The defence sector’s criteria document – chemical substances, chemical products and articles

Introduction

The purpose of the criteria document is to restrict the use of substances hazardous to human health and the environment, in chemical products and articles (materiel), used by the authorities of the defence sector (the Swedish Armed Forces, the Swedish Defence Material Administration, the Swedish National Defence College, the National Defence Radio Establishment, the Swedish Defence Research Agency, and the Swedish Fortifications Agency). The latest update of this document is available from the Swedish Armed Forces’ external web page, www.forsvarsmakten.se.

The criteria document is a tool for the defence sector to establish human health and environment requirements on procurement and purchasing of chemical products and articles, and also on applicable parts of services. By establishing such requirements the defence sector will contribute to reducing effects on the environment and humans. This is achieved by, inter alia, restricting which chemical substances which may be used in activities and the chemical products used in production and maintenance.

The criteria document is a governing document established by the respective authority in the defence sector. The basis for the document is the EU-regulations REACH ((EC) No 1907/2006) (hereafter referred to as REACH) and CLP ((EC) No 1272/2008) (hereafter referred to as CLP), and the new provisions introduced by these regulations. In order to promote the development of chemical products and articles with less effect on human health and the environment, the criteria document establishes more far-reaching requirements than current chemicals legislation in many cases. Specific exemptions are given by the defence sector when it is deemed to be currently not technically or economically feasible to avoid certain chemical products or certain chemical substances in articles. These exemptions are specified in appendix 2 of the criteria document.

The Swedish Parliament has adopted 16 national environmental quality objectives. One of these is a Non-toxic Environment with the Swedish Chemicals Agency as the agency responsible for following up, coordinating and evaluating how this objective is achieved. The work can be followed on the Swedish Chemicals agency’s web-page www.kemi.se. This objective is to be achieved by, among other things, the phasing out of dangerous substances. The defence sector has objectives linked to this environmental quality objective and these objectives can be found on www.forsvarsmakten.se.

It is important to take note of the fact that compliance with the criteria document does not remove the responsibility from the supplier to have adequate competence in, and responsibility for, substances in their chemical products and/or articles. The supplier is responsible for
complying with Swedish legislation as well as with regulations, directives and other pieces of legislation decided by the EU, that are applicable to the chemical product and/or articles.

The definition of the objective a Non-toxic Environment is as follows: "The occurrence of man-made or extracted substances in the environment must not represent a threat to human health or biological diversity. Concentrations of non-naturally occurring substances will be close to zero and their impacts on human health and on ecosystems will be negligible. Concentrations of naturally occurring substances will be close to background levels."

Limitations
The following is not covered by the criteria document as it is covered by specific legislation or international conventions:

Cosmetics and hygiene products, pesticides, chemical weapons according to the Chemical Weapons Convention, food, food packaging, other packaging than food packaging, radioactive substances and medicinal products.

Important definitions in the criteria document

Substance is defined as a chemical element and its compounds including any additives necessary to preserve its stability and any impurity deriving from the manufacturing process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Mixture is defined as a mixture or solution composed of two or more substances.

A chemical product is defined as a substance or a mixture of two or more substances.

An article is defined as 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. Examples of articles in the defence sector are different materiel such as vehicles, tents, desks, computers and pieces of uniforms etc.

Structure of the criteria document and guidance on use
The criteria document is structured as follows:

- Schematic guidance on how to apply the criteria document on chemical products

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1 For practical reasons, certain mixtures of closely related molecules are regarded as a substance. For example: laureth-3 is regarded as one substance although the molecules have straight carbon-chains with different chain-lengths, with an average of 12 carbons, and ethoxylate-chains of different lengths with an average of 3 ethoxylate-units.
Schematic guidance on how to apply the criteria document on articles

Criteria for chemical products:
  - Table 1 and table 2: Criteria for chemical products that shall be avoided
  - Table 3: Restrictions on substances in chemical products.

Criteria for substances in articles:
  - Table 4: Substances that shall not be intentionally added to articles.

Background information on criteria for substances, chemical products and articles

Examples of relevant legislation to consider regarding substances, chemical products and articles.

