ANNEX to Code of Conduct on REACH Defence Exemptions

FRAMEWORK FOR APPLYING FOR A DEFENCE EXEMPTION FROM A REQUIREMENT OF REACH

Table of Contents

DEFINITIONS

CAS – Chemical Abstract Service (American numbering system for chemical substances)

CLP (Regulation) – Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on **C**lassification, **L**abelling and **P**ackaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

CSA – Chemical Safety Assessment, ideally in REACH CSR (Chemical Safety Report) format

CSR - Chemical Safety Report : Chemical Safety Assessment, presented in format prescribed by the European Chemical Agency (ECHA)

DNEL - Derived No-Effect Level : Concentration at which no risk to Human Health is likely to occur

e-SDS – Extended Safety Data Sheet

EINECS - European Inventory of Existing Commercial Chemical Substances (European numbering system for chemical substances)

PNEC - Predicted No Effect Concentration : Concentration at which no risk to Environment is likely to occur

REACH (Regulation) - Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **Ch**emicals, 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.

SDS – Safety Data Sheet

1. INTRODUCTION

1.1. Purpose of Framework

The purpose of this Framework is to provide subscribing Member States (sMS) to the Code of Conduct on REACH Defence Exemptions guidance on REACH and the application of exemptions from REACH in the interest of defence and currently targets the most likely (based on the current return of experience of Member States) exemption cases (from registration, authorisation or restriction). It does not include all cases related to REACH obligations (for instance, communication under article 33). The Framework aims to standardise as far as reasonably practicable national REACH Defence Exemption procedures and provide an agreed set of minimum standards[1] in order to guarantee a safety standard equivalent with the REACH requirements, facilitate reciprocal acknowledgment of Defence Exemptions when needed and avoid an uneven field across procurement in the defence industry. sMS can include any additional requirements as required to meet national procedures. A short overview of the REACH Regulation is presented in Appendix A.

1.2. Overview of Article 2(3) of the REACH Regulation

The REACH Regulation makes provision for a Defence Exemption under Article 2(3); the Defence Exemption clause reads as follows:

*Member States **may** allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence.*

The terminology of the Defence Exemption leaves it up to individual nations to determine whether exemptions are required, the process by which the exemption process is managed and which substances, on their own, in a mixture or in an article should be exempted. Furthermore, a REACH Defence Exemption is valid only in the Member State that grants the exemption.

This has led to the following risks being identified:

- Lack of co-ordination on the exempting of sensitive items; one of the primary reasons for the inclusion of a Defence Exemption was to prevent Defence from

[1] The exemption dossier provided in the current framework aims to provide an easy to understand set of requirements, based on well-known tools (such as safety data sheets) and explicit risk level definitions, while simplifying the expectations for the exemption process in comparison to REACH processes (see Appendix B) without jeopardising safety and environmental safeguards. In the rare case that one of the recommended requirements may seem to go beyond the REACH Regulation, a footnote clarifies the conditions under which it may be downgraded (see table 1 or table 4), even though the collective set of requirements has been simplified.

having to register substances and uses that the disclosure of could harm National Security;

- No consistency in embedding of, or management of, Defence Exemption by Member States. This has the serious implication of potentially creating an uneven field across procurement in the Defence industry, along with impacting negatively on the circulation of substances across the EU markets.

In order to take these risks into account, the Framework proposed in this document identifies a number of different reasons (or **business cases**), why a Defence Exemption may be sought, such as:

- National Security i.e. providing information on defence substance uses would result in breach of security;
- Pre-existing national or foreign legislation or international commitments limiting the disclosure of the information;
- Protection of a critical capability i.e. avoidance of substance obsolescence or protection of substance supply chain and long-term security of supply when alternative substances and technologies are not available;
- Urgent Operational Requirements.

1.3. General Principle

sMS agree to the following general principle on the use of Article 2(3): **Where an exemption is sought, an exemption dossier, based on the minimum requirements identified below will be produced, to provide the rationale for the exemption.**

In case that more than one governmental and/or industrial entity are required to apply for a defence exemption for a specific substance, it is recommended that they form a Substance Information Exchange Forum (SIEF) in order to jointly prepare the relevant exemption dossier and potentially share related costs.

