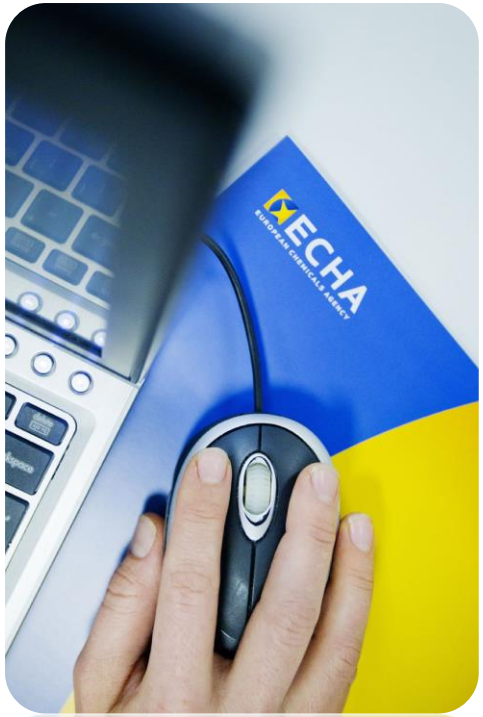
Online information session

Consultation on proposed restriction of substances in single-use baby diapers

26 January 2021
11:00 – 13:00 Helsinki time

What you can expect from today

- **Learn about** the REACH restriction process
- **Learn about** the proposed restriction of substances in single-use baby diapers and how you can contribute to the opinion-making process on the proposal
- Get **answers** to questions

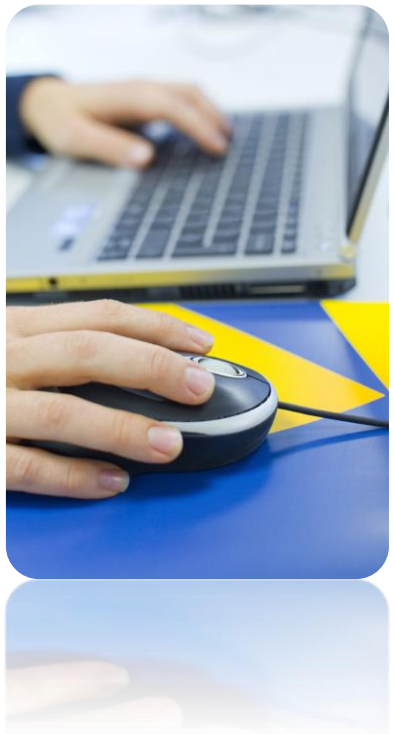


Programme

Time	Title	Speaker
11:00	Introduction to REACH restriction	Peter Simpson
11:20	The proposed restriction	Céline Dubois and Karine Fiore, ANSES
11:40	The specific questions for the consultation	Sanna Henrichson, ECHA
11:55	How to submit information	Bastian Zeiger, ECHA
12:00-13:00	Webinar remains open for questions	

Questions

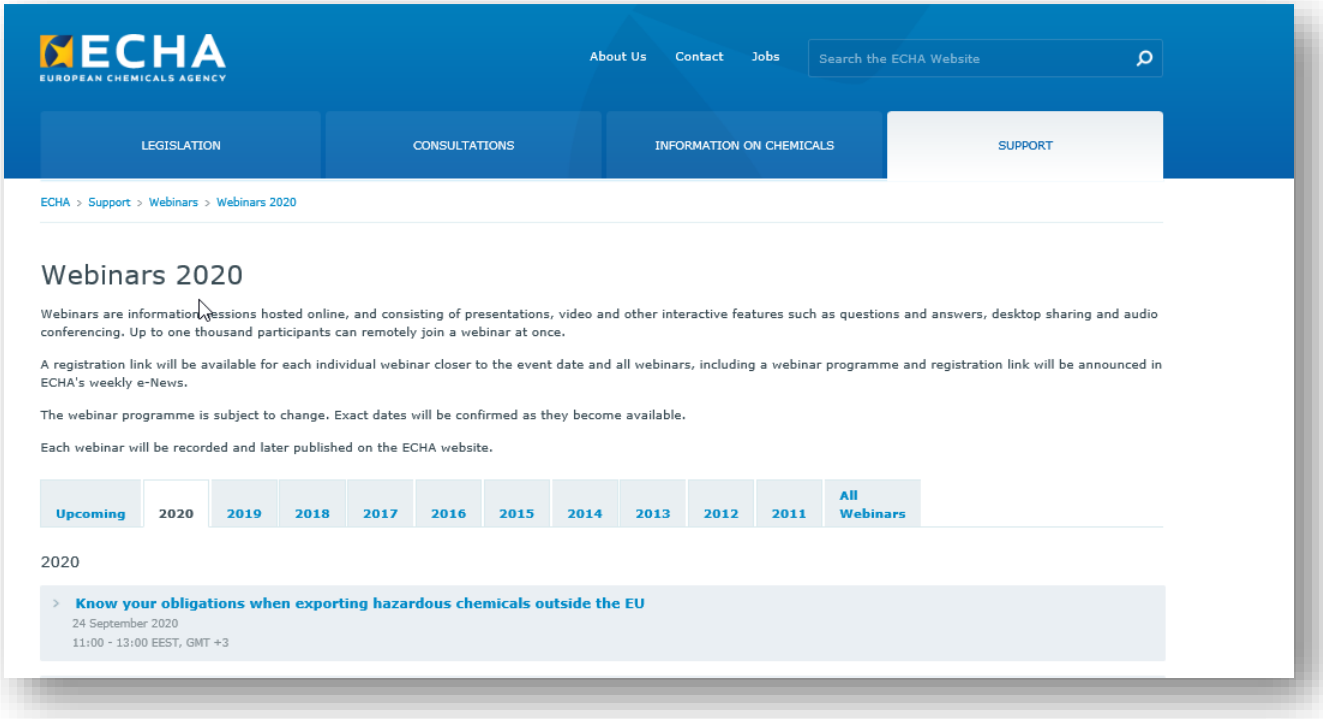
- Join Q&A at: slido.com
  Event code: #diapers2021
- Send questions from **11:00 to 13:00 EET, GMT+2**
- Only questions within webinar scope
- Question not answered?
  Contact us: echa.europa.eu/contact



