Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Substances in single-use baby diapers

ECHA/RAC/[Opinion N°(same as opinion number)]

ECHA/SEAC/[Opinion N°(same as opinion number)]

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted [xx Month 20xx]) and SEAC's opinion (adopted [xx Month 20xx])

Draft date: September 2021

[Date]

[RAC opinion number]

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): **Substances in single-use baby diapers**

EC No.: **-**

CAS No.: **-**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration on **21 December 2020**. Interested parties were invited to submit comments and contributions by **21 June 2021**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Veda VARNAI

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON SUBSTANCES IN SINGLE-USE BABY DIAPERS

Co-rapporteur, appointed by RAC: Sonja KAPELARI

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **[date of adoption of the opinion]**.

[The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article 69(6)).**]**[1]

The opinion of RAC was adopted **by [consensus**.**][a simple majority]** of all members having the right to vote. [The minority position(s) including their grounds are made available in a separate document which has been published at the same time as the opinion.**]**[4]

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Simon COGEN

Co-rapporteur, appointed by SEAC: Marit MÅGE

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **9 September 2021.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5 on **15 September 2021**. Interested parties were invited to submit comments on the draft opinion by **14 November 2021**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[2].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted **by [consensus**.**][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)
[2] Delete the unnecessary part(s)

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Substances	Conditions of the restriction
Formaldehyde (CAS Number: 50-00-0) Polychlorobiphenyls (DL-PCBs and NDL-PCBs) Polycyclic aromatic hydrocarbons (PAHs) Polychlorinated dibenzo-p-dioxins (PCDDs), Polychlorinated dibenzofurans (PCDFs) The PAHs, PCDDs, PCDFs, and PCBs involved in this restriction are listed in the table 1.	1. Shall not be placed on the market, after the 01/01/2024, in any of the disposable baby diapers such as: ○ **Traditional baby diapers,** ○ **Diaper pants** or **training pants** for toilet-training the child, ○ **Night diapers**, in order to help them with toilet training at night, ○ **Swimming diapers**, used when babies/children are engaging in water activities. Intended to be used for children and infants, if, the substances migrate in a concentration equal to or above the limits specified in paragraph 2. 2. For the entire articles listed in paragraph 1, the following substances should not migrate in a concentration equal to or greater than the migration limits specified below: i. Formaldehyde in individual migration limit equal to or greater than **0.42 mg/kg of diaper** for all the entire articles specified in paragraph 1. ii. The sum of the quantified PCDDs, PCDFs, and DL-PCBs in a migration limit equal to or greater than **0.0017 ng_{TEQ}[3]/kg of diaper** for all the entire articles specified in paragraph 1. iii. The sum of the quantified PCBs in a migration limit equal to or greater than **112 ng/kg of diaper** for all the entire articles specified in paragraph 1. iv. The sum of the detected or quantified PAHs in a migration limit equal to or greater than **0.023 ng_{TEQ}/kg of diaper** for all the entire articles specified in paragraph 1. 3. Paragraphs 1 to 2 shall apply without prejudice to the application of any stricter restrictions or existing regulations.

[3] TEQ used are the ones from WHO 2005, please refer to Annex B

	4. Paragraphs 1 to 2 shall not apply to i. Re-usable diapers ii. Incontinence diapers as defined as a medical device in the sense of the regulation EU 2017/745 5. An analytical method developed using extraction by urine simulant in a whole diaper shall be used as the test method for demonstrating the conformity of articles to paragraphs 1 and 2. A standardized method needs to be defined. The restriction shall apply 24 months after its entry into force.

DL-PCBs: Polychlorinated biphenyls having no or one chlorine substitution in the ortho position.
NDL-PCBs: Polychlorinated biphenyls having more than one chlorine substitution in the ortho position.

Table 1 List of substances that are involved in this restriction proposal

Group of substances	**Substance name**	**CAS Number**	**EC number**
Formaldehyde	Formaldehyde	50-00-0	200-001-8
PAHs	benzo[*c*]fluorene	205-12-9	205-908-2
	benz[*a*]anthracene	56-55-3	200-280-6
	cyclopenta[*c,d*]pyrene	27208-37-3	-
	Chrysene	218-01-9	205-923-4
	5-methylchrysene	3697-24-3	-
	benzo[*e*]acephenanthrylene	205-99-2	205-911-9
	benzo[*k*]fluoranthene	207-08-9	205-916-6
	benzo[*j*]fluoranthene	205-82-3	205-910-3
	benzo[*e*]pyrene	192-97-2	205-892-7
	benzo[*def*]chrysene	50-32-8	200-028-5
	dibenz[*a,h*]anthracene	53-70-3	200-181-8
	indeno[1,2,3-*c,d*]pyrene	193-39-5	205-893-2
	benzo[*g,h,i*]perylene	191-24-2	205-883-8
	dibenzo[*def,p*]chrysene	191-30-0	205-886-4
	naphtho[1,2,3,4-*def*]chrysene	192-65-4	205-891-1
	benzo(*r,s,t*)pentaphene	189-55-9	205-877-5
	dibenzo[*b,def*]chrysene	189-64-0	205-878-0
PCDDs	2,3,7,8-tetrachlorodibenzo[*b,e*][1,4]dioxin; 2,3,7,8-TCDD	1746-01-6	217-122-7
	1,2,3,7,8-pentachlorodibenzo-*p*-dioxin; 1,2,3,7,8-PeCDD	40321-76-4	-
	1,2,3,4,7,8-hexachlorodibenzo-*p*-dioxin; 1,2,3,4,7,8-HxCDD	39227-28-6	-
	1,2,3,6,7,8-hexachlorodibenzo-*p*-dioxin; 1,2,3,6,7,8-HxCDD	57653-85-7	-

	1,2,3,7,8,9-hexachlorodibenzo-*p*-dioxin; 1,2,3,7,8,9-HxCDD	19408-74-3	-
	1,2,3,4,6,7,8-heptachlorodibenzo-*p*-dioxin; 1,2,3,4,6,7,8-HpCDD	35822-46-9	-
	octachlorodibenzo-*p*-dioxin; OCDD	3268-87-9	-
PCDFs	2,3,7,8-tetrachlorodibenzofuran; 2,3,7,8-TCDF	51207-31-9	-
	1,2,3,7,8-pentachlorodibenzofuran; 1,2,3,7,8-PeCDF	57117-41-6	-
	2,3,4,7,8-pentachlorodibenzofuran; 2,3,4,7,8-PeCDF	57117-31-4	-
	1,2,3,4,7,8-hexachlorodibenzofuran; 1,2,3,4,7,8-HxCDF	70648-26-9	-
	1,2,3,6,7,8-hexachlorodibenzofuran; 1,2,3,6,7,8-HxCDF	57117-44-9	-
	2,3,4,6,7,8-hexachlorodibenzofuran; 2,3,4,6,7,8-HxCDF	60851-34-5	-
	1,2,3,7,8,9-hexachlorodibenzofuran; 1,2,3,7,8,9-HxCDF	72918-21-9	-
	1,2,3,4,6,7,8-heptachlorodibenzofuran; 1,2,3,4,6,7,8-HpCDF	67562-39-4	-
	1,2,3,4,7,8,9-heptachlorodibenzofuran; 1,2,3,4,7,8,9-HpCDF	55673-89-7	-
	octachlorodibenzofuran; OCDF	39001-02-0	-
PCBs	All the PCBs (DL and NDL are included in the scope of the restriction)		-

1.1. THE OPINION OF RAC

See RAC opinion

1.2. THE OPINION OF SEAC

The opinion of RAC did not consider that the proposed restriction is appropriate because the restriction under REACH is not considered to be the most appropriate EU wide measure to address the identified risks. Therefore, there is not a sufficient justification for a restriction and SEAC has no basis to support the proposed restriction as demonstrated in the justification supporting this opinion.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The restriction proposal aims at reducing health risks associated with the wearing of single-use baby diapers by children and infants.

Diapers are products made of several materials whose objectives are to absorb and retain the child's urine and faeces while keeping their skin clean and dry. Since the 1990s, single-use baby diapers have been used by more than 90% of families in most of the European Union countries. Estimates of the total number of single-use baby diapers used by a baby before the age of toilet training range from 3 800 to 4 800. These estimates vary depending on the age at which it is considered that children are fully toilet trained.

Polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and formaldehyde have been detected and/or quantified in single-use baby diapers through analytical tests using urine simulant.

Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity and skin sensitization according to the CLP Regulation. Furthermore, formaldehyde has been restricted in toys, in other articles and is intended to be restricted for its skin sensitization property in single-use baby diapers in the on-going restriction proposal according to REACH.

PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action. The PAHs addressed by this restriction proposal have a harmonised or a self-classification for carcinogenicity under the CLP regulation. Furthermore, some of these PAHs have been examined by RAC and SEAC for a restriction under REACH when present in granules and mulches used in synthetic turf pitches, or in loose forms at playgrounds and other sports facilities.

PCDD/Fs and DL-PCBs have been quantified in single-use baby diapers implying potential exposure for children and infants wearing these articles and have been targeted for various health effects (fertility, dermal, etc.).

According to the risk assessment performed, the Dossier Submitter concludes that the risk occasioned by the presence of PAHs, PCDD/Fs, PCBs and/or formaldehyde in single-use baby diapers is currently not adequately controlled. An analysis of several risk management options (RMOs) has therefore been conducted to identify the most appropriate measure to address the risk and to define the scope and conditions of the restriction proposal. It has been concluded that a restriction under REACH is the most appropriate RMO. Two restriction options are further analysed in the impact assessment. They all aim at limiting the above listed chemicals or groups of chemicals at specified migrations in single-use baby diapers placed on the market but differ in which substances are covered.

The restriction options further assessed are the following:

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

substances listed in RO1 and all the congeners of the PAHs, PCDD/Fs and DL-PCBs[4].

The Dossier Submitter considers these substances to have the potential to induce adverse effects in babies if present in single-use baby diapers that come into contact with the skin.

2.2. Summary of opinion

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties, the opinion of RAC, as well as other available information as recorded in the Background Document.

SEAC concluded that it has not been demonstrated that the proposed restriction would be proportionate based on several arguments which are elaborated throughout the opinion and summarised below.

RAC concluded that the uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. Therefore, SEAC does not find it appropriate to take action on a Union-wide basis.

It should be noted however that based on SEAC's assessment, the proposed restriction (RO1) would have been practicable, monitorable and the most appropriate EU-wide measure out of those assessed by the Dossier Submitter, if the Dossier Submitter had demonstrated an EU-wide risk related to single-use baby diapers.

There is uncertainty regarding whether the substances in scope are detected in single-use baby diapers above the proposed migration levels. There is also significant uncertainty as to the source(s) of the substances detected in diapers by the Dossier Submitter. While the Dossier Submitter has analysed possible sources of, for example potential contaminants, it is not clear whether these are the actual sources. Given that it is not known where the substances come from, there is also uncertainty about what industry would need to do to eliminate or reduce them. Furthermore, there is even uncertainty as to whether industry would be able to comply with the proposed restriction. As such, the Dossier Submitter's statement that feasible alternatives for all substances and possible sources are available, was questioned by SEAC.

Considering the identified uncertainties, SEAC found it difficult to reach a conclusion on the possible costs associated with the proposed restriction. On the benefits, the fact that there are no epidemiological studies or other forms of quantification of adverse effects associated with infants wearing single-use diapers, together with RAC's conclusion on risk, led SEAC to conclude that the benefits of the proposed restriction are not demonstrated.

As the benefits of the proposed restriction are not demonstrated and the costs are highly

[4] This is the wording used by the Dossier Submitter but SEAC notes that all PCBs, including DL-PCBs, are already covered by RO1.

uncertain, SEAC discussed possible scenarios[5] to underpin its conclusion on proportionality. For all possible scenarios SEAC concluded that there is no evidence that the proposed restriction would be proportionate.

If actions on substances in single-use baby diapers are reconsidered in the future (i.e. not as part of the opinion development of this dossier), SEAC considers that the following topics should be elaborated in order to minimise the uncertainties related to socio-economic impacts:

- evidence regarding whether the substances in scope are detected in single-use baby diapers above the proposed limit values,
- the possible sources of the substances in single-use baby diapers,
- the measures that industry would need to take to eliminate or reduce the presence of substances in single-use baby diapers, and
- the technical and economic feasibility of such measures, including what the impacts on different actors would be.

[5] Depending on whether substances within scope are detected or not, and whether measures to reduce any contamination are available or not.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

See RAC opinion.

3.1.2. Description of the risk(s) addressed by the proposed restriction

See RAC opinion.

3.1.3. Information on hazard(s)

See RAC opinion.

3.1.4. Information on emissions and exposures

See RAC opinion.

3.1.5. Characterisation of risk(s)

See RAC opinion.

3.1.6. Uncertainties in the risk characterisation

See RAC opinion.

3.1.7. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

See RAC opinion.

3.1.8. Evidence if the existing regulatory risk management instruments are not sufficient

See RAC opinion.

3.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

At EU level, baby diapers are subject to the general safety requirements defined by European legislation related to consumer goods. There is no regulatory framework specific to babies' diapers in the EU.

According to the Dossier Submitter, one of the primary reasons to act on a Union-wide basis is the cross-boundary human health problem: a risk from exposure exists in all Member States and because trans-boundary trade between Member States exists. A Union-wide regulatory measure would also ensure a harmonised high level of protection for human health across the Union.

SEAC and RAC conclusion(s):

Single-use baby diapers are produced, marketed, transported and used throughout the EU and traded between Member States. As such, action should be taken on a Union-wide basis if a risk from exposure to the substances targeted by this restriction would have been demonstrated.

Furthermore, based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that if action is deemed necessary in regard to single-use baby diapers, it should be implemented in all Member States.

However, RAC has concluded that uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. RAC and SEAC therefore conclude that it does not seem appropriate to take action on a Union-wide basis.

Key elements underpinning the SEAC and RAC conclusion(s):

The Dossier Submitter presents two reasons to justify acting on a union-wide basis:

A. Severity and extent of health risks

While no epidemiological data exists that shows an association between health effects and the wearing of diapers, the Dossier Submitter does contend that there is a risk of exposure to several hazardous substances present in single-use baby diapers above health thresholds. Additionally, children and infants' sensitivity to chemical exposure is known to be higher when compared to adults. The Dossier Submitter estimates that about 90% of European babies (about 14.5 million) wear only single-use diapers.

B. Free movement of goods

Single-use baby diapers, both imported and manufactured, circulate freely throughout the EU. If action is still deemed necessary by the Commission, despite the scientific uncertainties raised by RAC, it should be taken on a union-wide basis to have a harmonised treatment of these goods within the EU and to avoid competitive distortion.

Regarding the above two arguments, SEAC notes that RAC has concluded that uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. As such, the potential severity and extent of that risk and the free circulation of baby diapers throughout the Union do not justify Union-wide action.

3.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

3.3.1. Scope including derogations

Justification for the opinion of RAC

See RAC opinion.

Justification for the opinion of SEAC

Summary of proposal:

The intention of the proposed restriction is to minimise health risks associated with the wearing of single-use baby diapers by children and infants. The restriction proposal covers finished single-use baby diapers which are placed on the market for children and infants.

The articles covered by the restriction proposal are the following:

- Single-use baby diapers,
- Single-use baby diaper pants or training pants for toilet-training the child,
- Single-use night diapers in order to help children and infants with toilet training at night,
- Single-use swimming diapers used when babies/children are engaging in water activities.

The articles not covered by the current restriction proposal are the following:

- Re-usable diapers: Unlike single-use baby diapers, reusable diapers can be reused after being worn and washed. Different types of reusable diapers exist with all or only some parts of them that can be re-usable.
- Incontinence diapers: Incontinence diapers are articles made of various materials which objectives are to absorb and contain urines and (faeces) from incontinent persons while keeping their skin dry. Incontinence diapers are regulated by the regulation EU 2017/745 (Medical Devices) and the target group is adults.

The following REACH restriction options were considered by the Dossier Submitter:

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

RO1 only targets the substances that have been specifically identified as being present in single-use baby diapers. RO2 broadens the scope to also include all congeners of the targeted substance groups and, as was clarified during opinion-development, setting migration limits for each individual substance.

