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/RES-O-0000007017-78-01/F

ECHA/SEAC/RES-O-0000007046-77-01/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted [16 September 2021]) and SEAC's opinion (adopted [08 December 2021])

Draft date: 08 December 2021

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

16 September 2021

RES-O-0000007017-78-01/F

8 December 2021

RES-O-0000007046-77-01/F

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**

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 **16 September 2021**.

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

The opinion of RAC was adopted **by consensus**.

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 **8 December 2021**.

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.

The opinion of SEAC was adopted **by consensus** of all members having the right to vote.

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Tables

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}[1]/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.

[1] 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*-	39227-28-6	-

	dioxin; 1,2,3,4,7,8-HxCDD		
	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

RAC considers that the proposed restriction on substances in single-use baby diapers is not justified because the risk could not be demonstrated for formaldehyde and PCDD/Fs/DL-PCBs and could not be characterised for PAHs and NDL-PCBs.

RAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to:

- the identified risk;
- the options identified to reduce the risk;
- the comments submitted by interested parties, as well as;
- other available information as recorded in the Background Document.

1.2. THE OPINION OF SEAC

The opinion of RAC considered that the proposed restriction on substances in single-use baby diapers is not justified because the risk could not be demonstrated for formaldehyde and PCDD/Fs/DL-PCBs and could not be characterised for PAHs and NDL-PCBs. SEAC concluded that it has not been demonstrated that the proposed restriction would be proportionate. Therefore, there is insufficient 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 THE PROPOSAL AND OPINION

2.1. Summary of the proposal

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

Diapers are made of several materials whose purpose is to absorb and retain the child's urine and faeces, thus keeping their skin cleaner and dryer. 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 per baby before the age of toilet training range from 3 800 to 4 800.

The Dossier Submitter reports that formaldehyde, polycyclic aromatic hydrocarbons (PAHs), polychlorinated dibenzo-p-dioxins (dioxins or PCDDs), polychlorinated dibenzofurans (furans or PCDFs) and polychlorobiphenyls (PCBs) have been detected and/or quantified in single-use baby diapers through analytical tests using extraction with a urine simulant. These substances are either classified for carcinogenicity, mutagenicity and skin sensitisation according to the CLP Regulation (formaldehyde), investigated for their carcinogenic potential (PAHs), or associated with various health effects, including toxic effects, adverse reproductive, mutagenic, genotoxic and endocrine effects (PCDD/Fs, PCBs). This indicates the potential exposure of children and infants wearing these articles to the named groups of substances and the potential for various health effects.

The materials used to produce baby diapers can include hazardous substances in the form of impurities/contaminants. The Dossier Submitter carried out analytical chemistry research to identify which substances could pose a risk for babies and infants under the age of three, since this population is particularly vulnerable to adverse effects of exposure to chemicals and should therefore be protected from hazardous substances.

Based on the results of investigations of diaper samples, which were presented in a report published by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES, 2019), further analyses were carried out on diapers sold on the French market, using an experimental urine simulant methodology to extract the substances of concern from the diaper samples. Using these results as the basis for a quantitative risk assessment, the Dossier Submitter selected the substances to be included in the scope of the restriction proposal (i.e., formaldehyde, PAHs, PCDDs/Fs, DL-PCBs).

The Dossier Submitter concluded that the risks from formaldehyde, PAHs, PCDD/Fs, and/or PCBs in single-use baby diapers are not adequately controlled. An analysis of several risk management options (RMOs) was therefore conducted to identify the most appropriate measure to address the risk and to define the scope and conditions of the restriction proposal. The Dossier Submitter further concluded that a restriction under REACH is the most appropriate RMO. Two restriction options were further analysed in the impact assessment. They both aim at limiting the migration of substances in single-use baby diapers placed on the market but differ with respect to which substances are included.

The restriction options further assessed by the Dossier Submitter were:

- **Restriction option 1 (RO1):** Limiting the migration of formaldehyde, the sum of 17 detected or quantified PAHs, the sum of quantified PCDD/Fs and dioxin-like (DL)-PCBs

and the sum of quantified total 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.

A quantitative risk assessment was performed for each of the substances detected or quantified, based on which 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.

On the basis of an analysis of the effectiveness, practicality and monitorability of RO1 and RO2, and the impact assessment performed, RO1 was proposed by the Dossier Submitter as the preferred restriction option.

2.2. Summary of the opinion

RAC concurred, in general, with the Dossier Submitter that the substances in the scope of the proposal might have the potential to induce adverse effects in babies if they are present[2] (or are present above certain concentrations) in single-use baby diapers that come (directly or indirectly e.g. via urine) in contact with the skin.

RAC considered that the separate grouping approaches for (i) PAHs, (ii) PCDDs/Fs and DL-PCBs and (iii) total PCBs (comprising dioxin-like [DL] and non-dioxin like [NDL] congeners) were well justified. NDL-PCBs were not included in the ANSES (2019) study that was conducted in advance of the restriction proposal. Nevertheless, RAC considered that inclusion of these substances in the risk assessment (within the group of total PCBs) was justified due to their hazardous properties and since it is known that humans are always exposed to complex mixtures of PCBs comprising both DL-PCBs and NDL-PCBs.

In terms of the hazard assessment:

- **Formaldehyde**: RAC considered that the internal DNEL of 0.075 mg/kg/day derived by the Dossier Submitter is highly uncertain with respect to its relevance to a dermal route of exposure, which in the view of the Committee is the only relevant exposure route for this restriction proposal. In RAC's view, systemic effects of formaldehyde exposure via the dermal route are unlikely, and local effects, i.e., skin sensitisation, are more relevant.

- **PAHs**: RAC agreed with the Dossier Submitter's selection of carcinogenicity as the most critical long-term human health effect for PAHs. It also supported the Dossier Submitter's approach to derive a DMEL (at a 10^{-6} risk level) of 4 pg/kg bw/day for PAH mixtures based on dermal studies (Schmähl et al., 1977; Fhl, 1997) assessed by BAuA (2010), and of 6 pg/kg bw/day for BaP alone based on dermal carcinogenicity data for benzo[a]pyrene (BaP) obtained in mice (Knafla et al., 2006), with the application of Toxic Equivalency Factor (TEFs).

- **PCDDs/Fs/DL-PCBs**: RAC supported the Dossier Submitter's approach to derive an

[2] RAC notes that for some of the long-term effects mentioned above (related to PAH exposure), no threshold could be derived.

internal DNEL based on an epidemiological study in children (Minguez-Alarcon et al., 2017). RAC considered that the selected critical effect (fertility) is relevant and sensitive and agreed with the proposed internal DNEL of 0.3 pg_{TEQ}/kg bw/day. However, RAC noted that the uncertainties in the critical study are substantial, and that they are expected to have resulted in the derivation of a lower (i.e., more conservative) DNEL than necessary.

- **PCBs (DL and NDL)**: RAC concurred with the Dossier Submitter's approach to use oral data from long-term toxicity studies in monkeys and agreed with the proposed internal DNEL of 20 ng/kg bw/day. RAC considered that the critical effects chosen (immunotoxicity supported by neurobehavioral changes) are sensitive and relevant for humans, and that the critical studies are reliable and well reported.

In terms of the risk assessment:

RAC identified significant uncertainties/shortcomings in the reported risk assessment, as follows:

- Methodology used for the extraction, detection and quantification of substances from single-use diapers:
    - Whilst the Committee supported the use of the urine simulant extraction method in principle, it noted that the method requires further validation (e.g., representativeness of extraction time and volumes), and harmonisation to ensure its repeatability/reproducibility and relevance for use in risk assessment.
    - Further consideration should be given to prevent samples from being contaminated (e.g., replacement of manual steps in the extraction protocol; avoiding keeping the diaper in open containers overnight during the extraction period) and adequate control of any contamination by the use of blank sample analysis.
    - There is a lack of information on blanks in the first set of analyses (ANSES, 2019) and the blanks were not subtracted in the second set of analyses (performed in 2019), affecting the reliability of the results.
    - For PAHs, an adequate explanation was not provided as to why the results (including levels of detection (LoDs)/levels of quantification (LoQs)) quantified by SCL and DGCCRF/INC are orders of magnitude lower in the 2019 analytical campaign compared to the 2018 campaign.
    - For PAHs, the lowest LoD used is orders of magnitude greater than the proposed migration limits. Therefore, it is not known how many samples were above/below the proposed migration limits. In addition, such a high LoD in relation to the limit value would also make the implementation of the restriction proposal challenging because interested parties (enforcement, industry) would not know if a diaper is compliant with the restriction requirements or not.
    - The levels of dioxins, furans and PCBs determined by the urine simulant (water-based solution) extraction method were reported by the Dossier Submitter to exceed the risk threshold, while these substances, although highly lipophilic, were detected at lower concentrations or even not detected after solvent-based extraction of shredded diaper samples (ANSES, 2019); this

lack of consistency raises uncertainties about the reliability of the urine simulant extraction or analytical methodology.

- The measurement of PCDD/Fs in samples could potentially be caused by contamination from laboratory water (background amounts of PCDD/Fs, which can regularly be detected in the laboratory water of accredited laboratories that are specialised in dioxin/furan analyses, are within the concentration ranges that would be required to determine the levels of PCDD/Fs in the proposed restriction) questioning the reliability of the data.

- Daily exposure/dose calculation:
  - There are concerns that the levels of extractable substances estimated by the methodology are seriously overestimated when compared to a realistic worst-case scenario of conditions of use; primarily due to the large volume of urine simulant extracted from a diaper sample (220 to 250 mL) compared to that which would be expected under reasonable conditions of use (1 to 2 mL).
- Risk characterisation:
  - RAC does not support the use of an allocation factor of 10% of the risk characterisation ratio (to account for aggregate exposure from different routes) for substances with local dermal effects (formaldehyde and PAHs). For other substances with systemic effects (for instance, PCDD/Fs and PCBs), the use of an allocation factor of 10% has not been sufficiently justified by the Dossier Submitter.

In conclusion, and after considering the shortcomings and uncertainties identified above, RAC is of the opinion that the EU-wide risk for babies and infants wearing single-use diapers has not been demonstrated for the substances in the scope of the Annex XV dossier.

