



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

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COMMENTS TO THE RESTRICTION OF SUBSTANCES IN SINGLE-USE BABY DIAPERS

We welcome the dossier submitter's proposal for a restriction on single-use diapers.

Considering the wide use of such consumer products by families all across Europe (it is estimated that 14.5 million children are currently exposed to chemicals via the use the single-use diapers¹), the fact that children wear them every day all day over long periods going from months to years, and the vulnerability of the public targeted, we believe that an EU-wide restriction is the most efficient way to increase the general level of health protection equally all across the continent. This restriction also echoes the demand of thousands of EU citizens asking for toxic free nappies and tampons².

We submit comments on the following aspects of the risk assessment:

- 1. Vulnerability of the public targeted with the restriction proposal**
- 2. Hazard assessment**
 - a. All hazardous substances present in nappies should be included under the scope.**
 - b. Dioxins, furans and PCB should be considered non threshold chemicals.**
 - c. A mixture assessment factor should be used in the risk assessment to address the added risks of the exposure to the mixture of chemicals present in nappies.**
- 3. Representativeness of the test data used by the DS for the risk assessment.**
- 4. Approach to uncertainties**

¹ Annex XV report, p. 75

² <https://www.change.org/p/stop-selling-toxic-diapers-and-tampons>

1. Vulnerability of the public targeted with the restriction proposal

In our view, the effectiveness of the final restriction will heavily depend on its ability to take into account the high vulnerability of the main public targeted with this proposal, i.e newborns, toddlers and young children.

As is well scientifically established, at these early life stages, children are still developing and their sensitivity to chemical exposures is much more acute than that of adults. By way of preliminary remarks about the scale of the issue and the importance that the restriction proposal can play, **according to the World Health Organisation, over 30% of the global burden of disease in children can be attributed to environmental factors and 40% of this burden falls on children under five years of age, translating into three million deaths annually³. This is serious enough for the International Convention on the Rights of the Child foreseeing that States have a legal obligation to prevent exposure to toxics by children**, as reminded again by a recent report of the UN Special Rapporteur on Toxics⁴.

Preventing children's exposure to harmful chemicals through products such as single-use diapers should be the primary aim of this restriction effort, the more so as the substances covered by the scope of the proposal are known for their significant - and mostly irreversible - effects on health, including mutagenicity, carcinogenicity and reproductive toxicity⁵.

Important parameters regarding children vulnerability that should guide the restriction development include the following⁶:

- **Children cannot be considered small adults** and they are much more sensitive to impacts of harmful chemicals than them;
- **Children have a dynamic developmental physiology**. They receive higher exposure to environmental chemicals than adults, whereas their system is not yet fully equipped to deal with such exposures in the way adults would be.
- **This physiology can affect the kinetics, metabolism and dynamics of chemicals in the body, especially at young neonate stage.** There is no parallel to this stage in

³ World Health Organisation, Principles for evaluating health risks in children associated with exposure to chemicals (Environmental health criteria; 237); 2011;

www.who.int/ipcs/publications/ehc/ehc237.pdf; p.14

⁴ International Convention on the Rights of the Child,
<https://www.ohchr.org/en/professionalinterest/pages/crc.aspx>

Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, 2016; <http://www.srtoxics.org/wp-content/uploads/2016/09/Rights-of-Child-and-Toxics.pdf>

⁵ Annex XV report, p. 74

⁶ This is notably well documented in:

World Health Organisation, Principles for evaluating health risks in children associated with exposure to chemicals (Environmental health criteria ; 237); 2011;
www.who.int/ipcs/publications/ehc/ehc237.pdf

OECD, Considerations when assessing children's exposure to chemicals from products; 2019;
[https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2019\)29&docLanguage=en](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2019)29&docLanguage=en)

RIVM, Risk Assessment of Chemicals: What about Children?; RIVM report 613340005/2002;
<https://www.rivm.nl/bibliotheek/rapporten/613340005.pdf>

Philip J. Landrigan and Lynn R. Goldman, Children's Vulnerability To Toxic Chemicals: A Challenge And Opportunity To Strengthen Health And Environmental Policy, Health Affairs 2011 30:5, 842-850

adult physiology that would allow using existing chemical exposure and risk characterization that are available for adults.

- **Exposure to chemicals at these stages can have effects on proper development and functioning later in life, which can be irreversible.** Moreover, the earlier the exposure to harmful chemicals, the longer future adults will have to live with their potential associated effects. Independent scientists have long highlighted that early-life exposure to several of the chemical compounds targeted by the restriction, including dioxins and PCBs, is increasing the likelihood of disease onset later in life⁷.

