Online information session

Call for evidence on possible restriction of substances in single-use nappies for infants and children

30 January 2020

11:00 – 12:30 Helsinki time

With you today

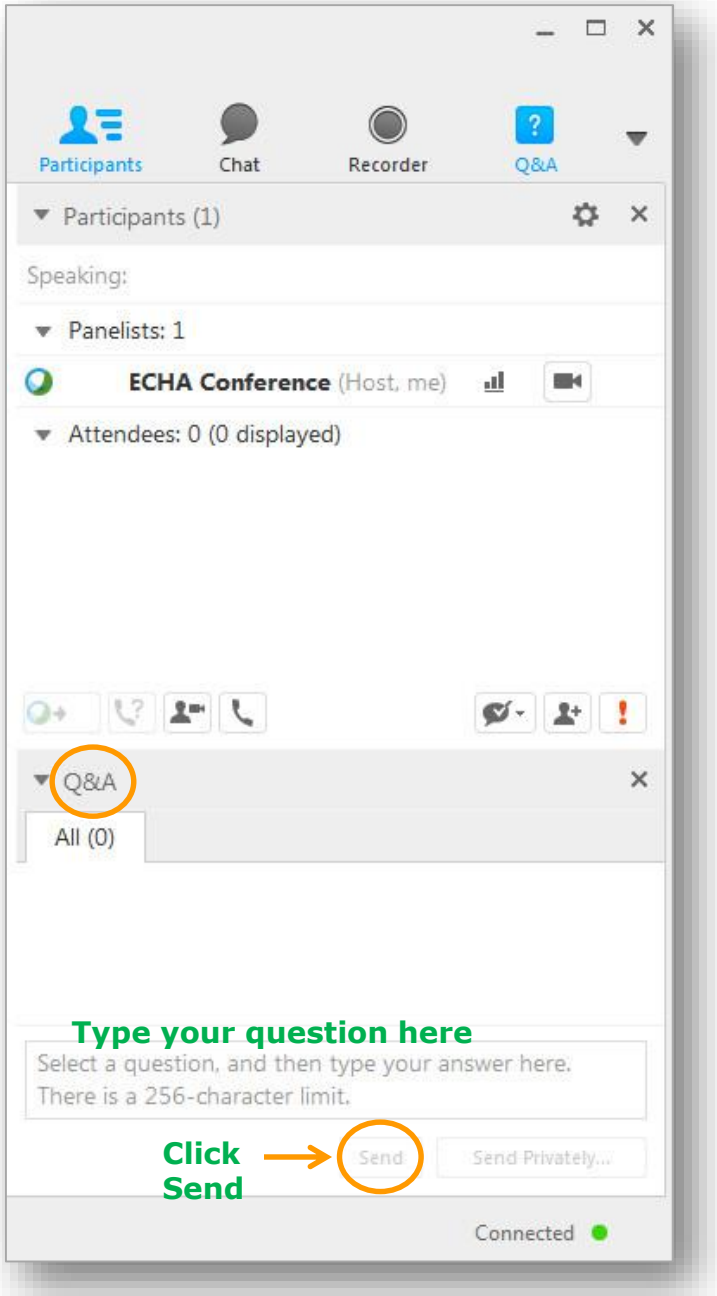
Peter Simpson
Restriction process coordinator (ECHA)

Céline Dubois
Scientific project manager (ANSES)

Karine Fiore
Regulatory and socio-economic projects manager (ANSES)