Appendix 1: Examples of substances covered by the restrictions in table 3 and 4.

Appendix 2: The defence sector’s exemptions for certain chemical products and substances.

The document includes several changes compared to earlier criteria documents, among other things, which criteria that are used to restrict the use of dangerous chemical products and substances in articles, specific exemptions for the use of certain substances/chemical products and schematic guidance on how the criteria document shall be applied to chemical products and articles respectively.

A presentation of the background information on the criteria and legislation that the defence sector want to point out as particularly relevant to consider regarding substances, chemical products and articles is included at the end of the criteria document.
Guidance on how to apply the criteria document on chemical products

The schematic guidance below, shows the approach to decide whether a chemical product can or cannot be accepted by the defence sector.

- The chemical product is a mixture
  - Is the mixture covered by the restrictions in tables 1 and/or 3?
    - Yes
      - Do alternatives not covered by a restriction exist?
        - Yes
          - Substitute!
        - No
          - Are exemptions allowed under Appendix 2?
            - Yes
              - The chemical product can be accepted
            - No
              - The chemical product can not be accepted
    - No
      - The chemical product is a substance
        - Is the substance covered by the restrictions in tables 2 and/or 3?
          - Yes
            - Apply for exemption if there is exceptional reasons
          - No
            - The chemical product can be accepted

Appendix 1: Examples of substances that are covered by the restrictions in tables 3 and 4.
Guidance on how to apply the criteria document on articles

The schematic guidance below shows the approach to decide whether an article can or cannot be accepted by the defence sector.

[Flowchart diagram]

- **Article**
- **Is the article covered by the restriction in table 4?**
  - **Yes**
    - **Do alternatives not covered by the restrictions exist?**
      - **Yes**
        - **Substitute**
      - **No**
  - **No**
    - **Are exemptions allowed under appendix 2?**
      - **Yes**
        - **Substitute**
      - **No**
        - **The article cannot be accepted**
          - **Apply for exemption if there is exceptional reasons**
        - **The article can be accepted**
## Criteria for chemical products

**Table 1.** Chemical products, defined as mixtures which **shall be avoided** if they are classified (according to KIFS 2005:7) as given below:

<table>
<thead>
<tr>
<th>Risk phrase</th>
<th>Danger symbol</th>
<th>Indication of danger</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 26 Very toxic by inhalation.</td>
<td></td>
<td>Very toxic</td>
</tr>
<tr>
<td>R 27 Very toxic in contact with skin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R 28 Very toxic if swallowed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R 39 Danger of very serious irreversible effects.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(in combination with R 26, R 27 and/or R 28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R 42 May cause sensitisation by inhalation.</td>
<td></td>
<td>Harmful</td>
</tr>
<tr>
<td>R 43 May cause sensitisation by skin contact.</td>
<td></td>
<td>Irritant</td>
</tr>
<tr>
<td>R 45 May cause cancer. (Carc. Cat 1/ Carc. Cat 2)</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>R 46 May cause heritable genetic damage.</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>R 49 May cause cancer by inhalation. (Carc. Cat 1/ Carc. Cat 2)</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</td>
<td></td>
<td>Dangerous for the environment</td>
</tr>
<tr>
<td>R 59 Dangerous for the ozone layer.</td>
<td></td>
<td>Dangerous for the environment</td>
</tr>
<tr>
<td>R 60 May impair fertility. (Repr. Cat 1/ Repr. Cat 2)</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>R 61 May cause harm to the unborn child. (Repr. Cat 1/ Repr. Cat 2)</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>R 64 May cause harm to breastfed babies.</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>
Table 2. Chemical products, defined as substances, which shall be avoided if they are classified (according to CLP) as given below:

