	CAS no.: 106-94-5
Bromoethane (ethyl bromide)	EC/List no.: 200-825-8	CAS no.: 74-96-4
Trifluoroiodomethane (trifluoromethyl iodide)	EC/List no.: 219-014-5	CAS no.: 2314-97-8
Chloromethane (methyl chloride)	EC/List no.: 200-817-4	CAS no.: 74-87-3

Table 18: Ozone-depleting substances covered by the ODS Regulation

Group of substances	Description
Controlled substances also covered by the Montreal Protocol (Annex I)	■ Group I and Group II: chlorofluorocarbons (CFCs) ■ Group III: Halons (1211, 1301, 2402) ■ Group IV: Carbon tetrachloride (CTC) ■ Group V: 1,1,1- Trichloroethane (TCA) ■ Group VI: Methyl Bromide (MB) ■ Group VII: Hydrobromofluorocarbon (HBFCs) ■ Group VIII: Hydrochlorofluorocarbon (HCFCs) ■ Group IX: V Bromochloromethane (BCM)
New substances (Annex II)	■ Dibromodifluoromethane (halon 1202) pursuant to Article 24(1) ■ 1-Bromopropane (n-propyl bromide), chloromethane (methyl chloride), bromoethane (ethyl bromide), and trifluoroiodomethane (trifluoroethyl iodide)

2.3.1.3 Governance

European Commission

At the European level, **DG CLIMA is responsible for implementing the Regulation**. Concretely, the Commission:

- operates the EU-wide ODS Licensing System and issues licences for import and export and production authorisations;
- determines the allocation of import and production quotas for exempted uses;
- manages registration for laboratory and analytical uses;
- reviews Annex VI to the Regulation and, if appropriate, adopts modifications to take into account the availability of technically and economically feasible alternatives or technologies (Article 13(2));
- may take measures to regulate new substances that are found to have ozone depleting potential;
- checks the annual reporting by national authorities and undertakings; and
- reports to the UNEP Ozone Secretariat on production, import, export and destruction of ozone-depleting substances in all EU Member States.

Other EU stakeholders

The **European Environment Agency (EEA) manages the system for annual reporting by companies** and publishes the aggregated data reported, in accordance with the Ozone Regulation, on the

import, export, production, destruction, feedstock and process agent use of ODS and presents trends over the years[123]. In fact, since 2012, the European Topic Centre on Climate Change Mitigation and Energy (ETC/CME) at the EEA is in charge of providing technical support to the ODS reporting process under Article 27[124].

Furthermore, **the European Aviation Safety Agency can be consulted** regarding specific tasks under the ODS Regulation[125].

Member States' competent authorities

A list of the competent authority or authorities responsible for the administrative tasks and enforcement of the Regulation for each Member State is available online[126]. Member States' authorities are responsible for the main tasks related to the enforcement of the Regulation, through reporting requirements, surveillance, inspections and custom controls, issuance of penalties in cases of non-compliance, as well as the promotion of recovery, recycling, reclamation[127] and destruction of ODS.

Pursuant to Article 25, a Member State Committee, **the Committee on ozone depleting substances**[128], must assist the Commission in the implementation of the Regulation. This Committee provides a platform for the Commission and Member States to meet and discuss the implementation of the Regulation, especially regarding the adoption of derogations, for instance.

[123] EEA (2020) Ozone-depleting substances 2020, Briefing no. 10/2020. Available at: https://www.eea.europa.eu/publications/ozone-depleting-substances-2020 (Last accessed on 04.12.2020)

[124] EEA (2019) Ozone-depleting substances 2019, Aggregated data reported by companies on the import, export, production, destruction, feedstock and process agent use of ozone-depleting substances in the European Union, 2006-2018, Report No 12/2019.

[125] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.30. Available at: https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=64482 (Last accessed on 12.10.2020)

[126] The list is available at: https://circabc.europa.eu/sd/a/34dce2ba-c117-4e31-b9c4-266c8c2926e9/MS%20contact%20200511.pdf (Last accessed on 12.10.2020)

[127] Pursuant to Article 3 of the Ozone Regulation, it is noted that the term 'reclamation' refers to *"the reprocessing of a recovered controlled substance in order to meet the equivalent performance of a virgin substance, taking into account its intended use"*.

[128] European Commission (2020) Committee information, Committee on ozone depleting substances: https://ec.europa.eu/transparency/comitology-register/screen/committees/C13800/consult (Last accessed: 10.11.2020). European Commission > Comitology Register > Search for Committees > Committee

Table 19: Non-exhaustive list of national competent authorities for the ODS Regulation and their respective roles, based on the consultation carried out during this study

Member State	Competent authority	Actions related to the defence sector and relations with the MoDs
France	MoE	The MoE is in charge of the implementation of the Regulation and participates in the Committee. It also takes part in the negotiations of the Montreal Protocol. The Ministry of Defence is always consulted to draft a French position on the points discussed and whenever a specific point relating to the military sector is raised. Finally, the Ministry of Defence gives an annual declaration of quantities of halons installed, stored or emitted pursuant to Article 26 of the Regulation. Officially, when a French position is required on the Ozone Regulation (mainly regulation modifications, derogations, etc.), the MoE sets up a draft position, which is then circulated to other Ministries by the General Secretariat for European Affairs (Secrétariat général des affaires européennes - SGAE), a Prime Minister's service coordinating the French position on EU policies. The Ministry of Defence is consulted by the SGAE at this stage. The Ministry of Defence's position is set after consulting with its relevant departments. In addition, the French Ministry of the Environment regularly directly informs the Ministry of Defence's legal department about its position on the evolution of the ODS Regulation.
Germany	MoE	For the military area, the enforcement of the Ozone Regulation and the authority to grant a defence exemption lies with the federal Ministry of Defence (BMVg) or with the body designated by it, primarily the BAIUDBw.
Netherlands	MoE	The Rijkswaterstaat (RWS) acts as Competent Authority on behalf of the Ministry of Economic Affairs and Climate Change for the Ozone Regulation. Every year they collect data from the Ministry of Defence on halon use, stocks, emissions and replacement, in regard to the critical uses mentioned in the Regulation. Recently, the Ministry of Defence was also granted an exemption for the extended use of HCFCs on submarines. RWS collected data on progress to replace HCFCs with alternatives, status of decommissioning and destruction of HCFCs.
Spain	MoE	The General Directorate of Infrastructure is responsible for environmental issues within the Spanish Ministry of Defence. It is in touch with the Ministry for Ecological Transition and the Demographic Challenge that is the MSCA in Spain. Both meet at least once a year.
Sweden	Swedish Environmental Protection Agency	The Swedish Environmental Protection Agency is the MSCA responsible for the Regulation. The Swedish Ministry of Defence and its underlying agencies (the Swedish Armed Forces, the Swedish Defence Material Administration, the Swedish Fortifications Agency, the National Defence Radio Establishment and the Swedish Defence Research Agency) follow the provisions of the Ozone Regulation.

2.3.1.4 Evaluation and review of the Regulation

An **evaluation of the Regulation was launched by the Commission in 2017** and completed in 2019[129]. Its conclusions showed that the Regulation **efficiently achieved its general objectives** and matched expectations and remained relevant for the EU's compliance to the Montreal Protocol[130]. It also underlined that ODS placed on the market usually fall within the scope of the REACH Regulation and require registration.

Based on the results of the evaluation, **the Commission has started an impact assessment** to examine if and how it can further improve the Regulation in the coming years. Based on the results of both assessments**, a proposal for revision should be put forward by the end of 2021**. It is noted that a public consultation was open until 9 November 2020 in this regard[131]. Policy options will focus on reaching a higher level of emission reductions, increasing efficiency, ensuring good monitoring, streamlining and clarifications, as the basis of the Regulation has already been laid down and proved to be effective.

2.3.1.5 Regulatory evolution of substances

As described previously, the Ozone Regulation establishes provisions regarding the general prohibition of the production, placing on the market and import and export of controlled substances as well as equipment relying on them. Chapter VI of the Regulation focuses on new substances and introduces restrictions for new ODS such as halon 1202. It also **empowers the Commission to adopt additional prohibitions for other new ODS** if this would appear appropriate based on the assessment of the Scientific Assessment Panel (SAP) under the Montreal Protocol. **So far, no new substance was added**[132]. This empowerment has not yet been used.

2.3.2 Interactions with REACH and CLP

The evaluation published in 2019, as well as its support study, **did not identify any outstanding inconsistency** with other EU or international legislation, which are generally well aligned[133]. It is noted that the absence of a major inconsistency between the Ozone Regulation and other Regulations may stem from the fact that the protection of the ozone represents a long-standing policy area which was developed alongside other legislations in other areas[134].

2.3.2.1 Interactions with REACH

ODS placed on the market **generally fall under REACH** and, as a consequence, require **registration**

[129] European Commission, Evaluation of the Ozone Regulation: https://ec.europa.eu/clima/events/evaluation-ozone-regulation_en (Last accessed: 12.10.2020)
European Commission > Energy, Climate change, Environment > Climate Action > Events.
[130] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, pp64-66.
[131] European Commission, Ozone layer protection – review of EU rules: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12310-Ozone-layer-protection-revision-of-EU-rules (Last accessed on 12.11.2020)
European Commission > Have your say > Published initiatives > Ozone layer protection – review of EU rules
[132] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p10.
European Commission > Energy, Climate change, Environment > Climate Action > Events.
[133] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.141.
[134] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p56.
European Commission > Energy, Climate change, Environment > Climate Action > Events.

and assessment processes. However, one potential shortcoming in the coordination of REACH and the Ozone Regulation lies in the fact that while the Ozone Regulation imposes restrictions and prohibitions on both the substances of concern and the production and use of equipment relying on those substances, **REACH has no provision on the restriction of equipment**[135].

Desk research and stakeholder consultations highlighted that **an exchange of information, as well as control mechanisms for substances, would favour synergies** to enhance the coherence and the implementation of both Regulations to comply with the Montreal Protocol. One example could be the **possibility of regulating very short-lived substances (VSLS) via REACH**, as it already restricts some of them[136]. VSLS have a lifetime or six months or less and are considered to break down more readily in the atmosphere. However, recent studies have started to show that their use is rapidly increasing and may consequently have a serious impact on the ozone layer, like other ODS[137]. The current issue is that some substances with suspected ozone depleting properties, such as these VSLS, might not be currently covered by the existing regime of the Ozone Regulation. However, these may be restricted under REACH for other reasons[138]. The current Impact Assessment carried out by the Commission aims at tacking this issue. In some cases, **an ODS phase-out system with extensive transitional periods may be preferable to the system of authorisation in place under REACH** which requires higher administrative costs. This was highlighted especially for the phasing-out of halons. These substances are covered by time-limited exemptions (Article 13 of the Ozone Regulation) and are used for 'critical uses' (firefighting uses listed in Annex VI to the Ozone Regulation), for instance in aircrafts, military ground vehicles, military surface ships and submarines, among others. Due to difficulties to find workable alternative to these substances, the aerospace and defence industry benefits from 'cut-off dates' (from 2010 to 2018), which apply to new equipment and facilities, and 'end-dates' (from 2013 to 2040), under which halons must be decommissioned, to ensure a progressive phase-out (Annex VI to the Regulation 'Critical uses of halon')[139]. The 2019 evaluation of the Ozone Regulation highlighted that **this progressive phase-out provided more flexibility than REACH authorisation** and allowed more time for defence stakeholders to search replacements[140]. However, while this procedure was successful and efficient for one group of substances, it might not be workable for larger groups of chemicals[141].

2.3.2.2 Interactions with CLP

Overall, it is considered that there is **good consistency between the Ozone Regulation and the CLP** Regulation as the latter was linked to the former through the **labelling requirements expected for**

[135] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.151.
[136] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.12.
[137] University of York, Ozone depleting substances: https://www.york.ac.uk/chemistry/research/wacl/ozone-depleting-substances/ (Last accessed on 10.11.2020)
University of York > Chemistry > Research > Wolfson Atmospheric Chemistry Laboratories > Ozone depleting substances.
[138] As an example, 1.2 dichloroethane is a carcinogenic substance which is subject to REACH authorisation.
[139] European Union Aviation Safety Agency (EASA)(2019) Halon replacement in the aviation industry, p.5. Available at: https://www.easa.europa.eu/document-library/general-publications/halon-replacement-aviation-industry (Last accessed on 12.10.2020)
EASA > Home > Document Library > Publications > General Publications > Halon replacement in the aviation industry.
[140] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report.
[141] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.103.

various ODS exempted from prohibition, which must comply with the CLP[142]. It is highlighted that as ODS used for feedstock, process agent, laboratory and analytical uses can be released for free circulation in the Union, it is necessary to differentiate them from substances produced for other uses. Furthermore, labelling requirements must facilitate the implementation of the Regulation and help inform end users. As a consequence, the Ozone Regulation refers to the fact that the labelling of substances and products under the Ozone Regulation, as provided by Articles 7, 8, 10, and 11, must comply with Regulation (EC) No 1272/2008[143].

2.3.3 Interactions with other chemicals regulations / directives

2.3.3.1 Ozone Regulation and BPR Regulation

See Section 2.1.3.2. 'BPR and Ozone Regulation'

2.3.3.2 ODS Regulation and POPs Regulation

See Section 2.2.3.2. 'POPs Regulation and Ozone Regulation'

2.3.3.3 Ozone Regulation and F-gas Regulation

The 2019 evaluation of the Ozone Regulation highlighted **potential important synergies between the ODS and F-gas Regulations**. In fact, it is pointed out that the F-gas Regulation '*can be seen as the brainchild of the ODS Regulation'*[144] as it is meant to regulate some of the substances that have been used to replace ODS since they do not harm the ozone layer but were found to have a high Global Warming Potential (GWP). As **they have been developed together and cover almost the same sectors with a similar goal** (refrigeration, air conditioning, aerosols and foams), no particular inconsistencies were identified. Usually, it is considered that ozone-depleting substances must be covered by the Ozone Regulation, while fluorinated gases should be included in the F-gas Regulation. However, the Commission underlined that some of the new substances identified presented characteristics that could qualify them to be regulated by both Regulations. In such cases the Commission would thus be to ensure that all new substances are included at least under one of the Regulations and that a clear link is made between the two. As an example, a suggestion was raised during the consultation carried out for the 2019 evaluation of the Regulation regarding the fact that some substances such as the refrigerant R-1233zdd (Solstice® zd)[145] could be regulated by the Ozone Regulation instead of the F-gas Regulation given the fact that it is an unsaturated HCFC[146]. In this regard, **the Commission highlighted that the evaluation and impact assessment of both the ODS and the F-gas Regulations will be used to streamline both pieces of legislation** and address any potential inconsistency that may be identified.

Some of the Ministries of Defence consulted also identified some challenges. First, because the two Regulations are often managed together and cover similar areas, it has been highlighted that, despite

[142] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.57.
[143] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
[144] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, pp.56-57.
[145] Trans-1-chloro-3,3,3-trifluoropropene 5 (EC/List no.:700-486-0; CAS no.: 102687-65-0).
[146] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final.

the potential for synergies regarding the coordinated management of the Regulations among authorities, this might cause confusion with defence stakeholders to differentiate the two. Second, it was underlined that the objective to reduce ODS emissions set globally by the Montreal Protocol indirectly led to new challenges as **some F-gases were introduced as substitutes for ODS in many sectors**, especially for refrigeration and air conditioning applications. This is especially the case for substances such as HFCs, PFCs and SF6. Regarding this last substance in particular, the Commission emphasised the fact that SF6 was used in aircraft in quantities that would require further research to assess whether it is necessary to regulate its use more closely.

2.3.3.4 ODS Regulation and RoHS Directive

None of the substances regulated by the Ozone Regulation are regulated by the RoHS Directive. As the ODS substances are not used in electrical and electronic equipment, there are no provisions in the legislation that would prevent overlaps in terms of substance coverage between the two regulations. **There are therefore no current interactions between the two**. No issues have been raised by stakeholders on the interface between those regulations.

2.3.3.5 ODS Regulation and aeronautics regulations

Following the impetus provided by the adoption of the Ozone Regulation at the European level, **the International Civil Aviation Organization (ICAO) also determined cut-off, as well as forward-fit dates to replace halons in fire safety systems in aircraft**[147]. These cut-off dates under ICAO shall be understood as the absence of any new application for Type Certificates if halon is present in the design (Annex 8 to the Convention on International Civil Aviation), while forward-fit requirements focus on new deliveries of individual certificates of airworthiness (Annex 6 to the Convention on International Civil Aviation).

[147] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.58.

Table 20: Dates for halon replacement according to the ODS Regulation, the Convention on International Civil Aviation and Regulation (EU) 2015/640. Source: European Union Aviation Safety Agency (EASA) 2019, Halon replacement in the aviation industry

Dates for halons replacement				
			Aviation standards	
Purpose	Fire Extinguisher location	*Ozone Regulation* Regulation (EC) No 1005/2009 as amended by (EU) 744/2010	ICAO Convention on International Civil Aviation	Regulation (EU) 2015/640 (Part-26) as amended by (EU) 2019/133
Retrofit (end date)	Unoccupied cargo compartments	2040	Not specified	Not specified
	Hand-held in cabin & crew compartments	2025		
	Lavatory waste receptacles	2020		
	Engine nacelle & Auxiliary Power Units	2040		
Forward fit (new CofA)	Unoccupied cargo compartments	Not specified	Not specified	Not specified
	Hand-held in cabin & crew compartments		2016 (Annex 6) 39th Assembly: shift to 2018	May 18, 2019
	Lavatory waste receptacles		2011	February 18, 2020
	Engine nacelle & Auxiliary Power Units		Not specified	Not specified
Cut-off (new application for type certificate)	Unoccupied cargo compartments	2018	2024 (Annex 8) 39th Assembly: will be adapted within 2 years.	Not specified
	Hand-held in cabin & crew compartments	2014	Not mentioned	
	Lavatory waste receptacles	2011	2014	
	Engine nacelle & Auxiliary Power Units	2014	2014	

Likewise, regarding European aviation standards, the **Commission Regulation (EU) 2015/640** provides forward-fit and cut-off dates (which differ from the ICAO standards) to ensure the replacement of halons in lavatories from 18 May 2019 and in handled fire extinguishers from 18 February 2020 for what concerns large aeroplanes and large helicopters. A comparative list of cut-off, forward-fit and end dates is provided in Table 21 below.

2.3.4 Impacts on the defence sector

2.3.4.1 Using the exemptions and derogations by defence authorities and stakeholders

A derogation for the use of halons is provided in Article 13(1) ODS Regulation: '*By way of derogation from Article 5(1), halons may be placed on the market and used for critical uses set out in Annex VI. Halons may only be placed on the market by undertakings authorised by the competent authority of the Member State concerned to store halons for critical uses*.'

The **derogation provided by Article 13(1) regarding the critical uses of halons** and decommissioning of equipment containing halons, which are covered by Annex VI to the Regulation, is of specific

relevance for the defence industry. These critical uses are **permitted for a limited period and the Regulation specifies progressive decommissioning dates for these substances**[148]. These critical uses are subject to two specific dates, "cut-off" dates by which the use of halons for new equipment and facilities must cease, and "end-dates" by which products and equipment containing halons must be decommissioned and halons must not be used[149]. As an example, Table 21 illustrates the definition of cut-off and end dates for the use of halons in aircrafts specifically. The substances concerned with exemption for critical uses (including military uses) under Article 13 are halon 1301, halon 1211 and halon 2402.

Table 21: Example of halon uses in aircraft and their cut-off dates, based on Annex VI to the Regulation. Source: European Union Aviation Safety Agency (EASA) 2019, Halon replacement in the aviation industry

Purpose	Type of extinguisher	Type of halon	Cut-off date (31 December)	End date (31 December)
Protection of normally unoccupied cargo compartments	Fixed systems	1301 1211 2402	2018	2040
Protection of cabins and crew compartments	Portable extinguishers	1211 2402	2014	2025
Protection of engine nacelles and auxiliary power units	Fixed systems	1301 1211 2402	2014	2040
Inerting of fuel tanks	Fixed systems	1301 2402	2011	2040
Protection of lavatory waste receptables	Fixed systems	1301 1211 2402	2011	2020
Protection of dry bays	Fixed systems	1301 1211 2402	2011	2040

According to the 2019 support study for the evaluation of the Ozone Regulation, **requests for derogations regarding the provisions of the Ozone Regulation from defence stakeholders was limited** and employed as safeguarding measures[150]. The Commission confirmed that no derogation regarding halon cut-off dates or end dates (Article 13(4) of the Ozone Regulation) has been requested by the defence sector in the past ten years. As explained later, there has just been one temporary exemption from a defence stakeholder regarding the use of a hydrochlorofluorocarbon (HCFC) as refrigerant (Article 11(8) of the Ozone Regulation). Most of the Ministries of Defence interviewed argue that **the general approach to ODS is to implement the Regulation as is**, and resort to the exemptions for critical uses already provided by the Regulation whenever there is a risk that military requirements may not be fulfilled or that the use of alternatives may have a negative impact on the functionality of the material. Some Ministries of Defence have even taken a more proactive approach regarding the enforcement of the Ozone Regulation and made attempts to replace controlled substances progressively to comply with the schedule set by the Regulation until the cut-off dates were reached[151]. This particularly concerns new products and equipment while

[148] The cut-off dates were added to Annex VI by Regulation (EU) 744/2010 amending Regulation (EU) 1005/2009.
[149] Annex VI to the Regulation (EU) 1005/2009
[150] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report.
[151] It is noted that the last cut-off date was reached in 2018 and concerned the use of halon 1301, 1211 and 2402 for the protection of normally unoccupied cargo compartments on aircrafts. Source: Annex VI to the Regulation (EU) 1005/2009

controlled substances are privileged for older systems with fixed devices and a service life which is about to end soon. As an example of **good practice**, in the year 2000 in Spain, the "Zero Contamination Ship" project replaced CFCs in old facilities by gases such as R 134a[152] for air conditioning and refrigeration, in addition to R 404a[153] for freezing, free of chlorine and bromine, which are harmful to the ozone layer. Halons are replaced by extraordinary high- and low-pressure water mist suppression agents in firefighting systems[154]. It is noted, however, that these alternative substances are now regulated under the F-gas Regulation.

During the consultation, the Commission recalled the **case of a temporary exemption** requested by the Dutch Ministry of Defence regarding the use of HCFC-22[155]. The authority requested the Commission to be authorised to use 324 kilograms of reclaimed HCFC-22 from January 2015 to December 2018 in order to maintain the refrigeration system of two of its Royal Navy submarines, for which no alternative substance could be found on time to meet military standards. The authorisation was granted by the Commission in 2014[156].

Overall, **halons**, which are classified as "Ozone 1 (H420 – Hazardous to the Ozone Layer)" represent the **most difficult group of substances to be phased-out** due to the difficulty to find workable alternatives for them in the aerospace and defence industry. Consequently, the time-limited exemptions guaranteed under Article 13 are regularly used by stakeholders and are considered to allow more flexibility than REACH authorisations, allowing stakeholders to have more time to search replacements[157]. As an example, the substance halon 1301 for instance is still used as a fuel tank inerting gas on aircrafts. The only alternative available to this date is nitrogen[158] [159]. However, this substance would be needed in much larger quantities to reach the level of protection ensured by halon 1301, which is often technically impossible to incorporate to the aircraft structure. Aircrafts would need to be equipped with On-Board Inert Gas Generating Systems which did not prove to be efficient and can be costly[160]. Most Ministries of Defence have stated to comply with the requirements of the Regulation in this regard, given the specific provisions provided for military uses. MoDs only make use of halons when these cannot be replaced and try to work on the development of substitutes to the extent possible without jeopardising the operability of the equipment and the safety of the personnel. In this regard, it is noted that the Appendix of the support study commissioned by DG CLIMA for the evaluation of the Ozone Regulation from 2019 provides a

[152] 1,1,1,2-tetrafluoroethane (EC/List no.: 212-377-0; CAS no.: 811-97-2).

[153] No CAS number was found for the refrigerant Gas R404a. It is a mixture of R134a and R125 (1,1,2,2 pentafluoroethane EC/List no.: 206-557-8; CAS no.: 354-33-6).

[154] Gobierno de España, Ministerio de Defensa, Prevención de la contaminación en las aguas marítimas, continentales y subterráneas: https://www.defensa.gob.es/medioambiente/luchacontaminacion/prevencioncontaminacion/ (Last accessed on 12.10.2020).
Ministerio de Defensa > Inicio > Lucha contra la contaminación > Prevención contaminación

[155] Chlorodifluoromethane 5EC/List no.: 200-871-9; CAS no.: 75-45-6).

[156] Commission Implementing Decision C(2014)7821/F1 on authorizing a temporary exemption request by the Netherlands, pursuant to Regulation (EC) No 1005/2009 of the European Parliament and the Council on substances that deplete the ozone layer, with regard to the use of reclaimed FCFC-22 by the Ministry of Defence: https://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=3&year=2014&number=7821&language=en (last accessed on 12.10.2020).
European Commission > Transparency > Access to documents > Register of Commission documents > Search result

[157] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.106.

[158] Nitrogen (EC/List no.: 231-783-9; CAS no.: 7727-37-9).

[159] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.105.

[160] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.101.

comprehensive table covering the critical halon uses, their purpose, and the potential alternatives available for military ground vehicles, military surface ships and submarines, and aircrafts[161].

2.3.4.2 Managing impacts of the Regulation in the defence sector

Regarding the EU chemicals' legislation specifically, it can be argued that defence related provisions may be addressed differently by the different pieces of legislation. While REACH and the CLP adopt a case-by-case approach to potential defence-related exemptions, the ODS allows for some critical uses such as military applications (through its Annex VI to the Regulation 'Critical uses of halon'). In fact, there is no "one-size-fits-all provision" to manage defence-related matters in terms of chemical legislation. Instead, provisions are progressively built throughout the legislative process depending on the needs identified in relation to the use of specific substance groups[162]. These differentiated approaches may lead to confusion among all the other regulations related to chemicals, as expressed by some defence industry stakeholders during the consultation.

As far as public authorities are concerned, most Ministries of Defence acknowledged impacts which mostly related to the **need to adapt their organisation to comply** with the phase-out of certain substances and train their workforce to handle new substances for military uses. One Ministry of Defence in particular expressed concerns regarding the fact that the substitution of halons especially represents a challenge, and some of them foresee a risk that their substitution will not succeed within the given period allowed.

Finally, from the defence industry perspective, the consultation carried out for this study highlighted their **low level of awareness regarding the Regulation's impact on their activity**. In fact, several of them did not identify any product affected by the provisions of the Regulation. Furthermore, they acknowledged difficulties for downstream users to identify restricted substances. The reason is that some substance entries in the Annexes to the ODS Regulation relate to a wide family of substances for which the CAS or the EC numbers have not been identified, which makes it very difficult to track them. It is noted that a CAS number is provided for all the substances listed in Annex I and II to the Regulation. The source of confusion may hence stem from the need to clarify which substances are specifically covered by the Annexes, underlining for instance that although the Ozone Regulation covers HCFCs, this does not entail that the Regulation concerns all HCFCs.

One positive impact of the Ozone Regulation identified is that the phase-out of substances **incentivised research** for alternatives and pushed discussions at the international level to introduce globally applicable phase-out dates. In fact, the search for alternatives to halons in applications where they are allowed (including military applications) has already allowed to find alternative substances for several uses in the EU (e.g., portable systems in airfields and airports, replacement in military ground vehicles) and the phase out schedule has strongly incentivised research for halon replacement[163].

[161] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, pp175-184.

[162] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.102.

[163] For further information, please refer to the support study for the evaluation of the ODS Regulation which provides a comprehensive table on the critical uses of halons, specifying the type of equipment for which the substance is used, its purpose, limitations and potential alternatives available, with dates by which the alternatives might be technically and economically feasible. Source: Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, pp175-184.

2.3.4.3 Availability of substances

Stakeholders highlighted several challenges to overcome in the coming years. First, the risk of **unavailability of substance**s represents an issue especially for products and equipment containing or relying on regulated substances which have a long lifetime. Refilling those products or equipment may become more and more difficult. In this sense, it is noted that, pursuant to Article 11(3), the maintenance or servicing of existing HCFC equipment is already forbidden since 31 December 2014. In addition, the search for alternatives may be complex. Some **alternatives** have not yet been proven to meet minimum standards for use in military equipment and can be either too "heavy" or not as effective as the ones regulated under the Ozone Regulation. This is especially true for halons for which alternatives tend to be more costly and not as efficient, as described above. According to defence stakeholders, this represents a serious challenge.

As mentioned in section 2.3.4.1, the **aerospace, land and naval sectors** have been identified as being among the main sectors impacted by the Ozone Regulation especially regarding fire extinguishing agents and aircraft fuel tank inerting.

Regarding **the use of halons in military equipment** specifically, the consultations carried out highlighted challenges due to the **difficulty to find alternatives** meeting military standards. The Ozone Regulation does not allow for exemptions other than those already specified. Though some MoDs anticipate that the timelines for these specific permissions will not be enough to secure a safe and adequate replacement of halon, others argued that research for alternatives is ongoing. Even though some of the developed alternatives still '*appear to pose difficulties such as requiring major technical modifications to the equipment or posing weight constraints*'[164], one MoD acknowledged most of the new design integrate suitable alternatives (mostly F-gases). **New naval and land systems are now mainly halon free** and comply with the ODS requirements. As an example, in new ships, sprays, watermist or Novec^{tm} 1230[165] are used for total flooding fixed extinguishers. However, it is noted that some of the replacements identified are only feasible in new installations or where no major technical adjustments will be needed[166]. The Commission is considering how to address this issue in the context of the ongoing impact assessment of the Ozone Regulation[167].

Another issue has been raised by stakeholders concerning the **obligation under the Ozone Regulation to replace chlorofluorocarbon (CFC), hydrochlorofluorocarbon (HCFC) and halons** for most uses since 2000. One of the solutions developed was to substitute the regulated substances with hydrofluorocarbons (HFCs) for refrigeration and as fire extinguishing agents, which are substances covered by the phase-down requirements of the F-gas Regulation in terms of production and maintenance from 2020. Consequently, HFCs are now being replaced by hydrofluoroolefins (HFOs). However, it appears that **HFOs do not present sufficient technical performance characteristics to fit within the design margins**, such as electric consumption or refrigeration power in terms of volume and mass or safety characteristics of the substances being phased out. Studies showed that the **substitution process stemming from both the Ozone and F-gas Regulations has had a major impact on naval systems**: '*each new alternative offers less efficiency, more bulkiness,*

[164] Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, p.30.
[165] EC/List no.: 436-710-6; CAS no.: 756-13-8
[166] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.46.
[167] European Commission, Ozone layer protection – review of EU rules: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12310-Ozone-layer-protection-review-of-EU-rules (Last accessed: 06.12.2020) European Commission > Have your say > Published initiatives > Ozone layer protection – review of EU rules

and in some cases, there seems to be a serious risk of fire in case of accident'[168].

2.3.4.4 Potential additional costs

Stakeholders also identified potential additional costs in relation to the implementation of the Regulation. First, **logistics and administrative costs are expected**. There is indeed a risk of an increase in the IT tools needed to track the substances. The need to supervise the implementation of the Regulation will also entail **a reorganisation of human resources**. To comply with the Regulation, **investments in R&D** will also be necessary to foster innovation and develop substitutes for the substances being phased out.

Furthermore, there may potentially be a higher cost for alternative substitutes. There could also be **costs linked to the retrofitting** of old equipment to comply with the Regulation's requirements. Likewise, investment will be needed to ensure a trained and qualified personnel is able to use these new substances and products. On the other hand, several MoDs highlighted that there will also be procurement costs regarding controlled substances as civil applications will decrease along with the availability of these substances. The maintenance of equipment for which viable alternatives have not yet been found will thus be more expensive.

It is noted that, according to the results of the evaluation of the Regulation carried out in 2019, the Regulation mitigated the potential impact of the costs of implementation. While it is acknowledged that compliance costs represent an important share of spending for stakeholders and that phase-out measures are especially costly, it appears that the system of exemptions and derogations helped minimise the impact of these costs, favouring a more progressive transition. Furthermore, once the phase-out of a substance is complete, no further costs are to be expected[169]. However, the evaluation does not specify to what extent these findings apply to the defence sector.

2.3.5 Summary

Regulation (EC) 1005/2009[170] on substances that deplete the ozone layer (the Ozone Regulation) supports the implementation of the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer but goes beyond by setting a higher level of ambition for the EU, establishing stricter phase-out schedules and covering a wider range of substances. Also, while the provisions of the Protocol for licensing system focus on the import and export of substances, the Regulation's licensing system also covers products and equipment containing or relying on those substances.

The Ozone Regulation defines several measures and requirements for Member States to regulate the use of ozone-depleting substances, in order to replace them with more climate-friendly alternatives. The Regulation aims for **controlling, monitoring and reporting** on the production, use, trade and handling of **ozone depleting substances (ODS)** and products relying on them, while ensuring the enforcement of ODS policies. **The controlled substances (alone or in a mixture, and virgin or recycled) are listed in Annex I to the Regulation and cover Chlorofluorocarbons (CFCs), Halons**

[168] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.106.

[169] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.138.
Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final, pp.43-50. Available at: https://ec.europa.eu/clima/events/evaluation-ozone-regulation_en (Last accessed on 12.10.2020)

[170] Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer

(1211, 1301, 2402), Carbon tetrachloride (CTC), 1,1,1- Trichloroethane (TCA), Methyl Bromide (MB), Hydrochlorofluorocarbon (HCFCs), Bromochloromethane (BCM). Furthermore, five additional 'new' substances are considered in Annex II, namely Dibromodifluoromethane (halon 1202), methyl chloride (MC), Bromoethane (ethyl bromide), trifluoroiodomethane (trifluoromethyl iodide), and 1-Bromopropane (n-propyl bromide). Article 13 of the Ozone Regulation provides for exemptions of 'critical uses' of halons (including military uses) which are permitted for a limited period. Annex VI to the Ozone Regulation specifies these critical uses along with progressive decommissioning dates. There are other derogation mechanisms (not specific to defence) defined in Chapter III of the Regulation.

It is considered that there is consistency between the Ozone Regulation and the CLP Regulation that are linked through the labelling requirements required for various ODS exempted from prohibition. Regarding REACH, ozone-depleting substances placed on the market generally fall under REACH and thus require registration and evaluation processes. It is noted that an exchange of information, as well as control mechanisms for substances, would enhance the coherence between the two Regulations. Some substances with ozone-depleting potential, such as very short-lived substances (VSLS), may already be restricted under REACH, while they might not be currently covered by the existing regime of the Ozone Regulation. It is noted that the Impact Assessment currently carried out aims at tackling this issue. The main interactions with other EU chemicals Regulations focus on the F-gas Regulation. The consultation carried out for this study showed that defence industries struggle with differentiating between the two. Some of the new substances identified may present characteristics that could qualify them to be regulated by both Regulations. Also, the reduction of ODS emissions fostered by the Montreal Protocol globally and the Ozone Regulation at the European level has led to the introduction of fluorinated gases (F-gases) as substitutes for ODS in sectors such as refrigeration and air conditioning applications. This becomes problematic when these F-gases subsequently are phased-down under the F-gas Regulation.

Overall, it appears that **requests for derogations from defence stakeholders have been limited**. However, the above-mentioned exemption under Article 13(1) of the Ozone Regulation concerning **critical uses of halons is of specific relevance for the defence sector**. According to the stakeholders consulted, halons, which are classified as "Ozone 1 (H420 – Hazardous to the Ozone Layer)" represent the most difficult group of substances to find workable alternatives for in the aerospace and defence industry. Therefore, the **time-limited exemptions granted under Article 13 are regularly used by stakeholders** and are considered to allow more flexibility than REACH authorisations, allowing stakeholders to have more time to search replacements. Most MoDs consulted have stated to comply with the requirements of the Ozone Regulation given the specific provisions provided for military uses. They only make use of halons when these cannot be replaced and try to work on the development of substitutes to the extent possible without jeopardizing the operability of the equipment and the safety of the personnel.

As far as MoDs are concerned, difficulties to manage the impacts of the Ozone Regulation mostly relate to the need to adapt their organisation to comply with the phase-out of certain substances and train their workforce to handle new substances for military uses. On the other hand, defence industry stakeholders highlighted difficulties for downstream users to identify restricted substances. The source of confusion regarding substance identification may then stem from the need to clarify which substances are specifically covered by the Annexes, underlining for instance that although the Ozone Regulation covers HCFCs, this does not concern all HCFCs.

During the consultation, several challenges to overcome in the coming years have been highlighted. First the risk of **unavailability of substances** represents an issue especially for products and equipment relying on controlled substances which have a long lifetime. Refilling those products or equipment may become more and more difficult. The **search for alternatives** may be complex as some alternatives have **not yet proven to meet minimum standards for use in military equipment**.

However, it is noted that one positive impact of the Ozone Regulation identified was that the phase-out of substances **incentivised research for alternatives** and pushed discussions at the international level to introduce globally applicable phase-out dates. Consequently, with the exception of aircraft fuel tank inerting, a majority of new design now integrate suitable alternatives (such as F-gases). There remains a challenge for existing systems still in operation.

Finally, all the stakeholders consulted identified several potential additional costs in relation to the implementation of the Regulation. **Logistics and administrative costs** are expected to reorganise and adapt the defence sector to the provisions of the Regulation. Further investments in R&D would also be necessary to search for innovative solutions and reduce the burden of alternative substances. The retrofitting of old equipment to comply with the Regulation will also lead to further spending as substitutes may be more expensive than ODS. MoDs highlighted that there will also be **procurement costs regarding controlled substances as civil applications will decrease** along with the availability of these substances.

2.4 F-GAS REGULATION (REGULATION (EU) NO 517/2014)

Regulation (EU) No 517/2014 (F-gas Regulation) aims for the protection of the environment and the fight against climate change by reducing the emission of the fluorinated greenhouse gases, F-gases. Pursuant to Recital (8) of the Regulation, the Kyoto Protocol constitutes a pillar of the European Union's action against F-gases. Repealing Regulation (EC) 842/2006, the new F-gas Regulation's objective is to cut the EU's 2014 F-gas emissions' level by two thirds by 2030[171]. The fluorinated greenhouse gases covered are Hydrofluorocarbons (HFCs), Perfluorocarbons (PFCs), and Sulphur hexafluoride (SF6)[172], as well as other fluorinated greenhouse gases subject to reporting listed under Annex II to the Regulation[173], in accordance with Article 19.

It is noted that, with this Regulation, the European Union played a proactive role in the sector and supported talks on actions on F-gases under Montreal Protocol on Substances that Deplete the Ozone Layer, which culminated with the adoption of the Kigali Amendment, which entered into force on 1 January 2019, and added HFCs to the list of controlled substances under the Montreal Protocol.

2.4.1 Implementation of the Regulation

The F-gas Regulation's overall objective is to **fight against climate change by reducing and preventing the EU's F-gas emissions** and supporting the implementation of the Montreal Protocol in the Union. To achieve this goal, the Regulation relies on a **general phase-down of HFCs to reduce their supplies on the EU market over time**, as well as a number of accompanying prohibitions (Annex III to the Regulation). Pursuant to Article 1, the Regulation defines four main types of measures to enforce a reduction in the emissions of F-gases. First, it is meant to determine rules regarding the containment, use, recovery and destruction of substances (detailed in Chapter II of the Regulation). In addition, it should regulate the placing on the market of specific products and equipment relying on those substances. It should also set out conditions on the specific uses of F-gases and finally, it should establish a quota system to phase-down the placing of HFCs on the market.

[171] European Commission, fluorinated greenhouse gases: https://ec.europa.eu/clima/policies/f-gas_en (Last accessed: 12.10.2020)
European Commission > Energy, Climate change, Environment > Climate Action > EU Action > Fluorinated greenhouse gases.

[172] Sulphur hexafluoride (EC/List no.: 219-854-2; CAS no.: 2551-62-4).

[173] These fluorinated greenhouse gases include three categories of F-gases, namely unsaturated hydro(chloro)fluorocarbons, fluorinated ethers and alcohols, and other perfluorinated compounds.

The F-gas Regulation entered into force in 2015 and replaced the previous Regulation (EC) 842/2006. The main changes introduced by the new Regulation relate to the phase-down of HFCs to transition to more climate-friendly technologies, the prohibition of certain substances in new products and equipment to favour safer alternatives, and the implementation of checks, servicing and recovery of F-gases at the end of an equipment's service life[174].

International legal basis

As for the ODS Regulation described in Section 2.3, the F-gas Regulation seeks to **ensure EU compliance with the Montreal Protocol** on Substances that Deplete the Ozone Layer at international level. However, contrary to the former, it is noted that **the F-gas Regulation pre-empted global rules on HFCs** and was developed with the objective of facilitating the reach of an agreement on hydrofluorocarbons (HFCs) on a global scale[175]. In fact, the Regulation entered into force in 2015, while the **Kigali Amendment**, which introduced controls on HFCs in the Protocol, only entered into force in 2019, following discussions which started in 2009 and led to an agreement reached during the 28th Meeting of the Parties in October 2016. The phase-down timeline for HFCs as planned by the Kigali Amendment[176] is described in Figure 5. To further expand the Protocol's reach and make it an ever more powerful instrument against global warming, this Amendment adds HFCs to the list of controlled substances and defines a phase-down timeline aiming to **achieve reduction of the consumption and production of HFCs to at least 80% of these substances by 2047**[177]. The progressive phase-down of F-gases under the Kigali Amendment relies on specific baseline calculations and initial steps to follow. For Non-Article 5 Parties[178], like all EU Member States, baselines were defined according to past HCFC consumption and production levels and HFC consumption and production levels for the period 2011-2013. For these countries, phase-down phase already took place in 2019 and will last until 2036[179].

It is noted that some differences exist between the F-gas Regulation and the Protocol. First, the Protocol's objective extends until 2036, while the Regulation's phase-down measure (i.e., the quota system) does not go further than 2030. Second, some of the EU's defined exemptions and thresholds are not included in the international agreement. On the other hand, the limitations on production set under the Montreal Protocol are not found in the EU Regulation[180], production is only indirectly affected by the consumption parameter.

---

[174] European Commission, EU legislation to control F-gases: https://ec.europa.eu/clima/policies/f-gas/legislation_en (Last accessed: 12.10.2020)
European Commission > Energy, Climate change, Environment > Climate Action > EU Action > Fluorinated greenhouse gases > Legislation.

[175] European Commission (2020) Combined evaluation roadmap/inception impact assessment, Ref. Ares(2020)3402178 - 29/06/2020

[176] UN Environment Programme, About Montreal Protocol: https://www.unenvironment.org/ozonaction/who-we-are/about-montreal-protocol (Last accessed on 12.10.2020)
UN Environment Programme > Ozonaction > Who we are > About Montreal Protocol.

[177] UN Industrial Development Organisation, The Montreal Protocol evolves to fight climate change: https://www.unido.org/our-focus-safeguarding-environment-implementation-multilateral-environmental-agreements-montreal-protocol/montreal-protocol-evolves-fight-climate-change (Last accessed on 12.11.2020)
UNIDO > Our focus > Safeguarding the environment > Implementation of multilateral environmental agreements > Montreal Protocol > Kigali Amendment.

[178] Article 5 Parties cover only developing countries. EU Member States are considered Non-Article 5 Parties to the Kigali Amendment.

[179] United Nations Environment Programme (UNEP), 2016, Frequently asked questions relating to the Kigali Amendment to the Montreal Protocol: https://ec.europa.eu/clima/sites/clima/files/faq_kigali_amendment_en.pdf (Last accessed on 03.12.2020)

[180] European Commission (2020) Combined evaluation roadmap/inception impact assessment, Ref. Ares(2020)3402178 - 29/06/2020.

Figure 5: Phase-down timeline of HFCs based on the Kigali Amendment[181]

	Non- Article 5 (Main Group)		Non- Article 5: Belarus, the Russian Federation, Kazakhstan, Tajikistan & Uzbekistan	
Baseline Years	2011, 2012 & 2013		2011, 2012 & 2013	
Baseline Calculation	Average production/consumption of HFCs in 2011, 2012 & 2013 *plus* **15%** of HCFC baseline production/consumption		Average production/consumption of HFCs in 2011, 2012 & 2013 *plus* **25%** of HCFC baseline production/consumption	
Reduction steps Step 1	**2019**	**10%**	**2020**	**5%**
Step 2	**2024**	**40%**	**2025**	**35%**
Step 3	2029	70%	2029	70%
Step 4	2034	80%	2034	80%
Step 5	2036	85%	2036	85%

2.4.1.1 Scope of the Regulation

Pursuant to Article 2 of the F-gas Regulation, the fluorinated greenhouse gases covered by the Regulation are **Hydrofluorocarbons (HFCs), Perfluorocarbons (PFCs), Sulphur hexafluoride (SF6).** These are all listed in Annex I to the Regulation, as well as Annex II for the other F-gases subject to reporting in accordance with Article 19. F-gases are man-made gases used in a range of industrial uses including refrigeration and air conditioning. They are not ozone-depleting substances, which is why they are often used as alternatives to them, however, some **of these gases may present a high or very high Global Warming Potential (GWP).** The GWP corresponds to the climatic warming potential of a greenhouse gas relative to that of carbon dioxide (Article 2). Annexes I, III, IV and V to the Regulation provide the specific GWP values allowed for each substance or mixture.

Some of the key principles included in the F-gas Regulation relate to **containment measures** (Chapter II of the Regulation), which ensure the prevention of emissions of F-gases (Article 3) by ensuring better leakage control through leak checks (Article 4), detection systems (Article 5) and record-keeping (Article 6). Producer responsibility schemes and certifications (Article 9 and Article 10) have been developed to make sure that F-gases are used and sold to trained users only.

Chapter III of the Regulation provides **measures on the placing on the market and control of use of F-gases** by defining bans on specific product and equipment placed on the market (Article 11), as well as on service and maintenance regarding the use of certain high GWP gases in existing equipment

[181] Source: UNEP, OzonAction Fact Sheet, The Kigali Amendment to the Montreal Protocol: HFC Phase-down. Available at: https://multimedia.3m.com/mws/media/1365924O/unep-fact-sheet-kigali-amendment-to-mp.pdf

(Article 13)[182]. For these restrictions, it is noted that the Regulation forbids the use of F-gases with a GWP higher than 2500 to service or maintain some refrigeration equipment. Article 11(1) provides that the products and equipment concerned shall be prohibited on a specific date and, when relevant, based on the type of GWP of the F-gases contained. These are detailed in Annex III to the Regulation. Finally, pursuant to Articles 15 and 16, the Regulation plans a phase-down of HFCs placed on the market (Chapter IV). An electronic registry for quotas for placing HFCs on the market has been established to monitor the phase-down (Article 17).

Several exemptions exist for military equipment under the F-gas Regulation, specifically under Article 2(35) which provides the narrow definition of 'military equipment' as understood under the Regulation, Article 11(1) on restrictions regarding the placing on the market, Article 13(3) on the control of use, and Article 15(2)(d) specifying an exemption from the phase-down (quota system) on HFCs directly supplied by a producer or an importer for use in military equipment[183]. As it will be seen in Sub-section 2.4.4, some of the Regulation's restrictions may still impact the defence industry despite these exemptions.

It is noted that Article 11(3) provides that **competent authorities are allowed to send a request to the Commission for a temporary exemption (up to four years)** regarding the placing on the market of products and equipment relevant for Annex III to the Regulation, if the authorities manage to prove that safe alternatives present a disproportionate cost or that none are as yet available.

2.4.1.2 Governance

European Commission

At the European level, **DG CLIMA** is responsible for implementing the Regulation. Concretely, the Commission:

- Allocates annual quotas for placing hydrofluorocarbons on the market for each producer and importer and ensures that the quantity of hydrofluorocarbons on the market does not exceed the annual maximum quantity;
- Follows compliance of quota holders with their annual quotas;
- Operates the electronic registry for quotas for placing hydrofluorocarbons on the market;
- Monitors the application and effects of this Regulation;
- Collects information from Member States on national codes, standards or legislation, certification and training programmes etc.;
- Updates Annexes I, II and IV to the Regulation on the basis of new Assessment Reports adopted by the Intergovernmental Panel on Climate Change or new reports of the Scientific Assessment Panel (SAP) of the Montreal Protocol.