Material published

Video recording, presentations and Q&A

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



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 (or a group of substances).
- 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(s) on its own, in a mixture or in an article. The substance(s) do not 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, or a group of substances, poses a risk to human health or the environment.
- 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.

Restriction proposal (Annex XV report)

- After notifying an intention a proposal is developed, which has to include:
  - Information on hazards and risk
  - Justification for action at an EU-wide level
  - Available information on alternatives
  - An analysis that demonstrate that a restriction is the most appropriate tool to address the identified risk.
- The proposal may also include an analysis of socio-economic impacts
- France submitted a restriction proposal to ECHA on substances in nappies on 09/10/2020

Evaluation after submission by ECHA

- RAC – risk assessment committee
- SEAC – socio-economic analysis committee
- 'Effectiveness' of a proposed 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)
- Consultations of interested parties

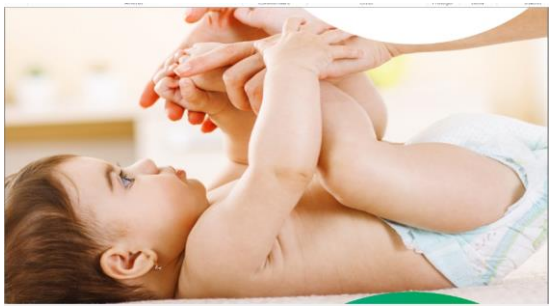
Evaluation timeline

- Restriction proposal made publicly available shortly after submission (~2 weeks)
- Opinion-making process (typically 12 months)
  - Starts with a six month consultation of interested parties after the proposal agreed 'in conformity' (21/12/2020)
  - Evaluation of the proposal by RAC and SEAC is set out in an 'opinion'
  - 2nd (60 day) consultation on the SEAC draft opinion (at month nine of the evaluation)
- Opinions published and sent to Commission for decision-making with background documents

anses
agence nationale de sécurité sanitaire
alimentation, environnement, travail

Connaître, évaluer, protéger

Restriction proposal of formaldehyde, dioxins, furans, PCBs and PAHs in single-use baby diapers



Dossier submitter: French Competent Authority

- The proposed restriction : substances and articles targeted in the restriction proposal
- Concern
- Risk Assessment
- Baseline
- Approach for the Analysis of Alternatives
- Socio-economic Analysis
- Uncertainties
- Need for restriction - summary

The identified problem

1. **A very used article**
   - Since the 90's more than 90% of the families in Europe have been using single use baby diapers
   - Until a child is toilet trained, he will use between 3,800 to 4,800 single use baby diapers.

2. **Baby diapers are subject to the general safety requirements, no regulatory framework specific to these articles**

3. **Hazardous chemicals found in single-use baby diapers**

- Anses evaluation : In 2018 ANSES undertook a study on the presence of chemicals in single-use baby diapers as well as a human health risk assessment
- This study, published in 2019, concluded that:
  - Hazardous chemicals are present in single-use baby diapers
  - Health risks for babies cannot be excluded
  - There is a need of risk management
  - RMOA : restriction is the best way to address the problem

The identified problem

- 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

4. It is difficult to avoid exposure to chemicals in single use baby diapers

- Most of the children and babies under the age of 3 will wear single-use baby diapers
- There is no information for the consumer on which chemicals are present in articles

The proposed restriction

- Substances covered

- **Formaldehyde**
- **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
- **PCBs** (including NDL PCBs and DL PCBs)
- **PCDDs:** 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
- **PCDFs:** 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

- Substances not covered

- Fragrances, VOCs, pesticides etc…

- Articles covered: DISPOSABLE ONES

- **Traditional baby diapers,**
- **Diaper pants** or **training pants** for toilet-training the child,
- **Night diapers**, intended for children over three years of age, in order to help them with toilet training at night,
- **Swimming diapers**, used when babies/children are engaging in water activities.