<table>
<thead>
<tr>
<th>Hazard statement</th>
<th>Hazard pictogram</th>
<th>Signal word</th>
</tr>
</thead>
<tbody>
<tr>
<td>H300 Fatal if swallowed. (category 1 and 2)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H310 Fatal in contact with skin. (category 1 and 2)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H317 May cause an allergic skin reaction. (category 1)</td>
<td>![Hazard pictogram]</td>
<td>Warning</td>
</tr>
<tr>
<td>H330 Fatal if inhaled. (category 1 and 2)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. (category 1)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H340 May cause genetic defects (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H350 May cause cancer (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H350i May cause cancer by inhalation. (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H360FD May damage fertility. May damage the unborn child. (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H360F May damage fertility. (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H360D May damage the unborn child. (category 1A and 1B)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H362 May cause harm to breast-fed children.</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>H370 Causes damage to organs (category 1)</td>
<td>![Hazard pictogram]</td>
<td>Danger</td>
</tr>
<tr>
<td>H410 Very toxic to aquatic life with long lasting effects. (category: Chronic 1)</td>
<td>![Hazard pictogram]</td>
<td>Warning</td>
</tr>
<tr>
<td>EUH059 Hazardous to the ozone layer.</td>
<td>-</td>
<td>Danger</td>
</tr>
</tbody>
</table>
Table 3. Restrictions on substances in chemical products

<table>
<thead>
<tr>
<th>Substances with PBT-properties(^2) shall not be present in concentrations ≥0,1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances with vPvB-properties(^3) shall not be present in concentrations ≥0,1%</td>
</tr>
<tr>
<td>Substances with a GWP-factor(^4) above 2000 (calculated over 100 years) shall not have been added intentionally</td>
</tr>
<tr>
<td>Substances specifically identified by the defence sector(^5) - shall not have been intentionally added</td>
</tr>
<tr>
<td>• Gamma-butyrolactone (GBL)</td>
</tr>
<tr>
<td>• Gamma-hydroxybutyrate (GHB)</td>
</tr>
<tr>
<td>• Methylene chloride</td>
</tr>
<tr>
<td>• Nonylphenolethoxylate</td>
</tr>
</tbody>
</table>

Application of transitional provisions

From and including the 1 December 2010 the provisions in force in CLP shall be applied to chemical products defined as substances, and at the latest by 1 June 2015 for mixtures. During a period there will therefore be two parallel classification- and labelling-systems for chemical products: CLP and the Swedish Chemicals Agency’s regulations (KIFS 2005:7) on Classification and Labelling of chemical products.

A chemical product defined as a substance, and placed on the market before the 1 December 2010 and which has not been classified and labelled according to the provisions in force of CLP, is, according to the legislation, covered by transitional provisions till the 1 December 2012. For such a chemical product, the supplier shall provide a safety data sheet giving the classification and labelling of the product according to CLP, or alternatively a separate document giving the product’s classification and labelling according to CLP.


\(^3\) See foot-note 2.

\(^4\) The GWP-factor for a substance is its Global Warming Potential. See GWP-values according to the latest IPCC-report or equivalent, or “listing of GWP-values” (FMV document designation 47238/2007) on [http://www.fmv.se/WmTemplates/Page.aspx?id=1370](http://www.fmv.se/WmTemplates/Page.aspx?id=1370)

\(^5\) Substances not covered by the criteria in table 3 or 4 and groups of substances where not all the substances are covered by the criteria in table 4, but that, because of other hazardous properties or regulatory restrictions are not wanted in the defence sector. See appendix 1 to the criteria document for the CAS-number of the substance and the justification for pointing out the substance as not wanted.
A chemical product defined as a mixture, may before 1 June 2015 be classified, labelled and packaged under CLP. The classification according to CLP shall then be included together with the classification under KIFS 2005:7 in the safety data sheet for the chemical product. In cases where the supplier has voluntarily chosen to classify, label and package the product (mixture) under CLP, the classification of the product under KIFS 2005:7 (as given in the safety data sheet) shall be evaluated versus table 1.

