**General comments and answers to specific information requests**

**Specific information requests:**

1. In its draft opinion, SEAC concluded that, for the time being, it has not been demonstrated that the proposed restriction would be proportionate. In section 3.3.3.4 of the opinion, SEAC discusses possible scenarios to underpin the conclusion on proportionality, as several crucial aspects are uncertain. Do stakeholders have any additional information on:
2. Whether the substances in scope are currently detected in single-use baby diapers and, if so, what may be the sources of contamination?
3. What additional measures exist to reduce the potential contamination, how effective they are and what are their associated costs?
4. Whether the substances in scope may stem from background contamination?

Please note that the information submitted in the consultation on the Annex XV report has already been considered by SEAC and should not be re-submitted in this consultation.

1. The Committee would like to have stakeholders’ view on the feasibility/appropriateness of the 24-month transition period proposed by the Dossier Submitter. In case of disagreement, please provide data to justify it.

Please note that the information submitted in the consultation on the Annex XV report has already been considered by SEAC and should not be re-submitted in this consultation.

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| Ref. | Date/Type/Org. | Comments |
| 975 | Date/Time:  2021/09/15 15:45  Type:  BehalfOfAnOrganisation  Org. type:  International organisation  Org. name:  Verband TEGEWA e.V.  Org. country:  Germany  Attachment: | General Comments:  Verband TEGEWA e.V. represents chemical suppliers manufacturing and providing spin finishes, i.e. process aids to serve fiber and nonwoven production. Therefore, TEGEWA focuses its comments on spin finish aspects only. To demonstrate the expected economical impact of this restriction proposal on producers of spin finishes, a test cost estimation - based on current best knowledge and due to necessary testing of spin finishes based on the proposed limit values of the original restriction proposal - is given in the enclosed attachment. Information on the specific information requests were already submitted during the first consultation on the Annex XV report. |
| SEAC Rapporteurs response:  Thank you for your comments. Where relevant they have been taken into account in the opinion. |
| 978 | Date/Time:  2021/10/14 16:03  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  EDANA  Org. country:  Belgium  Attachment: | General Comments:  Please refer to section IV Non-confidential attachment |
| Specific information 1:  Please refer to section IV Non-confidential attachment |
| Specific information 2:  Please refer to section IV Non-confidential attachment |
| SEAC Rapporteurs response:  Thank you for your comments. Where relevant, e.g. in relation to transition period and background contamination, these have been taken into account. |
| 979 | Date/Time:  2021/11/05 12:20  Type:  Individual  Country:  Belgium  Attachment: | General Comments:  Brussels, November 5, 2021  Dear Madam, Dear Sir,  I am writing in reference to the comment n° 3172 that I sent during the previous public consultation. I inform you that the manuscript I sent with this comment has been peer-reviewed, accepted for publication and now is in press in the International Journal of Environmental Research and Public Health (Impact factor, 3.39, open-access).  The manuscript is entitled "Dermal Exposure to Hazardous Chemicals in Baby Diapers: A Re-Evaluation of the Quantitative Health Risk Assessment Conducted by The French Agency for Food, Environmental and Occupational Health and Safety (ANSES)" by Alfred Bernard.  Please find attached the paper which is in press with the certificate of acceptance (inserted at the end).  Best regards,  Alfred Bernard  Emeritus Professor at the Catholic University of Louvain Honorary Research Director of the National Fund for Scientific Research (Belgium) |
| SEAC Rapporteurs response:  Thank you for your comments. These are relevant to the discussion in the SEAC opinion on the sensitivity of the analytical methods. |
| 980 | Date/Time:  2021/11/12 12:43  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  GROUP'HYGIENE  Org. country:  France | General Comments:  • Group’hygiène and its members would like to recall that traces of impurities not intentionnally added that could be found in the products do not in any way call into question the safety of baby diapers. Imposing manufacturers to test their products against a list of substances whose thresholds have been defined using extreme assumptions, overestimating actual daily exposure and then even allow only 10% of that calculated limit, does not improve the safety of babies. With this, the dossier submitter departs from the quantitative assessment of health risks associated with chemicals detected or quantified in single-use baby diapers. • Imposing diaper industries to identify alternative solutions for substances over which it is not the source