For **formaldehyde**, RAC concludes that risk of skin sensitisation is a more appropriate assessment endpoint in diapers than the systemic effects proposed by the Dossier Submitter and that exposure to formaldehyde via diapers would be likely to be 20 times below reported elicitation thresholds for sensitisation (see section 3.1.4). RAC also notes that as formaldehyde has a harmonised classification as a skin sensitiser it would be restricted in single-use diapers by means of the proposed restriction on skin sensitisers under REACH[3]; as such no further action for formaldehyde would appear to be necessary.

For **PCDD/Fs** and **DL-PCBs**, RAC undertook a sensitivity analysis of the Dossier Submitter's exposure assessment using more realistic conditions of use and concluded that risks for the endpoints assessed by the Dossier Submitter would be unlikely to occur from the wearing of single-use baby diapers because the assumptions used by the Dossier Submitter (and their inherent uncertainties) would tend to result in significant overestimates of exposure and risk. Nevertheless, RAC notes that the size of the allocation factor used for the risk characterisation is a critical uncertainty in determining whether a risk would occur for certain sub-populations

[3] The restriction proposes to restrict the use of all substances classified as skin sensitisers according to the CLP Regulation, as well as a list of disperse dyes, in various articles, including single-use baby diapers. The opinion was adopted in September 2020 and, at the time of writing, a decision by the European Commission is still pending. More information on this restriction proposal can be found here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

(i.e., formula-fed infants) and that the Dossier Submitter did not assess the potential for risks via all potentially relevant endpoints (e.g., via endocrine disruption). Therefore, it is not possible to conclude that there are no potential risks from these substances in single-use diapers based on the available assessment (see section 3.1.4).

For **PAHs**, RAC concluded that the available analytical data are of insufficient quality for a reliable exposure assessment, which means that risks cannot be reliably characterised (see section 3.1.4).

For **NDL-PCBs**, there are no analytical data upon which to base an assessment. Therefore, similarly to PAHs, RAC cannot conclude whether NDL-PCBs in diapers pose a risk or not (see section 3.1.4).

RAC points out that the degree of uncertainty associated with this proposal is greater than other, apparently similar, restriction proposals such as that for skin sensitising substances[4] where there was epidemiological data indicating the scale of the risks (and health impacts) that were not adequately controlled. For the restriction proposed on single-use baby diapers, there is no epidemiological data demonstrating an association between health effects and the wearing of diapers. On this basis, a simple comparison between these two restrictions is not possible. In the case of the skin sensitisers proposal, it was considered reasonable for RAC to support the introduction of concentration limits for a broad range of substances with a harmonised classification as skin sensitisers, despite the absence of standardised analytical methods for many of the substances within the proposed scope, as it was not the analytical data that was underpinning the justification for the need for a restriction, but the harmonised classification and the associated epidemiological data. The opinion of RAC on the skin sensitisers proposal noted that "*for most of the targeted skin sensitisers in the scope of this restriction proposal, the concentration limits, are far below the highest approximated concentrations in textile and leather at point of sale. Therefore, the risks from these substances are not adequately controlled for these uses*". As a general principle, there is an important difference between justifying a restriction based on analytical data of exposure (e.g. the approach put forward to justify a restriction of substances in single-use baby diapers) and restrictions to address widespread health concerns which require analytical methodology to be developed for the purpose of enforcement (e.g. the skin sensitisers proposal). The availability of reliable exposure data is comparatively more important in the former case, than the latter.

RAC is of the opinion that the following information (by the Dossier Submitter or other bodies) would be needed to address the identified (main) uncertainties concerning the exposure:

- Detailed information about
    - sample preparation;
    - analytical quality control and assurance information (including the use of blank samples) for analytical data.

In addition, if the risks of substances in single-use baby diapers are reconsidered in the future

[4] Restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances, ECHA (2020): https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

(i.e., not as part of the opinion development on this Annex XV dossier) the following topics should be elaborated in order to minimise the uncertainties:

- appropriate rewet factor;
- evaluation of direct exposure;
- reproducibility and relevance (to reasonably foreseeable conditions of use) of urine simulant extraction methodology;
- justification for the use of (and value for) an allocation factor

RAC notes that until the uncertainties/shortcomings concerning the restriction proposal on single-use baby diapers are resolved, the voluntary action by industry (the EDANA Stewardship Programme for Absorbent Hygiene Product) could further reduce the concentration of the substances in the scope of the proposed restriction (and also of other substances like phthalates, organotins, metals), in all single-use diapers placed on the European market. However, RAC does not accept that voluntary action is an effective risk management option should the risk from specific substances be adequately demonstrated. According to comments made by industry, currently about 85% of European single-use diaper manufacturers follow the EDANA programme, although this has not been confirmed by RAC. RAC notes that industry´s voluntary action has not been evaluated by RAC in terms of the migration limits it specifies or how effectively the member companies have implemented these limits, nor how it deals with imports of diapers.

RAC points out that the substances in the scope of the restriction proposal should be kept to a level as low as possible/feasible in single-use diapers, and preferably should not be present at all. RAC notes that the POPs (Persistent organic pollutants) regulation already 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 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 in 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.

However, 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 these substances in diapers, for example as 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 if the substances are detected above the proposed migration levels. Therefore, there is even uncertainty as to whether industry would be able to comply with the proposed restriction. As such, the Dossier Submitter's conclusion 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 uncertain, SEAC discussed a range of possible scenarios[5] to inform its conclusion on proportionality. For all of the scenarios assessed, 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)

Summary of proposal:

This restriction proposal aims at minimising health risks associated with the wearing of single-use baby diapers by children and infants under the age of three. Single-use diapers are placed on the market and according to the Dossier Submitter can contain formaldehyde, polycyclic aromatic hydrocarbons (PAHs), polychlorinated dibenzo-p-dioxins (dioxins or PCDDs), polychlorinated dibenzofurans (furans or PCDFs) and/or polychlorobiphenyls (PCBs).

In 2019, ANSES published a report on the risks associated with the presence of hazardous substances in single-use baby diapers and made recommendations for risk reducing measures. Analyses were carried out in a survey of 19 diaper samples (2018) and 32 samples (2019), reportedly including the best-selling products on the French market. An analytical laboratory developed and applied an experimental urine simulant methodology to extract the substances of concern from diaper samples. A quantitative human health risk assessment was then performed based on the results of diaper analyses undertaken by the SCL and the INC, including solvent extractions in shredded whole diapers or diaper parts (SCL, 2017; INC, 2017 and 2018; Group'Hygiène, 2018), extractions with a urine simulant in shredded whole diapers (SCL, 2017), and extractions with various urine simulants in whole diapers (SCL, 2018; Group'Hygiène, 2018). The risk assessment was first undertaken using a "worst-case" scenario in order to rapidly eliminate substances posing no health risks. In this scenario, conditions of use assumptions corresponding to a new-born with a very low body weight (2.6 kg) who is changed very frequently (12 times per day), with 100% dermal absorption, were used when estimating exposure. In cases when threshold values were exceeded, a "realistic" exposure scenario (a scenario whose parameters were intended to replicate commonly encountered actual conditions of use) was implemented separately for six age groups of children (0-6, 6-12, 13-18, 19-24, 25-30, 31-36 months). For the substances below the threshold value, the Dossier Submitter considered the possibility of exceeding threshold values due to aggregate exposure of substances via various exposure routes. These results were used as the basis for the proposed restriction.

According to the Dossier Submitter, the risk calculations for the substances detected or quantified in the migration tests using whole diapers, showed that for children aged 0 to 36 months it is not possible to rule out a health risk associated with the routine wearing of single-use diapers for: formaldehyde, the sum of 17 PAHs, the sum of PCDD/Fs and DL-PCBs, the sum of PCBs.

Based on these results, the Dossier Submitter concluded that the risk from formaldehyde, PAHs, PCDD/Fs, and/or PCBs in single-use baby diapers is not adequately controlled, and proposed the substances listed in Table 1 to be included in the scope of a restriction (RO1). Non-dioxin-like PCBs (NDL-PCBs) were not measured in single-use baby diapers. However, these substances are included in the scope of the proposed restriction since it is commonly known that when DL-PCBs can be quantified, NDL-PCBs are also likely to be present. NDL-PCBs have also been quantified in similar articles, i.e., in incontinence diapers (UFC Que Choisir, 2019).

Hazardous properties of the substances within scope

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

PAHs have been investigated for their carcinogenic potential and many 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 (ECHA 2019).[6]

PCDD/Fs and **DL-PCBs** have been targeted as potentially requiring restriction due to their potential to cause various adverse health effects, including hepatic, immunological, neurological, metabolic and endocrine toxic effects, adverse reproductive effects, mutagenicity effects and genotoxic effects.

Proposed migration limits are shown in Table 2.

Table 2 Proposed migration limits

Substance/group of substances	**Proposed migration limit**
Formaldehyde	
Formaldehyde	**0.42 mg/kg of diaper**
PCDDs/PCDFs/PCBs	
Sum of the quantified PCDDs/Fs/DL-PCBs **in TEQ[1]**	**0.0017 ng_{TEQ} /kg of diaper**
Sum of the quantified total PCBs	**112 ng/kg of diaper**
PAHs	
The sum for the detected or quantified PAH **in TEQ[2]**	**0.023 ng_{TEQ} /kg of diaper**

[1] TEQ from WHO 2005; [2] The Dossier Submitter selected TEFs for 17 PAHs from the existing TEFs defined by various organisations (OEHHA, 1993 revised in 2015; INERIS, 2003; AFSSA, 2003; DFG, 2008 cited in BfR, 2009b; US EPA, 2010) (Table 39 in the Background Document)

RAC conclusion(s):

Children, particularly infants, are especially vulnerable to the adverse effects of exposure to chemicals. Formaldehyde, PAHs, PCDDs (dioxins), PCDFs (furans), and PCBs (dioxin-like (DL) and non-dioxin-like (NDL)) possess various acute and chronic hazardous properties.

The risk posed by these substances was assessed quantitatively by the Dossier Submitter using a risk quotient approach. For substances with a threshold effect (formaldehyde,

[6] More information on this restriction proposal can be found here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d5746d

PCDD/Fs and DL-PCBs), and for substances with a non-threshold effect (PAHs), the risk level was characterised by means of a RCR, calculated as the ratio between the daily exposure dose and the appropriate internal DNEL or dermal DMEL (the latter expressed for PAHs at the 10^{-6} risk level). The value of this ratio was used to determine whether or not the dose received exceeded the DNEL or DMEL. Daily exposure dose was based on the concentration of the chemical extracted with a urine simulant from a whole diaper, considering the weight of the diaper, the volume of urine simulant used for the extraction, the frequency of diaper changes, the fraction absorbed by the skin, and the body weight of a child.