2. EXEMPTION DOSSIER

2.1. Overview of Exemption Dossier

Exemption procedures within sMS may vary due to differing national procedures; including information required as part of an exemption application, the scrutiny process and the signatories to the exemption certificate. This section does not override these

national procedures but provides guidance on what Defence Exemption dossiers should provide as a minimum.

The Exemption Dossier should contain all the information required for the relevant sMS authorities to determine whether a Defence Exemption is required. The information required for an exemption dossier varies depending on the type of exemption including Registration, Authorisation or Restriction and the volumes of substance.

The exemption dossier should contain 3 types of information:

- Basic application information (required for all exemption applications, see 2.2);
- Defence Exemption justification (required for all Defence Exemption applications, with additional information varying according to the risk level, see 2.3);
- Health and environmental risk assessment (information varying according to risk level, see 2.4).

2.2. Basic Application Information

- REACH Article for which exemption is sought;
- Name(s), details and role of applicant or applicant sponsor;
- Name(s) and details of beneficiaries (for example MoD Project);
- Substance Manufacturer, Importer, Distributer, downstream user or country (manufacturing, importing or distributing the substance);
- Location(s) where the substance is used;
- (Proposed) Security Classification;
- Substance information including:
    - Chemical Name and ID;
    - CAS numbers/names (if available);
    - EC/EINECS numbers/names (if available);
    - The classification and labeling of the substance (in line with CLP Regulations).
- Description of use for which the exemption is sought;

- Description of Identified use & quantities required.

- Unclassified summary of defence Interest;
- Timescales for which the exemption is sought – required start date and estimated end date.

This basic information gives a quick overview of the relevance of the exemption request and provides a useful summary of the exemption dossier to all authorities involved in analysing the exemption request. The use of this information is subject to applicable sMS national laws.

2.3. Defence Exemption Justification

The exemption application should provide information on the defence interest, and should provide justification on why a Defence Exemption is required. As a minimum, the following information has to be provided:

- Defence Exemption detailed business case (see 1.2), i.e. reasons which make the exemption from REACH necessary (see Appendix A) :
  - Detailed explanation of defence interest, use throughout the supply chain and justification for exemption request;
  - Summary of risk and benefits to defence capability including performance criticality.
- Information pertaining to relevant non-defence use. This should include commercial uses for which authorisation may be investigated or not;
- Analysis of any alternatives: In case the substance causes a high risk (see 2.4), the Defence Exemption justification should include information on any potential alternatives, and explanation on why the alternatives are not appropriate or available at this time;
- Time constraints/substitution plan for appropriate alternatives: In case the substance causes a high risk (see 2.4), the Defence Exemption justification should explain the time constrains related to substitution with alternatives, in order to justify timescales for which exemption is sought.

The exemption justification contains all the information justifying the need for an exemption. It is used by the administration(s) analysing if the exemption request is justified; it might contain sensitive project or technical information and may not be given to other administration(s) that may analyse the chemical safety assessment.

2.4. Health and Environmental Risk Assessment Requirements

All Defence Exemption requests will require some level of assessment of health and environmental risks associated with the substance(s) and/or use. The applicant will be responsible to provide a risk assessment; the detail and content of the information must be proportionate to the level of risk identified i.e. Low, Medium, or High.

The risk assessment will be scrutinised in line with national procedures. The scope of the information (including exposure scenario) should be agreed with the appropriate national authorities in advance, and must consider the relevant stages of the life cycle and defence uses.

The health and environmental risk assessment requirements are distinguished in three categories: namely Low, Medium and High Risk, as shown in Table 1.

