



Contribution to SEAC draft Opinion on single-use baby diapers restriction

European Environmental Bureau (EEB)
Health and Environment Alliance (HEAL)
ClientEarth

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 opinion¹, 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.**²

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.³

¹ See SEAC draft opinion, for instance:

"The opinion of RAC did not consider that the proposed restriction is appropriate because the restriction under REACH is not considered to be the most appropriate EU wide measure to address the identified risks. **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.**" p.3

"RAC concluded that the 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. **Therefore, SEAC does not find it appropriate to take action on a Union-wide basis.**" p. 5

² See previous EEB-ClientEarth-HEAL comments regarding RAC draft opinion, 21st June 2021, https://www.env-health.org/wp-content/uploads/2021/06/2021.06.21.NGO_comments_SU_Diapers_RAC.pdf

³ SEAC draft opinion, "The human health impact assessment has not been quantified and monetized due to uncertainties (no prevalence/incidence data, all DNEL/DMEL used in the risk assessment were derived based on oral route studies, dose-response relationships available for some substances in the scope only built on animal studies, etc.)", p. 55

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.

1) SEAC misrepresents RAC's conclusion on the appropriateness of the restriction

SEAC states⁴ that "the opinion of RAC did not consider that the proposed restriction is appropriate because the restriction under REACH is **not considered to be the most appropriate EU wide measure to address the identified risks**".⁴

This statement implies that the risk is known but a restriction is not adapted to address it. This is not what RAC concluded. It actually recognised that "Restriction under REACH, Article 69, would be the most appropriate risk management option for substances in scope of the Annex XV dossier which pose a risk for babies and children under the age of three." However RAC considered that because of uncertainties on the risk, "**it has not been demonstrated** that a restriction is the most appropriate measure".

The final decision will therefore have to decide how to handle this uncertainty. SEAC needs to support the Commission by being as precise as possible, and that involves to take into account the fact that **RAC acknowledges that a risk cannot be ruled out for some of the substances⁵ and that all the substances under the scope "should be kept to a level as low as possible/feasible, and preferably not present at all"**.⁶

Besides the harmful properties of the substances at stake, RAC acknowledged that no safe threshold may be derived for several of these chemicals. Combined with the high vulnerability of the part of the population targeted by the restriction proposal and the potential for continuous exposure, the result is serious potential risk. The Commission will have to decide whether to take a precautionary action despite the remaining uncertainties.

We recommend SEAC to reflect correctly the conclusions from RAC on the appropriateness of the restriction in its opinion, including RAC's opinion that a risk cannot be ruled out for some of the substances and that all the substances under the scope should be kept to a level as low as possible/feasible, and preferably not present at all.

2) SEAC gives excessive weight to industry claims and insufficient weight to public authorities

⁴ SEAC draft opinion, p. 3

⁵ RAC Opinion p. 9

⁶ RAC Opinion p. 10

The SEAC opinion highlights as a main uncertainty that the substances under the scope may not be detected in the nappies above the proposed migration limits and that they may stem from unavoidable background contamination. The issue is that when drawing this conclusion, SEAC gives more weight to industries' comments than evidence provided by the dossier submitter and by the EU BAT docs.

Against this conclusion, it is important to mention that:

First, **the restriction in discussion was proposed following product controls carried out by the French national authorities.** The data stemming from these controls surely have their limitations due to their very nature, and we acknowledge that this presents challenges for risk and socio-economic assessments. Nonetheless, the tests presented by the DS were performed by the [Joint Laboratory Service \(SCL\)](#), designated as the French national reference laboratory (NRL) and member of the Group of European Customs Laboratories, EU Taxation and Customs Union (DG TAXUD) and reference laboratories for official checks on food and non-food products. **SCL is accredited by ISO-certified quality system (ISO IC 17025) and by COFRAC-certified analyses.** The DS provided the complete test results including blanks for all chemicals except for dioxins. It is important here to stress that because the tests were performed by an accredited laboratory operating for the national control authorities, the French authorities could not ignore the results showing contamination of diapers by harmful substances and therefore, complying with their duty, they decided to take action to remedy the situation - hence the restriction proposal.