- Articles not covered
  - Re-usable diapers
  - Incontinence diapers

The proposed restriction

- Formaldehyde in individual concentration equal to or greater than **$2.1.10^{-1}$ mg/kg of diaper** for all the articles specified in paragraph 1.

- The sum of the quantified PCDDs, PCDFs, and DL-PCBs in concentration equal to or greater than **$7.0.10^{-10}$ mg_{TEQ}/kg of diaper** for all the articles specified in paragraph 1.

- The sum of the quantified PCBs in concentration equal to or greater than **$4.9.10^{-5}$ mg/kg of diaper** for all the articles specified in paragraph 1.

- The sum of the detected or quantified PAHs in concentration equal to or greater than **$3.7.10^{-6}$ mg_{TEQ}/kg of diaper** for all the articles specified in paragraph 1.

- The restriction shall apply **24 months** after its entry into force.

Concern

- **PAHs**
  - Mutagenicity
  - Carcinogenicity
- **Formaldehyde**
  - Dermal irritation and sensitization
  - Toxic effects in the tissues of direct contact after oral or dermal exposure
  - Mutagenicity
  - Carcinogenicity
- **Dioxins, Furans**
  - Carcinogenicity
  - Effects on reproduction
  - Hepatic, immunological, neurological, metabolic and endocrine effects
- **PCB (Dioxin-like and Non-dioxin like dioxin)**
  - Dermal irritation
  - Carcinogenicity (TEF)
  - Reprotoxic effects
  - Hepatic, immunological, neurological, metabolic and endocrine effects

Approach for the risk assessment

- All substances in the scope : quantified/detected in single use diapers implying potential exposure of children and babies.
- Usual Risk assessment approach in 4 steps : Hazard, Dose-response relationship, exposure and risks
- Hazards are established - Substances whose hazard profile suggests that exposure may cause adverse effects
- Internal DNEL corrected with the oral bioavailability, were used as reference dose
- The Dossier Submitter decided to limit the share allocated to baby diapers to 10% of the DNEL/DMEL.

Approach for the risk assessment

- Parameters needed to perform exposure assessment: most of them available
- Risk assessment performed: **quantitative approach**

Concentration limits calculated for the youngest class of age (0-6 months) to be the most protective: the so derived concentration limits will then cover all categories of ages and sizes of diapers available on the market.

Proposed concentration limits

SUBSTANCES OR GROUPS OF SUBSTANCES	PROPOSED CONCENTRATIONS LIMITS (mg/kg of diaper)
Formaldehyde	**2.1×10^{-1} mg/kg of diaper**
Sum of quantified PCDDs, PCDFs and DL-PCBs in TEQ	**7.0×10^{-10} mg_{TEQ}/kg of diaper**
Sum of quantified PCBs	**4.9×10^{-5} mg/kg of diaper**
Sum of quantified or detected PAHs in TEQ	**3.7×10^{-6} mg_{TEQ}/kg of diaper**

→ **The concentration limits should aim at preventing adverse effects in children and infants likely to be associated to the exposure to chemicals contained in single-use baby diapers.**

Uncertainties

- **Lack of harmonised analytical method**
- **Justified assumptions were used in those cases**
- **Public consultation may give more information**

The DS proposes an analytical method (considered as representative of the reality of use)

