Call for evidence on the use of skin sensitisers, skin irritants and corrosive substances in textile and leather articles, hides and furs

Background document

Background

Production and processing of textile and leather articles, hides and furs involves a large number of chemicals. These chemicals are used (intentionally or as impurities) in all parts of the process from fibre to finished product, as well as in product distribution. Some of them remain in the final article of clothing, footwear and other articles that come into contact with the human skin in concentrations high enough to constitute a risk for exposed individuals. There are concerns that some of those chemicals are likely to be responsible for allergic contact dermatitis and skin irritation in the EU. Allergic textile dermatitis and irritation may have a significant impact on a person's quality of life, partly because of skin reactions from exposures but also as a consequence of the measures they must take to avoid articles that may cause problems.

In 2016, KemI (Swedish Chemicals Agency) published a RMOA (Risk Management Option analysis) concluding that the most efficient regulatory approach to mitigate allergic textile dermatitis is to introduce a new restriction entry in Annex XVII in the REACH regulation[1]. In January 2018, KemI and Anses (French Agency for Food, Environmental and Occupational Health & Safety) notified ECHA their intention to jointly prepare an Annex XV restriction dossier according to article 69 of REACH Regulation No 1907/2006[2].

Scope

In the RMOA, KemI mainly focussed on sensitising substances (addressed as a group) and concluded that skin sensitising substances that may be present in finished textile articles should be included in the scope and that a harmonised classification as Skin Sens. 1/1A/1B under CLP Regulation No 1272/2008 should be a criteria for inclusion in a possible restriction. Taking into account the most recent available information, including an Anses 2018 study on the safety of footwear and garments, KemI and Anses are now jointly investigating a broader scope including skin irritants and skin corrosive substances as well as skin sensitising substances.

The starting point of the scope is therefore substances present in the relevant articles (such as listed below in table 1), which are either harmonised classified as Skin Sens. 1/1A/1B and/or Skin Irrit. 2 and/or Skin Corr. 1/1A/1B/1C, self-classified substances that meet the

[1] https://echa.europa.eu/pact/-/substance-rev/13911/del/50/col/synonymDynamicField_497/type/desc/pre/1/view.
[2] https://echa.europa.eu/sv/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

criteria for those classifications, or are recommended to be classified as such by RAC. Other substances that have been identified as of concern are also included in the scope.

There are currently 1 846 substances with a harmonised classification for either Skin Sens. 1/1A/1B, Skin Corr. 1/1A/1B/1C and/or Skin Irrit. 2. In addition, there are 10 substances with an adopted RAC opinion for either of these classifications that are not yet included in Annex VI of the CLP Regulation.

KemI and Anses have identified ~6,000 substances potentially used in textiles, leather, furs and/or hides. In addition, another ~6,000 substances with structural similarities to these have been identified. Out of these ~12,000 substances potentially used in textiles, leather, furs and/or hides, 321 substances have at least one of the harmonised classifications listed above. Furthermore, a number of substances used in textiles and footwear without any of the harmonised classifications above have been identified to cause allergic dermatitis in clinical tests.

The compiled list of the substances in the scope is available in a separate excel-file (see the Appendix attached to the Call for Evidence).

The preliminary scope of the restriction proposal covers the placing on the market of finished textile and leather articles, hides and furs intended to come into direct and prolonged contact with the skin under normal and reasonably foreseeable conditions of use. These articles aim to be sold to the general public, therefore, the consumers are the population at risk.

Table 1. Preliminary scope of the restriction proposal

Substances	Materials	Articles
Substances with a harmonised classification as Skin Sens. 1/1A/1B, Skin Irrit. 2, and/or Skin Corr. 1/1A/1B/1C according to Table 3 in Annex VI of the CLP Regulation (EC 1272/2008)[3]. Substances which meet criteria for classification as Skin Sens 1/1A/1B, Skin Irrit. 2, Skin Corr. 1/1A/1B/1C under CLP. Substances for which RAC has provided an	Textiles, leather, furs and hides.[4]	Clothing and related accessories. Articles other than clothing which come into contact with the human skin under normal or reasonably foreseeable condition of use, such as: - bed linen, - blankets, throws, - upholstery (fabric covering chairs, armchairs and sofas etc.) - cushion covers - bathrobes, towels - re-usable nappies and sanitary towels - sleeping bags