Second, **additional tests performed by other organisations have shown the presence in baby nappies of the substances covered by the restriction proposal at levels above the thresholds proposed by the dossier submitter.** Some of the test results backing the presence of high levels of these chemicals have been submitted during the public consultation by the Swiss Federal Food Safety and Veterinary Office (FSVO) and the Fédération Romande des Consommateurs (FRC). This consumer organisation tested 21 single-use diapers, detecting dioxins and PAH in several samples. PAH (pyrene) was present in levels ranging from 200 to 2430 microg/kg, ranges that are similar to the results from the tests performed by ANSES. Even the sectoral association EDANA, recognises that [these toxic chemicals may be present in the nappies](#) and has launched a voluntary agreement to reduce the concentration of a wide number of substances in the nappies marketed by their members.

Third, **even the information used as the basis of SEAC's opinion - which was provided by industry stakeholders - suggests that dioxins are present in nappies.** It is based on a study by De Vitto and Schechter, 2002 and a literature review by Procter and Gamble (Axegard, 2019). De Vitto and Schechter analysed dioxins in 4 samples of baby nappies marketed in San Francisco, USA. Although the methodology used to detect the dioxins is different from the methodology used by the DS, the US tests showed the presence of dioxins in all four samples [1.6–3.0 pg TEQ/g diaper]. The paper from Procter and Gamble also recognises bleaching of pulp with chlorinated chemicals as a source of dioxins - as do the EU BREF on paper (referred by the Dossier Submitter) and EDANA in its comments to the public consultation (comment #3165).

Modern plants using BAT may significantly reduce the formation of dioxins. This is the case for most European mills, but not for Northern American bleached kraft mills, which actually produce and export 85% of the pulp used in Europe to manufacture nappies, tampons, hygienic pads and other articles. Therefore, we concur with the DS regarding the hypothesis that the source of the dioxins and furans found in nappies are the raw material (low quality ECF pulp) and the production process. A more in depth explanation is provided in the **Annex** to our comments.

Furthermore, **the theory of background contamination as the main source of the dioxins raised by the industry stakeholders is a speculation** based on the similar profile of the dioxins present in most of the 4 samples of the study by De Vitto and the review by Procter and Gamble.

The only way to determine if PCDD/Fs are present from background contamination is to make a full congener analysis and to compare it to known sources and processes as well as to laboratory blanks and unbleached reference samples - as pointed by the Procter and Gamble paper (Axegård, 2019). However, industry stakeholders have not provided such evidence. None of these papers refer to background pollution as the source of the other chemicals under the scope of the restriction (PAH, formaldehyde, PCB). Since several analyses from other laboratories have found dioxins in diapers and tampons, it is most likely that the origin of these dioxins is the actual pulp, rather than a contamination from the Joint Laboratory Services.

Therefore, SEAC's statement that the substances in scope stem from unavoidable background contamination is based on speculations from the industry stakeholders that will be most affected by the restriction. It ignores the evidence provided by the dossier submitter, including the EU BREF on paper, and by other stakeholders during the public consultation.

We recommend SEAC to reassess the evidence provided by the DS, EU authorities, consumer organisations and industry. At the very least, SEAC must justify why it decided to give more weight to industry data rather than public data.

3) SEAC must conclude on socio-economic impacts independently from RAC

According to SEAC, it has not been demonstrated that the proposed restriction would be proportionate, due to the uncertainties raised by RAC in the context of the risk-assessment.⁷

Two elements are striking here:

→ The fact that SEAC refuses to conclude that the restriction is proportionate because RAC does not support the proposal. **REACH does not make the SEAC assessment dependent upon the results of RAC opinion.** The two Committees have distinct roles: one assesses the risk (RAC) while the other looks at socio-economic impacts and the availability of alternatives (SEAC). Art. 71 of REACH makes explicit that SEAC is required to provide an opinion "on the restriction and on the related socio-economic impact". What SEAC is required to do is to review the socio-economic assessment made by the public authorities, taking into

⁷ SEAC draft opinion, p. 45. See also p. 15

account other available information and uncertainties - even when RAC concluded that uncertainties remain on the risk. It is in fact for the Commission to assess whether or not the restriction is the most proportionate option, looking at both evidence on the risk (RAC opinion) and impacts (SEAC opinion). The importance of uncertainties on the overall proportionality of the restriction is therefore for the Commission to assess, which is what SEAC must highlight those uncertainties as transparently as possible.