RAC concurs, in general, with the Dossier Submitter that these substances might have the potential to induce adverse effects in babies if present[7] (or present above certain concentrations) in single-use baby diapers that come (directly or indirectly via e.g., urine) in contact with the skin. RAC also generally agrees with the Dossier Submitter that for the substances above, long-term effects are more relevant for this restriction proposal than acute effects, since the latter generally occur at higher exposure levels compared to long-term effects. However, RAC concludes that regarding formaldehyde, skin sensitisation would be a more relevant critical effect for this restriction proposal than long-term systemic effects observed in animal experiments (e.g., nephrotoxicity, reduced body weight gain).

The details concerning long-term hazardous effects of the substances/groups of substances listed above and the derived migration limits are dealt with in section 3.1.1.

RAC considers that the separate grouping approaches for (i) **PAHs**, (ii) **PCDDs/Fs and DL-PCBs** and (iii) **total PCBs** (DL and NDL) are well justified (see section *"Key elements underpinning the RAC conclusion"* below).

NDL-PCBs were not included in the ANSES (2019) study. RAC, nevertheless, considers that inclusion of these substances in the assessment (within the group of total PCBs) is justified due to their hazardous properties and since it is known that humans are always exposed to complex mixtures of PCBs comprising both DL-PCBs and NDL-PCBs.

RAC notes that there is very limited information available for the risk assessment of hazardous chemicals in baby diapers and a quantitative risk assessment for the chemicals in the scope (which are present at the levels of impurities in diaper samples on the EU market) is technically challenging and is associated with numerous uncertainties. It should also be noted that none of these substances are intentionally used in single-use baby diapers, but they are rather residues or contaminants (see *"Key elements underpinning the RAC conclusion(s)"* for further discussion).

Based on the above, RAC considers that the proposed restriction aims to minimise exposure of children to hazardous chemicals in the scope. However, due to the uncertainties and shortcomings related to the exposure assessment and risk characterisation, RAC concludes that the EU-wide risk for babies and infants wearing single-use diapers has not been demonstrated for the substances in the scope of the Annex XV dossier.

For **formaldehyde**, RAC concludes that risk of skin sensitisation is a more appropriate assessment endpoint in diapers than the systemic effects proposed by the Dossier Submitter and that exposure to formaldehyde via diapers is likely to be 20 times below reported elicitation thresholds for sensitisation (see section 3.1.4). RAC also notes that as formaldehyde has a harmonised classification as a skin sensitiser it would be restricted in single-use diapers by means of the proposed restriction on skin sensitisers under REACH and, should this restriction be implemented as proposed, no further action for formaldehyde would

[7] RAC notes that for some of the long-term effects mentioned above (related to PAH exposure), no threshold could be derived.

appear to be necessary.

For **PCDD/Fs** and **DL-PCBs**, RAC undertook a sensitivity analysis of the Dossier Submitter's exposure assessment using more realistic conditions of use and concluded that risks for the endpoints assessed by the Dossier Submitter would be unlikely to occur from the wearing of single-use baby diapers because the assumptions used by the Dossier Submitter (and their inherent uncertainties) would tend to result in significant overestimates of exposure and risk. Nevertheless, RAC notes that the size of the allocation factor used for risk characterisation is a critical uncertainty in determining whether a risk would occur for certain sub-populations (i.e., formula-fed infants) and that the Dossier Submitter did not assess the potential for risks via all potentially relevant endpoints (i.e., via endocrine disruption). Therefore, it is not possible to conclude that there are no potential risks from these substances in single-use diapers based on the available assessment (see section 3.1.4).

For **PAHs**, RAC concludes that the available analytical data are of insufficient quality for a reliable exposure assessment, which means that risks cannot be reliably characterised (see section 3.1.4).

For **NDL-PCBs**, there are no analytical data upon which to base an assessment. Therefore, similar to PAHs, RAC cannot conclude whether NDL-PCBs in diapers pose a risk or not (see section 3.1.4).

Fragrances, volatile organic compounds (VOCs), pesticides, and skin sensitisers (except those already included in the scope due to their other hazardous properties) were not included in the scope of this restriction proposal. Since they were not assessed by the Dossier Submitter, RAC cannot evaluate the appropriateness of the Dossier Submitter's decision to not include these substances in the scope of the restriction proposal.

Key elements underpinning the RAC conclusion(s):

Formaldehyde, and many of the PAHs, have a harmonised classification, making them relevant for this restriction proposal. Most of the substances in the other groups do not have harmonised classifications. They are either self-classified by industry, or there is no classification related to human health, but their hazardous properties have been recognised by different international bodies (e.g., WHO, IARC, ATSDR; see section 3.1.2. below).

Grouping of PAHs is well justified. Many PAHs share the same genotoxic mechanism of action. From the 17 PAHs included in the scope of the proposal, eight are classified as Carc. 1B (H350) according to CLP Regulation (EC 1272/2008), benzo[d,e,f]chrysene is also classified as Muta 1B (H340) and chrysene as Muta. 2 (H341), and further three substances are proposed to be classified as Muta. 2 (H341) and Carc. 1B (H350) by RAC.

Grouping of PCDDs, PCDFs and DL-PCBs: PCDDs (dioxins) and PCDFs (furans) are grouped under the term PCCD/Fs. PCCD/Fs form a group of 210 theoretical compounds or congeners: there are 75 possible PCDDs and 135 possible PCDFs (EFSA, 2018[8], Jaspers et al., 2014). Seven PCCDs and ten PCDFs are bioaccumulative in animals and humans. Human exposure to dioxins and furans has been associated with a variety of adverse effects, including skin disorders (e.g., chloracne), hepatotoxicity, immunotoxicity, reproductive toxicity and carcinogenicity.

[8] Risk for animal and human health related to the presence of dioxins and dioxin-like (DL-)PCBs in feed and food, adopted 14 June 2018; doi: 10.2903/j.efsa.2018.5333.

All DL-PCB and many NDL-PCB congeners accumulate in humans and animals[9] (Larsen et al., 2014). Human studies have identified associations between exposure to PCB mixtures and adverse immunological, reproductive, neurological and dermatological effects and cancer, and studies in primates showed adverse effects related to exposure to commercial mixtures of PCBs (WHO, 2003; ATSDR, 2000).

Grouping PCDDs/Fs and DL-PCBs is justified since both DL-PCBs and relevant PCDD/Fs are known to bind to the intracellular aryl hydrocarbon receptor (AhR) (EFSA, 2018). In addition, there are strong indications in epidemiological studies that fertility is declining due to exposure to these groups of substances. With regard to endocrine disrupting properties, it is noted that some PCDDs/Fs and PCBs are on the TEDX (The Endocrine Disruption Exchange Inc[10]) and the Sin List (Substitute It Now[11]).

Grouping of total PCBs (DL-PCBs and NDL-PCBs): A Joint FAO/WHO Expert Committee on Food Additives (JECFA) recognised that there are similarities in some of the reported effects for NDL-PCBs, and a risk estimation for combined exposure has been recommended (WHO, 2016). Some of the NDL-PCBs have hybrid activity, showing both dioxin-like and non-dioxin-like toxicity[12]. International bodies have identified seven 'indicator' PCBs that can be used to characterise the presence of PCB contamination. Six of these seven are NDL-PCBs and one is a DL-PCB (WHO, 2016). Also, it should be noted that humans are always exposed to complex mixtures of both DL-PCBs and NDL-PCBs, whose relative contribution to toxicity is unclear (WHO, 2016). RAC, therefore, agrees with the proposed grouping of these substances.

Available human and animal data provide very limited information for the assessment of health risk from hazardous substances present in baby diapers

There are some human studies that investigated whether use of disposable diapers by babies could be linked to increased risk for testicular cancer, but they did not study potential risk posed by specific substances in diapers. Rather, they were concerned with increased scrotal temperature due to diaper use (Møller, 2002; Partsch et al., 2000), and did not find the evidence for the association between use of disposable baby diapers and increased risk of testicular cancer later in life (Møller, 2002).

Animal data provide information on the hazardous properties of the substances within the scope of the proposed restriction, but typically at doses that are markedly higher than real-life exposure levels via diapers, and predominantly using the oral exposure route in adult animals.

[9] A subgroup of 12 PCB congeners that are non-ortho or mono-ortho chlorine substituted and contain at least four chlorine substituents can easily adopt a coplanar structure and show toxicological properties similar to tetrachlorodibenzo-p-dioxin (TCDD) and other PCDD/Fs. This subgroup is termed DL-PCBs. Due to their lipophilic properties and poor degradation they accumulate in the food chain and in the human body (EFSA, 2018).

[10] https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list

[11] https://sinlist.chemsec.org

[12] Primary toxic action of NDL-PCBs is not via AhR binding, but it is proposed to be rather via agonistic effect on nuclear hormone receptors (the constitutive androstane receptor, CAR, and pregnane X receptor, PXR) (Larsen et al., 2014). Other potential mechanisms, such as activation of ryanodine receptors (RyRs; which play a crucial role in calcium signalling and neurotoxicity), are proposed as well, but are not as much explored as NDL-PCBs effects on nuclear hormone receptors (WHO, 2016).

3.1.2. Information on hazard(s)

Summary of proposal:

For this restriction proposal, information on hazard properties was retrieved by the Dossier Submitter from published literature, reports and REACH registrations (in accordance with ECHA guidance on information gathering ECHA, 2012b).

Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity, skin corrosion and skin sensitisation according to the CLP Regulation (skin corrosion category 1B, skin sensitisation category 1, mutagenicity category 2, carcinogenicity category 1B). Given the targeting of this restriction proposal, only effects observed following oral or dermal exposure were addressed.

PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action. Given the targeting of this restriction proposal, only mutagenicity and carcinogenicity were addressed.

In humans, brief exposure to high levels of PCDD/Fs may result in skin damage. Long-term exposure is associated with hepatic, immunological, neurological, metabolic and endocrine effects. It should be noted that PCDD/Fs are among the first 12 POPs (persistent organic pollutants) included in the Stockholm Convention in 2001.

