Helsinki, September 2021

Scientific opinions on the restriction proposal for substances in single-use baby diapers – **questions and answers**

1. What are the roles of France, the scientific committees and ECHA secretariat in the restriction?

France is the *dossier submitter* and prepared the restriction proposal, also called an Annex XV restriction report, which it submitted to ECHA in October 2020.

The role of the committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) is to independently *evaluate the strengths and weaknesses* of the proposed restriction to underpin the decision of the European Commission and the Member States. RAC looks at the risks for the environment and to people's health, whereas SEAC evaluates the benefits of the proposal to people's health and the environment, and the associated costs and other socio-economic impacts.

RAC and SEAC form their own opinions based on the information contained in the restriction proposal and the comments received during the consultations.

The ECHA secretariat's role during opinion making is to *manage the stakeholder consultations and the committee meetings*. ECHA also ensures that the committees' evaluation is comprehensive, consistent and relevant to the European Commission and the EU Member States, who take the decision on the restriction.

2. What are the key points of the scientific opinion on the Committee for Risk Assessment (RAC)?

RAC considers that the proposed restriction is not justified (i.e. not necessary) because, based on the information and risk assessment available, the risks for all of the substances included in the proposed restriction were not demonstrated.

The substances proposed to be restricted are:

- formaldehyde;
- polychlorinated dibenzo-p-dioxins (PCDD);
- polychlorinated dibenzofurans (PCDFs);
- dioxin-like polychlorobiphenyls (DL-PCBs);
- polycyclic aromatic hydrocarbons (PAHs); and
- non-dioxin-like polychlorobiphenyls (NDL-PCBs).

RAC's conclusion is the consequence of the identification of various uncertainties and shortcomings in the risk assessment used by the dossier submitter to justify the proposal. The most prominent areas of uncertainty are the following:

- Shortcomings in the quality and reporting of the analytical data used for the assessment significantly affecting its reliability.
- Concerns that the assumptions used in the exposure assessment resulted in a

significant overestimate of exposure, when compared to a realistic worst-case scenario of use.

In general, RAC supported the use of a urine simulant extraction method for detecting the chemicals and their levels in diapers but considered that it could benefit from further development and validation.

According to RAC, the following elements of an assessment would be necessary to refine to address the identified uncertainties:

- Detailed information about sample preparation, analysed data and blank samples;
- Justification for the choice of rewet factor;
- Assessment of direct exposure;
- Further development of the urine simulant extraction method; and
- Justification for the use of an allocation factor.

RAC notes that until the uncertainties concerning the restriction proposal are resolved, the existing voluntary action by industry (the EDANA Stewardship Programme for Absorbent Hygiene Products) could help to further reduce the concentration of these chemicals. However, RAC does not see this programme as a substitute for a restriction under REACH, should such a risk be demonstrated in the future.

The RAC opinion will be available on ECHA's website shortly.

3. What are the key points of the *draft* opinion of the Committee for Socio-Economic Analysis (SEAC)?

SEAC considers in its *draft* opinion that it has not been demonstrated that the proposed restriction would be proportionate based on the following:

- RAC conclusions on risk, which lead to a finding by SEAC that it is not appropriate to take action at EU-level;
- Uncertainty regarding whether the substances in scope are detected in single-use baby diapers above the proposed migration levels;
- Uncertainty about the sources of any of the substances in scope that may be detected in the diapers. When it is not known where the substances come from, it is unclear what the diaper manufacturers and their supply chains would need to do to eliminate or reduce them;
- Uncertainty on whether industry would be able to comply with the proposed restriction;
- Difficulty to reach a conclusion on the associated costs considering the uncertainties related to what industry would need to do, if anything, to comply with the restriction; and
- The fact that there are no epidemiological studies or other quantification of adverse effects for children wearing single-use diapers, and taking into consideration RAC's conclusion on risk, SEAC considers that the benefits of the proposed restriction are not clearly demonstrated.

The *draft* opinion of SEAC will be available on ECHA's website shortly. A 60-day consultation on the opinion will start on 15 September 2021. The Committee is expected to adopt its opinion in December 2021.

4. How are stakeholders, e.g. NGOs and companies, involved in the restriction process? What about transparency?

Restriction proposals undergo two wide stakeholder consultations to which anyone can contribute. The consultation on the initial proposal (Annex XV report) is six months long. During the consultation, which ran from December 2020 to June 2021, 30 comments from different stakeholder groups were received. The consultation comments are available on ECHA's website (file RCOM).

ECHA's scientific committees are obligated to take the comments received into account when assessing the proposal and developing their opinions. There is always a second 60-day long consultation on the draft opinion of SEAC, which allows stakeholders to provide additional information on the impacts of the proposal. For the proposed restriction on substances in diapers, this consultation will take place from 15 September 2021 until 14 November 2021.

All non-confidential comments received during the consultations are published on ECHA's website. Regular and occasional stakeholders observe the meetings of RAC and SEAC to ensure the transparency of opinion making.

More about the committees' procedures: RAC | SEAC

5. How is it ensured that the two committees give independent opinions?

The members of the two committees are nominated by EU Member States and appointed by ECHA's Management Board in their personal capacity. The members are not allowed to be given instructions by their nominating or employing Member State and must also declare any conflicts of interest on the proposal. On the other hand, the Member States are obliged to support the work of their nominees.

In addition, it is the role of the chairs to ensure the evaluation is independent and consistent with other opinions made by the committees. ECHA supports the committee members appointed as rapporteurs.

Throughout the evaluation of the proposal, the scientific committees follow an evidence-based scientific approach.

6. How is the restriction proposal taken forward?

ECHA will send the proposal and the opinions of the committees for Risk Assessment and for Socio-economic Analysis to the European Commission by early 2022.

It is then up to the Commission to decide a way forward for the proposal together with the EU Member States in the Commission's REACH Committee.

European Commission's role in the REACH Regulation