The following risk management options were briefly considered, but not assessed further by the Dossier Submitter:

- Labelling requirements: Harmonised classification of substances according to the CLP regulation entails requirements, such as labelling, but would require a long process given that not all substances in the scope have harmonised classification. Since labelling does not force companies to replace the substances of concern, it is likely to have a smaller economic impact on the EU diaper sector, in comparison to a total ban or a REACH restriction limiting the migration.
- Identification as SVHC according to REACH Article 57 and subsequent authorisation:

SVHC identification and the authorisation system are designed for risk management of one substance (or similar substances) at a time and it would be a very time consuming, and therefore inefficient, process to regulate the risks taking each possible hazardous chemical in single-use baby diapers. Moreover, the requirements for authorisation only apply to articles produced in the EU. Furthermore, the Dossier Submitter notes that under REACH Article 33, the supplier of the article must provide information to consumers if the article contains more than 0.1% of an SVHC. But given that the substances of concern are found in concentrations far lower than 0.1% in single-use baby diapers, they would not need to be notified.

- Harmonised classification of substances under CLP (EC) No 1272/2008: similar challenges as for labelling above.
- Other legislations:
    - The General Product Safety Directive (GPSD) (EC) No 2001/95: Under this legislation consumer products that pose an acute health risk in various Member States, e.g. because of a specific chemical substance, may become temporarily restricted by a Commission Decision. This type of restriction, however, provides only short-term solutions that apply one year at a time awaiting permanent regulations. It does not directly apply in EU Member States, but must be implemented through national legislation, and does thus not imply a full harmonisation. Moreover, the GPSD deals with acute health risk while the concerns raised by the substances in the scope of this assessment are related to chronic health effects.
    - The Medical Device Regulation (EU) No 2017/745: Incontinence diapers are considered as medical device according to the regulation (EU) 2017/745. However, a single-use baby diaper cannot be considered a medical device because it is not an article used to achieve a function that the human body could not achieve anymore.
    - Childcare articles: Single-use baby diapers can be considered as childcare articles according to the definition in Directive 76/769/EEC. However, this definition does not imply any limitation regarding the chemicals present except for the phthalates that are restricted in childcare articles under REACH.
- Development of a specific EU product legislation covering single-use baby diapers: The development of a specific single-use baby diaper regulation is considered possible in the long-term only. Given the current conditions, the risks with chemicals in single-use baby diapers can be addressed under existing chemical regulations (meaning the restriction under REACH regulation). If a specific baby diapers regulation is further developed, existing restrictions could be integrated into that act.
- Voluntary actions: The Scientific Committee on Consumer Safety (SCCS) could be asked to develop an opinion on these chemicals, which could then be sent to industry as a guide to ensure safer single-use baby diapers. However, such a guide would not be mandatory for industry and would not include enforcement measures for the authorities to control if single-use baby diapers put onto the market follow the recommendations.

SEAC conclusion(s):

Since the scope of the proposed restriction only covers substances and articles contributing to the potential risk, SEAC agrees with the scope as defined, and clarified during opinion development, by the Dossier Submitter (proposed restriction RO1). The specific derogations proposed are considered justified by the Committee since the articles either do not contribute to the potential risk (re-usable diapers) or are targeted at a different age group and are used for medical purposes (incontinence diapers).

The Dossier Submitter assessed several Risk Management Options besides the REACH

restriction, such as classification and labelling, identification as SVHC and subsequent authorisation, use of legislations other than REACH or development of specific legislation to address the identified risks and voluntary actions. SEAC agrees that a REACH restriction would have been the most appropriate EU-wide measure out of those assessed by the Dossier Submitter, if a risk had been demonstrated by the Dossier Submitter.

Based on SEAC's assessment, RO1 would have been the most appropriate out of the two ROs considered, if the Dossier Submitter had demonstrated a risk related to single-use baby diapers. However, since RAC concluded that based on uncertainties related to the Dossier Submitter's risk assessment that this is not the case, SEAC considers RO1 to not be an appropriate measure.

Based on a comparison of the two ROs and the limited information available, SEAC considers RO2 to be even less appropriate than RO1 regarding potential/perceived risk reduction capacity, proportionality and enforceability.

Key elements underpinning the SEAC conclusion(s):

A. Scope

a. Substances covered by the proposed restriction

In 2019, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published a report on the potential risks associated with the presence of hazardous substances in single-use baby diapers and made recommendations for risk reducing measures. Based on chemical analysis performed on single-use diapers and consequent risk assessment, the following substances and/or substance groups were identified by the Dossier Submitter as posing a risk to children aged 0 to 36 months: formaldehyde, PAHs, (DL-)PCBS, PCDDs and PCDFs. It is important to note that the targeted substances are not intentionally added to the products.

The scope of the proposed restriction is directly informed by the ANSES report. It is important to note that for the different substance groups mentioned above only the substances that were directly detected in single-use diapers and posing a health risk, according to the Dossier Submitter, are covered by the proposed restriction. The Dossier Submitter did however indicate that single-use baby diapers were not analysed with respect to total PCBs and findings from incontinence diapers for adults were instead extrapolated due to the similarities between these two diaper types. Even though incontinence diapers were excluded from the scope (see later in the opinion), SEAC finds this assumption reasonable.

SEAC agrees with the approach employed by the Dossier Submitter, since only those substances and/or substance groups that contribute to the potential risks are targeted (under the proposed restriction RO1).

SEAC notes that from the proposed restriction wording, including the table of substances, the intended scope of the proposed restriction (RO1) was initially not clear when it comes to PCBs. During opinion development the Dossier Submitter however indicated that all PCBs are indeed intended to be within the scope of RO1. SEAC therefore suggests simplifying and clarifying the restriction proposal to reflect this better[6] if it would be deemed appropriate by the Commission to pursue the restriction proposal despite RAC's scientific concerns.

b. Articles covered by the proposed restriction

The wording of the restriction is very specific on the types of disposable diapers for children. The following are covered:

[6] See also section 3.3.3 on practicality in this opinion.

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

The Dossier Submitter clarified to SEAC that this covers all types of single-use diapers worn by children and infants until they are fully toilet-trained, which is usually around the age of three. While some children wear diapers a bit longer, the Dossier Submitter performed its risk assessment for children and infants under the age of three. It should also be noted that single-use baby diapers are sold according to the weight of the child rather than their age. SEAC supports the specificity when it comes to targeting since this will improve implementability and enforceability if action is taken. The Forum however raised concerns regarding this specificity since potentially some "special types" of diapers may not be covered. Forum therefore recommends referring to "single-use diaper products for babies and infants" instead of listing the different types if the Commission decides to go forward with the restriction proposal.

c. Articles derogated

Reusable diapers were excluded from the scope because the Dossier Submitter did not perform analytical tests, and, as a result, also no health risk assessment is available. As such there is no identified risk and SEAC agrees with the Dossier Submitter that reusable diapers should not be subject to the conditions of the proposed restriction. The Dossier Submitter also notes that reusable diapers are made of different materials (i.e. textiles), are washed and might have a different contaminant profile to single-use diapers.

Incontinence diapers defined as medical devices according to Regulation (EU) 2017/745 were excluded from the scope of the proposed restriction. The Dossier Submitter performed a limited health risk assessment in 2020 which showed possible risks, but because of the high uncertainty associated with this assessment due to a lack of data and few articles tested, the Dossier Submitter decided not to include incontinence diapers in the scope of the proposed restriction. SEAC agrees with the Dossier Submitter that it would not be justified to include these types of diapers in the scope based on limited and highly uncertain information.

SEAC also understands that the proposed restriction is intended to address a potential risk for children. Incontinence diapers are used for medical purposes and are targeted at adults, whose skin is known to be less sensitive to chemical exposure than that of children. Thus, incontinence diapers are within the scope of regulation EU 2017/745 (Medical Devices). As such SEAC agrees with the Dossier Submitter that this type of product should not be subject to the conditions of the proposed restriction.

d. Interaction with other (proposed) restrictions and regulations.

Four (proposed) restrictions have been identified by the Dossier Submitter where potential overlap/interaction with the single-use baby diapers restriction were considered a possibility. In addition, SEAC notes that certain PAHs are restricted in entry 72 on CMRs in textiles with a concentration limit of 1 mg/kg. However, given that entry 72 derogates single-use textiles, there is no overlap with the proposed restriction on single-use baby diapers.

- *Proposed restriction on skin sensitising substances*[7]

This potential overlap is relevant for formaldehyde and benzo[e]pyrene since both restriction

[7] More information on the proposed restriction on skin sensitising substances can be found here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

proposals cover these substances and their presence in single-use baby diapers. The Dossier Submitter contends that there is no potential for double regulation because i) the proposed restriction for single-use diapers will protect from all adverse effects and not just skin sensitisation, ii) the most realistic conditions for exposure are very different for both restrictions and iii) both restrictions will be enforced through dedicated analytical methods. SEAC notes that whether one restriction offers more protection than another, different analytical methods are used or both restrictions have distinct conditions of exposure, is irrelevant when determining the potential for double regulation.

However, during opinion development **the Dossier Submitter indicated that the limits set under the proposed restriction are not concentration, but migration limits** (unlike the proposed restriction on skin sensitising substances). As such, SEAC considers there to be no potential for double regulation.

- *Entry 50 of Annex XVII on the manufacture, placing on the market and use of 8 PAHs in certain mixtures and articles (e.g. childcare articles)*

The restriction under entry 50 targets, among others, rubber and plastic components of childcare articles. The Dossier Submitter contends that there is no potential for double regulation since the restrictions focus on different parts of single-use diapers[8]. SEAC's assessment is in this case similar to the one outlined in the previous section in that there does not seem to be a potential for double regulation.

- *Proposed restriction on formaldehyde and formaldehyde releasing substances in consumer articles*[9]

This proposal for a restriction targets articles produced with the intentional use of formaldehyde or formaldehyde releasing substances. As was made clear, formaldehyde is not intentionally added to single-use baby diapers. There is also no indication that formaldehyde releasing substances are intentionally added. SEAC therefore considers there to be no potential for double regulation.

- Persistent organic pollutants (POPs) Regulation

The POPs regulation covers the unintentional presence of PCBs in all articles, including diapers, and, as such, no PCB content above the detection limit would be allowed.

SEAC therefore considers that there is a concern related to the proposed restriction being counter to the objectives of the existing POPs regulation.

B. RMOA

a. Discarded ROs

- Harmonised classification and labelling requirements

SEAC agrees with the Dossier Submitter that harmonised classification and labelling requirement is not the most appropriate EU-wide measure, but rather a complementary measure to the proposed REACH restriction.

SEAC does however not agree with the justification for discarding this risk management

[8] Assuming baby diapers are considered to be childcare articles.

[9] More information on the proposed restriction on formaldehyde and formaldehyde releasing substances in articles can be found here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

option on the basis that the process is long. While this may be true, the same could be said of the restriction process. A shorter process could potentially reduce risks faster, but not always proportionately. SEAC does not think the difference in length of the restriction and classification process is significant enough to justify discarding this risk management option.

However, SEAC contends that harmonised classification and labelling requirements would not reduce any potential risk sufficiently since it would not lower exposure significantly as it would not directly force companies to substitute the substances of concern. At the same time, it should be noted that a classification as skin sensitisers would, if relevant, mean that the classified substance would be within the scope of the proposed restriction on skin sensitisers.

- Identification as SVHC and subsequent authorisation

  SEAC agrees that the authorisation process (from SVHC identification to authorisation decisions) would be less appropriate to address the potential risk since groups of substances cannot always be targeted efficiently. While the Annex XV dossier does not contain concrete information on the import of single-use baby diapers it cannot be ruled out and authorisation would not address the risks associated with imported articles (risks from imported articles would be addressed via a follow-up restriction procedure after the sunset date according to Article 69(2) of REACH.

  More importantly though, the substances covered by the proposed restriction are considered to be impurities and are not used as such. The authorisation requirement would therefore not apply. Furthermore, the information requirements (both article 7 and article 33 obligations) related to identification are linked to the 0.1% concentration limit and the chemicals of concern are found at concentrations far lower than that.

- Other legislation

  - General Product Safety Directive (GPSD)

    SEAC agrees with the Dossier Submitter that using the GPSD is not appropriate to address the potential risk. This legislation only provides a short-term solution for acute health risks, while the concerns raised with the substances covered by the proposed restriction are related to chronic health effects. Furthermore, measures taken under the GPSD must be implemented through national legislation and may therefore not be fully harmonised across the EU.

  - Medical device regulation

    While incontinence diapers and single-use baby diapers are made the same way and have a similar composition, they are used in entirely different circumstances. Incontinence diapers are a medical device used to avoid serious inconveniences related to the human body not working properly. Medical devices can be subject to restriction under REACH if there is an identified risk (that cannot be addressed by the sector-specific legislation). However, a single-use baby diaper is not used to treat a medical condition and thus cannot be considered as a medical device. Therefore, SEAC agrees with the Dossier Submitter that the Medical Device Regulation is not appropriate to address the potential risks.

  - Childcare articles

    Directive 76/769/EEC, which was repealed by REACH, included a definition for "childcare articles". Single-use baby diapers can, according to that definition, be considered childcare articles. Categorising single-use baby diapers as "childcare articles" does however not imply that certain standards need to be met to place them on the market. As such the potential risks would not be addressed.

- Specific EU product legislation

  SEAC agrees with the Dossier Submitter that this risk management option is more of a long-term option. While the Committee dismissed this argument when it came to

classification and labelling, it is valid to make here since adopting an EU regulation is a more complex process than introducing a restriction. Furthermore, to address the potential risks, initiating the process to develop a specific EU product regulation seems disproportionate to the Committee when the REACH restriction process is specifically designed to handle this type of issue efficiently.

As such SEAC agrees that this RO is not appropriate to address the potential risks.

- Voluntary actions

The Dossier Submitter specifically discusses the possibility of the Scientific Committee on Consumer Safety (SCCS) to develop an opinion based on the quantitative health risk assessment performed by ANSES. This opinion could then be used as guidance to ensure safer single-use baby diapers.

Since industry has indicated that they do not consider there to be any risks associated with single-use baby diapers, SEAC questions the efficacy of this measure especially considering its non-mandatory nature. Similarly, other voluntary actions on the part of industry do not seem likely and thus this risk management option is not considered to be appropriate in addressing the potential risks.

b. RO1 (proposed restriction) versus RO2

Based on the discussion on discarded ROs above it is clear to SEAC that a REACH restriction would have been the most appropriate EU-wide measure to address the risks had they been demonstrated.

The Dossier Submitter discusses two REACH restriction options:

- RO1 (proposed restriction): Limiting the migration of formaldehyde, the sum of detected or quantified 17 PAHs, the sum of quantified PCDD/Fs and DL-PCBs, the sum of quantified PCBs.

- RO2: Limiting the migration of all the substances and sum of substances listed in RO1 and all the congeners of the PAHs, PCDD/Fs and DL-PCBs.

RO1 only targets the substances that have been specifically identified as being present in single-use baby diapers. RO2 broadens the scope to also include congeners of the targeted substance groups and, as was clarified during opinion-development, setting migration limits for each individual substance.

In the Annex XV dossier both ROs are assessed according to their risk reduction capacity, proportionality, practicality and monitorability. It is stated that there are no significant differences between the two ROs when it comes to risk reduction capacity, practicality and monitorability. The Dossier Submitter contends that proportionality for RO2 is similar to that of RO1. Both RO1 and RO2 are however considered to be proportionate by the Dossier Submitter.

Based on SEAC's assessment, RO1 would have been the most appropriate EU-wide measure out of those assessed by the Dossier Submitter, if the Dossier Submitter had demonstrated a risk related to single-use baby diapers. However, since RAC concluded that based on uncertainties in the Dossier Submitter's risk assessment this is not the case, SEAC considers RO1 to not be an appropriate measure. Based on the limited information available to the Committee regarding RO2, SEAC cannot agree with the Dossier Submitter's assessment.

- Assuming the migration limits for each individual substance would correspond to the substance group migration limit set under RO1 (i.e. 112 ng/kg diaper is applicable to

each individual PCB, etc)[10], then it seems clear that the risk reduction capacity of RO2 is much lower than that of RO1. This is because allowing higher individual migration limit can lead to the sum of substances' migrations being higher than under RO1.

- Setting individual migration limits for more substances also significantly affects the practicality (including enforceability) of RO2 since compliance needs to be checked for each and every substance covered. This is especially troublesome given the sheer number of PCBs covered by the scope. While under RO1 the Dossier Submitter indicates that marker/indicator PCBs[11] could be used to check compliance, this cannot be done under RO2. It therefore also follows that testing costs under RO2 would be demonstrably and significantly higher.