Brief skin contact with PCBs causes local irritation, while repeated or prolonged contact may result in skin damage. Long-term exposure is associated with hepatic, immunological, neurological, metabolic and endocrine effects. PCBs like PCDD/Fs are also among the first 12 POPs covered the Stockholm Convention in 2001 (meaning they are known to be Persistent Organic Pollutants and regulated as such). Given the targeting of this restriction proposal, only effects observed following oral or dermal exposure were addressed.

For each chemical/group of chemicals, the human health reference values (HRVs) established by national (ANSES, US EPA, ATSDR, OEHHA, Health Canada, RIVM), European (EFSA, JECFA, ECHA) and international (WHO) organisations were identified, focusing on those developed for a chronic duration of exposure, which is regarded as most relevant in view of the context of this restriction proposal.

Since, dermal HRVs were not available except for PAHs, the Dossier Submitter chose chronic oral HRVs for formaldehyde, PCDD/Fs/DL-PCBs and total PCBs. After the selection of an HRV, the value was corrected for oral bioavailability in order to derive an internal dose (DNEL or slope factor) linked to the selected HRV.

DMEL were set for non-threshold effects of PAHs, while for other substances/groups of substances with threshold effects DNELs were set (see Table 3).

Table 3 Critical effects and DN(M)EL derivation for substances in the scope

Chemicals	HRV	Source	Value	Critical effect; species	Oral abs. (%)	internal DNEL/DMEL/TDI
Formaldehyde	Oral chr.	WHO/IPCS (2005)	TDI: 0.15 mg/kg/day	stomach irritation, nephrotoxicity; rats	50	0.075 mg/kg/day
PAHs	Dermal carc.	BAuA (2010) Knafla et al. (2006)	Slope factors	skin tumours; mice	NA	0.004 ng/kg/day for PAHs mixture 0.006 ng/kg bw/day for BaP

PCDD/Fs, DL-PCBs	Oral chr.	EFSA (2019)	TDI: 0.3 pg/kg bw/day	fertility effects; humans	100	0.3 pg/kg/bw/day
total PCBs (DL and NDL)	Oral chr.	WHO (2002b)	TDI: 20 ng/kg bw/day	immunotoxicity, neurobehavioral effects; monkeys	100	20 ng/kg bw/day

DL: dioxin like; NDL: non-dioxin-like; TDI: tolerable daily intake

RAC conclusion(s):

The Dossier Submitter retrieved detailed information on hazard properties from published literature, reports and REACH registrations, in accordance with ECHA guidance on information gathering (ECHA, 2012b).

RAC agrees that in the absence of toxicity data via the dermal route, an internal DNEL can be derived from the available oral (dietary) data (in line with Guidance on information requirements and chemical safety assessment, Chapter R.8, ECHA 2012).

Formaldehyde: RAC considers that the internal DNEL of 0.075 mg/kg/day derived by the Dossier Submitter from an oral chronic HRV based on histologically observed gastric changes and nephrotoxicity in rats is highly uncertain with respect to its relevance to a dermal route of exposure, which is the only relevant exposure route for this restriction proposal. Systemic effects of formaldehyde exposure via the dermal route are unlikely because:

- formaldehyde is not well absorbed via the skin and dermal absorption is limited to the cell layers immediately adjacent to the point of contact (ECHA, 2019);

- formaldehyde is rapidly metabolised at the site of initial contact and therefore distribution of formaldehyde to more distant organs is not likely, except from exposure to high concentrations (ECHA, 2019);

- there is no convincing evidence of formaldehyde-induced carcinogenic effects at distant sites or via routes of exposure other than inhalation;

- formaldehyde is present in diapers as an impurity and high concentrations are not expected (2.75 mg/kg was the highest concentration found among 51 samples analysed by the SCL (Service Commun des Laboratoires)).

In such circumstances, local effects, i.e., skin sensitisation, is more relevant than systemic effects.

PAHs: RAC agrees with the critical effect chosen for PAHs since carcinogenicity is generally known to be the most critical long-term human health effect associated with PAH exposure (ECHA, 2019). The Dossier Submitter's approach is to derive a DMEL (at a 10^{-6} risk level) of 4 pg/kg bw/day for PAH mixtures based on dermal studies (Schmähl et al., 1977; Fhl, 1997) assessed by BAuA (2010), and of 6 pg/kg bw/day for BaP alone based on dermal carcinogenicity data for benzo[a]pyrene (BaP) obtained in mice (Knafla et al., 2006), with application of TEFs. RAC agrees with this approach as it considers the dermal route (which is the relevant route for this restriction proposal), and available carcinogenicity data on PAHs following dermal exposure.

PCDDs/Fs/DL-PCBs: The data on the dermal toxicity of these substances is limited. Therefore, RAC supports the Dossier Submitter's approach to derive an internal DNEL based on an epidemiological study in children (Minguez-Alarcon et al., 2017), in which the primary source of exposure to this group of substances was via diet, with dermal absorption, inhalation, and hand-to-mouth transfer from contaminated dust and soil as additional exposure routes. RAC considers that the selected critical effect (fertility) is relevant and

sensitive, the critical study is well conducted and reported, with transparent methodology of HRV derivation, and agrees with the proposed internal DNEL of 0.3 pg_{TEQ}/kg bw/day. However, RAC notes that the uncertainties in the critical study are substantial, and that they are expected to lead to a lower DNEL than necessary (i.e., overprotective).

PCBs (DL and NDL): Since a dermal HRV derived by another EU or non-EU regulatory body is not available, RAC concurs with the Dossier Submitter's approach to use oral data from long-term toxicity studies in monkeys and agrees with the proposed internal DNEL of 20 ng/kg bw/day. RAC considers that the critical effects chosen (immunotoxicity supported by neurobehavioral changes) are sensitive and relevant for humans, and that the critical studies are reliable and well reported.

Key elements underpinning the RAC conclusions

These are explained in detail and discussed in Annex H in the Background Document.

3.1.3. Information on emissions and exposures

Summary of proposal:

Since the 1990s, single-use baby diapers have been used by more than 90% of families in most of the European Union (EDANA, 2011). Following chemical analysis performed in France (DGCCRF/INC, the French National Consumer Institute) and SCL (Service Commun des Laboratoires), single-use baby diapers have been reported as containing various hazardous chemicals that may impair the health of babies wearing/using these articles. Three types of analyses[13] were performed with single-use baby diapers.

The analyses were performed on 51 different diapers that were available on the French market between 2017 and 2019. The Dossier Submitter reported the exposure level according to the ECHA R.15 guidance, meaning that they calculated the Q95 of the distribution of the 51 samples. The following approach was chosen:

- if the substance was not detected, the LoD was retained,
- if the substance was detected, the LoQ was retained,
- if the substance was quantified, the concentration was retained.

The assessment of the exposure to chemical substances released by single-use baby diapers in urine simulant would ideally be based on the presence in single-use baby diapers and information on migration of the substance to skin during use. The parameters needed to perform the exposure assessment were, generally, available to the Dossier Submitter (concentration in a urine simulant, frequency of use, body weight, diapers weight, skin absorption). The exposure assessment relies on the calculation of a daily exposure dose, which is the quantity of a substance to which a child between zero and three years of age is exposed on a daily basis. The daily exposure dose is expressed in mg/kg bw/day.

The dermal route of exposure was the one considered in this assessment, and more specifically exposure in the diaper area.

The equation for the daily exposure dose for each chemical individually is:

$$\textbf{daily exposure dose} = (C_{diaper} \times W \times F \times Abs_{skin}) / BW$$

[13] Solvent extraction on shredded diapers, solvent extraction on shredded parts of diapers and simulant urine migration tests on shredded whole diapers and on whole diapers.

where:

- C_{diaper}: concentration of the chemical (in mg/kg of diaper) extracted with a urine simulant from a whole diaper, in relation to the weight of the diaper (W), taking into account the extracted simulant volume (V) [$C_{diaper} = C_{urine\ simulant} \times V_{urine\ simulant} / W$]
- W: average weight of a diaper (kg)
- F: frequency of use (number/day)
- Abs $_{skin}$: fraction absorbed by the skin (%)
- BW: body weight of a child (kg)

For PCDD/Fs and DL-PCBs, exposure was assessed using toxic equivalency factors (TEFs) indicating the toxicity of all congeners having the same mechanism of toxicological action as the "Seveso" dioxin (2,3,7,8-TCDD), considered as the most toxic. Exposure was therefore expressed in toxic equivalent quantities (TEQs). For PAHs, BaP was considered as a marker of PAH exposure and carcinogenic effects (WHO-IPCS, 1998), and the toxicity of other PAHs were estimated based on toxic equivalency factors (TEFs). The Dossier Submitter selected TEFs for 17 PAHs from the existing TEFs defined by various organisations (OEHHA, 1993 revised in 2015; INERIS, 2003; AFSSA, 2003; DFG, 2008 cited in BfR, 2009b; US EPA, 2010), and they are shown in Table 39 (*TEFs proposed by various organisations for PAHs*) in the Background Document.

Consequently, the calculation of the daily exposure dose is then:

daily exposure dose $_{TEQ}$ = (C_{diaper} x W x F x Abs skin x TEF) / BW

24 hours was selected as an appropriate time frame for exposure.

The Dossier Submitter assumed a dermal absorption rate of 50%[14] to calculate exposure.

The values of the parameters used by the Dossier Submitter to perform the exposure assessment (and calculate the daily exposure dose) are gathered in Table 4 below.

Table 4 Values of the parameters used in the exposure assessment

Parameter	**Realistic conservative approach**		
	Value		**Reference**
Weight of a diaper by age group (W)	0-6 months exclusive	23.1 g	Group Hygiène (2019) *via* personal communication
	6-12 months inclusive	31.0 g	
	13-18 months inclusive	31.0 g	
	19-24 months inclusive	31.0 g	
	25-30 months inclusive	46.3 g	
	31-36 months inclusive	46.3 g	
Daily frequency of use (average) (F)	0-6 months exclusive	7.98	UK Environment Agency, 2005b (average daytime frequency + one diaper/night)
	6-12 months inclusive	6.66	
	13-18 months inclusive	6.75	
	19-24 months inclusive	5.95	
	25-30 months inclusive	5.85	
	31-36 months inclusive	4.70	

[14] During opinion development the Dossier Submitter revised the dermal adsorption rate from 100% to 50% in response to feedback from RAC.