Other EU stakeholders

The **European Environment Agency compiles a report annually presenting the aggregated data reported by companies** on the production, import, export and destruction of fluorinated greenhouse gases in the EU. It is also noted that the European Topic Centre on Climate Change Mitigation and

[182] The Linde Group, 2014, Guide to the updated EU F-Gas Regulation (517/2014), Available at: https://www.linde-gas.com/en/products_and_supply/refrigerants/environment_and_legislation/global_warming_legislation_hfc_control/eu_f_gas_regulation/index.html (Last accessed on 08.12.2020)

[183] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.103.

Energy (ETC/CME) has provided technical support to the reporting process since 2012[184].

Alongside these institutional stakeholders, the Commission also has contacts with companies directly, running a helpdesk supporting companies with compliance, in particular the registry and the quotas. They are in touch with both large organisations at the European level and smaller companies that require some help in understanding the quota system.

Member States' competent authorities

A list of national competent authorities responsible for the F-gas Regulation is available on the Commission's website[185]. Member State authorities' main tasks relate to the enforcement of the Regulation, through the market surveillance, inspections and issuance of penalties in cases of non-compliance, as well as the certification and training of service personnel, promotion of recovery, recycling, reclamation and destruction of ODS and deriving emissions data.

Pursuant to Article 24, a Member States Committee, **the Committee on fluorinated greenhouse gases**[186], must assist the Commission in the implementation of the Regulation. It is a platform through which proposals for derogations and exemptions can be discussed. Furthermore, as per Article 23, a Consultation Forum was established as an official EC expert group to enable stakeholders from the industry or NGOs to discuss with Member States and the Commission[187]. Reports on the state of play of current alternatives can be prepared for that purpose, and the Forum helps provide feedback to the Commission regarding the implementation of the Regulation.

2.4.1.3 Evaluation and review of the Regulation

Regulation (EU) No 517/2014 is currently being reviewed for the first time. The Commission is proceeding to conduct the evaluation in parallel to the impact assessment. On **30 June 2020, a combined evaluation roadmap/inception impact assessment was published** to inform citizens and stakeholders and invite them to provide their views during a public consultation about the forthcoming review of EU rules on fluorinated greenhouse gases[188].

As identified by the roadmap published, the objective of this evaluation should be to overcome several challenges to the implementation of the F-gas Regulation. First, the EU is at risk of being non-compliant with the Montreal Protocol after 2030 as the last steps of the phase-down planned by the Regulation do not go beyond this date. The Regulation thus needs to seek alignment with the Protocol. Second, based on the recent technological developments, the EU should raise its ambitions regarding emission savings and ensure it is in line with the new European Green Deal. Finally, some challenges specific to the enforcement of the Regulation need to be addressed, especially regarding

[184] EEA (2019) Fluorinated greenhouse gases, Data reported by companies on the production, import, export, destruction and feedstock use of fluorinated greenhouse gases in the European Union 2007-2018, Available at: https://www.eea.europa.eu/publications/fluorinated-greenhouse-gases-2019/ (Last accessed on 12.10.2020)
European Environment Agency > Home > Publications > Fluorinated greenhouse gases.

[185] European Commission, Competent Authorities in Member States: https://ec.europa.eu/clima/sites/clima/files/f-gas/docs/contact_list_en.pdf (Last accessed on 12.10.2020)
European Commission > Energy, Climate change, Environment > Climate Action > Fluorinated greenhouse gases > Documentation.

[186] European Commission (2020) Committee information, Committee on fluorinated greenhouse gases: https://ec.europa.eu/transparency/comitology-register/screen/committees/C47200/consult (Last accessed on 10.11.2020).
European Commission > Comitology Register > Search for Committees > Committee

[187] European Commission, Consultation Forum according to Art.23 of Regulation (EU) 517/2014 on fluorinated greenhouse gases (X03338): https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3338 (Last accessed on 12.01.2021).

[188] European Commission (2020) Combined evaluation roadmap/inception impact assessment, Ref. Ares(2020)3402178 - 29/06/2020.

illegal imports and misuse of the quota system, monitoring, and the need to make use of the synergies available with the "Single Window for Custom"[189].

2.4.1.4 Regulatory evolution of substances

Pursuant to Article 21, the Commission is tasked to review and update the list of controlled substances available in Annexes I, II to the F-gas Regulation. These revisions should be based on the new Assessment Reports adopted by the Intergovernmental Panel on Climate Change (IPCC) or new reports of the Scientific Assessment Panel (SAP) under the Montreal Protocol.

2.4.2 Interactions with REACH and CLP

Interactions with REACH and CLP are very similar to the ones highlighted in Sub-section 2.3.2 regarding the ODS Regulation. There is **no outstanding inconsistency with other EU or international legislation**, as they are usually well aligned[190]. The stakeholder consultation did not reveal any major shortcoming, either. As opposed to the case-by-case approach under REACH and CLP follow a similar process, the F-gas Regulation provides for automatic exemptions for military equipment, Article 13(3), and Article 15(2)(d), as cited in Section 2.4.4.1.

2.4.3 Interactions with other chemicals regulations / directives

2.4.3.1 F-gas Regulation and BPR

See Section 2.1.3.3 'BPR and F-gas Regulation'

2.4.3.2 F-gas Regulation and POPs

See Section 2.2.3.3 'POPs Regulation and F-gas regulation'

2.4.3.3 F-gas Regulation and Ozone Regulation

See Section 2.3.3.3 'Ozone Regulation and F-gas Regulation'

2.4.3.4 F-gas Regulation and RoHS

None of the substances regulated by the F-gas Regulation are regulated by the RoHS Directive. Although there are no provisions in the legislation that would prevent overlaps in terms of substance coverage between the two pieces of legislation, **there are currently no interactions between the two**. No issues have been raised by stakeholders on the interface between those pieces of legislation.

[189] European Commission (2020) Combined evaluation roadmap/inception impact assessment, Ref. Ares(2020)3402178 - 29/06/2020.
[190] Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, p.141.

2.4.4 Impacts on the defence sector

2.4.4.1 Provisions relevant to defence

The following provisions of the F-gas Regulation are particularly relevant for the defence sector.

Provision of F-gas Regulation
Article 2(35) ''*military equipment' mean arms, munitions and war material intended specifically for military purposes which are necessary for the protection of the essential interests of the security of Member States*;' **Article 11(1)** '*The placing on the market of products and equipment listed in Annex III, with an exemption for military equipment, shall be prohibited from the date specified in that Annex, differentiating, where applicable, according to the type or global warming potential of the fluorinated greenhouse gas contained*.' **Article 13(3)** '*From 1 January 2020, the use of fluorinated greenhouse gases, with a global warming potential of 2 500 or more, to service or maintain refrigeration equipment with a charge size of 40 tonnes of CO2 equivalent or more, shall be prohibited.* *This paragraph shall not apply to military equipment or equipment intended for applications designed to cool products to temperatures below – 50 °C.* *The prohibition referred to in the first subparagraph shall not apply to the following categories of fluorinated greenhouse gases until 1 January 2030:* *(a) reclaimed fluorinated greenhouse gases with a global warming potential of 2 500 or more used for the maintenance or servicing of existing refrigeration equipment, provided that they have been labelled in accordance with Article 12(6);* *(b) recycled fluorinated greenhouse gases with a global warming potential of 2 500 or more used for the maintenance or servicing of existing refrigeration equipment provided they have been recovered from such equipment. Such recycled gases may only be used by the undertaking which carried out their recovery as part of maintenance or servicing or the undertaking for which the recovery was carried out as part of maintenance or servicing.* *The prohibition referred to in the first subparagraph shall not apply to refrigeration equipment for which an exemption has been authorised pursuant to Article 11(3*).' **Article 15(2)(d)** '*This Article shall not apply to producers or importers of less than 100 tonnes of CO_2 equivalent of hydrofluorocarbons per year.* *This Article shall also not apply to the following categories of hydrofluorocarbons:* *(…)* *(d) hydrofluorocarbons supplied directly by a producer or an importer for use in military equipment* *(…)*'

2.4.4.2 Using the defence exemption

The use of F-gases in military equipment **benefits from several exemptions** such as exemptions from the ban on uses of F-gases from January 2020 (Article 13(3)), and exemptions from quantitative limits for placing on the market (Article 15). Furthermore, pursuant to Article 11, the placing on the market of products and equipment for military uses is exempted from prohibition, contrary to uses listed in Annex III to the Regulation 'Placing on the market prohibitions referred to in Article 11(1)'. Note that the term 'military equipment' is narrowly defined in Article 2(35).

It appears that the implementation of these exemptions **varies across Member States**. During the consultation, most Ministries of Defence confirmed they usually **rely on** the **specific exemptions provided by the Regulation to meet the military standards** set for the equipment and their

functioning. Furthermore, in the interest of compliance with the Regulation's requirements, some of them would adopt a **more proactive approach,** promoting the research for viable alternatives and constraining the use of F-gases which are bound to disappear in the short or mid-term. As a consequence, when the safety of staff and the functionality of the equipment are not at stake, some Member States will avoid relying on exemptions and instead promote the use of alternative substances. This approach is especially used when purchasing new equipment which does not rely on controlled substances. However, it is noted that **some military uses remain very difficult to handle,** such as refrigeration application or fire protection systems. In this case, the use of F-gases can be tolerated under the scope of the Regulation, as provided by Article 11(1), Article 13(3) and Article 15(2)(d).

It is noted that from the perspective of the defence industry**, the consultation highlighted that a lack of information and awareness** regarding how F-gas Regulation affects their activity. In fact, defence industries stated they either did not have any product affected by the provisions of the Regulation or they did not observe any specific impact from the Regulation's provisions as they relied on the exemptions provided by the Regulation to avoid proceeding to any further checking. The complementarity of the ODS and F-gas Regulations also reinforce the risks of confusion for stakeholders who expressed their wish to be involved in awareness programmes or have more guidance.

With regards to the possibility for Member States to request a temporary exemption to allow the placing on the market of products and equipment listed in Annex III (Article 11(3)), it is noted that none of the stakeholders consulted mentioned any use of this provision so far. The Commission highlighted that the **derogation requests from defence stakeholders had been very limited** in the past ten years.

2.4.4.3 Availability of substances

Defence stakeholders agreed on the fact that the **difficulty to find appropriate alternatives** represented the main challenge of the F-gas Regulation. The main concern is the **lack of available alternative substances**. Some substitutes with lower global warming potential which are known to date are **very flammable and may not meet the existing standards.** A stakeholder expressed concerns regarding **existing legacy equipment which may not be supported in the future** if F-gases become obsolete and new equipment with non-F-gas alternatives are a fire hazard in a combat zone. One MoD consulted conceded that there was **a risk that a suitable substitute will not be found in time for all F-gases concerned,** to comply with the dates specified in Annex III to the Regulation.

Additionally, the results of the consultation carried out for this study also highlighted that **reformulation may affect the performance and reliability of products,** which may result in the fact that a larger amount of substances will be necessary to gain the same effect and meet minimum standards for use in military applications.

Finally, **commercial obsolescence** is also expected for instance for substances such as R404a, R134a[191], FM200[192]. As a result, some F-gases are beginning to disappear from the market as these substances will no longer be used for civil applications. However, it is noted that since these gases are subject to an exemption for military uses, it is still possible to import them if necessary.

In terms of **potential regrettable substitutions**, as mentioned in Sub-section 2.4.3, the planned phase-down of HFCs presents the risk of generating conflict uses with the Ozone Regulation as these substances have been introduced as substitutes for ODS. Finally, it is noted that many F-gases are

[191] 1,1,1,2-Tetrafluoroethane (EC/List no.: 212-337-0; CAS no.: 711-97-2).
[192] 1,1,1,2,3,3,3-heptafluoropropane (EC/List no.: 207-079-2; CAS no.: 431-89-0).

defined according to their GWP-values. F-gases with high GWP-values are restricted due to their negative impact on climate.

One MoD highlighted the fact that some of these F-gases with a high GWP-value may be replaced by another F-gas with a GWP-value that is considered lower but still presents a rather serious global warming potential, as this was the case for R 404a[193] (3921 GWP) which was replaced by R 134a[194] (1430 GWP). These substitutions can thus only constitute a temporary solution and a more sustainable alternative should be pursued. This represents a challenge particularly for fire protection applications for which military specifications ensure the safety of people inside vehicles. Extinguish gases need to have a low time of expand reaction and substation deployment has to be validated within the context of a military environment. On the other hand, substitutes with lower GWP-values should be better in respect to climate change impact. It is noted that substitutes may have other negative impacts on the environment and human health. However, potential negative impacts mostly concern synthetic substances.

The phase-down planned by the Regulation may cause **capability issues** as it may have an impact on some equipment such as long service life naval systems[195] or fire protection systems as mentioned above. As an example, the substance R 134a is being used in almost all professional refrigeration applications. In addition, one MoD underlined that a phase-down of this substance will affect the functioning and performance of equipment relying on it[196]. Consequently, some military specifications ensuring the safety of people inside a vehicle may not be fulfilled anymore with the use of substitutes.

2.4.4.4 Potential additional costs

Finally, most defence stakeholders highlighted that the implementation of the F-gas Regulation may entail some **potential additional costs** for the defence sector. Administrative costs are foreseen to comply with the inventory and reporting obligations while ensuring leakage control measures. Certified personnel will be needed to carry out some of these tasks, which will further **increase the costs of human resources**. The use of new alternatives and the development of new technologies may also entail costs to **ensure the remodelling and redesign of old equipment**. One MoD underlined that reformulation could pose a problem. This could be the case for refrigeration applications, where the use of potential alternative (R1234yf) may lead to additional costs. Likewise, regarding fire protection systems, the use of water mist suppression agents is accompanied by a performance decrease and issues with compactness and logistics.

Some **potential R&D costs** are also foreseeable to identify alternative substitutes, which in turn may also have a higher price than currently available substances. Regarding **controlled substances, they may become more expensive** as civil applications will decrease along with the phase-down dates, leading to smaller volumes of substances available. Commercial obsolescence may thus have an impact on the costs of purchase for defence stakeholders.

MoDs also underlined that some costs are to be expected for the use of F-gases in the future. These can include an **increase in the logistical resources needed to track the substances** (not only in terms of manpower but also IT tools). Furthermore, new logistics may lead to further spending as the use

[193] No CAS number was found for the refrigerant Gas R404a. It is a mixture of R134a and R125 (1,1,2,2 pentafluoroethane EC/List no.: 206-557-8; CAS no.: 354-33-6).
[194] 1,1,1,2-tetrafluoroethane (EC/List no.: 212-377-0; CAS no.: 811-97-2).
[195] REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.103.
[196] It is however noted that in the case of R 134a, recycled or regenerated forms of the substance are authorised until 2030 for the maintenance or servicing of existing refrigeration equipment, pursuant to Article 13(3)(b).

of substitutes may modify operational processes. For MoDs and their national Armed Forces, the main issues lie in **the new procurement strategies** to be adopted to acquire new products and equipment, as well as providing a **sufficient supply in substances** to ensure the maintenance of existing equipment. **Procurement costs** are especially predicted to obtain new defence equipment, compliant with the Regulation. Administrative costs are also foreseen in the **supervision of regulatory changes**. Finally, one MoD highlighted the need to **further invest in R&D** to develop innovative solutions and technologies to limit the use of F-gases with high global warming potential.

2.4.5 Summary

Regulation (EU) No 517/2014[197] (F-gas Regulation) aims for the protection of the environment and the fight against climate change by reducing the emission of the **fluorinated greenhouse gases**, F-gases, by two thirds compared with 2014 levels by 2030. In accordance with the objectives of the Kyoto Protocol, it constitutes a pillar of the European Union's action against F-gases. With this Regulation, the European Union played a proactive role on the international stage and supported talks on actions on F-gases under Montreal Protocol on Substances that Deplete the Ozone Layer, which culminated with the adoption of the Kigali Amendment, which entered into force on 1 January 2019, and added HFCs to the list of controlled substances under the Montreal Protocol.

Pursuant to Article 2, the fluorinated greenhouse gases covered are **Hydrofluorocarbons (HFCs), Perfluorocarbons (PFCs), and Sulphur hexafluoride (SF6)**. These are all listed in Annex I to the Regulation, as well as Annex II for the other F-gases subject to reporting in accordance with Article 19. It is noted that the reduction in the use of F-gases relies on the notion of Global Warming Potential (GWP) which corresponds to the climatic warming potential of a greenhouse gas relative to that of carbon dioxide (Article 2). Annexes I, III, IV and V to the Regulation provide the specific GWP values allowed for each substance or mixture.

The use of F-gases **in military equipment benefits from several exemptions**, such as exemptions from the ban on uses of F-gases from January 2020 (Article 13(3)), and exemptions from bans on products containing F-gases are listed in Annex III to the Regulation Article 11(1). Article 11(3) provides that competent authorities are allowed to send a request to the Commission for a temporary exemption (up to four years) regarding the placing on the market of products and equipment relevant for Annex III if the authorities manage to prove that safe alternatives present a disproportionate cost or that none are yet available yet. Finally, pursuant to Article 15(2)(d) exemptions from the quota system established for placing on the market may concern uses in military equipment, too.

Overall, the implementation of exemption mechanisms can **vary across Member States**. Some MoD do use specific exemptions to meet the military standards set for the equipment and their functioning, while others try to avoid the activation of the exemption mechanism by decreasing the use of F-gases. However, most stakeholders noted that some military uses are very difficult to handle such as refrigeration application or fire protection systems. In this case the use of F-gases can be authorised under the scope of the Regulation.

None of the stakeholders interviewed underlined any inconsistencies with the REACH or CLP Regulations or any other EU chemicals regulation, except with the Ozone Regulation. The objective of the Ozone Regulation is to replace chlorofluorocarbon (CFC), hydrochlorofluorocarbon (HCFC) and halons with substances with a limited ozone-depleting potential since 2000. One of the solutions found was to substitute the regulated substances with hydrofluorocarbons (HFC) for refrigeration

[197] Regulation (EU) 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006.

and as fire extinguishing agents. However, the F-gas Regulation requires the phase-out of HFCs in production and in maintenance (from 2020). Consequently, HFCs are now being replaced by hydrofluoroolefins (HFO). However, concerns were raised by the consulted stakeholders regarding the **technical performance characteristics of HFOs that may not fit within the design margins**, such as electric consumption or refrigeration power in terms of volume and mass or safety characteristics of the substances being phased out.

Further challenges regarding **regrettable substitution** were identified regarding the substitution of F-gases with a high GWP-value with other F-gases with a lower GWP-value, as this was the case for R 404a[198] (3921 GWP) which was replaced by R 134a[199] (1430 GWP). These substitutions can thus only constitute a temporary solution and a more sustainable alternative should be pursued. This represents a challenge particularly for fire protection applications for which military specifications ensure the safety of people inside vehicles.

In addition to the risk of potential substitutions between the Ozone Regulation and the F-gas Regulation, most of the consulted industry stakeholders agreed on the fact that the difficulty to find appropriate alternatives represented the main challenge of the F-gas Regulation. The main concern is that **some substitutes known to date are very flammable** and may not meet the existing standards for use in military applications. Moving away from F-gases with a high global warming potential, due to them being gradually phased out, is proving very difficult for the defence industry because F-gases with a low global warming potential are flammable, which is unacceptable in most air, maritime and land defence platforms. Existing legacy equipment is not going to be supported in the future if F-gases become obsolete and new equipment with non-F-gas alternatives are a fire hazard in a combat zone, according to some consulted stakeholders. Reformulation may lead to less effective refrigerants which may result in a use of larger volumes of refrigerants to gain the same effect and meet minimum standards for use in military applications. Furthermore, commercial obsolescence is also expected. Already some F-gases are beginning to disappear from the market. As these substances will no longer be used for civil applications, they will most likely become more expensive to purchase for use in military applications.

Finally, the implementation of the Regulation may entail some **potential additional costs** for the defence sector. There should be further **administrative costs** to ensure the supervision of regulatory changes, the implementation of provisions or the inventory and reporting obligations for specific substances. Consequently, an increase in the resources needed in terms of **manpower** (and the need for certified personnel) as well as **IT tools** to track substances is expected. There may also be some potentially higher costs to ensure the remodelling and redesign of old equipment. In fact, some MoDs underlined that reformulation could pose a problem, especially for refrigeration applications and fire protection systems. Lastly, **R&D** to identify alternative substances will also involve costs, which in turn may result in higher prices of the new substances than the currently available substances.

The recommendations developed in this study focus on the same measures proposed in relation to the Ozone Regulation, hence **increasing the level and timeliness of information** among the defence sector on legislative processes, providing **incentives to pursue research and innovation** to anticipate the phase-down of F-gases, as well as requiring the **mandatory identification of F-gases** in equipment by suppliers

[198] No CAS number was found for the refrigerant Gas R404a. It is a mixture of R134a and R125 (1,1,2,2 pentafluoroethane EC/List no.: 206-557-8; CAS no.: 354-33-6).
[199] 1,1,1,2-tetrafluoroethane (EC/List no.: 212-377-0; CAS no.: 811-97-2).

2.5 ROHS DIRECTIVE (DIRECTIVE 2011/65)

Directive 2011/65/EU provides for the restriction of the use of certain hazardous substances in **electrical and electronic equipment (EEE)**. It is often referred to as the RoHS 2 Directive as it replaced Directive 2002/95/EC (RoHS 1). The Directive entered into force on 21 July 2011.

Contrary to other pieces of legislation covered by the study, the RoHS Directive is a **product-specific legislatio**n, which aims to protect health and the environment by prohibiting the placing on the market of EEE containing certain substances above a defined concentration limit. EEE placed on the market must not contain:

- Substances listed in Annex II to the Directive ('*Restricted substances referred to in Article 4(1), and maximum concentration values tolerated by weight in homogeneous materials'*) in concentrations exceeding the limits provided in Annex II to the Directive[200],
- With the exception of exempted uses listed in Annexes III (*'Applications exempted from the restriction in Article 4(1)'*) and IV to the Directive *('Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments'*).

RoHS places obligations on manufacturers to ensure any EEE they produce is in line with the requirements set out in the Directive, and on importers and distributors to ensure that these requirements have been respected.

2.5.1 Implementation of the Directive

2.5.1.1 Transposition of the Directive by Member States

The RoHS Directive required Member States to adopt national transposing measures by 2 January 2013. All Member States have transposed the Directive. The list of transposing measures is available on the EUR-LEX website[201].

2.5.1.2 Scope of the Directive

Substances listed in Annex II to the RoHS Directive

The RoHS Directive **prevents the use in EEE of the substances listed in Annex II to the Directive in concentrations exceeding the maximum concentration value**. The values correspond to the percentage of the substance by weight in homogeneous materials. The restrictions on the four phthalates (DEHP, BBP, DBP, DIBP) were added to Annex II to the Directive in 2015 (Commission Delegated Directive (EU) 2015/863) and entered into force on 22 July 2019 (except for medical devices and monitoring and control instruments, which have time to comply until July 2021). The restricted substances and the tolerated concentration values are presented in Table 22 below.

[200] Concentration limits are expressed by weight in homogenous material, i.e. '1) A material with a uniform composition throughout; or 2) A material that consists of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes.' European Commission's Frequently Asked Questions Document for RoHS:
https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf
European Commission > Environment > Policies > Waste > Waste streams > RoHS in EEEs > Legislation > Guidance documents.

[201] National transposition measures communicated by the Member State: https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32011L0065&qid=1604402143268 (last accessed on 03.11.2020). EUR-Lex home > EUR-Lex - 32011L0065 – EN > National transposition.

Table 22: Substances listed in Annex II to the RoHS Directive

Substances	EC number	CAS number	Concentration limit
Lead	231-100-4	7439-92-1	0,1 %
Mercury	231-106-7	7439-97-6	0,1 %
Cadmium	231-152-8	7440-43-9	0,01 %
Hexavalent chromium	606-053-1	18540-29-9	0,1 %
Polybrominated biphenyls (PBB)	N/A	N/A	0,1 %
Polybrominated diphenyl ethers (PBDE)	N/A	N/A	0,1 %
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	0,1 %
Butyl benzyl phthalate (BBP)	201-622-7	85-68-7	0,1 %
Dibutyl phthalate (DBP)	201-557-4	84-74-2	0,1 %
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	0,1 %

Categories of EEE

The RoHS Directive **applies to EEE listed in Annex I to the Directive** *('Categories of EEE covered by this Directive'*), including:

1) large household appliances,
2) small household appliances,
3) IT and telecommunications equipment,
4) consumer equipment,
5) lighting equipment,
6) electrical and electronic tools,
7) toys, leisure and sports equipment,
8) medical devices,
9) monitoring and control instruments including industrial monitoring and control instruments,
10) automatic dispensers, and
11) other EEE not covered by any other category.

One of the main changes of the recast of the Directive in 2011 was to broaden the scope of the Directive to make it **applicable to all EEE** from 2019[202] and not only to categories of EEE specifically listed in the Directive as was the case in RoHS 1.

Scope exclusion

However, **several groups of EEE relevant to the defence sector are excluded from the scope of the RoHS Directive**. According to Article 2(4), the RoHS Directive does not apply to:

- Equipment which is *necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military*

[202] EEE that was outside the scope of RoHS 1, and which do not comply with RoHS 2, could still be placed on the market until 22 July 2019 (Article 2(2) of RoHS).

purposes (Article 2(4)(a));

- *'Equipment designed to be sent into space'* (Article 2(4)(b));
- *'Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall in the scope of the RoHS Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment'* (Article 2(4)(c));
- *'Large-scale fixed installations'* (Article 2(4)(e));
- *'Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved'* (Article 2(4)(f));
- *'Non-road mobile machinery made available exclusively for professional use'* (Article 2(4)(g)).

Implementation of Article 2(4)(a)

In relation to Article 2(4), four MoDs (France, Germany, Netherlands, Sweden) indicated that the general approach followed in procurement in their countries was to **require 'voluntary' compliance** with the RoHS Directive whenever possible, even for equipment excluded from the scope of RoHS. For military equipment, this is in part due to the procurement of **dual use equipment**, which cannot be exempted using Article 2(4)(a). In some cases, the French, German, and Swedish MoDs specified that they can contractually oblige suppliers to meet RoHS requirements regardless of whether the products are considered as out of the scope of RoHS. In the Netherlands, the use of a specific substance may be discouraged based on the List of Banned and Restricted Substances (LBRS) (see Annex V to this report) in which case the MoD decides case by case whether to require compliance with the LBRS for military equipment in the contract.

When contractors make use of the Article 2(4)(a) exemption, two MoDs (France, Sweden) indicated that they require suppliers to **report on the use of the Article 2(4)(a) exemption** (i.e., indicating which component of the equipment is concerned, which substances are exceeding concentrations listed in Annex II to the RoHS Directive) and on the use of exemptions listed in Annex III and IV to the RoHS Directive (see below). The French MoD also requires that suppliers provide a justification for the use of the Article 2(4)(a) exemption.

None of the MoDs mentioned have to take a formal decision on what equipment is considered as 'necessary for the protection of the essential interests of the security of Member States'. **Determining whether the equipment falls within the scope of Article 2(4)(a) is left to suppliers**.

2.5.1.3 Exemptions for specific uses

Exemptions – i.e., temporary permissions for placing EEE containing certain banned substances on the market – can be **granted for certain applications upon request from industry**. Those exemptions are listed in Annex III and IV to the Directive. Exemptions may be granted based on the following criteria, outlined in Article 5(1)(a):

Table 23: Criteria used to assess exemption requests [203]

Criteria	Explanation
Main criteria	
Exemptions do not 'weaken the environmental and health protection afforded by the REACH Regulation'	If a substance is included in REACH Annex XIV, and/or its intended use is restricted in REACH Annex XVII at the time of the evaluation, it must be evaluated whether the environmental and health protection afforded by REACH would be weakened if the exemption would be granted under RoHS
Elimination or substitution of the substance is scientifically or technically impracticable and the reliability of a substitute is not ensured	As the reliability of substitutes is an inherent condition of the 'scientific or technical practicability of substitution or elimination', those two criteria are evaluated jointly (except when substitutes are suitable for some applications, but not all). 'Elimination' is defined as avoidance of a restricted substance by changing the design or technology so that the material or component containing the restricted substance is no longer required. 'Substitution' is defined as replacing a restricted substance in a material by another substance. The reliability of a substitute is the 'probability that the EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is in use'. The assessment of this criterion requires clarifying the scope of applications of the requested exemption, the function of the RoHS substance within the application and the availability (at present or in the future) and reliability of possible alternatives.
The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits	The impacts of substitution stand to be significantly higher than those attributed to the use of the restricted substance in the application in question, where environmental, health and consumer safety aspects are considered. Life Cycle Assessment (LCA) is one method that can be used to provide evidence to substantiate this justification.
Additional criteria	
Socioeconomic impact of substitution	Socio-economic impacts can include adverse effects on the market for the application, impacts on competitiveness and impacts on employment in some regions. An exemption cannot be based on socio-economic impacts only, as it is not considered to be a criterion as significant as the three main criteria. However, if one of the main criteria is fulfilled, socio-economic parameters may influence the decision-making[204]. Where establishing the main criteria is difficult because of missing information, but where data provided by the applicant suggest that the socioeconomic impacts of substitution might have impacts comparable to the scientific and technical impracticability of substitution or

[203] Adapted from Oeko-Institut (2012) Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU, p.6. Available at: https://ec.europa.eu/environment/waste/rohs_eee/pdf/Guidance_Document.pdf and Oeko-Institut (2020) Draft Exemption evaluation methodology manual, as part of Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 -Task 4, draft final), p.11-13. Available at: https://rohs.exemptions.oeko.info/index.php?id=341.

[204] European Commission's Frequently Asked Questions Document for RoHS: https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf
European Commission > Environment > Policies > Waste > Waste streams > RoHS in EEEs > Legislation > Guidance documents.

Criteria	Explanation
	elimination (i.e., resulting in a market supply gap, or in outweighing the total environmental, health and consumer safety benefits of the substitution) then exemptions might be justified based on this criterion.
Availability of a substitute	Availability of a substitute on the market, within a reasonable time, and in the required quantities and qualities (for instance this criterion can apply to a substitute available in the lab but not yet on the market). Where establishing the main criteria is difficult because of missing information, but where data provided by the applicant suggest that the limited availability of as substitute might have impacts comparable to the scientific and technical impracticability of substitution or elimination (i.e., resulting in a market supply gap, or in outweighing the total environmental, health and consumer safety benefits of the substitution) then exemptions might be justified based on this criterion.
Potential adverse impacts on innovation	Impacts that the duration of an exemption may have on future efforts for developing possible substitutes.
Lifecycle assessment on the overall impacts of the exemption, where relevant	Comparison between the consumption of various resources and the environmental impacts attributed to the use of the restricted substance and its possible substitutes in the various life stages of the application: production, distribution, use and waste management at end of product lifetime.

However, **those criteria do not automatically provide justification for an exemption**. The exemption requires a **decision from the European Commission** on whether, and under which conditions, an exemption may be granted. An exemption can be withdrawn when, based on the criteria listed above, the exemption is no longer justified (Article 5(1)(b)). To revoke an exemption, the applicant should provide evidence showing that the elimination or substitution of the substance is scientifically and technically practicable, that the reliability of substitute is ensured and/or that the revocation does not lead to negative environmental, health and consumer safety impacts that outweigh the use of the restricted substance. If during the public consultation no objections are raised against the revocation, the exemption might be revoked, based on the evidence provided[205].

2.5.1.4 Governance

European Commission

In the implementation of the RoHS Directive, the Commission:

- Periodically reviews the list of restricted substances in Annex II to the Directive;
- Manages the application process for exemptions: provides a harmonised format for application, receives requests for exemptions, informs Member States of the application, decides on the exemption and informs applicants, makes a summary of the application available to the public.

Member States' Competent Authorities

Member States had to designate national competent authorities for the implementation of the RoHS Directive, which is in most cases the Ministry responsible for environment or the environmental agency and in some cases, the national chemicals' agency or the Ministry responsible for health. The list of national competent authorities can be found on the Commission's website[206].

[205] Oeko-Institut (2020) Draft Exemption evaluation methodology manual, as part of Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 -Task 4, draft final), p.14.
[206] List of RoHS competent authorities: https://ec.europa.eu/environment/waste/weee/pdf/contacts_ms_rohs.pdf

The Expert Group for RoHS 2 adaptation and enforcement[207] assists the Commission in the preparation of **delegated acts and on the implementation of the Regulation**. It is composed only of Member States' competent authorities (no EEA country representatives or observers are members of the group). However, industry stakeholders may be invited on an ad hoc basis to provide background presentations regarding requests for exemptions under the RoHS Directive[208]. The Expert group operates in an informal setting (i.e., without any formal rules of procedure) and meets at least once a year since 2013. It has two subgroups, one on RoHS enforcement and the second on RoHS delegated acts, hence dealing with exemptions, – the second one being the most active of the two.

2.5.1.5 Regulatory Evolution of substances

Amendments to Annex II to the RoHS Directive

Article 6(1) of the RoHS Directive required that a first review of the list of restricted substances in Annex II to the Directive was carried out before before 22 July 2014. It subsequently requires that a **review of the list is carried out periodically by the Commission**, on its own initiative or following the submission of a proposal for inclusion of a substance by a Member State. The review should be 'based on a thorough assessment', 'taking account of the precautionary principle', and ensure that it is 'coherent with other legislation related to chemicals' in particular REACH (Article 6(1)). In addition, the review should 'take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:

- *'could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE';*
- *'could give rise, given its use, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions';*
- *'could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes';*
- *'could be replaced by substitutes or alternative technologies which have fewer negative impacts'* (Article 6(1))'.

The Directive further specifies that **'interested parties**, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations' **must be consulted during the review** (Article 6(1)).

The first review was done in 2012-2014, the second in 2018-2020. In the first review, the Commission launched a study for the development of a methodology to identify and assess substances for inclusion in Annex II to the Directive based on the criteria in recital 10, and Article 6(1)

European Commission > Energy, Climate change, Environment > Waste > Waste streams > RoHS in EEE > Contacts and useful links.

[207] Expert Group for RoHS 2 adaptation and enforcement (E02810):
https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2810
European Commission > Register of Commission expert groups and other similar entities > Expert Group for RoHS 2 adaptation and enforcement (E02810).

[208] Minutes of the Meeting of the Expert Group for RoHS 2 adaptation and enforcement Sub-group for RoHS Delegated Acts, Brussels, 21/10/2019.

and 6(2) of the RoHS Directive. The methodology elaborated by this study[209] has been revised as part of the tender launched by the Commission for the 2018 substance review[210]. The methodology follows the following steps: substance identification, substance prioritisation, detailed assessment of substances, covering the substance's impacts on health, environment and resource efficiency, the availability and hazardous properties of potential substitutes/alternatives and socio-economic aspects of a potential future restriction[211].

The 2018 Substance review covered the following substances:

Table 24: Substances included in the 2018 substance review

Substance	EC number	CAS number
Cobalt dichloride	231-589-4	7646-79-9
Cobalt sulphate	233-334-2	10124-43-3
Nickel sulphate	232-104-9	7786-81-4, 10101-97-0, 10101-98-1
Nickel sulfamate	237-396-1	13770-89-3
Beryllium and its compounds	231-150-7	7440-41-7
Indium phosphide	244-959-5	22398-80-7
Tetrabromobisphenol-A	201-236-9	79-94-7
Medium Chain Chlorinated Paraffins	287-477-0	85535-85-9
Diantimony trioxide (ATO)	215-175-0	1309-64-4

Out of these seven substances, two have been recommended for inclusion in Annex II to the Directive, Medium Chain Chlorinated Paraffins and Tetrabromobisphenol-A.

Concerning the other substances not recommended for inclusion, the review recommends the following next steps:

- Nickel sulphate and Nickel sulfamate: the assessment recommends a future assessment of nickel and its compounds as a group for potential RoHS restriction;
- Diantimony trioxide: the assessment recommends a future group assessment of ATO and halogenated flame retardants;
- Indium phosphide: the assessment identifies current low volume uses but indicates that consumption could increase significantly. The substance might be subject to increased scrutiny;
- Beryllium and its compounds: the assessment recommends the selective restriction of copper beryllium alloys in some EEE, further workplace exposure controls, and voluntary reduction of beryllium in products;

[209] European Commission (2013) Study for the review of the list of restricted substances under RoHS2. Report prepared by Umweltbundesamt GmbH for the European Commission, DG Environment. Available at: https://op.europa.eu/en/publication-detail/-/publication/39eb0f95-27a8-4ae6-8ec3-627c7336ae65.

[210] Oeko-Institut eV (2019) Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive. Available at: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Pack_15_Substance_Review_Draft_Manual_Methodology_second_version_20190926.pdf.

[211] Oeko-Institut eV (2019) Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive, p. 21.

- Cobalt salts are subject to a restriction proposal under REACH. Based on this, and the conclusions from the assessment, it could be assumed that there will be no further risk management measures under RoHS.

Evaluation of exemptions

Requests for new exemptions, or to renew existing exemptions, are submitted by industry (companies, trade associations, or consortia of companies and/or trade association) to the European Commission, DG Environment, Unit B.3. Waste Management and Secondary Materials. The necessary steps for granting an exemption are summarised in Table 25 below.

Table 25: Steps for including an exemption in Annex III and IV to the RoHS Directive

Application receipt
Commission acknowledges receipt of the application in writing within 15 days of its receipt (Article 5(4)(a))
Commission informs the Member States of the application without delay and makes the application and any supplementary information supplied by the applicant available to them (Article 5(4)(b))
Commission informs the applicant, the Member States and the European Parliament of the timeline for deciding on the application within one month of the receipt of the application (Article 5(4)(ba))
Commission makes the summary of the application available to the public (Article 5(4)(c))
Commission launches the technical and scientific assessment (containing a single or multiple exemption requests)
Evaluation of the application[212]
Clarification phase
The consultant selected through a tendering procedure determines whether the application has been prepared according to the minimum information requirements listed in RoHS Annex V
If minimum information requirements are not met, the consultant requests additional information from the applicant. The applicant receives a clarification questionnaire and should reply within a reasonable timeline. Responses from the applicant are made publicly available.
Consultation phase
Eight-week online public consultation on the application, organised by the consultant. Relevant stakeholders are notified by email of the start and the duration of the consultation.
Evaluation phase
Assessment of the application according to Article 5(1)(a) criteria
Consideration of public consultation results
If relevant, the consultant communicates with the applicant mainly via questionnaires for clarifications or providing additional evidence to support the claim
If considered more efficient, a stakeholder meeting (virtual or physical) may be held
The consultant drafts a recommendation on whether the request should be accepted or not, including the evaluation results and a justification
Decision-making[213]
Based on the recommendation, the Commission prepares the draft Commission delegated act
Commission consults Member States Expert Group for RoHS 2 delegated acts
Commission internal consultation and translation
Notification of Council and Parliament
Publication of delegated act in the Official Journal of the European Union
Two-month period during which the European Parliament and the Council can object to the delegated act

The procedure can take up to one and half years. Start and end dates for exemptions are either explicitly provided in the entries of Annexes III and IV to the Directive or through the maximum validity period in Article 5(2) (i.e., five years for categories 1 to 7, 10 and 11 and seven years for categories 8 and 9). An application for renewal of an exemption must be submitted at the latest 18 months before the exemption expires. However, the approved exemption will remain valid until the

[212] Öko-Institut (2020) Draft Exemption evaluation methodology manual, as part of Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 -Task 4, draft final), p.11-13. Available at: https://rohs.exemptions.oeko.info/index.php?id=341.

[213] Öko-Institut (2012) Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU, p.9.

decision on the renewal has been made. When an exemption is not renewed or withdrawn, the exemption expires at the earliest 12 months, and at the latest 18 months, after the date of the decision (Article 5(6)).

2.5.1.6 Evaluation and review of the Regulation

The evaluation of the RoHS Directive (started in 2018) is ongoing, and the publication of **the Staff Working Document is planned for Q1 2021**. The evaluation will be the basis for the general review of the RoHS Directive that the Commission should carry out by July 2021 (Article 24(2)).

2.5.2 Interactions with REACH and CLP

2.5.2.1 Interactions with REACH

According to the Common Understanding paper on the interaction between REACH and the RoHS Directive[214], adopted by the Commission, the **REACH Regulation and RoHS Directive are complementary** as REACH is a horizontal regulation, ensuring that substances are controlled over their entire lifecycle, and RoHS is a product-specific legislation that contributes to the sound management of waste EEE, as it takes into account the waste management and recycling of EEE as well as the occupational and environmental exposure during waste management and recycling of EEE. **Some provisions in the RoHS Directive aim to ensure consistency between the two pieces of legislation.** According to Article 6(1) of the RoHS Directive, '*the review and amendment of the list of restricted substances in Annex II to the Directive shall be coherent*' with the REACH Regulation and '*take into account, inter alia, Annexes XIV and XVII to that Regulation*' (Article 6(1)).

The **scope of the REACH Regulation and the RoHS Directive can partially overlap** since REACH applies to all substances, including in mixtures and articles, which means it also applies to substances in EEE which is covered by the RoHS Directive. Potential overlaps between the REACH Regulation and the RoHS Directive might occur when risk management measures are taken under REACH or RoHS for substances that are already regulated under one of the two pieces of legislation. The Common Understanding paper identifies cases of potential overlaps between the two and outlines the agreed standard practice in those cases.

[214]European Commission (2014) REACH and Directive 2011/65/EU (RoHS). A common understanding.
European Commission > Departments and executive agencies > Internal Market, Industry, Entrepreneurship and SMEs > Business and industry > Business and industry by sector > Chemicals > REACH > Relationships with other legislation.

Restrictions

The Common Understanding paper covers the following three scenarios and provides the following interpretation of the interactions between REACH Annex XVII and RoHS:

Table 26: Interactions between REACH Annex XVII restriction and RoHS Annex II restriction [215]

Scenario in CU Paper	Status of REACH Restriction	Status of inclusion RoHS Annex II	Conditions	Action recommended
1	Under consideration	Already in force	A. If RoHS restriction provides the same level of protection as REACH Restriction	The REACH restriction should exclude EEE falling within the scope of RoHS, RoHS restriction remains unchanged.
			B. The REACH restriction provides greater protection than the RoHS restriction	Not discussed in paper. According to Öko-Institut, in this case the REACH restriction is to be preferred.
2	Already in force	Under consideration	A. REACH restriction is already in force and covers EEE	General practice would be to exclude the substance from the identification exercise for inclusion in Annex II to RoHS.
			B. It is decided to take action under RoHS to establish more stringent measures for EEE	Annex XVII to REACH should be amended to remove EEE from the scope of the restriction.
3	Under consideration	No restriction yet but should be taken into account in adopting REACH restriction	The restriction under REACH can be prepared and might be amended later to remove EEE from the scope of the restriction if the substance was included in Annex II to RoHS. The REACH restriction procedure could also be used to prepare an amendment of RoHS outside the periodic review, which happens every four years. For instance, when the RAC and SEAC opinions confirm that a restriction of the substance is needed in EEE, the restriction could be implemented through the inclusion of the substance in Annex II to RoHS rather than through the REACH restriction. In the event that the need for the restriction has been identified earlier, for instance, through an RMOA, it could be decided to initiate a restriction directly under RoHS, outside the normal cycle, instead of starting the restriction procedure under REACH.	

[215] Table based on European Commission (2014) REACH and Directive 2011/65/EU (RoHS). A common understanding and Oeko-Institut eV (2019) Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive (Table I p.16).

Authorisations

The Common Understanding paper covers the following three scenarios and provides the following interpretation of the interactions between REACH Annex XIV and RoHS:

Table 27: Interactions between REACH Annex XIV and RoHS Annex II restriction[216]

Scenario in CU Paper	Status of REACH Authorisation	Status of inclusion RoHS Annex II	Conditions	Action recommended
1	Under consideration	In force	A. If there are no exemptions under RoHS, use of the substance in EEE is prohibited. The REACH authorisation requirement would apply to companies using the restricted substance in the manufacture of EEE (which in principle is still allowed under RoHS but an unlikely scenario)	Likely no conflict between the REACH and the RoHS restrictions. The substance can be included in in Annex XIV to REACH.
			B. If exempted uses under RoHS, the REACH authorisation requirement would apply to EU manufacturers incorporating the substance in exempted EEE (annulling the exemptions under RoHS) but not to imported EEE/non-EU manufacturers.	Option 1[217]: based on Article 58(2) of REACH, exempt uses covered under the RoHS Directive (including uses exempted under RoHS Annex III and IV) from the REACH authorisation requirement.
				Option 2: if RoHS restriction does not constitute proper control according to Article 58(2) (case by case analysis), the REACH authorisation requirement could apply to EEE (only to EU manufacturers, not imported EEE).
2	In force	Under consideration	A. No exemptions under RoHS.	Authorisations granted become redundant unless parallel exemption granted under RoHS. An option can be to set

[216] Table based on European Commission (2014) REACH and Directive 2011/65/EU (RoHS). A common understanding and Öko-Institut eV (2019) Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive (Table I p.16).

[217] The paper considers that, because exemptions under RoHS are temporary and only granted and renewed after an analysis of possible alternatives and proposed actions for the development of possible alternatives (as stipulated in Annex V to RoHS), the RoHS Directive puts equivalent pressure to REACH on manufacturers to substitute hazardous substances. However, this remains a case-by-case analysis.

Scenario in CU Paper	Status of REACH Authorisation	Status of inclusion RoHS Annex II	Conditions	Action recommended
				entry into force of RoHS restriction on the expiry date of the first authorisation period set by the review clause.
			B. Exemptions under RoHS	It may be questioned if there is added value in continuing the REACH authorisation requirement for RoHS exempted applications.
3	Under consideration	No restriction		A. Include the substance in Annex XIV to REACH, and later exempt EEE from authorisation requirement (Case 2)
				B. Delay REACH authorisation until after the inclusion of the substance in Annex II to RoHS (so it can be discussed whether to exempt the use in EEE from the authorisation requirement).

The scenarios of the Common Understanding paper have been or might be applied in the future for the substances covered by RoHS, depending on their current status under REACH. The following table presents the status of the substances included in Annex II to RoHS in Annexes XIV and XVII to REACH, and tries to determine, based on it, the corresponding scenario of the Common Understanding paper.

Table 28: Status of RoHS substances in REACH and potential common understanding (CU) paper scenario

Substances	REACH Annex XIV	REACH Annex XVII	CU paper scenario
Lead	Candidate List for authorisation	REACH Annex XVII (entry 63) for specific uses (in jewelry) not related to EEE	Authorisation 1.B. (included RoHS Annex II with exemption when considered for REACH authorisation) Article 58(2) of REACH could be used to exclude EEE from authorisation requirement.
Mercury	N/A	REACH Annex XVII (entry 18a) for specific uses (mercury using thermometer and other measuring devices) not related to EEE	None
Cadmium	Candidate List for authorisation	REACH Annex XVII (entry 23) for specific uses (paints, painted articles, cadmium plating metallic articles) relevant for EEE. For cadmium plating metallic articles, restriction excludes aeronautical, aerospace, mining, offshore and nuclear sectors (23.7) Entry 23.7 Cadmium in electrical contacts excluded in REACH and RoHS but differently[218]	Restriction1 (already included in RoHS Annex II, with Annex III (to RoHS) exemptions, when considered for restriction under REACH) Authorisation 1B – if included in Annex XIV to REACH, Article 58(2) of REACH could be used to exclude EEE from authorisation requirement.
Hexavalent chromium	Some Hexavalent chromium compounds are listed in Annex XIV to REACH: Chromium trioxide (EC no. 215-607-8; CAS no.1333-82-0) Lead chromate (EC no. 231-846-0; CAS no. 7758-97-6) Lead sulfochromate yellow (EC no. 215-693-7 ; CAS no. 1344-37-2) Lead chromate molybdate sulfate red (EC no. 235-759-9; CAS no. 12656-85-8)	REACH Annex XVII (entry 47 chromium VI compounds) for specific uses (cement and leather products) not related to EEE	None

[218] According to Entry 23 of REACH Annex XVII on cadmium, 'electrical contacts in any sector of use [are excluded from the restriction on cadmium plating metallic articles] *where that is necessary to ensure the reliability required of the apparatus on which they are installed*'. In Annex III, entry 8b to the RoHS Directive, cadmium and its compounds are exempted from the RoHS restriction in electrical contacts in medical devices, monitoring and control instruments (until 2021, 2023 or 2024) and other EEE not covered by any other categories (category 11 of Annex I to RoHS) until 2024. Both instruments cover the same substance and applications, but slightly differently, which might create overlaps.