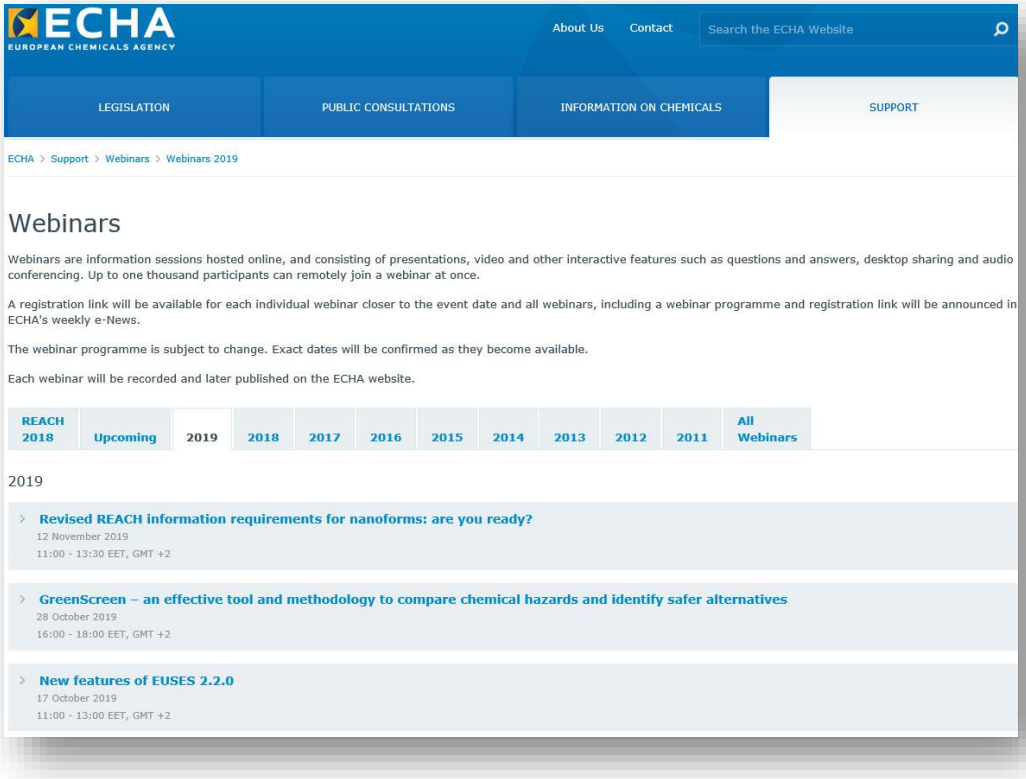
To ask a question

- Use the Q&A panel (256-character limit)
- We will answer as many as we can today
- Questions after the event: echa.europa.eu/contact
- Media enquiries: press@echa.europa.eu



Material published

- Recording and presentations
- Q&A document



echa.europa.eu/support/training-material/webinars

Today's objective

- To introduce the REACH restriction procedure
- To outline the scope of the ANSES investigation into 'substances of concern in single-use nappies for infants and children', which may result in a restriction proposal
- To help you decide if and what information you should submit in the call for evidence
- To clarify any elements of the information requested
- Not a debate about the need for a restriction

Programme

Time	Title	Speaker
11:00	Introduction to the session and its purpose	Peter Simpson, ECHA
11:10	Scope of the investigation	Karine Fiore, ANSES
11.50	Q&A	Karine Fiore and Céline Dubois, ANSES Moderator: Peter Simpson, ECHA
12:25	Concluding remarks and next steps	Peter Simpson, ECHA
12:30	Webinar ends	

Introduction to REACH restriction

Restrictions under REACH

- Restriction is a tool for protecting human health and the environment from the risks posed by chemicals
- Restrictions usually limit or ban the manufacture, placing on the market or use of a substance.
- In some cases, a restriction may set out specific conditions such as technical measures or labelling requirements.
- A restriction may be applied to any substance on its own, in a mixture or in an article. The substance may even be one that does need to be registered under REACH e.g. polymers, medicines, cosmetics

Restriction process

I Phase

Preparation and submission of a restriction proposal

- Starting the restriction process
- Notification of intention to submit a restriction proposal
- Registry of Intentions
- Preparing the restriction dossier
- Submission and conformity check

II-A Phase

Public consultations

- Public consultation on the restriction report
- Public consultation on SEAC's draft opinion

II-B Phase

Opinion development

- Advice from the Forum
- RAC's opinion
- SEAC's opinion

III Phase

Decision and follow-up

- Commission decision on restriction
- Complying with restriction
- Enforcing the restriction

https://echa.europa.eu/restriction-process

Starting the restriction process

- A Member State, the Commission or ECHA may have a concern that a substance poses a risk to human health or the environment. If so, preparatory work is undertaken to investigate the problem (RMOA).
- If a Member State, the Commission or ECHA concludes that a restriction is the best way forward, it has to notify its intention to prepare a restriction 12 months before it is submitted.
- France notified its intention to submit a restriction proposal on substances in nappies on 09/10/2019