Level of Risk	REACH Process	Risk criteria[2]		CSA Required ?	Analysis of alternatives risks required?	SDS / e-SDS required?
		Hazardous[3]	Tonnage [4]			
Low	Registration	LEVEL 0 or 1	1 - 10	No	No	SDS[5]
Medium	Registration	LEVEL 2	1 - 10	No	No	e-SDS[6]
		LEVEL 0, 1 or 2	> 10	Yes		
High	Authorisation, Restriction	LEVEL 3	> 0	Yes	Yes	e-SDS

Table 1. Health and Environmental Risk Assessment Requirements

[2] Two risk criteria are used to determine the level of risk: hazardousness of the substance and the tonnage used per year

[3] Hazardous: This criteria depends on the substance legal status with REACH and CLP (not on intrinsic hazardousness levels), and the four levels are described below:

- LEVEL 0: Substance does not meet the criteria for classification as hazardous in accordance with REACH and CLP (substance is not hazardous)
- LEVEL 1: Substance meets the criteria for classification as hazardous in accordance with REACH and CLP but is not hazardous as defined in level 2 or 3
- LEVEL 2: subgroup of hazardous substances classified as carrying a Carcinogenic, Mutagenic or Reproductive hazard (CMR category 1A or 1B according to CLP), substances which are Persistent, Bioaccumulative and Toxic (PBT), substances which are very Persistent and very Bioaccumulative (vPvB), and endocrine disruptor or equivalent level of concern, as defined in REACH article 57 a to f.
- LEVEL 3: Substances of level 2 included in Annex XIV and/or Annex XVII of the REACH Regulation

[4] Tonnage: tonnes per annum manufactured, imported or used.

[5] SDS or equivalent amount of information possibly structured differently from the SDS format; If the hazard is at least level 1, then the SDS is compulsory

[6] e-SDS or equivalent amount of information possibly structured differently from the e-SDS format. If the hazard is at least level 1 (hazardous in accordance with CLP) and the tonnage is more than 10 tonnes per annum, then the e-SDS is compulsory

The levels of risk are defined as follows:

- **Low risk:** deals with exemption from registration for substances in the indicated threshold. The substance is used[7] by the exemption applicant for an amount above 1 tonne per annum (tpa) and less than 10 tpa. The substance hazard is LEVEL 0 or 1 (as defined above in table 1). The minimum threshold is 1 tpa since the REACH Regulation doesn't require registration of a substance used in amount under 1 ton per annum.

- **Medium risk:** deals with exemption from registration for substances in the indicated threshold. This risk level is applied to substances used by the exemption applicant for an amount above 1 tpa with a LEVEL 2 hazard and above 10 tpa with a LEVEL 0, 1 hazard.

- **High risk:** deals with exemption from authorization or restriction. This risk Level 3 applies to substances included in Annex XIV (substances subject to authorization) and/or Annex XVII (Restricted Substances) of the REACH Regulation. In this case, the REACH Defence Exemption takes no tonnage threshold limit into account.

For substances which cause a Low or Medium Risk and are used in amount less than 1 tonne per annum, there is no need to apply for a REACH Defence Exemption.

2.4.1. Low Risk requirements

The applicant is required to provide a Safety Datasheet (SDS) as shown in Table 2 (or a collection of equivalent information if the substance is not considered hazardous under REACH or CLP (i.e. is Level 0)):

Low Risk Health and Environmental Risk Assessment: SDS[8]	
1. Safety Data Sheet : SDS	
1.1	Identification of the substance / mixture and of the Company/Undertaking
1.2.	Hazard information
1.3.	Composition / information on ingredients
1.4.	First aid measures
1.5.	Fire-fighting measures
1.6	Accidental release measures

[7] Used = imported, produced, or used in a manufacturing process

[8] Or equivalent level of information if the substance is not Level 1 hazard, i.e. not considered hazardous under REACH or CLP

1.7.	Handling and storage
1.8.	Exposure controls / personal protection
1.9.	Physical and chemical properties
1.10.	Stability and reactivity
1.11.	Toxicological information
1.12.	Ecological information
1.13.	Disposal consideration
1.14.	Transport information
1.15	Regulatory information
1.16.	Other information

Table 2. Contents of Low Risk Health and Environmental Risk Assessment

2.4.2. Medium and High Risk requirements

The applicant is required to provide an Extended Safety Data Sheet. It can provide a collection of equivalent information if the substance is not considered hazardous under REACH or CLP (i.e. case of Level 0 hazard in medium risk level), or if the amount is less than 10 tpa (i.e. case of Level 2 hazard < 10 tpa in medium risk level) and the risk is not high risk. The applicant is also required to supply a Chemical Safety Assessment in case the amount is more than 10 tpa in medium risk level, and in all cases when the risk level is high.