Criteria for articles

Table 4. Substances that shall not have been intentionally added to articles:

<table>
<thead>
<tr>
<th>Substances with CMR-properties(^6) in category 1 or 2 according to directive 67/548/EEC or category 1a or 1 b in the CLP regulation ((EC) regulation No 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances with PBT-properties(^7)</td>
</tr>
<tr>
<td>Substances with vPvB-properties(^8)</td>
</tr>
<tr>
<td>Substances on the Candidate list(^9)</td>
</tr>
<tr>
<td>Substances on Annex XIV to the REACH regulation</td>
</tr>
<tr>
<td>Substances with a GWP-factor above 2000 (calculated over 100 years)(^10)</td>
</tr>
<tr>
<td>Ozone-depleting substances(^11)</td>
</tr>
<tr>
<td>Substances specifically identified by the defence sector: (^12)</td>
</tr>
<tr>
<td>• Lead and its compounds/salts</td>
</tr>
<tr>
<td>• Decabromo diphenylether (Deca-BDE)</td>
</tr>
<tr>
<td>• Cadmium and its compounds/salts</td>
</tr>
<tr>
<td>• Mercury and its compounds/salts</td>
</tr>
<tr>
<td>• Nonylphenol ethoxylate</td>
</tr>
<tr>
<td>• Pentabromodiphenylether (Penta-BDE)</td>
</tr>
<tr>
<td>• Polybrominated biphenols (PBB)</td>
</tr>
</tbody>
</table>

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\(^6\) CMR = Carcinogenic, mutagenic (can cause heritable genetic defects) and/or toxic to reproduction (can impair fertility or harm the embryo/foetus). Examples of such substances can be found in the Classification list Annex VI, table 3.1 and 3.2 in CLP (EC) No 1272/2008, which contains harmonised and binding classification and labelling for substances and groups of substances.

\(^7\) See footnote 2.

\(^8\) See footnote 2.


\(^10\) See footnote 4.

\(^11\) Substances that may present a danger to the structure or functioning of the stratospheric ozone layer, that is fulfill classification criteria R59 (under KIFS 2005:7) or EUH059 (under CLP (EC) No 1272/2008)

\(^12\) See footnote 5.
Reach has introduced provisions that certain information on substances of very high concern included in articles shall be communicated to professional users (article 33 of REACH). The provision applies if a substance has been identified as particularly hazardous (also known as a SVHC, Substances of Very High Concern) on the Candidate list, and the concentration in the article is above 0,1 % weight by weight. The supplier of the article shall then provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

Note that Sweden and five other EU-countries have interpreted the concentration limit 0,1 % weight by weight as below, and that this interpretation shall be applied by suppliers that make articles and complex articles available to the defence sector:

- The concentration of the substance shall be determined as the ratio of the weight of the substance and the weight of individual articles, parts or materials that are parts of a complex article.
- For a complex article that consists of several parts, this means that the basis for calculations has to be the weight of the individual part that contains the substance, not the total weight of the complex article.

**Background information on criteria for substances, chemical products and articles**

The criteria document has taken into account that, during a time-period there will be two parallel classification and labelling systems (KIFS 2005:7 and CLP) for chemical products, by giving different criteria for chemical products defined as mixtures and substances respectively:

- Table 1 shall be used for chemical products defined as mixtures.
- Table 2 shall be used for chemical products defined as substances.

Chemical products which have been classified according to table 1 or 2 may cause serious health or environmental effects, even by a single or short-time use. Such chemical products shall therefore be avoided in the activities of the defence sector. Table 3 shows substances which, because of their properties are relevant to restrict in chemical products. For articles, no system for classifying and labelling exist as it does for chemical products, which means that the user does not receive information on whether the article contains hazardous substances (with the exception of substances on the Candidate list in a concentration >0,1 percent by weight, see under heading “REACH ((EC) regulation No 1907/2006”)”. The presence of substances that can cause serious effects on health and the environment, are for these reasons restricted by the criteria given in table 4.

The criteria in table 4 have been selected because they aim at restricting the presence of substances that can lead to serious effects on human health or adverse effects on the environment. Such effects are for example cancer, effects on fertility or increase in global
Examples of relevant legislation to consider regarding substances, chemical products and articles.