Substances	REACH Annex XIV	REACH Annex XVII	CU paper scenario
	Sodium chromate (EC no. 231-889-5; CAS no 7775-11-3) Sodium dichromate (EC no. 234-190-3; CAS no. 10588-01-9, 7789-12-0) Potassium chromate (EC no. 232-140-5; CAS no. 7789-00-6) Potassium dichromate (EC no. 231-906-6; CAS no. 7778-50-9) Ammonium dichromate (EC no. 232-143-1; CAS no. 7789-09-5) Strontium chromate (EC no. 232-142-6; CAS no. 7789-06-2) Dichromium tris(chromate) (EC no. 246-356-2; CAS no. 24613-89-6) Potassium hydroxyoctaoxodizincatedichromate (EC no. 234-329-8; CAS no. 11103-86-9) Pentazinc chromate octahydroxide (EC no. 256-418-0; CAS no. 49663-84-5) Acids generated from chromium trioxide and their oligomers: Chromic acid (EC no. 231-801-5; CAS no. 7738-94-5) Dichromic acid (EC no. 236-881-5; CAS no. 13530-68-2) Oligomers of chromic acid and dichromic acid		
Polybrominated biphenyls (PBB)	N/A	REACH Annex XVII (entry 8) for specific uses (textiles) not related to EEE	None
Polybrominated diphenyl ethers (PBDE)			
Pentabromodiphenyl ether (pentaBDE)	N/A	N/A	None – see below interactions RoHS/POPs
Tetrabromodiphenyl ether	N/A	N/A	None see below interactions RoHS/POPs

Substances	REACH Annex XIV	REACH Annex XVII	CU paper scenario
(tetraBDE)			
Hexabromodiphenyl ether (hexaBDE)	N/A	N/A	None – see below interactions RoHS/POPs
Heptabromodiphenyl ether (heptaBDE)	N/A	N/A	None – see below interactions RoHS/POPs
Decabromodiphenyl ether (decaBDE)	N/A	REACH Annex XVII (entry 67) Entry should be soon deleted from REACH, as substance included in Annex I to POPs Regulation	None – see below interactions RoHS/POPs
Octabromodephenyl ether (octaBDE)		REACH Annex XVII (entry 45) excludes uses in EEE covered by RoHS Directive	Restriction 1A (considered for REACH Restriction when already included in RoHS Annex II) – Restriction excludes uses in EEE.
Bis(2-ethylhexyl) phthalate (DEHP)	REACH Annex XIV (exempted use: packaging of medicinal products) sunset date 2015	REACH Annex XVII (entry 23) excludes uses in EEE covered by RoHS Directive	Authorisation 2A (already in Annex XIV to REACH when included in RoHS) no exemptions under RoHS and inclusion in RoHS after sunset date – as a result there is no overlap.
Butyl benzyl phthalate (BBP)	REACH Annex XIV (exempted use: packaging of medicinal products) last applications 2013; sunset date 2015	REACH Annex XVII (entry 23) excludes uses in EEE covered by RoHS Directive	Authorisation 2A (already in Annex XIV to REACH when included in RoHS) no exemptions under RoHS and inclusion in RoHS after sunset date – as a result there is no overlap.
Dibutyl phthalate (DBP)	REACH Annex XIV (exempted use: packaging of medicinal products) last applications 2013; sunset date 2015	REACH Annex XVII (entry 23) excludes uses in EEE covered by RoHS Directive	Authorisation 2A (already in Annex XIV to REACH when included in RoHS) no exemptions under RoHS and inclusion in RoHS after sunset date – as a result there is no overlap.
Diisobutyl phthalate (DIBP)	REACH Annex XIV (no exempted use) last applications 2013; sunset date 2015	REACH Annex XVII (entry 23) excludes uses in EEE covered by RoHS Directive	Authorisation 2A (already in Annex XIV to REACH when included in RoHS) no exemptions under RoHS and inclusion in RoHS after sunset date – as a result there is no overlap.

The table below presents the substances assessed for inclusion in the RoHS Directive as part of the 2018 substance review, their status under REACH and the possible scenarios that could be applicable, based on the Common Understanding paper.

Table 29: Status of substances assessed for inclusion in Annex II to RoHS in REACH and potentially applicable common understanding (CU) paper scenario

Substances	REACH Annex XIV	REACH Annex XVII	Other REACH processes	CU paper scenario
Recommended for inclusion				
Tetrabromobisphenol-A (EC no.: 201-236-9, CAS no.: 79-94-7)	None	None	▪ Substance evaluation ongoing: information requested on endocrine disruptive and PBT properties	Unknown
Medium Chain Chlorinated Paraffins (EC no.: 287-477-0, CAS no.: 85535-85-9)	None	None	▪ Substance evaluation conclusions: meets PBT/vPvB criteria ▪ Follow ups: Annex XV dossier for SVHC identification and Annex XV restriction dossier[219]	Restriction 3: potential inclusion in RoHS should be taken into account in REACH Annex XVII restriction.
Not recommended for inclusion				
Beryllium and its compounds (EC no.: 231-150-7, CAS no.: 7440-41-7)	None	Entry 28 – substances classified as carcinogens 1A or 1B under CLP are prohibited for supply to the general public	▪ Substance evaluation – suspected SVHC ▪ RMOA ongoing for beryllium oxide	N/A
Cobalt dichloride (EC / no.: 231-589-4, CAS no.: 7646-79-9) and Cobalt sulphate (EC / no.: 233-334-2, CAS no.: 10124-43-3)	None	None	▪ Candidate List of SVHC for authorisation (since 2008) ▪ Annex XV restriction dossier ongoing	Restriction 2A : restriction will likely apply to manufacturing of EEE. To be considered whether RoHS restriction is needed and if so, restriction conditions should

[219] Substance evaluation conclusion as required by REACH Article 48 and evaluation report for medium-chain chlorinated paraffins/alkanes, C14-17, chloro, December 2019. Available at: https://echa.europa.eu/documents/10162/a72b228a-e417-5b53-b2b9-3b45c8e6eec5 (Last accessed on 12.10.2020).

Substances	REACH Annex XIV	REACH Annex XVII	Other REACH processes	CU paper scenario
				avoid overlaps with REACH[220].
Diantimony trioxide (EC no.: 215-175-0, CAS no.: 1309-64-4)	None	None	▪ Substance evaluation ongoing: concerns about carcinogenicity	N/A
Indium phosphide (EC no.: 244-959-5, CAS no.: 22398-80-7)	None	Entry 28 – substances classified as carcinogens 1A or 1B under CLP are prohibited for supply to the general public	None	N/A The use of the substance in EEE would generally not be considered as a supply of the substance to the general public[221].
Nickel sulphate (EC / no.: 232-104-9, CAS no.: 7786-81-4, 10101-97-0, 10101-98-1) and nickel sulfamate (EC / no.: 237-396-1, CAS no.: 13770-89-3)	None	Entry 27: prohibits the use of nickel and its compounds in post assemblies and articles coming into direct and prolonged contact with the skin. Other entries applicable – Entry 28 and 30 prohibiting carcinogens 1A or 1B and reproductive toxicant 1A or 1B under CLP from supply to the general public;	▪ RMOA for nickel sulphate: conclusion to start a legislative proposal setting binding OEL.	N/A

The analysis provided in the Common Understanding paper, however, raises questions as regards the use of Article 58(2) to exempt the use of a substance in EEE covered by RoHS from the authorisation requirement in REACH, and contends that RoHS provides the same level of pressure to substitute on industry as the REACH authorisation requirement.

Regarding the use of Article 58(2) to exempt uses covered by RoHS from the REACH authorisation requirement, it can be questioned whether the criteria of Article 58(2) are met. Article 58(2) provides

[220] Oeko-Institut (2020) ROHS Annex II Dossier for cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate). Restriction proposal for substances in electrical and electronic equipment under RoHS. Version 3 – 26/03/2020. Available at: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/Cobaltsalts_RoHS_Dossier_V3_final.pdf (Last accessed on 12.10.2020).

[221] Oeko-Institut (2019) ROHS Annex II Dossier for indium phosphide. Restriction proposal for substances in electrical and electronic equipment under RoHS. Version 3 – 25/09/2019. Available at: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/Indium_phosphide_RoHS_Dossier_v3_final_rev.pdf (Last accessed on 12.10.2020).

that: '*uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'. The Common Understanding paper, while recognising that a case-by-case analysis might conclude that the risk is not properly controlled by RoHS, considers that the use of Article 58(2) can be made and expresses a preference for RoHS to deal with all aspects of the incorporation of substances in EEE. However, it should be noted that **RoHS does not control the use of a substance in the manufacturing process of EEE or at the workplace, it only restricts the substance in the end product**. In addition, as **several categories of EEE are excluded from the scope of RoHS (see 2.5.1.2), the Directive does not apply to all EEE**. Based on these considerations, **the possibility to use Article 58(2) to exempt uses covered by RoHS from the REACH authorisation requirement may be challenged**.

The Common Understanding paper considers that, because exemptions under RoHS are temporary and only granted and renewed after an analysis of possible alternative substances and proposed actions for the development of possible alternatives (as stipulated in Annex V to RoHS - '*Applications for granting, renewing and revoking exemptions as referred to in Article* 5'), the requirements from the RoHS Directive may be seen as 'mirroring the substitution objective of the REACH authorisation procedure'[222]. However, **because several categories of EEE are excluded from the scope of RoHS, the Directive has not always sufficiently encouraged the substitution of restricted substances in uses for which suitable alternatives exist** (see 2.5.4.3 on lead soldering). Therefore, the interpretation of the Common Understanding paper that RoHS provides for the same level of pressure to substitute as REACH, could be challenged, at least regarding groups of EEE that are excluded from the scope of RoHS, such as military equipment.

A similar reasoning may be applied to the possibility to remove uses covered by RoHS from the **REACH restriction requirement**. To this end, RoHS needs to be considered as affording 'adequate control of the risks presented by the substance in EEE throughout the lifecycle of the product such that those risks do not need to be addressed under REACH'. The Common Understanding paper recalls that the methodology for assessing substances for inclusion in Annex II to RoHS is 'required by Article 6(1) of RoHS to be "coherent" with REACH and could even be fully aligned with REACH risk assessment provisions'. In addition, 'RoHS takes into account the waste management and recycling of EEE, and the potential for exposure (of workers and the environment) during waste management and recycling is probably comparable or higher than during the manufacture of new EEE'[223]. However, as mentioned above, the fact that **RoHS does not control the use of a substance in the manufacturing process of EEE or at the workplace** (except during waste management) might still **raise issues as to whether the risk is comparably controlled by RoHS and REACH Annex XVII**. In addition, because of the **exclusion of several categories of EEE from the scope of RoHS, RoHS might not provide adequate control for all EEE**.

Issues raised in relation to the exclusion of military EEE from the scope of RoHS

One MoD consulted during the stakeholder consultation indicated that there might be inconsistencies between REACH and RoHS as regards defence EEE. When the use of a substance is banned or restricted under REACH, the authorisation or restriction requirements apply to the defence sector unless there is a specific derogation in the authorisation or restriction requirement for the defence sector or the Member State which applies for the defence exemption in Article 2(3) of REACH. If there are none of these exemptions, and the substance is also regulated under RoHS, this can lead to **inconsistencies between REACH and RoHS for defence/military EEE, to which the**

[222] Common Understanding paper, p. 6.
[223] Common Understanding paper, p. 3.

RoHS Directive does not apply.

More specifically on the interactions between inclusion in Annex XIV to REACH and Annex II to RoHS, the MoD raised an issue concerning the **applicability of Article 58(2) of REACH,** which can be used to exempt uses of a substance in EEE covered by the RoHS Directive from the authorisation requirements in REACH (see scenario 1B in the above table), **to uses in defence equipment excluded from the scope of RoHS based on Article 2(4)(a).** According to scenario 1B above, when the inclusion in Annex XIV to REACH is considered for a substance already included in Annex II to RoHS, and for which exemptions are provided in Annex III and IV to RoHS for specific uses in EEE, an option to ensure consistency between REACH and RoHS is to exclude uses in EEE from the REACH authorisation requirement. However, to exclude uses or categories of uses from the authorisation requirement, Article 58(2) requires that other EU legislation properly controls the risks for human health and the environment – in scenario 1B, the legislation controlling the risk would be the RoHS Directive. **For defence/military equipment**, which is excluded from the scope of RoHS , this raises an issue as **there is no EU legislation ensuring that the risk is properly controlled** (the RoHS Directive does not apply). Under a strict interpretation of REACH Article 58(2), military/defence equipment should not be exempted from the authorisation requirement. **The Common Understanding paper does not currently deal with interactions between REACH and RoHS with regard to the scope exclusion for military equipment** and could be revised to provide legal clarification in this issue.

Some defence industry stakeholders and MoDs also indicated that, despite the Common Understanding paper, the **interactions between REACH and RoHS were still relatively unclear or confusing for stakeholders**. Some defence industry stakeholders also mentioned that the differences in the calculation basis for concentration values (weight by weight for each component in REACH[224] vs weight in homogenous material in RoHS) create confusion and raise questions among suppliers and customers. Additional guidance by the Commission and/or ECHA highlighting the differences and interactions between REACH and RoHS was suggested by some of the defence industry stakeholders.

2.5.2.2 Interactions with CLP

The RoHS Directive does not contain any reference to the CLP Regulation, as it refers to specific substances (listed in Annex II to RoHS) but not to the classification of substances under CLP.

2.5.3 Interactions with other chemicals' regulations / directives

2.5.3.1 RoHS Directive and BPR

See section 2.1.3.4 'BPR and RoHS Directive'.

2.5.3.2 RoHS Directive and POPs Regulation

See section 2.2.3.4 'POPs Regulation and RoHS Directive'.

2.5.3.3 RoHS Directive and Ozone Regulation

See section 2.3.3.4 'Ozone Regulation and RoHS

[224] For both Article 7.2 notification and Article 33 communication in REACH, the 0.1% concentration threshold is calculated with regard to the weight of the substance in each component of an article when part of a complex article.

2.5.3.4 RoHS and F-gas Regulation

See section 2.4.3.4 'F-gas Regulation and RoHS Directive'.

2.5.4 Impacts on the defence sector

The availability of products, the cost of RoHS-compliance, and the use of the exemption for military equipment were the main topics highlighted by the consulted stakeholders.

2.5.4.1 Availability of products / equipment

Most MoDs did not report that the RoHS Directive leads to significant unavailability of products and substances, problematic reformulation, and did not report cases of regrettable substitution, mostly because of the application of the Article 2(4) exemption for military equipment. However, despite the exemption, the defence industry reported that the Directive could still negatively impact the availability of equipment, because defence industry relies significantly on **civil equipment and Commercial Off-The-Shelf (COTS) electronic components**, which must be compliant with RoHS. Manufacture of these components specifically for the defence industry is generally not possible as the defence market is too small to make the cost of manufacture viable for suppliers. According to ASD, this has reduced the availability of components coated with tin-lead solder alloy and the suitability of some components for defence applications, resulting in defence industries having to pay supplements for components specifically made for the defence industry or to apply or have the coating applied after the purchase of the components.

ASD also indicated that **the defence industry may be affected by upcoming inclusion of substances into Annex II to RoHS**. **Tetrabromobisphenol-A (TBBP-A), recommended for inclusion** by the 2018 substance review, is used as an additive **flame retardant**, especially for plastic housings of electronic components. As these components are **COTS**, **there might be impacts on the availability of such components**. TBBP-A is also used as a reactive flame retardant in laminated FR4-type Printed Wiring Boards (PWB) and in Epoxy resins used to encapsulate electronic components mounted directly on PWBs. For this particular use, ASD does not anticipate negative impacts, as the substance is normally not present in the final component in its original form but indicated that this should be confirmed. Medium Chain Chlorinated Paraffins (MCCP) are used as a flame retardant and plasticiser in PVC insulation for electric cables and in sealants. According to ASD, **there could be impacts from the inclusion of MCCP in Annex II to RoHS that need to be better assessed and understood by the defence industry**, in particular as **several flame retardants are under scrutiny under different legislation**.

Although other substances included in the 2018 review have not been recommended for inclusion in Annex II to RoHS, further actions were recommended for some of them (see section 2.5.1.5– Regulatory evolution of substances). In particular, ASD indicated that **there could be impacts from further actions taken on Diantimony trioxide (ATO),** for which a future group assessment of halogenated flame retardants and ATO is recommended. ATO is used in plastic EEE enclosures and in cables. According to ASD, there might be impacts on the defence sector that need to be better assessed by the industry in conjunction with other regulatory actions on flame retardants. One MoD mentioned that potential impacts linked to further regulatory actions on ATO, beryllium and its compounds, nickel sulphate and nickel sulfamate and cobalt dichloride and cobalt sulphate should be further assessed. The Beryllium Science and Technology Association also indicated that beryllium is used in defence application, in particular in aviation (e.g., copper-beryllium connectors, beryllium-containing alloys). According to the association, producing beryllium only for the defence market would not be economically viable, meaning that, if further regulatory action were taken, the defence exemption might not be sufficient to ensure continued use.

2.5.4.2 Costs linked to RoHS

Defence industry stakeholders and some MoDs reported that the RoHS Directive had an impact on the following costs:

- **Increased prices of some components**, resulting from the unavailability of components containing restricted substances under RoHS and the necessity to buy, in certain cases, component variants specifically transformed for defence applications or for defence industries to transform the components themselves. When alternative (RoHS compliant) components are used, they might be more expensive at the beginning;
- **Cost of stockpiling components** containing restricted substances along with the risks of obsolescence in long-term storage and limited flexibility if there are changes to design;
- **Research and development costs**: each inclusion into Annex II to RoHS triggers research and development activities, in particular regarding the inclusion of lead for which several MoDs and defence industry stakeholders have funded and conducted research programmes. ASD recalled that introducing a new technology in a sector such as defence requires long and complex procedures, starting with research and testing of alternatives not containing restricted substances, which can be a long step as a candidate technology should first reach sufficient maturity before being industrialised. Industrialisation requires an extensive step-by-step methodology to implement a qualified material or process throughout the manufacturing, supply chain and maintenance operations, leading to the final certification/qualification of the product;
- **Maintenance and inspection costs**: in cases where alternative components are used, the reliability of which over the service life of the equipment is poorly known, or in cases where reliability is known to be reduced;
- **Increased / more frequent product replacement** due to reduced product longevity, particularly for COTS components in electronic systems.

2.5.4.3 Importance and limitations of the scope exclusion

Defence industries and MoDs agreed on the **importance and effectiveness of the scope exclusion** contained in the RoHS Directive – i.e., the Directive 'does not apply to equipment which is necessary for the protection of the essential interests of the security of Member States'. ASD and two MoDs indicated that the defence sector still relies significantly on the exemption mechanism to meet safety standards for electronics used in military equipment. Defence industries and some of the MoDs consider that the exemption mechanism remains critical for some substances included in Annex II to RoHS and used in defence applications, for which there are so far no or insufficient alternatives, such as chromium and cadmium in military connectors and cables. Several stakeholders underlined that defence industry products are used in extreme conditions (temperature, vibrations, etc.), have safety critical or security critical applications, and have long service life, which justifies the use of the exemption for certain substances.

Several defence industries and one MoD mentioned that **the scope exclusion was often used for lead soldering** because lead-free solder/component alternatives **do not afford the same reliability in extreme conditions** and suitability over the long service life of some specific defence products, such as a number of military electronic equipment and military aircrafts. In particular, ASD mentioned that although alternatives have given positive results in relation to use at extreme temperatures, tests have so far not been sufficiently conclusive in relation to the combination of extreme temperature, vibration, and pressure cycling. ASD concluded that there is not sufficient evidence that alternatives to lead soldering are suitable for use in hostile environments, and that defence industries still need

to evaluate and gather evidence on the use of these alternatives in defence equipment.

In addition, defence industries indicated that **legacy products** – products placed on the market before the adoption of the RoHS Directive in 2011 – are not suited for the use of lead-free components. Given the **long service life of defence products**, these products are still in use and require the use of the exemption. In light of these observations, defence industry stakeholders mentioned that the defence exemption should be used to its full extent to ensure the production of equipment meeting military standards.

Nonetheless, **one MoD reported that some R&D studies have shown that alternatives to lead soldering exist in some cases and are performant including in hostile environments**. According to the MoD, the **broad scope exclusion does not encourage the development and uptake of suitable alternatives** – such as lead-free soldering alternatives for some uses – and sometimes leads to the **perpetuation of obsolete uses**, which in the medium term could be at risk of being impacted by REACH (as lead has been added to the Candidate List).

Several stakeholders pointed out the limits of the scope exclusion. Similarly, to the defence exemption in the BPR, the scope exclusion in RoHS does not mitigate impacts on all civil applications, and therefore cannot always prevent impacts on dual use equipment. In addition, where there is no viable market for the industry to produce non-RoHS compliant components, as shown above for COTS components, the **effectiveness of the scope exclusion might be limited as suppliers will likely discontinue the production**.

2.5.4.4 Input from the Aerospace Industries Association of America (AIA)

AIA indicated that the scope of the defence exemption under the RoHS Directive related to the 'essential interests of the security of the Member States' has been somewhat unclear and may need additional guidance at EU level to promote consistency across the Member-States. Regarding the necessity for the defence exemptions, AIA mentioned that although progress is being made to increase the reliability of unleaded solders, lead soldering is still needed for certain uses in commercial electronics that are used in military applications. Finally, AIA indicated that an alignment of defence exemptions between REACH and RoHS (on the model of the RoHS exemption and based on the same rational, i.e., the protection of the essential interests of the security of Member States) would be helpful for important military/ security equipment.

2.5.5 Summary

Directive 2011/65/EU[225] provides for the restriction of the use of certain hazardous substances in **electrical and electronic equipment (EEE)**. EEE placed on the market must not contain the following substances in concentrations exceeding the limits provided in Annex II to RoHS: **lead, mercury, cadmium, hexavalent chromium, PBB, PBDE, and four phthalates (DEHP, BBP, DBP and DIBP)**.

Several groups of EEE are excluded from the scope of the RoHS Directive, including '*necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes*'. Other groups of EEE excluded from the scope of RoHS are also relevant to the defence sector, such as equipment designed to be sent into space, parts of non-scope equipment, large-scale fixed installations, means of transport for persons or goods, except two-wheeled electric vehicles, and non-road mobile machinery made available exclusively for professional use. However, in several Member States, the general approach followed

[225] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88–110.

in procurement is to require 'voluntary' compliance with the RoHS Directive whenever possible, even for equipment excluded from the scope of RoHS, and to require suppliers to report on the use of the Article 2(4) exemption. In addition, exemptions – i.e., temporary permissions for placing EEE containing certain restricted substances on the market – can also be granted for certain applications upon request from industry. Those exemptions are listed in Annex III and IV to the Directive.

According to Article 6(1) of the RoHS Directive, the list of substances restricted in EEE in Annex II to RoHS must be periodically reviewed by the Commission, on its own initiative or following the submission of a proposal for inclusion of a substance by a Member State. The first review was done in 2012-2014, the second in 2018-2020. The 2018 Substance review covered seven substances, two of which have been recommended for inclusion in Annex II to RoHS – Medium Chain Chlorinated Paraffins and Tetrabromobisphenol-A. Further assessment or increased scrutiny are recommended for some of the other substances.

The **scope of the REACH Regulation and the RoHS Directive can partially overlap** since REACH applies to all substances, including in mixtures and articles, which means it also applies to substances in EEE which are covered by the RoHS Directive. Potential overlaps between the REACH Regulation and the RoHS Directive might occur when risk management measures are taken under REACH or RoHS for substances that are already regulated under one of the two. The **Common Understanding paper**[226], published by the Commission in 2014, identifies cases of potential overlaps between the two and outlines the agreed standard practice in those cases. A possibility highlighted by the paper to deal with overlaps is to exclude or remove EEE from the scope of REACH restrictions if the substance is included in Annex II to RoHS, or to exempt from the REACH authorisation requirement uses covered under the RoHS Directive. However, this approach assumes that RoHS provides the same level of protection as REACH, which can be challenged based on the fact that the RoHS Directive does not control the use of a substance in the manufacturing process of EEE or at the workplace (it only restricts the substance in the end product) and that several categories of EEE are excluded from the scope of RoHS. In general, the study found that the Common Understanding paper does not provide guidance on interactions between RoHS and REACH Annex XIV and Annex XVII with regards to EEE that are excluded from the scope of RoHS, such as military equipment. Consulted MoDs pointed at potential inconsistencies between REACH and RoHS for defence/military EEE excluded from the scope of RoHS.

Both MoDs and defence industries did not report significant impacts on defence equipment due to the use of the scope exclusion. However, the RoHS Directive can **negatively impact the availability of equipment necessary for the defence sector**, in spite of the scope exclusion, because the defence industry relies significantly on civil equipment and Commercial Off-The-Shelf (COTS) electronic components, which must be compliant with RoHS. This has reduced the availability of certain components (e.g., components coated with tin-lead solder alloy) and the **suitability of some components for defence applications**, resulting in **higher costs** for defence industries (e.g., higher costs of components specifically transformed for defence use, costs of stockpiling those components).

In addition, the defence sector might be affected by the upcoming inclusion of substances in Annex II to RoHS, such as Tetrabromobisphenol-A (TBBP-A) and Medium Chain Chlorinated Paraffins (MCCP), recommended for inclusion by the 2018 substance review[227], and other substances not recommended for inclusion but that are under increased scrutiny, such as diantimony trioxide (ATO). However, the concrete impacts still need to be fully assessed by the defence industry and MoDs.

[226] European Commission (2014) REACH and Directive 2011/65/EU (RoHS). A common understanding: https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en (Last accessed on 08.12.2020).
[227] Interim results of the 2018 substance review: https://rohs.exemptions.oeko.info/index.php?id=341

The defence industries indicated that the scope exclusion remains critical for some uses for which proven alternatives are lacking, to meet defence safety requirements. However, it was also reported that the scope exclusion slowed down the uptake of suitable alternatives – for example suitable lead-free soldering alternatives for some uses – and perpetuated obsolete uses, which could be at risk of being impacted by REACH (as lead has been added to the Candidate List).

2.6 SUMMARY OF FINDINGS ON THE FIVE CHEMICALS'/WASTE REGULATIONS (BPR, POPS, ODS, F-GAS, ROHS)

The analysis of the implementation and impacts on the BPR, POPs, ODS, F-gas Regulations and RoHS Directive revealed several implementation issues and negative impacts on defence stakeholders – both MoDs and defence industries. The key findings of the analysis which is mainly based on the input provided by stakeholders during the consultation are summarised in the table below.

Table 30: Key findings on BPR, POPs, ODS, F-gas Regulations and RoHS Directive

General findings
General Finding 1 : MoDs have different provisions and information requirements in procurement contracts The study showed that some MoDs have specific requirements in procurement contracts requiring suppliers to provide information on substances used in defence equipment to verify compliance with regulations such as BPR, POPs or RoHS. Each MoD has its own approach to procurement and specific provisions.
General Finding 2 : Some MoDs monitor substances used in defence equipment, in particular through information requirements in procurement contracts In addition to checking compliance, the information requirements in procurement contracts described above are used by MoDs for the mapping and monitoring of substances used in defence equipment. This provides a valuable inventory of substance used by the defence industry and may enable MoDs to anticipate substances that might be affected by regulations and take early actions.
General Finding 3 : Knowledge of the five regulations and their interactions with REACH and CLP is quite poor in the supply chain For all regulations covered by the study, defence industries indicated that the commonalities and differences of the five regulations, as well as their interactions with REACH and CLP, were generally poorly understood in the supply chain. In addition, several findings show that defence industry sometimes lacks awareness of procedures, tools to provide input (such as public consultations) or deadlines.
BPR
Availability of substances
Finding BPR 1: The BPR has reduced the availability of certain biocidal products and treated articles used by defence industries The BPR has reduced the availability of certain biocidal products, such as insect repellents for textile, anti-fouling products for the naval sector, or preservatives, and of treated articles. The reduction of substances and products could lead to reduced performance, reliability or longevity of the product, and may raise issues for the maintenance of legacy equipment still in use.
Finding BPR 2: Unavailability of substances results in some cases from the from the complexity and costs of application processes under the BPR Unavailability of substances can be caused by suppliers not applying for approval of active substances and/or authorisation of biocidal products because of lack of awareness of processes and deadlines (application starts late, only when the imminent threat to the product is understood) or lack of capacity (dossier submission is considered costly by suppliers of biocidal products).
Communication in the supply chain
Finding BPR 3: Communication in the supply chain of biocidal products used in treated articles is poor Requirements of the BPR related to the transfer of information on biocidal used in treated articles in the

supply chain are currently not fully implemented and this prevents defence industries from fully tracking biocidal uses in articles and ensuring compliance with the BPR and national procurement provisions requiring information on biocidal products used in procured equipment. This is more of a concern when suppliers are located outside the EU, as they are less aware of BPR requirements. Consequently, monitoring costs are significant for defence industries.

Limitations of the Article 2(8) defence exemption

Finding BPR 4: The Article 2(8) defence exemption is considered as a last resort by MoDs and seldomly used

The defence exemption established by Article 2(8), which provides for the possibility that Member States exempt specific uses of certain biocidal products, on their own or in a treated article, where necessary, in defence applications, is considered by some MoDs as a last resort, when complying with the BPR does not allow for compliance with defence safety standards. This is one of the reasons why the exemption mechanism is hardly ever used.

Finding BPR 5: Article 2(8) defence exemption is considered as a complex mechanism by defence industries

The defence exemption mechanism established by Article 2(8) is considered as complex by defence industries as each exemption is only valid in one Member State. If a defence industry wants to sell in several Member States, an exemption would have to be requested in all Member States where the product should be placed on the market. In addition, the process for requesting an exemption at national level is not always clear to defence industries – i.e., which institution to contact, which information to provide and in which format.

Finding BPR 6: The effectiveness of Article 2(8) defence exemption is limited in certain cases

The effectiveness of the exemption mechanism might be limited, in particular as it only applies to defence applications and cannot be used to secure the use of a dual use substance in civil applications, which is problematic as biocidal products used in defence applications are not specific to defence applications. In addition, there are risks that, even if a defence exemption is granted, it will not prevent suppliers from discontinuing their production of specific biocidal products or treated articles as the defence sector is a small market.

POPs Regulation

Process for inclusion of new POPs in the Stockholm Convention

Finding POPs 1: Interventions to secure defence exemptions as part of the process for inclusion of new POPs in the Convention are sometimes made late in the process

In the evaluation of DecaBDE for inclusion in the Convention, exemptions for military aircrafts – provided in the REACH Annex XVII restriction – were not initially identified by the POPRC as necessary but were included in the final amendment to the Convention following actions by MoDs and the EDA. Although exemptions were secured in the adopted decision, a more efficient process would have been to identify and negotiate necessary exemptions as early as possible.

Finding POPs 2 : The recast of the POPs Regulation in 2019 should ensure increased visibility of substances proposed for POPs and a formalised process for stakeholder consultation

Following the recast of the POPs Regulation, the process is now as follows: ECHA publishes a notice that a proposal for the listing of a substance will be prepared by the Commission. ECHA also organises a public consultation on the draft EU proposal to the Convention Secretariat for inclusion of a new substance, the draft risk profile and the draft risk management evaluation prepared by the POPRC. Submitted comments are published on ECHA's website.

Finding POPs 3: There can be valuable synergies between the REACH restriction process and the inclusion of a new POP in the Stockholm Convention

In cases where this is possible, starting the restriction process for a substance proposed for listing in the Stockholm Convention, can support the early launch of research and development activities to find alternatives and the early implementation of strategies by the defence industry to mitigate the impacts of the restriction, ahead of the listing in the Convention. The restriction process could also provide an opportunity to discuss possible exempted uses at an early stage to be fed later in the proposal for inclusion of the substance in the Convention (if the EU is the submitter) and/or in the work of the POPRC and final decision of the CoP.

Availability of substances

Finding POPs 4: The inclusion of PFOA in the POPs Regulation and future inclusion of substances, including other PFAS substances, raises concerns for certain defence applications

The inclusion of PFOA in the POPs Regulation had an impact on the availability of surface treatments available for textiles (for water and oil repellency and non-flammable properties). Inclusion of other PFAS substances in the Stockholm Convention is expected, following their inclusion in Annex XVII to REACH, which might impact the availability of substances meeting military standards for fire extinguishing equipment, military personal protection equipment and textiles. The substitution of long chain PFAS, such as PFOA, by short chain PFAS is therefore only a short-term solution and alternatives need to be secured. Concerns were also expressed in relation to the potential inclusion of Octamethylcyclotetrasiloxane (D4). Impacts of potential future inclusion of substances in the Stockholm Convention and POPs Regulation need to be further assessed by MoDs.

Communication in the supply chain

Finding POPs 5: Communication in the supply chain of POPs used in articles is poor

Knowledge of the POPs Regulation in the supply chain, particularly in SMEs, is quite low, which creates problems and delays for defence industries in tracing POPs in defence equipment, to comply with the Regulation and with national procurement provisions requiring information on substances used. Defence industries mainly rely on information provided by suppliers, which often do not track POPs themselves. It is particularly difficult to constrain suppliers outside the EU to track and substitute POPs, even though the Stockholm Convention is an international Convention. Consequently, monitoring costs are significant for defence industries. In addition, several stakeholders called for more guidance on the interactions between REACH and the POPs Regulation.

Ozone Regulation

Interactions between the Ozone Regulation, REACH and other chemical Regulations

Finding ODS 1:There are potential synergies with REACH which would require further coordination to ensure better enforcement of the two Regulations as well as with the Montreal Protocol

Some substances with ozone-depleting potential, such as very short-lived substances (VSLS), may already be restricted via REACH, while they might not be currently covered by the existing regime of the Ozone Regulation. Practices favouring the exchange of information would favour synergies to enhance the coherence and the implementation of both Regulations. Likewise, further coordination between the two different control mechanisms of the two Regulations (the phase-out system with extensive transitional periods for the Ozone Regulation and the authorisation process under REACH) may foster a better protection of the ozone layer from ODS. It is noted that, depending on the circumstances, the more flexible control mechanism of the Ozone Regulation may help avoid the administrative costs the REACH authorisation system may entail.

Finding ODS 2 : The complementarity of the Ozone and F-gas Regulations may favour synergies between the two

Both Regulations are complementary on the issues they cover as the F-gas Regulation is meant to regulate substances that are used as alternatives to ODS. They have been developed together and are both managed by DG CLIMA at the European level. At the national level, the two Regulations are often managed by the same MSCA, thus favouring better coordination. Furthermore, they cover almost the same sectors (refrigeration, air conditioning, aerosols and foams) with a similar goal, thus preventing any inconsistency. The main challenge for the Commission is now to ensure that all new substances are included at least under one of the Regulations and that a clear link is made between the two.

Finding ODS 3: Despite synergies, it is necessary to ensure consistency between the Ozone and the F-gas Regulation and avoid the risk of regrettable substitutions

Because the two Regulations are often managed together and cover similar areas, it has been highlighted that this might cause confusion among stakeholders to differentiate the two. Second, it was underlined that the objective to reduce ODS emissions indirectly led to new challenges as some F-gases were introduced as substitutes for ODS in many sectors, especially for refrigeration and air conditioning applications following the global phase-out of ODS substances under the Montreal Protocol. This is especially the case for substances such as HFCs, PFCs and SF6.

Finding ODS 4: There is no "one-size-fits-all" provision to manage defence-related matters in terms of chemical legislations, leading to potential confusion among industry stakeholders

Defence-related provisions may be addressed differently by the different pieces of legislation. While REACH and the CLP adopt a case-by-case approach to potential defence-related exemptions, the ODS allows for some critical uses such as military applications (through its Annex VI 'Critical uses of halon'). In fact, there is no "one-size-fits-all provision" to manage defence-related matters in terms of chemical legislation. Instead, provisions are progressively built throughout the legislative process depending on the needs identified in relation to the use of specific substance groups. These differentiated approaches may lead to confusion among all the regulations focusing on chemicals, as expressed by some defence industry stakeholders during the consultation. In this context, it is noted that the defence exemption mechanism established under the Ozone Regulation which allows for a progressive phase out of halons may be considered preferable to the REACH authorisation procedure as defence stakeholder have more time to adapt to the transition. However, though this system was made possible for the phase out of halons, it might be more complex to apply to broader groups of chemicals with a wide range of different substances.

Availability of substances

Finding ODS 5: HFOs do not present sufficient technical performance characteristics to fit within the design margins

Based on the obligation under the Ozone Regulation to replace chlorofluorocarbon (CFC), hydrochlorofluorocarbon (HCFC) and halons with substances that are less damaging to the ozone layer for most uses since 2000, a solution developed was to substitute the regulated substances with hydrofluorocarbons (HFCs) for refrigeration and fire extinguishing agents, which are substances covered by the phase-down requirements of the F-gas Regulation in terms of production and maintenance from 2020. Consequently, HFCs are now being replaced by many substitutes, some of which may be problematic. For instance, HFCs may be replaced by hydrofluoroolefins (HFOs) which, according to stakeholders, do not present sufficient technical performance characteristics to fit within the design margins, such as electric consumption or refrigeration power in terms of volume and mass or safety characteristics of the substances being phased out.

Finding ODS 6: Some substances may present a risk of unavailability as alternatives, especially for halons, have not yet proven to meet minimum standards for use in military equipment

The risk of unavailability of substances represents an issue for products and equipment containing or relying on regulated substances which have a long lifetime. Refilling those products or equipment may become more and more difficult. In addition, the search for alternatives may be complex. Some alternatives often tend to be not as effective as the ones regulated under the Ozone Regulation. This is especially true for halons for which alternatives tend to be more costly and not as efficient. It is noted however that ongoing research efforts contributed to finding appropriate substitutes for new naval and land systems. as described above. The unavailability of viable alternatives remains a challenge aircraft fuel tank inerting and existing systems that need remodelling or refilling. Most substitutes used are F-gases and will need to be replaced in the future based on the F-gas phase-down requirements.

Potential additional costs foreseen

Finding ODS 7: The implementation of the Ozone Regulation and the replacement of ODS by alternative substances may entail further costs for the defence stakeholders

Logistics and administrative costs are foreseen as there will be a greater need for IT tools to track the substances. The need to supervise the implementation of the Regulation will also entail a reorganisation of human resources. There are also costs linked to the retrofitting of old equipment and the purchase of potentially costlier substitutes to comply with the Regulation's requirements. Likewise, investment will be needed to ensure a trained and qualified personnel is able to use these new substances and products. Procurement costs are also to be considered regarding controlled substances as civil applications will decrease along with the availability for these substances.

F-gas Regulation

Availability of substances

Finding F-gas 1: Lack of available alternative substances meeting the military standards to efficiently replace F-gases

Some substitutes with lower global warming potential which are known to date are very flammable and may

not meet the existing standards, but others do not (e.g., CO2). A stakeholder expressed concerns regarding existing legacy equipment which may not be supported in the future if F-gases become obsolete (imports exempted) and new equipment with non-F-gas alternatives are a fire hazard in a combat zone. One MoD consulted conceded that there was a risk that a suitable substitute will not be found in time for all concerned F-gases to comply with the dates specified Annex III to the Regulation. Reformulation may affect the performance and reliability of products, which may result in the fact that a larger volume of substances will be necessary to gain the same effect and meet minimum standards. Commercial obsolescence is also expected for instance for substances such as R404a, R134a, FM200.

Potential additional costs foreseen

Finding F-gas 2: Several costs related to increased human resources, logistical needs to track substances, the remodelling and redesign of old equipment as well as procurement strategies

Administrative costs are foreseen to comply with the inventory and reporting obligations while ensuring leakage control measures. Certified personnel will be needed to carry out some of these tasks. Even though these investments should lead to better performance of the systems and longer lifetimes, they will also further increase the costs of human resources. The use of new alternatives and the development of new technologies may also entail costs to ensure the remodelling and redesign of old equipment as alternative substances may also be more costly. An increase in the logistical resources needed to track the substances is also expected. For MoDs and their national Armed Forces, the main issues lie in the new procurement strategies to be adopted to acquire new products and equipment, as well as providing a sufficient supply in substances to ensure the maintenance of existing equipment.

Lack of awareness

Finding F-gas 3: Confusion and low awareness from industry stakeholders regarding the provisions of the F-gas Regulation and how they may impact their activity

The consultation highlighted that there is a lack of information and awareness from the defence industry regarding how the Regulation affects their activity. In fact, defence industries stated they either did not have any product affected by the provisions of the Regulation or they did not observe any specific impact from the Regulation's provisions as they relied on the exemptions provided by the Regulation to avoid proceeding to any further checking. The complementarity of the ODS and F-gas Regulations also reinforces the risks of confusion for stakeholders who expressed their wish to be involved in awareness programmes or have more guidance.

RoHS Directive

Interactions between REACH and RoHS Directive

Finding RoHS 1: The Common Understanding paper lacks guidance for categories of EEE excluded from the scope of RoHS

The Common Understanding paper on the interactions between REACH and RoHS does not provide guidance on interactions between REACH Annex XIV and Annex XVII with regards to EEE that is excluded from the scope of RoHS, such as military equipment. Because of the scope exclusion, there might be inconsistencies between REACH and RoHS for defence/military EEE. In addition, there are doubts regarding the interpretation of Article 58(2) of REACH to exempt military equipment (excluded from the scope of RoHS) from the REACH authorisation requirement in case of a substance being included both in Annex XIV to REACH and Annex II to RoHS. More generally, the analysis provided in the Common Understanding paper does not take into account that several categories of EEE are excluded from the scope of RoHS, and that for this EEE, RoHS might not provide the same level of control of hazardous substances than REACH.

Finding RoHS 2: Relations between REACH and RoHS, including the differences in calculating concentration values, are still unclear for defence industries and their suppliers

Some defence industries and MoDs also indicated that, despite the Common Understanding paper, the interactions between REACH and RoHS were still relatively unclear or confusing for stakeholders. Some defence industry stakeholders also mentioned that the differences in the calculation basis for concentration values (weight by weight for each component in REACH vs weight in homogenous material in RoHS) create confusion and raise questions amongst suppliers and customers.

Availability of equipment
Finding RoHS 3: Because of the exclusion of defence equipment from the scope of RoHS, limited impact on the availability of equipment was reported Both MoDs and defence industries did not report significant impacts on defence equipment due to the use of the scope exclusion where there is a lack of alternatives.
Finding RoHS 4: Although defence equipment is excluded from the scope of RoHS, equipment and products – in particular COTS products – used by the defence sector are negatively impacted by RoHS The RoHS Directive can negatively impact the availability of equipment necessary for the defence sector, in spite of the scope exclusion, because the defence industry relies significantly on civil equipment and Commercial Off-The-Shelf (COTS) electronic components, which must be compliant with RoHS. This has reduced the availability of certain components (e.g., components coated with tin-lead solder alloy) and the suitability of some components for defence applications, resulting in higher costs for defence industries (e.g., higher costs of components specifically transformed for defence use, costs of stockpiling those components).
Finding RoHS 5: The impact on the defence sector of future inclusion of substances could be significant and should be monitored The defence sector might be affected by the upcoming inclusion of substances in Annex II to RoHS, such as Tetrabromobisphenol-A (TBBP-A) and Medium Chain Chlorinated Paraffins (MCCP), recommended for inclusion by the 2018 substance review, and other substances not recommended for inclusion but that are under increased scrutiny, such as diantimony trioxide (ATO). However, the concrete impacts still need to be fully assessed by the defence industry and MoDs.
Scope exclusion
Finding RoHS 6: Several Member States require compliance with RoHS for defence equipment whenever possible through procurement provisions, despite defence equipment being excluded from the scope of RoHS Four MoDs indicated that their general approach in procurement was to require 'voluntary' compliance with the RoHS Directive whenever possible through procurement provisions, even for military equipment, in part because of the procurement of dual use equipment, which are not excluded from the scope of the Directive by Article 2(4). Some of these MoDs also require suppliers to report on the use of the Article 2(4)(a) (i.e. indicating which component of the equipment is concerned, which substances exceed concentrations listed in Annex II to RoHS) and to report on Annex III and IV exemptions used. This approach did not seem to be understood well by defence industries.
Finding RoHS 7: The scope exclusion for defence equipment remains critical for some specific uses but may lead to the continuation of obsolete uses The defence industries indicated that the scope exclusion remains critical for some uses for which proven alternatives are lacking, to meet defence safety requirements. However, it was reported by one MoD that the scope exclusion slowed down the uptake of suitable alternatives – for example suitable lead-free soldering alternatives for some uses – and perpetuated obsolete uses, which could be at risk of being impacted by REACH (as lead has been added to the Candidate List).

2.7 RECOMMENDATIONS ON THE FIVE CHEMICALS'/WASTE REGULATIONS (BPR, POPS, ODS, F-GAS, ROHS)

Based on the findings listed above, this section includes recommendations by the contractor to mitigate the impacts of the five regulations covered by the study and to improve the consistency between those regulations and the REACH and CLP Regulations.

Recommendations are primarily addressed to EDA and MoDs. However, in some cases, other stakeholders – the Commission, ECHA, MSCAs, national helpdesks, ASD and NDIAs – may be better placed to implement the recommendations. In those cases, EDA and MoDs are recommended to liaise with these stakeholders to initiate the proposed actions.

The recommendations are assessed according to their feasibility (difficulty to implement) and expected benefits (impacts). The difficulty mainly considers the expected technical challenges to implement a given recommendation (e.g., additional tasks for a given stakeholder within its given remit is easier to achieve than the definition of a common approach involving a number of different stakeholders or a change of the legal text). Other elements (such as the required human and financial resources) are also important parameters determining the practical difficulty but could not be assessed within the scope of this study.

The following types are distinguished, based on the technical feasibility of their implementation:

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction
Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders
Difficult – Recommendations involving significant change in core processes of the legislation or amendment of the legal text.

2.7.1 General recommendations (for the five regulations)

2.7.1.1 Exchange of good practices in relation to procurement requirements

Exchange of good practices in relation to procurement requirements	Addressees
Exchange of good practices in relation to information requirements linked to specific regulations used in procurement, with EDA facilitating the exchange of good practices.	EDA, MoDs

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, General Finding 1 (MoDs have diverse provisions and information requirements in procurement contracts).

The study showed that some MoDs have specific requirements in procurement contracts requiring suppliers to provide information on substances used in defence equipment to verify compliance with regulations such as BPR, POPs or RoHS. Exchanging practices in relation to procurement could lead to clearer and more consistent requirements for industry. The recommendation is made to strengthen and contribute to the alignment of procurement requirements.

Recommendation implementation

It is proposed that MoDs exchange good practices in relation to information requirements linked to specific regulations used in procurement, with EDA facilitating the exchange of good practices.