The main (and significant) difference between a Medium Risk and a High Risk Defence Exemption Application is the need, in the High Risk Application, to analyse the availability of potential alternatives and their associated risks compared to the substance which they might replace, since the High Risk Application relates to a request for exemption from authorisation or restriction. Therefore it is important that the applicant shows the alternatives which have been considered, not only in terms of technological maturity but also in terms of health and environmental risks, in order to determine if these alternatives would be suitable and when, and to decide the proper duration of the exemption.

Unlike the manufacturer / importer who has to produce a REACH Registration dossier, for all the uses of its customers, the Ministry of Defence which applies or receives an application for a REACH Defence Exemption from registration, either already knows or is interested only in the specific use(s), within its national supply chain which are in relation with the object of the exemption request. In the case of an application for a Defence Exemption from authorisation or restriction, only the involved uses related to defence use are obviously mentioned. It is thus reasonable to ask that in the case of a

REACH Defence Exemption application, the Chemical Safety Assessment be limited to the relevant uses and exposure routes in the defence use.

The contents of the Extended Safety Datasheet in cases of Medium and High Risk Health & Environment Risk Assessment are shown in Table 3.

Medium and High Risk Health and Environmental Risk Assessment: e-SDS[9]+CSA	
1. Extended Safety Data Sheet (e-SDS)	
1.1.	Identification of the substance / mixture and of the Company/Undertaking
1.2.	Hazard information
1.3.	Composition / information on ingredients
1.4.	First aid measures
1.5.	Fire-fighting measures
1.6.	Accidental release measures
1.7.	Handling and storage
1.8.	Exposure controls / personal protection
1.9.	Physical and chemical properties
1.10.	Stability and reactivity
1.11.	Toxicological information
1.12.	Ecological information
1.13.	Disposal consideration
1.14.	Transport information
1.15	Regulatory information
1.16.	Other information
Annex	Exposure scenario's for workers and / or consumers
2. Chemical Safety Assessment, limited to the relevant uses and exposure routes	
2.1	Human health hazard assessment (DNEL)
2.2	Physicochemical hazard assessment (Classification)
2.3	Environmental hazard assessment (PNEC)
2.4	Exposure Assessment risk characterisation

Table 3. Contents of Medium and High Risk Health and Environmental Risk Assessment

[9] Or equivalent level of information if the substance is not considered hazardous under REACH or CLP, is less than 10 tpa, and is not high risk

2.5. Requirements Summary

A summary of the contents of the Defence Exemption application dossier is mentioned in Table 4. The differences between REACH requirements and the Framework to apply for a Defence Exemption are described in Appendix B.

Dossier Content (summary in relation to risk level)	**Low Risk**	**Medium Risk**	**High Risk**
REACH process	**Registration**	**Registration**	**Authorisation, restriction**
Basic Application Information:			
Information as required in paragraph 2.2	X	X	X
Defence Exemption Justification:			
Defence Exemption business case	X	X	X
Information regarding relevant non-defence use	X	X	X
Analysis of alternatives and time constraints/substitution plan for alternatives			X
Health and Environmental Risk:			
Safety Data Sheet / extended-Safety Data Sheet (or equivalent, according to hazardousness and tonnage detailed in 2.4)	SDS[10]	e-SDS[11]	e-SDS
Chemical Safety Assessment, limited to the relevant uses and exposure routes		X[12]	X
Analysis of risks associated with alternatives			X