**REACH (regulation (EC) No 1907/2006)**

REACH distinguishes between substances, mixtures and articles. REACH primarily regulates substances and mixtures, but some provisions also apply to articles containing hazardous substances. The definitions of substance, mixture and articles are given in article 3 of the regulation. Earlier legislation did not include requirements for users of chemicals corresponding to those under REACH. Some new requirements are also applied to articles containing chemical substances. Because “article” is a key element in REACH, it is used in this criteria document to describe various materiel used in the defence sector. If substances with adverse health and environmental properties are released from an article it can cause negative effects on human health and the environment. Such substances shall therefore be avoided in articles used in the defence sector.

An article is defined in REACH (article 3.3) as 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. A more thorough assessment of an object’s function and properties may be required to establish whether an object fulfils the definition of article under REACH. The European Chemicals Agency (ECHA) has published guidance on requirements for substances in articles, which, among other things gives guidance on what should be seen as an article and helps suppliers of articles to establish which requirements that must be fulfilled for production, import and supply of articles.

One example is the rubber handles of a bicycle. The complete bicycle is a complex article, where several articles (for example the rubber handles, the tyres, the frame) has been assembled to achieve a desired form, function and design. Articles and complex articles that may occur in the defence sector are various materiel such as ships, camouflage net, electrical fittings etc.

**CLP (Regulation (EC) No 1272/2008)**

CLP is a regulation that enters into force in January 2009 throughout EU. CLP introduces new rules on how to classify, label and package chemical substances and chemical products (substances or mixtures).

During a transitional period to 1 June 2015, different provisions apply to chemical products defined as substances and mixtures respectively. Substances shall be classified under CLP no later than the 1 December 2010, and the same applies to mixtures no later than the 1 June 2015.

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Up to the 1 June 2015 mixtures shall be classified under KIFS 2005:7 and may be labelled and packaged under KIFS 2005:7. The mixture can however be classified under CLP if the mixture is also labelled and packaged under CLP. Note that the mixture must be labelled and packaged under either KIFS 2005:7 or CLP.

If the mixture has been classified, labelled and packaged under CLP, the classification of the chemical product under CLP shall be given together with the classification under KIFS 2005:7 in the safety data sheet.

CLP introduces several changes in the labelling of chemical products. Hazard pictograms are used instead of symbols and the labelling shall also include hazard statements and precautionary statements, instead of the risk and safety phrases given in KIFS 2005:7. Indication of danger (for example Harmful) is replaced by the signal words ”Danger” or ”Warning”.


These Swedish Provisions apply to all activities in which air contaminants in the form of dust, smoke, mist, gas or vapour can be presumed to occur.

The Provisions include three appendices: A list of limit values, Compilation of data always to be furnished in a measurement report, and a third appendix containing two lists (group A and group B) of chemical substances. Group A is a list of substances that under section 21 may not be handled, and Group B is a list of Substances which under Section 23 may only be handled by permission of the Swedish Work Environment Authority. It is of major importance that substances in Group A and B is avoided in the activities of the defence sector.


The purpose of these Swedish Provisions is to prevent ill-health resulting from exposure to thermosetting plastic components, thermoplastic components, and air contaminants formed in connection with thermal degradation.

These Provisions apply to all activity which involves the handling of thermosetting plastic components constituting, by reason of their toxicological properties, a hazardous chemical substance as defined in the Provisions of the National Board of Occupational Safety and Health (AFS 2000:4) on Chemical Hazards in the Working Environment.

14 http://www.av.se/inenglish/lawandjustice/provisions/
15 http://www.av.se/inenglish/lawandjustice/provisions/
The provisions include specific requirements on certain thermosetting plastic components, such as: epoxy plastics, urethane plastics, acrylate plastics and amino- and phenolic plastics.

*The Chemical Products (Handling, Import, and Export Prohibitions) Ordinance (1998:944)*

This Swedish Ordinance contains specific prohibitions or other restrictions on the handling of:
1. cadmium;
2. chlorinated solvents;
3. mercury;
4. cadmium, mercury, lead, hexavalent chromium and other chemical products in electrical and electronic products and in batteries;
5. heavy metals in packaging;
6. ammunition that contains lead,
7. textile detergents containing phosphates, and
8. certain other chemical products and goods dangerous to health or the environment.

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16 The ordinance can be found at http://www.kemi.se/templates/Page_4780.aspx