Parameter	Realistic conservative approach		
	Value		Reference
Dermal absorption rate (Abs $_{skin}$)	50%		ANSM (2010)
Body weight (BW)	0-6 months exclusive	5.2 kg	BEBE-SFAE (2013)
	6-12 months inclusive	7.5 kg	
	13-18 months inclusive	9.6 kg	
	19-24 months inclusive	10.9 kg	
	25-30 months inclusive	12.0 kg	
	31-36 months inclusive	12.0 kg	

RAC conclusion(s):

RAC concurs with the Dossier Submitter that frequent use of single-use baby diapers over a longer period of time could lead to exposure of children and infants to hazardous substances should they be present - particularly where exposure occurs under occlusive conditions. RAC further notes that babies often suffer from baby rash, which might enhance the absorption of substances from diapers.

RAC agrees with the Dossier Submitter that any hazardous substances present in diapers could be either directly released or extracted by urine. Due to the effect of urine migration, even substances from the inner parts of the diapers could potentially migrate to the outer layer and come into contact with a baby's skin.

RAC considers that using a urine simulant for extraction is representative of indirect exposure to diaper core constituents, but that direct exposure is not adequately addressed in the exposure scenario, especially to lipophilic substances which could come into direct contact with the baby's skin.

RAC concurs with the Dossier Submitter that using a urine simulant to detect or quantify the concentration of the hazardous substances in the scope of the proposed restriction provides a better representation of actual use, compared to solvent extraction but notes that the method requires additional validation and standardisation. In general, RAC also supports the Dossier Submitter's approach to base their quantitative exposure assessment on the following parameters:

- the absorption fraction,
- the frequency of use,
- body weight of the babies,
- diapers weight and
- the concentration of the substances of interest in the urine simulant extracted from the diaper under predefined conditions.[15]

RAC considers that most of the exposure variables selected by the Dossier Submitter are well explained and, in general, realistically reflect the population's habits and children's body weight. However, RAC considers that the way these variables were used in daily exposure

[15] Briefly, whole diapers are soaked with urine simulant and placed in oven at 37 °C for 16 hours. 200 mL of urine simulant is added to a diaper, for 3 times (600 mL total), with 30-minute rest period between each addition. The simulant is recovered by gentle pressing at room temperature (for 5 to 10 minutes) in a stainless-steel container, and 220 to 250 mL are recovered.

dose calculation led to a clear overestimation of exposure, particularly due to the disparity in the "rewet" factor (quantity of urine refluxed from a diaper) assumed by the Dossier Submitter compared to representative values reported by industry.

Regarding the results of diaper sample analysis undertaken by SCL and DGCCRF/INC, RAC recognises major uncertainties/shortcomings described in the section "*Key elements underpinning the RAC conclusion(s)"*. RAC considers that these uncertainties and shortcomings seriously impede the reliability of the exposure assessment for the substances of concern.

Key elements underpinning the RAC conclusion(s):

A. Exposure scenario parameters

The first studies on composition of single-use diapers were performed by the INC (French National Consumer Institute)[16] and by the French Joint Laboratory SCL (Service Commun des Laboratoires)[17] in 2016, 2017 and 2018, using solvent extraction for screening chemicals in 19 of the best-selling commercial single-use diapers on the French market (see ANSES report (2019).

SCL also performed migration tests with shredded whole diapers in 2017 and whole diapers in 2018, using a urine simulant for both of these migration studies on the same 19 single-use diapers.

The analyses in 2018 were carried out by soaking entire single-use diapers with urine simulant for 16 hours at a temperature of 37 °C as described in Annex B.9.2.2. of the Background Document, noting that about 220 to 250 mL of the 600 mL urine simulant added was recovered by pressing the diaper. In 19 single-use diapers analysed, formaldehyde was quantified or detected in 13 diapers, PAHs were detected but not quantified in 16 diapers, PCDD/Fs, and DL-PBCs were quantified in all diapers (see Table 5).

In addition to the analyses in 2018, SCL performed a follow-up study in 2019 with 32 single-use diapers. The results of both of these studies are included in Table 6. RAC notes that due to lack of information it is not clear whether the diaper brands analysed by the SCL are representative for the whole EU/EEA. However, RAC notes that the largest manufacturers produce diapers in different countries of Europe and might therefore not only use the same materials for the different production sites but also sell their diapers in several countries in Europe.

[16] Pesticides, PAHs, dioxins and furans, fragrances and volatile organic compounds (VOCs), heavy metals, nonylphenol, octylphenol and nonylphenol monoethoxylates were screened by INC.

[17] Pesticides, PAHs, dioxins, furans, DL-PCBs, phthalates, organotins, VOCs, fragrances and azoic dyes were screened by SCL.

Table 5 Quantities of chemicals extracted by urine simulant in relation to diaper weight; second exploratory study (SCL, 2018)

Anonymised products	Formaldehyde (mg/kg)	Total DL-PCBs (ng/kg)	Total PCDD/Fs (ng/kg)	benzo[e]pyrene (mg/kg)	benzo[a]pyrene (mg/kg)	benzo[b]fluoranthene (mg/kg)	dibenzo[a,h]anthracene (mg/kg)	5-methylchrysene (mg/kg)	Chrysene (mg/kg)	benzo[g,h,i]perylene (mg/kg)	benzo[k]fluoranthene (mg/kg)	Benzo[j]fluoranthene (mg/kg)
1	3.57	35.67	0.43	-	-	-	-	-	-	-	-	-
2	1.86	30.80	0.3	<LQ=2	-	-	-	-	-	-	-	-
3	-	34.03	0.67	-	<LQ=2.21	-	-	-	-	-	-	-
4	1.66	13.76	0.09	-	-	<LQ=1.82	<LQ=0.54	-	-	-	-	-
5	-	6.04	0.13	<LQ=1.58	-	-	-	-	-	-	-	-
6	1.23	11.44	0.06	-	-	-	-	<LQ=1.7	-	-	-	-
7	2.91	34.84	0.83	<LQ=2.2	-	-	-	-	-	-	-	-
8	-	7.39	0.84	<LQ=1.93	-	<LQ=1.93	-	-	-	-	-	-
9	1.99	379.6	1.36	<LQ=3.26	-	-	-	-	-	-	-	-
10	1.15	43.40	0.16	<LQ=1.36	-	-	-	-	<LQ=1.36	<LQ=1.36	-	-
11	1.62	36.94	0.36	-	<LQ=1.92	-	-	-	-	-	-	-
12	4.98	29.94	0.64	<LQ=1.72	-	<LQ=1.72	-	-	-	<LQ=1.72	-	-
13	7.18	20.38	0.30	<LQ=1.71	-	<LQ=1.71	-	-	-	-	-	-
14	4.66	27.24	0.25	-	-	-	-	-	-	-	-	-
15	7.5	25.71	0.12	<LQ=2.28	-	-	-	-	-	<LQ=2.28	-	-
16	-	20.73	0.04	-	-	<LQ=2.08	-	-	-	<LQ=2.08	-	-
17	-	12.13	0.07	<LQ=2.01	-	<LQ=2.01	-	-	-	<LQ=2.01	<LQ=2.01	<LQ=2.01
18	ND (LQ=1.07)	12.48	0.06	-	<LQ=1.77	-	-	-	-	-	-	-
19	1.10	8.76	0.06	-	-	-	-	-	-	-	-	-

ND: not detected; The results in the table correspond to the concentrations extracted in the urine simulant without considering the volume recovered (200 to 250 mL).

Table 6 Aggregated results from the 2018 and 2019 studies on migration of substances, using urine simulant extraction from whole diaper (according to Table 51, Background Document)

Substance	**No of Analyses****	**Detection/ quantification for number of diapers**	**LoD* (Range)**	**LoQ* (Range)**	**Substance**	**No of Analyses****	**Detection/ quantification for number of diapers**	**LoQ* (Range)**
Formaldehyde (mg/kg of diaper)	**51**	quantified No = 22; detected No = 17	0.269 – 0.742	0.403 - 2.75	**DL-PCBs (ng/kg of diaper)**	**51**	quantified	
PAHs (mg/kg of diaper)	**51**	detected, not quantified			PCB 77		quantified No = 40	0.038 - 2.72
benzo[e]pyrene		detected No = 10		0.499 -0.836	PCB 81		quantified No = 2	0.048 – 0.072
benzo[a]pyrene		detected No = 4		0.649 - 0.81	PCB 123		quantified No = 40	0.022 – 0.051
benzo[b]fluoranthene		detected No = 6		0.627 -0.763	PCB 118		quantified No = 51	0.749 -9.119
dibenzo[a,h]anthracene		detected No = 2		0.198	PCB 114		quantified No = 31	0.0309 – 0.291
5-methylchrysene		detected No = 1		0.623	PCB 105		quantified No = 51	0.3063 – 5.232
chrysene		detected No = 1		0.499	PCB 126		quantified No = 3	0.011 – 0.069
benzo[g,h,i]perylene		detected No = 5		0.499 – 0.836	PCB 167		quantified No = 32	0.0073 – 0.919
benzo[k]fluoranthene		detected No = 1		0.737	PCB 156		quantified No = 47	0.0449 – 1.857
benzo[j]fluoranthene		detected No = 1		0.737	PCB 157		quantified No = 17	0.0114 -0.412
Benzo[a]anthracene		detected No = 4		0.0004 –0.001	PCB 169		quantified No = 3	0.0068 – 0.06
PCDFs (ng/kg of diaper)	**50**	quantified			PCB 189		quantified No = 23	0.0051 – 0.353

Substance	**No of Analyses****	**Detection/ quantification for number of diapers**	**LoD* (Range)**	**LoQ* (Range)**	**Substance**	**No of Analyses****	**Detection/ quantification for number of diapers**	**LoQ* (Range)**
1,2,3,6,7,8 HxCDF		quantified No = 7		0.0004 – 0.015	**PCDDs (ng/kg of diaper)**	**51**	quantified	
2,3,4,6,7,8 HxCDF		quantified No = 13		0.0007 – 0.031	1,2,3,4,6,7,8 HpCDD		quantified No = 48	0.0017 - 0455
1,2,3,4,6,7,8 HpCDF		quantified No = 43		0.0008 – 0.059	OCDD		quantified No = 48	0.0032 – 0.372
OCDF		quantified No = 43		0.0008 – 0.078	1,2,3,6,7,8 HxCDD		quantified No = 5	0.0004 – 0.015
2,3,7,8 TCDF		quantified No = 2		0.00066	1,2,3,4,7,8 HxCDD		quantified No = 2	0.0039 – 0.0047
1,2,3,7,8 PeCDF		quantified No = 1		0.0039	1,2,3,7,8,9 HxCDD		quantified No = 2	0.0051 – 0.0097
2,3,4,7,8 PeCDF		quantified No = 9		0.0007 – 0.015				
1,2,3,4,7,8 HxCDF		quantified No = 4		0.0027 – 0.013				
1,2,3,7,8,9 HxCDF		quantified No = 2		0.0056 – 0.0067				
1,2,3,4,7,8,9 HpCDF		quantified No = 4		0.0067 – 0.014				

** The concentrations indicated in the table have been transformed from the concentration measured in ng of substance per mL of urine simulant into the concentration of mg or ng of substance/kg of diaper according to the volume of urine simulant added in the diaper (660 mL) and the volume of urine simulant extracted (220 to 250 mL) which is different for each diaper examined.*

With regard to PAHs, there are uncertainties about the values presented, including whether the values are LoDs or LoQs.

