Call for evidence on a possible restriction on PAHs, furans, dioxins, PCBs and formaldehyde in single-use baby nappies

Background document

Introduction

In January 2019, ANSES (French Agency for Food, Environmental and Occupational Health & Safety) published a health risk assessment on chemicals found in single-use baby nappies that identified risks for babies[1] (under three years old) and concluded that the existing regulatory measures are insufficient. In August 2019, ANSES published an RMOA (Regulatory Management Option analysis) concluding that the most efficient regulatory approach to address these risks is to introduce a new restriction entry in Annex XVII of the REACH regulation[2]. This RMOA was subject to a public consultation during summer 2019. In September 2019, the French Competent Authority notified ECHA of its intention to prepare an Annex XV restriction dossier according to article 69(1) of the REACH Regulation No 1907/2006[3]. ANSES is in charge of preparing this proposal. The anticipated submission date of this Annex XV report describing ANSES assessment and their proposed restriction is 9 October 2020.

As part of its investigation, ANSES is undertaking a call for evidence and information. This call is intended to gather information on the use of certain chemicals identified as of concern in single-use baby nappies. The information gathered will be used to assess the risk on an EU-wide basis and assess the socio-economic impacts of the proposed restriction.

Elements of an Annex XV assessment

The elements that need to be considered during the preparation of a restriction proposal are set out in Annex XV of REACH and further elaboration in ECHA Guidance documents[4]. These can be summarised, as follows:

- A characterisation of exposure and resulting risks to human health from use of a substance;
- A justification that risks are not adequately controlled and occur on a Union-wide basis;
- An analysis of the availability, technical and economic feasibility of alternatives to the substance to be restricted;
- A socio-economic analysis (e.g. costs and benefits to society) that would arise from a restriction, including impacts on human health, environment (if relevant), industry, consumers, etc.

[1] https://www.anses.fr/fr/system/files/CONSO2017SA0019Ra.pdf
[2] http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/rmoa_baby_diapers.pdf
[3] https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5
[4] https://echa.europa.eu/fr/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

Problem identification

Following tests performed in France (INC, DGCCRF/SCL), single-use baby nappies have been reported to contain hazardous chemicals at levels that may cause diseases to babies that are in direct contact with these articles. A health quantitative risk assessment (HQRA) was carried out for each of the substances found. Under representative and realistic assumptions of exposure, this HQRA concluded that for some of the substances of concern, health-based thresholds are exceeded, and that a risk for babies' health associated with the wearing of single-use nappies cannot be ruled out (carcinogenicity, toxicity for reproduction and developmental effects as well as immunosuppressive and neurological effects). Therefore, regulatory action to address these risks is justified.

Scope of our investigation

The scope of ANSES' current investigation is extensive and includes the following articles:

- Traditional single-use baby nappies (regular nappies worn during the day and night from birth)
- Nappy pants or training pants for toilet-training of children (made with specific features)
- Swimming nappies used when babies/children are engaging in water activities (made of an absorbent material that does not swell up in water)
- Night nappies intended for children over three years old, in order to help them with toilet training at night (made with specific features)

The scope of ANSES' current investigation includes the following substances and groups of substances:

- The following PAHs: benzo[c]fluorene, benzo[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene, Indeeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene, Dibenzo[a,l]pyrene, Dibenzo[a,e]pyrene, Dibenzo[a,i]pyrene, Dibenzo[a,h]pyrene;
- The following Dioxins: 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD, 1,2,3,4,7,8-HxCDD, 1,2,3,6,7,8-HxCDD, 1,2,3,7,8,9-HxCDD, 1,2,3,4,6,7,8-HpCDD, OCDD;
- The following Furans: 2,3,7,8-TCDF, 1,2,3,7,8-PeCDF, 2,3,4,7,8-PeCDF, 1,2,3,4,7,8-HxCDF, 1,2,3,6,7,8-HxCDF, 1,2,3,7,8,9-HxCDF, 2,3,4,6,7,8-HxCDF, 1,2,3,4,6,7,8-HpCDF, 1,2,3,4,7,8,9-HpCDF, OCDF;
- The following DL-PCBs: PCB 81, PCB 77, PCB 123, PCB 118, PCB 114, PCB 105, PCB 126, PCB 167, PCB 156, PCB 157, PCB 169, PCB 189:
- Formaldehyde;
- The sum of the above dioxins and furans;
- The sum of the above DL-PCBs;
- The sum of the dioxins, furans and DL-PCBs;

According to the comments received from the consulted stakeholders during earlier stages of the assessment, none of these substances are intentionally added to nappies during the manufacturing process, but rather they are residues or contaminants.