Based on its assessment, SEAC considers RO2 to be even less appropriate than RO1 regarding potential/perceived risk reduction capacity, proportionality and enforceability.

3.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

RAC conclusion(s):

Key elements underpinning the RAC conclusion(s):

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

3.3.3.1. Costs

Summary of proposal:

The substances within the scope are not intentionally added to single-use baby diapers during the manufacturing process, but they are rather residues or contaminants. The economic impacts expected from the proposed restriction largely depend on the way industry is likely to react to the new obligations introduced by the restriction and the measures they will implement to reduce contamination of their products to meet the legal migration limits, if possible. Based on information from industry, the Dossier Submitter discusses possible sources of contamination as well as possible alternatives and technical changes.

While the exact industry reactions are uncertain, the possible actions and the associated impacts are outlined in the table below.

Table 2 Costs of substitution / technical changes and adaptations likely to reduce contamination (from Annex XV report)

Type of economic impacts	Costs	Other economic impacts (benefits and others)	Uncertainties

[10] The restriction dossier does not contain information regarding individual migration limits under RO2, therefore this assumption is necessary for SEAC to even have a basic discussion on the comparison of RO1 and RO2.

[11]In the restriction dossier the Dossier Submitter did not give any indication of which marker PCBs could or should be used to check compliance.

Substitution/better selection of raw materials	Moving to total chlorine-free (TCF) pulp	• €200 000 - €400 000 per year per company (> +17% per year; +1% and +2% of current costs per product range) i.e., between €950 000 and €5 700 000 for the whole EU manufacturing market. • €1-1.5 million (extra investments due to technical treatment challenge of TCF fibre) (per site?) • Extra-cost due to higher quantity of raw material and more transport (not provided) • Extra-cost due to further air filtration (more dust) (not provided) • Extra cost due to additional FSC certification (not provided)	• Shortage of TCF pulp (low availability) and finished products • Extra-profit for TCF pulp suppliers	++ (time needed to adapt > 2 years)
	Total costs of moving to TCF pulp for EU diapers manufacturing companies: €5-25 M/year, with a central estimate of €15 M/year (corresponding to 0.07 %- 0.30 % of the annual market diapers revenue with a central estimate of 0.2 %. (annualized net present value calculated based on a 4 % discounting rate over 10 years from 2024, based on assumptions that between 50 % and 100 % of the diapers manufacturers would switch to TCF pulp (among the 95 % manufacturers that currently use ECF pulp) and that the investment would be split 50 % in 2022 and 50 % in 2023.) For sensitivity analysis purposes, if it is assumed for the low scenario that no diapers manufacturers would switch to TCF pulp (therefor that between 0 and 100 % of the diapers manufacturers would switch to TCF pulp), this cost would thus be €0-25 M/year.			
	Removal or substitution of wetness indicator	• Loss of manufacturers' sales and profits due to marketing asset?	Cost saving due to fewer materials to purchase and process	++
	Removal or substitution of pigments	• Loss of manufacturers' sales and profits due to marketing asset?	Cost saving due to fewer materials to purchase and process	++
	Overall better selection and control of raw materials: moving to best practices	• Higher costs due to lower availability of raw materials due to more stringent selection requirements (not provided) • Higher costs due to more tests (see below)		
Technical measures on the manufacturing process	Further control of temperatures	• More frequent lines monitoring and maintenance (costs not provided but considered insignificant)		
	Further control of manufacturing processes	• Higher tests and controls on each step of the manufacturing process (see below)		
	Further decontamination of indoor air	• Broad estimate "in the millions euros per production plant"		++
Technical measures on packaging	Removal of vent holes (already done by industry)	• Negligible extra-cost		

The Dossier Submitter has also quantified the testing costs of the proposed restriction for industry, although they note that these costs are rather uncertain and that, since companies may already undertake testing for chemicals in single-use baby diapers, not all of the costs appear to be incremental to the proposed restriction. Due to these uncertainties and to the current lack of harmonised analytical methods, these costs (outlined in the below table) are not considered an actual estimate of the expected testing costs but rather as an indication of possible testing costs.

The assessment of the testing costs has evolved during the opinion making process and the consultation on the Annex XV report. The table below shows both the industry claims that are not confidential, and the last assessment made by the Dossier Submitter.

Table 3 Testing costs expected for industry

Type of costs	costs	Frequency of tests	Other impacts due to additional tests	Uncertainties
Extra analysis cost to test raw materials (based on industry claims)	• €50 000 - 200 000 /year/company (+300% extra cost), i.e., between €600 000 and €80 000 000 for the whole EU manufacturing market[12] • €1000 – 3000 charged by laboratories per material • Up to 35 materials to test	• Raw material suppliers: once a month • Manufacturers: quarterly to every second year (if no change in supplier)	Delays in production of diapers and increased inventories	++
Extra analysis costs to test raw materials for EU diapers manufacturers (based on DS further assessment)	• €0,6 – 82 M/year • Central estimate of €41 M/year	Quarterly to weekly		+
Extra analysis costs to test finished diapers (based on industry claims)	• €100 000- 200 000/year/company (+25%-50% extra costs), i.e., between €240 000 and €23 000 000 for the whole EU manufacturing market[13] • ≥€1000 charged by laboratories per product tested	• Manufacturers: between once a month and twice a year, at the end of the production line • Distributors: once a year on product samples in shops	Delays in production of diapers and increased inventories	++
Extra analysis to test finished diapers (based on DS further assessment)	• €0,24 – 23 M /year • Central estimate of €4,8 M/year	Monthly to weekly		+

[12] Based on: 10-15 manufacturing companies; 15-35 materials tested and a testing frequency from 4 to 52 times per year

[13] Based on: 10-15 manufacturing companies; 2-10 products ranges tested and a testing frequency from 12 to 52 times per year

TOTAL[14] testing costs for diapers	**€0.6-80 million /year with a central estimate of €35 million / year (corresponding to 0.01%-1.1% of the annual diapers market revenue with a central estimate of 0.5%)** (annualized net present value calculated based on a 4% discounting rate over 10 years from 2024)			
Extra audits on manufacturing site	• €20 000 per audit per year €1 000 per process step analyzed	Not available	Not available	**++**
Testing costs for diapers importing companies	Not available	Not available		

Regarding enforcement costs for authorities, the Dossier Submitter takes forward ECHA's average estimate of €55 600 per year, although they note that there are some uncertainties also regarding this cost. The annualised NPV of the enforcement costs was estimated at €45 000/ year (discounted at 4% from 2024).

SEAC conclusion(s):

SEAC finds that there are many uncertainties in the cost assessment, and that it is difficult to reach a clear conclusion on the possible costs. First, there is a lot of uncertainty regarding the possible sources of contamination. The Dossier Submitter has analysed possible sources of contaminants, but it is not clear whether these are the actual sources. The Dossier Submitter concludes that there are feasible alternatives available, but SEAC does not find this to be clearly justified by the Dossier Submitter for all the substances and the possible sources.

Given that it is not known where the contaminants come from, there is also uncertainty about what industry would need to do to eliminate or reduce them. SEAC concludes that it is not fully understood what industry will need to do to comply with the proposed restriction, and what the associated socio-economic impacts would be. Furthermore, comments in the consultation on the Annex XV report (#3162, 3165, 3166, 3168, 3313 and 3319) indicate that the substances in scope are at environmental background levels, which makes it uncertain whether industry would be able to comply with the proposed restriction under any circumstances.

The Dossier Submitter has quantified some possible costs for actions that industry could take and has described other potential impacts qualitatively. The cost assessment for those potential actions seems to be appropriate based on the limited information available. Nevertheless, given the above uncertainties, SEAC notes that there are likely to be other costs not captured in the current cost assessment. It is also uncertain to what degree the measures for which the Dossier Submitter has quantified the associated costs will eliminate or reduce the substances in scope and therefore whether they would be measures taken by industry to comply with a restriction as proposed by the Dossier Submitter.

[14] NPV, annualized net present value calculated based on a 4 % discounting rate over 10 years from 2024.

Therefore, SEAC highlights the limited knowledge and data as a source of uncertainty that may result in under- or overestimation of the total costs. Industry has already started to implement preventive measures to reduce the concentration of the impurities within the scope of the restriction (such as performing audits on suppliers and manufacturing processes, strengthening traceability and conducting more testing), but it is unclear what effect this has had on current migration levels in single-use baby diapers. Therefore, SEAC has a limited understanding of which further measures this restriction proposal would imply for industry, whether such measures would be feasible and what the associated costs would be.

The Dossier Submitter has also presented potential costs for consumers, in case that industry would pass on additional costs to them. The Dossier Submitter believes that the competition in the market is so strong that industry could not pass the costs down to the consumers. However, industry has indicated that there might be an increase in the price of single-use diapers. SEAC considers it likely that some of the increased costs will be passed on to consumers, but does not currently have any information about either the total costs, nor how large a fraction of the costs that could be pushed to the consumers (see section 3.3.2.3 for more information on SEAC's reasoning regarding impacts on consumers).

The Dossier Submitter has assessed costs for two restriction options, although to different levels of detail for each with the focus on restriction option RO1. Because only a brief qualitative cost assessment has been done for RO2, SEAC has not been able to assess the costs of RO2 in detail.

SEAC notes that the possible range for the estimated testing costs are large (depending e.g. on the frequency of tests and the number of components tested), and there is uncertainty about the costs per test given that the proposed migration limits are lower than those that industry currently has experience of.

SEAC finds the reasoning for using ECHA's estimate of enforcement costs for the authorities as reasonable, based on the currently available information.

Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter has assessed costs for two restriction options:

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

The Dossier Submitter proposes RO1, and the cost assessment is also focusing on RO1. The costs for RO2 are not quantified.

Below SEAC discusses both restriction options in more detail.

A. RO1 (Proposed restriction)

In this restriction option migration limits are set for formaldehyde, the sum of the PAHs, the sum of PCDD/Fs and DL-PCBs and the sum of quantified PCBs. This option is assessed further in the impact assessment and defined as RO1.

The Dossier Submitter describes how they expect actors in the supply chain to react on the proposed restriction:

- The single-use baby diapers industry in the EEA30 will in some cases incur increased costs due to the proposed restriction. These costs are discussed below. Some of these

costs may be passed down the supply chain to consumers. The Dossier Submitter considers that this potential price increase is limited, given the strong competition on price in the diapers market.
- Consumers are not expected to limit their demand, since demand in this market seems to be quite inelastic driven by the need for a baby to wear a diaper.
- Industry claims to already have made considerable efforts to further control and test their diapers. Therefore, the Dossier Submitter states that it remains to some extent uncertain whether part of the costs is already borne by companies or whether they are wholly, or only partly, attributable to this restriction.
- The transition period will allow industry to sell off existing diapers before the restriction enters into force.
- According to the Dossier Submitter, the analysis of alternatives performed shows that technically and economically feasible technical solutions exist.
- The transitional period of 24 months is considered as necessary to develop new analytical methods to ensure compliance and enforce the restriction.

During the development of the dossier, industry has identified possible sources of contamination and has identified some possible technical and substitution solutions. Different industry players have overall proposed similar solutions, and the Dossier Submitter thus finds it likely that implementation is possible. The costs are based on the information collected from the stakeholders consulted during the development of this restriction proposal. The economic impacts include direct costs of removing or reducing contaminants from raw materials, manufacturing process and other steps in the supply chain, as well as testing costs.

SEAC reviewed the analysis provided by the Dossier Submitter regarding the potential for reducing contaminants in single-use baby diapers. In SEAC' view there is a lot of uncertainty regarding the possible sources of contamination. The possible sources of contamination and ways to further reduce or prevent this contamination are discussed below.

i. <u>Removing and reducing contaminants</u>

Based on the information collected from industry and from literature, the Dossier Submitter assumes that some critical raw materials such as cellulose (pulp), glues, wetness indicators and pigments are likely to be the main sources of contaminants. Substitution of these materials with safer options may be one of the solutions to reduce or remove contaminants.

Several comments to the consultation on the Annex XV report (#3165, 3166) confirmed that none of the substances targeted by the restriction proposal are added to raw materials or used as ingredients in the manufacturing of diapers.

- <u>Raw materials</u>

Total Chlorine Free Pulp

According to the Dossier Submitter, there are currently two bleaching processes used for bleaching cellulose: elemental chlorine free (ECF) and totally chlorine free (TCF). Moving from ECF bleaching process to TCF for bleaching cellulose is, according to the Dossier Submitter, a possible way forward to reduce the migration of contaminants in diapers.

According to the Annex XV report, 5% of the diapers manufacturers already use TCF pulp over ECF pulp. Most of them seem to have made this move more by precaution than based on evidence of chemical contamination. Other manufacturers are sceptical about the benefit of moving from ECF to TCF to reduce contaminants in the pulp.

Based on the information at hand, the Dossier Submitter states that it is difficult to have a clear-cut conclusion about whether TCF pulp would address the substances and health

concerns targeted by the proposed restriction, as compared with ECF pulp. The Dossier Submitter was not able to conclude that substitution to TCF would address the identified risks.

The Dossier Submitter estimated the costs to single-use baby diaper manufacturers of using TCF in different scenarios, according to different assumptions on how many companies that are in the market and how industry will react. The assumptions of the different scenarios are outlined in Table 6. The high scenario assumes that all of the manufacturers still using ECF would switch (i.e. 95% of the manufacturers on the market given that 5% has already started to use TCF), while the low scenario assumes that only half of the manufacturers currently using ECF will switch to TCF (i.e. 47.5%). The central scenario is the mid-point between the low and the high scenarios. Table 6 outlines the costs to single-use baby diaper manufacturers in the first year (investment and annual cost). The total quantified costs over an analytical period of ten years are presented in the section 'Total costs' later in this opinion.

The Dossier Submitter has not quantitatively assessed the impacts to the pulp manufacturers but explains that such a move would affect the market for TCF pulp. Even though the diaper manufacturing industry has estimated the costs of moving from the use of ECF pulp to using TCF pulp, there might be some uncertainty regarding how the market for TCF pulp will react to an increase in demand. The Dossier Submitter states that the impact of moving to TCF pulp will depend on the capability of the TCF suppliers to adapt and to the elasticity in the TCF pulp market. An increase in demand can lead to a shortage in the short run, it can lead to a price increase if the availability is scarce, and it may lead to a price decrease if new suppliers enter the market.

The Dossier Submitter has proposed a transition period of 24 months, to assure that the market for TCF will have time to adapt. According to the Background Document, industry reports that at least two years is needed to be able to switch from ECF to TCF. Comment #3165 to the consultation of the Annex XV report confirmed that planning, financing, equipment procurement and manufacturing, delivery, installation and start-up of the new process related to TCF pulp can take up to 24 months.

Table 4 Costs of changing to TCF, for single-use diapers manufacturers in the EEA in the first year (€)

Scenario	Low	Central	High
Single-use diaper manufacturers	10	13	15
Expected yearly costs of using TCF instead of ECF (including pulp costs) per company	200 000	300 000	400 000
Share of manufacturers expected to switch	47.5%	71.25%	95%
Expected yearly cost of moving from ECF to TCF materials for the whole diapers market	950 000	3 325 000	5 700 000
Extra one-off investment costs per company	1 000 000	1 250 000	1 500 000

Extra one-off investment costs for the whole diapers market	4 750 000	13 062 500	21 375 000
Total expected switching costs for the diapers market in the first year	**5 700 000**	**16 387 500**	**27 075 000**
Switching costs as a percentage of revenue	0.07 %	0.2 %	0.3 %

SEAC finds the estimation of these costs appropriate given the information available, but underlines that there is an uncertainty regarding the market for TCF and what the price of TCF pulp could be.

Importantly, there is also a major uncertainty regarding the potential for reducing or removing the substances in scope with this measure. The Dossier Submitter states that it is uncertain to what degree a move from ECF to TCF would reduce the contamination of the substances proposed to be restricted. Comments in the consultation on the Annex XV report also question to what extent a move from ECF to TCF would be a solution. An industry association (#3165) stated that the highly chlorinated dioxins and furans identified in the report (1,2,3,6,7,8 HxCDD, 1,2,3,4,6,7,8-HpCDD, OCDD, 1,2,3,6,7,8 HxCDF, 2,3,4,6,7,8 HxCDF, 1,2,3,4,6,7,8 HpCDF, 1,2,3,4,7,8,9 HpCDF, and OCDF) are much more characteristic of incineration sources than of pulp bleaching sources. The comment states that bleaching may have been a source of dioxins when chlorine gas was used but that ECF bleaching today produces pulp with no or very low levels of dioxins and furans. This is supported by a French union (#3166) stating that the purification process to bleach the fluff used in diapers made by their members has not been made from elemental chlorine for decades.