→ **SEAC recognises that the restriction could be an adequate option**, had RAC concluded differently on the risk and that is what SEAC is expected to report to the Commission. It is outside of SEAC's mandate to investigate risk-related arguments, or to comment on the RAC opinion - as already underlined above.

4) There are benefits to the restriction - which SEAC must identify and assess

SEAC mentions the presence of various uncertainties concerning the costs and benefits, which is one of the main reasons invoked to justify its reluctance to support the restriction (p. 19). However **SEAC does not exclude that the restriction could be a well-suited option** to deal with the presence of harmful substances in nappies.

First, in a context of uncertainties about existing data regarding both costs and benefits, we are struck by the fact that the **SEAC opinion appears to put more emphasis on potential costs rather than on benefits**. This is especially striking considering that the restriction at play is about the presence of known harmful substances in items worn 24/7 over long periods that can go from several months to several years by a very vulnerable group of the population.

Second, the opinion shows that **there are many uncertainties with regard to possible costs**. This means that very little information was made available on the real impacts that might be incurred, e.g. on the pulp industry, as a result of the restriction. Such a lack of information should be interpreted as an indication that the proposed restriction would in fact have little impact on the relevant sectors - in line with the ECHA guidance on this issue.⁸ Moreover, some impacts could be mitigated thanks to ANSES' proposal to include a transition period of 24 months, which would ensure time for the market to adapt.⁹ Finally, when it comes to the different quantification attempts of industry costs as a result of the restriction option 1, it is also important to put them back in context. The SEAC opinion itself refers to the revenues of the diapers market in Europe - an estimated 7,443 billion Euros a year¹⁰ - which actually shows that the estimate range for the grand total associated to the restriction - between 6 to 100 million Euros per year with a central estimate of a yearly 50 million Euros¹¹ - appears far from disproportionate, especially in the context of the restriction objective to protect a very vulnerable part of the population.

Third, while SEAC reports uncertainties on the benefits of having a restriction, it is also clear from the opinion that **industry has already mobilised to reduce the presence of the**

⁸ f816a6f6-34bd-4df4-8249-5f1d26dedf21 (europa.eu) p. 20

⁹ Annex XV Dossier, p. 22

¹⁰ SEAC draft opinion, p. 34

¹¹ SEAC draft opinion, p. 36

substances in baby diapers.¹² As indicated by ANSES in the restriction dossier¹³, some companies have already started implementing preventive measures to e.g. reduce the concentration of the impurities within the scope of the restriction.¹⁴ The EDANA voluntary stewardship programme is another important signal to the market that not only is it technically possible to market diapers with a lower content of toxic chemicals, but it is also economically feasible. This is a crucial argument in favour of the proportionality of the restriction - and SEAC cannot ignore it.

Regarding this aspect of the discussion, we are surprised to notice that the SEAC opinion refers in numerous places to the comments filed by one single industry association, EDANA, in the RCOM process when it comes to questioning the restriction proposal (referred to as association #3165), without properly reflecting that the dossier submitter has had numerous exchanges with several industry actors in the context of its proposal development. While we acknowledge that sectoral industry associations should share their expertise in those processes, it is important that all market perspectives are properly reflected. This is particularly important because the exchanges held between the dossier submitter and industry actors during the development of the dossier seem to point to possible measures to reduce contamination levels in diapers¹⁵ (which is also in line with the latest findings of the French control authorities that we have already referenced earlier in these comments).