anses

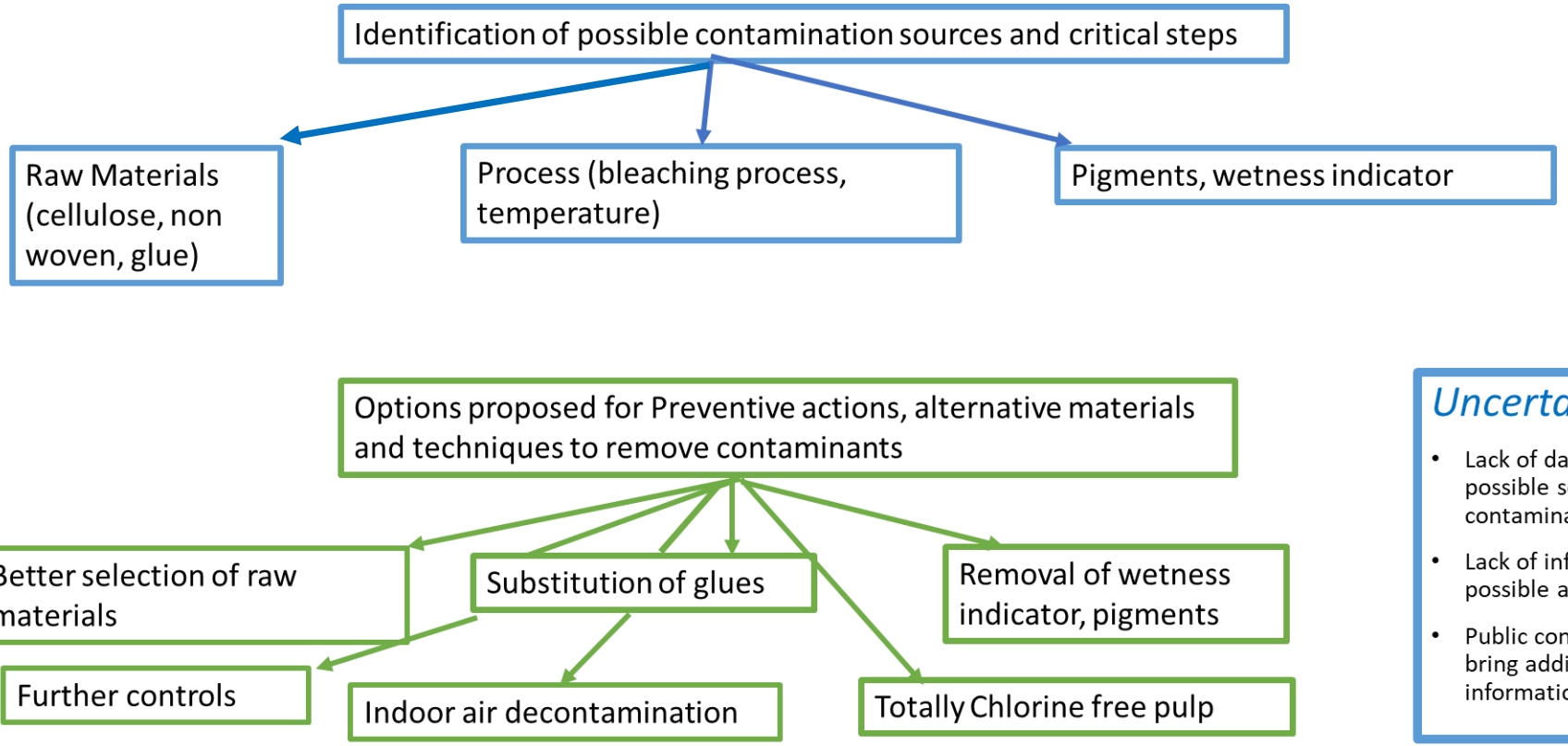
Baseline

- Geographical boundaries for the assessment are the countries of EEA31
- Voluntary actions and label exist. (can be effective and help to achieve public policy aims but they are not REGULATORY schemes)
- Diapers consumption has constantly grown since the 80's and will continue to grow
- Assumption of 90% of European children and babies wear only single-use baby diapers. (i.e. 14.5 million of babies and infants)

Diseases linked to the chemicals of concern in single-use baby diapers, will steadily increase over time.

Approach for the Analysis of Alternatives

- Substances in the scope are not voluntarily added to single use baby diapers, they seem to be **CONTAMINANTS** for most of them



Uncertainties

- Lack of data for some possible sources of contamination
- Lack of information on possible alternatives
- Public consultation may bring additional information

SEA - The expected costs of the proposed restriction

- 'Substitution' costs: unusual approach since chemicals are mostly contaminants
  - Costs of changes in raw materials selection, technical adaptations, further controls along the supply chain => semi-quantitative assessment
  - For example :
    - +200,000€ - 400,000€ per year per company (> +17% per year; +1% and +2% of current costs per products range) to switch from ECF to TCF bleaching process + 1 million€ extra- investments
    - Further controls of temperatures : insignificant costs
    - Further decontamination of indoor air: broad estimate "in the millions euros per production plant"

✓DS conclusion:

- ✓Industry has already implemented many changes since 2019 therefore many costs are not due to the restriction but are already borne
- ✓Costs assessment is mainly indicative since they will depend on actions industry will actually opt for
- ✓Industry claim that at least 2 years would be needed to implement the remaining compliance changes and adaptations
- ✓Some uncertainties

Uncertainties

- Public consultation may bring additional information
- Some possible overlapping