In the case of single-use diapers, it is also important to recall that:

- **Children wear diapers 24/7 for at least several months, and most often for several years;** this contributes to specific patterns of exposure that contrast with those of adults.
- **Children have a high body surface/weight ratio in comparison to adults** (for neonates, it is estimated that the ratio is 2.5 times higher than adults⁸). This matters in terms of dermal exposure, which is the main exposure route of interest in the case of chemical compounds in diapers and because we also know that neonates' skin is very sensitive, notably with a more efficient absorption potential of hydrophilic substances than adults⁹. In the annex XV report, the dossier submitter acknowledges that "all DNEL/DMEL used in the risk assessment performed in this restriction proposal were derived based on oral route studies, which is a significant source of uncertainty when it comes to assess actual human health impacts and disease burden of a risk generated through dermal exposure"¹⁰ - a statement which calls for a precautionary approach in the actual risk characterisation related to children's chemical exposure through the wearing of diapers.
- **Children are all different** (size, weight, growth rate, habits, movements) and therefore it is impossible to make one-size-fits-all assumptions about exposure scenarios, in particular regarding chemical uptake through dermal contact with the diapers, urine retention, compression of the diapers through movement or because of weight, influence of potential use of skin cream on chemical uptake.
- **Single-use diapers are predominant on today's market and children have no ability to decide whether to wear them or not.**
- **Parents on the other hand know very little about the constituents of the diapers, expecting them to be fully free of harmful constituents.** Moreover, they can do virtually nothing to influence how the diapers are being worn once placed, and have little instruction on optimal rhythm for changing them.

Implications for the development of the restriction

Based on the above, the developing restriction should:

⁷ Endocrine Society, EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, 2016, <https://dx.doi.org/10.1210%2Fer.2015-1010>

⁸ RIVM, p.12

⁹ WHO, Ibid, p. 25

¹⁰ Annex XV report, p. 73

- Aim at avoiding any exposure to the targeted chemicals through diapers, rather than developing acceptable scenarios based on quantification methods that will inherently carry wide uncertainties.

The EU Chemicals Strategy for Sustainability promise to extend the generic approach to risk management in order to guarantee that consumer products, including children's products, are free of harmful chemicals provides further impetus for this restriction to show zero tolerance for the presence of any of the harmful substances targeted.

- Account for the existing uncertainties regarding exposure by using a default precautionary approach and consider that these uncertainties likely contribute to an underestimation of the risks faced by children rather than the contrary.
- Because of the high vulnerability of the public targeted by this restriction proposal and the difficulties to quantify the risk with certainty, the use of an allocation factor is therefore justified. This has already been acknowledged by the Dutch RIVM in a publication dedicated to chemicals risk assessment in relation to children¹¹:

"At present there is not sufficient information, however, to give a general quantitative statement whether the presently used default assessment factor of 10 for intraspecies variation is adequate to protect children in risk assessment of chemicals. However, in general, the use of an intraspecies factor of 10 implies that the most sensitive child is about 10x more sensitive than the average human, and thus that there is a 100-fold variation in susceptibility in the entire human population. In addition, the use of the default assessment factor of 10 for interspecies extrapolation implies that the average human is 10 times more sensitive than the most sensitive animal tested."

In general, if a full set of toxicological data is available, the presently used assessment factors (10 x 10) are considered adequate in safeguarding the human population. However, the use of an additional assessment factor in order to protect the sensitive groups in the human population, among others children, should always be considered, on a case-by-case basis."

2. Hazard assessment

- a) All hazardous substances present in nappies should be included under the scope.

The Annex XV report describes several groups of chemicals that have been found to be present in nappies, including PAH, PCB, dioxins and furans, fragrances, pesticides, and VOC, however only three groups (PAH, PCB, dioxins and furans) and formaldehyde have been included under the scope. Given the high vulnerability of babies to chemicals as described above and the intention of the Chemicals Strategy for Sustainability to protect the most vulnerable groups from the risks posed by chemicals, we consider that no toxic chemicals

¹¹ RIVM, Risk Assessment of Chemicals: What about Children?; RIVM report 613340005/2002; <https://www.rivm.nl/bibliotheek/rapporten/613340005.pdf>

should be allowed in baby articles, and therefore, **the scope of the proposal should be extended to all the groups of chemicals identified as being present in nappies by the dossier submitter.**

b) Dioxins, furans and PCB should be considered non threshold chemicals.

The DS has decided to consider reproductive effects of dioxins and immunotoxicity supported by neurobehavioral changes of PCB as critical threshold effects for the risk assessment. However, the hazard data submitted by the DS in the restriction proposal acknowledges that several organisations consider dioxins, furans and PCB as non-threshold substances (based on carcinogenicity, i.e. liver tumours).