Evidence and information to be collected

The objective of this call is to gather information or comments on the following topics for each of the articles and substance or group or substances listed above:

1. Scope of the restriction
    a. Articles intended to be included
        i. Regarding the types of nappies listed above, information about: their features, composition materials, or any other information on their specificities (e.g. one layer, multiple layers?)
    b. Substances within the scope of the investigation
        i. Quantity of the substances detected or quantified in nappies
        ii. Origin of the presence of the substances detected or quantified
            1. May they come from raw materials used? if so, please provide information and elaborate on the origins of those raw materials.
            2. May they come from the manufacturing process? if so, please provide information and elaborate on how and where those substances contaminate the products during the process.
            3. Other origins?
        iii. Any other substance measured?
        iv. Information about any measurements, specifications and actions carried out by industry to control and monitor any chemicals of concern (including those targeted by this restriction proposal) in their manufacturing site and along the supply chain.

2. Exposure assessment: information about:

    a. Weight of the various types of single use babies nappies
    b. Skin absorption for each substance or group of substances (including possible migration of substances through layers, from outer to inner layer)
    c. Transfer from nappies to the skin (via direct contact, or via indirect contact, i.e. transfer of substances after solubilisation in urine and contact by rewetting with adsorbed liquid)
    d. Babies body weight
    e. Number of articles used per 24h period
    f. Differences of use within EU Member States

3. Concentration limits and analytical methods

    a. As shown in the ANSES RMOA, there are no available standardised methods to measure the substances as of concern in a urine simulant. Indeed, the analytical tests performed for the ANSES' 2019 study to demonstrate the presence of hazardous substances in single-use baby diapers were built especially for ANSES' HQRA and are not standardised. Is any laboratory currently working on a standardised method based on the one published in France in 2019 by SCL and used to perform the tests in the ANSES 2019 report? For ongoing work, when is it expected to be conclusive?
    b. Information about daily volume of urine for babies under the age of three (with the associated literature references)

4. Alternatives
    a. If none of the substances detected or quantified in nappies is intentionally added during the manufacturing process, and if they are residues or contaminants, information about:
        i. The detailed description of the typical manufacturing process of a nappy (or the typical processes if they are of several types)
        ii. The identification of the critical steps that are responsible for the presence of the substances targeted by the restriction in the final products
        iii. Any possible technical means to remove these substances from the final nappies
        iv. Potential impacts of implementing these means, including :
            1. Information on their technical feasibility
            2. Quantitative (or by default, qualitative) information on associated implementation costs
            3. Other potential impacts stemming from the removal of those residues and contaminants, e.g. discontinuation of certain products, changes in product performance, etc.
            4. Any risks associated with the implementation of these means
        v. Occurrence and implementation of best practice to minimise such residues and contaminants
    b. If the substances detected or quantified in nappies may come from the raw materials used, information about :
        i. The detailed description of the typical raw materials used in the manufacturing of a nappy
        ii. The identification of the most critical raw materials that are responsible for the presence of the substances targeted by the restriction in the final products and the reasons why they are responsible for it (country of origin? Specific steps in the life cycle of the raw materials? etc.)
        iii. Current best practice in the selection and traceability of raw materials
    c. The availability, technical and economic feasibility and hazards/risks of potential alternatives

5. Information on socio-economic impacts in response to a possible restriction, i.e. quantitative or qualitative information on potential advantages and disadvantages, including:
    a. Costs and benefits to affected actors, e.g. producers, professionals, consumers. Please provide data and information on key economic parameters, such as profit-loss or cost-savings, potential gain of market share related or not with an improved image of single-use baby nappies, turnover, the number of people employed in the EU or abroad if relevant, current share of products, and any information enabling to characterise potential impacts on the nappies market within the EU.

Additional information that could also be potentially relevant is also welcome and should be submitted. Please note that ANSES will undertake their own search of the scientific literature, but they would be interested in being informed of any ongoing research that might be published during 2019-2020 (e.g. ongoing research or submitted but not published literature).

Who should participate in the call for evidence?

This call for evidence is intended for interested parties such as private companies (manufacturers, suppliers, distributors, importers etc.), trade associations, scientists, NGOs, labels and certification bodies and any other stakeholders or Member States holding relevant information. Information can be submitted confidentially and will be treated as such by ECHA and ANSES. The information provided will be used to determine if any derogations would be necessary in the scope of the restriction proposed. However, derogations cannot be proposed without adequate information on risk and socio-economic information, including alternatives. If a derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on a comprehensive information on risk, socio-economic elements and alternatives, during the opinion-making process after formal submission. The comments received from stakeholders during the public consultation on the RMOA will also be taken into account in the elaboration of the restriction proposal.

ECHA invites interested parties to respond to the call for evidence by 31/03/2020. Any early comments would be highly appreciated by 20/02/2020.
https://echa.europa.eu/calls-for-comments-and-evidence

We will hold a webinar with interested stakeholders to answer questions on the call for evidence on 30/01/2020. Please see ECHA website for further details[5].

For any clarifications, please contact: celine.dubois@anses.fr / karine.fiore@anses.fr

[5] https://echa.europa.eu/-/call-for-evidence-on-proposed-restriction-of-substances-of-concern-in-baby-diapers