The industry association (#3165) also referred to several studies indicating that dioxins and furans are present in the environment. For example, DeVito & Schecter (2002)[15] found that the studied congener profiles present in both disposable and reusable diapers suggest that these dioxins may be derived from background contamination rather than from the pulp manufacturing process. Berry et al. 1993[16] found dioxins and furans in all studied samples of household materials, including paper bleached with hydrogen peroxide in a TCF process. A review by Axegard (2019)[17] covering a broad range of studies over three decades reports that replacing elemental chlorine with chlorine dioxide of high quality in pulp bleaching eliminates the formation of 2,3,7,8-TCDD and 2,3,7,8 TCDF during the bleaching process. This study

[15] Michael J. DeVito, Arnold Schecter. Exposure Assessment to Dioxins from the Use of Tampons and Diapers. Environmental Health Perspectives (2002) • VOLUME 110 | NUMBER 1 |

[16] Berry, R. M., Luthe, C. E., & Voss, R. H. Ubiquitous nature of dioxins: a comparison of the dioxins content of common everyday materials with that of pulps and papers. Environmental science & technology (1993), 27(6), 1164-1168.

[17] Axegard, Peter. The effect of the transition from elemental chlorine bleaching to chlorine dioxide bleaching in the pulp industry on the formation of PCDD/Fs, Chemosphere 236 (2019) 1244386 (open access).

also brings attention to that PCDD/Fs can be found in background levels in ecosystems, food, soil and air, as well as in unbleached pulp, bleached pulp and paper and fibre products.

Comments #3166, 3208 and 3320 also stated that there are no scientific studies that show that ECF pulp is more contaminated than TCF pulp.

Comment #3322 states that it is possible to change the manufacturing from ECF to TCF pulp in five months and that the estimated cost is 6 billion yen (i.e. approximately €46.2 million[18])[19].

SEAC notes that there is no evidence that a switch to TCF pulp would reduce dioxins and furans. In its tests on single-use diapers, the Dossier Submitter did not compare the results for diapers made with TCF pulp with the results for diapers made with ECF pulp. SEAC notes that consultation comment # 3166 states that no scientific studies have shown that ECF pulp is more contaminated than TCF. SEAC also notes that there are several studies that suggests that dioxins and furans may be derived from background contamination rather than from the pulp manufacturing process. SEAC notes that if a move to TCF does not reduce the substances at stake, the costs associated with such a move are not relevant for assessing the impacts of the proposed restriction. As there is no evidence that the use of TCF pulp instead of ECF pulp would reduce dioxins and furans, and the Dossier Submitter itself states that it is uncertain if this measure would reduce the substances, SEAC cannot conclude that a move to TCF pulp would be a suitable alternative. It is technically feasible to change from ECF pulp to TCF pulp, the costs of a change are quantified in a reasonable manner, but it is not clear whether a change would reduce the migration of dioxins and furans in single-use baby diapers.

Glues

Glues used to assemble the different parts of a single-use baby diaper are generally hot melt adhesives. According to experts and chemists consulted by the Dossier Submitter, glues are not expected to be the source of contaminants per se, but they could be if heated during the manufacturing process to temperatures > 200 C.

Based on those findings, the Dossier Submitter does not consider substitution of glues as a solution to reduce contamination of finished products and concludes that it may not be necessary. Therefore, there are no substitution costs associated.

SEAC notes that comments submitted to the consultation on the Annex XV report (#3162 and #3165) argue that the conditions for PAH formations from glues are never fulfilled in the diapers manufacturing process.

Comment #3162 and 3165 to the consultation on the Annex XV report explain that formation of PAH requires temperatures of 350 – 1200°C. The production lines for diapers use 90 – 170°C. They explain that the production process is controlled both automatically and by an operator and thus that it is not likely that the heating procedures lead to PAH contamination. The comments also state that if temperatures were somehow to reach 200°C (well below the

[18] https://www.xe.com/currencyconverter/convert/?Amount=6000000000&From=JPY&To=EUR

[19] https://technology.risiinfo.com/company/daio-paper

350°C required for PAH generation), adhesive performance would degrade. Quality control would be alerted, and the diapers produced rejected, so they would not enter the sales channels to consumers.

Based on the information from both the Dossier Submitter and the consultation on the Annex XV report, SEAC finds that there is no evidence that the use of glues contributes to contamination with the substances in scope. The costs of substituting glues are thus not relevant for the impact assessment of the proposed restriction. *Wetness indicator*

A wetness indicator is a common feature in many single-use baby diapers. It is a feature that reacts to exposure of liquid to discourage the wearer to urinate or as an indicator for parents that the diaper needs changing. According to the Annex XIV report, many diapers that contain a wetness indicator seem to use a chemical called bromophenol blue. However, during opinion-development, the Dossier Submitter clarified that this substance seems to be used in wetness indicators, but that it is not known whether it is the cause of the presence of PAH.

The Dossier Submitter states that regardless of the substitution costs due to the replacement of wetness indicators, the acceptability of using harmful materials in the finished products may be questioned given that wetness indicators do not have an essential function to the diaper.

If the wetness indicators are one of the possible sources of contamination of the diaper, the Dossier Submitter states that one option could be to not use wetness indicators in diapers. The Dossier Submitter states that removing the wetness indicator would not affect the basic function as absorbent of baby urine and faeces.

In terms of economic impacts, the removal of wetness indicators may affect manufacturers' sales and profits. According to the Dossier Submitter, the industry did not provide any evidence for such a loss. The Dossier Submitter states that it is also possible to expect that removing the indicators would present cost savings for manufacturers.

SEAC notes that it is not clear from the information available whether wetness indicators are a source of contaminants. The assumption that wetness indicators would be a source of contaminants seems to be based on speculative information from one diaper manufacturer. Given that the Dossier Submitter did not in its analytical tests compare the results for diapers with and without wetness indicators, there is no evidence that wetness indicators would actually be a source of contaminants.

In case wetness indicators are a source of contaminants and industry would need to remove them to comply with the proposed restriction, SEAC finds it reasonable that wetness indicators are secondary to the main function of the single-use diapers. Nevertheless, SEAC also recognises that there is a market for diapers with wetness indicators, which means that there is a demand for these diapers, and that the removal of wetness indicators may therefore imply a welfare loss for consumers and reduce the profits of manufacturers delivering diapers with wetness indicators. While the lost sales from diapers with wetness indicators are expected to be overall compensated by increased sales of those without wetness indicators, the profit associated with the latter may be lower (as it can be assumed that consumers who want wetness indicators are willing to pay a bit more for them). Therefore, SEAC concludes that, overall, some loss of profits could be reasonably expected, although it is not possible to quantify it based on the available information.

Furthermore, comments received in the consultation on the Annex XV report questioned that there would be any issues with the safety profile of wetness indicators and highlighted their benefits for consumers in providing guidance as to when a diaper needs to be changed. An industry association (#3165) said that feedback from consumers suggests they would need to change more frequently without wetness indicators, increasing the use of diapers. Further, it stated that for new-born and small sizes used in hospitals, wetness indicator is a required feature by midwives and nurses as it enables easy checks for urination frequency in the early days of life without disturbing the new-born. Also, comments (#3162, 3165) noted that the feature is of help for inexperienced parents who can learn, based on their own experience, how quickly the diaper of the baby is filled and how often it needs to be changed.

In SEAC's view, this indicates that the removal of wetness indicators could have hygiene implications, environmental impacts from higher use of diapers and be considered a welfare loss for consumers. Therefore, SEAC considers that the impacts of removing wetness indicators may be larger than indicated by the Dossier Submitter, although it is not possible for SEAC to quantify such impacts based on the data available. SEAC also notes that there is no clear evidence that wetness indicators are a source of contamination. And SEAC notes that the potential costs of removing wetness indicators are not quantified.

Pigments

External sheets of single-use baby diapers may be coloured to make them more aesthetically attractive. According to one company, a green pigment used for this purpose may be the source of OCDF and OCDD. This company informed the Dossier Submitter that reformulations of the green pigment allowed to reduce levels of PCDD/Fs to a non-detectable level.

The Dossier Submitter questions the acceptability of using pigments in the finished products, that do not have an essential technical function. On this basis the Dossier Submitter indicates that pigments should no longer be used in the single-use baby diapers given that they are possible sources of contamination.

SEAC notes that is unclear from the available information whether pigments are a source of contaminants. SEAC notes that the Dossier Submitter did not compare the test results for diapers with and without pigments.

SEAC also takes note of comments in the consultation on the Annex XV report highlighting that pigments can have a function in diapers beyond aesthetics (which they note is also valued by children and caregivers). According to an industry association (#3165), artwork on the outer back sheet is in many diapers designed to enable easy symmetrical fastener tape placement, which helps ensure that the diaper fits properly and thus performs its function correctly. The industry association also states that the coloured area is on the outer layer, and therefore not likely to be in contact with either skin or urine.

Comment #3313 states that organic pigments are regularly tested and regarded as safe for this purpose.

In SEAC's view, this indicates that consumers could be negatively impacted if pigments were to be removed from single-use diapers. SEAC considers that in terms of economic impacts, the removal of pigments may negatively affect sales and profits, since this feature could be a competitive advantage. While the lost sales from diapers with pigments are expected to be overall compensated by increased sales of those without pigments, the profit associated with

the latter may be lower (as it can be assumed that consumers who want pigments are willing to pay a bit more for them). Therefore, SEAC concludes that, overall, some loss of profits could be reasonably expected, although it is not possible to quantify it based on the available information.

SEAC notes that there is no clear evidence that the pigments are a source of contamination, and that one comment states that they are regarded as safe. Nevertheless, the company that reported in the Annex XV report the green pigment as a possible source of OCDF and OCDD has made reformulations of the green pigment with levels of PCDD/Fs to a non-detectable level. SEAC assumes that this, supported by the comment that organic pigments are regarded as safe, implies that alternative pigments that are not a source of contamination are available. This may imply that it is technically feasible to find pigments that are not a source of contamination. Neither the Dossier Submitter nor the comments from the consultation have given information on the possible costs of changing to alternative pigments.

SEAC finds it difficult to draw conclusions on the costs of moving to alternative pigments, as neither the Dossier Submitter nor information from the consultation has given any indication on which pigments could be sources of contamination, nor on how large a fraction of the diapers are using pigments that could be a source of contamination. Furthermore, the costs of moving to alternative pigments are not estimated.

Overall better selection and control of raw materials

The Dossier Submitter is of the view that overall, the diapers industry from upstream to downstream should be particularly careful about raw materials used and present in the diapers they produce, supply, and sell, by a stricter and better selection of raw materials.

The Dossier Submitter considers that more stringent regulations on single-use baby diapers, such as this restriction proposal, are expected to lead to a re-think and trigger best selection and manufacturing practices towards safer and more eco-friendly raw materials.

The Dossier Submitter states that it is difficult to estimate the cost of moving to safer raw materials due to the high number of raw materials at stake. The manufacturers consulted indicate that stricter chemical quality requirements from suppliers would reduce the variety of sources of raw materials and would lead to extra costs.

From the information currently available, it is unclear to SEAC what the overall selection and control of raw materials would mean in practice (e.g. which raw materials the Dossier Submitter is referring to and whether it is likely to remove the contaminants within the scope of the proposed restriction). Nevertheless, SEAC finds it reasonable that better selection and control of raw materials could lead to higher costs for the manufacturers. As the Dossier Submitter has not been able to make some estimates, it is currently not possible for SEAC to assess these costs in a better manner.

An industry association (#3165) informed in the consultation on the Annex XV report that the EDANA stewardship programme for absorbent hygiene products is established. It is a voluntary initiative regarding trace levels of impurities found in absorbent hygiene products. Signatories to the programme undertake e.g. to monitor the presence of a defined list of trace chemicals in absorbent hygiene products and to take action to ensure that they do not exceed agreed guidance values. While SEAC recognises these industry efforts, it’s not clear what impact they have had on impurities in single-use baby diapers.

Several comments (#3165, 3166) stated that traces of substances possibly present in the raw materials are unavoidable as they are present in the environment. These can originate from a variety of sources, such as anthropogenic pollutants from agriculturally sourced feedstocks, impurities in raw materials originating from e.g., catalysts used in feedstock production, trace levels of unreacted monomers, processing aids etc. or might be caused by naturally occurring disasters e.g., wildfires. The comments state that the Dossier Submitter is speculating on the possible sources of c contamination. They state that given the likelihood that any trace substances stem from unavoidable environmental background contamination, going below the limit of quantification is not technically feasible, nor necessary from a safety point of view and thus not proportionate.

SEAC notes that the consultation on the Annex XV report has challenged the Dossier Submitter's assumption that it would be possible to move to safer raw materials. SEAC currently has no clear understanding of whether any of the substances in scope could be reduced or removed from raw materials, and thus the costs (if any) are not known. Finally, SEAC notes that some comments indicate that the substances stem from unavoidable background contamination, and thus that it is not technically feasible to remove the contamination.

- Manufacturing process

Controlling temperatures

According to the Dossier Submitter, excessive temperatures cannot be discarded as one of the possible causes of contamination of the products during the manufacturing process and should be further controlled. These controls should be targeted primarily on hot points such as the ones involving gluing and thermo-welding operations. According to the Dossier Submitter the costs of further controlling temperatures has not been communicated by diapers manufacturers. None of them consider that temperatures may be a cause of contamination during the production, therefore they do not see the need for further controls. In case they would have to implement stricter and more regular controls on their production lines, they expect extra costs. The Dossier Submitter does not have further information allowing for a quantification of the associated cost. However, the Dossier Submitter does not expect these costs to be significant since the manufacturers already do controls routinely.

SEAC notes that the comments by #3162 and 3165 highlighted in the previous section on glues are also relevant here.

SEAC finds industry's explanation on temperature control reasonable. As temperatures above 200°C would degrade the quality of the diaper in such a manner that it would be rejected, the manufacturers have an incentive for keeping the temperature below 200°C, and thus it is not likely that the temperatures would exceed 350°C, which is required for PAH contamination.

Glueless diapers

According to the Dossier Submitter, glue represents less than 3% of the weight of the diaper, but despite the small amount per product, the high consumption of diapers in the EU means that 25 200 tonnes of glue are consumed annually. In addition to material resources, glue-based bonding of diaper materials is an energy-intensive process and it also requires substantial maintenance costs. Glue-based bonding can be avoided or reduced by using a

novel bonding technology.

Due to a lack of information about what types of chemicals are used in this alternative process and what type of investments and costs implementation of the technology would require, the Dossier Submitter states that it is not able to recommend this technology as a possible solution to glues contamination.

SEAC notes that the comments by #3162 and 3165 highlighted in the previous section on glues are also relevant here.

Based on the information from both the Dossier Submitter and the consultation on the Annex XV report, SEAC finds it unlikely that the use of glues contributes to contamination with the substances in scope. The costs of substituting to glueless diapers are thus not relevant as an impact of the proposed restriction.

Fluffless diapers

The majority of cores are made of a mix of fibres (generally fluff) and superabsorbent polymer (SAP). The former represents the matrix to stabilize the latter and keep it fixed in the core. Removing the fluff leads to a thinner core and a less expensive product.

Due to a lack of information and possible higher pollution using fluffless diapers, the Dossier Submitter states that it is not able to recommend this technology as a possible solution.

Similarly to the other possible sources and alternatives, it is unclear to SEAC whether fluff is a source of contaminants. According to an industry association (#3165) it is unlikely that truly fluffless diapers will become the standard, nor is it warranted. The comment states that there is no evidence that fluff pulp is contributing to the substances in scope of the proposed restriction.

SEAC acknowledges that the Dossier Submitter is not able to recommend this technology and that stakeholders find it unlikely that fluff pulp is contributing to the contamination. SEAC thus finds that there is no evidence that a move to fluffless diapers would reduce the contamination of substances in scope of the proposed restriction.