2.7.1.2 Exchange of intelligence based on monitoring of substances used in defence applications

Exchange of intelligence based on monitoring of substances used in defence applications	Addressees
Monitoring of substances used in defence application through implementation of the Regulations, including procurement.	MoDs
Exchange in intelligence information gathered through the implementation of the Regulations, including procurement, with EDA facilitating the exchange of information, to identify early on uses threatened by regulatory obsolescence and consider possible action.	EDA, MoDs, consultation with industry

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, General Finding 2 (Some MoDs monitor substances used in defence equipment, in particular through information requirements in procurement contracts)

The study revealed that anticipating regulatory developments was key to mitigate impacts of the regulations on the defence sector, as it allows MoDs and/or defence industries to identify and make use of the possibilities offered by regulations (defence exemptions, derogations etc.) if necessary, to apply for product authorisation if not already done (i.e. under BPR), and to launch R&D activities to identify and test suitable alternatives to impacted substances. The study showed that, in certain cases, impacts were not anticipated early enough, which led to implementing hasty solutions at the last moment.

Better anticipation of regulatory impacts is based on the monitoring of substance uses in defence equipment, as well as the monitoring of regulatory evolutions under the different regulations. Monitoring activities are carried out by defence industries that trace substances used in the articles/components they use to the extent possible, and their associations (ASD at EU level and NDIAs at national level) that follow regulatory evolutions under REACH and other regulations, although the multiplicity of regulations to follow is considered as a barrier by some defence industries. Monitoring is also done by some MoDs, which collect information on substances used in defence equipment in general, and also through procurement clauses requiring defence industries to provide for instance information on biocidal products or POPs used, or uses of substances that are restricted under RoHS (based on the scope exclusion). The recommendation is made to increase the effectiveness of national monitoring activities and ensure more efficient anticipation and management of regulatory impacts.

Recommendation implementation

It is proposed that MoDs exchange, when possible with regard to confidentiality of information, intelligence, information gathered in general and through procurement, with EDA facilitating the exchange of information. Based on this information, uses threatened by regulatory obsolescence could be more easily identified and, where relevant joint action could be considered (e.g., joint R&D activities, use of exemption or derogation mechanisms). In some cases, earlier communication with defence industries could be initiated to consider possible action (e.g., preparing a dossier for the approval of an active substance or the authorisation of a product if not done yet, complementary R&D activities).

2.7.1.3 Awareness raising on commonalities and differences and interactions between the different chemicals/waste regulations

Awareness raising on commonalities and differences and interactions between the different chemicals'/waste regulations	Addressees
EDA to flag defence industries' needs to the Commission and ECHA and discuss options for further promoting knowledge of the five regulations and their relationships with REACH and CLP among defence industry stakeholders. MoDs could liaise with MSCAs and helpdesks to consider action at national level	EDA, MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, General Finding 3 (Knowledge of the five regulations and their interactions with REACH and CLP is quite poor in the supply chain) and specific findings: Finding BPR 2 (Unavailability of substances results in some cases from the complexity and costs of application processes under the BPR), Finding BPR 3 (Communication in the supply chain of biocidal products used in treated articles is poor), Finding POPs 5 (Communication in the supply chain of POPs used in articles is poor), Finding ODS 4 (There is no "one-size-fits-all" provision to manage defence-related matters in terms of chemical legislations, leading to potential confusions among industry stakeholders), and Finding RoHS 2 (Relations between REACH and RoHS, including the differences in calculating concentration values, are still unclear for defence industries and their suppliers).

For all regulations covered by the study, defence industry indicated that the commonalities and differences of the five regulations, as well as their interactions with REACH and CLP, were generally poorly understood in the supply chain. In addition, several findings show that defence industry sometimes lacks awareness of procedures, tools to provide input (such as public consultations) or deadlines, which may threaten the use of substance in defence equipment because action was not taken early enough by defence industries or risks were not flagged to MoDs or EU institutions. The recommendation is made to raise awareness of defence industries of regulations (aside from REACH and CLP) that may affect them.

Recommendation implementation

EDA could start discussions with the Commission and ECHA on options for further promoting existing guidance or creating new guidance documents where gaps are identified. MoDs could also liaise with MSCAs and Helpdesks to flag defence industries' needs regarding guidance/awareness raising.

In addition, EDA could flag to the Commission that raising awareness on the existence of the Common Understanding papers on REACH and POPs Regulation and REACH and RoHS Directive could be useful, as not all stakeholders seem to be aware of their existence. As the documents are not easy to find on DG GROW's website, it could become part of ECHA's guidance documents (as most industry stakeholders look there for guidance).

2.7.2 Recommendations for the Biocidal Products Regulation

2.7.2.1 Discussion at EDA level about consequences of BPR on availability of products and possible actions

Discussion at EDA level about consequences of BPR on availability of products and possible actions	Addressees
MoDs to discuss at EDA level whether active substances/biocidal uses identified by the study as being negatively affected by the BPR do create significant issues for MoDs. If so, joint action could be discussed.	EDA, MoDs, consultation with industry

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding BPR 1 (The BPR has reduced the availability of certain biocidal products and treated articles used by defence industries) and Finding BPR 6 (The effectiveness of Article 2(8) defence exemption is limited in certain cases).

MoDs and defence industries have raised specific impacts of the BPR on the availability of certain biocidal products and treated articles for defence applications. The recommendation is made to investigate potential joint action by EDA and MoDs on those specific cases.

Recommendation implementation

EDA and MoDs could share further experience on the issues raised by the study and consider follow up actions, including:

- Evaluating the extent of the impact and investigate jointly available alternatives;
- Examining the possibility of carrying joint R&D efforts (also at EDA level) for critical substances impacted;
- Examining possibilities offered by the Regulation (e.g., defence exemption, transitional measures, derogations for essential uses, derogations under Article 55) to mitigate impacts on critical substances impacted.

2.7.2.2 Propose awareness raising actions at EU and national level on information obligations laid down in Article 58 of the BPR

Propose awareness raising actions at EU and national level on information obligations laid down in Article 58 of the BPR	Addressees
Increasing the focus on these issues in information campaigns, guidance, or webinars organised at EU and national level could support the better implementation of these obligations.	Main addressees: EDA, MoDs Implementing stakeholders: ECHA, MSCAs, BPR helpdesks, industry associations

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding BPR 3 (Communication in the supply chain of biocidal

products uses in treated articles is poor).

Literature and stakeholder consultation have shown that information obligations in the supply chain in relation to treated articles are not currently fully implemented, which prevents defence industries from fully tracking biocidal use in articles.

The recommendation is made to support better implementation of BPR requirements on communication in the supply chain and increased awareness of the supply chain of biocidal products use in treated articles.

Recommendation implementation

Although the recommendation is primarily addressed to EDA and MoDs, they are not the main stakeholders to implement this recommendation, as awareness raising activities on communication of biocidal uses through the supply chain would be more effective if they target a wide audience of manufacturers, suppliers and users of biocidal products, that would be more easily reached by ECHA, MSCAs/helpdesks and industry associations. EDA could, however, liaise with ECHA and ASD/NDIAs, and MoDs with MSCAs to raise the issue and suggest them to increase the focus of awareness raising activities on the communication through the supply chain.

Various awareness raising activities could be implemented by different stakeholders at EU and national level, such as a practical guidance by ECHA on requirements related to communication in the supply chain, webinars by ECHA, or typical awareness raising activities organised by MSCAs and helpdesks, such as media/social media campaigns, information workshops, newsletters, awareness raising material on the website etc. ASD and NDIAs could also have a role in raising awareness among defence industries on the necessity to track biocidal uses in treated articles and support them to implement processes to do so. A combination of such activities could be more effective.

2.7.2.3 Increase awareness on the process to request a defence exemption at national level

Increase awareness on the process to request a defence exemption at national level	Addressees
Provide easily accessible information on the procedure to request an exemption (i.e., which institution to contact, list of information required, format for providing the information, process for examination of and decisions on requests, duration of exemption and process for renewal)	Main addressees: EDA, MoDs Other implementing stakeholders: MSCAs, BPR helpdesks

Difficulty to implement

Where the recommendation mostly entails communicating information on the exemption process, it should be easy to implement. If in some Member States, the national procedure for requesting exemptions is not fully established, then the difficulty to implement the recommendation should be medium.

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, Finding BPR 4 (Article 2(8) defence exemption is considered as a complex mechanism by defence industries).

Industry stakeholders mentioned that the process to request a defence exemption at national level was not always clear to them – i.e., which institution to contact, which information to provide and in which format. The BPR leaves it to Member States to establish the process for requesting defence exemptions and for the examination of and decision on requests. The Regulation also does not

specify the duration of the exemptions and whether they can be renewed. Finally, the BPR leaves it to the discretion of Member States to define what is a 'necessary' exemption in the interest of defence and to specify what types of information and justification should be provided by defence industry when requesting an exemption. As a result, procedures can vary across Member States and might be unclear for defence industries, in particular if they need to request exemptions in several Member States.

The recommendation is made to provide easily accessible information to defence industries on the process to request defence exemptions under the BPR.

Recommendation implementation

In Member States where this has not been done, adopting a formal procedure, possibly by means of a regulatory act, providing the main information on how to make a request for exemption (which institution to contact, which information/justification to provide, in which template/format), as well as the steps and timing of the process, would be a first step. The process established for the BPR could be very similar as the process adopted for REACH defence exemptions. One MSCA that replied to the consultation indicated that a ministerial decree is being drafted to describe the procedure for applying, evaluating and granting a defence exemption, and that indeed, the process will closely follow the procedure implemented under the REACH Regulation.

Communication to stakeholders on the process to request an exemption can go through several channels:

- EDA REACH portal, which already contains information on the national procedures for REACH defence exemptions and could be complemented with information on the procedure for BPR defence exemptions. This might be the best channel to target defence industries, as this is already the place where they are likely to look for information on REACH defence exemptions;
- BPR webpages of MSCAs, which usually contain information on procedures to apply for authorisation of biocidal products but might not contain information on the defence exemption. MoDs could liaise with MSCAs to ensure that the information is provided on the MSCA's webpages;
- BPR Helpdesks' webpage, which might not contain information on the defence exemption. BPR helpdesk can also respond to stakeholders' questions on all topics related to the implementation of the BPR. MoDs could liaise with MSCAs and the Helpdesk to ensure that the information is provided on the Helpdesk's webpage.

2.7.2.4 Harmonisation of the implementation of defence exemptions across Member States

Harmonisation of the implementation of defence exemptions across Member States	Addressees
Harmonise the implementation of defence exemption across Member States, to possibly lead to reciprocal acknowledgement of defence exemptions across Member States.	EDA, MoDs (in cooperation with MSCAs where relevant)

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding BPR 4 (Article 2(8) defence exemption is considered as a last resort by MoDs and seldom used) and Finding BPR 5 (Article 2(8) defence exemption is considered as a complex mechanism by defence industries).

Defence industries underlined that the procedure for requesting exemption under the BPR was perceived as burdensome because of the necessity to apply for an exemption in all Member States where the product is sold, according to the procedures established in each Member State.

The recommendation is made to improve the efficiency and use of the exemption mechanism and to reduce administrative burden on defence industries and MoDs and/or MSCAs.

Recommendation implementation

Similar to EDA's Code of Conduct on REACH defence exemptions and its Annex (Framework for Applying for a Defence Exemption from a Requirement of REACH), the EDA and MoDs could adopt common goals and principles for the granting of defence exemptions under the BPR, which could be quite similar to those adopted for REACH. This framework would consider the current Member States' approach to consider the defence exemption as a last resort. This could lay the ground for the reciprocal acknowledgement of defence exemptions across Member States, as exemptions would be granted according to similar justification and risk assessment requirements. Reciprocal acknowledgement of exemptions would mean that the defence industry that applies for and is granted an exemption by one Member State, could request, in case it requires an exemption for the same substance by another Member State, that the second Member State considers (to the extent possible) the defence exemption that has been granted by the first Member State. This would ensure that the process in the second Member State is concluded expeditiously and without the industry having to go through the full national process.

2.7.3 Recommendations for the POPs Regulation

2.7.3.1 Discussion at EDA level about consequences of POPs Regulation on availability of products and possible actions

Discussion at EDA level about consequences of POPs Regulation on availability of products and possible actions	Addressees
MoDs to discuss at EDA level whether substances and equipment identified by the study as being negatively affected by the POPs Regulation do create significant issues for MoDs. If so, joint action could be discussed.	EDA, MoDs, consultation with industry

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding POPs 4 (The inclusion of PFOA in the POPs Regulation and future inclusion of substances, including other PFAS substances, raises concerns for certain defence applications).

MoDs and defence industries have raised specific impacts of the POPs Regulation on the availability of certain substances used in defence applications and there are concerns related to the possible future inclusion of substances, for which alternatives suitable for defence applications still need to be secured. The recommendation is made to investigate potential joint action by EDA and MoDs on those specific cases.

Recommendation implementation

EDA and MoDs could share further experience on the issues raised by the study and consider follow up actions, including:

- Evaluating the extent of the impact and investigate jointly available alternatives;
- Examining the possibility of carrying out joint R&D efforts (also at EDA level) for critical substances impacted; and
- Discuss early on whether exemptions for specific defence uses should be brought to the attention of the Commission and ECHA, and ultimately the POPRC.

2.7.3.2 Discuss and coordinate response to public consultation between MoDs and EDA

Discuss and coordinate response to public consultation between MoDs and EDA	Addressees
Discuss between MoDs and EDA the potential impacts of proposals for inclusion of substances in the Convention on the defence sector and, where relevant, use the public consultation to provide information and suggest requests for exemptions if no alternatives are available.	EDA, MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding POPs 1 (Interventions to secure defence exemptions as part of the process for inclusion of new POPs in the Convention are sometimes made late in the process) and (The recast of the POPs Regulation in 2019 should ensure increased visibility of substances proposed for POPs and a formalised process for stakeholder consultation).

Following the recast of the POPs Regulation, and ECHA's new role in the EU process for nominating substances for inclusion in the Convention, stakeholders are informed about which substances are considered (by a notice on ECHA's website) and have the opportunity to provide comments on the draft EU proposal to be submitted to the Secretariat of the Convention. In addition, ECHA organises public consultation on the draft risk profile and the draft risk management evaluation prepared by the POPRC, in parallel to POPRC's calls for information.

The study highlighted the necessity to manage potential impacts of the POPs Regulation as early as possible when a substance is considered for inclusion in the Annexes to the Convention to ensure that appropriate exemptions can be proposed and negotiated at the POP Review Committee. The recommendation is made to take advantage of the public consultation process established by the POPs Regulation for that purpose.

Recommendation implementation

The recommendation proposes that, when ECHA publishes a notice that a proposal for inclusion of a substance in the Convention will be prepared, MoDs and EDA discuss the potential impacts of the proposal on the defence sector and, if relevant, use the public consultation to provide information on the substance, its uses in the defence sector, and potentially to suggest requests for exemptions if no alternatives are available.

2.7.3.3 Discuss with the Commission the creation of a cooperation mechanism between the Commission and the EDA in relation to substances proposed for inclusion in the Convention

Discuss with the Commission the creation of a cooperation mechanism between the Commission and the EDA in relation to substances proposed for inclusion in the Convention	Addressees
Discuss the possibility with the Commission of creating a cooperation mechanism through which EDA would be informed of substances proposed as POPs in advance of draft proposals.	EDA, MoDs

Difficulty to implement

Difficult – Recommendation involving some significant change in core processes of the Regulations.

Rationale

Reference is made to section 2.6, Finding POPs 1 (Interventions to secure defence exemptions as part of the process for inclusion of new POPs in the Convention are sometimes made late in the process).

The study highlighted the necessity, in the absence of provisions allowing to derogate to the POPs Regulation, to manage potential impacts of the POPs Regulation as early as possible when a substance is considered for inclusion in the Annexes to the Convention, to ensure that appropriate exemptions can be proposed and negotiated at the POP Review Committee. The recommendation is made to facilitate early communication and generally facilitate exchanges between the Commission and EDA on substances proposed for inclusion in the Convention.

Through this cooperation mechanism, the Commission would communicate to EDA about the substances proposed as POPs in advance of draft proposals, so that the EDA and MoDs have time to assess the potential impacts on the defence sector and prepare requests for exemptions for specific uses. The creation of a formal cooperation mechanism is considered as difficult to implement since it would mean a specific mechanism created at EU-level for cooperation between Commission and a specific sector (defence) which, at Commission level, is considered as challenging.

Recommendation implementation

The recommendation can be implemented through the following steps:

- As a first step, EDA and MoDs discuss the feasibility and benefits of creating a formal cooperation mechanism, through informal consultation also with the Commission, especially on the feasibility of creating such a cooperation mechanism;
- If based on the outcome of the above step, it is deemed that the cooperation mechanism is feasible and beneficial, initiate more formal consultations with the Commission in view of its implementation.

2.7.3.4 Discuss with MSCAs, where considered relevant, the possibility to initiate a restriction procedure under REACH following the nomination of a substance for inclusion in the Convention

Discuss with MSCAs, where considered relevant, the possibility to initiate a restriction procedure under REACH following the nomination of a substance for inclusion in the Convention	Addressees
MoDs to check the status of the substance (registry of restriction intention, Candidate List) and discuss with the relevant MSCA whether starting a restriction in parallel with the procedure for listing in the Convention is appropriate.	MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding POPs 3. There can be valuable synergies between the REACH restriction process and the inclusion of a new POP in the Stockholm Convention).

Starting a restriction process for a substance proposed for listing in the Stockholm Convention is possible when no concrete action has been taken yet under REACH, for instance when the substance is on the Candidate List, but the authorisation process has not started. In those cases, starting the restriction process for a substance proposed for listing in the Stockholm Convention, can support the early launch of research and development activities to find alternatives and the early implementation of strategies by the defence industry to mitigate the impacts of the restriction, ahead of the listing in the Convention. The restriction process could also provide an opportunity for MoDs to discuss, at an early stage, possible exempted uses to be included in the proposal for inclusion of the substance in the Convention (if the EU is the submitter) and/or in the EU position for the POPRC meeting. The recommendation is to exploit the synergies between REACH and the POPs Regulation.

Recommendation implementation

In cases that are considered relevant by MoDs (e.g., exemptions for defence uses are likely to be needed), MoDs could see whether the substance is on the registry of restriction intention or on the Candidate List and discuss with the relevant MSCA (which has put the substance on the registry of intention or submitted the Annex XV SVHC dossier) and if relevant with ECHA whether starting a restriction in parallel to the procedure for listing in the Convention is appropriate. Consideration should be given to the possible burden on MSCAs, ECHA's committees and the Commission that this process would entail, compared to the potential benefits that the restriction could bring.

2.7.4 Recommendations for the Ozone Regulation

2.7.4.1 Make the Ozone Regulation part of a tool like the PACT tool of ECHA

Make the Ozone Regulation part of a tool like the PACT tool of ECHA	Addressees
Defence industry criticised that they are not made aware early enough of legislative developments, e.g., addition of new substances. Stakeholders suggested that the Ozone Regulation could become part of ECHA's PACT tool. The public activities' coordination tool (PACT) provides an overview of the substance-specific activities that authorities are working on under REACH and the CLP Regulation. It is unlikely that the Ozone Regulation will be considered by PACT since it is not within the competence of ECHA, but a similar tool managed by, for example, DG CLIMA, could be developed.	Main addressee: EDA Implementing stakeholder: European Commission (DG CLIMA)

Difficulty to implement

Difficult – Recommendation involving significant change in core processes of the Regulations.

Rationale

Reference is made to section 2.6, Finding ODS 1 (There are potential synergies with REACH which would require further coordination to ensure better enforcement of the two Regulations as well as with the Montreal Protocol), Finding ODS 3 (There is no "one-size-fits-all" provision to manage defence-related matters in terms of chemical legislation, leading to potential confusions among industry stakeholders).

Desk research highlighted that chemical legislation was varied and presented many specificities depending on the Regulation used. In this context, stakeholders may not be able to follow regulatory evolutions as they are developed and may miss the most recent developments.

Recommendation implementation

DG CLIMA and the EDA should collaborate to study the benefits and opportunities of creating such a tool and how it could be adapted to the specificities of the Ozone Regulation. National authorities could also provide their input regarding their perspective and use of the existing PACT tool.

2.7.4.2 Streamline processes under Ozone and F-gas Regulations

Streamline processes under Ozone and F-gas Regulations	Addressees
Stakeholders stressed that the objective of reducing ODS emissions indirectly led to new challenges as some F-gases were introduced as substitutes for ODS in many sectors, especially for refrigeration and air conditioning applications. This is especially the case for substances such as HFCs, PFCs and SF6. When adding substances to the Ozone Regulation, this consideration should be an integral part of the assessment prior to the decision.	Main addressee: EDA Implementing stakeholder: European Commission (DG CLIMA)

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, Finding ODS 3. (Despite synergies, it is necessary to ensure consistency between the Ozone and the F-gas Regulation and avoid the risk of regrettable substitutions) and Finding ODS 4 (There is no "one-size-fits-all" provision to manage defence-related

matters in terms of chemical legislations, leading to potential confusion among industry stakeholders).

Literature and stakeholder consultation have shown that the synergies and complementarity of the two Regulations may have the potential to lead to regrettable substitutions or at least confusion among stakeholders regarding the different substances regulated under the Regulations. It is therefore recommended to further streamline the requirements and processes under the two Regulations to avoid overlaps.

Recommendation implementation

EDA could suggest DG CLIMA to use the opportunity of the current evaluation of the F-gas Regulation and the impact assessment of the ODS Regulation to coordinate revisions and potential amendments, in light of what will be raised in the public consultations launched this year.

2.7.4.3 Provide incentives for the development of innovative solutions for alternative substances, ensure the retrofitting of equipment and reduce any potential additional costs

Provide incentives for the development of innovative solutions for alternative substances, ensure the retrofitting of equipment and reduce any potential additional costs	**Addressees**
Authorities should determine strong design specifications (besides the activation of the military exemption) to prepare industrial contractors while also supporting research for innovative solutions.	Main addressees: national MoDs Other implementing stakeholders: defence stakeholders at the national level, EDA for coordinated guidance at the European level

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, Finding ODS 5 (HFOS do not present sufficient technical performance characteristics to fit within the design margins), Finding ODS 6 (Some substances may be unsuitable as alternatives, especially for halons, since they have not yet proven to meet minimum standards for use in military equipment) and Finding ODS 7 (implementation of the Ozone Regulation and the replacement of ODS by alternative substances may entail further costs for the defence stakeholders).

The study showed that challenges remained with regards to the availability of alternative substances to replace ODS. To comply with both the Ozone and the F-gas Regulation, defence stakeholders must find substitutes which can meet minimum military standards in equipment. This may entail further investments and spending for the sector. Therefore, the recommendation encourages the gathering of knowledge on the current substitutes available in the defence sector, and foster efforts at the national level to provide strong incentives to defence stakeholders to pursue research and look for innovative solutions to find climate-friendly alternatives while mitigating the potential additional costs.

Recommendation implementation

Strong incentives to pursue R&D efforts should encourage the development of projects on the search for climate-friendly alternatives to ODS. In this regard, at the European level, the European Defence Fund (EDF) aims at supporting cross-border cooperation between Member States, industries and

research centres. Funding will contribute to Europe's strategic autonomy in defence by financing both research and capacity-building projects. In 2018, the Commission[228] proposed to dedicate a EUR 13 billion budget for the 2021-2027 period[229].

MoDs could provide further guidance regarding the design of military equipment to encourage defence stakeholders to find innovative ways to replace ODS in their systems while meeting military standards.

2.7.5 Recommendations for F-gas Regulation

2.7.5.1 Make F-gas Regulation also part of a tool like the PACT tool of ECHA

Make F-gas Regulation also part of a tool like the PACT tool of ECHA	Addressees
During the consultation, the defence industry expressed concerns about the fact they are not made aware early enough of legislative developments, e.g., addition of new substances. Stakeholders suggested that the F-gas Regulation could become part of ECHA's PACT tool. The public activities' coordination tool (PACT) provides an overview of the substance-specific activities that authorities are working on under REACH and the CLP Regulation. It is unlikely that the F-gas Regulation will be considered by PACT since it is not within the competence of ECHA, but a similar tool managed by, for example, DG CLIMA.	Main addressee: EDA Implementing stakeholder: European Commission (DG CLIMA)

Difficulty to implement

Difficult – Recommendation involving significant change in core processes of the Regulations.

Rationale

Reference is made to section 2.6, Finding F-gas 3 (Confusion and low awareness from industry stakeholders regarding the provisions of the F-gas Regulation and how they may impact their activity).

Consultation with stakeholders from the defence industry showed that the specific requirements and impacts of the F-gas Regulation are not always well-known and may get confused with the ODS Regulation.

Recommendation implementation

DG CLIMA and the EDA should collaborate to study the benefits and opportunities of creating such a tool and how it could be adapted to the specificities of the ODS regulation. National authorities could also provide their input regarding their perspective and use of the existing PACT tool.

[228] It is noted that although information on the European Defence Fund is available through DG GROW, the Fund is in fact handled under the responsibility of the new DG DEFIS (formed in January 2020). For further information please see: https://ec.europa.eu/info/departments/defence-industry-and-space_en (Last accessed on 08.12.2020).

[229] European Commission, European Defence Fund: https://ec.europa.eu/growth/sectors/defence/european-defence-fund_en (Last accessed on 08.12.2020)
European Commission > Internal Market, Industry, Entrepreneurship and SMEs > Sectors > Defence Industries > European defence fund

2.7.5.2 Mandatory identification of F-gases in equipment

Mandatory identification of F-gases in equipment and incentives to develop innovative solution to anticipate the phase-down of substances	Addressees
Some MoDs suggested making traceability of substances mandatory to identify F-gases in the Ministries of Defence fleets with systematic mappings for an efficient obsolescence management.	Main addressees: national MoDs Other implementing stakeholders: defence stakeholders at the national level

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding F-gas 1 (Lack of available alternative substances meeting the military standards to efficiently replace F-gases) and Finding F-gas 3 (Confusion and low awareness from industry stakeholders regarding the provisions of the F-gas Regulation and how they may impact their activity).

Many stakeholders, from MoDs and the defence industry, warned about the fact that there were not many workable alternatives to F-gases in the military sector due to standards being difficult to meet. Therefore, the recommendation encourages the gathering of knowledge on the current F-gas substances used in the defence sector, and foster efforts at the national level to provide strong incentives to defence stakeholders to pursue research and look for innovative solutions.

Recommendation implementation

MoDs could gather national expertise and develop traceability systems in addition to the provisions of the F-gas Regulation to ensure data is available to develop systematic mapping of the MoDs fleets.

2.7.5.3 Incentives to develop innovative solutions to anticipate the phase-down of substances

Incentives to develop innovative solution to anticipate the phase-down of substances and guidance regarding design of military equipment	Addressees
Authorities should: - determine strong design specifications (besides the activation of the military exemption) to prepare industrial contractors, and - support research on innovative solutions.	Main addressees: national MoDs Other implementing stakeholders: defence stakeholders at the national level, EDA for coordinated guidance at the European level

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, Finding F-gas 1 (Lack of available alternative substances meeting the military standards to efficiently replace F-gases) and Finding F-gas 2(Several costs related to increased human resources, logistical needs to track substances, the remodelling and redesign of old equipment as well as procurement strategies).

Many stakeholders, from MoDs and the defence industry, warned about the fact that there were not many workable alternatives to F-gases in the military sector due to standards being difficult to meet. Therefore, the recommendation encourages the gathering of knowledge on the current F-gas substances used in the defence sector, and foster efforts at the national level to provide strong incentives to defence stakeholders to pursue research and look for innovative solutions.

Recommendation implementation

Strong incentives to pursue R&D efforts should encourage the development of projects on the search for alternatives to F-gases. As mentioned earlier in section 2.7.4.3, the European Defence Fund (EDF) could represent a powerful instrument at the European level to support such projects[230].

MoDs could provide further guidance regarding the design of military equipment to encourage defence stakeholders to find innovative ways to replace F-gases in their systems while meeting military standards.

2.7.6 Recommendations for the RoHS Directive

2.7.6.1 Discuss with the Commission the possible revision of the Common Understanding paper to provide adequate guidance in relation to categories of EEE excluded from the scope of RoHS

Discuss with the Commission the possible revision of the Common Understanding paper to provide adequate guidance in relation to categories of EEE excluded from the scope of RoHS	Addressees
EDA to discuss with the Commission the possible revision of the Common Understanding paper to take better account of issues related to EEE excluded from the scope of RoHS, and to provide input, in cooperation with MoDs, to the revision of the paper, would such a revision be agreed.	EDA, with input from MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding RoHS 1 (The Common Understanding paper lacks guidance for categories of EEE excluded from the scope of RoHS).

The Common Understanding paper on the interactions between REACH and RoHS does not provide guidance on interactions between REACH Annex XIV and Annex XVII with regard to EEE that is excluded from the scope of RoHS, such as military equipment. This concerns in particular inconsistencies created by the fact that REACH authorisation and restriction requirements apply to defence equipment (unless specifically stated otherwise or unless the defence exemption is used) and the RoHS Directive does not apply to defence equipment. It was raised during the stakeholder consultation that there are also doubts regarding the interpretation of Article 58(2) of REACH to

[230] European Commission, European Defence Fund: https://ec.europa.eu/growth/sectors/defence/european-defence-fund_en (Last accessed: 08.12.2020)
European Commission > Internal Market, Industry, Entrepreneurship and SMEs > Sectors > Defence Industries > European defence fund

exempt military equipment (excluded from the scope of RoHS) from the REACH authorisation requirement, when a substance being included both in Annex XIV to REACH and Annex II to RoHS (see 2.5.2.1). The revision of the Common Understanding paper would be an opportunity to provide legal clarification on these issues. The recommendation is made to improve legal clarity as regards interactions between REACH and RoHS.

Recommendation implementation

EDA may address a request to DG GROW and DG Environment's point of contacts to open the discussion on the issues raised by the study, to request legal clarification from the Commission on those issues and discuss the possible revision of the Common Understanding paper. The opinion provided by the Commission would be discussed between EDA and MoDs, and if a revision of the Common Understanding paper was agreed with the Commission, EDA and MoDs would provide input to the revised version.

2.7.6.2 Propose to the Commission the drafting of additional guidance about the differences in concentration values between REACH and RoHS

Propose to the Commission the drafting of additional guidance about the differences in concentration values between REACH and RoHS	Addressees
Propose to the Commission that they provide additional guidance to industry on the differences in the calculation of concentration values between REACH and RoHS (weight by weight for each component in REACH vs weight in homogenous material in RoHS).	EDA, with input from MoDs and consultation with industry

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding RoHS 2**Error! Reference source not found.** (Relations b etween REACH and RoHS, including the differences in calculating concentration values, are still unclear for defence industries and their suppliers).

Some defence industries indicated that the differences in the calculation basis for concentration values (weight by weight for each component in REACH vs weight in homogenous material in RoHS) create confusion and raise questions in the supply chain (suppliers and customers). The recommendation is made to improve the clarity of requirements and legal certainty for defence industries.

Recommendation implementation

The recommendation proposes that the Commission provides additional guidance to industry on the differences in the calculation of concentration values between REACH and RoHS. It is proposed that EDA requests the Commission (DG Environment B.3 Waste Management and Secondary Materials) to create the guidance and let them suggest which type of guidance would be most appropriate (format, location on the website). Possibly, the Commission could be supported by ECHA in this task as the guidance would partially concern the REACH Regulation. The proposal could be discussed with MoDs and EDA could liaise with ASD to gather their opinion on the format, content and accessibility of the guidance on the Commission's website.

2.7.6.3 Discussion at EDA level about consequences of the RoHS Directive on availability of products and possible actions

Discussion at EDA level about consequences of the RoHS Directive on availability of products and possible actions	Addressees
MoDs to discuss at EDA level ■ Whether joint action could be useful to address issues raised in the study linked to dual use equipment/civil applications used by the defence sector ■ Whether substances recommended for inclusion in Annex II to the RoHS by the 2018 substance review (and substances under increased scrutiny) might create issues for dual use equipment/civil applications used by the defence sector, and whether joint action would be useful.	EDA, MoDs, consultation with industry

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding RoHS 3 (Because of the exclusion of defence equipment from the scope of RoHS, limited impact on the availability of equipment was reported), Finding RoHS 4 (Although defence equipment is excluded from the scope of RoHS, equipment and products – in particular COTS products – used by the defence sector are negatively impacted by RoHS), Finding RoHS 5 (The impact of future inclusion of substances on the defence sector could be significant and should be monitored).

Consultation with defence industries showed that the RoHS Directive can negatively impact the availability of equipment necessary for the defence sector, in spite of the scope exclusion, because the defence industry relies significantly on civil equipment and Commercial Off-The-Shelf (COTS) electronic components, and that those components could be affected by the inclusion of new substances in Annex II to RoHS, as recommended by the last substance review. The recommendation is made to investigate potential joint action by EDA and MoDs on those specific issues.

Recommendation implementation

EDA and MoDs could share further experience on the issues raised by the study and consider follow up actions, including:

- Evaluating the extent of the impact and investigate jointly available alternatives;
- Examining the possibility of carrying out joint R&D efforts (also at EDA level) for critical substances impacted;

2.7.6.4 Harmonisation of approach towards requiring voluntary compliance with RoHS for EEE excluded from the scope of the Directive

Harmonisation of approach towards requiring voluntary compliance with RoHS for EEE excluded from the scope of the Directive	Addressees
Discuss among MoDs the possibility to harmonise across Member States the approach towards requiring voluntary compliance with RoHS whenever possible for military equipment.	EDA, MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to section 2.6, Finding RoHS 6 (Several Member States require compliance with RoHS for defence equipment whenever possible through procurement provisions, despite defence equipment being excluded from the scope of RoHS).

Several MoDs indicated that their general approach in procurement was to require 'voluntary' compliance with the RoHS Directive, whenever possible, through procurement provisions, even for military equipment. Information requirements regarding the use of Article 2(4) vary across Member States. The recommendation is made to simplify procurement procedures for defence industries by further aligning Member States' requirements.

Recommendation implementation

MoDs could discuss the approach taken as regards requiring 'voluntary' compliance with the RoHS Directive, whenever possible, for military equipment across all EDA participating Member States and consider whether further alignment between procurement provisions is feasible. EDA would facilitate the discussion.

2.7.6.5 Raise awareness of alternatives to lead soldering and other uses of restricted substances under RoHS for which suitable alternatives exist

Raise awareness of alternatives to lead soldering and other uses of restricted substances under RoHS for which suitable alternatives exist	Addressees
Gather knowledge at EDA level on available alternatives to lead soldering and other uses of restricted substances under RoHS and prepare and disseminate documentation on those alternatives at EU and national level.	EDA, MoDs

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to section 2.6, and Finding RoHS 7 (The exclusion of defence equipment from the scope remains critical for some specific uses but may lead to the continuation of obsolete uses).

It was reported by one MoD that the exclusion from the scope slowed down the uptake of suitable alternatives – for example suitable lead-free soldering alternatives for some uses – and perpetuated obsolete uses. The recommendation is made to promote the uptake of existing alternatives to the uses of restricted substances under RoHS.

Recommendation implementation

EDA and MoDs could gather knowledge and expertise related to suitable alternatives to uses of restricted substances under RoHS – i.e., alternatives that meet military standards. Based on this exercise, EDA could publish a brochure, factsheet or other publication targeting defence industries on the Agency's website and promote this publication with the ASD. MoDs could promote this publication at national level.

2.7.7 Summary of recommendations

This section provides a summary of the recommendations on the five Regulation to EDA/MoDs with regard to their corresponding findings, and attempts at prioritising them based on their importance and impact vs. their feasibility/difficulty to implement.

Linkages between findings and recommendations

Table 31: Overview of linkages between findings and recommendations

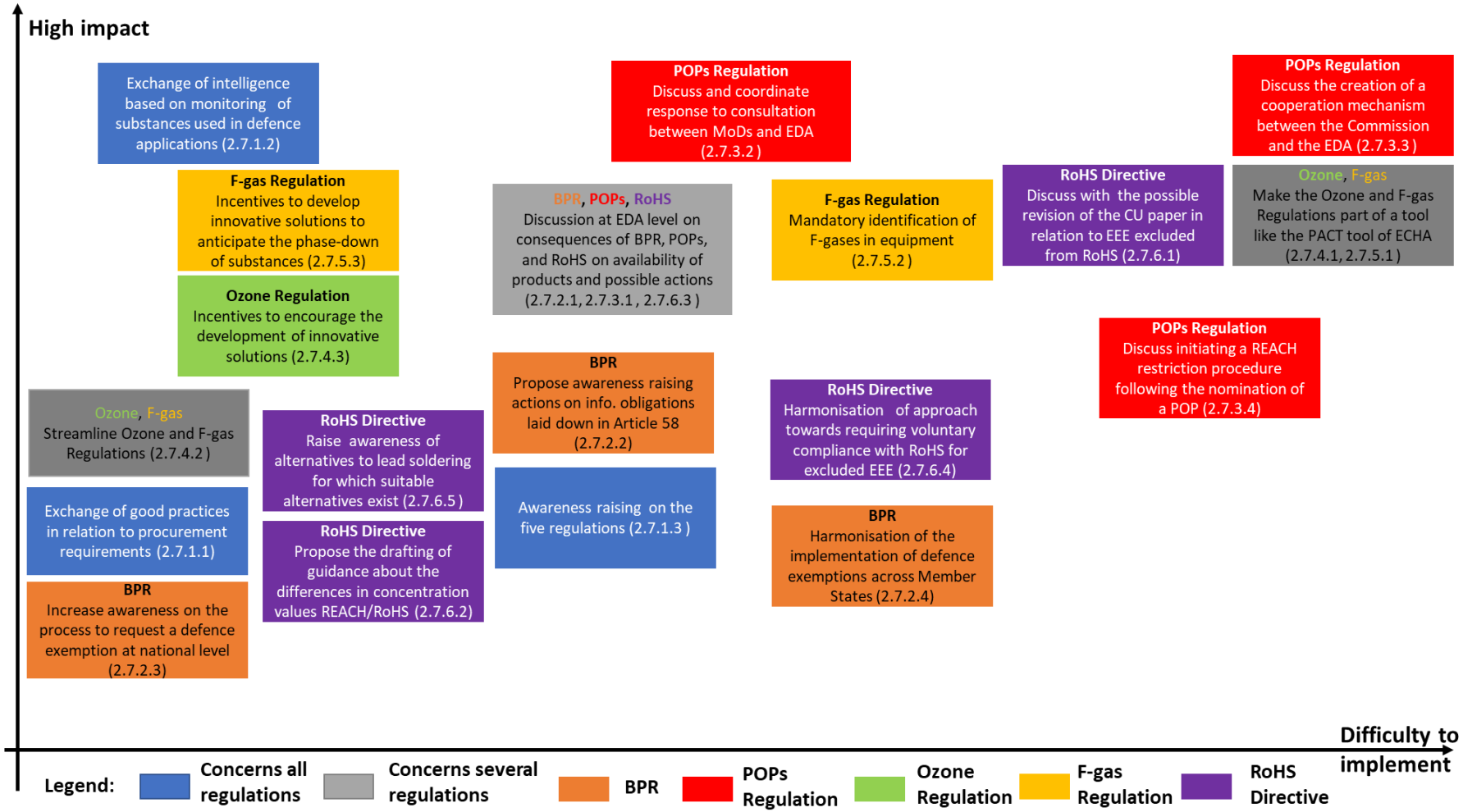
Recommendations	Corresponding findings
General recommendations	
Exchange of good practices in relation to procurement requirements	General Finding 1
Exchange of intelligence based on monitoring of substances used in defence applications	General Finding 2
Awareness raising on commonalities and differences and interactions between the different chemicals'/waste regulations	General Finding 3; Finding BPR 2;Finding BPR 3; Finding POPs 5; Finding ODS 4; Finding RoHS 2
Recommendations on the BPR	
Discussion at EDA level about consequences of BPR on availability of products and possible actions	Finding BPR 1; Finding BPR 6
Propose awareness raising actions at EU and national level on information obligations laid down in Article 58 of the BPR	Finding BPR 3
Increase awareness on the process to request a defence exemption at national level	Finding BPR 4
Harmonisation of the implementation of defence exemptions across Member States	Finding BPR 4; Finding BPR 5
Recommendations on the POPs Regulation	
Discussion at EDA level about consequences of POPs Regulation on availability of products and possible actions	Finding POPs 4
Discuss and coordinate response to public consultation between MoDs and EDA	Finding POPs 1; Finding POPs 2
Discuss with the Commission the creation of a cooperation mechanism between the Commission and the EDA in relation to substances proposed for inclusion in the Convention	Finding POPs 1
Discuss with MSCAs, where considered relevant, the possibility to initiate a restriction procedure under REACH following the nomination of a substance for inclusion in the Convention	Finding POPs 3
Recommendations on the Ozone Regulation	
Make the Ozone Regulation part of a tool like the PACT tool of ECHA	Finding ODS 1, Finding ODS 2**Finding ODS 3**
Streamline processes under Ozone and F-gas Regulations	Finding ODS 3Finding ODS 4
Provide incentives for the development of innovative solutions for alternative substances, ensure the retrofitting of equipment and reduce any potential	Finding ODS 5Finding ODS 6Finding ODS 7

Recommendations	Corresponding findings
additional costs	
Recommendations on the F-gas Regulation	
Make F-gas Regulation also part of a tool like the PACT tool of ECHA	Finding F-gas 3
Mandatory identification of F-gases in equipment and incentives to develop innovative solution to anticipate the phase-down of substances	Finding F-gas 1; Finding F-gas 3
Incentives to develop innovative solutions to anticipate the phase-down of substances and guidance	Finding F-gas 1, Finding F-gas 2
Recommendations on the RoHS Directive	
Discuss with the Commission the possible revision of the Common Understanding paper to provide adequate guidance in relation to categories of EEE excluded from the scope of RoHS	Finding RoHS 1
Propose to the Commission the drafting of additional guidance from the Commission about the differences in concentration values between REACH and RoHS	Finding RoHS 2
Discussion at EDA level about consequences of the RoHS Directive on availability of products and possible actions	Finding RoHS 3 ; Finding RoHS 4;Finding RoHS 5
Harmonisation of approach towards requiring voluntary compliance with RoHS for EEE excluded from the scope of the Directive	Finding RoHS 6
Raise awareness of alternatives to lead soldering and other uses of restricted substances under RoHS for which suitable alternatives exist	Finding RoHS 7

Prioritisation of recommendations

The priority of the recommendations was assessed according to their implementation feasibility/difficulty vs. their expected benefit (impact) for the European defence sector, as illustrated in an indicative way by Figure 6 below.

Figure 6: Priority for recommendations



3 WFD ARTICLE 9 / SCIP DATABASE

The Waste Framework Directive 2008/98/EC as revised by Directive (EU) 2018/851 (hereinafter "revised WFD" or "WFD")[231], which entered into force in July 2018, provided the ECHA with the task of establishing a database with information on articles containing Substances of Very High Concern (SVHCs) on the REACH Candidate List (WFD Article 9(2)). This database is named **'SCIP' database** which stands for **"Substances of Concern In articles, as such or in complex objects (Products)"**. EU Member States shall ensure that any supplier of an article containing such SVHC(s) in a concentration above 0.1% weight by weight (w/w) provides the information pursuant to Article 33(1) of REACH to ECHA from 5 January 2021 (WFD Article 9(1)(i)) – so-called **"SCIP notification"**. The SCIP database aims to ensure that the information about the presence of SVHCs is available throughout the whole lifecycle of products and materials, including at the waste stage.

This Chapter contains an analysis – by way of stock-taking and elaboration of the overall issue – of the implementation of the new Article 9 of the revised WFD on SCIP notification and database, assesses the potential impacts[232] on defence sector stakeholders (MoDs and defence industry) and provides recommendations to mitigate these impacts. The implementation analysis covers both EU (Commission and ECHA) and national governmental (Member State) level. EU level representatives of the recycling industry and SMEs were also consulted specifically on SCIP.

> **Note**: The impact of the ECHA final SCIP information requirements (published in late October 2020) and its principles on dissemination and confidentiality in the SCIP database (published in July 2020), on defence-related cases could not be elaborated in detail as part of the present study, based on the input from the (earlier) stakeholder consultation. EDA together with the MoDs and possible support of the defence industry could further assess the impacts of these principles for defence-related cases in the future, following the entry into application of the notification duty as from 5 January 2021, including but not limited to potential security risks for MoDs and defence industry impacts.

3.1 EU LEGAL PROVISIONS ON SCIP

The new provisions on SCIP notification and database are set out in Article 9(1)(i) and (2) of the revised WFD. Furthermore, WFD Article 9(1)(i) contains two essential links to the REACH Regulation.

3.1.1 Revised Waste Framework Directive (WFD)

The revised WFD provides in its Article 9 titled *'Prevention of waste'*:

'1. Member States shall take measures to prevent waste generation. Those measures shall, at least:

[…]

(i) promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level, and ensure that any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council [the REACH Regulation] *provides*

[231] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste, OJ L 150, 14.6.2018, p. 109-140. The revised WFD entered into force in July 2018. The current consolidated version of 5 July 2018 of Directive 2008/98/EC is available at https://eur-lex.europa.eu/eli/dir/2008/98/2018-07-05.

[232] The impact analysis focuses on the additional burden from the SCIP requirements compared with existing obligations, such as REACH Articles 7(2) and 33.

the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021;[233]

[…]

2. The European Chemicals Agency shall establish a database for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2020 and maintain it. The European Chemicals Agency shall provide access to that database to waste treatment operators. It shall also provide access to that database to consumers upon request.'[234]

Recital (38) of Directive (EU) 2018/851 describes the **rationale** of these provisions as follows:

'When products, materials and substances become waste, the presence of hazardous substances may render that waste unsuitable for recycling or the production of secondary raw materials of high quality. Therefore, in line with the 7th Environment Action Programme, which calls for the development of non-toxic material cycles, it is necessary to promote measures to reduce the content of hazardous substances in materials and products, including recycled materials, and to ensure that sufficient information about the presence of hazardous substances and especially substances of very high concern is communicated throughout the whole life cycle of products and materials. In order to achieve those objectives, it is necessary to improve the coherence among the law of the Union on waste, on chemicals and on products and to provide a role for the European Chemicals Agency to ensure that the information about the presence of substances of very high concern is available throughout the whole life cycle of products and materials, including at the waste stage.'

Thus, this new notification duty foreseen under WFD Article 9 complements the existing information obligations under REACH Article 33(1) and REACH Article 7(2), **with special regard to the waste stage**.

Directive (EU) 2018/851 foresees three **implementation milestones** for WFD Article 9/SCIP database, the first addressed to ECHA, the second to EU Member States and the third to EU article suppliers:

1. by 5 January 2020: ECHA to establish the SCIP database;
2. by 5 July 2020: EU Member States to transpose the revised WFD (including its Article 9(1)(i) on SCIP notification) into their national laws [235];
3. as from 5 January 2021: The date of entry into application of the SCIP notification duty, subject to national transposition, for any EU supplier of an article containing a Candidate List substance in a concentration above 0.1% w/w.

3.1.2 REACH Regulation

Article 9(1)(i) of the revised WFD makes reference to two provisions in the REACH Regulation for the definition of the duty holder ('supplier of an article as defined in point 33 of Article 3') and the information to be provided to ECHA ('the information pursuant to Article 33(1)'):

- 'supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market' (REACH Article 33 point 33);
- 'any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow

[233] So-called SCIP notification.
[234] So-called SCIP database.
[235] Article 2(1) of Directive (EU) 2018/851.

safe use of the article including, as a minimum, the name of that substance' (REACH Article 33(1)). Hence, the substance scope is limited to SVHCs included in the REACH Candidate List[236].

3.2 IMPLEMENTATION AT EU LEVEL

This Section outlines the implementation of WFD Article 9/SCIP database by ECHA – based on the available guidance/views of the European Commission[237] – with regard to the main elements of interest to defence. The Commission views (DG ENV) are mainly reflected in its 'non-paper on the implementation of articles 9(1)(i) and 9(2) of the revised Waste Framework Directive 2008/98/EC'[238]. The non-paper relies on legislation (see Section 3.1) and case law (judgment of the CJEU of 10 September 2015 in case C-106/14) for the minimum information requirements outlined in it. ECHA relies on these Commission views for the implementation of SCIP notification, database requirements and tools. Besides the non-paper, ECHA also referred to its guidance on substances in articles[239] and took into account the contributions received from various bodies/stakeholders such as the European Commission, Member States (Waste expert group and CARACAL), trade and industry associations/companies and NGOs through various channels.