*** RAC notes that several diaper samples of the same brand could be included in these tests. RAC notes that there is an inconsistency in the numbers on detected/quantified analytes provided by the Dossier Submitter which could not be solved during the opinion making process.*

Table 7 Concentrations of substances in the scope in two SCL studies (2018 and 2019)

	Formaldehyde [mg/kg]	Sum PAHs (TEQ) [mg/kg]	Sum PCDDs (TEQ) [ng/kg]	Sum PCDFs (TEQ) [ng/kg]	Sum DL-PCBs (TEQ) [ng/kg]
SCL (2018), 19 samples					
Lowest value	0.015	**0.377**	0.0001	0.0004	0.300
Median value	0.609	**0.587**	0.0010	0.0021	0.302
95th percentile	2.644	**1.372**	0.0055	0.0060	0.303
SCL (2019), 32 samples					
Lowest value	0.110	**0.0002**	0.0001	0.0001	0.300
Median value	0.425	**0.0004**	0.0003	0.0006	0.301
95th percentile	1.106	**0.0009**	0.0019	0.0039	0.301

Population to be included in the scope: The risk assessment was undertaken for children aged from birth to 36 months. Since, according to UK Environment Agency data (2005b), by that age about 5% of children still wear diapers, the age range covered by the restriction proposal seems reasonable. Six age groups were described by the Dossier Submitter, to account for baby weight and psychomotor development. However, the Dossier Submitter decided to calculate the RCR using the parameters related to babies aged between zero to six months, as for this category the ratio bodyweight/weight is the lowest and so the RCR will be the worst case over the six classes of age.

Contact between single-use baby diapers and skin: RAC agrees with the Dossier Submitter that the exposed skin area is 100% covered by a diaper material.

Exposure duration: RAC supports a 24-hour period as an appropriate time frame for exposure duration for substances with a threshold effect (formaldehyde, PCDD/Fs, PCBs), given that exposure is expected throughout the day until the child or the infant is fully toilet trained. This scenario is applicable also for bioaccumulative PCDD/Fs and DL-PCBs, since the EFSA CONTAM Panel applied a toxicokinetic model that considered bioaccumulation as part of TDI derivation for these substances (EFSA, 2018).

Child body weight: The Dossier Submitter's rationale to use the data from the BEBE-SFAE study (2013) is well explained (Table 4). RAC notes the Dossier Submitter used the 25th percentile of the body weight for each age group. The 3rd percentile could have also been considered since "normal growth/weight relationship" for babies and children up to three years is in the range of 3rd to 97th percentile according to the WHO Child Growth Standards[18]. However, the 25th percentile is commonly used in exposure assessments.

Absorbed fraction by the skin: For all substances in the scope, the Dossier Submitter

[18] WHO MULTICENTRE GROWTH REFERENCE STUDY GROUP, Mercedes de Onis et al.: Acta Paediatrica 95 (Suppl 450) (2006).

assumed 50% absorption rate to calculate exposure for babies, including preterm babies.

Until a child is toilet trained, the diaper area is a warm, occlusive (although nowadays highly breathable diapers are used) and moist environment with ideal kinetic conditions for percutaneous absorption of substances. Compromised skin conditions, such as diaper dermatitis, a common skin disorder in babies, contact dermatitis, or prematurity could potentially increase dermal penetration of chemicals. The diaper area contains not only skin but mucous membranes as well. Due to these reasons, it is often recommended that a safety assessment of ingredients used in the diaper area is based on an assumption of 100% dermal penetration (Felter et al., 2017; *Agence nationale de sécurité du médicament et des produits de santé* (ANSM))[19]. However, this "default value" approach with 100% absorption rate has been criticised recently (e.g. Felter et al., 2017; Dey et al., 2016) as follows:

- Significant decrease in the incidence and severity of diaper dermatitis has been observed over the past few years (ANSM, 2010) due to improved design of single-use diapers and of wipes, use of barrier emollients, and improved general skin care of infants. Diaper rash is generally an episodic inflammatory reaction, with a mean duration of 2 to 3 days, and it affects only a portion of total diaper skin area.

- RAC also notes that although prematurity could play a role, it is assumed that premature neonates born after 34 weeks of gestational age generally have dermal barrier functions similar to full-term neonates and babies up to six months of age (CIR, 2014). In infants of less than 34 weeks of gestational age, rapid epidermal cell differentiation occurs in the first few weeks of life and, structurally, the skin of the most immature infants resembles that of full-term infants by several weeks (two to four weeks) (Kalia et al., 1998). Only for early gestation premature infants (23 to 25 week of gestational age), the authors found that complete development of a fully functional stratum corneum can require significantly longer than four weeks (Kalia et al., 1998).

- Although it has been shown that genital mucous membranes rapidly absorb chemicals without metabolising them (Nicole et al., 2014), they represent only a small fraction of the total skin area in contact with diapers.

- Regarding physiological differences between infant and adult skin, SCCS (2018) states that in full-term newborns and infants "the skin possesses all skin structures of adult skin, and anatomically these structures do not undergo dramatic changes after birth" and "the dermal absorption in skin of new-borns is similar to that observed in adult skin, when the skin is intact". Similarly, EFSA considers that "age-dependent differences in skin properties and functions do not require a separate approach for children and adults when determining absorption values" (EFSA, 2011, 2012). Higher surface area/body weight ratio, which is up to 2.3-fold higher in new-borns than in adults (changing to 1.8- and 1.6-fold at 6 and 12 months, respectively) is considered to be covered by the intraspecies assessment factor of 10 (SCCS, 2018).

- Dermal penetration and systemic bioavailability of chemicals following dermal exposure could be affected by age-dependent enzymatic biotransformation in the skin[20] (CIR, 2014). However, this issue is largely unexplored. Both under-estimation

[19] Manufacturers of products intended to be used for infants, including diapers and wet wipes, often start with an assumption of 100% chemical absorption in the diaper area (Felter et al., 2017).

[20] The metabolic capacity of liver enzyme systems matures rapidly in the neonates, achieving, or even exceeding, adult capacities mostly within about 6 months to 1 year after birth. If development of enzymatic systems in the skin parallels development in the liver, many enzyme systems in the skin will be fairly mature by about six months of age (CIR, 2014).

and over-estimation of systemic bioavailability in infants compared to adults is possible, depending on a substance (SCCS, 2018).

RAC notes that in the most recent (10th) revision of the SCCS guidance for the testing of cosmetic ingredients and their safety evaluation (SCCS, 2018), it is stated that "a tiered quantitative approach to take the potential for diaper rash into consideration when doing a safety evaluation for products used in the diaper area has been proposed by Felter et al. (2017)". Based on the published literature on diaper rash and data from unpublished clinical studies by Procter and Gamble (P&G), Felter et al. (2017) proposed that the following conservative assumptions should be made when evaluating the potential impact of diaper rash on the integrity of the skin barrier:

- An infant experiences diaper rash ~6 days/month (20% of the time).
- When rash is present, it involves 25% of the total surface area of the diapered skin.
- When rash is present, 60% is assumed to be mild and 40% is assumed to be moderate to severe.

The authors state that *"these assumptions are based on the high end of values in the published data as well as P&G's extensive clinical database. While difficult to quantify, each assumption is conservative; when taken together, the overall degree of conservatism is compounded*". The tiered approach proposed by the authors could be summarised as follows:

- for substances with dermal absorption of 50% or higher, there is no impact on the overall exposure assessment;
- for substances that have a low degree of dermal penetration (10%), the impact is less than two-fold; and
- for substances with a very low degree of dermal penetration (1%), the impact is less-than four-fold. It is recommended that for such compounds, an explicit consideration of the impact of diaper rash be considered.

For these reasons, and considering the comments provided in the consultation, RAC supports a lower default dermal absorption rate of 50% as proposed by the Dossier Submitter. This value is recommended by the Scientific Committee on Consumer Safety (SCCS). RAC notes that substance-specific dermal absorption data should be preferred over a default value. However, this approach is not feasible since data for dermal absorption of chemicals in infants (or suckling animals) are lacking.

Exposure frequency: The number of diapers used per day is influenced by the age of the child, the size of the diaper, the type of diaper used, the country and cultural habits. It ranges, on average, from seven per day at birth to five per day at the age of 2.5 years. Analysing the data gathered through the call for evidence and literature search (Tables 58 and 59 in Annex B.9.4.6. of the Background Document), the Dossier Submitter decided to use the data from a robust study undertaken in 2002 to 2003 in the United Kingdom in more than 2 000 households (Table 64 in Annex B.9.4.6. of the Background Document; Table 4 in this opinion). RAC supports this choice.

Baby diaper weights: Since the average weight of a single-use baby diaper decreased by almost 50% since the 1980s, the Dossier Submitter gathered new data through the call for evidence and literature search (Tables 61 and 62 in Annex B.9.4.7. of the Background Document) and decided to use the most recent data available from a European industrial association (Group'Hygiène, 2019, via personal communication) (Table 4 in this opinion). The weights of premature babies' diapers could not be considered in the weight of diapers by age group due to lack of available data.

Nevertheless, during the consultation on the Annex XV report it was proposed that the actual weight of diapers is lower (comment #3165) than the values selected by the Dossier Submitter. In addition, it was noted that diapers are not made or marketed for a specific age group (comment #3176). Diapers are developed/designed for specific body weight intervals.

Besides, diapers made for the same weight interval can vary substantially in weight between producers and models. RAC, therefore, notes that there are minor uncertainties about the diaper weight.