Further decontamination of indoor air

According to the Dossier Submitter, the chemicals in scope are ubiquitous substances and can thus be suspected to come from contaminated environment and air. According to the Dossier Submitter, industry reports that, for instance, PCFD/F levels in the air can be high enough to trigger detection of trace quantities in diapers.

According to the Dossier Submitter, good practice, air filtration and dust management systems are in place at production sites to help reduce levels of airborne pollutants. Materials are covered in protective packaging materials until they are delivered to the production line to be used. Indoor air is centrally filtered to guarantee certain air quality (blockage of pesticides and reduction of other potential chemical traces such as PCDD/Fs, PCB from outdoor air).

The Dossier Submitter states that producing in clean rooms is considered infeasible and absolute filtration cannot be reasonably guaranteed. Nevertheless, based on their own air

analysis at production site, some companies recognize the necessity of generalizing central air filtration to reduce as far as possible (not eliminate) the presence of outside air pollutants indoor. These companies did, however, not communicate precise estimates of extra costs due to e.g. additional investment nor any economic feasibility concern associated with further air filtration. Industry only broadly reports that the investments are estimated to amount "in the million euros per production plant". The Dossier Submitter does not have further information allowing for a quantification or specification of these costs.

According to the Dossier Submitter the diapers industry is currently investigating solutions to further isolate the supply chain from environmental elements. They report development and significant capital investment to achieve this, but do not provide any cost estimate. The comments to the consultation on the Annex XV report did not provide detailed cost estimates, but one comment (#3165) indicated a cost of several million euros per production plant, as also reported to the Dossier Submitter during the development of the dossier. The comments also underlined that the possible measures would differ between plants, as existing installations also differ.

According to comments submitted to the consultation on the Annex XV report (#3165, 3166, 3169, 3318), given that the exposure time in consumers' homes of an opened pack of diapers is days or weeks in some cases, it is disproportionate to impose further restrictions on diaper manufacturers given that the air quality is unlikely to be radically different between the home and the production site. The hygiene level in most production sites is according to these comments already very good.

SEAC finds that it is difficult to conclude on the possible benefits of further decontamination of indoor air. SEAC notes that there are several possible technical measures, such as air filtration and dust systems, and that several companies already have these installations in place. Neither the Dossier Submitter nor the comments from the consultation have specified in more detail the possible measures. SEAC notes that the costs of these measures are not estimated in detail either but are rather reported as 'several million euros per plant'.

SEAC also notes that it is not clear to what degree further decontamination of indoor air in the plants would result in less contamination of the diapers. SEAC recognizes that, in case the substances are already present as background contamination, the diapers most likely will be contaminated from the air in the household when the packages are opened, but it is not clear what the level of background contamination in the households typically is.

- Packaging changes

All companies consulted during the preparation of the restriction proposal stated that they have implemented, as a preventive measure, the removal of vent holes on their diaper packages, to make them more "air-contaminant-proof" during storage and transport.

According to the Dossier Submitter, the removal of vent holes could prevent release of other chemical substances like volatile organic compounds.

According to the Dossier Submitter, industry also indicated that the cost of this measure is negligible and only requires slight re-conception of packaging bags and slight adjustment on the packaging automatic machine. One company still reports some decrease in bagging pace. The Dossier Submitter does not consider this decrease as causing any extra cost.

An industry association (#3165) states that the implication in the Annex XV report that small vent holes (a few mm in diameter) used in some finished product packaging could be a cause of contamination is unsubstantiated with any data and therefore speculative. The comment further states that, in general, the primary package containing single-use baby diapers are stored and shipped in additional protective packaging which contains several individual packages of diapers. These are typically sealed cardboard outer cases or secondary packages of some other material which are used to ship to customers, frequently on pallets, further wrapped in stretch film. The potential for traces to penetrate these small holes in this situation is, according to the comment, extremely low. Once a package is opened in the nursery at home, exposure to the indoor air environment is possible and uncontrolled, especially as many consumers remove diapers from the package and store them separately. According to the comment, any precautions taken during the production and shipping stages are thus of no or limited value and disproportionate given levels being discussed in the restriction submission are at levels of prevalent environmental background levels of the subject contaminants.

SEAC notes that the Dossier Submitter and the industry association have different views on the usefulness of reducing contamination by restricting vent-holes on the packages. SEAC notes that it is technically feasible to remove the vent holes and that the costs seem negligible. Some manufacturers have removed the vent-holes, but SEAC has no clear information on the fraction of diapers that have vent-holes. SEAC finds it reasonable that contamination under shipping and transport is not so dependent on the vent holes, because the primary packages have additional protective packaging. At the same time, it is not clear to SEAC what the benefits of vent holes are and whether these benefits could be lost if they were removed. SEAC also acknowledges that the diapers may be contaminated when the package is opened. SEAC finds that it is not clearly demonstrated whether this measure would reduce contaminants.

- Overall availability of alternatives

The Dossier Submitter concludes that the analysis of alternatives performed shows that technically and economically feasible solutions exist. However, in SEAC's view, it is not possible to conclude that suitable alternatives are available based on the currently available information. For several of the identified alternatives (such as better selection of raw materials or moving to fluffless diapers), it is not clear what contaminants they are expected to reduce or eliminate. Some of the alternatives identified for possible sources of contaminants in raw materials (e.g. moving to TCF pulp, substitution of glues, moving to glueless diapers) seem not to be regarded as fully suitable alternatives by the Dossier Submitter either.

As part of the opinion development, the Dossier Submitter has provided a categorisation of the substances in scope that are likely to be contaminants, from which sources and what the alternatives may be. Categorisations of the possible sources have also been incorporated into the Background Document (Tables 76-78 in the Annexes). The categorisation has not brought up clear evidence about the sources for contamination.

Comments submitted in the consultation on the Annex XV report (#3162, 3165, 3166, 3168, 3169) confirmed that the substances in scope are not intentionally added during manufacturing (not to the raw materials used nor as ingredients by themselves) and that they have no function in the diaper. They stated that the substances in scope are naturally present in the environment, which explains why traces of the substances may be present in raw materials and the end products, with one comment (#3162) arguing that it is impossible to

determine the actual source of contamination because of this. One comment (#3168) argued that the proposed 'concentration limits'[20] may be below environmental background levels. One comment (#3165) stated that it is impossible to determine the actual source of contamination because everything is lost in the "noise". Therefore, acting upon reducing these concentrations further is, according to this comment, pointless.

According to an industry association (#3165), once reasonable steps are taken to minimize risk from dust or airborne contaminants, there is little preventable systemic risk in diaper manufacturing operations. The association argued that trace substances may come from different sources in our daily environment e.g., incineration/combustion from traffic, crematories or energy production, air or naturally occurring disasters e.g., forest fires and volcanoes. It further clarified that the diaper manufacturing process is almost entirely an assembly process and therefore does not generate any of the substances in scope. In the view of this industry association, further reduction of the trace levels is not technically feasible. A company (#3168) stated that their manufacturing operations include processes to protect the product from environmental sources and that audit assessments have shown that the manufacturing processes are not the source of contamination of the product.

Comment #3165 states that "background" amounts of dioxins/furans can regularly be detected in the laboratory water of accredited laboratories that specialize in dioxin/furan analyses. These background amounts (a) fluctuate over time and (b) are within the same concentration ranges that would be required to determine the levels of dioxins/furans at the limits proposed by the Dossier Submitter. This can introduce a high risk of "false positive" detects. This risk must be understood and controlled in each specific laboratory. The Dossier Submitter has indicated that part of the contamination could be background contamination, but at the same time the Dossier Submitter claims that it is not possible to compare the concentration levels from single-use diapers with levels in e.g., air and water. SEAC considers that it is likely that a part of the contamination in single-use baby diapers come from background contamination, but SEAC does not have any clear view on how large this part is.

In SEAC's view, the comments received highlight the many uncertainties regarding sources of contaminants and possible alternatives. SEAC notes that there is no clear evidence on what the sources of the contaminants are, nor where in the manufacturing process the substances might occur. Several comments indicate that the contaminants are naturally present in the environment, which explains why traces may be present in raw materials.

SEAC notes that for none of the suggested measures it is documented that they would reduce or remove the substances in scope. This means that there is little evidence on what measures the manufacturers of diapers can undertake to reduce the contaminants. SEAC also notes that if the substances come from different sources in our daily environment, as several comments indicate, there are likely few measures that the manufacturers can undertake to reduce the substances.

ii. Testing and control costs

[20] The Annex XV report that third parties commented on during the consultation referred to 'concentration limits'. However, the Dossier Submitter clarified during opinion development that they meant migration limits and updated the Background Document accordingly.

The diapers industry would have to implement tests on their raw materials, their products and manufacture lines to ensure compliance with the proposed restriction. After entry into force of the restriction, the enforcement authorities would also have to test finished products to ensure that they are compliant with the migration limits as proposed in the restriction.

According to the Dossier Submitter there is no standard analytical method to measure the substances covered by the restriction. The Dossier Submitter considers that a transitional period of 24 months would provide sufficient time for manufacturers, laboratories, and other economic operators in the supply chain to adapt to the requirements of the proposed restriction, including to develop an appropriate analytical method to measure the migration levels proposed. The Dossier Submitter notes that some companies have expressed concerns that without a validated method and scientifically sound thresholds, it might be difficult for industry to comply with the restriction.

The Dossier Submitter has calculated testing costs for diapers manufacturers, differentiating between the cost to test raw materials and the cost to test finished products. In the Annex XV report, the Dossier Submitter had initially assumed that:

- the extra cost **to test raw materials** would range from €50 000 to €200 000 per year per manufacturing company, depending on their size, monitoring strategy and productive volume.
- the extra analysis cost **to test finished products** would range from €100 000 to €200 000 per year per diapers manufacturing company depending on their size and their production volume.

The above initial assumptions would have given total testing costs for single-use baby diaper manufacturers in the range of €1 500 000 - €6 000 000 per year for the whole European market. The information in the Annex XV report was provided by the manufacturers of single-use baby diapers themselves and not the suppliers of raw materials. The possible testing costs to suppliers of raw materials were not estimated. Whether part of these testing costs is already borne and internalized by companies, or whether the whole part of them is only attributable to this restriction proposal, is also unclear.

In response to the initial assumptions in the Annex XV report, comment #3165 in the consultation presented "a hypothetical example of testing costs". It suggested a testing cost of €3 000 per test, with 25 components in the diaper needing testing, 10 different products per manufacturer needing testing, and weekly testing. According to the comment, this sums up to a total testing cost of €39 000 000 per manufacturing plant per year. In addition to this, it argued that there would be further costs for the tests that the raw material suppliers will be required to do. According to the comment, these are done daily and would over-run the analytical capabilities of the production laboratories.

SEAC found the hypothetical example interesting, although some of the assumptions seemed exaggerated. The testing costs of €3 000 corresponds to the upper level of testing costs reported by laboratories in the Annex XV report. SEAC notes that the frequency reported in the example is much higher than in the information provided to the Dossier Submitter during the development of the dossier (which indicated that testing would be done between once a quarter to every 2 year on raw materials and once a month (to twice a year on finished products). SEAC also notes that comment #3165 makes no distinction between testing of raw materials and testing of finished diapers in its hypothetical example. Furthermore, while it

seems reasonable that a diaper manufacturer could have ten different products, it seems likely that many of the components would be used in several different products.

Nevertheless, in the Background Document the Dossier Submitter updated the estimation of the testing costs, with various assumptions, to get a better view of the possible magnitude of the testing costs. The **testing costs for raw materials** are now estimated based on the following assumptions:

- Frequency: quarterly to weekly
- Cost per raw material tested from €1 000 to €3 000
- Number of materials tested from 15 to 35

Based on these assumptions, the annual testing costs for raw materials would be in the range of € 0.6 – 82 million /year for the whole EU diapers manufacturing market. The central estimate is €41 million /year for the whole EU manufacturing market.

The **testing costs for the finished diapers** are now estimated based on the following assumptions:

- Frequency: monthly to weekly
- Cost per diaper tested from €1 000 to €3 000
- The number of products tested are from 2 to 10

Based on the assumptions, the annual testing costs for finished diapers would be in the range of €0.24 – €23 M /year for the whole EU diapers manufacturing market. The central estimate is €4.8 M /year for the whole EU market.

The Dossier Submitter has then estimated the **total testing costs**, for both the raw materials and the finished diapers to be in the range of €0.8 – 1050 M /year. By annualising the net present value calculated based on a 4% discount rate over 10 years from 2024, the Dossier Submitter concludes that the annual testing cost would be €0.6-80 million with a central estimate of €35 million / year. According to the Dossier Submitter the revenue of the diapers market in Europe is €7 443 B /year and the testing costs would hence represent 0.01 – 1.1 % of the market revenue, with the central estimate at 0.5 %.

Several comments in the consultation on the Annex XV report (#3162, 3163, 3166, 3168, 3169) state that the proposed limits are below today's possible analytical levels, that reputable analytical laboratories have not been able to replicate ANSES' analytical results, and that it is impossible for industry to improve what laboratories cannot detect. Comment #3169 states that due to the extremely low limit values requested, the testing costs will be significantly higher than the current testing costs. They comment that the demanded limit values are below the current level of detection and that the lower the values that have to be detected, the higher the efforts and costs to measure these values, due to implementing measurements to avoid unwanted cross-contamination.

SEAC finds it possible that testing costs for these limits might be higher than current testing costs. The comments did not provide any estimates of how much higher the testing costs could be. As the comment is not supported by any estimates, it is not possible for SEAC to use the information to update the cost assessment.

SEAC notes that background contamination with the substances in scope makes the testing more complicated and that migration limits below environmental background levels would further complicate the testing possibilities. A regional authority (#3164) states that they are developing a validated analytical method for the analysis of sanitary napkins, tampons and diapers, and assumes that it will be ready in 2021.

Comments #3302 and 3316 point out that frequency of testing is a decision made by the manufacturer and is driven by risk. If the manufacturer is confident that it can meet the requirements, the frequency can be limited, but in case fluctuations are expected, the frequency goes up. When a tested product has a detect of a restricted chemical above the set limit, that will automatically imply that all raw materials used in the production of the specific product need to be tested for the presence of the chemical in question. Comment #3316 states that if extremely sensitive test methods become available, a potential consequence is that uncontrollable background levels of chemicals in the scope of the restriction will be detected in many or all tested samples. These products are then not compliant and cannot be sold to customers. Frequent detection of chemicals will result in a need for frequent testing, and an inability to release products to the market for an undefined period of time leading to even higher testing costs and supply disruption. The comments provide some calculations of the testing costs, although parts of the estimations are confidential, and thus not possible to refer to. The estimations are assuming detects and the costs of testing through the whole supply chain, but there is no justification or explanation of the number of potential detects. SEAC finds the reasoning that a detect will lead to additional testing to find the source as reasonable but does not have any reliable information about the magnitude of possible detects and additional testing.

To conclude on testing costs for industry, SEAC finds the Dossier Submitter's estimates of the testing costs overall reasonable but finds that there are uncertainties regarding a standard analytical method not being in place, and the potential that a new standard analytical method will be more costly than current methods. This implies that the testing costs could be higher than estimated. SEAC also recognizes that the frequency of testing is an essential parameter in the assessment, and that the risk for detecting the substances could lead to a higher frequency of testing and thus higher testing costs. Nevertheless, there has been no clear evidence in the consultation that a higher frequency than assumed by the Dossier Submitter would be required.

The enforcement costs for the authorities are administrative costs incurred by the Member States' enforcement agencies to ensure that economic actors on the EU-27 market comply with the EU regulations. ECHA has previously assessed the administrative burden of enforcement for new restriction proposals and found that the average cost of enforcing a restriction is approximately €55 600 per year (although this excludes testing costs for authorities). The Dossier Submitter suggests that this value, rounded up to €60 000, could be an illustration of the enforcement costs. The Dossier Submitter also states that due to the lack of harmonized analytical methods, the enforcement costs could be higher than this estimate.

SEAC considers it appropriate to use the average enforcement costs as an indication for the enforcement costs for this restriction proposal. The proposed restriction has a relatively limited and targeted scope, and thus it is not likely that the enforcement costs will exceed the average enforcement costs.