of contamination and over which it has no control, would entail costs that are out of proportion to the objective sought and have no effect notable on security . • On the other hand, setting too high a threshold or restriction could lead to situations of shortage in the market for essential products of everyday life, when they are safe for the health of babies. • In fact, the implementation of the possible restriction would lead to a massive increase in the cost of raw material analyzes with negligible benefit for safety given the thresholds are based on inaccurate assumptions. These costs concern not only the suppliers but also their available subcontractors, quantities of materials as well as quantities of diapers. This also means subsequent increases in sales prices for the consumers. • The threshold limits by the Dossier Submitter are not justified as having any beneficial effect on health. A reasonable examination of the requested levels against the prevailing environmental background levels would confirm that this is an unreasonable and impractical proposition. The industry can maintain high quality standards and commit to reducing as much as possible the substances unintentionally present in diapers is a priority, well demonstrated by the Product Stewardship program from Edana. |
| Specific information 2:  In 24 months or at another time, it is difficult to see how manufacturers could comply with so unrealistic constraints that they reach the limits of test methodologies and raise the question of test reproducibility. |
| SEAC Rapporteurs response:  Thank you for your comments. Where relevant these have been taken into account in the opinion (e.g. in relation to transition period). |
| **981** | **Date/Time:**  2021/11/12 17:08  **Type:**  BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  European Environmental Bureau, ClientEarth, HEAL  **Org. country:**  Belgium  **Attachment:** | **General Comments:**  The EEB, HEAL and ClientEarth welcome the opportunity to comment on the draft opinion of SEAC related to the proposal to restrict a number of substances of concern present in single-use baby diapers.  As a preliminary observation, we regret that the joint comments that we submitted in the context of the development of the RAC opinion - the latter is referred to a number of times in the SEAC opinion - have not been considered properly. SEAC should develop its own opinion independently of RAC’s opinion, but since it mentions the latter as an important factor in the outcome of its own opinion, we feel the necessity to stress this important shortcoming. In particular, our previous comments have highlighted in detail how the vulnerability of the targeted public of this restriction should be an important guiding aspect in its development and how it justifies a precautionary approach in the use of existing data related to exposure as well as uncertainties.  We are concerned to see SEAC giving its opinion on RAC issues such as the routes of exposure, the reliability of the test data, or the dose-response relationships.  We would like to comment on the following issues that we consider of utmost importance: - SEAC misrepresents RAC’s opinion regarding the appropriateness of the restriction; - SEAC gives excessive weight to industry claims and insufficient weight to public authorities data considering the presence of the chemicals - SEAC fails to fulfil its mandate under REACH, which requires it to conclude on socio-economic impacts; - SEAC fails to consider the benefits of restricting these hazardous chemicals in baby nappies and rather mostly accounts for the potential costs for industry players.  Please see our comments in the attached document. |
| **Specific information 1:**  See attached document |
| **SEAC Rapporteurs response:**  Thank you for your comments. We want to take this opportunity to address some of your concerns.   1. “*SEAC misrepresents RAC’s opinion regarding the appropriateness of the restriction*”   We have reworded section 1.2 to better reflect the changes that were made to the RAC opinion late during opinion development.  Section 1.2 now reads as follows:  “*The opinion of RAC considered that the proposed restriction on substances in single-use baby diapers is not justified because the risk could not be demonstrated for formaldehyde and PCDD/Fs/DL-PCBs and could not be characterised for PAHs and NDL-PCBs. SEAC concluded that it has not been demonstrated that the proposed restriction would be proportionate. Therefore, there is not a sufficient justification for a restriction and SEAC has no basis to support the proposed restriction as demonstrated in the justification supporting this opinion.*”  It is important to note that the RAC and SEAC opinions are not delivered to the Commission as separate documents. Furthermore, RAC’s opinion is highly relevant to SEAC’s analysis.  