3.2.1 Objectives and implementation milestones

The three main objectives of the SCIP database to support the circular economy policy are the following, according to ECHA[240] :

- decrease the generation of waste containing hazardous substances by supporting the **substitution** of substances of concern in articles placed on the EU market[241];
- make information available to further **improve waste treatment operations**;
- **allow authorities to monitor** the use of substances of concern in articles and initiate appropriate actions over the whole lifecycle of articles, including at their waste stage.

The development of the SCIP database and related submission tools by ECHA has followed a stepwise approach. According to the revised WFD, ECHA had to establish the SCIP database by 5 January 2020 (see Section 3.1.1 above). In October 2019, ECHA had set up a "SCIP IT User Group" with broad industry participation, to help develop the database and related submission tools[242]. On 17 February 2020 ECHA published a SCIP database 'prototype' for testing purposes by potential duty holders[243]. The final database (SCIP v1.0) enabling the submission of SCIP notifications to fulfil legal obligations was launched on 28 October 2020, i.e., about two months in advance of the entry into application date of the legal SCIP notification duty[244]. Within the first month after the launch ECHA has received over 50 000 notifications[245].

The SCIP database is connected to the Circular Economy Action Plan and the Chemicals Strategy for

[236] The Candidate List is available at https://echa.europa.eu/candidate-list-table.
[237] Commission and ECHA views are not presented separately in this Section unless they differ. In principle their views are understood to be aligned.
[238] EC (2019, June 20).
[239] ECHA (June 2017). This Guidance on requirements for substances in articles covers the application of REACH Articles 7 and 33. It was developed by including a consultation of the Partner Expert Group (PEG) selected from ECHA's accredited stakeholders, the Enforcement Forum and CARACAL.
[240] ECHA, Q&A ID 1605 of 9 September 2019 (with further detail), https://echa.europa.eu (last viewed 11 November 2020).
[241] Note: Only Candidate List substances are in the legal scope of WFD Article 9(1)(i), see already above Section 3.
[242] The materials from the SCIP IT user group meetings are published at https://echa.europa.eu/scip-it-user-group.
[243] https://echa.europa.eu/-/substances-of-concern-in-products-database-try-out-the-prototy-1
[244] https://echa.europa.eu/-/tracking-chemicals-of-concern-in-products-scip-database-ready-for-use
[245] https://echa.europa.eu/documents/10162/30160741/scip_database_news_20201202_en.pdf

Sustainability (CSS). The CSS foresees actions on non-toxic material cycles to minimise the presence of substances of concern[246] in products and to ensure availability of information on chemical content and safe use, by introducing information requirements in the context of the Sustainable Product Policy Initiative and tracking the presence of substances of concern through the life cycle of materials and products, notably building on ECHA's SCIP database (among others)[247]. The main legislative proposal on Sustainable Products is planned for the end of 2021 (indicative timing)[248].

3.2.2 Duty holders for SCIP notification

As already mentioned (Section 3.1), SCIP notification applies to 'any supplier of an article as defined in point 33 of REACH Article 3', i.e. 'any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market'. This could potentially cover any imported article into the EU, because REACH Article 3 point 12 Sentence 2 states: 'Import shall be deemed to be placing on the market' [249]. This also implies that **"importers"** of articles for own (final) use, - i.e. where the article is not supplied further by the importer – would be covered by the obligation. Such extensive interpretation raises several concerns relating to the application of the notification obligations:

- It creates new SCIP duty holders beyond the scope of REACH Article 33(1), because there is no EU supply chain in such cases - REACH Article 33(1) does not apply;
- It raises legal concerns with regard to the definition of 'supplier of an article' in REACH Article 3 point 33[250] and the coherence between SCIP and REACH Article 33(1);
- SCIP notification would be due by the time of "import" from outside the EU rather than the supply by the EU article supplier to the EU recipient (as the trigger for the REACH Article 33(1) duty);
- It may also lead to different national interpretations of "placing on the market", and hence different SCIP duty holder definitions, thus challenging the EU level playing field for industry. As an example, the national provision in Sweden transposing SCIP notification seems to restrict placing on the market to supply **to someone else**, thus deviating from REACH Article 3 point 12 Sentence 2[251].

Given the potential relevance to defence (among other sectors), the contractor has therefore raised the question of 'import' for own (final) use with the Commission (as advised by ECHA) and also Member States during the study[252]; while Member States did not comment, at the time of the

[246] 'Substances of concern' include, in the context of the CSS and related actions, primarily those related to circular economy, substances which have a chronic effect on human health or the environment (Candidate List in REACH and Annex VI to the CLP Regulation) but also those which hamper recycling for safe and high quality secondary raw materials. Note that the legal scope of SCIP is currently limited to SVHCs included in the REACH Candidate List, according to WFD Article 9(1)(i).

[247] EC (2020, October 14), Communication, page 6.

[248] EC (2020, October 14), Annex, page 1.

[249] ECHA (October 2020), Section 1.2; ECHA, answer to REACHLaw of 5 June 2020, ref. No INC000000305762; in its answer, ECHA makes reference "for definitive guidance" to Q&A ID 1607 of 10 July 2020, https://echa.europa.eu; Q&A ID 1609 of 30 January 2020, https://echa.europa.eu (last viewed 5 October 2020)..

[250] REACH Article 3 point 33 refers to 'importer of an article […] *placing an article on the market*'. An interpretation covering all imports regardless of onward supply would make the *latter part of the definition* redundant and seems to run counter to the common meaning of a 'supplier', who provides something to someone else.

[251] § 2 of KIFS 2020:6 refers to § 2 of the Regulation (2008: 245) on chemical products and biotechnological organisms, which defines 'placing on the market' as "providing or making available to someone else" (*"Släppa ut på marknaden: tillhandahålla eller göra tillgänglig för någon annan"*), see https://www.riksdagen.se.

[252] Joint meeting of the Waste and CARACAL Expert Groups, 9 July 2020; submission by the contractor titled 'Applicability of SCIP notification to 'import' for own (final) use', 30 June 2020, ref. RL_20.ISE.OP.020_CAJM_09072020.

submission of this report an answer from the Commission is still under development/expected.[253]

While the Commission's clarification is pending on this issue (also at the request of ECHA), ECHA has no authority to exclude importers of articles for own use and therefore advises such actors to submit SCIP notifications.

Non-EU suppliers of articles to the EU market are not duty holders for SCIP notification. Hence, they need to provide the information required for SCIP notification to the EU importers as the primary duty holders. However, ECHA has introduced a '**foreign user**' concept, that allows third parties – such as non-EU companies – to submit SCIP notifications on behalf of the duty holder, i.e. the EU importer. Nevertheless, the latter remains legally responsible for the SCIP notification in this case[254].

3.2.3 Information requirements

According to the non-paper of the Commission (DG ENV)[255], the information made available to the waste treatment operators via the database '*has to be useful for the waste treatment phase of the article's lifecycle and enable the identification and effective treatment of waste containing SVHC* […]'. Therefore, the Commission non-paper suggests that a wider scope[256] of information relating to the identification of the article and the SVHC (name, concentration range and location) has to be communicated by the duty holder to ECHA, to comply with the SCIP notification requirements.

ECHA has implemented this approach in its document titled ***'Requirements for SCIP Notifications'***[257]. Each information requirement is classified as either:

- **'mandatory'**: data must be provided, because it is legally and/or technically necessary; if data is not provided for the requirement, the submission of the notification fails and the obligation is not fulfilled;
- **'required'**: it requires an input to be provided, for example by selecting among options in a drop-down list or by checking a box; however, it can be fulfilled without providing data; not providing the input by making that selection or checking fails the submission of the notification for technical reasons;
- **'optional'**: the data may only be provided optionally but its submission is encouraged; the submission of the notification is successful even if data is not provided.

The following table provides a brief overview of the data for SCIP notifications together with their classification; for the complete presentation reference is made to Section 2 of the aforementioned ECHA document.

[253] With e-mail of 5 October 2020 the Commission informed the contractor that input from EC legal services related to the "import for own use" aspect is still awaited.
[254] See also Section 3.3.1.1 below regarding the additional possibility for non-EU article suppliers to appoint an Only Representative (REACH Article 8) in the Swedish national law transposing the revised WFD.
[255] EC (2019, June 20), page 1.
[256] In comparison with REACH Article 33(1), where communicating only the name of the SVHC may be sufficient.
[257] ECHA (October 2020). It replaces the document 'Detailed information requirements for the SCIP database' of September 2019.

Table 32 SCIP information requirements in a nutshell

Category	SCIP information requirement	Classification
Common requirements for both articles as such and complex objects	**Name of the article** (article as such or complex object)	Mandatory
	Other name(s), e.g. brand, model	Optional
	Primary Article Identifier	Mandatory
	Other article identifier(s)	Optional
	Article category (based on CN/TARIC codes and descriptions on function/use)	Mandatory
	Production in the European Union	Required*
	Characteristics and picture(s)	Optional
	Safe use instruction(s), if necessary	Required*
	Disassembling instructions	Optional
Additional requirements for complex objects only	**Complex object components, if applicable** (see Section 3.2.4 below for more details)	Mandatory
	Number of units of concerned complex object components	Optional*
Additional requirements for articles as such only (concern elements)	**Candidate List (CL) substance** (name; EC and CAS no., if available)	Mandatory
	CL substance concentration range, incl. > 0.1% w/w and ≤ 100% w/w	Required*
	Material category for the article containing the CL substance **and/or Mixture category (EuPCS)** containing the CL substance in article	Mandatory
	Additional material characteristics	Optional
	CL substance no longer present (indicate as part of voluntary update)	Optional
*This information requirement was previously classified as « mandatory », as then defined in the previous ECHA 'Detailed information requirements for the SCIP database of September 2019. Additionally, in that document, the « Candidate List version » was still a « mandatory » information requirement in the « concern element » but has now been removed.		

As some of these information requirements for SCIP, such as mandatory category information and information on complex object components, are not specified in REACH Article 33(1) being the provision referred to in WFD Article 9(1)(i), they could potentially be interpreted as going beyond the WFD/REACH legal text[258]. Therefore, they raise some legal concerns[259].

ECHA on the other hand stresses that it has kept the constraints that would fail a SCIP notification submission to a minimum, thus providing a lot of discretion – with increased **responsibility** associated with it – for the **duty holders** on how to report data to the SCIP database. ECHA highlights that the responsibility for the quality, accuracy, completeness and robustness of the submitted data always remains with each duty holder; to support duty holders, ECHA has provided some recommendations on the appropriate level of structuring and submitting data[260].

3.2.4 Level of reporting for (very) complex objects

According to ECHA – in cases of complex objects – the information on article identifiers and categorisation shall be mandatory not only for the complex objects supplied, but also for relevant complex object components, until the 'article as such' containing the Candidate List substance in a concentration above 0.1% w/w is identified; resulting in a product breakdown structure to locate the

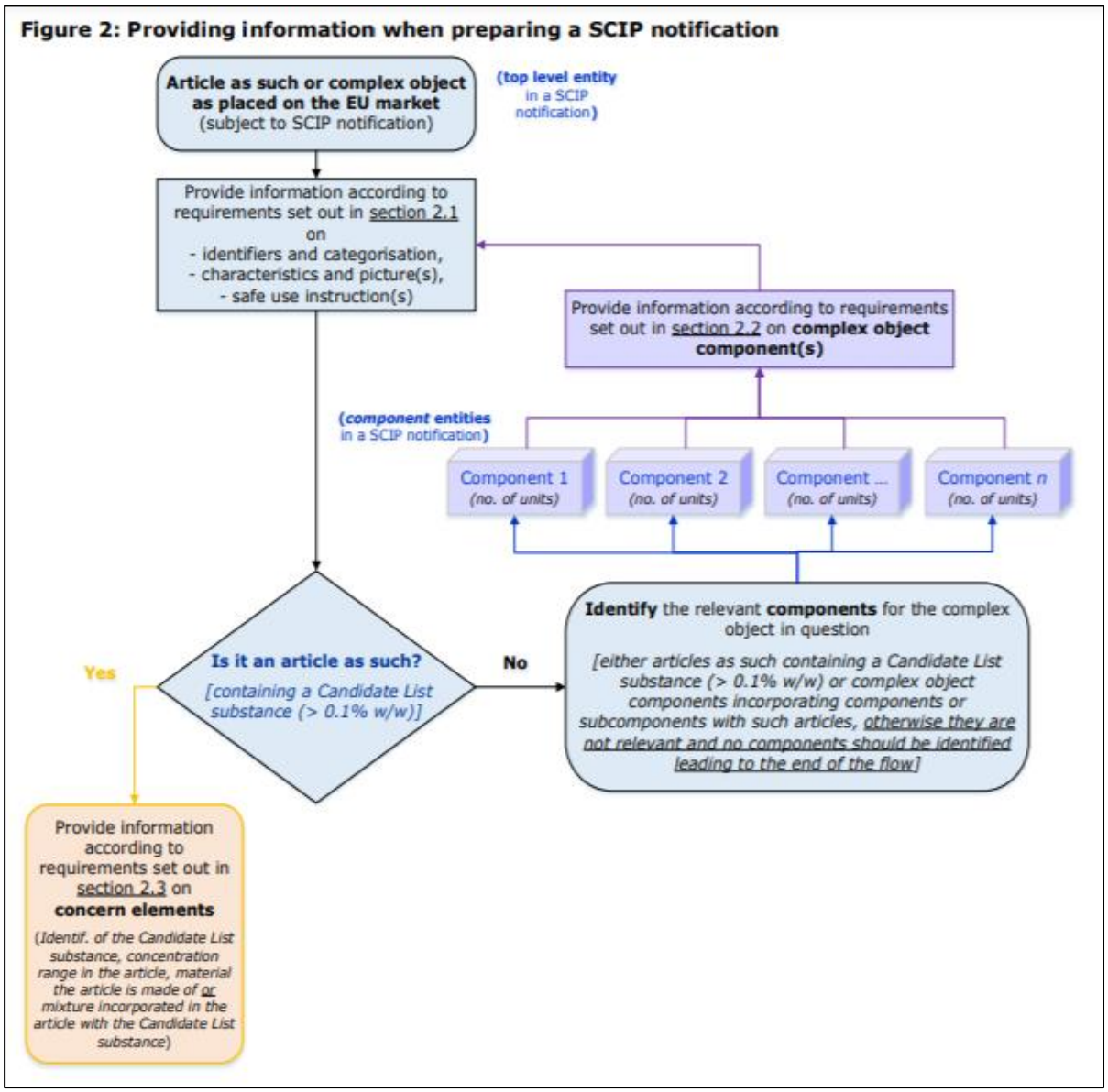
[258] REACH Article 33 provides that the only name of the Candidate List substance needs to be provided "as a minimum". For this reason the CJEU (2015) in case C-106/14 has held (par. 81): *"That requirement, which is minimal in nature, cannot be regarded as being an excessive burden."*

[259] See e.g. Becker T. (2019).

[260] ECHA (October 2020), in particular Section 2.4 and Section 3.

SVHC(s) (see Figure 7[261]). To justify this broad interpretation, ECHA refers to its (updated) Guidance on requirements for substances in articles of June 2017[262], which addresses the judgment of the CJEU of 10 September 2015 in case C-106/14[263].

Figure 7: ECHA view of component-level reporting for complex objects under SCIP



The 'level of reporting' issue according to ECHA[264] addresses the questions of ***'grouping'*** (whether identical or quasi-identical articles as such and complex objects (products)/units can be included in a single SCIP notification) and ***'hierarchy'*** (i.e., how many layers of components and subcomponents of a complex object have to be reported in a SCIP notification in order to allow the identification and ***'location'*** of the article containing the Candidate List substance). On 'hierarchy' ECHA recommends

[261] ECHA (October 2020), page 14, 'Figure 2: Providing information when preparing a SCIP notification'.
[262] ECHA (2017).
[263] CJEU (2015).
[264] ECHA (October 2020), Section 3.

following the components placed on the market and incorporated in complex objects **at each assembling stage** through their respective name and article category (CN/TARIC code and description). According to ECHA[265], for most common products, two to five layers are sufficient, while for the most complex ones no more than seven would be appropriate.

Additionally, more far-reaching 'grouping' approaches have been considered, especially the 'representative article approach' for extremely complex objects (e.g., airplanes). Following this approach, articles in complex objects with different Candidate List substances in their composition are reported in the SCIP notification under a generic identification for those complex objects. While this approach is not recommended by ECHA due to legal and other concerns, its acceptance (at least temporarily) is left for the Member State competent authorities[266]. Hence, it could be used by companies as interim solution and at their own risk.

Based on the first notifications after launch of the SCIP database on 28 October 2020, ECHA noted that some companies submit dossiers of disproportionate size. ECHA therefore recommends including a **maximum of 1 000 components within one dossier**, as bigger dossiers will be very complex to understand for waste operators and consumers[267].

3.2.5 SCIP notification format and submission tools

ECHA has established a harmonised SCIP format compatible with IUCLID for preparing SCIP notifications[268]. The submission of data should be done in the ECHA Submission Portal[269]. Notifications may be done either manually or in an automated way, using a System-to-System (S2S) service.

In order to ensure a harmonised transposition of the SCIP requirements according to ECHA's tools, ECHA has recommended the following wording to Member States for the transposition of Article 9(1)(i) of the revised WFD[270]:

'Any supplier of an article as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council shall provide the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021 using the format(s) and submission tool(s) provided by this Agency for that purpose.'

More specifically, ECHA has encouraged the REACH and Waste authorities to ensure a **harmonised transposition** of Article 9 of the WFD into national law, taking into consideration the clarifications provided in the Commission non-paper and the information requirements as set forth by ECHA. According to ECHA, any deviations will not be able to be accommodated technically by the ECHA systems and would also distort the level playing field for industry across the EU.

Therefore, if a company does not submit a SCIP notification according to the SCIP format, no proof of submission is issued by ECHA.

As an option for complex object components – instead of providing the full SCIP dataset for those – ECHA has developed the concept of ***'referencing'*** where the producer of a complex object incorporating these components may insert a **SCIP number** for the component when notifying the complex object. This SCIP number – generated by ECHA – is to be provided in the supply chain by the

[265] https://echa.europa.eu/documents/10162/30160741/scip_database_news_20201202_en.pdf
[266] ECHA (October 2020), Section 3.1.5 and Appendix 2.
[267] https://echa.europa.eu/documents/10162/30160741/scip_database_news_20201202_en.pdf
[268] https://echa.europa.eu/scip-format.
[269] ECHA (2020, October 28).
[270] Latest: ECHA (2020, April 16), Chapter 6 'Member State transposition'.

component supplier who has already made the SCIP notification to ECHA[271]. ECHA also recommends 'referencing' – if necessary – to split up big dossiers by notifying the larger components separately (e.g., engine, seats, battery) and then reference them in the top-level complex object (e.g., car)[272].

Another option to refer to SCIP data already submitted to ECHA is the so-called ***'Simplified SCIP Notification (SSN)'*** for the same product, in particular where distributors are involved in the supply chain; in case of a SSN no IUCLID dossier needs to be prepared by the duty holder, but only the relevant SCIP number needs to be shared and submitted[273].

3.2.6 Public access and confidentiality protection

Going beyond Article 9(2) of the revised WFD[274], ECHA is planning to publish the data submitted to the SCIP database, precisely as received, on its website (online access)[275]. This means that the data will be accessible to everybody worldwide. The dissemination solution will be gradually developed and rolled out as data become available from 2021 onwards; the release of version 1 of the SCIP Dissemination Portal is planned for February 2021.

Also, it is currently **not possible to delete** a SCIP notification once submitted. However, it is understood that this possibility is in ECHA's backlog for future improvements[276]. It is also possible to update a notification after submission.

However, there are some limited exceptions to protect confidential information where justified, in particular regarding data that allow links to be established between actors in the same supply chain. Hence, the following data from SCIP notifications shall not be disclosed by ECHA on its dissemination website:

- identity of the submitters (duty holder),
- specific names (e.g. brand, model) or identifiers of complex object components,
- SCIP numbers used for SSN or 'referencing'.

Regarding complex object components and subcomponents this means that only the name and the article category – harmonised description based on function and use by using the CN/TARIC codes – will be publicly available, as well as safe use instructions, disassembling instructions and characteristics (if notified).

For information to be disseminated, according to ECHA it is for the submitter to ensure the quality, accuracy, completeness and robustness of the submitted data and that no confidential information (e.g., detailed product composition) is transmitted as part of SCIP notifications.

[271] ECHA (August 2020), page 17 et seqq. for more details.
[272] https://echa.europa.eu/documents/10162/30160741/scip_database_news_20201202_en.pdf.
[273] ECHA (August 2020), page 7 et seqq. for more details.
[274] Article 9(2) WFD only requires "access to waste treatment operators" and "to consumers upon request".
[275] ECHA (July 2020); ECHA (2020, June 25); including for the following details on dissemination and confidentiality protection in this Section.
[276] ECHA, 'Get ready to submit your SCIP notification', webinar on 19 November 2020; questions and answers available at https://app.sli.do/event/ixsfeh1g/live/questions (last viewed 4 December 2020).

Example: Satellites, including military ones, are extremely complex objects and highly customised for a given mission. Providing a product breakdown when reporting at "single product unit" level[277] could disclose information that knowledgeable people could use to determine what the satellite is going to do and for whom, therefore compromising National Security. According to ECHA, it is within the responsibility of each individual Member State to allow (or not) 'grouping' according to more far-reaching 'grouping' approaches in exceptional and justified cases, mentioning satellites and airplanes as examples, among others[278].

In response to the study consultation, ECHA highlighted that the SCIP information requirements already include some measures to avoid the submission of information that could undermine the protection of confidentiality interests, for example **no details are requested concerning the chemical composition of articles**, it is only required to identify the main material that an article is made of ('material category') or the category of the mixture incorporated in articles in a further processing step of the article ('mixture category') and the Candidate List substance present in the article, as well as its concentration range in the article. Another example is the requirement to identify the function or use of the article ('article category') based on the CN/TARIC codes and descriptions which **do not require the submission of a precise function, use or application of the article** or complex object. ECHA also expects that due to the relatively low number of articles in a complex object containing Candidate List substances in a concentration above 0.1% w/w compared to the total number of articles incorporated in that complex object, **only a small part of the whole structure of a complex object needs to be provided** in a SCIP notification through the hierarchy of components and subcomponents.

With regard to Member State enforcement ECHA has clarified[279] that there are currently no plans (yet) to develop a specific data portal for authorities, nor integration with the ECHA Interact portal[280]. Authorities will have the same public access to the SCIP data as all other users. If specific confidential data are required (e.g. name of data submitter or data to identify linked articles inside a complex object) a specific request will have to be made to ECHA, which can consider such a request.

There is no provision in the revised WFD that would address the specific interest of defence or wider security, which could be affected by SCIP notifications and database disclosure. However, based on the non-paper of the Commission (DG ENV) ECHA has clarified for the implementation of WFD Article 9(1)(i) in the Member States[281]:

'Where necessary, in the interests of defence, Member States may allow for exemptions from the REACH Regulation in specific cases for certain substances on their own, in a mixture or in an article (Article 2(3) of the REACH Regulation). Therefore, in case a Member State considers that the reporting obligations are detrimental to its national interests in the area of defence, then a Member State may choose to invoke this article[282] to provide a specific exemption from the obligation of Article 33(1) of REACH, and to Article 9(1)(i) of the WFD respectively. Furthermore, Member States are not obliged to supply information the disclosure of which they consider to be contrary to the essential interests of its security (Article 346 TFEU[283]).'

[277] See ECHA (October 2020), Section 3.1.4, page 45.
[278] ECHA, ibid., Section 3.1.5, pages 45/46; see also Section 3.4.2.7 of this report.
[279] ECHA (2020, April 16).
[280] ECHA Interact is the central portal that supports Member States, Committees and working groups of ECHA in their tasks related to the REACH process, https://echa.europa.eu/interact.
[281] ECHA (October 2020), Section 1.3, page 8; Q&A ID 1608 of 15 October 2020, https://echa.europa.eu (last viewed 7 November 2020); EC (2019, June 20).
[282] I.e. REACH Article 2(3).
[283] Treaty on the Functioning of the European Union.

For completeness, Article 346 TFEU reads as follows[284]:

'1. The provisions of the Treaties shall not preclude the application of the following rules:

(a) no Member State shall be obliged to supply information the disclosure of which it considers contrary to the essential interests of its security;

(b) any Member State may take such measures as it considers necessary for the protection of the essential interests of its security which are connected with the production of or trade in arms, munitions and war material; such measures shall not adversely affect the conditions of competition in the internal market regarding products which are not intended for specifically military purposes.

2. The Council may, acting unanimously on a proposal from the Commission, make changes to the list, which it drew up on 15 April 1958, of the products to which the provisions of paragraph 1(b) apply.'

3.2.7 Summary

According to ECHA, SCIP notification and database aim to support the circular economy policy by promoting substitution of substances of concern, making information available to further improve waste treatment operations and allow better monitoring for authorities on substances of concern in articles. The SCIP database is connected to the Circular Economy Action Plan and the Chemicals Strategy for Sustainability of 14 October 2020, with possible further evolutions in the frame of the upcoming Sustainable Product Policy Initiative.

The development of the SCIP database and related submission tools by ECHA has followed a stepwise approach. The final database (SCIP v1.0) enabling the submission of SCIP notifications to fulfil legal obligations was launched on 28 October 2020, i.e., about 2 months in advance of the entry into application date of the legal SCIP notification duty.

Based on the European Commission (DG ENV) non-paper on WFD Article 9(1)(i) and (2), ECHA has developed extensive SCIP requirements which could potentially be interpreted as going beyond the legal text of WFD Article 9(1)(i) and (2) and the linked communication obligation in REACH Article 33(1) in several aspects:

- SCIP notification should apply to '*any [EU] supplier of an article as defined in point 33 of REACH Article 3'*. This could potentially cover importers of articles for own (final) use, i.e., where the article is not supplied further by the importer. Such interpretation raises a number of concerns relating to the application of the notification obligations; the requested Commission clarification is still pending;
- Some SCIP information requirements, such as mandatory category information and information on complex object components, are not specified in REACH Article 33(1) being the provision referred to in WFD Article 9(1)(i);

[284] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12016E346. Note: Even though the Commission in its non-paper makes reference to the whole Article 346 TFEU, the clause '*Member States are not obliged to supply information the disclosure of which they consider to be contrary to the essential interests of its security'* refers specifically to what is mentioned in Article 346***(1)(a)*** TFEU. This is particularly relevant for dual use. The Commission's Interpretative Communication on the application of Article 296 of the Treaty (now Article 346 TFEU) in the field of defence procurement, COM(2006) 779 final/7 December 2006 (EC. (2006)), clarifies its view that: '*In contrast to Article 296(1)(b), Article 296(1)(a) TEC can also cover the procurement of dual-use equipment for both military and non-military security purposes, if the application of Community rules would oblige a Member State to disclose information prejudicial to the essential interests of its security.'* This suggests that Article 346(1)(a) TFEU may be applicable to dual use, while Article 346(1)(b) TFEU is not (it is applicable only for military use/equipment, and especially linked to Council Decision/list of 255/58 of 15 April 1958).

- According to ECHA – in case of complex objects – the information on article identifiers and categorisation shall be mandatory not only for the complex objects supplied, but also for relevant complex object components, until the 'article as such' containing the Candidate List substance in a concentration above 0.1% w/w is identified; resulting in a product breakdown structure to locate the SVHC(s);
- ECHA insists that its harmonised SCIP formats and submission tools have to be used, and recommended to the Member States to make their use mandatory. According to ECHA, any deviations will not be able to be accommodated technically by the ECHA systems and would also distort the level playing field for industry across the EU. Therefore, if a company does not submit a SCIP notification according to the SCIP format, no proof of submission is issued by ECHA;
- Going beyond WFD Article 9(2), ECHA is planning to publish the data submitted to the SCIP database, precisely as received, on its website (online access). There are some limited exceptions to protect confidential information (duty holder names are not published, nor identifiers of complex object components other than their name and article category). ECHA also highlights that the data required are rather generic (categories) and are expected to concern only a small part of the whole structure of a complex object.

ECHA stresses that it has kept the constraints that would fail a SCIP notification submission to a minimum, thus providing a lot of discretion – with increased responsibility associated with it – for the duty holders on how to report data to the SCIP database. ECHA highlights that the responsibility for the quality, accuracy, completeness and robustness of the submitted data always remains with each duty holder; in order to support duty holders, ECHA has also provided some recommendations on the appropriate level of structuring and submitting data.

There is no provision in the revised WFD that would address the specific interest of defence or wider security, which could be affected by SCIP notifications and database disclosure. However, the Commission (DG ENV) has clarified that a Member State may provide a specific exemption with regard to REACH Article 2(3) or have recourse to Article 346(1)(a) TFEU ('essential interests of its security').

3.3 IMPLEMENTATION AT NATIONAL (GOVERNMENTAL) LEVEL

This Section elaborates on the implementation of WFD Article 9 on SCIP notification and database at national (governmental) level, especially in relation to potential links to defence-related considerations (Section 3.3.1). Furthermore, it summarises and reflects on the potential impacts on MoDs as reported during the study consultation (Section 3.3.2).

3.3.1 Analysis of national provisions

The transposition of Article 9(1)(i) WFD on SCIP notification is still pending in a number of EDA participating Member States, in spite of the expiry of the transposition deadline on 5 July 2020. The transposition is the responsibility of the Member States[285], and the transposition process is being followed closely by the European Commission.

Annex VIII 'SCIP Transposition Mapping' enclosed with this report provides a high-level overview of the WFD/SCIP transposition status in the EDA participating Member States[286]; for Member States

[285] See also ECHA (October 2020), Section 3.1.5 'Responsibilities of Member States: transposition of WFD Article 9(1)(i) and enforcement'.

[286] See also https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32018L0851 on the national transposition measures communicated by the Member States concerning Directive (EU) 2018/851.

consulted as part of this study, the relevant national SCIP clauses (final or draft) are also reflected in that Annex (if available), both in their native language and unofficial translation into English.

The following analysis covers the general (not defence specific) provisions transposing WFD Article 9(1)(i) and then – more in detail – the defence-specific provisions (SCIP defence exemptions) and their way of working.

3.3.1.1 General provisions transposing WFD Article 9(1)(i)

The available general (not defence specific) provisions transposing WFD Article 9(1)(i) have the reference to REACH Article 33(1) for the scope of SCIP notification in common. However, the provisions differ to some extent, especially in the branch of national law where they are included, as regards whether or not they make a reference to the SCIP database, related ECHA formats and submission tools, and in their further level of detail:

- The transposition is foreseen either in the national legislation on chemicals or waste law; this reflects the nature of the SCIP provisions at the interface of these different related policy fields;
- A literal transposition of the Directive text in WFD Article 9(1)(i) on SCIP notification is initially foreseen/proposed in a number of Member States (e.g., FR, NL, RO, arguably also DE). Going beyond literal transposition, the use of ECHA's SCIP format/content/submission tools is explicitly required by a number of Member States (e.g., ES, IT, SE), thus following the ECHA recommendation (see Section 3.2.5). Delegated powers to make more detailed provisions on SCIP implementation in the future, e.g., by ordinance or ministerial regulation, are foreseen/proposed, e.g., in DE, FR, IT and NL, thus leaving flexibility for future SCIP implementation;
- Additional provisions on the definition of 'placing on the market' (deviating from REACH Article 3 point 12) and the possibility for non-EU companies to notify through an appointed Only Representative have been introduced in SE[287].

Not much is known today on national **sanction** provisions for non-compliance with SCIP or related enforcement plans in the Member States.

> **Note**: As already mentioned at the beginning of this Chapter, this study contains an analysis – by way of stock-taking and elaboration of the overall issue – of the implementation of the new Article 9 of the revised WFD on SCIP notification and database at EU and national (governmental) level. The focus is on *defence-related* considerations (see also Section 3.3.1.2 below). The further (legal) analysis of validity and consequences of these different *general* national provisions transposing WFD Article 9(1)(i)/SCIP (such as potential notifications outside the ECHA SCIP notification format and submission tools) as well as their compliance with the WFD/other EU/national laws is not within the scope of this study. All these provisions have only been adopted during the course of this study or adoption is still pending/transposition to be completed. The same applies to the defence-related provisions discussed in Section 3.3.1.2 below.

3.3.1.2 SCIP defence exemptions and their way of working

Specifically in relation to defence, a number of participating Member States, for which information is

[287] § 2 and § 5 of KIFS 2020:6, available at https://www.kemi.se/download/18.164ad6b3172927a92892c38f/1594644296486/kifs-2020-6.pdf.

available, foresee specific provisions to the end that a SCIP notification is or may not be required with view to defence-related considerations (e.g. in DE, ES, FR, SE), while others refer to the REACH defence exemption process already in place (e.g. RO). However, these specific provisions are drafted in a different way, especially with regard to the need for Member State involvement to be freed from SCIP notification in a specific case, and the statement of grounds based on which, such an exemption may be granted. By way of example, Table 33 below provides an overview of the different defence exemption clauses adopted or proposed in selected Member States.

Table 33: Overview of different national SCIP defence exemptions

Member State	Transposition status	SCIP defence exemption clause (unofficial translation)
France	Adopted	'The information the disclosure of which may prejudice the essential interests of national defence is not communicated.'
Germany	Adopted	'[SCIP notification] does not apply to articles with a military purpose.'
Spain	Draft	'Regarding the obligation contained in Article 18.2, when confidentiality needs to be guaranteed, the exception provided for in Article 2.3 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of December 18 2006, will apply.'
Sweden	Adopted	'The obligation also does not apply to articles covered by a decision on an exemption from Article 33 (1) of Regulation 1907/2006 issued by the Swedish Defence Inspector for Health and the Environment (Department of Defence Inspector) on the basis of section 24, first paragraph, point 1 of Regulation (2008:245) on chemical products and biotechnological organisms.'

The analysis of national provisions shows that there are three different types of SCIP defence exemptions that vary regarding the **need for Member State involvement in a specific case**:

1) Automatism: No Member State involvement is needed to be freed from SCIP notification based on the clause. This is the case of Germany. The German provision clearly sets out that SCIP notification '*does not apply to articles with a military purpose'*. Such articles are thus excluded from application in the law itself. The exclusion is provided for a number of reasons, according to the German MoD. First, the justified protection goal of processing the affected products specifically so that they cannot contaminate further material cycles has already been implemented as a common practice. The *Bundeswehr* (German Armed Forces) always has a product-related environmental impact analysis and risk assessment down to component level with a comprehensive disposal concept. Military goods are commissioned for disposal processing to particularly qualified companies, to which the necessary information is passed on. Furthermore, the SCIP database – by referring to the date of initial supply of the article – is deemed non-suitable to reflect the actual state for long lifecycle defence products, as the condition of the material changes in the subsequent in-service phase due to repairs or upgrades. Finally, a generally accessible database discloses classified information on military goods and jeopardises the readiness of the Armed Forces, according to the German MoD.

2) Member State involvement (case-by-case assessment on request): In some other Member States consulted there is a need for Member State involvement to obtain an exemption from SCIP notification in the interest of defence, based on a case-by-case assessment on request, as under REACH Article 2(3). This may be achieved via a defence exemption pursuant to REACH Article 2(3) from the linked requirement of REACH Article 33(1). An example of the latter is § 4 of KIFS 2020:6 in Sweden[288]. Another option is to grant a specific exemption from the SCIP notification requirement. An example of the latter is the Spanish Draft Waste Law, fourth additional provision, second

[288] In Sweden the exemption is to be requested through one of the specific agencies under the Swedish MoD as applicants.

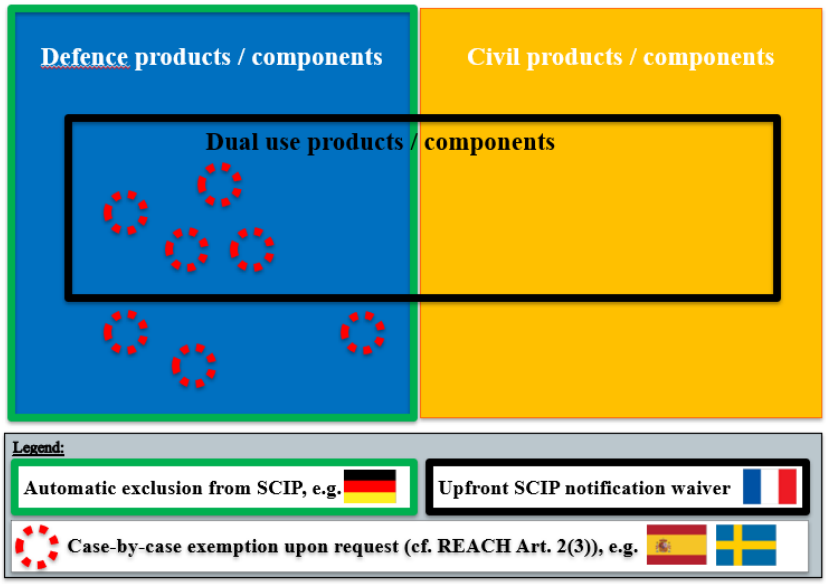
paragraph '*when confidentiality needs to be guaranteed*'[289].

3) 'Hybrid model' (reference to Article 346(1)(a) TFEU): France has adopted a model that could result in a general waiver of the SCIP notification at least for some products. The provision does not refer to REACH Article 2(3). As a result, the 'exemption' would not require a request in a specific case and could potentially apply through the whole supply chain. The communication and storing of information into the SCIP database in the cases to be defined is seen as detrimental to the 'essential interests of national security' (reference to Article 346(1)(a) TFEU). However, unlike under the German automatic provision there is an important prerogative for the Member State to decide (instead of the private SCIP duty holders who cannot make this call) on what 'essential interests of national security' means, i.e., which of the products are exempted. No formal decision has been taken yet; however, the French MoD has been working on an approach defining the products covered and implementing the exemption (e.g., by reference to a legal text). Private duty holders will be informed about the outcome.

Figure 8: Types of national SCIP defence exemptions

Figure 8 provides a summary illustration of these three different types of national SCIP defence exemptions.

Figure 8: Types of national SCIP defence exemptions



3.3.1.3 Summary

The transposition of Article 9(1)(i) WFD on SCIP notification is still pending in a number of EDA participating Member States, in spite of the expiry of the transposition deadline on 5 July 2020. Annex VIII 'SCIP Transposition Mapping' provides a high-level status overview and includes the legal text of relevant national SCIP clauses available for this study. National transposition measures are also listed at https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32018L0851.

The available general provisions transposing WFD Article 9(1)(i) have the reference to REACH Article 33(1) for the scope of SCIP notification in common, otherwise they differ to some extent. In particular, some national provisions initially foresee/propose a literal transposition of WFD Article

[289] In Spain an application by the duty holder requiring acceptance by the MoD is to be made.

9(1)(i) (e.g., FR, NL, RO, arguably also DE), while others make an explicit reference to the SCIP database/related ECHA formats/submission tools (e.g., ES, IT, SE). Some Member States foresee additional details (e.g., in SE on 'placing on the market' and Only Representative) or delegated powers to make more detailed provisions (e.g., DE, FR, IT, NL). Not much is known today on national sanction provisions.

Specifically in relation to defence, a number of participating Member States, for which information is available, foresee specific provisions to the end that a SCIP notification is or may not be required with view to defence-related considerations (e.g. in DE, ES, FR, SE), while others refer to the REACH defence exemption process already in place (e.g. RO). The analysis of national provisions shows that there are three different types of SCIP defence exemptions that vary regarding the need for a Member State involvement in a specific case to be freed from SCIP notification: (1) Member State involvement is not required (automatic exclusion, case of DE for 'articles with a military purpose'); (2) Member State involvement with exemption request is required in each specific case (e.g. ES, SE); (3) Member State clarifies upfront which products are considered as exempted (FR).

3.3.2 Potential impacts on MoDs

Potential impacts on MoDs from implementation of WFD Article 9 on SCIP have been identified in relation to the setup and management of defence exemption processes (where applicable), potential security risks for MoDs in complex scenarios and the possible existence of an own SCIP notification duty in some Member States consulted. In addition, MoDs have commented on whether there are potential benefits of SCIP requirements. These are elaborated further in this Section.

3.3.2.1 Setup and management of defence exemption processes

Potential impacts on MoDs from implementation of WFD Article 9 are mainly seen with regard to the application and management of SCIP defence exemptions, where those require Member State involvement. Expected costs for the management of defence exemptions depend on the way of working of the national provision (see Section 3.3.1.2).

Therefore, no impact is anticipated in Germany, where an automatic exclusion of articles with a military purpose is foreseen. In France (applying the 'hybrid model'), initial costs are expected to set up the implementation of the defence exemption (assess the different cases and possible solutions, communication to duty holders, get the whole mechanism approved). It is hoped that after these initial setup costs, the impact will be minimised for the MoD. There should be no application and assessment of the application, unlike under the REACH defence exemption mechanism as implemented in France.

MoDs consulted in Member States, where a defence exemption with view to REACH Article 2(3) is being implemented ('case-by-case Member State involvement'), anticipate that the need for defence exemptions will increase in the future – likely significantly – or arise for the first time, if the exemption has not yet been used under REACH and defence exemptions will be necessary in order to secure national interests and to stop classified information from being reported in the SCIP database. This is of course associated with additional management costs for those MoDs.

One MoD expressed that it would of course have been good if there had been an official defence exemption possibility in the revised WFD, especially in respect to defence interests and the SCIP notification obligations. Yet another MoD suggested that should problematic individual cases arise in the future, the military sector should be excluded directly from WFD Article 9 on SCIP.

3.3.2.2 Potential security risks for MoDs in complex scenarios

The consultation of MoDs has revealed some complex scenarios, where the national SCIP defence exemption does not, or might not, apply. These include: components provided by higher-tier suppliers, cross-border supplies and dual use products[290]. These scenarios are not addressed explicitly in any of the national SCIP defence exemption provisions available for this study and can only partly be resolved through the interpretation of the provisions at the national level. The potential risk which they have in common is that military classified information (e.g., on detailed product composition) is provided to the SCIP database and published by ECHA, even where national SCIP defence exemptions apply elsewhere (e.g. to the complex assembly but not the component; in the law of the supplier country but not in the country of destination; to dual use defence products but not the corresponding civil products). This could present severe security risks according to MoDs. However, no experience is currently available. The complex scenarios are further explained here below. An additional impact on security has been flagged by one MoD due to the fact that as of today SCIP notifications done by mistake or containing mistakes cannot be deleted.

Components provided by higher-tier suppliers

According to MoDs consulted for this study and the wording of the clauses presented in Annex VIII 'SCIP Transposition Mapping' SCIP defence exemptions generally apply to or may cover EU article suppliers in the defence industry. This applies at least to a direct supplier of military equipment to the MoD. However, **a specific concern has been expressed in relation to suppliers of components upstream of the system integrator of the final military equipment** (i.e., upstream supplies to defence industry), **which are not direct suppliers to the MoD**; as SCIP notification generally applies to EU article suppliers at each level of the supply chain (Section 3.2.2). In case of a contractual solution (i.e., if the MoD "exempts" its direct supplier), it is expected that it will be difficult to ensure an efficient control of the replication of such a SCIP notification exemption clause in the supply chain and to assess up to which level in the supply chain a SCIP notification exemption would apply; this may vary depending on the criticality of the sub-components/articles. These aspects are considered to be very unclear and problematic since they may cause a severe security risk according to some MoDs. According to these MoDs there is also a risk that higher-tier suppliers report to ECHA components that are essential downstream for military equipment and may reveal information on capabilities of the Armed Forces in the long run. Those cases should be identified and further studied, according to the contractor (see recommendation in Section 3.7.5).

Cross-border supplies

MoDs consulted provided different responses to the question about whether national defence exemptions from SCIP notification could cover a product supplied across borders to other EU Member States. MoDs consulted have expressed that no experience is available to date given that the SCIP notification duty was not yet in force at the time of the study consultation. In any case, references in national provisions on SCIP to 'articles with a military purpose' (DE) or 'interests of national defence' (FR) do not preclude an application of the exemption to cross-border transfers.

The following theoretical examples have been provided by one MoD:

> ***Example 1A****: A defence company in Member State A is selling military equipment to a company in Member State B, which would then sell a final piece of equipment to the MoD of Member State B. Member State B applies a SCIP defence exemption. The*

[290] Note that the issue of cross-border supplies and dual use were also identified as complex areas / limitation with view to the application of the defence exemption pursuant to REACH Article 2(3) in the 2016 EDA REACH/CLP Study. However, the situation will have to be addressed separately for the implementation of WFD Article 9(1)(i) as a distinct piece of legislation.

defence company in Member State A is also a supplier/provider of the MoD in Member State A.

According to the MoD providing this example, the company in Member State A has to comply with the national provision in Member State A transposing the SCIP notification requirement. If Member State A also considers the equipment supplied to Member State B as justifying an exemption from SCIP notification, the company should not submit such a notification.

***Example 1B**: Like 1A, but the defence company in Member State A is not a direct or indirect supplier of the MoD of Member State A and there has been no clarification on whether or not the military equipment supplied by this company is subject to SCIP notification.*

According to the MoD providing this example, to avoid such a case in a real situation, the MoD of Member State A should do its best to clarify the situation of military equipment in general with regard to SCIP notification duties.

Cross-border supplies thus raise not only the question as to whether a given defence exemption can be applied in this scenario, they also raise the **question, which national SCIP regime applies**, i.e. the law of the supplier country or the law of the recipient country. This question is not explicitly addressed in the WFD nor in the national provisions available for this study. MoDs commenting on this aspect have provided different responses. The examples above imply that the supplier country should have a say. It was also mentioned by the same MoD that on the ground of Article 346 TFEU, the SCIP defence exemption should prevail, even when the national transposition act does not refer to it. According to another MoD's opinion it should be decided by the Member State for which the delivery is intended[291]. According to the latter MoD, should problematic individual cases arise in the future, the military sector should be excluded directly from WFD Article 9 on SCIP (see already Section 3.3.2.1).

Dual use

MoDs consulted provided different – mainly undecided – responses concerning the question as to whether their national exemption rules may cover dual use products (same or similar product as the military product is supplied also for civil purpose). **Most MoDs consulted have either not yet considered or answered the issue of dual use products, or they consider that their national SCIP exemption provision is meant to cover only military articles**.

In France, however, the exemption provision does not differentiate between dual use and military specific products. As long as it is of national defence interest not to communicate information about a dual use product in the SCIP database, the French SCIP duty holder should not communicate it, subject to the decision prerogative of the French Member State/MoD.

Based on the input provided by one MoD information requested for the SCIP database may be seen for dual-use items (DUI) as technological information, which in some cases is subject to export control, as provided by Council Regulation (EC) No 428/2009 (DUI Regulation)[292]. This is currently being assessed by the legal service of that MoD.

It also remains unclear, *how* Article 346(1)(a) TFEU (see above Section 3.2.6) could be used to provide

[291] In the case of military equipment jointly procured with other EU Member States' MoDs, this MoD opinion further suggests that the procedure could be agreed among Member States, e.g. based according to the *focus of the procurement*.

[292] Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (Recast), OJ L 134, 29.5.2009, p. 1–269. The latest consolidated version of 31 December 2019 is available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R0428-20191231.

a direct legal recourse for a Member State to invoke 'essential interests of its security' to exempt SCIP notifications *by industry* for dual use civil products, as the provision refers to (non-) supply of information *by Member States*. The study consultation has not provided further insights, either. It appears that it is for the Member States to conciliate such interests (e.g., the aforementioned national essential security interests) and apply Article 346(1)(a) TFEU, either directly (i.e., without specific mentioning in the national law) *when implementing* or indirectly *when transposing* into national law EU Directives such as the present revised WFD and its Article 9. The latter is, for example, the French approach to SCIP exemptions.