The Forum has in its advice concluded that the restriction is enforceable. The Forum has found no available information on the costs of the analysis but notes that they probably will be in the range of relatively expensive analysis, given the number of substances to check, the low limit values and the specific protocols for preparing the sample. SEAC takes notes of the Forum's views.

iii. Total costs

After discussions with SEAC, the Dossier Submitter calculated the total quantified costs using an analytical period of ten years and a discount rate of 4%. Given the limited information on costs currently available, the calculations are now only based on the costs for diapers manufacturers of switching to TCF pulp, the testing costs for diapers manufacturers and the enforcement costs. The annualised cost is €50 million in the central scenario (with a range of €6 - €100 million considering the low and the high scenarios). SEAC notes that the cost of switching to TCF pulp is rather uncertain, given that it is not known whether that measure would reduce dioxins and furans. In case only the testing costs are considered, the annualised costs would be €35 million in the central scenario (with a range of €0.6 million - €80 million considering the low and the high scenarios).

Table 5 Total costs

	Annualized net present value of the costs, discounted at 4 % over 10 years from 2024
Total costs of moving to TCF pulp	€5-25 million/year Central estimate €15 million/year
Total testing costs	€0.6 – 80 million/year Central estimate €35 million/year
Total enforcement costs	€45 000 /year
Grand total	€6 – 100 million/year Central estimate €50 million/year

SEAC notes that the above cost assessment assumes that there are feasible measures available for manufacturers to reduce contaminants in single-use baby diapers. However, comments from the consultation indicate that it may not be possible to reduce contaminants in single-use baby diapers to the proposed migration limits. SEAC finds that the Dossier Submitter has not clearly demonstrated that there are feasible measures that the manufacturers could undertake, and that the consultation has not shown feasible measures but has instead indicated that there may be no feasible measures available.

As presented in the specific cost sections discussed above (see 'Overall availability of alternatives'), several consultation comments state that the substances in scope come from background contamination.

SEAC considers that if more of the substances in scope are found in single-use diapers, testing costs are likely to be higher, as detection will lead to additional testing of all materials in the specific single-use diaper to find the source of contamination. SEAC also considers that the more detects of the substances in scope that are found in single-use diapers, the more diapers will be removed from the market and thus lead to higher costs in the form of market disruption. SEAC does not have any information about how high these potential costs could be. If all diapers that are tested have detects of the substances in scope, and there are no feasible measures that industry could undertake to reduce these contaminations, it would imply that single-use baby diapers could no longer be placed on the European market. The consequences of no longer having single-use baby diapers on the market are not analysed in detail neither by the Dossier Submitter nor in the comments from the consultation. Nevertheless, SEAC considers that the removal of single-use baby diapers from the European market would lead to both a significant welfare loss for consumers, lost profits for the manufacturers and job losses.

At the same time, SEAC notes that industry comments #3165, 3176, 3302 and 3316 have provided information showing that they did not detect the substances when replicating the analytical method used by the Dossier Submitter to the extent that information about the method was available and using samples from the exact same products that ANSES tested. The comments state that the laboratories had the technical capability to find traces of the substances in scope at the levels indicated by the Dossier Submitter (the LOQ values were the same) yet did not detect any. The results and information about the methods have been provided to RAC/SEAC (but are partly claimed confidential). They argue that laboratories have been working for two years but have not been able to replicate reported detected results associated with the Dossier Submitter protocol. Industry does not envision that instrument sensitivity will be substantially different in 24 months than today and thus considers that the analytical methods will not be improved. SEAC notes that it is not known if other laboratories could replicate the Dosser Submitter's results. SEAC notes that if the laboratory results provided in these comments mean that single-use baby diapers generally don't contain the substances in scope above the proposed migration limits, then this means that industry may not need to take any further measures to reduce migrations (such as switching to TCF pulp) but would instead only need to do periodic regular testing to ensure that there is no migration above the proposed migration levels.

B. RO2

This restriction option has a broader scope than RO1. It covers the same chemicals as RO1 and all the congeners of the PAHs, all the congeners of the PCDD/Fs, and DL-PCBs which means that a migration limit would also be defined for each congener. The conditions of the restriction are unchanged compared to RO1.

The Dossier Submitter expects that measures and technical solutions implemented by the industry to remove the chemicals covered by RO1 should in principle also be efficient in removing their congeners covered by RO2, without additional efforts. Therefore, the risk reduction capacity of RO2 is expected to be similar to RO1.

The testing and enforcement costs from RO2 are expected to be somewhat similar to RO1 even though a higher number of substances would have to be tested and monitored (not quantified) since congeners and substances would be tested simultaneously without additional testing burden. According to the Dossier Submitter, having the congeners in the scope of RO2 would not impact the analytical practicalities and a harmonized analytical method with urine

simulant would equally allow measuring chemicals as well as their congeners. An industry association (#3165) states that if analytical methods for the substances of interest were to exist and were readily available, in diaper matrices, at the LOQs necessary for the restriction to be implemented, no additional testing burden is required by RO2 over RO1. The per-congener analysis (PAHs, D/F/DL-PCBs) required by RO2 already must be done to calculate sum-TEQ values. The association #3165 judges that – given the existence of suitable, routine tests – the Dossier Submitter's estimate of up to €3000 per sample, across all substances required, is a reasonable estimate.

Another industry association (#3169) is of a different view and says that, as RO2 covers more substances, at least testing costs for RO2 will be higher than for RO1, because more substances have to be considered and monitored.

Based on the limited information available and the limited assessment of RO2, alongside with the conclusion that it is not clear weather feasible measures to reduce the contamination in RO1 exists, SEAC considers that it is not clear that feasible measures exist for RO2 either. There are therefore similar uncertainties associated with the costs of RO2 as with RO1 and therefore it is also not possible to derive a total cost for RO2. Nevertheless, as explained in section 3.3.1, SEAC considers that the testing costs under RO2 would be significantly higher than for RO1 given that individual migration limits would be set for more substances and compliance would hence need to be checked for each substance covered.

3.3.3.2. Benefits

Summary of proposal:

According to the Annex XV report, it is difficult to estimate the incidence and prevalence of adverse effects in babies likely to be associated with the exposure to chemicals contained in single-use baby diapers for several reasons.

Firstly, there are no epidemiological studies available on this exposure source and these specific chemicals.

Secondly, all DNEL/DMELs 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 assessing actual human health impacts and disease burden of a risk generated through dermal exposure.

Thirdly, the dose-response relationships available for some substances in the scope were built on animal studies. Therefore, they do not allow quantifying the actual number of babies at risk, i.e. the number of babies exposed who would develop adverse effects. This is particularly the case of PAHs and formaldehyde. The dose-response relationships available for PCDD/Fs and DL-PCBs were built from human data which could have made them fit-for-purpose but, again, they are based on the oral route which is a source of uncertainty when assessing human health impacts of a risk generated through dermal exposure.

Finally, most of the substances in the scope are ubiquitous and without epidemiological studies or appropriate dose-response relationships. Therefore, there are no robust and scientifically based means to estimate the attributable fraction of babies who would at older ages or in their adulthood develop adverse effects from having worn single-use diapers.

However, the chemicals within the scope show severe hazard profiles:

- Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity and skin sensitization according to the CLP Regulation.

- PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action. Most of the PAHs in the scope have a harmonised classification or a self-classification for carcinogenicity under the CLP Regulation. Furthermore, two of them have also a harmonised classification for mutagenicity and one is additionally classified as reprotoxic and skin sensitizer. For two of them RAC has adopted opinions that deal with harmonised classifications for mutagenicity and carcinogenicity.

- PCDD/Fs and PCBs show hazardous properties for fertility and carcinogenicity. Some of them show mutagenicity properties.

- Moreover, PAHs, formaldehyde and some PCDD/Fs and PCBs are suspected endocrine disruptors.

Based on this, the Dossier Submitter concludes that by being exposed to these chemicals through their diapers, children and infants may develop very severe, various and latent diseases such as:

- Cancers (skin tumours),
- Impact on their fertility and other reprotoxic effects,
- Endocrine disrupting effects,
- Skin sensitisation.

Although the exact number of babies who might develop adverse effects cannot be estimated due to the above-mentioned reasons, given the severity, the variability and the latency of the effects of concern, the Dossier Submitter considers that the proposed restriction is expected to have positive health impacts since it will prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their single-use baby diapers every year. When it cannot be determined to what extent illness or disease will occur, the risk assessment undertaken can be used as a proxy of the health impacts. According to the Dossier Submitter, the risk assessment undertaken by them shows plausible risks. The Dossier Submitter also emphasizes that babies represent a particularly vulnerable sub-population as well as future generations that should be protected also based on equity and distributional considerations.

SEAC conclusion(s):

RAC has concluded that uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed.

SEAC concludes that the benefits of the proposed restriction are not demonstrated. The conclusion is based on RAC's assessment and its conclusion that a risk is not demonstrated, as well as the fact that there are no epidemiological studies or other forms of quantification of adverse effects associated with infants wearing single-use diapers. The conclusion is also supported by comments from the consultation indicating that industry has not been able to detect the substances in scope, when using the same analytical methods as the Dossier Submitter. If the laboratory results provided by these comments are also representative of

the wider industry (which is not known), then this indicates that single-use baby diapers may not contain the substances in scope above the proposed migration limits and, hence, the proposed restriction would result in no additional benefits. Finally, the conclusion is underpinned by comments from the consultation which refer to studies that indicate that the substances in scope come from unavoidable background contamination. If the substances in scope are present at similar levels in the environment, it is likely that there are no specific measures available to reduce the contamination (or even if there were, the diapers may be contaminated when the package is opened at home), and thus that the proposed restriction may not result in any benefits.

Key elements underpinning the SEAC conclusion(s):

SEAC notes that the Dossier Submitter has found that there are 16.1 million infants in the age of 0-3 years in Europe. The Dossier Submitter assumes that 90% of infants between 0 and 3 years use single-use diapers every day, and that it implies that 14.5 million infants and children in Europe are using single-use diapers every year. SEAC finds this assumption reasonable.

The lack of epidemiological data means that it is not possible to determine or quantify to what extent infants experience adverse effects due to their wearing of single-use baby diapers. The Dossier Submitter instead argues that its risk assessment can be used as a proxy of the health impacts. The Dossier Submitter states that the risk assessment shows that substances found in the baby diapers exceed health thresholds. However, the Dossier Submitter also states that due to the lack of epidemiological studies, of robust and extrapolatable dose-response relationships, and the substances in scope being ubiquitous, there is no scientifically based means to estimate the incidence and prevalence of adverse effects caused by wearing diapers. Therefore, the Dossier Submitter's approach of assessing human health benefits is qualitative.

SEAC acknowledges that a qualitative assessment can be useful, although it makes the comparison of benefits and costs more challenging.

SEAC notes that other regulatory agencies have also undertaken studies on the presence of hazardous substances in diapers. In the Background Document, the Dossier Submitter has added reference to several studies by various governments or agencies regarding the presence of hazardous chemicals in single-use diapers.

- In 2009 the Danish Environmental Protection Agency published a study on exposure of two-year-old children to chemical substances in consumer products. In the study they found low levels of formaldehyde in the diapers, but the levels were at the detection threshold. The Danish study did not make an explicit conclusion on the safety of diapers, but the study did conclude that for DBP, dioxin and dioxine-like PCBs, the highest amounts are contributed by food, indoor air, and dust.
- The Belgian Federal Public Service of Health, Food Chain Safety and Environment (VITO) concluded in a study from 2018 that baby diapers are safe, since the concentrations were found to be low.
- A Swiss study from the Swiss Federal Food Safety and Veterinary Office from 2018, concluded that baby diapers do not contain chemicals likely to pose health risks for infants and toddlers.

The Dossier Submitter states that they chose to not retain the substances detected and/or quantified in these studies in the present restriction proposal for several reasons: either

because these studies are too old, and the diapers composition may have evolved over the years or either because the extraction methods used are not the one recommended in the present restriction proposal.

SEAC notes that these studies have not found a risk associated with single-use baby diapers, and that there does not seem to be a common view regarding the safety of single-use baby diapers.

SEAC further recognizes that comments in the consultation (#3165, 3176, 3302 and 3316) indicate that industry did not detect any of the substances in scope when attempting to replicate the analytical method used by the Dossier Submitter (to the extent publicly disclosed). SEAC notes that if these laboratory results submitted by industry are also representative of the wider industry (which is not known) then this indicates that single-use baby diapers may not contain the substances in scope above the proposed migration limits and, hence, the proposed restriction would result in no additional benefits. This uncertainty contributes to the conclusion that the benefits of the proposed restriction are not demonstrated.

RAC has concluded that uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. This means that the benefits of the proposed restriction are not demonstrated. SEAC takes RAC's conclusion into account and concludes that the benefits of the proposed restriction are not demonstrated.

SEAC also finds that the comments from the consultation stating that the substances in scope stem from unavoidable background contamination support the conclusion that the benefits of the proposed restriction are not demonstrated. If the substances in scope are background contamination, it is likely that there are no specific measures that the manufacturers could undertake to reduce the contamination, and the single-use diapers will anyway be contaminated when the package is opened at home and thus the proposed restriction may not lead to further benefits.

3.3.3.3. Other impacts

Summary of proposal:

In terms of impacts on consumers, it may be anticipated that some of the industry compliance costs may be pushed down the supply chain to the distributors and finally to the consumers. Industry has indicated as a rough estimate that a price increase of 2-10% per stock-keeping unit at point of sale is expected. The Dossier Submitter does not have further information to challenge this price increase and considers it largely uncertain. Nevertheless, the Dossier Submitter has estimated that an increased sales price of 2-10% per stock-keeping unit would correspond to a price increase to consumers of about:

- €1-€7.50 for a typical month pack of 250 single-use baby diapers for babies between 2-5 kgs
- €0.80-€6 for a typical month pack of 200 single-use baby diapers for babies between 5-9 kgs.
- €0.60-€4.50 for a typical month pack of 150 single-use baby diapers for babies between 9-15 kgs.
- €0.44-€3.30 for a typical month pack of 110 single-use baby diapers for babies above

18 kgs.

The Dossier Submitter considers the lower bound of the possible price increase as rather low at any baby's age and that it should be affordable for consumers (€0.44-€1 per month). However, if realistically estimated, the upper bound of the price increase may be considered as rather significant especially for low incomes families and might be less affordable (€3.30-€7.50 per month). The price increase burden would be higher for families of new-borns in the very first months after birth and would then be lower. In any case, any price increase would only be temporarily borne by consumers since after 3 years old, most children stop wearing diapers. The Dossier Submitter concludes that the potential price increase (if any) would likely be limited given the very high level of price competition on the single-use baby diapers market currently within EEA30.

In terms of social impacts, industry has argued that employment in the sector might be reduced due to the increased costs of manufacturing diapers. The Dossier Submitter does not have further information to assess this statement or to quantify such impacts.

In relation to distributional impacts, SMEs may have more difficulties to comply with the restriction because the costs may be relatively more significant for them. Moreover, a higher frequency of test and controls to be carried out on their manufacturing process, products and raw materials may be financially and logistically more difficult to handle. Consequently, one may expect that SMEs might hardly absorb the extra-costs and might pass them down onto the consumers. However, the single-use baby diapers market is mostly dominated by big companies and the number of SMEs is minor. SMEs contacted during the preparation of the proposal provided information on the additional costs they may face but did not raise major concerns about the affordability of the costs to comply with the proposed restriction.

SEAC conclusion(s):

SEAC concludes that there might be impacts on the consumers, in the form of a price increase for single-use baby-diapers. SEAC does not find that the estimates provided by industry during dossier development are backed up by further justifications and thus, finds it difficult to conclude on how large the impact for consumers could be. SEAC is not convinced that the price increase would be limited, as argued by the Dossier Submitter. Nevertheless, this makes little difference for the assessment of overall costs and the proportionality of the restriction as the effects of whether the compliance costs would fall on industry or consumers are mainly distributional.

SEAC concludes that there is a lack of information on social impacts and distributional impacts.

Key elements underpinning the SEAC conclusion(s):

In addition to the costs for the manufacturers, there are also implications for the consumers, social impacts, and distributional impacts to be considered.

Impacts on consumers

The Dossier Submitter states that it is uncertain whether the extra costs for the diapers industry due to the proposed restriction would be passed on to the consumers or borne by industry.

According to the Dossier Submitter, industry reports that a price increase for the consumers

is likely. Industry has indicated a possible price increase in the range of 2% and 10%. This would imply a price increase of €0.004 - €0.03 per diaper. The prices for a single diaper are in the range of €0.2 - €0.3 and the potential price increase will thus lead to prices in the range of €0.204 - €0.33.

