ECHA PROPOSES A RESTRICTION ON FORMALDEHYDE RELEASED FROM CONSUMER ARTICLES [1]

Summary

Formaldehyde is a highly reactive, acutely toxic gas and a genotoxic carcinogen. It is predominantely used as a chemical intermediate to manufacture formaldehyde-based resins and other chemicals. Formaldehyde off-gassed from articles produced using formaldehyde-based substances contributes to consumer exposure in indoor environments. Wood-based panels, which use formaldehyde-based resins as bonding agent for wood particles, and articles made from such panels (e.g. furniture) are the major formaldehyde emission sources. The WHO established an indoor air quality guideline for formaldehyde exposure of 0.1 mg/m^3, which is considered protective for the general population. In most cases, formaldehyde concentrations in indoor environments in the EU are below the WHO guideline, though estimations by ECHA suggest this guideline can be exceeded under certain circumstances. ECHA proposes a restriction under REACH to keep formaldehyde concentrations in indoor environments below the WHO guideline. The proposal would limit formaldehyde releases from consumer articles marketed or used in the EU to < 0.124 mg/m^3 (measured in the air of a test chamber). This proposal is considered effective, practicable and proportionate. The benefits of reduced formaldehyde exposure that would result from this measure are expected to be achievable at limited costs to EU society. This is because some industry sectors have already adopted voluntary measures to reduce formaldehyde emissions from articles and only certain categories of articles with high formaldehyde emissions, such as some wood-based panels, are expected to be affected by the proposed restriction.

Pages 5-9 of the Annex XV restriction report give a more detailed summary of the proposal.

The public consultation on this proposed restriction will start on 20/03/2019 and ends on 20/09/2019.

When responding to the public consultation, stakeholders should take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings and time their submissions accordingly (multiple submissions are possible throughout the consultation):

	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 costs of the proposed restriction and hold preliminary discussions on its benefits.

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

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)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus 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.

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, beneifts 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 access to the dossier much earlier than in the past, as it is published two weeks after submission or 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.

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 webform.

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 information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

1. **Information on test methods for determination of formaldehyde emissions from articles:**
    - Do you have information on the use of the chamber test methods EN 717-1 or EN 16516 to measure formaldehyde emissions from articles other than wood-based panels?
    - Do you have information on other test methods used for the determination of formaldehyde emissions from articles?

    Please provide information on method used (e.g. reference to relevant standard), type of tested article, material of which the article is made, sampling method, test conditions, provisions for sampling and testing big articles and complex articles, and testing costs.

2. **Information on formaldehyde emissions from articles other than wood-based panels:**
    - Do you have information on formaldehyde emissions from articles other than wood-based panels used in indoor environments?

    Please provide information on measured emissions with specific reference to article type, source of information (e.g. research study), test method used (e.g. reference to relevant standard), and test conditions (e.g. loading factor, air exchange, temperature, humidity).

3. **Information on formaldehyde concentrations in indoor environments other than buildings:**
    - Do you have information on measured formaldehyde concentrations in indoor environments other than buildings, such as cars, trucks, buses, trains, airplanes, mobile homes, or container homes?

    Please provide information on measured concentrations with specific reference to source of information (e.g. research study), measurement method used

(e.g. reference to relevant standard), and measurement conditions (e.g. air exchange, temperature, humidity).

4. **Information on the impact of the restriction proposal on different industry sectors:**

   The restriction proposal targets all articles for consumer use. How does the proposed restriction affect your business/sector in terms of products placed on the EU market (either imported or manufactured in the EU), compliance costs, and transition period?

5. **Information on availability of alternatives:**

   Please provide information on the availability and suitability of alternatives:

   - to urea formaldehyde (UF) resins used in the production of wood-based panels;
   - to formaldehyde releasing resins/mixtures used in the production of articles other than wood-based panels.

   For each alternative, please indicate the formaldehyde releasing substance(s) replaced and provide information on the identity of the alternative substance(s), including information on possible release of hazardous substances and advantages and disadvantages from use of alternatives. In case the alternative is a different formaldehyde releasing substance, please indicate the reduction in formaldehyde emissions from the use of the alternative.

The final opinions of both Committees are scheduled to be available by March 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.