Fourth, **there are actual benefits to the restriction that SEAC must account for.** Additionally to reducing the exposure of babies to the most toxic chemicals known so far (dioxins, furans, PCB) as reflected by the Annex XIV dossier, **benefits include inter alia:**

- Reducing the exposure of workers in factories,
- Reducing emissions to the environment.
- Reducing the exposure of millions of girls and women to the toxic chemicals under the scope, which are also present in tampons and hygienic pads, as all these articles are made of the same pulp,
- Reducing the exposure of elderly and and vulnerable population using incontinence pads, which are made with the same pulp as nappies,

Fifth, **SEAC may not hide behind the difficulty to quantify benefits because these can be assessed qualitatively.**¹⁶ The SEAC opinion states indeed that the Committee was not able to conclude on the benefits based on the lack of epidemiological studies or other forms of quantification of adverse effects associated with infants wearing single-use diapers. This is a flawed approach because the mere presence of these chemicals in diapers contributes to children's chronic and long-term exposure and therefore contributes to a real risk, albeit hard to quantify. Moreover, it is clear from ECHA guidance that both quantitative and qualitative

¹² SEAC draft opinion, p. 19

¹³ Annex XV Dossier, p. 20

¹⁴ Ministère de l'Economie et des Finances, [Substances chimiques dans les couches pour bébés : la dernière enquête de la DGCCRF confirme l'amélioration de la qualité des produits](#), 23 February 2021

¹⁵ See for instance SEAC draft opinion, "From the publication of ANSES 2019 and French RMOA reports, companies on the single-use diapers market state that they have already started to implement technical and substitution measures in order to reduce/remove contaminants in their products.", p. 55

¹⁶ SEAC draft opinion, p. 5

approaches may be used by SEAC in order to assess the potential impacts of a restriction.¹⁷ In fact, ECHA considers that not attempting to qualitatively assess impacts that cannot be quantified would seriously decrease the quality and credibility of a socio-economic analysis.¹⁸

To conclude we would like to remind SEAC that the mere presence of uncertainties is not sufficient to question the overall proportionality of a restriction.¹⁹ Scientific excellence requires SEAC to present results that are thoroughly justified, logical, and based on verifiable data. To do so, a supported analysis of the nature and impact of uncertainties must be done. That is then for the Commission to make the final proportionality assessment.

ANNEX

Generation of dioxins during pulp production

ECF (Elemental Chlorine Free) is mostly used to bleach wood pulp today. Best Available Technology (BAT) document stipulates that only TCF and ECF (below AOX 0,20 kg/ADt) is allowed (Suhr et al., 2015).

Most modern pulp mills produce chlorine dioxide at the pulp mill via the chemical reduction of sodium chlorate to chlorine dioxide. There are several commercially available processes for this. Elemental chlorine can be formed as an impurity in the chlorine dioxide generation system depending on which process is used. Therefore, a careful selection of the chlorine dioxide generation method will decrease the formation of elemental chlorine impurities and the formation of dioxin (PCDD/Fs).

Earlier most of the reduction of chlorate to chlorine dioxide was carried out with hydrogen chloride (HCl). The HCl-based method results in a significant formation of elemental chlorine, and risk of dioxin formation, in the chlorine dioxide. The HCl method is therefore not used by modern kraft pulp mills producing ECF-bleached pulp.

EU's 2015 Best Available Technology (BAT) document says that “the only processes that can provide chlorine dioxide without formation of elemental chlorine are methanol-based and hydrogen peroxide-based SVP-and R-processes and the sulfur dioxide-based Mathieson process” (Suhr et al., 2015).

Today, chlorine dioxide in the vast majority of bleached kraft pulp mills is produced using hydrogen peroxide or methanol as a reductant resulting in levels of elemental chlorine in the chlorine dioxide at less than 0.3% (Axegård, 2019). This 0.3% means that you normally end up with an AOX below 0.2 kg/ADt and within the BAT range 0 - 0.2. However, it is possible to exceed this limit if you have a very high kappa number into the bleaching plant. But in modern EU mills the risk is minimal.

¹⁷ Guidance on SEA in restriction, p. 41

¹⁸ Guidance on SEA in restriction, p. 46

¹⁹ Guidance on SEA in restriction, p. 46

This means that chlorine dioxide still can be contaminated with elemental chlorine if the process is not the most modern.

EU demand of fluff pulp was 1,6 million tonnes in 2019²⁰. The two largest fluff pulp producers in the EU are STORAENSO and UPM. Together they have a fluff pulp capacity of 500 000 tonnes/y, being able to support around 30% of EU hygiene products with fluff pulp. Both also produce TCF fluff pulp.