SEA - The expected costs of the proposed restriction

- Testing costs: further testing due to regulatory compliance (new concentration limits)
  - Test of raw materials: 50,000€ - 200,000€ per year per company (+300% extra cost); 1,000-3,000€ charged by laboratories per material tested; up to 35 materials to test
  - Test of finished products: 100,000-200,000€ per year per company (+25%-50% extra cost); >1,000€ charged by laboratories per product tested
  - Extra audits on manufacturing site: 20,000€ per audit per year - 1,000€ per process step analysed
  - No information about testing costs for importing companies (very few)
  - Scarce information on testing frequency

✓ DS conclusion:
  ✓ Industry has already strengthened their testing practices since 2019 therefore many costs are not due to the restriction but are already borne
  ✓ Costs assessment is mainly indicative

- Enforcement costs: on average, all Member States spend approximately 55 600€ per restriction per year (in 2014 values) to ensure compliance with Annex XVII of REACH
  - May be lower : economies of scale with other restrictions

Uncertainties

- Public consultation may bring additional information
- Testing costs will depend on the availability and feasibility of a harmonised analytical method

SEA -The expected costs of the proposed restriction

- Impacts on consumers

  - Average price at point of sale ≈ 0,20€ - 0,30€ / diaper
  - Industry claim between +2% + 10% price increase (rough, no justification)

  ⇒ Distributional effects on consumers and households

  !!However:

  - Highly competitive market on price; mass consumption market
  - Market players are expected to most probably absorb extra costs

  ✓DS conclusion:

  ✓Price increase (if any) would be moderate and temporary

  ✓The restriction is considered affordable

SEA - The expected human health benefits

Qualitative assessment

- No epidemiological studies
- No data to model the diseases occurrence in babies
- No prevalence data and no attributable fraction available

!!Nevertheless :

- A risk has been demonstrated
- CMR substances and some suspected EDCs
- Severe, various and latent diseases: cancers, fertility, ED properties, irritation and skin sensitization

✓DS conclusion:

✓Significant benefits : 90% of European babies would be protected = 14.5 million babies

✓vulnerable population, intergenerational and equity considerations

Uncertainties

- Lack of harmonized analytical method
- Few low-dose dermal studies
- Expert judgement for some parameters in the exposure assessment
- Lack of information regarding the possible sources of contamination
- Lack of data regarding the possible alternatives
- Impacts and socio-economic analysis :
  - uncertainties on actual reactions of industry (actions to be implemented to reduce contamination)
  - uncertainties on actual costs associated
  - uncertainties actual costs of testing with a harmonized analytical method

Main conclusions- Need for restriction

- Risks from formaldehyde, PAHs, PCDD/Fs, PCBs in single-use baby diapers:
  - Are not adequately controlled
  - Pose an EU-wide risk

- The restriction proposal is proportionate to the risk and affordable:
  - Human health benefits (not quantified) expected to be significant
  - Compliance costs (semi-quantified) expected to be affordable to industry but uncertainties remain

- The restriction proposal is:
  - Effective
    - Targeted to the exposure that causes the risk
    - Capable to reduce the risks to human health to an acceptable level after 2 years of EIF
  - Practical (implementable, enforceable, manageable) and monitorable
    - Costs of testing however are uncertain (no harmonised analytical method)

- Public consultation may bring additional information

Thank you for your attention

Specific information requests

Consultation on proposed restriction of substances in single-use baby diapers

26 January 2021

Sanna Henrichson

What to submit?

- Any information you consider relevant
- Some topics on which Committees and dossier submitter particularly welcome information. Covered in ‘Specific Information Requests’
- Remember to give evidence to support any claims you make in your responses

Question 1
Sources and alternatives

1. Please provide, if possible and specifying clearly which substance(s) within the scope of the proposed restriction the information relates to, more detailed information on:

a) Whether any of the substances in the scope of the restriction are intentionally used in the manufacture of single-use diapers.

b) Possible sources of contamination by the substances covered by this restriction.

Question 1
Sources and alternatives

c) Which efforts (e.g. change of mechanical processes, technical improvements, substitution of raw materials, cleaning of raw materials) have already been undertaken by industry lately to reduce the contamination in baby diapers, for example through voluntary actions and good practice?

d) Ways/additional effort to further reduce or prevent this contamination and the (dis)advantages/costs associated with these.

Question 2

Restriction scenario

2. Please provide information on how industry would respond if the proposed restriction enters into force and what the associated impacts would be (e.g. costs to industry players, impacts on consumers). Please be as specific as possible and provide the break-down for any costs provided.

Question 3
Costs and proportionality

3. The Annex XV dossier makes several assumptions on costs and proportionality. Please provide specific and detailed feedback on the following:

a) The Annex XV report suggests that contaminants may be reduced by moving from elemental chlorine free (ECT) to total chlorine-free (TCF) pulp. Do you have any further information on how many companies and sites would need to move to TCF in the EEA in order to comply with the proposed restriction and on the associated costs presented in the report (increased operating cost of €200 000 - 400 000 per year per company and additional investment cost of €1 million per site)?

