SWEDEN AND FRANCE PROPOSE A RESTRICTION ON SKIN SENSITISING SUBSTANCES IN TEXTILES, LEATHER, HIDE AND FUR ARTICLES[1]

Summary

The Annex XV report outlines a proposal to restrict the placing on the market of clothing, footwear (and other articles which come into contact with human skin similar to clothing) that contain skin sensitisers. The proposed restriction aims to reduce the risk for the general public of becoming sensitised via the skin to substances in finished textile, leather, hide and fur articles.

Skin sensitisation is a health effect which leads to a lifelong sensitivity to a specific allergen. Once a person is sensitised to an allergen, they must avoid exposure to it for the rest of their life in order to prevent allergic reactions.

The proposed restriction would cover substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in Annex VI to Regulation (EC) No 1272/2008, as well as a list of disperse dyes that are indicated to have skin sensitising properties (see Table 2 in the section on specific information requests).

Active ingredients in biocidal products are not covered by the proposed restriction. The restriction would not apply to personal protection equipment, medical devices and second-hand articles.

The public consultation on this proposed restriction will start on **19/06/2019** and will end on **19/12/2019**.

When responding to the public consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation)

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the public consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have had access to the dossier much earlier in the process than in the past, as it is published two weeks after submission (more than six weeks in advance of the start of the public consultation).

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

[1] The information note has been prepared based on the Annex XV report prepared by France and Sweden.

	Committee	
Plenary meeting of the Committee (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after PC starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on the costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after PC starts)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months after PC starts)	Conclude on –any derogations. Finalise the opinion and justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion and justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion public consultation. Adopt the final opinion.

How to submit a comment in the Consultation on the proposed restriction

Firstly please read the consultation guidance that describes the relevant information that should be submitted. It is available here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal – both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do

not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socio-economic analysis.

- Section 4: Non-confidential attachments can be added here.
- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the web form.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.

Specific information requests

In addition to the general comments, outlined above, the consultation includes several specific questions to gather further/additional information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

1. Regarding hazards and risks:
    a. Specific information from literature or other sources is sought to confirm the skin sensitisation hazard profile or properties of the 24 disperse dyes included in Table 2 of the Annex XV report (reproduced below).

Table 1: Disperse dyes included in the scope of the proposed restriction

Substance name	CAS No.	EC No.
CI Disperse Blue 3	2475-46-9	219-604-2
CI Disperse Blue 7	3179-90-6	221-666-0
CI Disperse Blue 26	100357-99-1 13324-23-7 3860-63-7 2580-56-5	600-078-1 603-725-6 223-373-3 219-943-6
CI Disperse Blue 35	12222-75-2 56524-77-7	602-260-6 260-243-5
CI Disperse Blue 102	12222-97-8	602-282-6
Ci Disperse Blue 106	12223-01-7	602-282-2
CI Disperse Blue 124	61951-51-7	612-788-9
CI Disperse Brown 1	23355-64-8	245-604-7
CI Disperse Orange 1	2581-69-3	219-954-6
CI Disperse Orange 3	730-40-5	211-984-8
CI Disperse Orange 37 /59/76	13301-61-6 12223-33-5 51811-42-8	236-325-1 602-312-8
CI Disperse Red 1	2872-52-8	220-704-3
CI Disperse Red 11	2872-48-2	220-703-8
CI Disperse Red 17	3179-89-3	221-665-5
CI Disperse Yellow 1	119-15-3	204-300-4
CI Disperse Yellow 9	6373-73-5	228-919-4

CI Disperse Yellow 39	12236-29-2	602-641-7
Ci Disperse Yellow 49	12239-15-5 54824-37-2	235-473-4 611-202-9
CI Disperse Orange 149	85136-74-9	400-340-3
CI Disperse Blue 291[1]		
CI Disperse Violet 1	128-95-0	204-922-6
CI Disperse Violet 93	122463-28-9	602-785-0
CI Disperse Yellow 64	10319-14-9	233-701-7
CI Disperse Yellow 23	6250-23-3	228-370-0

[1]For CI Disperse Blue 291 CAS and EC numbers not specified, because there are numerous CAS and EC numbers associated with this chemical.

b. Regarding the risks, specific information is sought on migration data and on elicitation threshold doses for substances within the scope of the proposed restriction in textiles as well as how this migration might differ depending on the type of material (leather vs textile) and specific information on use pattern and exposure frequency of textiles.

