FRANCE PROPOSES RESTRICTION ON SUBSTANCES IN SINGLE-USE DIAPERS[1]

Summary

The restriction proposal aims at reducing health risks associated with the wearing of single-use baby diapers by children and infants under the age of three.

Polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and formaldehyde have been detected and/or quantified in single-use baby diapers through analytical tests using urine simulant. Based on the risk assessment performed, the Dossier Submitter concludes that the risk of these substances in single-use baby diapers is currently not adequately controlled.

The proposed restriction sets concentration limits for these substances in single-use diapers intended to be used for children and infants. Re-usable diapers and incontinence diapers as defined in Regulation EU 2017/745 are not covered by the proposed restriction.

The consultation on this proposed restriction will start on 21/12/2020 and ends on 21/06/2021.

When responding to the 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).

	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	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree

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

	final opinion.	the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion 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, benefits and derogations by month four of the 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 pre-published approximately two weeks after submission or more than six weeks in advance of the start of the 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. Please provide, if possible and specifying clearly which substance(s) within the scope of the proposed restriction the information relates to, more detailed information on:
    a. Whether any of the substances in the scope of the restriction are intentionally used in the manufacture of single-use diapers.
    b. Possible sources of contamination by the substances covered by this restriction. Sources/production processes that could be covered according to the Annex XV report are:
        - Raw materials used
        - Oils/glues used
        - Wetness indicator used
        - Pigments used
        - Packaging
        - Temperature control during manufacture
        - Moving to total chlorine-free (TCF) pulp
        - Moving to fluffless diapers (with a core made of superabsorbent polymer)
        - Indoor air contamination
        - Transport/storage
    c. Which efforts (e.g. change of mechanical processes, technical improvements, substitution of raw materials, cleaning of raw materials) have already been undertaken by industry lately to reduce the contamination in baby diapers, for example through voluntary actions and good practice?
    d. Ways/additional effort to further reduce or prevent this contamination and the (dis)advantages/costs associated with these.

2. Please provide information on how industry would respond if the proposed restriction enters into force and what the associated impacts would be (e.g. costs to industry players, impacts on consumers). Please be as specific as possible and provide the break-down for any costs provided.

3. The Annex XV dossier makes several assumptions on costs and proportionality. Please provide specific and detailed feedback on the following:

    a. The Annex XV report suggests that contaminants may be reduced by moving from elemental chlorine free (ECT) to total chlorine-free (TCF) pulp. Do you have any further information on how many companies and sites would need to move to TCF in the EEA in order to comply with the proposed restriction and on the associated costs presented in the report (increased operating cost of

€200 000 - 400 000 per year per company and additional investment cost of €1 million per site)?

b. The Annex XV report suggests that one way of reducing the contaminants could be further decontamination of indoor air with a broad cost estimate "in the millions euros per production plant". Please provide more information on whether this measure would be likely to help industry to comply with the restriction and, if so, provide more specific information on the associated costs, including how many production plants that would incur such costs.
c. The Annex XV report outlined possible testing costs for industry to test raw materials and final products but states that these are uncertain. Please provide specific and detailed information about:
    a. the current testing practices and associated costs for the single-use diapers sector.
    b. the expected incremental testing costs associated with the proposed restriction (i.e. the additional costs as compared with the current ones).
    c. how many companies would incur incremental testing costs as a result of the proposed restriction.
d. The Annex XV report states that the diaper market is expected to grow or at least stay as it is now, but birth rates are slowly slowing down. Would you agree and why (not)?
e. In relation to impacts on consumers:
    a. Would there be consumer surplus losses (i.e. a loss of utility for consumers buying the products) related to the restriction? Do you have any studies or other information on how valuable consumers consider wetness indicators, pigments or other functional additives in diapers that may need to be removed to comply with the proposed restriction?
    b. The Annex XV report assumes that the diaper market is highly competitive on price and increased costs in production is not likely to be passed on to consumers. Would you agree and why (not)? If you think the restriction would result in a price increase for diapers, please specify how much and justify such an increase based on the information you have provided about the costs incurred by industry.
f. The Annex XV report presents two restriction options:
    a. Restriction option 1 (the proposed restriction, RO1): Limiting concentrations of formaldehyde, the sum of detected or quantified 17 PAHs, the sum of quantified PCDD/Fs and PCBs, the sum of quantified PCBs.
    b. Restriction option 2 (RO2): Limiting concentrations of all the substances and sum of substances listed in RO1 and all the congeners of the PAHs, PCDD/Fs and DL-PCBs.

    Please provide information about how the costs and benefits of RO2 would compare with those of RO1.

4. Are you aware of any human or animal biomonitoring data regarding the exposure to hazardous substances via baby diapers? Are you aware of any human or animal data on adverse health effects following exposure to the substances in the scope via baby diapers (excluding skin allergies or irritation)?

5. Are you aware of any analytical methods which can be used to measure the substances, at the levels proposed in this restriction, in diapers or in other

comparable products/compositions/textiles? If not, how long would it take to develop a (i) validated and (ii) standardised analytical method with the required LoQ (limit of quantification)?

6. Can you provide comments on the approach used for the risk assessment? This would be particularly relevant for:
    a) the values used for the parameters for risk assessment, as well as the studies that would support the possible choice of other values.
    b) the effectiveness, appropriateness and reliability of the extraction procedure, the urine simulant method, etc. to extract chemicals from diapers

The final opinions of both Committees are scheduled to be available by December 2021. 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 consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.