Registry of intentions

- ECHA maintains a public Registry of Intentions (RoI), which indicates when a new restriction dossier is being planned to be submitted to ECHA for a particular substance.
- It enables interested parties – citizens, organisations, companies and authorities – to plan for and contribute to the consultations in the restriction process.

https://echa.europa.eu/registry-of-restriction-intentions

Restriction proposal (Annex XV report)

- The restriction dossier has to include:
  - Information on hazards and risk
  - Justification for action at an EU-wide level
  - Available information on alternatives
- The proposal has to show that a restriction is the most appropriate risk management measure to address the identified risk.
- The proposal may also include an analysis of socio-economic impacts

Evaluation after submission by ECHA

- RAC – risk assessment committee
- SEAC – socio-economic analysis committee
- 'Effectiveness' of a proposed restriction
  - key criteria for justifying a restriction
- Restriction must be
  - Targeted to the effects or exposures resulting in the risk
  - Capable of reducing these risks within a reasonable time period (proportionate to the risk)
- Socio-economic analysis
  - Net benefits (human heath and environment)
  - Net costs (manufacturers, importers, consumers)

Timeline after submission

- Restriction dossier made publicly available shortly after submission (~2 weeks)
- Opinion-making process (typically 12 months)
  - Conformity check prior to 6 month public consultation
  - Evaluation of the proposal set out in an 'opinion'
- Opinions published and sent to Commission for decision along with background documents

Scope of the ANSES investigation into substances of concern in single-use baby nappies

Substances in single-use baby nappies

- Anses Expertise including Human Health Risk Assessment 2019
- French RMOA published in July 2019
- French RMOA submitted to public consultation, Summer 2019
- Restriction Intention added to ROI, September 2019
- Annex XV report expected to be submitted in October 2020

Documentation:
https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5

Why are we intending to restrict some substances in single-use baby nappies?

- In 2018 ANSES undertook a study on the presence of chemicals in single-use baby nappies as well as a human health risk assessment
- This study, published in 2019, concluded that:
  - Hazardous chemicals are present in single-use baby nappies
  - Health risks for babies cannot be excluded
  - There is a need of risk management
- A RMOA was published in July 2019 concluding that:
  - the existing regulatory measures are insufficient to address these risks
  - The most efficient regulatory option is the introduction of a new restriction entry in Annex XVII of the REACH Regulation
- French CA mandated ANSES to develop an Annex XV restriction report on single-use nappies in September 2019
  - Expected submission in October 2020

French RMOA on chemicals present in single-use nappies

- RMOs discarded:
  - CLH under CLP Regulation
  - Other legislations (GPSD, Medical Devices, Childcare articles)
  - Development of a specific legislation
  - Development of a specific guide (SCCS)
  - SVHC/Authorisation under REACH
- REACH Restriction = the best RMO
  - Harmonized regulation / equal conditions
  - Allows for grouping
  - Addresses several hazard endpoints
  - Covers internal market products + imported products

Existing regulation / labels

Country/region	Brief details
Germany	baby diapers are commodities included in the German Food and Feed Code (LFGB): recommendations on materials and chemicals used
Cosmetics Regulation (EU) 1223/2009	chemicals used in lotions
Eu Ecolabel	criteria that companies must comply with to label their baby diapers with EU Ecolabel
Nordic Swan Ecolabel	criteria that companies must comply with to label their baby diapers with Nordic Swan Ecolabel
Oeko Tex Label	criteria that companies must comply with to label their baby diapers with Oeko Tex Label
FSC Label	criteria that companies must comply with, e.g. the products are sourced from sustainably managed forests
TCF, PCF SI Labels	criteria that companies must comply with, such as certifying that the products have been manufactured and bleached without any use of chlorine
OK biobased Vinçotte Label	criteria that companies must comply with, such as the concentration of the products in renewable raw materials.
GPSD (2001/95/EC)	Only regulation these articles are subjects of
EDANA guides	Guidelines (diaper consumer test, sampling, performance test etc..)