In addition, the restriction report describes that long-term exposure to these chemicals is associated with hepatic, immunological, neurological, metabolic and endocrine effects and that PCDD/Fs and PCB are among the first 12 POPs (persistent organic pollutants) included in the Stockholm Convention in 2001. Both chemicals are also considered endocrine disrupters by TEDX¹², WHO¹³. As endocrine disruptors and as POPs, dioxins, furans and PCB should be considered as **non-threshold chemicals**. Therefore, **any exposure should be considered to pose a risk.**

The use of the threshold approach by the DS might therefore be underestimating the risks to babies' health posed by the presence of dioxins, furans and PCB in nappies.

c) A mixture assessment factor should be used in the risk assessment to address the added risks of the exposure to the mixture of chemicals present in nappies.

A mixture of chemicals is present in baby nappies as described in the restriction report and acknowledged by the industry association EDANA¹⁴ including PAH, PCB, dioxins and furans, fragrances, pesticides, and VOC.

As recognised by the scientific community:

"different chemicals can act together by 'simply' adding on to each other's effect (additivity), by exceeding the expectations of additivity and independence in reinforcing each other's effect (synergism) or by reducing each other's effect (antagonism). These interactions seem to occur without a threshold to a combined effect, meaning that all combined exposures will lead to some form of combined effect, which may already become apparent below the no observed effect concentrations (NOEC) or no observed adverse effect levels (NOAEL) of the individual substance in the mixture (e.g. Carvalho et al. 2014; Kortenkamp, 2014; Bal-Price, 2019; Bopp, 2018)"¹⁵.

¹² Endocrine Disruption Exchange <https://endocrinedisruption.org/>

¹³ State of the science of endocrine disrupting chemicals 2012 / edited by Åke Bergman, Jerrold J. Heindel, Susan Jobling, Karen A. Kidd and R. Thomas Zoeller. United Nations Environment Programme and the World Health Organization, 2013

¹⁴ EDANA, CODEX List of trace chemicals [https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products/the-edana-absorbent-hygiene-product-stewardship-programme-codex/trace\)](https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products/the-edana-absorbent-hygiene-product-stewardship-programme-codex/trace)

¹⁵ Scoping paper Workshop on a pragmatic approach to regulatory measures addressing the risk from combined exposure to chemicals – REACH as an example.

As a way forward to address these “cocktail effects”, academia and authorities support the use of mixture assessment factors in the risk assessments and the EU Chemical Strategy for Sustainability will assess how to introduce “(a) mixture assessment factor(s) in Annex I of REACH”.

This approach has already been used by the RAC when assessing the risks of tattoo inks. In its opinion on the restriction of tattoo inks RAC used an assessment factor of 10 to

“...account for: mixture /cumulative effects and uncertainties, possibility of combined effects of several reprotoxicants present in tattoo inks with the same mode of action, including ED effects and the possibility that more potent substances may be present in tattoo inks...”¹⁶

A similar mixture assessment factor should be used to better protect babies from the combined exposure to the hazardous chemicals present in nappies.

3. Representativeness of the test data used by the DS for the risk assessment

We support that the test data used by the DS are representative of the EU market given that single-use baby diapers market is largely concentrated in very few companies globally and in Europe¹⁷.

It should be noted that 90% of fluff production worldwide originates in the United States, who supplies approximately 75-80% of fluff pulp demand in the EEA. The remaining 25-80% of the fluff pulp is produced by European Nordic countries and mostly used by production companies for products of their own brands¹⁸. Most (98%) of the fluff production in the United States is still based on chlorine bleaching¹⁹.

60% of the brands analysed by ANSES containing toxic chemicals are selling all over Europe, as presented by the DS.

In addition, tests performed in 21 single-use diapers by the Swiss Federal Food Safety and Veterinary Office (FSVO) and the Fédération Romande des Consommateurs (FRC) also found dioxins and PAH in the nappies. PAH (pyrene) was present in levels ranging from 200 to 2430 microgr./kg, ranges that are similar to the results from the tests performed by ANSES in 2018²⁰.

<https://www.chemischedestoffengederegeld.nl/content/scoping-paper-workshop-pragmatic-approach-regulatory-measures-addressing-risk-combined>].

¹⁶ RAC opinion Substances in tattoo inks and permanent make up (page 23)

<https://echa.europa.eu/documents/10162/02c49916-e21c-be9e-ba3e-9d4fdfa73ffe>

¹⁷ Page 18 Annex to the restriction report.