Question 3
Costs and proportionality

b) The Annex XV report suggests that one way of reducing the contaminants could be further decontamination of indoor air with a broad cost estimate “in the millions euros per production plant”. Please provide more information on whether this measure would be likely to help industry to comply with the restriction and, if so, provide more specific information on the associated costs, including how many production plants that would incur such costs.

Question 3
Costs and proportionality

c) The Annex XV report outlined possible testing costs for industry to test raw materials and final products but states that these are uncertain. Please provide specific and detailed information about:

- the current testing practices and associated costs for the single-use diapers sector.
- the expected incremental testing costs associated with the proposed restriction (i.e. the additional costs as compared with the current ones).
- how many companies would incur incremental testing costs as a result of the proposed restriction.

d) The Annex XV report states that the diaper market is expected to grow or at least stay as it is now, but birth rates are slowing down. Would you agree and why (not)?

Question 3
Costs and proportionality

e) In relation to impacts on consumers:

- Would there be consumer surplus losses (i.e. a loss of utility for consumers buying the products) related to the restriction? Do you have any studies or other information on how valuable consumers consider wetness indicators, pigments or other functional additives in diapers that may need to be removed to comply with the proposed restriction?
- The Annex XV report assumes that the diaper market is highly competitive on price and increased costs in production is not likely to be passed on to consumers. Would you agree and why (not)? If you think the restriction would result in a price increase for diapers, please specify how much and justify such an increase based on the information you have provided about the costs incurred by industry.

Question 3
Costs and proportionality

e) The Annex XV report presents two restriction options:

- Restriction option 1 (the proposed restriction, RO1): Limiting concentrations of formaldehyde, the sum of detected or quantified 17 PAHs, the sum of quantified PCDD/Fs and PCBs, the sum of quantified PCBs.
- Restriction option 2 (RO2): Limiting concentrations of all the substances and sum of substances listed in RO1 and all the congeners of the PAHs, PCDD/Fs and DL-PCBs.

Please provide information about how the costs and benefits of RO2 would compare with those of RO1.

Question 4

Data on exposure and adverse effects

4. Are you aware of any human or animal biomonitoring data regarding the exposure to hazardous substances via baby diapers? Are you aware of any human or animal data on adverse health effects following exposure to the substances in the scope via baby diapers (excluding skin allergies or irritation)?

Question 5

Analytical methods

5. Are you aware of any analytical methods which can be used to measure the substances, at the levels proposed in this restriction, in diapers or in other comparable products/compositions/textiles? If not, how long would it take to develop a (i) validated and (ii) standardised analytical method with the required LoQ (limit of quantification)?

Question 6

Risk assessment

6. Can you provide comments on the approach used for the risk assessment? This would be particularly relevant for:

a) the values used for the parameters for risk assessment, as well as the studies that would support the possible choice of other values.

b) the effectiveness, appropriateness and reliability of the extraction procedure, the urine simulant method, etc. to extract chemicals from diapers.

What happens to your comments?

- Published on our website (circa monthly).
- Scrutinised by the Dossier Submitter (France), RAC and/or SEAC and – if considered significant, addressed in the background document and/or in the opinion
- Dossier Submitter and RAC and/or SEAC provide a response to all comments and submitted information
  - Responses published on our website at the end of the process

