ECHA PROPOSES A RESTRICTION ON D4, D5 and D6[1]

Summary[2]

The Annex XV report outlines a proposal to restrict the placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance. These substances are manufactured and used in a variety of sectors in the European Economic Area. They are mainly used as intermediates for the production of silicone polymers but are also used as substance on their own or in mixtures that are subsequently used by consumers and professionals. Derogations have been proposed for the placing on the market of D5 and D6 in certain medical devices and for the use of D5 for dry cleaning in certain circumstances. Additional information will be needed before other derogations can be considered. D4, D5 and D6 have been identified as substances of very high concern on the basis of their PBT/vPvB properties.

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

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

[2] An elaborated summary of the proposal is presented on pages 2 to 5 of the Annex XV report.

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 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.

Please note that alongside the Annex XV report and annexes, a supplementary document has been prepared by the Dossier Submitter outlining the potential overlap between the proposed restriction on the use of D4, D5 and D6 and the proposed restriction on intentionally-added microplastics, which was also submitted in January 2019.

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. Cosmetic products: According to the Annex XV report (Annex C), there is no single 'drop-in' or 'one-for-one' alternative substance that could be used to replace D4, D5 or D6 in leave-on cosmetic products or D6 in rinse-off cosmetic products. However, as noted in the report, many cosmetic products within the same product category do not contain D4, D5 or D6. On this basis, the Dossier Submitter has concluded that alternatives are available. Please tell us which ingredients are used in these alternative cosmetic product formulations (differentiated between product groups). In addition, where you have knowledge in substituting D4, D5 or D6 in cosmetic formulations, is your experience different from the assumptions outlined in section 2.5.1?

2. Dry cleaning: According to the Annex XV report, it is proposed that 10 years after the entry in force the use of D5 for dry-cleaning will continue to be permitted only if 'D5 is fully recycled or incinerated, and where there is no release to air or wastewater.' Do you have information on the availability of dry cleaning equipment that would fulfil these criteria either now or in the future? When could these criteria be fulfilled and how much would this cost? What would be the impact of (i) bringing the date forward by five years or (ii) if no derogation for dry cleaning was proposed.

3. Use of D4, D5 and D6 in pharmaceutical products and medical devices: The Annex XV report provides aggregated tonnage data for all types of pharmaceutical products/medical devices. This includes two types of products (scar and wound treatments and stoma care products) for which a derogation is proposed. In order to support the proposed derogation, can you provide information on the tonnage of D4, D5 and D6 placed on the market in scar and wound treatments and stoma care products?

4. Presence of D4, D5 or D6 as residues in silicone polymers used by consumers and professionals: According to the Annex XV report, it is possible that some silicone polymers mixtures, used by consumers and professionals, may unavoidably contain D4, D5 or D6 residues above 0.1% w/w of each substance. Under the proposed restriction, these mixtures would no longer be allowed to be placed on the market after the proposed transitional period ends. This may particularly affect mixtures containing silicone polymers used as sealants in construction or as medical devices (e.g. dental impressions/imprints). However, sufficient detailed information was not available during the preparation of the restriction proposal to allow the Dossier Submitter to conclude on the precise conditions of a derogation that would prevent these unintended impacts. For a derogation to be considered you must provide specific, concrete and detailed information in the public consultation on:

    a) the identity of the mixture (brand name if relevant),

b) the specific function of the mixture, its sector of use (e.g. construction, dentistry), and the quantity of mixtures placed on the market,
c) the residual concentration (%w/w) of D4, D5 or D6 in the mixture,
d) information on why it is not feasible to reduce these concentrations below 0.1% w/w, and
e) analysis to demonstrate and if possible quantify the negative impact of not derogating the use.

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.