We would also like to note that, in our view, RAC’s conclusion that it was not able to rule out a risk is not contradictory to a conclusion that the Dossier Submitter did not demonstrate that the proposed restriction proposal is an appropriate EU-wide measure. According to Article 69 of REACH a restriction proposal should be based on a risk to human health or the environment that is not adequately controlled and needs to be addressed, not on the possibility of there being one.   1. “*SEAC gives excessive weight to industry claims and insufficient weight to public authorities*”   SEAC only takes into account comments that are relevant and sufficiently justified by robust data. This has also been the case here.  More specifically you mention the issue of background contamination and that the available analytical methods would prevent some substances from being detected in baby diapers above the proposed migration limits. It is noteworthy that these issues were also acknowledged by the Dossier Submitter in the Annex XV report as well as in the FORUM advice, which forms the basis for the section on enforceability in SEAC’s opinion (which was written in conjunction with RAC). Furthermore, a comment was received during the consultation on the SEAC draft opinion (comment #979) which confirms the problems related to the sensitivity of the analytical methods. As such SEAC rapporteurs took into account all relevant and robust information irrespective of its origin (i.e public or private actors).    It is suggested that SEAC unequivocally states that “*the substances in scope stem from unavoidable background contamination*”. This constitutes a clear misrepresentation of the nuanced discussion SEAC documented in the opinion. We would like to draw your attention to the fact that section 3.3.3.4 of the SEAC opinion on “Overall proportionality” presents a detailed discussion of different scenarios developed in response to the uncertainties related to the migration limits and their effect on proportionality. This demonstrates that SEAC rapporteurs do not assume that “*the substances in scope stem from unavoidable background contamination*”.   1. “*SEAC must conclude on socio-economic impacts independently from RAC*”   SEAC has concluded that it has not been demonstrated that the proposed restriction would be proportionate. This is a conclusion in and of itself and takes into account more than just the RAC opinion. Furthermore, given the many uncertainties and information gaps, SEAC does not consider that it would be appropriate to make a “firmer” conclusion that the restriction would be either proportionate or not proportionate.  It is important to note that RAC’s opinion has to inform SEAC’s analysis, because the benefits and appropriateness of the proposed restriction are directly related to the risk assessment. SEAC rapporteurs noted RAC’s opinion on risk and took it into account for SEAC’s opinion. “Risk*-related arguments*” were not an element of the SEAC opinion.   1. “*There are benefits to the restriction - which SEAC must identify and assess*”   It is important to note that “*based on SEAC’s assessment, RO1 would have been the most appropriate of the two ROs considered, if the Dossier Submitter had demonstrated a risk related to single-use baby diapers*”.  This is completely different from the statement in your comment (“*SEAC does not exclude that the restriction could be a well-suited option to deal with the presence of harmful substances in nappies*”).  It is not possible to respond to your statement “*that the SEAC opinion appears to put more emphasis on potential costs rather than on benefits*” since no substantiation of this view has been provided for the SEAC rapporteurs to respond to.  The SEAC rapporteurs would like to note that your representation of the uncertainties related to costs is incorrect. The fundamental issue is that the Dossier Submitter did not clearly show what the sources of contamination for the substances in scope are, what industry would need to do to eliminate or reduce them and which costs would be associated with this. This is the basis for the uncertainty related to the cost assessment and is much more fundamental to the discussion than the uncertainty on the costs themselves (which is an additional complication). In other words, SEAC cannot conclude that the restriction “*would in fact have little impact on the relevant sectors*” since it is not known what the actual impacts would be.  This fundamental issue is also at the heart of the benefits discussion. If SEAC does not understand what the sources of contamination for the substances in scope are and what industry would need to do to eliminate or reduce them, then it is also not possible to understand what the benefits of the proposed restriction would be. It is also worthwhile to reiterate that RAC has concluded that uncertainties in the restriction proposal’s risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. It therefore also follows that the benefits of this restriction are not demonstrated. The benefits you mention in your comment are speculative because it is assumed that the sources of contamination and the actions needed to mitigate them are known, which is, as noted above, not the case. Since the benefits are unknown, they can also not be assessed, quantitively or qualitatively. |