[3] https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp

[4] The definitions used for the animal based materials are as follows:

- Hide is animal skin treated for human use.
- Leather is a hide that has been subject to tanning.
- Fur is treated pelt, which in turn is animal skin with the hair retained.

opinion for the classifications above. Additional substances of concern. (see the Appendix attached to the Call for Evidence).		- yarn and fabrics intended for use by the final consumer - carpets, mats and rugs - bags, like handbags, backpacks, briefcases, - fashion accessories - soles Footwear (such as defined by Directive 94/11/EC)

<u>The articles not covered by the scope are the following</u>

- Jewellery
- glasses and sunglasses
- curtains
- textile lampshades and wall decorations
- napkins and table linen
- filling materials in chairs, armchairs and sofas
- second hand articles
- disposable nappies and sanitary towels
- articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment
- articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Objective of the call for evidence

The goal of proposing a restriction is to sufficiently reduce the risks for allergic textile dermatitis and skin irritation in the EU without causing a disproportionate burden on the EU market for the articles in the scope. Therefore, in order to carry out an in-depth analysis on the proportionality of a restriction, more information about the uses, the exposures as well as the possibilities for substitution to safer alternatives is needed. For that purpose, KemI and Anses are undertaking this call for evidence and information.

Specific questions:

1. Which of the substances in the provided excel-file are likely to remain in any of the finished articles listed in Table 1 to be sold to the general public? If available, also provide information on concentration of the substance in the finished products. Relevant substances are those that are used (either intentionally added or as impurities) anywhere in the supply chain and that are likely to remain in the finished product.

2. How are these substances used in the articles of concern?

    - In what quantity (tons or number of articles per year) is the substance used in the articles that are sold (including imported

articles) and/or produced in the EU? Is the annual quantity increasing or decreasing?

- In what way is the substance used and for what purpose? Is it a process chemical (e.g. solvent) or a functional substance (e.g. fragrance, colourants, etc.)?
- Where in the supply chain is the substance used?

3. Can you provide any human health exposure data related to the substances likely to be found in the relevant finished articles to be sold to the general public (including parameters such as migration rates, leaching, solubility, how the substance is contained in the matrix, etc.)?

4. Can these substances be substituted, and, if so, how? Note that substitution is not only replacing a hazardous substance with a less hazardous substance, it also includes replacing a hazardous substance with another technology.

   - Economic feasibility of substitution: what would be the cost of substitution (per ton, per article, per business and/or in total for textiles on the EU market) and the composition of this cost (alternative substance price, new equipment, training, research and development etc.)?
   - If the substance can't be substituted at this point of time:
     - Provide economic and technical information as to why these substances cannot be substituted today. Are substitutes lacking because they are not available or are the performance of alternatives not considered adequate?
     - Will substitutes be available within a foreseeable future? If so, which are these substitutes and when will they be available in sufficient quantities to supply the market?

The information gathered will be used to determine whether these uses pose a risk on an EU-wide basis and assess the socio-economic impacts of the restriction proposed.

Who should participate in the call for evidence?

This call for evidence is intended for interested parties such as companies (manufacturers, importers, formulators, distributors of mixtures used in textile and leather articles hides and furs -from fiber production to finishing treatments- and/or used before/during transport, distribution, sales and retail; and manufacturers, importers, distributors, suppliers of textile and leather articles hides and furs), trade associations, scientific bodies and any other stakeholders or Member State Authority holding relevant information.

Information can be submitted confidentially and will be treated as such by ECHA. Any information provided will be used, amongst other issues, to determine if any derogations are required for any potential restriction that is proposed. However, derogations cannot be proposed without adequate information on risk and socioeconomic

information, including alternatives. If a derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on a comprehensive information on risk, socio-economic elements and alternatives, during the opinion-making process.

ECHA invites interested parties to respond to the call for evidence by 03 09 2018. https://echa.europa.eu/calls-for-comments-and-evidence

For any clarifications on the call, please contact Dr. Karine Fiore: Karine.FIORE@anses.fr