Current impossibility to delete SCIP notifications

An additional impact on security has been flagged by one MoD because as of today SCIP notifications done by mistake or containing mistakes cannot be deleted[293]. This means that if a notification is done by a duty holder while it should not have because of a SCIP defence exemption on the product notified, this cannot be removed (unless an update is possible), thus leaving defence sensitive information accessible worldwide. According to this MoD, the impact does not only concern MoDs, but also defence industry (see Section 3.4.2) which will not be able to correct mistakes revealing classified data or become compliant with a SCIP defence exemption, after undue notification.

It is understood that a deletion possibility is in ECHA's backlog for future improvements. EDA could be advised to follow up with ECHA on this aspect (see Section 3.7.10).

3.3.2.3 Potential own duty in some Member States

MoDs have provided different answers regarding a potential own duty to make a SCIP notification. No potential duty is seen categorically by the German MoD with a view to the clear exclusion for *"articles with a military purpose"* in the new § 16f of the Chemicals Act and the legal position that the *Bundeswehr* is considered neither an 'actor in the supply chain' nor a 'supplier'[294]. Other MoDs consulted either see a potential duty based on the specific circumstances, or they have not fully evaluated this question yet.

Some potential scenarios have been raised in the MoD consultation, where a duty on the MoD could exist in the Member State concerned:

> ***Example 1****: An MoD buys military equipment/blocks, either outside or inside the EU, and mandates a company to install this equipment into a bigger military equipment/system.*
>
> ***Example 2****: Government sales to other countries regarding military systems. However, in these cases the SCIP notification duty is still seen primarily on the producing industry.*
>
> ***Example 3****: The MoD acts as an 'importer' where import is considered as 'placing on the market' (based on REACH Article 3 point 12, but see above Section 3.2.2). Note that in Sweden the national definition of 'placing on the market' in § 2 of the Regulation (2008: 245) deviates from REACH Article 3 point 12 Sentence 2, as it does not include a mere 'import', without onward supply to someone else, thus limiting the scope of any potential duty (see Section 3.2.2).*

Any such scenarios will have to be further studied by the MoD(s) concerned. Then it will have to be decided on a case-by-case basis, whether a SCIP notification duty actually exists and – and if it does –

[293] See Section 3.2.6.

[294] See REACHLaw (2016), EDA Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, Final Report, 16 December 2016, Section 5.1, pp. 80 et seqq., available at https://www.eda.europa.eu.

whether a defence exemption may be applied, i.e., the specific national defence exemption clause or Article 346(1)(a) TFEU which could also apply *directly* in this case because a supply of (SCIP) information *by the Member State* is in question.

3.3.2.4 Potential benefits from MoD perspective

MoDs consulted either do not expect benefits of the new SCIP requirements for the defence sector, or they consider that – while the overall aim of the SCIP database is considered as good – benefits are associated with big risks for the secrecy of military information. Benefits are seen by some MoDs in relation to civil/dual use products for which useful information may be available in the SCIP database or as part of more structured databases for REACH Article 33 information in the civil/dual sector supply chain. However, the latter is not seen as a benefit *for the defence sector*. Reporting on hazardous substances in military equipment to MoDs is expected to continue as is, based on contractual requirements and REACH Article 33 (where applicable), including requests for localisation of SVHCs.

3.3.2.5 Summary

Potential impacts on MoDs from implementation of WFD Article 9 are mainly seen with regard to the application and management of SCIP defence exemptions, where those require a Member State involvement. MoDs in those Member States expect costs to set up and manage the defence exemption process. Where the process is linked to REACH Article 2(3), MoDs anticipate that the need for defence exemptions will increase in the future – likely significantly – or arise for the first time, if the exemption has not yet been used under REACH and defence exemptions will be necessary in order to secure national interests and to stop classified information from being reported in the SCIP database.

With regard to the different national SCIP-related provisions in the area of defence, some MoDs consider further collaboration on implementation among EU Member States / MoDs or possible provisions in the WFD to explicitly include an EU-level SCIP defence exemption clause.

The consultation of MoDs has revealed some complex scenarios, where the national SCIP defence exemption does not or might not apply. These include components provided by higher-tier suppliers, cross-border supplies, and dual use products. The potential risk which they have in common is that military classified information (e.g., on detailed product composition) or technological information on dual-use items subject to export control according to Council Regulation (EC) No 428/2009 is provided to the SCIP database and published by ECHA, even where national SCIP defence exemptions apply elsewhere. This could present severe security risks according to MoDs. However, no experience has been made to date given that the SCIP notification duty was not yet in force at the time of the study consultation. An additional impact on security (and defence industry) has been flagged by one MoD stressing that as of today SCIP notifications done by mistake or containing mistakes cannot be deleted. Further analysis / follow-up of these issues after this study in the EDA framework is recommended.

MoDs have provided different answers regarding a potential own duty to make a SCIP notification. No potential duty is seen categorically by the German MoD, based on the new § 16f of the Chemicals Act and its elaborated legal position (2016). Other MoDs consulted either see a potential duty based on the specific circumstances, or they have not yet fully evaluated this question. Any potential duty scenarios will have to be further studied by the MoD(s) concerned and resolved based on the outcome.

MoDs consulted either do not expect benefits of the new SCIP requirements for the defence sector, or they consider that – while the overall aim of the SCIP database is considered as good – benefits

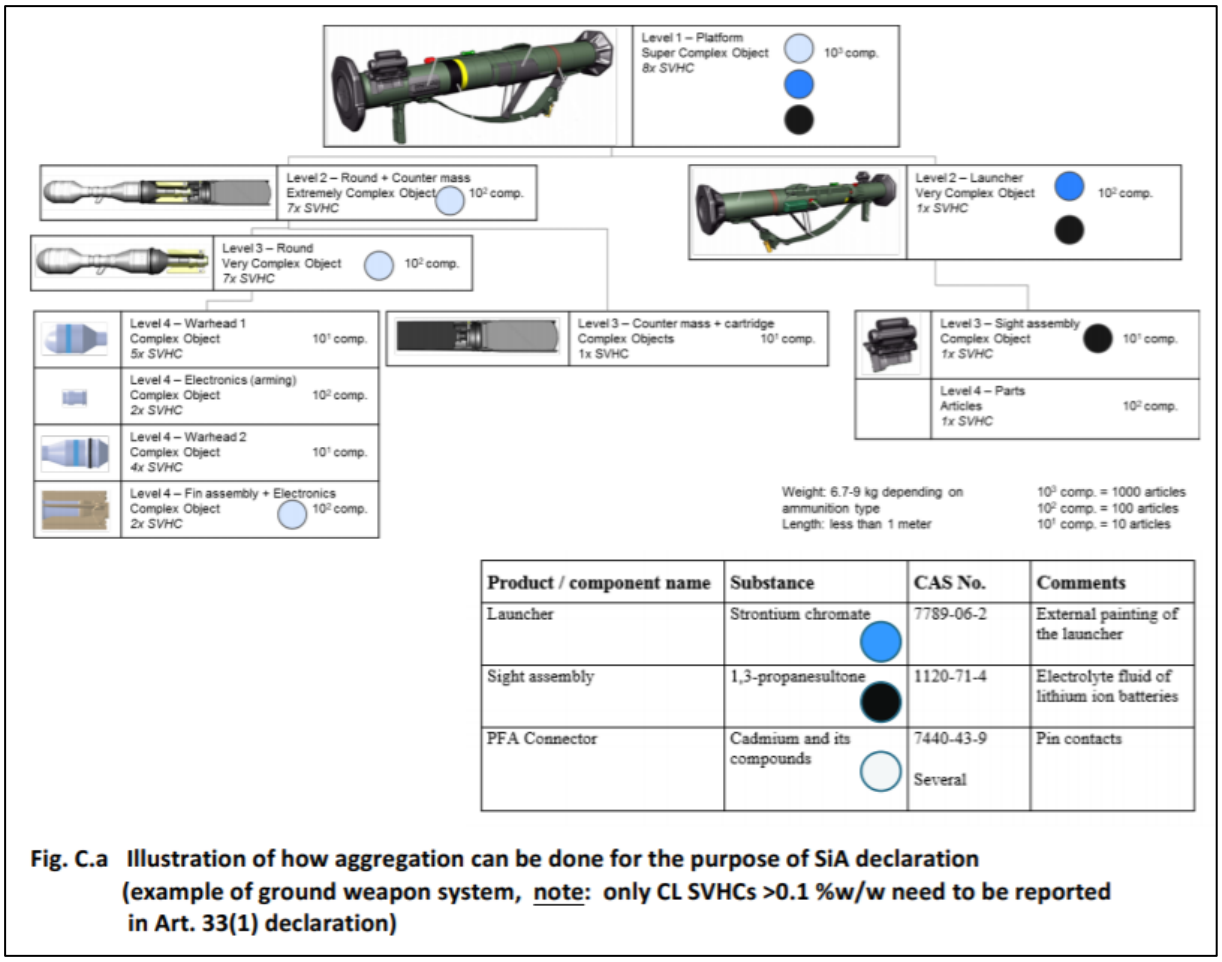
are associated with big risks for the secrecy of military information. Reporting on hazardous substances in military equipment to MoDs is expected to continue as is, based on contractual requirements and REACH Article 33 (where applicable), including requests for localisation of SVHCs.

3.4 DEFENCE INDUSTRY COMPLIANCE PLANS AND POTENTIAL IMPACTS

The EU defence industry, represented by ASD on the European level, has been very active towards the EC and ECHA throughout the development phase of the SCIP database since 2018, to convey its concerns relating to the proportionality, complexity, confidentiality and workability of SCIP notifications and database[295]. ASD has been promoting a more manageable and much simpler system based on aggregated information at a meaningful product assembly level also protecting classified data, which has worked in the Aerospace and Defence (A&D) sector for several years under REACH Article 33 (see illustrative example in Figure 9[296]), instead of the 'article-centric approach' pursued by ECHA. ASD has also been asking for an **impact assessment not previously conducted**, which would involve suitable downstream article manufacturing experts to assess the cross-sector issues of managing the processes proposed by the WFD Article 9/SCIP. ASD stressed that such a database for substances in articles information should rather be designed around how waste operators can realistically use information, i.e., focusing on information for specific waste streams (electronics, metals, plastics, etc.) instead of articles-centric information.

[295] See e.g. ASD (2018).
[296] ASD (2017), page 49, 'Appendix C: Illustrative example of aggregation method'.

Figure 9: Illustrative example of aggregation method for REACH Article 33 reporting (ASD, 2017)



Product / component name	Substance	CAS No.	Comments
Launcher	Strontium chromate	7789-06-2	External painting of the launcher
Sight assembly	1,3-propanesultone	1120-71-4	Electrolyte fluid of lithium ion batteries
PFA Connector	Cadmium and its compounds	7440-43-9 Several	Pin contacts

Fig. C.a Illustration of how aggregation can be done for the purpose of SiA declaration (example of ground weapon system, note: only CL SVHCs >0.1 %w/w need to be reported in Art. 33(1) declaration)

As part of the present study, defence industry stakeholders were consulted on their plans to comply with the SCIP requirements as implemented by ECHA ("article-centric approach") on the EU and Member States on national levels (Section 3.4.1), as well as the related potential impacts on them (Section 3.4.2).

3.4.1 Industry compliance plans

Generally speaking, manufacturers of complex products will find compliance with SCIP requirements extremely challenging if not impossible to meet within the current timeframe. Against this background the defence industry plans to take the following overall approach (as reported by ASD):

- analyse the national legal implementations of WFD Article 9 in respect of defence exemptions;
- for remaining notification obligations, to protect in any case the defence-sensitive/classified information and/or confidential business information (CBI)[297];
- start with IT implementation programmes for system-to-system interfaces with the SCIP database;
- only for cases where no national defence exemptions exist or dual-use products are within the scope, provide SCIP/national legally required mandatory data as "available to the supplier" using sub-assembly level aggregated information, i.e. as provided by REACH Article 33(1) from the supply chain in an aggregated manner;
- accept a certain level of non-compliance[298] to the compliance requirements as defined by ECHA and in the Commission non-paper as information on article categories, material/mixture categories for sub-systems and articles as such are not available to the supplier/duty holder for a longer timeframe.

Given the large scale and complexity of the project, ASD as part of a coalition of 40 industries (groups) has been asking the EC for a postponement of the SCIP notification deadline[299]. One of the reasons is that ECHA did not establish the SCIP database by 5 January 2020 as required in WFD Article 9(2), leaving industry/duty holders with only about two months from publication of the final SCIP requirements and functionalities in (late) October 2020[300] to adapt their IT landscape and collect the data from their global supply chain. According to ASD, the massive COVID-19 impacts on the A&D sector further justifies the requested postponement as this unprecedented crisis will restrict workforce, investment and time schedule for activities in 2020 and even beyond at least in 2021. The EC replied that it is not empowered to modify the SCIP notification duty and deadline laid down by the co-legislators in Directive (EU) 2018/851 and encouraged companies to do what is possible within these limitations[301].

ASD has clarified, that the protection of defence-sensitive/classified information and/or CBI in any case would need to be achieved through various methods, if no SCIP defence exemptions are applicable. The defence industry may use highly aggregated notifications up to fully flattened Bills of Materials (BOMs) with highly generic article categorisations and article identifiers and by only indicating SVHCs in the predefined open range of > 0.1% w/w and ≤ 100% w/w. In addition, no linking of SVHCs to any disclosed BOM structures or concern elements (article as such) is considered. Furthermore, ASD recommends notifying where legally justified based on "information available to the supplier", using sub-assembly level aggregated information and "dummy codes" for SCIP fields where information is not available but mandatory such as material codes (e.g. "others") and 'article as such' identifiers. According to ASD, a more detailed elaboration of such "camouflage methods"

[297] See details at the end of this Section, in Section 3.4.2.2 and the example for (military) satellites in Section 3.2.6.
[298] See also Section 3.4.2.7. The enforcement of duty holders' compliance with the SCIP notification duty according to WFD Art. 9(1)(i), as transposed in the respective national law, is the responsibility of the Member States. See also ECHA (October 2020), Section 3.1.5 and the recommendation to MoDs in Section 3.7.1 of this report.
[299] ACEA et al. (2020); see Press Release.
[300] See also the changes highlighted above in Section 3.2.3 and Table 32 for the final SCIP requirements as published in late October 2020 vs. the 'detailed information requirements for the SCIP database' of September 2019.
[301] EC (2020, October 12).

will probably be discussed in the course of the next months when the final SCIP database and the national transpositions will be available, and more experience will be collected.

3.4.2 Potential impacts on the defence industry

This Section takes stock of the potential impacts from the SCIP requirements as regards the administrative burden and costs, the required protection of confidential information and the use of national SCIP defence exemptions. In addition, specific challenges for SMEs and the non-EU defence industry are highlighted. Furthermore, comments on potential benefits of SCIP have been made. Finally, the issue of possible non-compliance to the demands of ECHA is raised.

3.4.2.1 Potential costs / resources to manage SCIP compliance

During the stakeholder consultation carried out for this study, ASD informed that it conducted a survey amongst its membership anticipating strong negative impacts on the A&D sector:

- It is estimated that more than 1 million notifications[302] will be submitted by the sector to the SCIP database in 2021. Notifications per company are expected to span from below 100 up to 200,000 per annum;
- The expected number of product declaration levels[303] according to the SCIP requirements varies in average from 2 to 7 levels, with a typical value of 4 and a maximum of 12 (e.g. for the most complex objects like aircraft or armoured vehicles);
- A vast majority of respondents estimate that they will need over three hours per SCIP notification[304]. However, for very complex objects such as an entire platform (e.g. aircraft or armoured vehicles), it could take a week or more;
- The overall effort for the sector to perform SCIP notifications without IT system-to-system interfaces could be around 3,900 full time equivalents per annum, representing about 0.4% of the sector's employees;
- As manual data entry to SCIP will not be affordable nor practicable for the majority of ASD members, companies will have to invest in new IT systems and/or update existing material/substance tracking tools with an expected investment of minimum EUR 30-45 million and an operating cost of minimum EUR 3-5 million per annum;
- Additional ~230 persons per year, starting in 2021, would be needed to obtain additional, not legally mandated information (on top of REACH Article 33) for completing the SCIP database fields – as defined by ECHA as "mandatory/required" – (mainly on material/mixture category and the article category). Furthermore, availability of the full data set will require contractual amendments for the global supply chain. It will take a long time, at least 5-10 years to obtain all required data;
- (Reflecting status at study consultation time) the national implementation status of the defence exemptions is still largely uncertain. Therefore, the efforts needed to obtain an exemption are still unknown; and
- Companies do not have resources to perform SCIP notifications. They will have to allocate

[302] As the level of defence exemptions cannot be foreseen, the numbers include all civil and military business of the sector.
[303] I.e. the layers of components and subcomponents of a complex object that should be reported in a SCIP notification; see Section 3.2.4.
[304] Covering only the effort of manually entering a product notification to SCIP, assuming that all necessary information is available.

budget to hire qualified resources and to get the necessary material to complete this task.

According to anecdotal evidence from the defence industry, new staff have already been hired for SCIP, who need a lot of support from various departments not related to REACH / Article 33 (e.g., to get the tariff code or material category information).

With regards to ECHA's proposals for simplified notifications and how to use and provide SCIP numbers in the supply chain[305] defence industry stakeholders have noted that this will take many years to be effective.

3.4.2.2 Public disclosure and protection of CBI/classified data

During the stakeholder consultation, ASD expressed its opinion that CBI and classified data will have to be protected in any case and shall not be notified to SCIP even if defined as 'mandatory' by ECHA (see Section 3.4.1 for details). The criticality of such information (BOM product breakdown, material information indicating classified technologies, violation of data protection and "Need to know" principles" for handling of classified data) and the need for data protection and defence exemptions have been highlighted in previous ASD contributions to ECHA during the elaboration of SCIP information requirements and database and have been reiterated as part of the stakeholder consultation; some key examples include:

- Public disclosure of elements of internal design and component part selection is illegal for defence equipment manufacturers who must comply with **technology export controls** (see also info box below on export control) and may impact the protection of the essential interests of the security of Member States;
- For military classified goods and other goods subject to technology export controls in the EU or in other jurisdictions, **aggregation** of information for complex assemblies is **vital**. If this is not possible, then some way will be needed to exclude such applications from the scope;
- A hierarchical **breakdown along the BOM** (multiple nesting of complex objects down to single article levels with article reference) is to be strongly rejected. Breakdown of a product structure/ BOM as such or in parts would jeopardize confidentiality when disclosed in the publicly accessible SCIP database, and besides are technically unfeasible especially for very complex objects[306];
- The **treatment of waste** resulting from defence equipment requires confidentiality[307];
- The serious concern to protect military classified data in the context of the SCIP database has been acknowledged through the **dedicated Commission clarification on SCIP defence exemptions**[308] and **explicit national provisions on SCIP implementation in the area of defence**, going as far as foreseeing a non-application of SCIP notification for all articles with a military purpose (example of DE)[309].

[305] Section 3.2.4.

[306] ECHA noted that the recommendation for 'hierarchy' in structuring the data in a SCIP notification could help in minimising publication of sensitive information (see Section 3.2. in ECHA 'Requirements for SCIP notifications' and above Section 3.2.4). Further analysis / follow-up of this issue in the EDA framework with consultation of ASD and possible feedback to ECHA after this study could be considered (see study recommendation in Section 3.7.10).

[307] See also Section 3.4.2.6 below.

[308] See Section 3.2.6 above.

[309] See Section 3.3.1.2 above.

Specific concerns expressed by ASD on SCIP requirements with regard to export control legislation:

Under export control legislation, only authorised personnel from Member States export control authorities may access controlled technical data. Therefore, the obligation to provide the lowest level article identifiers for every product and sub-assembly containing the lowest level article into a public database, even with strong security controls, creates a risk of data disclosure (e.g., product breakdown structures, technologies), whether through hacking, deliberate act or access-to-information requests. The administrators of the database and its staff enjoying full access to such a database would not be accountable to export controls legislation nor security clearance requirements.

An NDIA expressed its opinion that, since SCIP is a database accessible to anyone, there is also the concern that international competitors could access any such information.

In addition, one defence industry has expressed concerns that NGOs might look up information in the SCIP database on defence products specifically and use this for targeted lobbying / putting pressure on suppliers with activities in the area of defence, to not supply to the defence industries anymore. Furthermore, this industry notes that if no defence exemptions can be used, a lot of information on defence products may be publicly available; this defence industry estimated that 80% of its products are "SVHC-contaminated".

Reference is also made to the potential impact for defence industry flagged by one MoD due to the current impossibility to delete SCIP notifications, as the duty holder would not be able to correct mistakes revealing classified data or become compliant with a SCIP defence exemption, after undue notification[310].

3.4.2.3 Challenging use of national SCIP defence exemptions

As the provisions governing implementation of SCIP in the area of defence are to be implemented separately in each EU Member State[311], defence industry stakeholders consulted have expressed unanimously that their harmonisation is of utmost importance as supply chains are mostly transnational today and the industries involved cannot, or hardly, manage unharmonised exemptions.

One defence industry expressed that it will be very difficult (at least based on information publicly available at that time) to understand which kind of defence exemption applies for which EU country; it suggests that the EDA should provide a table for comparison of what defence exemption rules apply on SCIP per country (for industry to be better informed than currently). This defence industry also fears that the defence exemptions for SCIP will not be able to be used in practice due to the non-harmonised application. According to this defence industry, the best way to achieve the needed harmonised application would be a "generic exemption" of all defence material, without the need for specific applications to be made. In light of the foregoing, **precautionary SCIP notifications** are envisaged[312] by this defence industry for military products sold in the EU as of January 2021, unless there is a clear exemption (such as in DE).[313] To safeguard sensitive information in this context, dummy names / descriptions that "camouflage" the product type as much as possible are

[310] Section 3.3.2.2 'Current impossibility to delete SCIP notifications'.
[311] See above Section 3.1.1 and Article 2(1) of Directive 2018/851.
[312] Note: Contractual MoD requirements should be complied with when implementing such approach.
[313] See also Section 3.4.2.2 with Section 3.3.2.2 concerning the current impossibility to delete SCIP notifications.

considered[314].

3.4.2.4 SME-specific issues and challenges

ASD indicated during the stakeholder consultation that SMEs already struggle with the requirement stemming from REACH on product declaration for complex objects, i.e., REACH Article 33(1). WFD/SCIP will require even more information not available to SME as of today. As a consequence, SMEs are not expected to have all mandatory data and skilled staff available to comply with SCIP notification from day 1 onwards (5 January 2021). According to ASD, SMEs will in many cases also not use IT systems for material/substance tracking for their products and procured parts, they will be obliged to make manual SCIP notifications instead of a more efficient system-to-system communication. A manual data entry is much more time consuming, the burden to comply with WFD will be disproportionally higher for SME than for larger sized companies.

It was also reported by an NDIA that many SMEs do not know about their obligation as importers that they must make notifications (and preferably, to provide the SCIP numbers to their customers).

3.4.2.5 Non-EU-specific issues and challenges

According to AIA, the level of additional data – with mandatory SCIP data fields being in AIA's opinion far beyond the legal requirements of REACH Article 33(1) declarations – which is required from the non-EU supply chain will be significant and will require additional time and resources to develop in order to provide meaningful data. For US military hardware supplied to EU, the SCIP reporting requirements and public database are found by this association to directly **conflict with the requirement to safeguard product and technical information governed by the International Traffic in Arms Regulations (ITAR)**, to which the US defence industries represented are legally bound. US defence industries would not be authorised to disclose such information. The associated security risks may possibly pre-empt compliance with SCIP reporting requirements, AIA indicated. Where available, US defence industries would have to seek national defence exemptions to continue to provide EU Member States with military products due to restrictions on disclosures of technical data covered by ITAR requirements. According to AIA, the ability to provide US defence products to EU Member States could be impacted if such defence exemptions cannot be secured and detailed product information disclosures, to comply with the WFD, should be required. To avoid this scenario, all defence products should be exempted from these requirements, according to AIA.

3.4.2.6 Potential benefits from defence industry perspective

While defence industry stakeholders support the overall intent of the circular economy, they have serious concerns linked to the SCIP database "one-size-fits-all" design and implementation. Defence products are not manufactured with the intention of being conventionally recycled, and they have bespoke instructions that determine how they should be disposed of. Therefore, the consulted defence industry does not identify any benefits of applying these reporting requirements to defence products.

ASD provided the following viewpoints during the stakeholder consultation, focusing on (very) complex objects and illustrative examples thereof being the main issue[315]:

- As no impact assessment was performed at any time in the EU WFD amendment process, there

[314] See also Section 3.4.1 for the more detailed ASD input on possible means of confidentiality protection when notifying to ECHA.

[315] No detailed information has been received in the study consultation for simpler defence products.

is no evidence on any potential benefit to the targeted waste operators;

- It is unclear how the regulated A&D industry dismantlers and recyclers will practically use SCIP information for the purpose of circular economy;
- Typically, defence products are of high value with a high expectation for long product life. Due to the professional user base and products where many parts have life management plans, many component parts are tracked, supporting a high level of part reuse. Where parts cannot be reused, specialist dismantling facilities are in place;
- For the treatment of waste stemming from defence equipment, which is subject to particular confidentiality requirements, dismantling and disposal are strictly controlled and facilities require specific certifications and skilled operators. For example, only one company in the EU is certified by NATO for the dismantling and recycling of tanks;
- Further examples show the limited to no-added value of the database for the sector:
- *Armoured vehicles* and tanks are expected to have a long life-cycle (between 30-40 years). Their dismantlement is carried out by the companies themselves (Defence service) and will not be done by civil waste operators who are not equipped to treat them;
- Most *ammunition* that needs to be destroyed is burned by qualified personnel to control the pyrotechnic risks. Moreover, ammunition cannot be handled by civilians such as waste operators (not qualified by the MoD);
- Overall, the sector has addressed and continues to responsibly address its duties linked to the treatment of its products once they reach their end of life.

3.4.2.7 Non-compliance with the demands of ECHA

ASD had noted early on during the SCIP database development that enforcement authorities could be in the difficult position of having high expectations, which companies cannot comply with, while the requirements as defined by ECHA are not stated explicitly in the law. This situation would undermine enforcement and does not help it[316].

ECHA stresses the application of its 'Guidance on requirements for substances in articles', requiring **systematic communication** of the name/identification of the individual article(s) containing a Candidate List substance above 0.1% w/w even for the most complex objects[317]. According to ASD, such a strict interpretation would require that the supplier will provide a complete list of SVHC containing articles in a complex assembly to the recipient. For an aircraft containing millions of articles, this could include the lowest level of articles such as a lead containing pin of an electronic component on a circuit board in a black box somewhere in the structural depths of the aircraft. As such, a simple list could include thousands of lines of information, the vast majority of **which would be irrelevant to the user but would hide the essential information necessary to protect those most at risk of exposure**. Aggregation of data combined with targeted provision of SVHC and safety information in manuals as identified in the ASD guidelines[318] was considered as the most efficient and effective way to provide essential information to those at risk of exposure whilst complying with Art 33(1) of REACH and the CJEU judgment in case C-106/14. ASD further notes that the proposal for creation of a working group of experts from MSCAs and industry to further analyse the needs, scope and conditions of workable solutions for very complex objects, such as electronic components and assemblies, has not materialised so far.

[316] ASD (2018).
[317] ECHA (2017), referring to subchapters 3.2.1 and 3.4.1; ECHA (CA/54/2018), page 6.
[318] ASD (2017).

Specifically with regard to SCIP, ASD also notes that official recommendations for notifications of extremely complex objects like airplanes, that are both legally compliant (according to ECHA requirements) and usable for the target audiences of SCIP, are not available today[319].

3.4.3 Summary

- The EU defence industry, represented by ASD on the European level, has been very active towards the EC and ECHA throughout the development phase of the SCIP database since 2018, to convey its concerns relating to the proportionality, complexity, confidentiality and workability of SCIP notification and database based on the "article-centric approach" pursued by ECHA. Manufacturers of complex products will find compliance with SCIP database requirements extremely challenging if not impossible to meet within the current timeframe. The defence industry (as reported by ASD) plans to analyse the national legal implementations of WFD Article 9 in respect of defence exemptions as a first priority. For remaining notification obligations, the defence-sensitive/classified information and/or CBI shall be protected in any case, notably through highly aggregated notifications, limitation of data reported to the legal minimum as "available to the supplier" (REACH Article 33(1)) and (other) "camouflage methods" to be still elaborated in more detail. A certain level of non-compliance will need to be accepted.
- Given the large scale and complexity of the project, ASD as part of a coalition of 40 industries (groups) has been asking the EC for a postponement of the SCIP notification deadline. On 12 October 2020, the Commission replied that it is not empowered to change the date – and encouraged companies to do what is possible within the limitations.
- A survey conducted by ASD among its membership in 2020 anticipates strong negative impacts on the A&D sector. It is estimated that more than 1 million notifications (comprising both civil and military business) will be submitted by the sector to the SCIP database in 2021. Notifications per company are expected to span from below 100 to up to 200,000 per annum. The expected number of product declaration levels according to the SCIP requirements varies in average from 2 to 7 levels, with a typical value of 4 and a maximum of 12 (e.g., for the most complex objects such as aircraft or armoured vehicles). Companies do not have resources to perform SCIP notifications. They will have to allocate budget to hire qualified resources and to get the necessary material to complete this task.
- As the provisions governing implementation of SCIP in the area of defence are to be implemented separately in each EU Member State, defence industry stakeholders consulted have expressed unanimously that their harmonisation is of utmost importance as supply chains are mostly transnational today and the industries involved cannot, or hardly, manage unharmonised exemptions. According to anecdotal evidence from the defence industry consultation, precautionary SCIP notifications are envisaged for military products sold in the EU as of January 2021, unless there is a clear exemption (such as in DE).
- With regard to SMEs, specific challenges arise due to their often lower availability of skilled staff, other resources and data. Also, they will need to do the less efficient manual SCIP notifications more often, as expected by ASD.
- For US military hardware supplied to EU, the SCIP reporting requirements and public database are found by AIA to directly conflict with the requirement to safeguard product and technical information governed by ITAR, to which the US defence industries are legally bound. The associated security risks may possibly pre-empt compliance with SCIP reporting requirements. According to AIA therefore, the ability to provide US defence products to EU Member States

[319] The 'representative article approach' is not recommended by ECHA, see Section 3.2.4.

could be impacted if defence exemptions cannot be secured. To avoid this scenario, all defence products should be exempted from these requirements, according to AIA.

- Asked about the potential benefits of SCIP requirements from their perspective, defence industry stakeholders do support the overall intent of the circular economy, but have serious concerns linked to the SCIP database "one-size-fits-all" design and implementation. Defence products are not manufactured with the intention of being conventionally recycled, and they have bespoke instructions that determine how they should be disposed of. Therefore, the consulted defence industry does not identify any benefits of applying these reporting requirements to defence products.

3.5 NON-DEFENCE STAKEHOLDER VIEWS

Specific non-defence stakeholders were chosen by EDA and MoDs to complement the study consultation or volunteered to participate. Their input and related information is reflected hereafter.

European Recyling Industries' Confederation (EuRIC)

EuRIC has submitted a 'Technical Paper on the SCIP Database'[320] as part of the stakeholder consultation. Whereas the paper does not specifically address defence products or components, it raises the following two general main issues with the ECHA SCIP database, which are also relevant for defence products, as mirrored by MoD and defence industry input:

- The database does not address the question of **legacy substances**, which is the most problematic issue for the recycling industry. This concerns substances contained in products supplied before SCIP notification starts to apply and substances to be added to the Candidate List only after supply. Therefore, products with a long-life cycle (e.g. end-of-life vehicles) will not be addressed by the database[321];
- The **article-based design** of the database is unlikely to fit the technical and economic constraints of the recycling industry. Given its complexity, it could be difficult to use the database without threatening the viability of the recycling process. A proper interface between the database and the operator would be needed, for instance through an **appropriate level of data aggregation**[322]. The only information that recyclers would potentially benefit from is knowledge of what kind of contaminants they should screen for in their output streams.

Similar concerns have also been voiced by groups of complex products' manufacturers, who argue that instead of a one-size-fits-all solution[323] a more differentiated and specified solution would be more effective, based on the question (not answered before the adoption of the SCIP requirements), which SVHCs prevent successful recycling and re-use in which waste stream[324].

Additional information on waste operator views: ECHA has highlighted that there is further background work carried out by a contractor to ECHA concerning SCIP data and its possible uses by waste operators. Some reports are published at https://echa.europa.eu/waste-operators. Furthermore, ECHA makes reference to an article on its website titled 'Cleaning up Europe's act with the SCIP database' by representatives of waste operators (*European Union for Responsible*

[320] EuRIC/PRE (2020).
[321] EuRIC further notes in its paper that short use phases such as packaging are less impacted at the moment as there is relatively rapid elimination of SVHCs.
[322] ECHA has highlighted that it would like to further investigate these possibilities and potential benefits. ECHA may further work on this with the collaboration of waste operators.
[323] ECHA has justified its option in Section 3 (introductory part) of the "Requirements for SCIP notifications", page 35.
[324] ZVEI et al. (2020).

Incineration and Treatment of Special Waste 'EURITS' and *Hazardous Waste Europe*), complemented by a presentation 'Using data on harmful chemicals to improve circularity' at the Safer Chemicals conference 2020 by ECHA on 2 June 2020. ECHA also points to the views of *Fédération Européenne des Activités de la Dépollution et de l'Environnement 'FEAD'* delivered at the SCIP workshop of 12 November 2019 organised by ECHA, which is titled 'View of waste operator on use cases for the database and best way to make the data available'.

ASD-Eurospace / WFD Space Task Force

Furthermore, with special regard to equipment designed to be sent into **space** and related means of transport, which do not result in waste on the EU territory and are therefore not part of the circular economy, the European Space Sector argues to be outside the scope of the SCIP requirements[325]. However, given the absence of an explicit exemption in the WFD and national laws the Space Sector prepared a Best-Practice Guidance to SCIP notification based on the aggregation concept by ASD[326].

SMEunited

SMEunited confirmed the general (not defence specific) concerns expressed by ASD with regard to SCIP and SMEs. In addition, the overall English-language system at ECHA for SCIP is deemed non-acceptable from an SME perspective[327], an average SME cannot handle such a complex notification with such tools and will therefore regularly need external support, which is costly. According to SMEunited companies frequently struggle already with the basics of SCIP notification such as the 'article' definition or the concept of a 'complex object', assuming no duty where there is one (e.g. in the electronics sector) or the other way around. The major trigger at the moment – by far – for SCIP notification is expected to be lead metal, which was included in the Candidate List in 2018 and is still widely used in various sectors. Overall, SMEunited estimates SCIP compliance costs for SMEs in the EU between EUR 48 to 67 billion per year[328]. The actual cost will largely depend on the final implementation of SCIP requirements and the usefulness of simplified tools. Benefits of the SCIP database are not seen, as the "wrong data" are gathered, such as generic categories for articles, materials and mixtures.

Beryllium Science and Technology Association (BeST)

The *Beryllium Science and Technology Association (BeST)* has noted that while beryllium is not an SVHC, the substance is mainly used as an alloying element in copper. These copper-beryllium alloys may contain other metals including lead, which provides machinability properties. Hence, SCIP notifications for articles containing such alloys may be necessary. Beryllium-containing alloys are used for bushings and bearings of airplanes, including also defence applications.

3.6 SUMMARY OF FINDINGS

This **initial** analysis of the current implementation status of WFD Article 9 on SCIP notification and database – conducted in the months before the entry into application of the SCIP notification duty as from 5 January 2021 – has revealed several issues for defence stakeholders, including **potential** severe security risks to MoDs. The key findings of the analysis are summarised in the table below:

[325] ASD-Eurospace (2019). In June and August 2019 the EC had responded to the request by ASD-Eurospace for legal clarification that all suppliers who have the obligation to comply with Article 33(1) of the REACH Regulation have to comply with Article 9(1) of the WFD. The legislator has not foreseen any exclusion to the rule. See also Section 3.2.2 above.
[326] ASD-Eurospace (2020).
[327] ECHA has highlighted that it is preparing translations of its 'Requirements for SCIP notifications' document by end of the year, beginning of 2021; noting that it was not possible to make these translations earlier. ECHA is currently evaluating how to publish and translate further support to SMEs.
[328] SMEunited (2020).

Table 34: Summary of findings of the WFD Article 9/SCIP analysis

EU LEVEL IMPLEMENTATION OF SCIP
SCIP finding 1 – Stepwise SCIP database development The development of the SCIP database and related submission tools by ECHA has followed a stepwise approach. The final database (SCIP v1.0) enabling the submission of SCIP notifications to fulfil legal obligations was launched on 28 October 2020, i.e., about two months in advance of the entry into application of the legal SCIP notification duty. (Section 3.2.1)
SCIP finding 2 – SCIP requirements could potentially be interpreted as going beyond the WFD/REACH legal text Based on the European Commission (DG ENV) non-paper on WFD Article 9(1)(i) and (2), ECHA has developed extensive SCIP requirements which could potentially be interpreted as going beyond the legal text of WFD Article 9(1)(i) and the linked communication obligation in REACH Article 33(1) in several aspects. Some SCIP information requirements, such as mandatory category information and information on complex object components, are not specified in REACH Article 33(1) being the provision referred to in WFD Art. 9(1)(i). Furthermore, SCIP could potentially cover importers of articles for own (final) use, i.e., where the article is not supplied further by the importer (no corresponding Article 33(1) duty); the requested Commission clarification is still pending. Third, ECHA insists that its harmonised SCIP formats and submission tools have to be used. If a company does not submit a SCIP notification according to the SCIP format, no proof of submission is issued by ECHA. (Sections 3.2.2-5)
SCIP finding 3 – Duty holder responsibility for SCIP notification ECHA stresses that it has kept the constraints that would fail a SCIP notification submission to a minimum, thus providing a lot of discretion - with increased responsibility associated with it – for the duty holders on how to report data to the SCIP database. In order to support duty holders, ECHA has also provided some recommendations on the appropriate level of structuring and submitting data, including for (very) complex objects with regard to possible 'grouping' of similar products into a single notification and the 'hierarchy' (i.e. how many layers of components and subcomponents of a complex object have to be reported in a SCIP notification). (Section 3.2.4)
SCIP finding 4 – Public database and possible access to confidential information Going beyond WFD Article 9(2), ECHA is planning to publish the data submitted to the SCIP database, precisely as received, on its website (online access). There are some limited exceptions to protect confidential information (duty holder names are not published, nor identifiers of complex object components other than their name and article category). ECHA also highlights that the data required are rather generic (categories) and are expected to concern only a small part of the whole structure of a complex object. (Section 3.2.6)
SCIP finding 5 – No EU level SCIP defence exemption in WFD There is no provision in the revised WFD that would address the specific interest of defence or wider security, which could be affected by SCIP notifications and database disclosure. However, the EC (DG ENV) has clarified that a Member State may provide a specific exemption with regard to REACH Article 2(3) or have recourse to Article 346(1)(a) TFEU ("essential interests of its security"). (Section 3.2.6)
NATIONAL LEVEL IMPLEMENTATION OF SCIP
SCIP finding 6 – Transposition delay in Member States The transposition of Article 9(1)(i) WFD on SCIP notification is still pending in a number of EDA participating Member States, in spite of the expiry of the transposition deadline on 5 July 2020. Annex VIII 'SCIP Transposition Mapping' provides a high-level status overview and includes the legal text of relevant national SCIP clauses available for this study. National transposition measures are also listed at https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32018L0851. (Section 3.3.1)
SCIP finding 7 – Different general requirements The available general provisions transposing WFD Article 9(1)(i) have the reference to REACH Article 33(1) for the scope of SCIP notification in common. Otherwise, they differ to some extent. In particular, some national provisions initially foresee a literal transposition of WFD Article 9(1)(i) (e.g., FR, NL, RO, arguably also DE), while others make an explicit reference to the SCIP database / related ECHA formats / submission tools (e.g., ES, IT, SE). Some Member States foresee additional details (e.g., in SE on 'placing on the market' and Only Representative) or delegated powers to make more detailed provisions (e.g., DE, IT, FR, NL). Not much is

known today on national sanction provisions. (Section 3.3.1.1)

SCIP finding 8 – Different types of SCIP defence exemptions
Specifically in relation to defence, a number of participating Member States, for which information is available, foresee specific provisions to the end that a SCIP notification is or may not be required with a view to defence-related considerations (e.g. in DE, ES, FR, SE), while others refer to the REACH defence exemption process already in place (e.g. RO). The analysis of national provisions shows that there are three different types of SCIP defence exemptions, that vary regarding the need for a Member State involvement in a specific case to be freed from SCIP notification: (1) Member State involvement is not required (automatic exclusion, case of DE for "articles with a military purpose"); (2) Member State involvement with exemption request is required in each specific case (e.g. ES, SE); (3) Member State clarifies upfront which products are considered as exempted (FR). (Section 3.3.1.2)

POTENTIAL IMPACTS TO MODs FROM SCIP

SCIP finding 9 – Setup and management costs for defence exemption processes
Potential impacts on MoDs from implementation of WFD Article 9 are mainly seen regarding the application and management of SCIP defence exemptions, where those require a Member State involvement. MoDs in those Member States expect costs to set up and manage the defence exemption process. Where the process is linked to REACH Article 2(3), MoDs anticipate that the need for defence exemptions will increase in the future – likely significantly – or arise for the first time, if the exemption has not yet been used under REACH and defence exemptions will be necessary to secure national interests and to stop classified information from being reported in the SCIP database. (Section 3.3.2.1)

SCIP finding 10 - Complex scenarios - Potential security risks for MoDs
The consultation of MoDs has revealed some complex scenarios, where the national SCIP defence exemption does not or might not apply. These include components provided by higher-tier suppliers, cross-border supplies and dual use products. The potential risk which they have in common is that military classified information (e.g., on detailed product composition) or technological information on dual-use items subject to export control according to Council Regulation (EC) No 428/2009 is provided to the SCIP database and published by ECHA, even where national SCIP defence exemptions apply elsewhere. This could present potential severe security risks according to MoDs. However, no testimoniesis available to date given that the SCIP notification duty was not yet in force at the time of the study consultation. An additional impact on security (and defence industry) could be due to the current impossibility of deleting erroneous SCIP notifications (Section 3.3.2.2, 3.4.2.2)

SCIP finding 11 – Potential own duty in some Member States
MoDs have provided different answers regarding a potential own duty to make a SCIP notification. No potential duty is seen categorically by the German MoD, based on the new § 16f of the Chemicals Act and its elaborated legal position (2016). Other MoDs consulted either see a potential duty based on the specific circumstances, or they have not fully evaluated this question yet. Any potential duty scenarios will have to be further studied by the MoD(s) concerned and resolved based on the outcome. (Section 3.3.2.3)

DEFENCE INDUSTRY PRACTICAL PLANS TO COMPLY WITH SCIP

SCIP finding 12 – Analyse defence exemptions first, otherwise CBI-compliant but highly aggregated reporting
Manufacturers of complex products will find compliance with SCIP database requirements following ECHA's "article-centric approach" extremely challenging if not impossible to meet within the current timeframe. The defence industry (as reported by ASD) plans to analyse the national legal implementations of WFD Article 9 in respect of defence exemptions as a priority. For remaining notification obligations, the defence-sensitive/classified information and/or CBI shall be protected in any case, notably through highly aggregated notifications, limitation of data reported to the legal minimum as "available to the supplier" (REACH Article 33(1)) and (other) "camouflage methods" to be still elaborated in more detail. A certain level of non-compliance will need to be accepted. (Section 3.4.1)

POTENTIAL IMPACTS TO DEFENCE INDUSTRY FROM SCIP

SCIP finding 13 – High order of magnitude of SCIP notifications in A&D sector
A survey conducted by ASD amongst its membership in 2020 anticipates strong negative impacts on the A&D sector. It is estimated that more than 1 million notifications (comprising both civil and military business) will be submitted by the sector to the SCIP database in 2021. Notifications per company are expected to span from below 100 up to 200,000 per annum. The expected number of product declaration levels according to the SCIP

requirements varies in average from 2 to 7 levels, with a typical value of 4 and a maximum of 12 (e.g., for the most complex objects like aircraft or armoured vehicles). Companies do not have the resources to perform SCIP notifications. They will have to allocate budget to hire qualified resources and to get the necessary material to complete this task. (Section 3.4.2.1)

SCIP finding 14 – Challenges of using national SCIP defence exemptions

As the provisions governing implementation of SCIP in the area of defence are to be implemented separately in each EU Member State, defence industry stakeholders consulted have expressed unanimously that their harmonisation is of utmost importance as supply chains are mostly transnational today and the industries involved cannot or hardly manage unharmonised exemptions. According to anecdotal evidence from the defence industry consultation, precautionary SCIP notifications are envisaged for military products sold in the EU as of January 2021, unless there is a clear exemption (such as in DE). (Section 3.4.2.3)

SCIP finding 15 – Potential conflict of SCIP and ITAR requirements for US military hardware

For US military hardware supplied to the EU, the SCIP reporting requirements and public database are found by AIA to directly conflict with the requirement to safeguard product and technical information governed by ITAR, to which the US defence industries are legally bound. The associated security risks may possibly pre-empt compliance with SCIP reporting requirements. According to AIA therefore, the ability to provide US defence products to EU Member States could be impacted if defence exemptions cannot be secured. To avoid this scenario, all defence products should be exempted from these requirements, according to AIA. (Section 3.4.2.5)

OTHER RELEVANT IMPACTS

SCIP finding 16 – Additional challenges for SMEs to comply with SCIP

SMEs already struggle with the requirement stemming from REACH on product declaration for complex objects, i.e., REACH Article 33(1). WFD/SCIP will require even more information not available to SME as of today. Therefore, SMEs are not expected to have all mandatory data and skilled staff available to comply with SCIP notification from day 1 onwards (5 January 2021). SMEs will in many cases also not use IT systems for material/substance tracking for their products and procured parts, they will be obliged to make manual SCIP notifications instead of a more efficient system-to-system communication – the burden to comply with WFD will be disproportionally higher for SMEs than for larger sized companies. Another notable issue for SMEs is the overall English-language system at ECHA for SCIP, which is deemed non-acceptable from an SME perspective, an average SME cannot handle such a complex notification with such tools and will therefore regularly need external support, which is costly. The major trigger at the moment – by far – in terms of SCIP notification is expected to be lead metal, which is still widely used in various sectors. *SMEunited* estimates SCIP compliance costs for SMEs in the EU between EUR 48 to 67 billion per year. (Section 3.4.2.4, 3.5)

SCIP finding 17 – No/limited benefits of the SCIP database for the sector

All stakeholders consulted support the overall intent of the circular economy. However, they do not expect benefits of the "one-size-fits-all" article-centric SCIP requirements for the defence sector, or they consider that any benefits are associated with big risks for the secrecy of military information. Defence products are not manufactured with the intention of being conventionally recycled, and they have bespoke instructions that determine how they should be disposed of. Reporting on hazardous substances in military equipment to MoDs is expected to continue as is, based on contractual requirements and REACH Article 33 (where applicable), including requests for localisation of SVHCs. (Sections 3.3.2.4, 3.4.2.6, 3.5)

LIMITATIONS OF THE PRESENT SCIP ANALYSIS

SCIP finding 18 – MoD and defence industry implementation just started and need for further analysis

The SCIP requirements / related views have been evolving during the study and are still evolving at EU (Commission and ECHA) and national levels (Member State transposition, including on defence-related provisions). SCIP notifications with view to the entry into application date for the notification duty as from 5 January 2021 according to WFD Article 9(1)(i) – subject to national transposition – have only started. Therefore, it is still very unclear how the system will finally work. Hence, the final impacts and implementation strategies of MoDs and the defence industry are still widely unclear or to be further elaborated. It is also therefore difficult to answer which problems will arise and how to best handle them. This will be a learning curve for all stakeholders involved to find solutions that balance the interest in transparency of certain hazardous substances in articles, while at the same time allowing for the secure handling of military classified data and preventing them from being reported in the SCIP database, especially considering the eventual publication of

SCIP database information. The present SCIP analysis has been an important first step of a long process, and EDA together with the MoDs and in consultation with defence industry as appropriate are advised to further assess and elaborate solutions to mitigate the impacts of the evolving requirements for defence-related cases in the future, taking into account further experience gained in the meantime. (entire Chapter 3, in particular Sections 3.2.6., 3.3 and 3.4)

3.7 RECOMMENDATIONS

On the basis of the outcome of the implementation and impact analysis for WFD Article 9/SCIP database and the key findings derived from it (see above Sections 3.1– 3.6), this Section includes related specific recommendations by the contractor on proposed joint mitigation actions in relation to SCIP implementation in the area of defence **towards *EU MoDs***, with the support of EDA and possible consultation with MSCAs and the defence industry. These actions aim to mitigate negative impacts from SCIP implementation especially for MoDs, but also for the defence industry.

