



Brussels, 26 January 2022

Open Letter to the European Commission:

Dr Stella Kyriakides, European Commissioner for Health and Food Safety, European Commission. Via email: cab-kyriakides-contact@ec.europa.eu

Mr. Thierry Breton, European Commissioner for Internal Market, European Commission. Via email: cab-breton-contact@ec.europa.eu

Mr. Virginijus Sinkevičius, European Commissioner for Environment, Oceans and Fisheries, European Commission. Via email: cab-sinkevicius-contact@ec.europa.eu

Subject: French proposal for an EU restriction of highly hazardous substances in single-use baby diapers

Dear Commissioner Kyriakides, Commissioner Breton and Commissioner Sinkevičius,

The EU Chemicals Strategy for Sustainability promises to make consumer products, including children's products, free of the most harmful chemicals (p.10).

In 2020, the French authorities (ANSES) proposed to restrict a group of extremely hazardous substances in baby diapers throughout the EU under the REACH Regulation.ⁱ The scientific committees of the European Chemicals Agency (ECHA) have discussed this proposal and provided their respective opinions.ⁱⁱ It is now for the European Commission to take a decision on whether the risk posed by the presence of the targeted substances in single-use diapers is acceptable or not, and

accordingly whether it must be addressed at the EU level through a REACH restriction.ⁱⁱⁱ

With this letter, we would like to ask you to support the proposed restriction. In making your decision, we draw your attention to the key responsibility of the Commission to take into account the particular vulnerability of the newborns and toddlers that this important restriction aims to protect.

This restriction proposal aims at reducing health risks associated with wearing single-use diapers for infants and children under the age of three. ANSES has provided evidence that diapers can contain substances with very severe hazard profiles, including polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and/or formaldehyde.

Without the proposed EU restriction in place, millions of newborns and toddlers wearing single-use diapers may be potentially exposed to harmful chemicals on a daily basis for several years. Chronic and long-term exposure to these substances may lead to a range of health effects such as skin sensitisation, cancer, adverse reproductive effects, genotoxic and endocrine effects - which can sometimes manifest later in life.

The ECHA scientific committees have justified their negative opinions to the proposed restriction by flagging significant uncertainties with regards to the characterisation of the risk arising from the exposure to the targeted chemicals during the wearing of diapers. Nonetheless they acknowledged two fundamental aspects: firstly **a risk cannot be ruled out for some of the substances**; secondly **it is necessary to keep these substances to as low a level as possible/feasible** in baby diapers, and **preferably not have them present at all**.^{iv}

Based on the above, and keeping in mind that continuous long-term exposure to the targeted substances can result in serious potential risks for a particularly vulnerable group of the population, a precautionary approach should be adopted when deciding on the fate of the proposed restriction. In practice, this means that existing uncertainties should not be used to discredit the proposal for restriction, but rather to support it in the aim of increased health protection.

Therefore, **we call on you to support the development of this restriction**, in line with existing protection commitments under the EU Chemicals Strategy for Sustainability, especially towards very vulnerable parts of the population.

Yours sincerely,

Jeremy Wates
Secretary General of the European Environmental Bureau



On behalf of:

ClientEarth
Health and Environment Alliance (HEAL)
Zero Waste Europe (ZWE)
Arnika – Toxics and Waste Programme
the Center for International Environmental Law (CIEL)
ChemSec
ECOCITY
Fondo para la Defensa de la Salud Ambiental (FODESAM)
Forbrugerrådet Tænk – Danish
Consumer Council
Gallifrey Foundation
Génération Futures
Health Care Without Harm (HCWH)
Europe
Hogar sin Tóxicos
the Nappy Alliance
Réseau Environnement Santé (RES)
REZERO
Tegengif - Erase all Toxins
CHEM Trust
Corporate Europe Observatory (CEO)
Ecobaby Foundation

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WOMEN ENGAGE FOR A COMMON FUTURE France (WECF)
WECF INTERNATIONAL
Women's Environmental Network (Wen)
Zero Waste Lviv
No Plastic In My Sea
ZERO Portugal- Associação Sistema Terrestre Sustentável
HEISupport
Ekologi brez meja/Ecologists
Andy Gheorghiu Consulting
Changing Markets Foundation
Plastic Soup Foundation
Sciaena (Portugal)
Humusz Szövetség/Humusz Waste Prevention Alliance

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ANNEX to OPEN LETTER to the European Commission

French proposal to restrict hazardous substances in single-used baby diapers.

This restriction proposal aims **at reducing health risk associated with infants and children under the age of three wearing single-use baby diapers** that are placed on the market and can contain polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and/or formaldehyde.

All those substances have very severe hazard profiles. The restriction report[1] describes that long-term exposure to these chemicals is associated with cancer, damage to the reproductive system, and hepatic, immunological, neurological, metabolic and endocrine effects.

Moreover, as there are other potential sources of exposure to these substances in children aged 0 to 36 months and considering the higher vulnerability of children to chemicals, the possibility of cumulative exposure via various routes increasing in the risks therefore cannot be ruled out.

Without the EU restriction in place, millions of newborns and toddlers wearing single-use diapers may be potentially exposed to toxic chemicals every single day, across long periods of time.

We, the undersigned, are deeply concerned that the European Chemicals Agency's Committees for Risk Assessment (RAC) considered that the Dossier Submitter had not demonstrated an EU wide risk, due to uncertainties related to the exposure and the risk assessment.