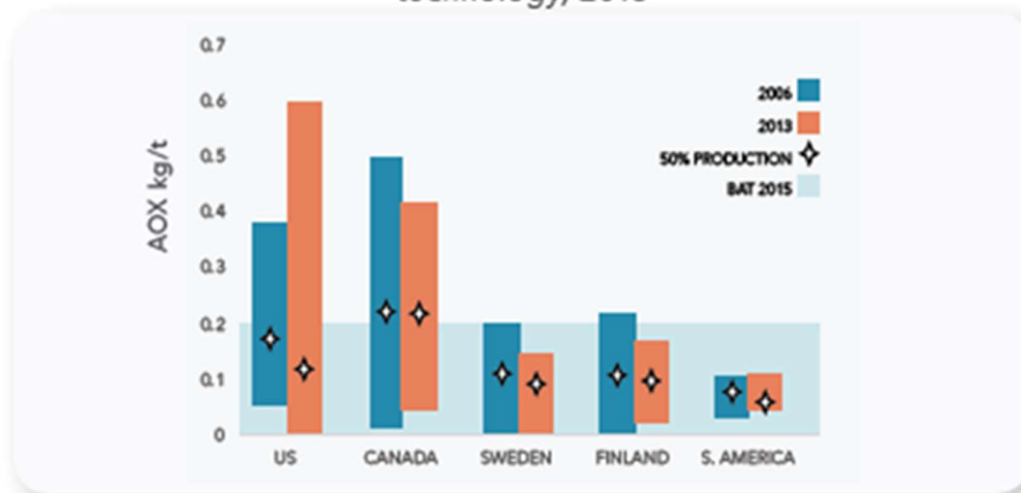
As most of the fluff pulp used in the EU is imported from North America it is most likely that the dioxins contaminated pulp originates there.

EU's 2015 Best Available Technology (BAT) document stipulates that "BAT-associated emission levels for the direct wastewater discharge to receiving waters from a bleached kraft pulp mill" is 0-0,2 kg/ADt. This also applies to imported pulp.

It is documented that a large portion of North American bleached kraft mills has higher emission values in terms of important parameters than most of the corresponding European mills (EKONO Inc. Strategy study. Environmental performance regulations and technologies in the pulp and paper industry, 2015, August 2016).

As so many of the North America mills have a higher performance regarding AOX discharges than the EU Bat level of 0,20; this is most probably the source of the dioxins found in the nappies marketed in the EU.

Figure 1: Aox maximum, minimum and average performance of pulp mills, by region, with comparison to European Union best available technology, 2013



The figure above shows the maximum and minimum levels for one of the most important effluent discharge components and its changes between 2006 and 2013. The level at 50% of the region's production is also marked as well as BAT (Best Available Technique) permitted levels in the European Union as of 2015 (EKONO, 2016).

²⁰ https://events.risiinfo.com/north-american-conference/sites/default/files/presentations/2020/Cavanagh_Fluff_Pulp_2020_0.pdf

As said above it is reported that ECF bleaching levels of elemental chlorine in the chlorine dioxide at less than 0.3% (AOX 0,20) results in low or zero dioxins. At the same time levels above 0,3% chlorine contamination results in several times higher dioxins levels (Axegård and Bergnor (2011)). Still it can be called ECF bleached as chlorine dioxide is the original compound.

Although it is said that the US stopped using chlorine for bleaching in year 2000, it is reported that between 2012 and 2020 at least 7 US pulp mills reported plans to stop using chlorine gas in their production. The question is how many still use chlorine in their production.²¹

A submission report from University of Texas shows that still chlorine was used at the Foley Cellulose mill in Florida. This mill produces among other qualities bleached fluff pulp²². The environmental pollution caused by this plant has been highlighted in the [Environmental Justice Atlas](#).

²¹ <https://enviro.epa.gov/facts/tri/p2.html>

²² Tier 2 Online Submission Report. Chemical Inventory Information. E-Plan - University of Texas at Dallas. Facility name: Foley Cellulose. January 1, 2015 - December 31, 2015.