However, the Dossier Submitter considers that this potential increase would likely be limited, given the very high level of price competition on the single-use baby diapers market. The Dossier Submitter assumes that the extra costs would be borne by the diapers industry and absorbed by the upstream supply chain. SEAC considers it likely that industry will pass some of the costs on to consumers. The market is oligopolistic, which means that there are a few large manufacturers and some small as well. The competition in oligopolistic markets can vary. The Dossier Submitter has assumed that the competition in the market is fierce, but has not presented any evidence on this, neither for France nor Europe. SEAC finds that it is uncertain how fierce the competition is, and that it is uncertain if the competition differs between countries.

The Dossier Submitter also brings forward the argument that the competition is fierce on price, to explain why they believe that the potential price increase will be limited. SEAC notes that the Dossier Submitter has provided no evidence to support the evidence that competition is driven by price and notes that e.g. the performance of the diaper may also be a driver. SEAC finds that on the other hand, oligopolistic markets make it easier for the manufacturers to keep an eye on what the others do, which could imply that they push the increased costs down to the consumers. The demand for single-use baby diapers is quite inelastic, which means that the consumers will continue to buy the same number of diapers, even if the prices increase, and this is a reason that makes it possible for the manufacturers to pass increased costs on to the consumers. Therefore, SEAC finds it likely that some of the costs will be passed on to consumers. But because of the possible fierce competition, SEAC considers it likely that not all the costs are passed on. SEAC does not have a clear opinion on how large the price increase might be for the consumers.

SEAC acknowledges that most families with babies will consider single-use baby diapers as a necessary article. SEAC also acknowledges that for low-income families, a price increase on single-use baby diapers might have a significant effect on their purchasing power.

Social impacts

According to industry consulted during the preparation of the dossier, employment in the sector might be reduced due to the higher costs of manufacturing diapers. The Dossier Submitter does not have further information to assess this statement or to quantify such impacts.

SEAC does consider it quite unlikely that employment in the sector might be reduced, as SEAC supports the Dossier Submitter's view that the demand for single-use diapers is inelastic. The demand for baby diapers is driven by the birth rate in the EU, and the proposed restriction will not affect the birth rate. The proposed restriction will also apply to imported single-use baby diapers.

Distributional impacts

The restriction proposal is expected to generate distributional impacts. The Dossier Submitter considers that SMEs may have more difficulties to comply with the restriction because they

would be disproportionately affected by the extra-costs, since they are smaller. On the other hand, the market is dominated by large companies and the number of SMEs is small. Most of the SMEs differentiate their products by specificities, like eco-friendly, organic etc. If the companies selling diapers that are organic, eco-friendly etc already sell diapers that are not contaminated, this would imply that they do not need to make major changes due to the proposed restriction. But if the diapers manufactured by SMEs would also be contaminated, it is possible that the reduction of contaminants would be less feasible for them than for larger companies. During the preparation of the proposal, the SMEs provided information on the extra costs, but they did not raise major concerns about the affordability.

SEAC does not have further information related to distributional impacts.

3.3.3.4. Overall proportionality

Summary of proposal:

The Dossier Submitter argues that proposed restriction will bring benefits to society due to the avoided health impacts of adverse effects on babies' health even though their magnitude could not be accurately assessed. The Dossier Submitter expects potentially very severe, variable and latent diseases affecting their quality of life over their lifetime, such as cancers, suspected endocrine disruption and reprotoxic effects, to be avoided in children at older ages and in their adulthood. Given the widespread use of single-use baby diapers, the Dossier Submitter expects the proposed restriction to prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their diapers every year.

While the impacts on companies are uncertain, the Dossier Submitter does not expect major critical economic impacts that would be unaffordable by the supply chain and of a nature to threaten industry activities, neither in EEA30 nor outside. Positive economic impacts for the supply chains are possible, given a potential increased level of confidence of consumers in single-use baby diapers as a result of the restriction proposal. Additionally, some extra-profits could arise for more 'eco-friendly' and safer raw materials suppliers, such as current TCF pulp companies and possibly new ones that may enter this market. The risk of negative economic impacts for consumers is considered very limited and also when considering uncertainties regarding potential price increase, the restriction is considered affordable to consumers.

The Dossier Submitter therefore considers that the proposed restriction is affordable and proportionate. The other restriction option, RO2, is also considered proportionate by the Dossier Submitter. When comparing the two restriction options, the Dossier Submitter expects the benefits and proportionality of RO2 to be similar to RO1.

RAC and SEAC conclusion(s):

RAC notes that from a risk point of view, the uncertainties related to the restriction proposal's risk assessment are such that a risk for babies has not been demonstrated for formaldehyde and PCDDs/Fs/DL-PCBs, and cannot be characterised for PAHs and NDL-PCBs.

To conclude on proportionality, SEAC needs to compare benefits and costs. The Dossier Submitter has not quantified the benefits, and RAC's conclusion implies that the Dossier Submitter has not demonstrated that there would be benefits arising from the proposed restriction. The only costs that are quantified are those related to a possible switch from ECF to TCF, testing and enforcement. It is still uncertain if the costs associated with switching

from ECF to TCF are relevant and there may also be other, currently unknown, costs. There is still uncertainty regarding what industry would need to do to comply with the restriction, including whether any measures could be undertaken to reduce or remove the contaminants. There is also uncertainty about the potential costs of these measures, if they are available. Lastly, there is not yet a standardised analytical method to test for these levels of migration of the substances.

Based on this, SEAC concludes that it has not been demonstrated that the proposed restriction would be proportionate, as the benefits of the proposed restriction are not demonstrated and the costs are highly uncertain. It is however clear that the restriction would at least lead to additional testing and enforcement costs (as well as potentially also other costs).

As there are large uncertainties on different levels of the assessment, SEAC will discuss possible scenarios to underpin the conclusion on proportionality, and assess a break-even analysis made by the Dossier Submitter during the opinion development.

Key elements underpinning the RAC and SEAC conclusion(s):

It is difficult to compare the costs and benefits given that the benefits are not quantified. Some of the potential substitution costs, as well as the testing and enforcement costs, are quantified. But there is still uncertainty regarding which costs are relevant because it is uncertain which measures, if any, the manufacturers would need to undertake to reduce or remove the substances in scope.

Break-even analysis

During the opinion-development, the Dossier Submitter carried out a break-even analysis, to get a better understanding of the proportionality. The analysis aims at illustrating and putting into perspective the health benefits that would be required for the proposal to break even, i.e. to generate benefits that are greater than or equal to costs.

The break-even analysis uses avoided skin cancer cases as a proxy for benefits, considering the other endpoints are too uncertain and vague to be "translated" into precise and valuable diseases. The break-even analysis was performed on the total costs, which implies the costs of changing from ECF to TCF pulp, testing and enforcement costs, as these costs are the only ones that have been estimated. Therefore, the break-even analysis does not fully account for the expected benefits and economic impacts of the restriction proposal, but only a part of them. The costs used here are the total annualized costs, over a 10-year period. The column named "Break-even" stands for: Number of skin cancer cases to be avoided each year to break even.

Table 6 Break-even analysis

	Annualized costs	Value of an avoided skin cancer case	Break-even	Number of EU population exposed (in Million)	Skin cancer incidence among exposed babies (cases per	Actual skin cancers incidence rate according to GDP	Actual skin cancers incidence rate converted to in 1 Million, based on EU 27	Break-even analysis incidence compared to actual incidence (%)

					Million)		(447 M people)	
Min	≈€6 000 000	€121 567	49	14.5	3.4	429 837	962	0.4%
Mean	≈€50 000 000	€143 375	349	14.5	24.1	534 018	1 195	2.0%
max	≈€100 000 000	€158 745	630	14.5	43.4	628 967	1 407	3.1%

The Dossier Submitter finds that between 49 and 630 cancer cases would have to be avoided each year for the restriction proposal to break even. The Dossier Submitter has then calculated the incidence per million that is needed for the proposal to break even and compared this to the actual incidence of skin cancer in Europe. The Dossier Submitter concludes that one would need to see a reduction in the actual incidence of 0.4% for the low-cost scenario, 2.0% for the central scenario and 3.1% for the high scenario.

Given the lack of epidemiological data, SEAC considers that in general a break-even analysis could be helpful for considering the proportionality of the proposed restriction. Knowing how many cancer cases would have to be prevented by the implementation of the restriction, in order for the benefits to be equal to or higher than the costs, could underpin the conclusions on proportionality by considering the likelihood of this reduction in cancer cases actually occurring

Nevertheless, SEAC does not consider the Dossier Submitter's break-even analysis useful in this case, as there are some very important uncertainties associated with it. In particular:

- The quantified costs used for the break-even analysis are very uncertain. As described in the earlier sections of this opinion, it is currently not fully understood what industry would actually need to do in order to comply with the proposed restriction and what the associated costs would be. The quantified costs only represent the costs related to switching from ECF to TCF pulp (which may not reduce furans and dioxins based on the available information), testing costs and enforcement costs. There may also be other costs that simply have not been quantified.

- The break-even analysis only focuses on one endpoint: carcinogenicity. SEAC understands why the Dossier Submitter has focused on carcinogenicity, but as there are several potential endpoints, and a lack of information on the relative importance of carcinogenicity compared to the other potential end-points, it is difficult to draw conclusions from the break-even analysis on the question of proportionality.

- Causes of skin cancer:

    - There is no clear evidence that wearing of diapers could be a cause of skin cancer

    - Latency has not been considered in the Dossier Submitter's analysis. Seeing as there are many compounding factors leading to skin cancer, it is not clear

how exposure to the substances in scope in early life contributes to skin cancer later in life.

- In the medical literature, it is stated that overexposure to sunlight is one of the major causes of skin cancer. According to WHO[21], experts believe that 4 of 5 skin cancer cases are caused by overexposure to sunlight.

SEAC notes that for all the different cost scenarios, the incidence of skin cancer in the EU is far higher than the incidence needed for the restriction proposal to break even in this analysis. Given that the "break-even analysis incidence" is within the actual incidence it is theoretically possible that the proposed restriction could break even.

In cases where the incidence rates needed for a restriction proposal to break even are far higher than the actual incidence rates, it is possible to draw the conclusion that the cases needed to break even are unlikely to be achieved. But when the situation is the opposite, and the actual incidence rates are higher than the levels needed to break even, it is more difficult to draw clear conclusions.

In this specific case, it is uncertain if the costs used in the assessment are representative of the costs of the proposed restriction. Only one of the potential endpoints are used in the break-even analysis and it is unclear if it really is an endpoint, and what relative importance the potential endpoint has. Finally, one may ask whether it is relevant to look at the whole incidence rate of skin cancer, as a major fraction of the skin cancer cases probably is caused by overexposure to sunlight. Based on all these uncertainties, SEAC is not able to draw any conclusions on proportionality from the break-even analysis.

Proportionality discussion for different scenarios

There are several uncertainties regarding the proposed restriction, which have implications for the proportionality discussion. This section discusses proportionality based on three key questions:

1. Are the substances in scope detected in single-use baby diapers above the proposed migration levels?
2. If they are detected, are there available measures to reduce the migration levels to the limits proposed?
3. If they are detected, do the substances in scope stem from unavoidable background contamination?

From these questions, the following scenarios are considered:

A. The substances in scope ARE NOT detected in single-use baby diapers above the migration levels
B. The substances in scope ARE detected in single-use baby diapers above the migration levels
    i. The substances are detected in single-use baby diapers above the migration levels and there ARE NO available measures to reduce the migration levels to

[21] https://www.who.int/activities/raising-awareness-on-ultraviolet-radiation

the limits proposed

ii. The substances are detected in single-use baby diapers above the migration levels and there ARE available measures to reduce the migration levels to the limits proposed

1. Are the substances in scope detected in single-use baby diapers above the migration levels?

As outlined e.g. in the section 'Total costs', industry comments #3165, 3176, 3302 and 3316 have provided information showing that they did not detect the substances when attempting to replicate the analytical method used by the Dossier Submitter. SEAC notes that it is not clear if other laboratories could replicate the Dosser Submitter's results. If the information provided in these comments mean that single-use baby diapers generally don't contain the substances in scope above the proposed migration limits, then this means that industry may not need to take any further technical measures to reduce migrations (such as switching to TCF pulp) but would instead only need to do additional testing. In that scenario (scenario A), given that the single-use baby diapers currently don't contain the substances in scope then the proposed restriction would result in no additional benefits but additional testing and enforcement costs and would hence not be proportionate.

If, on the other hand, the substances in scope are detected in single-use baby diapers, then the question becomes whether there are measures available to reduce the migration levels. SEAC notes that whether or not substances are detected in single-use diapers also depends on the technical capacity and the level of quantification (LOQ)/level of detection (LOD) levels.

SEAC also notes that a possible scenario could be that some of the substances could be detected in some of the diapers, but SEAC does not have any information on the probabilities of detection related to the substances in scope.

2. Are there available measures to reduce the migration levels to the limits proposed?

As discussed in more detail in the section on costs, SEAC found that the Dossier Submitter has not clearly demonstrated that there are feasible measures that industry could undertake to reduce any migration of the substances, and that the consultation has not shown feasible measures but has instead indicated that there may be no feasible measures available.

In the scenario that there are available measures (scenario Bi), it is not clear what these measures are and what the costs of them would be. In that scenario, SEAC is not able to conclude if the restriction would be proportionate or not. More information would be needed on the industry measures that would be required to comply with the restrictions before a conclusion on proportionality could be reached.

In the scenario that there are no available measures (scenario Bii), then it would be impossible for industry to comply for at least a share of the single-use baby diapers on the market and hence these diapers would need to be withdrawn from the market. In addition to increased testing costs, this would result in profit losses and disposal costs for industry. As these costs are not expected to be compensated by benefits to other actors, they would be net costs for society rather than distributional impacts. Given that it has not been demonstrated that there would be any benefits attributed to the proposed restriction, SEAC considers that the net costs are likely to outweigh the potential health benefits. Therefore, the restriction would be

likely not proportionate in this scenario.

If the share of diapers that must be withdrawn is large enough, then it means that in addition to the impact on industry, consumers would have to switch to re-usable diapers, with the resulting additional negative economic and social impacts. In this scenario, the restriction would be likely even less proportionate.

3. Do the substances in scope stem from unavoidable background contamination?

As explained in previous sections, several consultation comments indicated that some of the proposed substances may be present in the environment in the form of background concentrations. SEAC found it likely that at least part of the substances in scope stem from background contamination.

If the assumption is that all of the substances in scope stem from background contamination at the proposed migration levels, it would imply that there are likely no specific measures that industry could undertake to reduce migrations. It would also imply that if extremely sensitive test methods become available, a potential consequence is that uncontrollable background levels of chemicals in scope will be detected in many or all tested samples. This implies that the larger the fraction of the substances in scope that come from background contamination, the less likely it is that the proposed restriction could be proportionate. If the fraction stemming from environmental background contamination would be low, the question is then whether industry has available measures to reduce the migration levels to the limits proposed, which is discussed under question 2 above.

Conclusions on proportionality

The above discussion about proportionality in different scenarios shows the many uncertainties and information gaps that remain related to the proposed restriction. SEAC notes that while the scenarios provide an overview of the key points for its evaluation of proportionality, in reality several of the scenarios may be relevant (e.g. perhaps some substances would be detected in some diapers, while other tested diapers would give no detections).

In any case, SEAC notes that for none of the scenarios is there any evidence demonstrating that the restriction would be proportionate. This is further supported by RAC's conclusion that the uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed. Therefore, SEAC concludes that it has not been demonstrated that the proposed restriction would be proportionate.

3.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal

Difficulties are expected from a technical and/or economic standpoint regarding the analytical feasibility for testing and monitoring capacity of the restriction. For now, no standardised analytical method exists using an extraction by urine simulant in a whole diaper. Considering

that companies, laboratories but also EU enforcement services will have to build this new analytical method, even define a CEN standard, the transitional period of 24 months is considered by the Dossier Submitter as necessary.

RAC and SEAC conclusion(s):

SEAC considers that the proposed restriction (RO1) is practical and enforceable if certain considerations are taken into account:

- Clarifying the scope in regard to the PCBs covered and how to check compliance (i.e. use of marker/indicator PCBs)
- Clarifying how the migration limits should be applied to the substances covered.
- Providing a framework for enforcement of the proposed restriction (RO1) until a standardised analytical method has been developed.
- Migration limits are brought in line with the Forum recommendations.