2. The Dossier Submitter has developed a list of substances that can potentially be present in finished articles made of textile, leather hides and fur.
   a. Please provide information on any substances that have been missed in the screening done by the Dossier Submitter, and listed in Table 20 in Annex E.
   b. Please provide further information regarding the availability of test methods for the substances in Table 20 in Annex E as well as the associated costs for testing.
   c. Please provide information on whether the estimated mg/kg concentrations indicated in Table 20 in Annex E are correct.
   d. In order to justify the proposed concentration limits, please provide information on the presence of the substances below the limit of concentration indicated in paragraph 3 (from I to V) of the proposed restriction, as well as any further information related to risks or socio-economic impacts.
   e. The Dossier Submitter has not been able to confirm whether the following substances are present in articles placed on the market for the general public:
      i. Benzenesulfonic acid, 3-nitro-, sodium salt (1:1)(CAS 127-68-4/EC 204-857-3) used as intermediate in dye synthesis,
      ii. Tall-oil rosin (CAS 8052-10-6/EC 232-484-6), which may be used in coated, pigment printed textiles.

      If they are present in articles placed on the market for the general public, please provide any information on concentrations and on possible alternatives to them.

3. The Annex XV report does not identify alternatives for some of the substances, or groups of substances, that would be affected by the proposed restriction. Please provide any information you have regarding the availability and suitability of alternatives to substances that would be covered by the proposed restriction. In particular, information on alternatives to the following groups of substances would be useful:

a. Solvents (general information on their presence and use in formulations would also be useful),

b. Formaldehyde (CAS 50-00-0/EC 200-001-8) for leather, hide and fur applications,

c. Glutaraldehyde (CAS 111-30-8 EC 203-856-5). Furthermore, information is sought on whether the existing supply of vegetable tanning is large enough to substitute both chromium VI and glutaraldehyde.

d. Metals (e.g. cobalt) and inorganic compounds.

e. Benzenamine (aniline) (CAS 62-53-3/EC 200-539-3).

f. Industry has indicated that some of the identified alternatives may be regrettable substitutes. Please provide further information about:

i. dioctyl sebacate (CAS 117-84-0/EC 204-214-7), dioctyl adipate (CAS 123-79-5/EC 204-652-9), dioctyl phthalate (CAS 117-84-0/EC 204-214-7) and diisononyl phthalate (CAS 28553-12-0/EC 249-079-5) for neoprene applications, which are within the intended scope of the proposed restriction,

ii. acrylics, polyurethanes and other binders for rosins,

iii. acetyl tri-butyl citrate (ATBC) (CAS 77-90-7/EC 201-067-0) and dibutyl phthalate (CAS 84-74-2; 93952-11-5/EC 201-557-4) for phthalate esters.

4. For some of the substances proposed to be restricted, there is information in the Annex XV report on the identity of the most likely alternatives but further information is sought about the associated costs and hazards. In particular, information on the following:

a. The cost of implementing best practice to reduce levels of diisocyanates in articles placed on the market for the general public. Also information on the costs of moving towards best practice for other substances would be useful.

b. Information on whether the cost assumptions for alternative rubber accelerators are correct (e.g. the number of required reformulations and cost per reformulation). Also information of whether reformulations will be necessary for other substances, and the associated costs, would be useful.

c. Some of the alternatives identified have a lower cost than the substances proposed to be restricted (e.g. phthalate esters and plasticiser for neoprenes, which are both within the intended scope of the proposed restriction). Please provide information about whether there are any other impacts expected from implementing these lower cost alternatives. Please try to monetise or quantify these impacts to the extent possible.

5. According to the restriction on chromium VI in leather articles (2012)[2], the use of best practice can keep the chromium VI concentration in leather articles placed on the market for the general public below 3 mg/kg. The Dossier Submitter has

[2] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180d737d9

assumed that best practices can achieve a concentration of 1 mg/kg in leather articles. Please confirm if:

a. It is possible to achieve a concentration of 1 mg/kg in leather articles.

b. There are analytical methods which can enforce this limit of 1 mg/kg in the finished articles.

6. The proposal makes reference to EN testing methods. However, it would be good to receive information regarding available analytical methods (CEN developed or otherwise, with a known limit of detection) to achieve these limits.

The final opinions of both Committees are scheduled to be available by June 2020. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the public consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.