It should be noted that this study does **not** contain recommendations on joint mitigation actions directed **towards the *defence industry***. However, some of the recommendations propose a consultation of the defence industry by MoDs.

The recommendations are assessed according to their feasibility (difficulty to implement) and expected benefits (impacts). The difficulty mainly takes into account the expected technical challenges to implement a given recommendation (e.g., additional tasks for a given stakeholder within its given remit is easier to achieve than the definition of a common approach involving a number of different stakeholders or a change of the legal text). Other elements (such as the required human and financial resources) are also important parameters determining the practical difficulty but could not be assessed within the scope of this study.

The following types are distinguished, based on the technical feasibility of their implementation:

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction
Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders
Difficult – Recommendation involving significant change in core processes of the legislation or amendment of the legal text.

3.7.1 Collaboration within Member States on SCIP enforcement

Collaboration within Member States on SCIP enforcement	Addressee
Raise awareness with national enforcement authorities (NEAs) on specificities of defence products with regard to SCIP, taking into account EU and national SCIP implementation. Given the stepwise SCIP development at ECHA and delays at national levels but also the significant compliance challenges for the defence industry a *moratorium* on SCIP enforcement is a possible option that could be explored.	MoDs (after possible consultation of national defence industry) with their NEAs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to Section 3.6, especially the findings concerning the stepwise SCIP database development (finding No. 1), the transposition delay and differences in Member States (No. 6, 7), as well as the findings concerning the extent and (increased) duty holder responsibility regarding SCIP notification and publication of SCIP data on the one hand (No. 2-4, 13) and the identified challenges for SCIP implementation in the area of defence – including but not limited to the application of SCIP defence exemptions – on the other hand (No. 8-10, 12, 14, 15). Reference is also made to finding 16 (additional challenges for SMEs to comply with SCIP), finding 17 (no/limited benefits of the SCIP database for the sector) and finding 18 (MoD and defence industry implementation just started and need for further analysis).

Apart from clear exceptions (e.g., supply of defence products to DE MoD) – given the large scale and complexity of the project (see Section 3.4) – it is expected to take time for the defence industry to determine whether SCIP notifications are required in a given Member State and how they should be made, or whether, and under which conditions and process defence exemptions can be obtained. This is true in particular for defence products supplied across borders to other Member States (see Sections 3.3.2.2 and 3.4.2.3). It is also not clear today, to what extent SCIP notifications for (very) complex objects can be made in a way that preserves the confidentiality obligations of the defence industry and is also legally compliant with SCIP (see especially Sections 3.2.3, 3.2.4, 3.2.6, 3.4.1 and 3.4.2.2). At the same time, the SCIP notification duty is linked to the supply of the product without any grace period; it may not be possible to delay the supply without jeopardising defence interests.

As a result – and as pointed out by ASD – the defence industry is forced to accept a certain level of non-compliance to the compliance requirements as defined by ECHA while it is concerned about high expectations of enforcement authorities (see Section 3.4.1). Thus, raising awareness and facilitating understanding of the NEAs about the specificities of defence products regarding SCIP could help set more realistic expectations.

Implementation of recommendation

As given in the description of the recommendation.

MoDs are advised to communicate to their NEAs on specificities of defence products regarding SCIP. Before reaching out to their NEAs, MoDs may want to consult with their national defence industry on the latest status and persisting challenges of SCIP implementation, building further on the defence industry's SCIP compliance plans reflected in Section 3.4.1 (notably with regard to the concept of aggregation, limitation to data "available to the supplier" and (other) means of confidentiality protection), the potential impacts to on the defence industry (Section 3.4.2) as well as the potential impacts on MoDs (Section 3.3.2).

It should be noted that NEAs are often located at regional level and may be numerous. In this case enforcement coordinators, working groups or the MSCA at the federal/national level could be approached instead.

3.7.2 Raising awareness of national SCIP provisions on defence

Raising awareness of national SCIP provisions on defence	Addressee
Add information on national provisions governing SCIP implementation in the area of defence to the EDA website, including but not limited to defence exemption clauses, procedures and number of decisions (if applicable)	EDA with support of MoDs (provide MS information)

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to Section 3.6, finding 8 (different types of SCIP defence exemptions), 9 (setup and management costs of defence exemption processes, 12 (regarding defence industry plans to analyse exemptions first), 14 (challenges of using national SCIP defence exemptions) and 18 (MoD and defence industry implementation just started and need for further analysis).

The information on the EDA REACH Portal[329] gives a structured and useful overview of the questions around the REACH defence exemption, the EDA Code of Conduct 2015 and information on national defence exemption procedures.

In the contractor's opinion, a single point of access to national SCIP defence exemption clauses, procedures and number of decisions (if applicable) on the EDA website – similar to the EDA REACH Portal – would improve the awareness of applicable provisions for the defence industry, allowing quicker access to the relevant rules. For MoDs, too, such a single point of access could promote the harmonisation on national SCIP defence exemptions (see also Recommendation 3.7.3).

Implementation of recommendation

As given in the description of the recommendation. The recommendation is primarily addressed to the EDA as website host, but it relies on the technical input from the MoDs.

3.7.3 Harmonisation of SCIP implementation in the area of defence

Harmonisation of SCIP implementation in the area of defence	Addressee
(1) Discuss possibilities to harmonise the application of national provisions governing SCIP implementation in the area of defence, including SCIP defence exemptions, where the MS provisions are similar	EDA with MoDs of MSs with *similar* provisions, with possible consultation of defence industry
(2) If based on this analysis all stakeholders agree that there are strong arguments for harmonisation: collaborate on appropriate solutions for defence products and components. Those may include for example: work on a new EDA Code of Conduct to address WFD Article 9/SCIP database	EDA with MoDs
(3) If harmonisation within the existing national provisions cannot be achieved (step (1) above), discuss possibilities to harmonise the legal provisions governing SCIP in the area of defence across the MSs	EDA with all MoDs (in consultation with their MSCAs)

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

The implementation of **step (3)** of the recommendation (harmonise the legal provisions governing SCIP in the area of defence across the Member States) would be **difficult** to achieve, as it requires rewriting the (core) national legal texts (needs formal process of opening the legal text) in a

[329] https://reach.eda.europa.eu.

harmonised manner across different Member States.

Rationale

Reference is made to Section 3.6, finding 8 (different types of SCIP defence exemptions), 9 (setup and management of defence exemption processes), 10 (complex scenarios – potential security risks for MoDs) and 14 (challenges in using national SCIP defence exemptions). Reference is also made to finding 18 (MoD and defence industry implementation just started and need for further analysis).

The recommendation is made to promote the EU-level harmonisation of SCIP implementation in the area of defence in the interest of a level playing field for the defence industry and to address possible concerns relating to the potential disclosure of defence-sensitive information in the SCIP database, which must be avoided.

In the contractor's opinion, the different national provisions on SCIP defence exemptions are very likely to lead to different Member State decisions, including for the same defence products. As an example, the same/similar defence product exempted from SCIP notification in Member State A for reasons of protection of defence-sensitive information could remain subject to SCIP notification in Member State B and the information published on the ECHA website. This again could potentially undermine the exemption in Member State A.

Also, in the contractor's opinion the **"last resort approach"** to defence exemptions adopted for **REACH** in the EDA Code of Conduct of 2015 (i.e., referring industry to standard compliance as a primary course of action) is not necessarily appropriate in relation to SCIP implementation in the area of defence, as SCIP notifications are to be made on a product level (including product and substance information), not for chemical substances. This **article-centric approach** to SCIP notification in combination with ECHA's detailed information requirements and the final publication of notified information on the ECHA website to be visible to everybody, bear a potential significant risk of disclosure of defence-sensitive information for a wide scope of products and components. Given the different legal basis (WFD/SCIP vs. REACH only) the defence specificities/provisions would probably be treated quite differently and would address possibly very distinct issues.

Implementation of recommendation

As given in the description of the recommendation, MoDs are advised to work together in the EDA framework to discuss possibilities to harmonise the application of national provisions governing SCIP implementation in the area of defence, including SCIP defence exemptions, where the Member State provisions are similar. If based on this examination all stakeholders agree that there are strong arguments for harmonisation, then EDA, together with MoDs, are advised to collaborate on developing appropriate solutions for defence products and components.

3.7.4 Collaboration on cross-border supplies vs. SCIP

Collaboration on cross-border supplies vs. SCIP	Addressee
(1) Identify in the EDA framework possible cases of concern with regard to cross-border supplies (e.g., same products supplied to different Member States)	EDA with MoDs, with possible consultation of defence industry
(2) If based on this analysis all stakeholders agree that there are concerns that cannot be resolved unilaterally in Member States: collaborate on appropriate solutions for defence products and components. Those may include for example: ■ Joint exemption process for SCIP (where *similar* provisions exist) ■ Recognition of exemptions in the Member State of origin	EDA with MoDs

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to Section 3.6, finding 8 (different types of defence exemptions), 9 (setup and management costs of defence exemption processes), 10 (complex scenarios – potential security risks for MoDs) and 14 (challenges of using national SCIP defence exemptions). Reference is also made to finding 18 (MoD and defence industry implementation just started and need for further analysis).

The recommendation is made to achieve a workable process for the implementation of SCIP in the area of defence in transnational scenarios and in particular to address possible concerns relating to the disclosure of defence-sensitive information in the SCIP database for products exempted in one Member State but not in others where the product is supplied.

In the contractor's opinion, the different national provisions on SCIP defence exemptions are very likely to lead to different Member State decisions, including for the same defence products. As an example, the same defence product exempted from SCIP notification in Member State A for reasons of protection of defence-sensitive information, could remain subject to SCIP notification in Member State B and the information published on the ECHA website. This again could undermine the exemption in Member State A.

Recommendation implementation

As given in the description of the recommendation, MoDs are advised to work together in the EDA framework to first identify possible cases of concern with regard to cross-border supplies and then collaborate on appropriate solutions.

Should it prove not possible to resolve problematic cases concerning cross-border supply in this way, the proposal of an EU level general exclusion for the military sector directly from WFD Article 9 on SCIP, should be investigated (see Recommendation 3.7.7).

3.7.5 Collaboration within Member States on complex SCIP scenarios

Collaboration within Member States on complex SCIP scenarios	Addressee
(1) Identify possible cases of concern where the SCIP notification would cause a security risk for an MoD, and cannot be resolved by the national SCIP defence exemptions (e.g., dual use products, upstream components)	MoDs, with possible support of EDA and consultation of the relevant industry stakeholders (incl. but not limited to suppliers to the MoDs)
(2) If based on this analysis a potential or even real case and security risk for an MoD are identified: discuss/agree with the MSCA, how the duty holder can be freed from SCIP notification, incl. based on TFEU Article 346(1)(a)	MoD with MSCA

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

If the national law requires a change to implement the exemption from SCIP notification in a complex SCIP scenario, the difficulty to implement increases further.

Rationale

Reference is made to Section 3.6, finding 10 (Complex scenarios – Potential security risks for MoDs), and in particular the analysis in Section 3.4.2.2 in relation to components provided by higher-tier suppliers and dual use; it was highlighted that overall no experience is currently available, but potential severe security risks for MoDs are feared given the challenges to capture these scenarios under defence-specific provisions. Reference is also made to finding 18 (MoD and defence industry implementation just started and need for further analysis).

Implementation of recommendation

As given in the description of the recommendation. The recommendation concerns scenarios, that are limited to a given Member State. Where a cross-border issue is identified, reference is made to Recommendation 3.7.4 (Collaboration on cross-border supplies vs. SCIP).

It is further noted that step (2) (exemption from SCIP notification) could potentially require a change of the legal text, if required in the national legal system.

3.7.6 Potential own duty in some Member States

Potential own duty in some Member States	Addressee
(1) Identify actual case(s) where a SCIP notification duty on a national MoD/Armed Forces is deemed to exist	MoDs, in consultation with their legal departments and possibly the MSCA
(2) If based on this analysis a real case is identified: assess whether the MoD/Armed Forces may be freed from SCIP notification based on the specific national defence exemption clause or directly based on Article 346(1)(a) TFEU	MoDs, possibly in consultation with the MSCA

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to Section 3.6, finding 11 (Potential own duty in some Member States). Reference is also made to finding 15 (Conflict of SCIP and ITAR requirements for US military hardware) and finding 18 (MoD and defence industry implementation just started and need for further analysis).

It is noted that the recommendation does not apply to Member States where there is an automatic exclusion for defence products (e.g., in DE, where articles with a military purpose are excluded from SCIP notification and a legal analysis has already been completed by the German MoD).

Implementation of recommendation

As given in the description of the recommendation.

3.7.7 EU level exclusion from SCIP for defence in the WFD

EU level exclusion from SCIP for defence in the WFD	Addressee
(1) National assessment of the necessity to include an exclusion for defence from the WFD in the legal text, in relation to WFD Article 9(1)(i) & (2) *Consider coverage of dual use and wider security interests*	MoDs, in consultation with MSCAs and their national defence industries
(2) If national review is completed and a wide number of Member States support further examination: further discussion of such an exclusion in the EDA framework	EDA with MoDs
(3) If based on this assessment all stakeholders to be involved agree that there are strong arguments: pass on this proposal to the Commission for possible action	EDA and MSs (MoDs and/or MSCAs)

Difficulty to implement

Difficult – Recommendation involving significant change in core processes of the legislation or amendment of the legal text.

Rationale

Reference is made to Section 3.6, especially:

- finding 5 – no EU level SCIP defence exemption in WFD;
- the findings linked to the challenges of the current national approach (8 – different types of SCIP defence exemptions; 10 – complex scenarios; 14 – (industry) challenges of using national SCIP defence exemptions);
- the findings linked to confidentiality issues (4 – public database; 15 – conflict of SCIP and ITAR requirements for US military hardware);
- the findings linked to the expected administrative burden for MoDs (9 - setup and management costs of defence exemption processes) and defence industry (12 – analyse exemptions first);
- finding 17 – no/limited benefits of the SCIP database for the defence sector;
- finding 18 – MoD and defence industry implementation just started and need for further analysis.

As shown, some MoDs (see especially Section 3.3.2.1) and defence industry stakeholders (see Section 3.4.2.3) consider that a uniform legal basis / SCIP defence exemption in the Directive or a "generic exemption" of all defence material without the need for specific applications to be made would be

the best option to achieve the needed harmonisation in the area of defence.

In the contractor's opinion the current approach of different national provisions governing SCIP defence exemptions poses significant challenges for MoDs and the defence industry, as companies supply the same or similar products in various countries, and military products are the result of complex international supply chains. The required national exemption procedures (unless the provision is automatic such as in DE) increase the resource needs for both MoDs / other MSCA involved in granting defence exemptions and the defence industry without real added value for any of the stakeholders visible today.

Implementation of recommendation

As given in the description of the recommendation, following national assessment, further discussion of such an exclusion and its scope may be carried out within the EDA framework, with the support of the MoDs.

If eventually considered as necessary by all involved defence stakeholders, the implementation of an exclusion for defence in the WFD, which does not require national case-by-case exemptions, would require a change of the WFD legal text, and hence a proposal from the Commission and a co-decision by the European Parliament and the Council of the European Union.

3.7.8 Application of SCIP to 'import' for own (final) use

Application of SCIP to 'import' for own (final) use	Addressee
Follow up with the EC (DG ENV) to obtain its legal clarification on whether SCIP notification based on WFD Article 9(1)(i) also applies to 'import' for own (final) use	EDA

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to Section 3.2.2 (Duty holders for SCIP notification) and Section 3.6, finding 2 (SCIP requirements could potentially be interpreted as going beyond the WFD/REACH legal text). Reference is also made to finding 18 (MoD and defence industry implementation just started and need for further analysis).

Implementation of recommendation

As given in the description of the recommendation.

3.7.9 Discussions of potential conflict of SCIP and ITAR

Discussions of potential conflict of SCIP and ITAR	Addressee
(1) Discuss on a contract-by-contract basis how to deal with the SCIP reporting in the light of ITAR requirements for US military hardware	MoDs concerned with their contractors
(2) Discuss the issue of potential conflict of SCIP and ITAR requirements for US military hardware and possible solutions in the area of defence at EDA level, and in consultation between EDA and AIA as necessary.	EDA and MoDs with AIA

Difficulty to implement

Easy – Recommendation could be implemented within the current legal text, without complex stakeholder interaction

Rationale

Reference is made to Section 3.6, finding 15 (Potential conflict of SCIP and ITAR requirements for US military hardware). Reference is also made to finding 18 (MoD and defence industry implementation just started and need for further analysis).

It is noted that the recommendation does not apply to Member States where there is an automatic exclusion for defence products (e.g., in DE, where articles with a military purpose are excluded from SCIP notification and a legal analysis has already been completed by the German MoD)

Implementation of recommendation

As given in the description of the recommendation.

3.7.10 Setup of a dedicated SCIP activity at EDA level

Setup of dedicated SCIP activity at EDA level	Addressee
Based on the present study, further assess and elaborate solutions to mitigate the impacts of the evolving SCIP requirements for defence-related cases in the future, taking into account further experience gained in the meantime. Key issues include: • Uptake of the other study recommendations • Identification of specific confidentiality issues when notifying defence/civil dual use products to the SCIP database • Confirmation of security risks to MoDs • Further assessment of the potential conflict of SCIP reporting with Council Regulation (EC) No 428/2009 on dual-use items • Identification of and exchange on issues and best practices on SCIP implementation in the area of defence at the MoD level • EDA follow-up with ECHA on the deletion possibility for erroneous SCIP notifications • Exchange with the defence industry, EC and ECHA on SCIP implementation issues	EDA together with MoDs and in consultation with defence industry, EC and ECHA as appropriate

Difficulty to implement

Medium – Recommendation could be implemented within the current legal text, but requires collaboration and agreement of various stakeholders

Rationale

Reference is made to Section 3.6, especially finding 18 (MoD and defence industry implementation just started and need for further analysis), but also finding 3 (Duty holder responsibility for SCIP notification), finding 4 (Public database and possible access to confidential information), findings 6-8 relating to national level implementation of SCIP, findings 9-11 relating to potential impacts to MoDs and findings 12-15 relating to defence industry compliance plans and potential impacts.

The present study has been conducted before the entry into application of the SCIP notification duty on 5 January 2021 and while key provisions (especially the national laws transposing WFD Article

9(1)(i)) were only in the process of being adopted. Also, the SCIP database only went "live" on 28 October 2020 and key ECHA documents and recommendations were provided only during or after the end of the stakeholder consultation. Therefore, only initial and potential impacts for MoDs and defence industry could be determined, e.g., in relation to confidentiality protection when notifying to ECHA and potential security risks to MoDs.

Implementation of recommendation

As given in the description of the recommendation. It should be considered that such a dedicated SCIP activity will have to interact with ongoing and relevant REACH activities at the EDA, since the SCIP requirements are intrinsically linked to REACH requirements (REACH Art. 33(1)), the key definitions of 'article' (REACH Article 3 No. 3) and 'supplier of an article' (REACH Article 3 No. 33 and associated definitions) and – in some Member States following the Commission advice (see above Section 3.2.6 and Section 3.3.1.2) – to the defence exemption possibility in REACH Art. 2(3).

3.7.11 Summary of recommendations

This Section provides a structured summary of the SCIP recommendations to EDA/MoDs with regard to their corresponding SCIP findings and their priority vs. difficulty to implement.

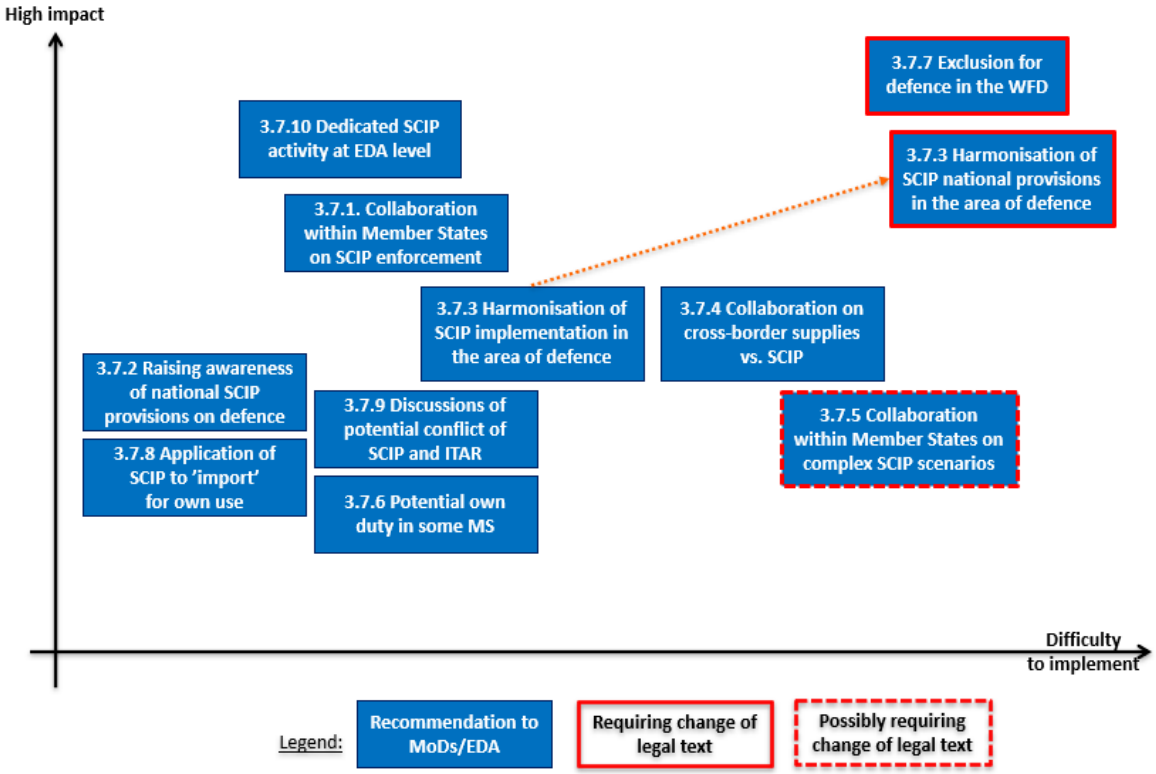
Table 35 SCIP recommendations vs. SCIP findings

SCIP recommendations (Section 3.7.1-10)	SCIP finding(s) (Section 3.6)
3.7.1 Collaboration within Member States on SCIP enforcement	Findings 1, 2-4, 6-10, 12-17, 18
3.7.2 Raising awareness of national SCIP provisions on defence	Findings No. 8, 9, 12, 14 and 18
3.7.3 Harmonisation of SCIP implementation in the area of defence	Findings 8-10, 14 and 18
3.7.4 Collaboration on cross-border supplies vs. SCIP	Findings 8-10, 14 and 18
3.7.5 Collaboration within Member States on complex SCIP scenarios	Findings 10 and 18
3.7.6 Potential own duty in some Member States	Findings 11,15 and 18
3.7.7 EU level exclusion from SCIP for defence in the WFD	Findings 4, 5, 8-10, 12, 14, 15, 17, 18
3.7.8. Application of SCIP to 'import' for own (final) use	Findings 2 and 18
3.7.9 Discussion of potential conflict of SCIP and ITAR	Findings 15 and 18
3.7.10. Setup of a dedicated SCIP activity at EDA	Findings 3, 4, 6-8, 9-11, 12-15, 18

Priority vs. difficulty to implement

The priority of the recommendations is determined as a function of their implementation feasibility (difficulty) vs. the expected benefit (impact) for the European defence sector, as illustrated in an indicative way in Figure 10 below. The Figure shows that those recommendations with a higher number of corresponding findings (see above) tend to have a higher impact (expected benefit).

Figure 10: Priority of recommendations



All recommendations could make a real difference regarding mitigation of impacts from WFD Article 9/SCIP database in the European defence sector. Recommendations addressing the **collaboration** on and **harmonisation** of SCIP implementation in the area of defence across different Member States and alleviation of possible adverse impacts to the defence industry are considered to be of the highest priority. At the same time, these recommendations contribute to the vital protection of **confidentiality** and avoidance of any supply disruptions in the defence sector due to SCIP. The recommendations addressing certain **legal issues** are also important to this end.

BIBLIOGRAPHY

BPR Regulation

Legislation/conventions

- Regulation (EU) 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123
- Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014, p. 1–34.
- Commission Decision 2014/395/EU of 24 June 2014 concerning the placing on the market for essential use of biocidal products containing copper, OJ L 186, 26.6.2014, p.103-107.
- Commission Regulation (EC) No 1451/2007of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12.2007, p.3-65.
- Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships, OJ L 115, 9.5.2003, p. 1–11.

Other sources

- EASA (2020) Safety Information Bulletin No 2020-06 of 20 March 2020 on the use of DuPont Kathon™ FP 1.5 Biocide, https://ad.easa.europa.eu/ad/2020-06 (Last accessed 02.10.2020).
- BAUA – Federal Office for Chemicals (2020) General decision on authorisation of the biocidal product "Biobor JF" for preventive antimicrobial treatment of fuel systems of temporarily decommissioned planes by professional users due to a danger to public health, 07/04/2020, https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/EN/Biozide/general_decision_jet-fuel.pdf?__blob=publicationFile&v=3 (Last accessed 02.10.2020).
- ECHA, Understanding BPR, https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr (Last accessed on 12.11.2020)
- ECHA, Q&As Biocidal Product Regulation, https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/Biocidal+Products+Regulation?_journalqadisplay_WAR_journalqaportlet_INSTANCE_70Qx_backURL=https%3A%2F%2Fecha.europa.eu%2Fsupport%2Fqas-support%2Fbrowse%3Fp_p_id%3Djournalqadisplay_WAR_journalqaportlet_INSTANCE_70Qx%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_pos%3D2%26p_p_col_count%3D3 (Last accessed on 12.11.2020)
- ECHA (2020) Questions and answers: advice for companies on making disinfectants available on the EU/EEA market, 15 June 2020 – version 4.0, https://echa.europa.eu/documents/10162/28801697/q_a_covid_disinfectants_en.pdf/f380496a-d61a-1ff1-ee78-12d302c5d520 (Last accessed on 12.11.2020)
- ECHA (2019) Introductory Guidance on the CLP Regulation. Version 3.0: https://www.echa.europa.eu/documents/10162/23036412/clp_introductory_en.pdf/b65a97b4-

8ef7-4599-b122-7575f6956027 (Last accessed on 01.10.2020)

- ECHA (2013) Rules of procedure for the Biocidal Products Committee, https://echa.europa.eu/documents/10162/4221979/bpc_procedure_rules_en.pdf/4462dc96-b5ed-414b-b000-6dc5dbc799e7 (Last accessed on 01.10.2020)
- KEMI (2016) Market survey on articles treated with biocides, PM 6/16, https://www.kemi.se/en/publications/pms/2016/pm-6-16-market-survey-on-articles-treated-with-biocides (Last accessed on 02.10.2020).

POPs Regulation

Legislation/conventions

- Stockholm Convention on persistent organic pollutions (POPs), Text and Annexes, Revised in 2017, http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx (Last accessed 12.11.2020)
- UNECE, Protocol on Persistent Organic Pollutants (POPs), http://www.unece.org/env/lrtap/pops_h1.html (Last accessed on 08.10.2020)
- Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 169, 25.6.2019, p. 45–77.
- Corrigendum to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, OJ L 179 of 9.6.2020 p.4-6.
- Commission Delegated Regulation (EU) 2020/1204 of 9 June 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of dicofol OJ L 270, 18.8.2020, p. 4–6.
- Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188 I/1, 15.6.2020.
- Commission Regulation (EU) 2016/293 of 1 March 2016 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, OJ L 55, 2.3.2016, p. 4–8.
- Commission Regulation (EU) 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III, OJ L 223/29, 25.8.2010.

Other sources

- Competent Authorities expert group for Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs) (2019) Summary record of the 21st Meeting of the CAs on Regulation (EU) 2019/1021 on POPs, 26 November 2019, point 18, https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17912 (Last accessed on 09.10.2020).
- ECHA, Understanding POPs: https://echa.europa.eu/understanding-pops (Last accessed on 12.11.2020)
- EC, DG Environment, Persistant Organic Pollutants (POPs) :
- https://ec.europa.eu/environment/chemicals/international_conventions/index_en.htm (Last

accessed on 09.11.2020).

- EC (2019) European Union Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants, SWD(2018) 495 final/2, 21.1.2019, http://www.pops.int/Implementation/NationalImplementationPlans/NIPTransmission/tabid/253/Default.aspx (Last accessed on 08.10.2020)
- EC (2018) Report from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the review and update of the second European Union Implementation Plan in accordance with Article 8 (4) of Regulation No 850/2004 on persistent organic pollutants, COM(2018) 848 final, Brussels, 4.1.2019
- EC (2014) REACH and the Stockholm Convention as well as the UNECE Protocol. A common understanding, https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en (Last accessed on 12.11.2020)
- RIVM (2011) Identifying potential POP and PBT substances. Development of a new Persistence/Bioaccumulation-score. RIVM Report 601356001/2011, https://www.rivm.nl/bibliotheek/rapporten/601356001.pdf (Last accessed on 09.10.2020)
- Stockholm Convention website: http://chm.pops.int/Home/tabid/2121/Default.aspx (Last accessed on 12.11.2020)

Ozone Regulation

Legislation/conventions

- Regulation (EC) 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, OJ L 286, 31.10.2009, pp. 1–30
- Regulation (EC) 2037/2000 of the European Parliament and on the Council of the 29 June 2000 on substances that deplete the ozone layer OJ L 244, 29.09.2000, pp. 1-24
- Commission Implementing Decision C(2014)7821/F1 on authorizing a temporary exemption request by the Netherlands, pursuant to Regulation (EC) No 1005/2009 of the European Parliament and the Council on substances that deplete the ozone layer, with regard to the use of reclaimed FCFC-22 by the Ministry of Defence: https://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=3&year=2014&number=7821&language=en (Last accessed on 12.10.2020)

Other sources

- Commission Staff Working Document on the evaluation of Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, SWD(2019)407final https://ec.europa.eu/clima/events/evaluation-ozone-regulation_en (Last accessed on 12.10.2020)
- Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=64482 (Last accessed on 12.10.2020)
- European Union Safety Agence (EASA) (2019) Halon replacement in the aviation industry https://www.easa.europa.eu/document-library/general-publications/halon-replacement-aviation-industry (Last accessed on 12.10.2020)

- European Environment Agency (EEA) (2019) Ozone-depleting substances 2019, Aggregated data reported by companies on the import, export, production, destruction, feedstock and process agent use of ozone-depleting substances in the European Union, 2006-2018, Report No 12/2019 https://www.eea.europa.eu/publications/ozone-depleting-substances-2019 (Last accessed on 12.10.2020)
- REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.106.
- European Commission's webpage on Committee information about the Committee on ozone depleting substances https://ec.europa.eu/transparency/comitology-register/screen/committees/C13800/consult (Last accessed on 10.11.2020)
- European Commission's webpage on the EU Single Window environment for customs https://ec.europa.eu/taxation_customs/general-information-customs/electronic-customs/eu-single-window-environment-for-customs_en (Last accessed on 13.10.2020)
- European Commission's webpage on the evaluation of the ODS Regulation https://ec.europa.eu/clima/events/evaluation-ozone-regulation_en (Last accessed on 12.11.2020)
- European Commission's webpage on the public consultation open for the ODS Regulation https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12310-Ozone-layer-protection-revision-of-EU-rules (Last accessed on 12.11.2020)
- University of York's webpage on ozone depleting substances: https://www.york.ac.uk/chemistry/research/wacl/ozone-depleting-substances/ (Last accessed on 10.11.2020)
- Spain's Ministry of the Environment's webpage on their "Zero Contamination Ship" initiative https://www.defensa.gob.es/medioambiente/luchacontaminacion/prevencioncontaminacion/ (Last accessed on 12.11.2020)

F-gas Regulation

Legislation/conventions

- Regulation (EU) 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006, OJ L 150, 20.5.2014, p. 195–230

Other sources

- European Commission (2020) Combined evaluation roadmap/inception impact assessment, Ref. Ares(2020)3402178-29/06/2020
- Ramboll (2019) Support study for the evaluation of Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, final report, https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=64482 (Last accessed on 12.10.2020)
- European Environment Agency (EEA) (2019) Fluorinated greenhouse gases, Data reported by companies on the production, import and export, destruction and feedstock use of fluorinated greenhouse gases in the European Union 2007-2018, Report No 20/2019 https://www.eea.europa.eu/publications/fluorinated-greenhouse-gases-2019/ (Last accessed: 12.10.2020)

- The Linde Group (2014) Guide to the updated EU F-gas Regulation (517/2014) https://www.linde-gas.com/en/products_and_supply/refrigerants/environment_and_legislation/global_warming_legislation_hfc_control/eu_fgas_regulation/index.html (Last accessed: 08.12.2020)
- REACHLaw (2016) Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector, final report, p.106.
- European Commission's webpage on the F-gas Regulation https://ec.europa.eu/clima/policies/f-gas_en (Last accessed on 12.10.2020)
- European Commission's webpage on Committee information about the Committee of fluorinated greenhouse gases https://ec.europa.eu/transparency/comitology-register/screen/committees/C47200/consult (Last accessed on 10.11.2020)
- UN Environment Programme's webpage on the Montreal Protocol https://www.unenvironment.org/ozonaction/who-we-are/about-montreal-protocol (Last accessed on 12.10.2020)
- UN Industrial Development Organisation's webpage on the Montreal Protocol https://www.unido.org/our-focus-safeguarding-environment-implementation-multilateral-environmental-agreements-montreal-protocol/montreal-protocol-evolves-fight-climate-change (Last accessed on 12.11.2020)

RoHS Directive

Legislation/conventions

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88–110

Other sources

- ASD feedback to the Öko-Institut consultation linked to the review of the list of restricted substances under RoHS (as part of the consultation for the Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)), 14 June 2018, https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_ASD_General_TBBPA_Be_Ni_InP_Co_RoHS_Consultation_ASD_input_14.06.2018.pdf (Last accessed on 12.11.2020)
- EUR-Lex, National transposition measures communicated by the Member State: https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32011L0065&qid=1604402143268 (last accessed on 03.11.2020)
- European Commission, The RoHS Directive: https://ec.europa.eu/environment/waste/rohs_eee/index_en.htm (Last accessed on 12.11.2020)
- European Commission (2014) REACH and Directive 2011/65/EU (RoHS). A common understanding, https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en (Last accessed on 12.11.2020)
- European Commission (2013) Study for the review of the list of restricted substances under RoHS2. Report prepared by Umweltbundesamt GmbH for the European Commission, DG Environment, https://op.europa.eu/en/publication-detail/-/publication/39eb0f95-27a8-4ae6-

8ec3-627c7336ae65 (Last accessed on 12.11.2020)

- European Commission (2012) RoHS 2 FAQ, https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf (Last accessed on 12.11.2020)
- Öko-Institut (2020) Draft Exemption evaluation methodology manual, as part of Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 -Task 4, draft final), https://rohs.exemptions.oeko.info/index.php?id=341 (Last accessed on 12.11.2020)
- Öko-Institut (2020) ROHS Annex II Dossierfor Cobalt dichloride, cobalt sulphate, cobalt dinitrate, cobalt carbonate and cobalt di(acetate). Restriction proposal for substances in electrical and electronic equipmentunder RoHS. Version 3 – 26/03/2020,
- https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/Cobaltsalts_RoHS_Dossier_V3_final.pdf (Last accessed on 12.11.2020)
- Öko-Institut (2019) Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive, https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Pack_15_Substance_Review_Draft_Manual_Methodology_second_version_20190926.pdf (Last accessed on 12.11.2020)
- Öko-Institut (2019) ROHS Annex II Dossier for Indium phosphide. Restriction proposal for substances in electrical and electronic equipment under RoHS. Version 3 – 25/09/2019, https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/Indium_phosphide_RoHS_Dossier_v3_final_rev.pdf (Last accessed on 12.11.2020)
- Öko-Institut (2012) Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU,
- https://ec.europa.eu/environment/waste/rohs_eee/pdf/Guidance_Document.pdf (Last accessed on 12.11.2020)
- United Kingdom Environment Agency (2019) Substance evaluation conclusion as required by REACH Article 48 and evaluation report for Medium-chain chlorinated paraffins/alkanes, C14-17, chloro, https://echa.europa.eu/documents/10162/a72b228a-e417-5b53-b2b9-3b45c8e6eec5 (Last accessed on 12.11.2020).

Waste Framework Directive

Legislation/conventions

- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (Recast), OJ L 134, 29.5.2009, p. 1–269. The latest consolidated version of 31 December 2019 is available at https://eur-lex.europa.eu/eli/reg/2009/428/2019-12-31Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste, OJ L 150, 14.6.2018, p. 109-140, https://eur-lex.europa.eu/eli/dir/2018/851/oj
- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3–30. The latest consolidated version of 5 July 2018 is available at https://eur-lex.europa.eu/eli/dir/2008/98/2018-07-05
- Treaty on the Functioning of the European Union, Article 346, https://eur-lex.europa.eu/eli/treaty/tfeu_2016/art_346/oj

Other sources

- ACEA et al. (2020) Industry letter to President von der Leyen "The notification deadline for the SCIP database must be postponed", 21 September 2020
- ASD (2018) Detailed response to the call for input on the task of ECHA to develop a database on articles containing Candidate List substances under the Waste Framework Directive, 9 October 2018
- ASD-Eurospace. (2020) Best-Practice Guidance for the European Space Sector to comply with SCIP notification, 30 September 2020, https://eurospace.org/wp-content/uploads/2020/10/scip-space-best-practice-guidance-final-30092020-1.pdf
- ASD-Eurospace. (2019) Space Industry Position regarding Article 9 of the revised Waste Framework Directive 2008/98/EC, 9 September 2019, https://eurospace.org/wp-content/uploads/2019/09/wfd-position-eurospace-09092019-signed.pdf
- Becker, T. (2019) The SCIP Database under Directive (EU) 2018/851, StoffR 4/2019, pp. 156-164, https://www.reachlaw.fi/wp-content/uploads/2020/01/scip-database_-stoffr_-zeitschrift-fur-stoffrecht.pdf
- EC (2020, October 12) Response to ACEA et al. (2020) Industry letter to President von der Leyen, ref. Ares(2020)5424145
- EC (2019, June 20) Non-paper on the implementation of articles 9(1)(i) and 9(2) of the revised Waste Framework Directive 2008/98/EC, ref. Ares(2019)3936110, 20 June 2019, available at https://eurospace.org/wp-content/uploads/2019/09/annex-3-com-non-paper-wfd-20062019.pdf
- EC (2006) Interpretative Communication on the application of Article 296 of the Treaty in the field of defence procurement, COM(2006) 779 final, 7 December 2006, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52006DC0779&from=LT
- ECHA (2020, October 28) SCIP Database Notifications. How to prepare and submit a SCIP notifications, Version 3.0, 28 October 2020, https://echa.europa.eu/documents/10162/28213971/SCIP_Database_Notifications.pdf/63a1dbe6-20ce-2e37-46be-4293c809dc2f
- ECHA (October 2020) Requirements for SCIP notifications, October 2020, https://echa.europa.eu/documents/10162/28213971/Information_requirements_for_scip_notifications_en.pdf/db2cf898-5ee7-48fb-e5c8-4e6ce49ee9d2
- ECHA (August 2020) Tools to refer to SCIP data already submitted to ECHA, Version 1.0, August 2020, https://echa.europa.eu/documents/10162/13567/tools_to_refer_to_already_submitted_sip_data_en.pdf
- ECHA (July 2020) Dissemination and confidentiality in the SCIP Database, July 2020, https://echa.europa.eu/documents/10162/28213971/dissemination_confidentiality_scip_en.pdf/e0efbea1-d8ec-b67c-de8f-1838b480db6d
- ECHA (2020, June 25) SCIP database update for the joint meeting of the Waste and CARACAL Expert Groups on 9 July 2020, Doc. CA-JM/02/2020, 25 June 2020
- ECHA (2020, April 16) Written consultation of the members of the Waste and CARACAL Expert Groups, Update on the SCIP database of articles containing Candidate List substances, 16 April 2020
- ECHA (2019) Detailed information requirements for the SCIP database, September 2019,

https://echa.europa.eu/documents/10162/28213971/scip_information_requirements_en.pdf

- European Recycling Industries' Confederation (EuRIC) / Plastics Recycler Europe (PRE) (2020) Technical Paper on the SCIP Database, 20 February 2020
- SMEunited (2020) Impact of the upcoming SCIP on SMEs, letter to Mr. Virginijus Sinkevičius, 31 July 2020
- ZVEI et al. (2020) Comments on the "Written consultation of the members of the Waste and CARACAL Expert Groups" concerning an "Update on the SCIP database of articles containing Candidate List substances", 11 May 2020

REACH and CLP Regulations

Legislation

- Commission Delegated Regulation (EU) 2017/227 of 9 February 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(pentabromophenyl)ether, OJ L 35/6, 10.2.2017.
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396 30.12.2006, p. 1-849. The latest consolidated version of 24 August 2020 is available at https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:02006R1907-20200824

Other sources

- ASD (2017) Sectoral Guidance for Substances in Articles under REACH, Version 1, November 2017, https://www.asd-europe.org/sites/default/files/atoms/files/ASD%20SiA%20Guidance_v1_Nov2017_1_0.pdf
- CJEU (2015) Judgment of the Court (Third Chamber) of 10 September 2015 in case C-106/14, http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14
- ECHA (2019) Introductory Guidance on the CLP Regulation. Version 3.0,
- https://www.echa.europa.eu/documents/10162/23036412/clp_introductory_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027 (Last accessed on 01.11.2020)
- ECHA (CA/54/2018) Substances in Articles – Follow-up activities to the Guidance update – Specific challenges for very complex and/or very small articles, 12 June 2018, Doc. CA/54/2018
- ECHA (2017) Guidance on requirements for substances in articles, June 2017, Version 4.0, https://echa.europa.eu/documents/10162/23036412/articles_en.pdf
- ECHA (2014) Guidance on the preparation of dossiers for harmonised classification and labelling Version 2.0, https://echa.europa.eu/documents/10162/23036412/clh_en.pdf/36b11f14-01a0-4474-be46-e48dd9b27849 (Last accessed on 09.11.2020).
- EDA (2015) EDA Code of Conduct on REACH Defence Exemptions, Adopted (SB Doc 2014-28), https://eda.europa.eu/docs/default-source/documents/eda-code-of-conduct-on-reach-defence-exemptions.pdf

- REACHLaw (2016) EDA Study on the Impact of REACH and CLP European Chemicals Regulations on the Defence Sector, Final Report, 16 December 2016, https://www.eda.europa.eu/docs/default-source/documents/eda-reach-study-final-report-2016-december-16-p.pdf

Other references

- Amec Foster Wheeler (2018) Study supporting the fitness check on the most relevant chemicals legislation, final report, https://op.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF (Last accessed on 12.11.2020)
- EC, Comitology Register, https://ec.europa.eu/transparency/comitology-register/screen/home (Last accessed on 12.11.2020)
- EC, Register of Commission expert groups and other similar entities,
- https://ec.europa.eu/transparency/regexpert/ (Last accessed on 12.11.2020)
- EC (2020, October 14). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability, Towards a toxic-free environment, 14 October 2020, COM(2020) 667 final, https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
- EC (2020, October 14). Annex to Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability, Towards a toxic-free environment, 14 October 2020, COM(2020) 667 final, Action Plan, https://ec.europa.eu/environment/pdf/chemicals/2020/10/Annex.pdf
- EC (2019) Commission Staff Working Document of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, SWD(2019) 199 final/2
- EC (2019) Commission Staff Working Document accompanying the COM(2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements - Conclusions and Actions, SWD/2018/058 final (Last accessed on 12.11.2020)
- RPA, Milieu, Ökopol, Ricardo AEA (2017) Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, final report, https://op.europa.eu/en/publication-detail/-/publication/7e26e205-18f9-11e7-808e-01aa75ed71a1 (Last accessed on 12.11.2020)

ANNEX I LIST OF STAKEHOLDERS CONTACTED

Stakeholder group	Organisation	Input	Status
EU institution	DG GROW D.1 REACH	Kept informed of the progress of the study	**Completed**
EU institution	DG ENV.B.3 - Waste Management & Secondary Materials (RoHS Directive and Waste Framework Directive)	Questionnaire on WFD/ SCIP Interview on RoHS	**Completed**
EU institution	DG ENV B.2 Sustainable Chemicals	Questionnaire on POPs Regulation	**Completed**
EU institution	DG CLIMA.A.2 Climate Finance, Mainstreaming, Montreal Protocol	Interview on ODS and F-gas Regulations	**Completed**
EU institution	DG SANTE E.4 Pesticides and biocides	Comments on Draft final report study report	**Completed**
EU institution	DG DEFIS.A.1 Defence Market and Industry Policy	Kept informed of the progress of the study	**Completed**
EU institution	ECHA – POPs	Questionnaire on POPs Regulation	**Completed**
EU institution	ECHA – BPR	Comments on Draft final study report	**Completed**
EU institution	ECHA – WFD	Questionnaire on WFD/ SCIP	**Completed**
EU institution	EASME	Kept informed of the progress of the study Questionnaire for industry	**Did not participate**
MoD	Finnish MoD	Questionnaire for MoDs	**Did not participate**
MoD	French MoD	Questionnaire for MoDs	**Completed**
MoD	German MoD	Questionnaire for MoDs	**Completed**
MoD	Italian MoD	Questionnaire for MoDs	**Completed**
MoD	Dutch MoD	Questionnaire for MoDs	**Completed**
MoD	Romanian MoD	Questionnaire for MoDs	**Completed**
MoD	Spanish MoD	Questionnaire for MoDs	**Completed**
MoD	Swedish Mod	Questionnaire for MoDs	**Completed**
MSCA	Finland	Questionnaire for MSCAs	**Did not participate**
MSCA	France: Ministry of Ecological Transition (BPR, POPs, ODS, F-gas)	Questionnaire for MSCAs	**Completed**
MSCA	France: Ministry of Ecological Transition	Questionnaire for	**Did not**