RO2 is considered to be even less appropriate than RO1 in regard to practicality and enforceability due to the application of individual migration limits to the large number of substances within scope.

Key elements underpinning the RAC and SEAC conclusion(s):

According to SEAC, RAC and Forum several issues are of particular importance when discussing the practicality, including enforceability, of the proposed restriction.

1. Scope

From an enforceability standpoint it is clear which substances are covered by the proposed restriction (RO1). Annexed to the restriction wording is a table that includes formaldehyde, as well as an exhaustive list of which specific PAHs, PCDDs and PCDFs are covered.

The Dossier Submitter has also indicated that all PCBs (209 congeners in total) are within the scope of the proposed restriction. If all PCBs are intended to be covered then SEAC considers it sufficient and less confusing to state that all PCBs are covered by the proposed restriction. During opinion development the Dossier Submitter indicated that individual testing for all PCB congeners is not practical and therefore suggests using so-called indicator/marker PCBs to check compliance. SEAC agrees with this and suggests listing which indicator/marker PCBs should be used[11].

The Dossier Submitter clarified to SEAC that the proposed restriction covers all types of single-use diapers worn by children and infants until they are fully toilet-trained, which is usually at the age of three. The scope of the risk assessment targets children and infants from 0-36 months. It does have to be noted that single-use diapers seem to be categorised by baby weight rather than baby age. While correlation tables between median baby weight and age exist, diaper categories for older babies will not correspond cleanly with a baby age of 36 months. RAC and SEAC do not consider this to severely hamper enforcement. The Forum stated in its advice that it may be helpful to use more general terms, such as "single-use diaper products for babies and infants" instead of listing various diaper products. This might reduce the risk of specialised products not falling under the specific definitions given in the restriction.

The Forum indicated that some unclarity exists over whether the entire diaper is within the scope of the restriction since the restriction does not mention this explicitly. During the opinion development the Dossier Submitter clarified that the entire diaper is targeted since chemicals can migrate from the other parts of the diapers (due to urine simulant, the sweat or to the ability itself of the chemicals to migrate). The proposed restriction requires compliance to be checked through a specific analytical method mimicking real-life conditions of use and therefore exposure. However, the preferred protocol by the Dossier Submitter only targets the extractable parts of the diaper. As such RAC and SEAC share the Forum's concern. Specifying the analytical method and aligning the scope to it would negate this unclarity.

To avoid different interpretations between Member States, the Forum also recommended that terms such as "baby", "infant", "child", "all the article", "re-usable", as well as the various types of diapers should be defined. The TEQ mentioned in paragraph 2 would according to the Forum also require closer definition.

2. Migration limits

The Forum indicated unclarity in regard to how the migration limit is set up for PCCD/Fs and DL-PCBs. The proposed restriction wording, as amended in the BD, states (RO1):

> The sum of the quantified PCDDs, PCDFs, and DL-PCBs in a migration limit equal to or greater than **0.0017 ng_{TEQ}/kg of diaper** for all the entire articles specified in paragraph 1.

This could be interpreted as 1. corresponding to the sum of all categories of substances together (PCCDs+PCDFs+DL-PCBs) or 2. to the sum of each category of substances (∑PCCDs, ∑PCDFs, ∑DL-PCBs). The Dossier Submitter has indicated that the second interpretation is correct with the caveat that DL-PCBs migration must also be counted toward the total PCB migration. The Dossier Submitter does not consider this double counting since two different health reference values (HRVs) are used to propose migration limits. RAC has agreed with this approach. SEAC and RAC do however agree that this interpretation is not clear from the restriction wording and should therefore be reconsidered.

The Dossier Submitter has indicated that "*in some cases, the restriction would require to measure levels close to or in some cases even below current LOQ achievable even by best in class specialized laboratories*". This was confirmed by the Forum through an analysis of the limit values (LV) and their relation to the LoD/LoQ (see table below). The relation "LoQ ≤ 0.3 LV" is used as an indication of the enforceability of a limit value using currently available analytical methods.

Table 7 Current LoD/LoQs for the substances in the scope of the Annex XV proposal

Substances	LOD	LOQ	LV	LOQ ≤0.3 LV
PAHs	Between 0.03 and 0.1 mg/kg	Between 0.1 and 0.4 mg/kg	0.000000023 mg/kg (0.023 ng_{TEQ}/kg)*	no
Dioxins & furans & DL-PCBs	From 0.002 to 1ng/kg regarding the test sample	From 0.002 to 1ng/kg regarding the test sample	0.0017 ng TEQ/kg*	no

Total PCBs	From 0.05 to 3.2 ng/kg according to the test sample	From 0.05 to 3.2 ng/kg according to the test sample	112 ng/kg	yes
Formaldehyde	0.11 mg/kg	0.35 mg/kg	0.42 mg/kg	no

* In the Forum advice, the Forum considered the limit values proposed by the Dossier Submitter at that time. However, after the Forum advice had been developed, the Dossier Submitter updated the limit values for PAHs from 0.034 ng/kg to 0.023 ng/kg and for dioxins & furans & DL-PCBs from 1700 ng_{TEQ}/kg to 0.0017 ng_{TEQ}/kg. With this update, the relation LOQ ≤0.3 *Limit Value is no longer satisfied for dioxins & furans & DL-PCBs (it would have been with the originally proposed limit value of 1700 ng_{TEQ}/kg).

Based on this analysis, it can be concluded that:

- For PAHs the limit value should be set between 0.3 and 1.3 mg PAH/kg considering the currently achievable LoQs.
- For formaldehyde the limit value should be set to at least 1.16 mg formaldehyde/kg considering the currently achievable LoQs.
- For dioxins, furans and DL-PCBs the limit value should be set between 0.0067 and 3.3 ng/kg considering the currently achievable LoQs.
- For the sum of total PCBs, the proposed limit value should be enforceable considering the currently achievable LoQs.

3. Analytical method

The Dossier Submitter specifies that an analytical method using urine simulant needs to be used to check compliance and that a standardised method needs to be developed. Since no standardised analytical methods exist, harmonised enforcement of the proposed restriction is not guaranteed. For past restrictions the absence of a standardised analytical method was acknowledged as a barrier to enforceability, but not a requisite to conclude that a proposed restriction is unenforceable.

However, the Dossier Submitter discussed analytical methods that differs from other studies looking at these types of products (solvent extraction[22] vs urine simulant method). As such RAC and SEAC consider that providing a framework for enforcement of the proposed restriction is necessary until a standardised analytical method has been developed.

According to RAC and SEAC this framework can be provided in one of two possible ways.

a. Adding a specific testing protocol as an annex to the restriction which would ensure more harmonised compliance and enforcement within the whole of the Union[23]. The downside would be that an adaptation to scientific progress would require a legislative change to the restriction.
b. Providing guidelines on a urine simulant analytical method to be used by companies and enforcement. These guidelines could be based on the preferred analytical method

[22] Used in the Belgian, Danish and Swiss studies and considered to be more extreme and not approximating real life use conditions.

[23] It is however recognised that harmonisation/standardisation is complex. Having a protocol can harmonise a modus operandi for testing, but it does not necessarily mean that results obtained with the protocol in different laboratories will not be subject to unacceptable variability.

discussed by the Dossier Submitter (see Appendix: SCL methodology study at the end of the BD). This option would not ensure harmonised enforcement throughout the Union but could afford companies and enforcement agencies to adapt quickly to scientific progress.

RAC and SEAC wish to reiterate that whatever choice is made, this should only be seen as a temporary measure until a standardised analytical method is developed to check compliance with the proposed restriction (RO1).

4. Enforceability of RO2[24]

As a reminder, the scope of RO2 covers RO1 and adds all congeners of PAH and PCDD/F. Furthermore, the migration limits are applied to the individual congeners and not their sum.

Remarks made in points 1-3 are also valid here, but RAC and SEAC consider that the application of migration limits to the individual congeners of the substance groups covered, renders RO2 much less appropriate in regard to enforceability compared to RO1, due to the sheer number of substances within scope.

3.3.4.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The implementation of this restriction proposal will imply testing and controls costs for industry and authorities (see the section on costs for more information). Nevertheless, for the time being, no harmonized analytical method is available based on urine simulant although EDANA is currently working on the establishment of guidelines for all Absorbent Hygiene Products (AHPs) with a common analytical method that may help the stakeholders defining, before the end of the transitional period, a harmonized analytical method. In conclusion, to enable the monitoring of the results of the implementation of the proposed restriction, a harmonized method should be developed during the transitional period.

RAC and SEAC conclusion(s):

SEAC considers that the proposed restriction (RO1) is monitorable if the considerations mentioned under section 3.3.3 (Practicality including enforceability) are taken into account.

Since the Committee considers RO2 to be less appropriate than RO1 in regards to enforceability, it follows that it is also less monitorable.

Key elements underpinning the RAC and SEAC conclusion(s):

The discussion on monitorability is in this case intimately linked to the practicality, including enforceability, of the proposed restriction. As such, please refer to that section of the opinion for a more in-depth discussion. The conclusions for this section can be found above.

[24] See also discussion under section 3.3 (scope, including derogations) of this opinion.

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

The Dossier Submitter has listed and described several uncertainties. These can be categorised as follows:

Human health hazard assessment: Formaldehyde: The route-to-route extrapolation is questionable because observed effects are correlated with the route of exposure. These are only local effects. Systemic toxicity has not been demonstrated. PAHs: dermal DNEL calculated by ECHA and expressed in µg/cm²/d but not usable to perform the DED calculation. The DED calculation could have been done if data on surface weight had been made available to the Dossier Submitter.

Exposure assessment: Test method: SCL tests with entire diapers, extraction with a urine simulant. Representative of normal use enabling the chemicals actually extracted by urine to be identified. Skin Absorption: The Dossier Submitter decided to use a value of 100% for skin absorption assuming that baby skin can be damaged and enhance the penetration. The approach was adopted by the SCCS and ANSM for products for the buttocks area due to the frequency of skin diseases in the diaper area in babies.

Risk assessment: Risk characterisation. The calculations to generate migration limits are based on worst case scenarios.

Analysis of Alternatives: The identification of the contamination sources for the chemicals of concern has been difficult due to lack of data. Link between FSC certification to get TCF pulp claimed by industry to be a problem to switch to TCF pulp. According to experts consulted, FSC certification is linked to sustainable forest management and not wood transformation.

Human health impact assessment: The human health impact assessment has not been quantified and monetized due to uncertainties (no prevalence/incidence data, all DNEL/DMEL used in the risk assessment were derived based on oral route studies, dose-response relationships available for some substances in the scope only built on animal studies, etc.).

Analytical feasibility: No harmonized test method is available for now.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.4.2. SEAC

Summary of proposal:

Analysis of Alternatives: The identification of the contamination sources for the chemicals of concern has been difficult due to lack of data.

Human health impact assessment: The human health impact assessment has not been quantified and monetized due to uncertainties (no prevalence/incidence data, all DNEL/DMEL used in the risk assessment were derived based on oral route studies, dose-response relationships available for some substances in the scope only built on animal studies, etc.).

Economic Impacts/substitution Costs: Industry reactions to the restriction cannot be anticipated and remain to some degree uncertain; From the publication of ANSES 2019 and French RMOA reports, companies on the single-use diapers market state that they have already started to implement technical and substitution measures in order to reduce/remove contaminants in their products.

Some costs reported by industry are unspecific, some only concern a part of companies' products ranges and some expected costs depend on the companies' size and production or sales volume and may not be representative of the whole market. Some reported costs might present some overlapping between extra-costs already borne due to new measures implemented as a voluntary response from industry since ANSES' expertise and French RMOA have been published and extra-costs specifically attributable to this restriction proposal.

Costs associated with moving to TCF pulp: based on the information at hand, it is difficult for the Dossier Submitter to have a clear-cut conclusion about the better capability of TCF pulp to address the health concerns targeted in this restriction proposal over ECF pulp. Within all the possible solutions to reduce contamination in baby diapers identified, moving to TCF pulp could be an option but given the uncertainties associated with its benefits to human health, its availability in the future and its economic feasibility especially for SMEs, the Dossier Submitter cannot strongly recommend this substitution without reservation. Nevertheless, if industry would decide to switch to TCF pulp, the information presented, in particular regarding expected economic impacts, would be useful to anticipate the possible costs.

Costs associated with the removal or substitution of wetness indicators and removal or substitution of pigments: the Dossier Submitter does not have information allowing to confirm and quantify any loss in profit from the removal of these materials. Industry consulted did not provide any marketing or economic evidence to prove such a loss. It is thus considered as highly uncertain. Moreover, it may be expected that removing these materials from their products would represent cost savings for manufacturers due to fewer materials to purchase and process.

Costs associated with further air decontamination: The Dossier Submitter does not have further information allowing for a quantification or specification of these costs. It is uncertain whether the implementation of further filtration would imply re-investing in completely different air decontamination systems or simply adjusting the system on the spot.

Economic Impacts/testing and enforcement Costs: From the publication of ANSES 2019 and French RMOA reports, companies on the single-use diapers market state that they have already started to implement more regular and stricter testing and controls of their raw

materials, their finished products and their production lines (additionally to the tests they already performed beforehand). Whether part of the testing costs reported in the restriction proposal are already borne and internalized by companies (driven by the publication of ANSES's risk assessment and the French RMOA) or the share of them attributable to this restriction remain unclear.

Due to the lack of harmonized analytical methods and the challenges of measuring very low migration limits such as proposed herein (lower than the current LoD/LoQ) (see Annex E8), the testing costs may be actually somehow higher than reported during the consultation by the Dossier Submitter. This is a source of uncertainty.

Regarding enforcement costs for authorities, they are somehow uncertain. Whether these costs will converge to ECHA's average estimate of €55 600 enforcement costs per restriction per year in total or whether the costs would be higher remains uncertain. There may be some economies of scale in testing practices and costs in connection with the restriction on skin sensitizing substances in textile, leather, furs and hides. However, here again there may be extra-costs due to the lack of harmonized analytical methods and the challenges of measuring very low migration limits such as proposed herein (lower than the current LoD/LoQ).

Economic Impacts/Consumers: Industry claims between +2% and 10% price increases at point of sale as a consequence of this restriction. This expected price increase has been indicated as a rough estimate by industry without evidence. The Dossier Submitter does not have further information to challenge this price increase estimated by industry and considers it as largely uncertain. Moreover, this increase incurred per baby diaper (if any) is considered overall low and affordable by the Dossier Submitter. This conclusion is strengthened by competition considerations since the Dossier Submitter assumes that competition in the diapers market is fierce and largely driven by price. Therefore, the restriction is considered affordable for consumers. SEAC considers it likely that industry will pass some of the costs on to consumers. The market is oligopolistic, which means that there are a few large manufacturers and some small ones as well. The competition in oligopolistic markets can vary. The Dossier Submitter has assumed that the competition in the market is fierce, but has not presented any evidence on this, neither for France nor Europe. SEAC finds that it is uncertain how fierce the competition is, and that it is uncertain if the competition differs between countries.

SEAC conclusion(s):

In SEAC's view the restriction proposal contains several major uncertainties and data gaps, which would need to be addressed to demonstrate that the restriction is justified and proportionate.

Key elements underpinning the SEAC conclusion(s):

The restriction proposal contains several major uncertainties.

The possible sources of substance contamination have been discussed but none of them have been possible to confirm. Given that comments in the consultation have provided evidence that industry have not been able to detect the substances in scope, it is uncertain whether single-use baby diapers generally even contain the substances in scope above the migration levels proposed. In case single-use baby diapers do contain the substances, it is unclear if feasible measures to reduce substances are available. It is therefore also uncertain what

industry would need to do to comply with the proposed restriction and what the associated costs would be. The only costs known to be incurred in case the proposed restriction enters into force are those related to testing and enforcement. The cost for industry to switch from ECF to TCF pulp has also been quantified, but there is no clear evidence that this measure would be needed.

On the benefit side, there is no epidemiological data demonstrating an association between health effects and the wearing of diapers. Furthermore, RAC has concluded that uncertainties in the restriction proposal's risk assessment are such that the Dossier Submitter has not demonstrated that there is an EU-wide risk that needs to be addressed.

All in all, significant uncertainties and data gaps would need to be addressed to demonstrate that the restriction is justified and proportionate.

3.5. REFERENCES