¹⁸ EUROPEAN COMMISSION, DG Competition. Case M.8096 - INTERNATIONAL PAPER COMPANY / WEYERHAEUSER TARGET BUSINESS. REGULATION (EC) No 139/2004. MERGER PROCEDURE. Article 6(1)(b) NON-OPPOSITION. Date: 20/10/2016 (pages 3, 5, and 10)

https://ec.europa.eu/competition/mergers/cases/decisions/m8096_255_7.pdf

¹⁹ ECF and TCF Bleaching. Pratima Bajpai, in Environmentally Benign Approaches for Pulp Bleaching (Second Edition), 2012. <https://www.sciencedirect.com/topics/engineering/elemental-chlorine>

²⁰ The Fédération Romande des Consommateurs (FRC) have informed us that they have submitted the results of their tests through the public consultation.

4. Approach to uncertainties

The Dossier Submitter has highlighted that uncertainties remain in the scientific assessment, specifically with regard to:

- 1) The quantification of the exposure to chemicals
- 2) The lack of epidemiological data demonstrating an association between health effects and the wearing of diapers
- 3) The availability of harmonised analytical methods

Uncertainties are part of any risk assessment and should therefore be rigorously identified and acknowledged. However they cannot be a sufficient reason for disregarding the unacceptability (REACH Art. 68. 1) of what is here a potential high risk due to the prolonged exposure of a highly vulnerable population to very hazardous substances - which has been recognised in various past restrictions.

Indeed, and firstly, the dossier presented by ANSES demonstrates that **an unacceptable risk to human health exists**. As underlined previously, the proposed restriction deals with substances with severe hazard profiles in consumer products, which are known to be widely used and lead to exposure of young children across long periods of time across the EU. Health risk thresholds have been shown to be exceeded.²¹ The dossier also mentions that the possibility of cumulative exposure to some of the chemicals cannot be ruled out.²² The risk may not be fully characterised due to missing data, but there is proof that it is likely to occur and may be extremely severe, which is why the analysis presented by the dossier submitter should be considered sufficient to spur regulatory action. That is the meaning of the precautionary approach promoted in EU legislation, including REACH.²³

A second important remark should be done regarding **past restrictions where similar uncertainties were raised**. Notably, the lack of standard methods is a recurring issue in restrictions.²⁴ In the skin sensitisers in textiles' restriction, the unavailability of standard methods, for instance to measure lower levels of chromium VI compounds in leather, was identified as a major issue. However the scientific committees of ECHA estimated that the risk at stake justified the restriction and that setting an implementation period would allow the development of relevant tests.²⁵ In the context of the current proposal for single-use baby diapers, a similar implementation period has been suggested by ANSES, which should be deemed sufficient to alleviate the uncertainty with regard to the availability of standard methods - in line with the approach adopted in other restrictions. Likewise, ANSES noted that the concentration of some of the substances could not be quantified, although they were detected in the nappies.²⁶ The lack of quantification with high precision should not prevent the

²¹ ANSES study (2019), see Annex XV Dossier, p. 25

²² Annex XV Dossier, p. 18

²³ The precautionary principle justifies the adoption of restrictive measures if "the likelihood of real harm to public health persists should the risk materialise": Case C-192/01, *European Commission v Denmark*, para.52; Case C-343/09, *Afton*, para.171, Case E-3/00 *EFTA Surveillance Authority v Norway*, para.31; Case C-282/15, *Queisser Pharma*, para.55

²⁴ See for example the ECHA proposal to restrict intentionally-added microplastics

²⁵ RAC Opinion, p. 39

²⁶ For example in the Annex XV p. 45, it is noted: "All PCDD/Fs and DL-PCBs were not quantified in each diaper but could be found in some of them leading, when performing the QHRA to risk ratios higher than 0.1 (see Annex B.10). These risk assessments showed that risks exist for the chemical groups quantified in single-use baby diaper."

characterisation of the risk, inasmuch as there is evidence of the presence of the substance. RAC supported this approach when assessing the proposal to restrict skin sensitisers in textiles, as well as the restriction proposal for substances used in tattoo inks and permanent make-up for example.²⁷ In other words, although no full quantitative analysis of the risks of all substances that are currently used in diapers is possible, the available measured values for certain of the chemicals make clear that risks for human health cannot be excluded.

To conclude, we believe **the fact that the presence of the listed substances in single-use baby diapers has been shown to pose an unacceptable risk for human health should suffice to justify the need for an EU wide restriction**. Given the important size of the population targeted by this restriction and its high vulnerability, **uncertainties should not prevent or undermine regulatory action**. That is key to push industries and the regulatory community to implement innovative solutions and fill in existing knowledge gaps.

²⁷ See RAC and SEAC consolidated Opinion, p. 115