B. Extraction method with urine simulant

The extraction method as described by the Dossier Submitter was still being developed during the assessment reported by ANSES (2019) and is not yet standardised or validated. Additional concerns were raised during the consultation on the Annex XV report[21] in relation to the methodology leading to a two orders of magnitude overestimation of the levels of extractable substance compared to a realistic worst-case scenario of use.

RAC notes that according to comments received during the consultation (e.g., #3135, #3166, #3167), the volume of urine simulant extracted from a (diaper) sample (220 to 250 mL) might be two orders of magnitude larger than would be expected in reality (1 to 2 mL). A laboratory test provided by industry shows that a diaper (size 4) loaded with 220 mL of urine (which represents four episodes of urination, 55 mL each time), results in a small amount of liquid extracted (0.7 mL), imitating a baby of about 10 kg body weight, sitting on the diaper) (rewet factor). That means that approximately 35% of the urine simulant was extracted from single-use diapers in the SCL analyses (2018, 2019), while only less than 1% of the baby's urine was extracted from a diaper under industry laboratory conditions (e.g., 0.25% found by Rai et al., 2009; 0.32 to 0.66% obtained by Dey et al., 2016).

The Dossier Submitter considered 24 hours to be an appropriate time frame for risk calculation. Over this period of time, however, only a frequency of two diaper changes should be used in the exposure assessment due to the fact that in the exposure scenario diapers were soaked over 16 hours with the urine simulant. RAC notes that the Dossier Submitter provided a sensitivity analysis considering a diaper change of two in 24 hours (this topic is further elaborated in section 3.1.5). However, the volume of urine simulant used to soak a diaper sample during one extraction period was 600 mL. Therefore, even with two "diaper changes per day" used in the calculation, the total urine simulant volume is 1 200 mL, while daily urine output for babies aged 2 to 12 months is only 400 to 600 mL. This leads to overestimation by a factor of two to three. On the other hand, it is not known whether the urinary simulant extraction of the substances in the scope of the proposed restriction follows a linear function or whether the extraction capacity is greatest when diapers are first wet and then reduces over time. Namely, if most of the extraction happens at the beginning of the extraction period, two extraction periods of 16 hours each (two "diaper changes per day") would yield lower amounts of extracted substances compared to more frequent extraction periods of shorter duration (e.g., 4 times 6 hours extraction period).

Urinary output in infants: RAC notes that the urinary output of babies aged between zero and

[21] **Comment #3166 (Industry)**: Some of the exposure parameters selected lead to unrealistic situations: A baby 0 to 6 months does not urinate 4.700 mL of urine per 24 hours; The principle of a baby diaper is to pick up baby's urine and hold it according to the dry-keeping mechanism, and diapers do not release 200 mL of urine. An average overnight diaper is "loaded" with approx. 210 mL (not 600 mL) and only releases up to 2 mL back the skin (known as rewet in the industry).
Comment #3167 (MSCA): "… the analysis of extractable chemicals was carried out with whole diapers soaked in artificial urine, incubated at 37 degrees Celsius for 16 hours, during which an additional 3*200 mL of urine was added. Extraction was performed thereafter by pressing out excess urine. In combination with a use frequency of 4.7 to 7.98 diapers per day, this would correspond to a urinary output of around 3000 to 5000 mL depending on age, which largely exceeds children's actual daily urinary output (approximately 200 to 600 mL per 24 hours, depending on age). This is not realistic and likely overestimates the levels of extractable substance compared to a realistic scenario of use. Moreover, the incubation time should for a realistic scenario, considering the diaper use frequency, be between 3 to 5 hours, depending on the age of the child."

six months varies (see Table 8 below). However, RAC considers that the amount used in the exposure estimate is overly conservative and not sufficiently realistic (see paragraph above).

Table 8 Reference values for urinary output (Guide pratique des analyses médicales, 4th edition), see Background Document

Age group	Urinary output (mL/24 hours)
New-born	15 - 60
Two weeks	100 - 300
One to two months	250 - 450
Two to 12 months	400 - 600
Two to four years	500 - 800

C. Daily exposure dose calculation

The daily exposure dose calculation considered only the substances extracted with the urine simulant, since the objective was to measure the quantity of impurities/contaminants that is not retained in the core of the diaper. The Dossier Submitter, however, did not specifically consider transfer of substances in diapers to baby skin via direct skin contact. DGCCRF/INC and SCL analysed certain relevant substances (i.e., PAHs, PCDD/Fs and PCBs, but not formaldehyde)[22] in shredded diaper parts by solvent extraction (ANSES, 2019), but these data were not used by the Dossier Submitter for exposure and risk assessment. In the opinion of RAC, this introduces an uncertainty in the exposure (and risk) assessment of lipophilic substances (PAHs, dioxins, furans, PCBs). Namely, in comparison to the extraction with water-based solutions (baby urine and urine simulant), these substances could be expected to be more efficiently absorbed during direct contact with baby's skin, especially considering that baby's skin is often treated with a lotion and that some diapers' topsheet may also be treated with a lotion.

In the Background Document, a relatively new method for calculating direct contact transfer and reflux has been used (Dey et al., 2016) to simulate exposure to hazardous substance by wearing of diapers (Prolonged Exposure Rewet Method in Diapers, PERMID). This is based on gravimetry where collagen is used to mimic skin, considering:

- the pressure a child may apply to a diaper,
- a representative urine load during diaper wear,
- the gap between urine voids,
- exposed surface area,
- and diaper wear time.

Diaper topsheet-lotion transfer was used as a model for direct transfer of substances to skin from the topsheet. Indirect contact (rewet) was calculated as a fraction of total liquid load that resurfaces back to the topsheet after absorption due to applying pressure on the

[22] Dioxins and furans were found in outer/inner diaper layer, and in other diaper parts, except the core. PAHs (benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3- c,d]pyrene, benzo[g,h,i]perylene) were detected in the elastics. Health thresholds were not exceeded for children aged 0 to 36 months in the ANSES risk assessment in these 23 diaper samples (ANSES, 2019).

absorbent material. This pressure was measured in 174 children between the ages of two weeks and 56 months, in four positions (sitting up straight, lying on the stomach, lying on the back, and falling on the buttocks).

For direct contact, 4% transfer was calculated after three hours of wear, 3% after six hours of wear, and 4.3% after a night. For indirect contact, an average reflux factor of 0.46% (range 0.32 to 0.66%) was adopted, considering that 50% of the diaper surface area (since in real conditions of use the applied pressure from the baby will not be on 100% of the diaper surface area at all times). These results are in line with earlier report by Rai et al. (2009) (0.25%), as well as with the values claimed by the industry during the consultation on the Annex XV report (e.g., comments #3165, 3166).

RAC considers that 4.3% for direct contact and 0.66% for indirect contact (rewet) could represent realistic worst-case values and uses them in the sensitivity analysis for the risk characterisation (Tables 11 to 13 in section 3.1.4).

D. Uncertainties/shortcomings in the exposure assessment concerning the analytical method

RAC considers that there are major uncertainties regarding the results of the diaper sample analysis undertaken by SCL and DGCCRF/INC, especially related to PAHs and other lipophilic substances (e.g., dioxins, furans, PCBs). These include:

- Overall, it has not been possible to confirm the reliability of the analytical data.

- The sample preparation and extraction method with urine simulant is not yet standardised and validated. This introduces further uncertainty into the exposure assessment, especially considering major uncertainties related to exposure scenario (e.g., disparity in the rewet factor between the Dossier Submitter's proposal and information provided by the industry). RAC notes that uncertainties in the analytical method required to assess the risk and justify a restriction is much more critical than the availability of a standard method needed for the purpose of enforceability (which could be developed later on during implementation).

- In 2019, three blank tests were performed. The values for PCDD/Fs and DL-PCBs obtained from the blank samples were not subtracted from those obtained in the diaper extraction tests. According to the Dossier Submitter, there is no European harmonisation with regard to the removal of blanks. RAC considers that lack of information on blanks in the first set of analyses (ANSES, 2019) and not accounting for background concentrations of dioxins and furans in the second set of analyses (performed in 2019) is a methodological shortcoming.

- Concerning PAHs, it is not clear why the measured values are orders of magnitude lower in 2019 compared to the 2018 analysis (Table 7). RAC notes that the LoDs/LoQs were three orders of magnitude lower for the 2019 analysis compared to the 2018 analysis. The Dossier Submitter noted that the analytical method was the same in 2018 and 2019 and suggested that there might have been improvements in the manufacture of diapers since EDANA has started developing an industry guidance on trace substances (Codex™ see section 3.3.) in 2017. However, according to industry, no such extensive changes in the quality of materials occurred in this short timeframe.

- For PAHs, the LoD of the methods used in the analyses was between 0.03 and 0.1 mg/L, and the LoQ was between 0.1 and 0.4 mg/L, while the migration limits proposed for PAHs is 0.023 ng_{TEQ}/kg. Although a simple comparison between the LoD of the analytical method to the proposed migration limit is not possible, it is obvious that the difference is several orders of magnitude (when calculated by the Dossier Submitter, the lowest value in the dataset of measured values for PAHs in diaper samples was

100 ng/kg). It is unknown whether the real values were above or below the proposed limits.

- The levels of dioxins, furans and PCBs determined by the urine simulant (water-based solution) extraction method exceeded the DNELs, while these substances, although highly lipophilic, were detected at lower concentration or even not detected by solvent-based extraction from shredded diaper samples (ANSES, 2019).

- Background concentrations of PCDD/Fs can regularly be detected in the water supplies of accredited laboratories that are specialised in dioxin/furan analyses (comment #3165). These background amounts fluctuate over time and are within the concentration ranges that would be required to determine the levels of PCDD/Fs at the limits proposed in the Annex XV dossier. This can introduce a high risk of "false positive" detections.

- The extraction protocol has several manual steps and keeping the diaper in open containers overnight (for extraction with urine simulant) could introduce contamination. The artificial urine used is made of several ingredients, which also increase the risk of introducing contamination (and demands the strict use of method blanks).

The exact magnitude of the uncertainties and shortcomings regarding the analytical method is unclear, however the reliability of the analytical results is likely to be severely affected by the described uncertainties.

In addition, RAC notes an inconsistency[23] in the number of analytes presented by the Dossier Submitter.