Voluntary actions

- Based on ANSES 2019 report, FR CA ask distributors and manufacturers to take measures to remove hazardous chemicals present in single use baby nappies. Voluntary actions agreed on:
  - To remove allergenic chemicals, especially fragrances
  - To identify and remove all the contamination sources possible due to hazardous chemicals, by an exhaustive analysis of their supply chain and process. Action plan based on 2 axes:
    - *Regarding raw materials*: industry to complete a diagnosis of the quality of their supply chain. Based on this diagnosis, industry to take necessary measures like for example reinforced quality controls.
    - *Regarding the process*: industry to make a detailed audit of their manufacturing process to identify for each step, where hazardous chemicals are formed. On this basis, industry to take measures to improve their process.
  - To inform the consumer regarding the products compositions through their website and then through labelling on packaging

Scope of our investigation / articles

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

Scope of our investigation / chemicals

- PAHs
- Dioxins
- Furans
- DL-PCBs
- 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

Elements of assessment

- Risk assessment
  - Concentrations
  - Human health assessment (via nappies wearing)
- Analysis of alternatives (unintentional uses)
  - Technical and economic feasibility of alternatives
- Socio-economic analysis
  - Costs: costs for affected industry / society
  - Benefits: valuation of human health benefits

Timeline (2019/2020)

Q4
- Project scoping and information / data gathering (RMOA public consultation)
- Literature review

Q1
- Further information / data gathering
- **'Call for evidence' (11 weeks until 31 March 2020)**

Q2
- Annex XV report writing

Q3
- Finalisation of Annex XV report for submission in October 2020 (if restriction proposed)

Call for evidence

- Open until 31 March 2020

Substance Details

Name	Substances in single-use nappies
EC Number	-
CAS Number	-
Start of consultation	15/01/2020
Deadline for providing input	31/03/2020
Subject of the call	Preparation of an Annex XV restriction dossier on the use of certain chemicals identified as of concern in single-use baby nappies
Objective of the call	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.
Target group	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.
How to submit your contribution	**Give Comments**
Related documents	
Background note	

Who should participate in the call

- Manufacturers, suppliers, distributors, importers
- Trade associations
- Scientists
- NGOs
- Labels and certification bodies
- Member States

Information can be submitted confidentially

Specific evidence and information requested

Q1. Scope of the restriction (1/2)

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?)

Q1. Scope of the restriction (2/2)

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?
2. May they come from the manufacturing 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 in their manufacturing site and along the supply chain.

Q2. Exposure assessment, information about:

a. Weight of the various types of single use baby nappies
b. Skin absorption for each substance or group of substances
c. Transfer from nappies to the skin
d. Babies body weight
e. Number of diapers used per 24h period
f. Differences of use within EU Member States

Q3. Concentration limits and analytical methods

a. There are no available standardized methods to measure the substances of concern in a urine simulant. Information about any laboratory currently working on a standardized method based on the one published in France in 2019 by SCL and used to perform the tests in the ANSES 2019 report?

b. Information about daily volume of urine for babies under the age of three

Q4. Analysis of alternatives (1/2)

a. If none of the substances detected or quantified in nappies is intentionally added during the manufacturing process:

   i. Detailed description of the typical manufacturing process of a nappy

   ii. Identification of the critical steps responsible for the presence of the substances of concern

   iii. Any possible technical means to remove these substances from the final nappies

   iv. Potential impacts of implementing these means

   v. Occurrence and implementation of best practice to minimize such residues and contaminants

Q4. Analysis of alternatives (2/2)

b. If the substances detected or quantified in nappies may come from the raw materials used:

i. Detailed description of the typical raw materials used in the manufacturing of a nappy

ii. Identification of the most critical raw materials that are responsible for the presence of the substances of concern

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

Q5. Information on socio-economic impacts in response to a possible restriction :

a. Quantitative or qualitative information on:

   i. Costs and benefits to affected actors;

   ii. 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, turnover

   iii. Number of people employed in the EU or abroad

   iv. Any information enabling to characterise potential impacts on the nappies market within the EU.

Q&A

Q&A session

Peter Simpson
Restriction process coordinator (ECHA)

Céline Dubois
Scientific project manager (ANSES)

Karine Fiore
Regulatory and socio-economic projects manager (ANSES)

Next steps

- Q&A document based on questions received: as soon as possible
- Information session recording online
- End of call for evidence: 31 March 2020

Thank you!

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