Stakeholder group	Organisation	Input	Status
	(RoHS)	MSCAs	**participate**
MSCA	France: Ministry of Ecological Transition (WFD/SCIP)	Questionnaire for MSCAs	**Did not participate**
MSCA	Germany: BAuA, UBA, BMU	Questionnaire for MSCAs	**Completed**
MSCA	Italy	Questionnaire for MSCAs	**Did not participate**
MSCA	Netherlands: Ministry of Environment	Questionnaire for MSCAs	**Completed**
MSCA	Romania: Ministry of Environment	Questionnaire for MSCAs	**Completed**
MSCA	Sweden: Swedish Chemicals Agency / Swedish EPA	Questionnaire for MSCAs	**Completed**
EU / Intl Defence industry Association	ASD	Questionnaire for industry	**Completed**
EU / Intl Defence industry Association	AIA	Questionnaire for industry	**Completed**
NDIA	AFDA - Association of Finnish Defence and Aerospace Industries	Questionnaire for industry	**Did not participate**
NDIA	GIFAS - Groupement des Industries Françaises Aéronautiques et Spatiales	Questionnaire for industry	**Did not participate**
NDIA	GICAT - Groupement des Industries Françaises de Défense Terrestre	Questionnaire for industry	**Did not participate**
NDIA	GICAN - Groupement des Industries de Construction et Activités Navales	Questionnaire for industry	**Did not participate**
NDIA	BDSV - Federation of German Security and Defence Industries	Questionnaire for industry	**Did not participate**
NDIA	BDLI - German Aerospace Industries Association	Questionnaire for industry	**Did not participate**
NDIA	AIAD – Italian Industries Federation for Aerospace, Defence and Security	Questionnaire for industry	**Did not participate**
NDIA	AIPAS - Association of Italian Space Companies	Questionnaire for industry	**Did not participate**
NDIA	ROMARM	Questionnaire for industry	**Completed**
NDIA	AESMIDE - Association of Defence Suppliers Companies	Questionnaire for industry	**Did not participate**
NDIA	TEDAE - Spanish Association of Defence, Aeronautics, Security and Space Technology Companies	Questionnaire for industry	**Did not participate**
NDIA	SOFF - Swedish Security and Defence Industry Association	Questionnaire for industry	**Completed**
Defence industry	Etienne Lacroix Group	Questionnaire for industry	**Completed**
Defence industry	RUAG Ammotec	Questionnaire for industry	**Completed**
Defence industry	Rheinmetall	Questionnaire for industry	**Completed**

Stakeholder group	Organisation	Input	Status
Defence industry	Enegothech Group	Questionnaire for industry	**Completed**
Defence industry	BAE Systems Sweden	Questionnaire for industry	**Did not participate**
Defence industry	Naval Group	Questionnaire for industry	**Did not participate**
Other	Austrian Chamber of Commerce (on behalf of SME United)	Interview	**Completed**
Other	Enterreprise Europe Network	Questionnaire for industry	**Did not participate**
Other	CEFIC	Questionnaire for industry	**Did not participate**
Other	CMR Alliance	Questionnaire for industry	**Completed**
Other	International Antimony Association	Questionnaire for industry	**Did not participate**
Other	International Lead Association	Questionnaire for industry	**Did not participate**
Other	EuRIC	Questionnaire for industry	**Completed**
Other	Eurometaux	Questionnaire for industry	**Did not participate**
Other	CII	Questionnaire for industry	**Did not participate**

ANNEX II DEFINITIONS / GLOSSARY

Terms	Definitions/glossary
Actors in a supply chain	All manufacturers and/or importers and/or downstream users in a supply chain (REACH Article 3 point 17)
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (REACH Article 3 point 3). Pursuant to the "once an article, always an article" principle confirmed by the CJEU, such an 'article' remains an 'article' also if assembled or joined with other articles (forming 'complex objects') until it becomes 'waste' as defined in the WFD (judgment of the CJEU of 10 September 2015 in case C-106/14)
CARACAL	CARACAL (Competent Authorities for REACH and CLP) is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. CARACAL is composed of representatives of Member States competent authorities for REACH and CLP, representatives from competent authorities of EEA-EFTA countries as well as several observers from non-EU countries, international organisations and stakeholders.
Classified information/data/goods	Information that should not be disclosed in the interest of defence. Stakeholders use different terms to refer to such information and the degree of their protection (e.g. "protected", "confidential", "(top) secret", "(defence-) sensitive", "confidential business information"/"CBI"). It should not be confused with substances "classified" regarding their human health/environmental hazards (e.g. classified as carcinogenic or mutagenic or toxic for reproduction).
Complex object	The term is not defined in the REACH Regulation nor the WFD. According to ECHA (implementing the judgment of the CJEU of 10 September 2015 in case C-016/14) it refers to any object made up of two or more articles 'as such' which are assembled or joined together. The more articles such an object is made of, the more complex the object becomes.
Consumer	The term is not defined in the REACH Regulation, but referred in various REACH provisions, such as Article 3(13) ["…a consumer is not a downstream user"] and Article 33(2) [Article supplier's duty to communicate information on substances in articles "on request by a consumer…"]. Consumers do not have obligations under REACH.
Distributor	Any natural or legal person established within the Community [EU], including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties (REACH Article 3(14))
Downstream user	Any natural or legal person established within the Community, [EU] other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. (REACH Article 3(13))
Dual use	Dual use is not legally defined. For the purpose of this study, dual use refers to products/components that are/can be used for both military and civil purposes.
Exemption (vs. exclusion)	For the purpose of this study "exemption" refers to any exception from the application of standard requirements (e.g. SCIP notification) of the legislation in question for certain cases foreseen in the legal text, be it in full, with respect to specific requirements, or subject to a case-by-case decision by an authority (such as in case of REACH Article 2(3)). However, for the purpose of RoHS Article 2(4)

Terms	Definitions/glossary
	the term "disapplication" as the common denomination by some MoDs is used for lit. (a) and "exclusion" for the other cases listed. The term "exclusion" (from the scope) is also used where military products or uses are taken out of the scope of the legislation or specific requirement automatically fully or partly (without the need to grant case-by-case exemptions).
European Economic Area (EEA)	All Member States of the European Union (EU) incl. French Guiana, as well as in Norway, Iceland and Liechtenstein. REACH applies in the EEA territory. Switzerland, Turkey or Russia are not part of the EEA. *References to "EU" in this study shall be understood to comprise also the EEA countries Norway, Iceland and Liechtenstein, provided that the EU regulation/directive in question also applies to these countries.*
Importer	Any natural or legal person established within the Community [EU] who is responsible for import; import means the physical introduction into the customs territory of the Community (REACH Article 3 points 11 and 10)
Member State Competent Authority (MSCA)	National competent authority or competent authorities in a Member State, which is/are responsible for performing the tasks allotted to the Member States in the respective EU regulation/directive and for cooperating with the EC and the ECHA on implementation aspects.
Only Representative	A natural or legal person established outside the Community [EU] who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Community [EU] may by mutual agreement appoint a natural or legal person established in the Community [EU] to fulfil, as his only representative, the obligations on importers under this Title [Title II: Registration of substances]. The representative shall also comply with all other obligations of importers under this Regulation. (REACH Article 8(1) and (2)1). In *Sweden* the obligation to notify under SCIP may instead of an importer be fulfilled by an only representative appointed in accordance with REACH Article 8 (§ 5 of KIFS 2020:6)
Placing on the market	Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (REACH Article 3 point 12). In *Sweden* § 2 of KIFS 2020:6 refers to § 2 of the Regulation (2008: 245) on chemical products and biotechnological organisms, which defines 'placing on the market' as "providing or making available to someone else", see https://www.riksdagen.se.
Producer of an article	Any natural or legal person who makes or assembles an article within the Community [EU] (REACH Article 3(4))
Referencing	A technical solution developed by ECHA, allowing a company to refer to SCIP articles data already notified by its supplier, when incorporating them into complex objects (products), by using the SCIP number provided by the component supplier. This solution could be useful especially for 'assemblers'.
Regulations	The term "regulations" as used in this report may refer both to "Regulations" (such as BPR, CLP, ODS, POP and REACH) and "Directives" (such as RoHS, WEEE and WFD) as distinct pieces of EU legislation in terms of EU law. *Regulations* as defined in Article 288 of the Lisbon Treaty are of general application, binding in their entirety and directly applicable in all Member States. *Directives* are binding, as to the result to be achieved, upon any or all of the Member States to whom they are addressed, but leave to the national authorities the choice of

Terms	Definitions/glossary
	form and methods.
SME	Small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).
Substance of Very High Concern (SVHC)	Substances with certain dangerous properties, which may be included in Annex XIV of REACH (see REACH Article 57)
Supplier of an article	Any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market (REACH Article 3 point 33)

ANNEX III PRODUCT TYPES LISTED IN ANNEX V TO THE BPR

Number	Product type	Description
Main group 1: Disinfectants		
PT1	Human hygiene	Products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp
PT2	Disinfectants and algaecides not intended for direct application to humans or animals	Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
PT3	Veterinary hygiene	Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function Used to disinfect the materials and surfaces associated with the housing or transportation of animals
PT4	Food and feed area (i.e. used for the disinfection equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals Used to impregnate materials which may enter into contact with food
PT5	Drinking water	Used for the disinfection of drinking water for both humans and animals
Main Group 2: Preservatives		
PT6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life Used as preservatives for the storage or use of rodenticide, insecticide or other baits
PT7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works
PT8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of

Number	Product type	Description
		wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products
PT9	Fibre, leather, rubber and polymerised materials preservatives	Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits
PT10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack
PT11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type
PT12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction
PT13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials
Main Group 3: Pest control		
PT14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction
PT15	Avicides	Used for the control of birds, by means other than repulsion or attraction
PT16	Molluscicides, vermicides and products to control other invertebrates	Used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction
PT17	Piscicides	Used for the control of fish, by means other than repulsion or attraction
PT18	Insecticides, acaricides and products to control other arthropods	Used for the control of arthropods (e.g. insects, arachnids, and crustaceans), by means other than repulsion or attraction
PT10	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or

Number	Product type	Description
		animals
PT 20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction
Main Group 4: Other biocidal products		
PT21	Antifouling products	Used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water) for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction
PT22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof

ANNEX IV INFORMATION REQUIREMENTS BIOCIDAL PRODUCTS (SWEDEN)

(See separate PDF)

ANNEX V LIST OF BANNED AND RESTRICTED SUBSTANCES (LBRS) (NETHERLANDS)

(See separate Word document)

ANNEX VI MEMBERS OF THE COMPETENT AUTHORITIES EXPERT GROUP FOR REGULATION (EU) 2019/1021 ON PERSISTENT ORGANIC POLLUTANTS (POPS) (E01656)

Member State	Committee members
Austria	Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology
Belgium	Federal Public Service Public Health, Safety of the Food Chain and Environment Directorate General for Natural Resources and the Environment (Wallonia) Brussels Environment OVAM Public Flemish Waste Agency
Bulgaria	Ministry of Environment and Water of the Republic of Bulgaria
Croatia	Ministry of Environment and Nature Protection
Cyprus	Cyprus Ministry of Labour & Social Insurance Ministry of Agricultural, Natural Resources and Environment
Czechia	Ministry of the Environment
Denmark	Environmental Protection Agency Ministry of Environment
Estonia	Ministry of Environment
Finland	Finnish Environment Institute Ministry of the Environment
France	Ministry of Ecological Transition
Germany	Federal Institute for Occupational Medicine (BAuA) Federal Environment Agency (UBA)
Greece	Ministry of Finance, General Chemical State Laboratory of Directorate of Energy, Industrial and Chemical Products
Hungary	Ministry of Water and Environment Central Service for Plant Protection and Soil Conservation (CSPPS) Research Institute for Environment and Water (VITUKI)
Ireland	Department of Communication, Climate Action and Environment (DCCAE) Environmental Protection Agency
Italy	Ministry for the Environment, Land and the Sea
Latvia	Ministry of the Environment
Lithuania	Ministry of Environment
Luxembourg	Environmental Administration
Malta	Malta Environment and Planning Authority
Netherlands	Ministry of Housing, Spatial Planning and the Environment Expertise Centre for Substances (RIVM-SEC)
Poland	Ministry of the Environment Ministry of Agriculture and Rural Development
Portugal	Portuguese Environmental Agency
Romania	Ministry of Environment
Slovakia	Ministry of the Environment of the Slovak Republic
Slovenia	Ministry of Environment, Spatial Planning and Energy Environmental Agency Ministry of Health
Spain	Ministry of the Environment and Rural and Marine Affairs

Sweden	Swedish Chemicals Agency Environmental Protection Agency

ANNEX VII DEFENCE SECTOR'S CRITERIA DOCUMENT (SWEDEN)

(See separate PDF)

ANNEX VIII SCIP TRANSPOSITION MAPPING

This Annex provides a high-level overview of the WFD/SCIP transposition status in the EDA participating Member States[330]; for Member States consulted as part of this study, the relevant national SCIP clauses (final or draft) are also reflected in that table (if available), both in their native language and unofficial translation into English.

Important notes:

The final national provisions transposing WFD Article 9(1)(i) are still pending in a number of Member States, even though the transposition deadline expired on 5 July 2020. As far as the provisions reflected are only legislative proposals, they may still be subject to changes.

Even if the transposition status is given below as "adopted", this does not necessarily imply that the transposition is complete (e.g. defence-specific provisions may still be pending and/or the use of ECHA tools and format be made mandatory).

Translations of national provisions into English (if the official language is other than English) have been derived by REACHLaw staff, and with the support of the EDA and MoD REACH experts. No certified translation agency has been used.

Austria

Transposition status: Adopted

National legal basis: Amendment of Chemicals Act 1996, new § 19(5). Official publication: Bundesgesetzblatt für die Republik Österreich (BGBl.); Number: BGBl. I Nr. 140/2020; Publication date: 22/12/2020.

Link to legal text (draft/final):
https://www.ris.bka.gv.at/eli/bgbl/I/2020/140/20201222

Details on (draft/final) transposition: Literal transposition of WFD Art. 9(1)(i), but with reference to placing on the market ("Inverkehrbringen") as the obligation trigger and to WFD Art. 9(2) on SCIP database; enforcement to be assumed by the same authorities in charge of REACH Article 33

Belgium

***Transposition status*:** Adopted

***National legal basis*:** Royal Decree of 23 March 2020 (C - 2020/41331)

***Link to legal text (draft/final)*:**
http://www.ejustice.just.fgov.be/eli/besluit/2020/03/23/2020041331/justel
https://emis.vito.be/nl/node/77344

Details on (draft/final) transposition: Transposition foresees the use of the ECHA formats and software (Article 2); allowance for defence exemptions to be confirmed

[330] See also https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32018L0851 on the national transposition measures communicated by the Member States concerning Directive (EU) 2018/851.

Bulgaria

Transposition status: To be confirmed

***National legal basis*:** Not available

***Link to legal text (draft/final)*:** Not available

Croatia

Transposition status: To be confirmed

National legal basis: New Waste Act

***Link to legal text (draft/final)*:** Not available

Czech Republic

***Transposition status*:** Adopted

***National legal basis*:** § 22(7) of the Chemicals Act No. 350/2011, as amended by Act No. 543/2020; in force from 1 January 2021

***Link to legal text (draft/final)*:**
https://www.zakonyprolidi.cz/cs/2011-350#f6950348

Details on (draft/final) transposition: The transposition foresees the provision of the information to the ECHA database prior to placing on the market. On defence, the Chemicals Act foresees the allowance of exemptions pursuant to REACH Article 2(3) by the Ministry of the Environment (§24(1)(g)), subject to a binding opinion of the Ministry of Defence (§26a(c)). On enforcement, specific provisions are made in the Chemicals Act, defining the violation of § 22(7) as an offence (§ 34(21)) and fines of up to CZK 500,000 for the same (§ 34(24) e)).

Cyprus

Transposition status: To be confirmed

National legal basis: New Waste Act

***Link to legal text (draft/final)*:** Not available

Estonia

Transposition status: Ongoing

National legal basis: §21 and §136 of Waste Act and Packaging Act Amendment Act.

Link to legal text (draft/final):
https://www.riigikogu.ee/tegevus/eelnoud/eelnou/cf2190f4-e433-4590-8667-2ae543bcb20f/J%C3%A4%C3%A4tmeseaduse%20ja%20pakendiseaduse%20muutmise%20seadus

Finland

***Transposition status*:** Ongoing

National legal basis: New draft 22 a § of the Chemicals Act 599/2013

***Link to legal text (draft/final)*:** Not available

Details on (draft/final) transposition: There will (very likely) be a defence exemption from the SCIP reporting obligation in Finland (amendment of 3 § of the Chemicals Act 599/2013 - wording to be confirmed).

France

***Transposition status*:** Adopted

National legal basis: Article 1 of ordinance no. 2020-920 of 29 July 2020 relating to waste prevention and management (JORF no. 0186 of 30 July 2020)

***Link to legal text (draft/final)*:**
https://www.legifrance.gouv.fr/eli/ordonnance/2020/7/29/TREP2013741R/jo/texte

Details on (draft/final) transposition: Literal transposition of WFD Art. 9(1)(i). However, a decree is currently under consultation that would foresee provisions for non-compliance and would empower Minister of Environment to adopt a text precising the conditions/arrangements of information communication to ECHA for article suppliers; this text could possibly mandate the use of the ECHA SCIP format (info dd. 30/09/2020)

Legal text:

Official version	Unofficial translation
Article 1er A l'article L. 521-5 du code de l'environnement, il est ajouté un III ainsi rédigé : « III.-Afin de favoriser la réduction de la teneur en substances dangereuses des matériaux et des produits, tout fournisseur d'un article au sens du règlement (CE) n° 1907/2006 du Parlement européen et du Conseil communique, à compter du 5 janvier 2021, les informations prévues à l'article 33, paragraphe 1, de ce règlement à l'Agence européenne des produits chimiques. « Les informations dont la divulgation serait susceptible de porter atteinte aux intérêts essentiels de la défense nationale ne sont pas communiquées. »	Article 1 To Article L. 521-5 of the environment code a III worded as follows is added: "III. - In order to promote the reduction of the content of dangerous substances in materials and products, any supplier of an article within the meaning of Regulation (EC) No 1907/2006 of the European Parliament and of the Council shall communicate, from 5 January 2021, the information provided for in the article 33 (1) of that regulation to the European Chemicals Agency. The information the disclosure of which may prejudice the essential interests of national defence is not communicated."

Germany

***Transposition status*:** Adopted

National legal basis: New § 16f of the Chemicals Act (ChemG) / Gesetz zur Umsetzung der Abfallrahmenrichtlinie der Europäischen Union. Official publication: Bundesgesetzblatt Teil 1 (BGB 1); Number: 48; Publication date: 28/10/2020; Page number: 02232-02245

***Link to legal text (draft/final)*:** https://www.gesetze-im-internet.de/chemg/__16f.html

Details on (draft/final) transposition: Literal transposition of WFD Art. 9(1)(i), but with reference to WFD Art. 9(2) on SCIP database and non-application to articles with a military purpose.

Legal text:

Official version	Unofficial translation
„§16f Informationspflicht der Lieferanten (1) Wer als Lieferant im Sinne des Artikels 3 Nummer 33 der Verordnung (EG) Nr. 1907/2006 Erzeugnisse im Sinne der Verordnung (EG) Nr. 1907/2006 in den Verkehr bringt, hat ab dem 5. Januar 2021 die Informationen gemäß Artikel 33 Absatz 1 der Verordnung (EG) Nr. 1907/2006 der Europäischen Chemikalienagentur nach Artikel 9 Absatz 2 der Richtlinie 2008/98/EG zur Verfügung zu stellen. Satz 1 gilt nicht für Erzeugnisse mit militärischer Zweckbestimmung. (2) Die Bundesregierung wird ermächtigt, durch Rechtsverordnung mit Zustimmung des Bundesrates näher zu bestimmen, auf welche Art und Weise und mit welchen Maßgaben die Verpflichtung nach Absatz 1 unter Berücksichtigung der auf Unionsebene entwickelten Vorgaben für die Datenbank zu erfüllen ist.“	“Section 16f Information obligation of suppliers (1) Whoever as a supplier within the meaning of Article 3 number 33 of Regulation (EC) No. 1907/2006 places articles within the meaning of Regulation (EC) No. 1907/2006 on the market, must as from 5 January 2021 provide the information pursuant to REACH Article 33(1) to the European Chemicals Agency pursuant to Article 9(2) of Directive 2008/98/EC. Sentence 1 does not apply to articles with a military purpose. (2) The Federal Government is empowered to determine in more detail by ordinance, with the consent of the Bundesrat, in what way and to what extent the obligation under paragraph 1 is to be met, taking into account the requirements for the database developed at Union level.”

Greece

Transposition status: Ongoing

National legal basis: To be confirmed

Link to legal text (draft/final): http://www.opengov.gr/minenv/?p=11440

Details on (draft/final) transposition: The Ministry of Environment and Energy has issued a draft law for public consultation, which ended on 4 December 2020. The article in question is Article 18, and in paragraph 4, there is the exemptions provision; it states that ''By a joint ministerial decision of the Ministers of Finance, Defence and Environment, it is possible to grant exemptions to article suppliers from the notification procedures of the SCIP database, where necessary in the interests of national defence, considering the paragraph 3 of article 2 of the EC 1907/2006''. As the public consultation ended on 4 December 2020, the Greek government (which has the legislation initiative) will proceed to the voting of the law, according to the Hellenic Parliament regulations. After the law is published in the official journal of the government of Greece, a draft of the joint ministerial decision will be prepared by the Ministries involved. That decision will specify the exact procedures of granting exemptions.

Hungary

Transposition status: Ongoing

National legal basis: Bill T / 13958 amending certain laws on energy and waste management, especially chapter 6 'Modification of the Chemical Safety Law 2000.XXV'; prepared by the Ministry of Innovation and Technology

Link to legal text (draft/final): https://www.parlament.hu/irom41/13958/13958.pdf

Details on (draft/final) transposition: Exemption under REACH Article 2(3) may be granted by the Hungarian Chief Medical Officer upon request, but the procedure is conditional on domestic transposition.

Ireland

Transposition status: Adopted

National legal basis: European Union (Waste Directive) Regulations 2020, Official publication: Iris Oifigiúl; Number: 70 of 2020; Publication date: 01/01/1001; Statutory Instrument No. 323 of 2020, new Section 27A (5) of the Act of 1996 (Prevention of Waste)

Link to legal text (draft/final): http://www.irishstatutebook.ie/eli/2020/si/323/made/en/pdf

Italy

Transposition status: Adopted

National legal basis:

Legislative Decree of 3 September 2020, n. 116 Implementation of Directive (EU) 2018/851 amending Directive 2008/98 / EC on waste and implementation of Directive (EU) 2018/852 amending Directive 1994/62 / EC on packaging and packaging waste. (20G00135) (Official Gazette of the Italian Republic General Series n.226 of 11-09-2020)

- Article 1 amending the legislative decree of 3 April 2006, n. 152 Part IV Rules on waste management and the remediation of polluted sites - Title I Waste management - Chapter I General provisions.

-- paragraph 6 point 3 amending Article 180 of the legislative decree of 3 April 2006

Link to legal text (draft/final):
https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2020-09-11&atto.codiceRedazionale=20G00135&elenco30giorni=false

Legal text:

Official version	Unofficial translation
6. L'articolo 180 del decreto legislativo 3 aprile 2006 e' sostituito dal seguente: «Art. 180 (*Prevenzione della produzione di rifiuti*). - [...] 3. A decorrere dal 5 gennaio 2021, ogni fornitore di un articolo,quale definito al punto 33 dell'articolo 3 del regolamento (CE) n. 1907/2006 del Parlamento europeo e del Consiglio, trasmette le informazioni di cui all'articolo 33, paragrafo 1, del suddetto regolamento all'Agenzia europea per le sostanze chimiche tramite il format e la modalita' di trasmissione stabiliti dalla medesima Agenzia ai sensi dell'articolo 9, paragrafo 2, della direttiva 2008/98/CE. L'attivita' di controllo e' esercitata in linea con gli accordi Stato-regioni in materia. Con successivo decreto del Ministero dell'ambiente e della tutela del territorio e del mare, di concerto con il Ministero della salute, sono stabilite le modalita' di analisi dei dati trasmessi dai	6. Article 180 of the legislative decree of 3 April 2006 is replaced by the following: "Art. 180 (*Prevention of waste production*). - [...] 3. Starting from January 5, 2021, each supplier of an article, as defined in point 33 of Article 3 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, transmits the information referred to in Article 33 (1) of the aforementioned regulation to the European Chemicals Agency through the format and method of transmission established by the same Agency within the meaning of Article 9 (2) of the Directive 2008/98/EC. The control activity is exercised in line with the State-regional agreements on the subject. With subsequent decree of Ministry of the Environment and Land and Sea Protection, of in agreement with the Ministry of Health, the

fornitori di articoli. [...]"	modalities of the analysis of the data transmitted by the suppliers of articles are established. [...]"

Latvia

Transposition status: Adopted

National legal basis: Amendments to the Chemicals Law. Official publication: Latvijas Vēstnesis; Number: 12A, new Article 9(9); Publication date: 18/01/2021.

Link to legal text (draft/final):
https://eur-lex.europa.eu/legal-content/LV/TXT/PDF/?uri=CELEX:72018L0851LVA_202100444&from=EN

Details on (draft/final) transposition: Literal transposition of WFD Art. 9(1)(i); no specific exemptions for defence and security at the moment; nevertheless, when such exemption will be seen as potential requirements, Latvia will adopt its national provisions accordingly as it is explained also in ECHA Q&A with ID 1608.

Lithuania

Transposition status: To be confirmed

National legal basis: Not available

Link to legal text (draft/final): Not available

Luxemburg

Transposition status: Ongoing

National legal basis: As part of the "waste package" transposition: The provisions of the Article 9 of the WFD will be included within the national law on waste management.

Link to legal text (draft/final): Not available

Details on (draft/final) transposition: No specific defence exemption in relation to the SCIP database is planned in the national legislation in Luxembourg. However, a case-by-case exemption from REACH Article 33(1), and Article 9(1)(i) of the WFD could be applied for.

Malta

Transposition status: To be confirmed

National legal basis: Not available

Link to legal text (draft/final): Not available

Netherlands

Transposition status: Adopted

***National legal basis*:**

Decision of 18 June 2020, implementing certain provisions of Directive (EU) 2018/851 and amending the Decree on reporting industrial waste and hazardous waste substances, Artikel 7a.

Link to legal text (draft/final):
https://zoek.officielebekendmakingen.nl/stb-2020-197.html

Details on (draft/final) transposition: Defence exemption provisions to be confirmed

Legal text:

Official version	Unofficial translation
Artikel 7a 1. Elke leverancier van een voorwerp als bedoeld in artikel 3, onderdeel 33, van de EG-verordening registratie, evaluatie en autorisatie van chemische stoffen, verstrekt de informatie, bedoeld in artikel 33, eerste lid, van deze verordening, aan het Europees Agentschap voor chemische stoffen. 2. Bij ministeriële regeling kunnen nadere regels worden gesteld met betrekking tot de uitvoering van het eerste lid.	Article 7a 1. Each supplier of an article as referred to in Article 3, part 33, of the EC Regulation on Registration, Evaluation and Authorization of Chemicals shall provide the information referred to in Article 33, first paragraph, of this Regulation to the European Chemicals Agency. 2. Further rules may be set by ministerial regulation with regard to the implementation of the first paragraph.

Norway

Transposition status: Ongoing. Requires incorporation of the revised WFD into the EEA Agreement.

National legal basis: The requirements are proposed to be implemented in the national regulation Produktforskriften (FOR-2004-06-01-922).

Link to legal text (draft/final): https://www.miljodirektoratet.no/hoeringer/2020/desember-2020/forslag-til-forskrift-om-leverandorers-plikt-til-a-gi-opplysninger-om-produkters-innhold-av-svhc-stoffer-til-echascip-databasen

Details on (draft/final) transposition: The Norwegian Environment Agency (NEA) is the competent authority for the implementation of WFD Article 9/SCIP. They have sent a proposal for legal text for public consultation, with a deadline of 15 January 2021. On defence, the national regulation Produktforskriften (FOR-2004-06-01-922) already has a paragraph that allows for exemption(s).

Poland

Transposition status: To be confirmed

National legal basis: Not available

Link to legal text (draft/final): Not available

Portugal

Transposition status: Adopted

National legal basis: Decree-Law No. 102-D / 2020. Official publication: Diaro da Republica I; Number: 239/2020, 1º Suplemento; Publication date: 10/12/2020.

Link to legal text (draft/final): https://data.dre.pt/eli/dec-lei/102-D/2020/12/10/p/dre

Details on (draft/final) transposition: Annex V Par. 9 contains a literal reflection of WFD Art. 9(1)(i). Article 22 Par. 3 contains a reference to the ECHA SCIP database.

Romania

Transposition status: Ongoing

National legal basis: Law no. 211/2011, republished, on the waste regime. The final form of the national provisions on SCIP notifications are not yet released.

Link to legal text (draft/final): Not available

Details on (draft/final) transposition: On defence, there are no specific requirements within the waste law. If the case, Romania will use REACH Article 2(3). Based on the ministerial order no. 108/2013 the national exception for the defence sector can be granted on request (case by case situation).

Slovakia

Transposition status: To be confirmed

National legal basis: Not available

Link to legal text (draft/final): Not available

Slovenia

Transposition status: Adopted

National legal basis: Regulation amending the Regulation implementing the REACH Regulation, new Article 4a; to apply from 5 January 2021 (Official Gazette of the Republic of Slovenia, No. 191/20)

Link to legal text (draft/final):
http://www.pisrs.si/Pis.web/pregledPredpisa?sop=2020-01-3351

Details on (draft/final) transposition: The information to be provided to ECHA in the form and manner intended for transmission to the database referred to in WFD Art. 9(2). On enforcement, Article 8(1) No. 29 foresees the possibility of a fine of 1,000 – 20,000 euros for a violation of Article 4a.

Spain

Transposition status: Ongoing

National legal basis: Article 18.2 of the Draft Waste Law

Link to legal text (draft/final):

https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/participacion-publica/200602aplresiduosysc_informacionpublica_tcm30-509526.pdf

Legal text:

Official version	Unofficial translation
Artículo 18. Medidas de prevención. **2.** Para fomentar la reducción del contenido de sustancias peligrosas en materiales y productos, a partir del 5 de enero de 2021 todo proveedor de un artículo, tal como se define en el artículo 3.33, del Reglamento (CE) nº 1907/2006 del Parlamento Europeo y del Consejo, de 18 de diciembre de 2006, deberá facilitar la información de conformidad con el artículo 33.1, de dicho Reglamento, a la base de datos creada por la Agencia Europea de Sustancias y Mezclas Químicas, con el contenido y formato determinado por ésta. Los operadores de tratamiento de residuos tendrán acceso a la base de datos creada por la Agencia Europea de Sustancias y Mezclas Químicas. Asimismo, los consumidores también podrán acceder a la base de datos mencionada, previa solicitud.	**Article 18. Prevention measures.** **2.** To promote the reduction of the content of dangerous substances in materials and products, as of January 5, 2021, every supplier of an article, as defined in article 3.33, of Regulation (EC) No. 1907/2006 of the Parliament European and Council, of December 18, 2006, must provide the information in accordance with article 33.1 of said Regulation, to the database created by the European Chemicals Agency, with the content and format determined by this. Waste treatment operators will have access to the database created by the European Chemicals Agency. Likewise, consumers may also access the aforementioned database, upon request.
Disposición adicional cuarta. Aplicación de las leyes reguladoras de la Defensa Nacional. Lo establecido en esta ley se entiende sin perjuicio de las previsiones recogidas en la normativa de la Defensa Nacional. En lo relativo a la obligación recogida en el artículo 18.2, cuando sea necesario garantizar la confidencialidad, será de aplicación la excepción prevista en el artículo 2.3 del Reglamento (CE) nº 1907/2006 del Parlamento Europeo y del Consejo, de 18 de diciembre de 2006.	**Fourth additional provision. Application of the laws regulating National Defense.** The provisions of this law are understood without prejudice to the provisions contained in the National Defense regulations. Regarding the obligation contained in Article 18.2, when confidentiality needs to be guaranteed, the exception provided for in Article 2.3 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of December 18 2006 will apply.

Sweden

Transposition status: Adopted

National legal basis: New Chapter 12 § 1-6 amending Swedish Chemical Agency´s regulation KIFS 2017:7 ("Kemikalieinspektionens föreskrifter om kemiska produkter och biotekniska organismer"), which was published on 13 July 2020 and enters into force on 5 January 2021.

Link to legal text (draft/final):
https://www.kemi.se/download/18.164ad6b3172927a92892c38f/1594644296486/kifs-2020-6.pdf

Details on (draft/final) transposition: Sanctions have not been implemented yet. Defence exemptions (Chapter 12, § 4) need to be applied through one of the competent authorities in Sweden who will act as the main applicant for the exemption. However, according to a proposed amendment to extend the possibility of exemption for defence interests in section 24 of the ordinance (2008:245) on chemical products and biotechnological organisms – proposed to enter into force on 23 March 2021 – exemption requests with regard to REACH Art. 33(1) could also formally be made by the defence industry (link to the consultation page containing the amendment proposal ref. M2020/01980 of 7 December 2020).

Legal text:

Official version	Unofficial translation
12 kap. Uppgiftsskyldighet (KIFS 2020:6) **Tillämpningsområde** 1 § Bestämmelserna i 2–6 §§ i detta kapitel genomför i svensk rätt artikel 9.1.i) Euro-paparlamentets och rådets direktiv 2008/98/EG av den 19 november 2008 om avfall och om upphävande av vissa direktiv. […] **Information om särskilt farliga ämnen i varor** 2 § Termerna i 3–6 §§ har samma betydelse som i förordning (EG) nr 1907/2006 (Reach), med undantag för termen utsläppande på marknaden som har samma betydelse som i 2 § förordningen (2008:245) om kemiska produkter och biotekniska organismer. 3 § I artikel 33.1 i förordning (EG) nr 1907/2006 (Reach) finns bestämmelser om att leverantörer av varor som innehåller ämnen som uppfyller kriterierna i artikel 57 och identifieras enligt artikel 59.1 i förordningen ska lämna information om säker använd-ning till mottagare av varan, åtminstone ämnets namn, när halten i varan av sådana ämnen överstiger 0,1 viktprocent. 4 § Leverantörer av varor som är skyldiga att lämna information enligt artikel 33.1 i förordningen 1907/2006 (Reach) ska också lämna den informationen till den Europeiska kemikaliemyndigheten (Echa). Skyldigheten enligt första stycket gäller dock inte distributörer som enbart tillhanda-håller varor direkt till konsumenter. Skyldigheten gäller inte heller varor som omfattas av beslut om dispens från artikel 33.1 i förordning 1907/2006 som Försvarsinspektören för hälsa och miljö meddelat med stöd av 24 § första stycket punkten 1 förordningen (2008:245) om kemiska produkter och biotekniska organismer. 5 § Skyldigheten att lämna information kan i stället för av en importör fullgöras av en enda representant som har utsetts enligt artikel 8 i förordningen (EG) nr 1907/2006 (Reach). 6 § Information enligt 4 § ska lämnas till Echa i det elektroniska format och med det innehåll som följer av det tekniska stöd för inlämnandet som Echa tillhandahåller. Informationen, inklusive ändringar av tidigare lämnad information, ska lämnas senast när varorna släpps ut på marknaden.	**Chapter 12 Notification Obligation** (KIFS 2020:6) **Scope** § 1 The provisions of §§ 2–6 of this chapter transpose Article 9.1.i) of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain directives into Swedish law. […] Information on substances of very high concern in articles § 2 The terms in §§ 3–6 have the same meaning as in Regulation (EC) No 1907/2006 (REACH), with the exception of the term placing on the market which has the same meaning as in § 2 of the Regulation (2008: 245) on chemical products and biotechnological organisms. § 3 Article 33 (1) of Regulation (EC) No 1907/2006 (REACH) provides that suppliers of articles containing substances that meet the criteria of Article 57 and identified under Article 59 (1) of the Regulation shall provide information on safe use to recipients of the article, at least the name of the substance, when the content of such substances in the article exceeds 0.1% by weight. § 4 Suppliers of articles that are required to provide information in accordance with Article 33 (1) of the Regulation 1907/2006 (REACH) shall also provide that information to the European Chemicals Agency (ECHA). However, the obligation under the first paragraph does not apply to distributors who only supply articles directly to consumers. The obligation also does not apply to articles covered by a decision on an exemption from Article 33 (1) of Regulation 1907/2006 as communicated by the Defence Inspector for Health and the Environment (Department of Defence Inspector) on the basis of section 24, first paragraph, point 1 of Regulation (2008:245) on chemical products and biotechnological organisms. § 5 The obligation to provide information may instead of an importer be fulfilled by an only representative appointed in accordance with Article 8 of Regulation (EC) No 1907/2006 (REACH). § 6 Information according to §4 shall be provided to ECHA in the electronic format and with the content that follows from the technical support for

	the submission that ECHA provides. The information, including changes to previously provided information, must be provided no later than when the articles are placed on the market.

ANNEX IX LIST OF SUBSTANCES REFERENCED IN THE STUDY

Name	EC/CAS number	Regulation
Acids generated from chromium trioxide and their oligomers: ▪ Oligomers of chromic acid and dichromic acid	N/A	REACH Annex XIV
▪ Chromic acid	EC no. 231-801-5 ; CAS no. 7738-94-5	
▪ Dichromic acid	EC no. 236-881-5 ; CAS no. 13530-68-2	
Aldrin	EC no. 206-215-8; CAS no. 309-00-2	POPs Regulation
Alpha hexachlorocyclo-hexane	EC no. 206-270-8; CAS no. 319-84-6	POPs Regulation
Ammonium dichromate	EC no. 232-143-1 ; CAS no. 7789-09-5	REACH Annex XIV
Beryllium and its compounds	EC no.: 231-150-7, CAS no.: 7440-41-7	Under scrutiny for inclusion in RoHS Directive
Beta hexachlorocyclo-hexane	EC no. 206-271-3; CAS no. 319-85-7	POPs Regulation
Bis(2-ethylhexyl) phthalate (DEHP)	EC no. 204-211-0; CAS no. 117-81-7	RoHS Directive
Bromochlorodifluoromethane	EC/List no.: 206-537-9; CAS no.: 353-59-3	ODS Regulation
Bromochloromethane	EC/List no.: 200-826-3; CAS no.: 74-97-5	ODS Regulation
Bromomethane	EC no.: 200-813-2; CAS no.: 74-83-9	Not authorised anymore under EU legislation
Butyl benzyl phthalate (BBP)	EC no. 201-622-7; CAS no. 85-68-7	RoHS Directive
Cadmium	EC no. 231-152-8; CAS no. 7440-43-9	RoHS Directive
Carbon tetrachloride	EC no.: 200-262-8; CAS no.: 56-23-5	ODS Regulation
Chlordane	EC no. 200-349-0; CAS no. 57-74-9	POPs Regulation
Chlordecone	EC no. 205-601-3; CAS no. 143-50-0	POPs Regulation
Chlorodifluoromethane	EC no.: 200-871-9; CAS no.: 75-45-6)	ODS Regulation
Chlorpyrifos	EC no. 220-864-4; CAS no 2921-88-2	Proposal under development for inclusion in Stockholm Convention
Chlorpyrifos-methyl	EC no. 227-011-5; CAS no. 5598-13-0	Proposal under development for inclusion in Stockholm Convention
Chromium trioxide	EC no. 215-607-8 ; CAS no.1333-82-0	REACH Annex XIV

Name	EC/CAS number	Regulation
Cobalt dichloride	EC / no.: 231-589-4, CAS no.: 7646-79-9	Under scrutiny for inclusion in RoHS Directive
Cobalt sulphate	EC / no.: 233-334-2, CAS no.: 10124-43-3	Under scrutiny for inclusion in RoHS Directive
Copper	EC no. 231-159-6, CAS no. 7440-50-8	BPR
DDT	EC no. 200-024-3; CAS no. 50-29-3	POPs Regulation
Decabromodiphenyl ether (c-decaBDE)	EC no. 4-604-9; CAS no. 1163-19-5	POPs Regulation
Dechlorane plus	EC no. 236-948-9; CAS no. 13560-89-9	Risk profile under development for inclusion in Stockholm Convention
Diantimony trioxide	EC no.: 215-175-0, CAS no.: 1309-64-4	Under scrutiny for inclusion in RoHS Directive
Dibromotetrafluoroethane	EC no.: 247-042-8; CAS no.: 25497-30-7	ODS Regulation
Dibutyl phthalate (DBP)	EC no. 201-557-4; CAS no. 84-74-2	RoHS Directive
Dichromium tris(chromate)	EC no. 246-356-2; CAS no. 24613-89-6	REACH Annex XIV
Dicofol	EC no. 204-082-0; CAS no. 115-32-2, 10606-46-9	POPs Regulation
Dieldrin	EC No. 200-484-5; CAS no.60-57-1	POPs Regulation
Diisobutyl phthalate (DIBP)	EC no. 201-553-2; CAS no. 84-69-5	RoHS Directive
Endosulfan	EC no. 204-079-4 ; CAS no. 959-98-8, 33213-65-9, 115-29-7, 1031-07-8	POPs Regulation
Endrin	EC no. 200-775-7 ; CAS no.72-20-8	POPs Regulation
Heptabromodiphenyl ether	EC no. 273-031-2 and others; CAS no. 68928-80-3 and others	POPs Regulation
Heptachlor	EC no. 200-962-3; CAS no. 76-44-8	POPs Regulation
1,1,1,2,3,3,3-heptafluoropropane	EC no.: 207-079-2; CAS no.: 431-89-0	F-gas Regulation
Hexabromobiphenyl (HBB)	EC no. 52-994-2; CAS no. 36355-01-8	POPs Regulation
Hexabromocyclododecane (HBCDD)	EC no. 247-148-4, 221-695-9; CAS no. 25637-99-4, 3194-55-6	POPs Regulation
Hexabromodiphenyl ether	EC no. 253-058-6 and others; CAS no. 36483-60-0 and others	POPs Regulation

Name	EC/CAS number	Regulation
Hexachlorobenzene (HCB)	EC no. 204-273-9; CAS no. 118-74-1	POPs Regulation
Hexachlorobutadiene (HCBD)	EC no. 201-765-5; CAS no. 87-68-3	POPs Regulation
Hexavalent chromium	EC no. 606-053-1; CAS no. 18540-29-9	RoHS Directive
Icaridine	EC no.: 423-210-8; CAS no.: 119515-38-7	BPR
Indium phosphide	EC no.: 244-959-5, CAS no.: 22398-80-7	Under scrutiny for inclusion in RoHS Directive
Lead	EC no. 231-100-4; CAS no. 7439-92-1	RoHS Directive
Lead chromate	EC no. 231-846-0; CAS no. 7758-97-6	REACH Annex XIV
Lead sulfochromate yellow	EC no. 215-693-7; CAS no. 1344-37-2	REACH Annex XIV
Lead chromate molybdate sulfate red	EC no. 235-759-9; CAS no. 12656-85-8	REACH Annex XIV
Lindane	EC no. 200-401-2; CAS no. 58-89-9	POPs Regulation
Long-chain chlorinated paraffins (LCCPs)	EC no. 264-150-0; CAS no. 63449-39-8	Under scrutiny for proposal for inclusion in Stockholm Convention
Medium Chain Chlorinated Paraffins (MCCP)	EC no.: 287-477-0, CAS no.: 85535-85-9	Recommended for inclusion in RoHS Directive by 2018 substance review
Mercury	EC no. 231-106-7; CAS no. 7439-97-6	RoHS Directive
Methoxychlor	EC no. 200-779-9; CAS no. 72-43-5	Risk profile under development for inclusion in Stockholm Convention
Mirex	EC no. 19-196-6; CAS no. 2385-85-5	POPs Regulation
N-(3-aminopropyl)-N-dodécylpropane-1,3-diamine	EC no.: 219-145-8; CAS no.: 2372-82-9	BPR
Nickel sulphate	EC / no.: 232-104-9, CAS no.: 7786-81-4, 10101-97-0, 10101-98-1	Under scrutiny for inclusion in RoHS Directive
Nickel sulfamate	EC / no.: 237-396-1, CAS no.: 13770-89-3	Under scrutiny for inclusion in RoHS Directive
Nitrogen	EC no.: 231-783-9; CAS no.: 7727-37-9	ODS Regulation
Octamethylcyclotetrasiloxane (D4)	EC no. 209-136-7; CAS no 556-67-2	Proposal under development for inclusion in Stockholm Convention
Pentabromodiphenyl ether	EC no. 251-084-2 and others; CAS no. 32534-81-9 and others	POPs Regulation

Name	EC/CAS number	Regulation
Pentachlorobenzene	EC no. 210-172-0; CAS no. 608-93-5	POPs Regulation
Pentachlorophenol (PCP)	EC no. 201-778-6 and others; CAS no. 87-86-5	POPs Regulation
Pentazinc chromate octahydroxide	EC no. 256-418-0; CAS no. 49663-84-5	REACH Annex XIV
Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds	EC no. 206-587-1 (and others); CAS no. 355-46-4 (and others)	Recommended by POPRC for inclusion in Annex A to the Stockholm Convention without specific exemptions
Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride (PFOS)	EC no. 217-179-8 220-527-1 249-644-6 249-415-0 274-460-8 260-375-3 223-980-3 250-665-8 216-887-4 246-262-1 206-200-6 and others; CAS no. 1763-23-1 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8 4151-50-2 31506-32-8 1691-99-2 24448-09-7 307-35-7 and others	POPs Regulation
Perfluorooctanoic acid (PFOA)	EC no. 206-397-9 and others; CAS no. 335-67-1	POPs Regulation
Permethrin	EC no.: 258-067-9, CAS no.: 52645-53-1	BPR
Polybrominated biphenyls (PBB)	N/A	RoHS Directive
Polybrominated diphenyl ethers (PBDE)	N/A	RoHS Directive
Polychlorinated biphenyls (PCB)	EC no. 215-648-1 and others; CAS no. 1336-36-3 and others	POPs Regulation
Polychlorinated dibenzo-p-dioxins (PCDD)	EC no. 217-122-7; CAS no. 1746-01-6	POPs Regulation
Polychlorinated dibenzofurans (PCDF)	N/A	POPs Regulation
Polychlorinated naphthalenes (PCN)	EC no. 274-864-4 and others; CAS no. 70776-03-3 and others	POPs Regulation
Polycyclic aromatic hydrocarbons (PAHs)	EC no. 205-916-6 and others; 207-08-9 and others	POPs Regulation
Potassium chromate	EC no. 232-140-5; CAS no. 7789-00-6	REACH Annex XIV
Potassium dichromate	EC no. 231-906-6; CAS no. 7778-50-9	REACH Annex XIV
Potassium hydroxyoctaoxodizincatedichromate	EC no. 234-329-8; CAS no. 11103-86-9	REACH Annex XIV
Quinoxyfen	EC no. 602-997-3; CAS no. 124495-18-7	Under scrutiny for proposal for inclusion in Stockholm

Name	EC/CAS number	Regulation
		Convention
Short chain chlorinated paraffins (SCCPs)	EC no. 287-476-5; CAS no. 85535-84-8	POPs Regulation
Sodium chromate	EC no. 231-889-5; CAS no 7775-11-3	REACH Annex XIV
Sodium dichromate	EC no. 234-190-3; CAS no. 10588-01-9, 7789-12-0	REACH Annex XIV
Strontium chromate	EC no. 232-142-6; CAS no. 7789-06-2	REACH Annex XIV
Sulphur hexafluoride	EC no.: 219-854-2; CAS no.: 2551-62-4	F-gas Regulation
Tetrabromobisphenol-A	EC no.: 201-236-9, CAS no.: 79-94-7	Recommended for inclusion in RoHS Direcrive by 2018 substance review
Tetrabromodiphenyl ether	EC no. 254-787-2 and others; CAS no. 40088-47-9 and others	POPs Regulation
1,1,2,2-tetrafluoroethane	EC/Listno.: 206-628-3; CAS no.: 359-35-3	ODS Regulation
Toxaphene	EC no. 32-283-3; CAS no. 8001-35-2	POPs Regulation
Trans-1-chloro-3,3,3-trifluoropropene 5	EC/List no.:700-486-0; CAS no.: 102687-65-0	ODS Regulation
1,1,1-trichloroethane	EC/List no.: 200-756-3; CAS no.: 71-55-6	ODS Regulation
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	EC no. 247-384-8; CAS no. 25973-55-1	Proposal submitted for inclusion in Stockholm Convention