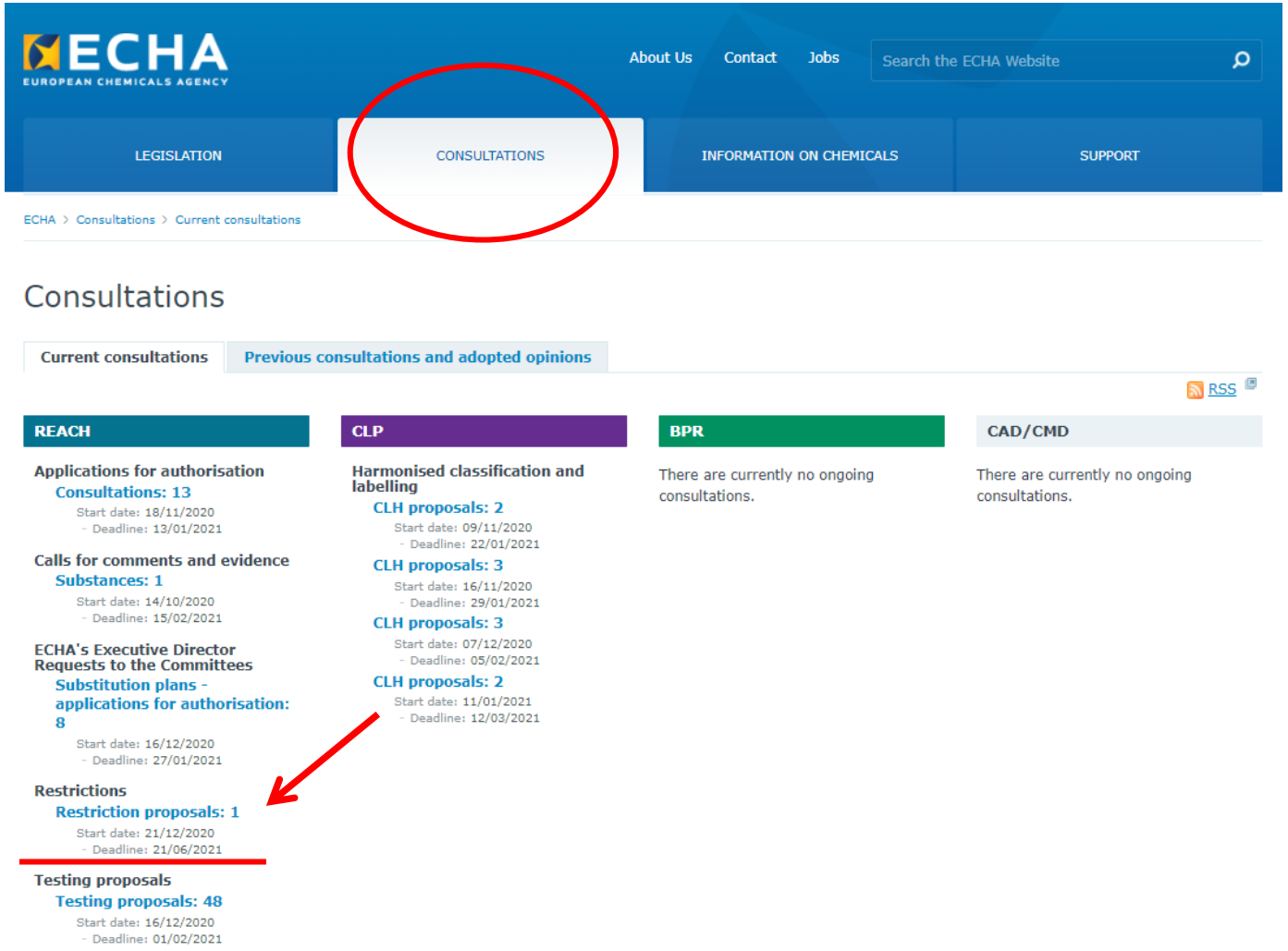
How to give input?

Consultation on proposed restriction of substances in single-use baby diapers

26 January 2021

Bastian Zeiger

https://echa.europa.eu/consultations/current



Submitted restrictions under consideration

https://echa.europa.eu/restrictions-under-consideration

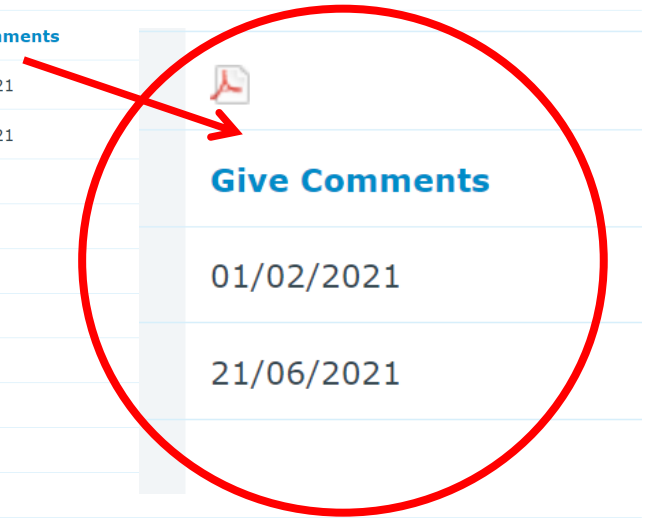
Submitted restrictions under consideration

Name	EC Number	CAS Number	1st deadline for comments on restriction report	Final deadline for comments on restriction report	Deadline for comments on SEAC draft opinion	
Substances in single-use nappies	-	-	01/02/2021	21/06/2021		Details
undecafluorohexanoic acid (PFHxA), its salts and related substances	-	-	13/05/2020	25/09/2020		Details