ECHA experts gave excessive weight to industry claims and insufficient weight to public authorities' data considering the presence of the chemicals in baby diapers. Studies that fully characterise the skin transfer and absorption of chemicals in infants, and epidemiological data demonstrating health effects related to wearing of diapers are still missing. On the other hand, for many it might come as a surprise that the industry producing diapers, used for years by millions of babies and toddlers, have not performed such studies. A question arises how certain the industry can be about safety of the diapers without good characterisation of the skin transfer and absorption of chemicals through this particular exposure route? "Safe

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until proven otherwise” strategy of restricting chemicals has proven itself to be ineffective at safeguarding humans and the environment from hazardous chemicals.

However, ECHA’s Risk Assessment Committee acknowledged that[2]:

1. **All chemicals considered in the dossier are dangerous** (they are known to cause health effects like cancer, adverse reproductive effects, mutagenicity effects, genotoxic effects, endocrine effects and skin sensitisation) **and can be found in the diapers.**
2. Besides the harmful properties of the substances at stake, **no safe threshold may be derived for several of these chemicals.**
3. Frequent use of single-use baby diapers over a longer period of time could lead to **exposure of children and infants to hazardous substances** should they be present as impurities - particularly where exposure occurs under occlusive conditions. RAC further notes that babies often suffer from baby rash, which might enhance the absorption of substances from diapers;
4. Even **substances** from the inner parts of the diapers **could potentially migrate** to the outer layer **and come into contact with a baby’s skin;**
5. Using a urine simulant to detect and/or quantify the concentration of the hazardous substances provides a better representation of actual use, compared to “traditional” solvent extraction;
6. **A risk cannot be ruled out for some of the substances and it is necessary to keep these substances to a level as low as possible/feasible** in such articles, and **preferably they shouldn’t not be present at all.**

The SEAC opinion[3] highlights as a main uncertainty that the substances under the scope may not be detected in the diapers above the proposed migration limits and that they may stem from “*unavoidable background contamination*”. The issue is that when drawing this conclusion, SEAC gave more weight to industries' comments than evidence provided by the dossier submitter. Moreover, additional tests performed by other organisations (the Swiss Federal Food Safety and Veterinary Office and the Fédération Romande des Consommateurs) have shown the presence in baby diapers of the substances covered by the restriction proposal at levels above the thresholds proposed by the dossier submitter. Even the sectoral

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association EDANA, recognises that these toxic chemicals may be present in the diapers and have subscribed a voluntary agreement with its members to reduce the concentrations of these chemicals in their products.

Furthermore, the theory of ‘*background contamination*’ as the main source of the dioxins raised by the industry stakeholders is a speculation, since several analyses from other than French laboratories have found dioxins in diapers and tampons, and it is most likely that the origin of these dioxins is the bleached pulp rather than a contamination. As suggested by the dossier submitter, the **majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination or be formed during manufacturing processes such as bleaching or bonding** (e.g. DL-PCBs, furans and dioxins). It is therefore a responsibility of the manufacturers / supply chain to adjust the process appropriately and to avoid presence of these substances in diapers.

EU pulp producers have made an effort in the last years to improve their production processes to reduce the release to the environment of these toxic chemicals and avoid their presence in their final products. Most EU producers of pulp used in baby diapers follow EU Best Available Technologies that significantly reduce the formation of dioxins. Unfortunately, this is not the case not for Northern American bleached kraft mills, which produce and export 85% of the pulp used in Europe to manufacture diapers tampons, hygienic pads and other articles.

To summarise, the risk may not be fully characterised due to missing data but there is proof that it is likely to occur and may be severe. **Therefore, to date and in the current state of knowledge, it is not possible to rule out a health risk associated with wearing single-use diapers** which is why the analysis presented by the dossier submitter should be considered sufficient to spur regulatory action.

Equally important, the EU Chemicals Strategy for Sustainability promises to extend the generic approach to risk management in order to **guarantee that consumer products, including children’s products are free of harmful chemicals**. This new strategy aims to be active rather than reactive; it provides therefore further impetus for this restriction to show **zero tolerance for the presence in diapers of any of the harmful substances targeted**.

Given the important size of the EU population targeted by this restriction and its high vulnerability, the potential risks associated with EU manufactured or imported single-use baby diapers articles containing the chemicals of concern need to be

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addressed on a EU-level. Uncertainties should not prevent or undermine regulatory action.

We call the Commission to show a commitment to implement its own ambitious strategy and take the necessary action, i.e. restrict hazardous substances (considered in the dossier) in baby diapers throughout the EU.

Further information:

[Comments from the European Environmental Bureau \(EEB\), the Health and Environment Alliance \(HEAL\) and ClientEarth on the restriction of substances in single-use baby diapers \(June 2021\)](#)

[Contribution from the EEB, HEAL and ClientEarth to SEAC's draft Opinion on the single-use baby restriction \(November 2021\)](#)

i Annex XV Restriction Report Proposal for Restriction

ii Registry of restriction intentions until outcome - ECHA (europa.eu)

iii Based on Article 68(1), REACH.

iv ECHA,2021. RAC Opinion on an Annex XV dossier proposing restrictions on Substances in single-use baby diapers (p.46)

[1] ANSES, 2020. ANNEX XV Restriction report proposal for a restriction of substances in single-use baby diapers.

[2] ECHA,2021. RAC Opinion on an Annex XV dossier proposing restrictions on Substances in single-use baby diapers

[3] SEAC Dreaft Opinion on an Annex XV dossier proposing restrictions on Substances in single-use baby diapers, ECHA 16 September 2021

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