Table 4. Defence Exemption Application Dossier Requirements based on Risk

Appendix A: Short Overview of REACH
Appendix B: Difference between REACH requirements and Framework for Applying for a Defence Exemption

[10] SDS or equivalent amount of information possibly structured differently from the SDS format; If the hazard is at least level 1, then the SDS is compulsory

[11] e-SDS or equivalent amount of information possibly structured differently from the e-SDS format. If the hazard is at least level 1 (hazardous in accordance with CLP) and the tonnage is more than 10 tonnes per annum, then the e-SDS is compulsory

[12] If tonnage imported, manufactured, or used by organisation seeking exemption is more than 10 tonnes par annum

Appendix A: Short Overview of REACH

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European Union Regulation. It came into force on the 1st of June 2007 and replaced around 40 European Directives and Regulations with a single system. REACH has 4 primary objectives which are:

- Ensure the protection of human health and the environment from the risks that can be posed by chemicals;
- Enhance the competitiveness and innovation of the EU industry, as key element for the economy of the EU;
- Promote alternative methods for the assessment of hazards of substances;
- Ensure the free circulation of substances on the internal market of the European Union.

REACH has 4 main processes:

- **Registration:** REACH requires manufacturers and importers of chemical substances (≥1 tonne/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely. Each manufacturer and importer must submit a registration dossier documenting the data and assessments to the European Chemicals Agency (ECHA)**.** A summary is shown in Table 5.
- **Evaluation:** ECHA and the Member States competent authorities perform dossier and substance evaluation and therefore no exemption is foreseen.
- **Authorisation:** The European Commission (EC) may decide to require an authorisation for placing on the market or use of certain Substances of Very High Concern (SVHC). These substances are included in Annex XIV of the REACH Regulation. Companies may apply for authorisation for placing on the market or using these substances. Companies applying for authorisation will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. Applicants also have to investigate the possibility of substituting these substances with safer alternatives or technologies, and prepare substitution plans, if appropriate. An authorisation is valid within the entire EU and has a limited duration of time.

- **Restriction:** The European Union can impose restrictions and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances or group of substances when unacceptable risks to humans or the environment have been identified. These restrictions will be included in Annex XVII of the REACH Regulation.

Annual production / import		Registration before	Content of REACH Registration Dossier	CSR Required
Hazard[13]	**Volume (tpa)**			
Yes or No	<= 1	No obligation to register	No obligation to register	No
Yes	> 1	01-12-2010	Annex VI, VII and other Annexes of the REACH Regulation, depending on annual production / imports	Yes
No	> 1000	01-12-2010	Annex VI to X[14] of the REACH Regulation	Yes
No	100 – 1000	01-06-2013	Annex VI to IX of the REACH Regulation	Yes
No	10 – 100	01-06-2018	Annex VI to VIII of the REACH Regulation	Yes
No	1 – 10	01-06-2018	Annex VI and VII of the REACH Regulation	No

Table 5. Summary of the REACH Registration Requirements

[13] As defined in Article 23 of REACH Regulation

[14] Annexes VII till X of the REACH Regulation prescribe in detail which Human and Environmental data the applicant must include in his Registration Dossier. The applicant needs this data to establish DNEL and PNEC

Appendix B: Difference between REACH requirements and Framework for Applying for a Defence Exemption

The current Framework draws heavily from the requirements of the REACH Regulation processes.

However, some simplifications have been made, especially for low and medium risk (exemption from registration) since the Ministry of Defence may not always require the same information as REACH, but rather needs to grant a Defence Exemption for a single or a few specific uses of a substance in the interest of defence for a given period of time while managing health and environmental risks and keeping in check obsolescence risks.

The simplifications are:

- Information on substances and on their exposure scenarios in a e-SDS format
- Freedom of format for the CSA (Chemical Safety Assessment), even if the same kind of information is asked as in the REACH CSR (Chemical Safety Report)
- When the CSA is required, it is limited to the relevant uses and exposure routes
- Alternatives analysis: it is required only in the high risk case, not for an exemption from registration