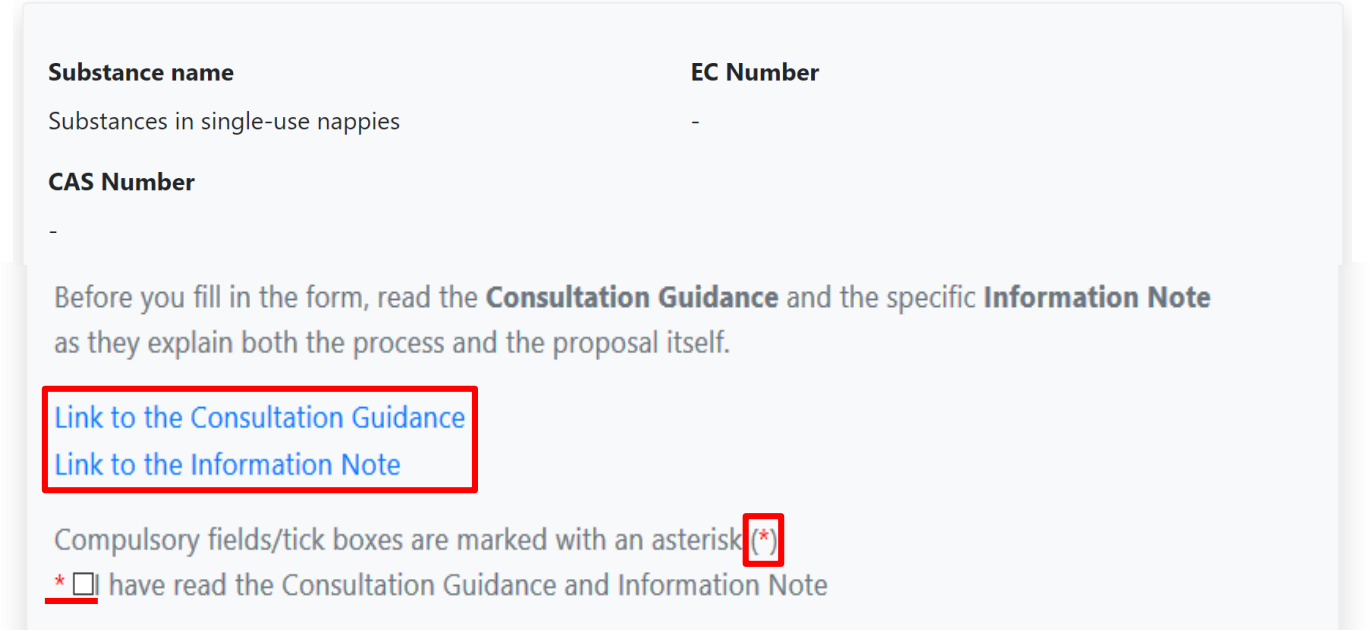
Substance details

Substance Details

Name	Substances in single-use nappies
EC Number	-
CAS Number	-
Submitted by	France
Scope	Restriction on the placing on the market of disposable baby nappies (diapers) containing the following chemical/chemical groups, such as PAHs, formaldehyde, dioxins, furans, PCBs, ...
Information note on restriction report	
Restriction report	
Restriction report annexes	
Consultation on restriction report	**Give Comments**
1st deadline for comments on restriction report	01/02/2021
Final deadline for comments on restriction report	21/06/2021
Comments submitted to date on restriction report	
Response to comments on the restriction report	
Draft opinion of SEAC	
RAC & SEAC (draft) Background document	
RAC & SEAC (draft) Background document appendix	
Consultation on SEAC draft opinion	
Deadline for comments on SEAC draft opinion	
Comments submitted to date on SEAC draft opinion	
Response to comments on the SEAC draft opinion	



Comments for Annex XV restriction report



Substance name

Substances in single-use nappies

EC Number

-

CAS Number

-

Before you fill in the form, read the **Consultation Guidance** and the specific **Information Note** as they explain both the process and the proposal itself.

Link to the Consultation Guidance
Link to the Information Note

Compulsory fields/tick boxes are marked with an asterisk (*)
* ☐ I have read the Consultation Guidance and Information Note

Consultation guidance

- What information can be submitted and the level of information needed
  Consultation (6 months) on Annex XV restriction report
- Is it your first consultation?

Information note

- Summary of proposed restriction
- Timeline of consultation
- How to submit a comment

Filling in the form

SECTION I. Personal information

SECTION II. Organisation

SECTION III. Non-confidential comments

- General comments

  (General comments can be on any aspect of the Annex XV restriction proposal, including issues related to socio-economic analysis)

- Specific information requests

  (These are several specific questions for which we would like to have your input where possible)

SECTION IV. Non-confidential attachment

SECTION V. Confidential Attachment

Responses can be entered directly into the form or through section IV or V as attachments

Submission of comments

! It is **not possible to save your submission** and come back to it. Prepare your comments in an attachment or saved in another format in advance

- Once finished, press submit and your comments will be sent to us. You will receive a **submission number** via e-mail. **Refer to it in any communication with us** on this topic
- It is not possible to retrieve your submission. You can take a screen shot, or printed copy for your reference

Once you are ready

Submit to ECHA

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