Table 9 The main uncertainties/shortcomings incl. the effect of concern and the level of concern

Uncertainties/shortcomings	Effect on concern	Level of concern
Uncertainties and shortcomings concerning the analytical method	↑↓	Very high
Use of the exposure variables in the daily exposure dose calculation, particularly the disparity in the "rewet" factor (baby's urine refluxed from a diaper):	↓	High (approximately two orders of magnitude overestimation)
Lacking assessment of direct exposure - especially regarding extraction of lipophilic substances which could come into direct contact with baby's skin;	↑	Medium

3.1.4. Characterisation of risk(s)

Summary of proposal:

Given that most of the estimated exposure levels are above the calculated limits for adverse effects, the Dossier Submitter concludes that the risk from the substances in the scope of the restriction is not adequately controlled.

[23] The number of quantified analytes for PCDDs/Fs and DL-PCBs is not consistent in the documents provided by the Dossier Submitter.

For substances with a threshold effect, meaning formaldehyde, PCDD/Fs and DL-PCBs, and for substances with a non-threshold effect (mainly genotoxic carcinogens, in this restriction dossier, PAHs), the risk level is expressed by the RCR, which is the ratio between the daily exposure dose and the appropriate internal DNEL or dermal DMEL, expressed for **10^{-6} risk level**. The numerical value of this ratio is used to determine whether or not the dose received exceeds the $DNEL_{in}$ or $DMEL_{dermal}$.

RCR = daily exposure dose/$DNEL_{in}$ or $DMEL_{dermal}$.

The numerical value of the RCR is interpreted as follows: an RCR greater than 1 means that the toxic effect may occur, without being possible to predict its likelihood of occurrence in the exposed population, whereas an RCR lower than 1 means that no toxic effect is theoretically expected in the exposed population provided that the exposure to the substance is only due to the single-use baby diaper.

Single usable baby diapers are not the only source of exposure to substances. The Dossier Submitter states that the intake of chemicals from single-use baby diapers is small in comparison with that from other sources, such as food, air, drinking-water and other consumer products. So, some consideration is needed as to the proportion of the DNEL that may be allowed from different sources.

The approach of using an allocation factor ensures that the total daily intake from all sources does not exceed the DNEL. For example, an allocation of 10% of the TDI to the intake of formaldehyde from toys was used to derive a migration limit for formaldehyde in toys (Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC[24]). According to RIVM (2008), this allocation factor was already used in 1984 by the Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds to propose thresholds for metals (report EU 12964 EN not available) (RIVM, 2008).

The possibility of cumulative exposure through other sources (environmental, food, etc.) leading to an increase in the total daily exposure dose cannot be ruled out, meaning that the exposure to the chemicals in the scope of the proposed restriction is likely not to be limited to diapers only. Therefore, the Dossier Submitter decided to limit the share allocated to single-use baby diapers to 10% of the DNEL/DMEL.

The limits in single-use baby diaper were therefore calculated using the following equation:

$$\mathbf{C_{diaper} = RCR \times 10\% \times BW \times DNEL_{in}} \text{ or } DMEL_{dermal} \mathbf{/ (W \times F \times Abs_{skin} \times TEF)}$$

With:

- $DNEL_{in}$: internal DNEL (mg/kg bw/d)
- $DMEL_{dermal}$: dermal DMEL (mg/kg bw/d)
- BW: body weight of a child (kg)

[24] COMMISSION DIRECTIVE (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council for the purpose of adopting specific limit values for chemicals used in certain toys, as regards formaldehyde: https://eur-lex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:32019L1929&from=EN

- W: weight of a diaper (kg)
- F: frequency of use per 24h (number/24h)
- Abs_{skin}: fraction absorbed by the skin (%)
- TEF: toxic equivalent factor (only used for PCDD/Fs and DL-PCB and PAHs)
- C_{diaper}: migration limit of the chemical extracted with a urine simulant from a whole diaper, in relation to the weight of the diaper considering the extracted simulant volume (mg/kg of diaper)

The concentration of the **available** substance expressed in mg/kg of diaper cannot be directly measured. It is proposed to be determined after extraction of said substance from a whole diaper with a urine simulant. It is thus related to the weight of the diaper, and to the extracted simulant volume. The migration limit of available substance expressed in mg/kg of diaper can thus be transformed into a limit concentration of the **available** substance expressed in mg/L of urine simulant using the following equation:

$C_{urine\ simulant}$ [mg/mL urine simulant] = ($C_{diaper\ simulant}$ [mg/kg diaper] x weight of the diaper [kg]) / extracted volume [mL]

The Dossier Submitter chose to report the concentration level detected/quantified according to the ECHA R.15 guidance, meaning that the Dossier Submitter calculated the 95th percentile of the distribution of the 51 samples, including a default for those below LoD and/or LoQ. Indeed, for this calculation, the LoD was retained, if the substance was not detected. The LoQ was retained, if the substance was detected and if the substance was quantified the quantified concentration was retained.

Using the formula

$$\mathbf{CL_{diaper} = RCR \times 10\% \times DN(M)EL \times BW / (W \times F \times Abs_{skin} \times TEF)}$$

the Dossier Submitter calculated the migration limits in single-use baby diapers.

Formaldehyde

Migration limit (mg/kg diaper) = 0.1 x 0.075 X 5.2 /(0.0231 X 7.98 X 50%) = **0.42 mg/kg**

The sum of PAHs

Migration limit (ng_{TEQ}/kg diaper) = 1 X 0.1 X 0.004 X 5.2 /(0.0231 X 7.98 X 50%) = **0.023 ng_{TEQ}/kg**

The sum of PCDD/Fs/DL-PCBs

Migration limit (ng $_{TEQ}$/kg diaper) = 1 X 0.1 X 0.0003 X 5.2 /(0.0231 X 7.98 X 50%) = **0.0017 ng $_{TEQ}$/kg**

The sum of the total PCBs

Migration limit (mg/kg diaper) = 1 X 0.1 X 2.10^{-5} X 5.2 /(0.0231 X 7.98 X 50%) = **112 ng/kg**

Table 10 Calculated migration limits for the substances in scope (according to Table 71 in the Background Document)

Substance/group of substances	Proposed migration limit
Formaldehyde	
Formaldehyde	**0.42 mg/kg of diaper**[3]
PCDDs/PCDFs/PCBs	
Sum of the quantified PCDD/Fs **in TEQ**[1]	**0.0017 ng_{TEQ} /kg of diaper**
Sum of the quantified total PCBs	**112 ng/kg of diaper**
PAHs	
The sum for the detected or quantified PAH **in TEQ**[2]	**0.023**[4] **ng_{TEQ} /kg of diaper**

[1] TEQ from WHO 2005; [2] The Dossier Submitter selected TEFs for 17 PAHs from the existing TEFs defined by various organisations (OEHHA, 1993 revised in 2015; INERIS, 2003; AFSSA, 2003; DFG, 2008 cited in BfR, 2009b; US EPA, 2010) (Table 39 in the Background Document)
[3] This migration limit is proposed to cover all categories of ages and all sizes of diapers available on the market.
[4] Final value, corrected in the last version of the report by the Dossier Submitter following RAC's indication as there was a calculation mistake.

RAC conclusion(s):

RAC supports the Dossier Submitter's approach to calculate the risk for the population in the scope of the risk assessment (children aged between zero to 36 months), based on the most vulnerable group within this population (babies aged between zero to six months).

RAC concurs with the Dossier Submitter to express the risk level by the risk characterisation ratio (RCR) for substances with a threshold effect (formaldehyde[25], PCDD/Fs and DL-PCBs) as well as for substances with non-threshold (carcinogenic) effect. The RCR is therefore the ratio between the daily exposure dose and the appropriate internal $DNEL_{in}$ or $DMEL_{dermal}$, **expressed at 10^{-6} risk level**.

Nevertheless, RAC notes that:

- there are significant uncertainties related to the analyses of diaper samples carried out by DGCCRF/INC and SCL (in 2018 and 2019), especially regarding PAHs, PCDDs/Fs and DL-PCBs (i.e., all lipophilic substances in the scope), as already described in section 3.1.3. "*Information on emissions and exposures"*;
- there is likely overestimation in the daily estimated dose, and consequently the RCRs calculated by the Dossier Submitter, due to a two order of magnitude greater rewet factor and approximately 4-times greater volume of urine simulant used for diaper

[25] In this Annex XV dossier, the carcinogenic effects of formaldehyde were not considered since via the dermal route the skin sensitising effects are of relevance but not the carcinogenic ones.

sample extraction, compared with a realistic volume of urine output in babies of that age;

- for PAHs, since the lowest LoD is orders of magnitude higher than the proposed migration limits, it is not known how many samples were above/below the proposed limits - such a high LoD in relation to the limit value makes the restriction proposal impractical because interested parties (enforcement, industry) would never know if a diaper is compliant with the conditions of the restriction or not;
- RAC does not support the use of an allocation factor for the calculation of risks for local dermal effects (formaldehyde and PAHs). For other effects (PCDD/Fs and PCBs), the value of an allocation factor of 10% is not considered to be sufficiently justified by the Dossier Submitter.

RAC concurs with the Dossier Submitter that other studies that analysed contaminants in baby diapers are either: old and do not adequately reflect the present manufacturing process of diapers; the extraction methods used (solvent extractions) differed from the one recommended in the present restriction proposal (urine simulant extraction); or are too limited in reporting the study methodology.

Taking these issues into consideration, RAC concludes the following for the risk characterisation for substances in the scope of the proposed restriction:

Formaldehyde: In contrast to the Dossier Submitter's calculation, the sensitivity analysis performed by RAC showed RCR values below 1, with or without the allocation factor of 10%. However, RAC considers that skin sensitisation is probably the most sensitive critical effect following dermal exposure to formaldehyde in any case. Although this critical effect has not been assessed by the Dossier Submitter, an illustrative example calculated by RAC does not indicate a risk for skin sensitisation. RAC, therefore, concludes that the risk posed by formaldehyde has not been demonstrated by the Dossier Submitter. It should be also pointed out that formaldehyde in single-use diapers is within the scope of the proposed restriction on skin sensitisers in textiles (ECHA, 2020).

PAHs: Similar to the Dossier Submitter's analysis, RAC's sensitivity analysis showed RCR values several orders of magnitude above 1, both for direct and indirect exposure. The allocation factor was not applied, since local effect, i.e. skin tumorigenesis, was the critical effect. Nevertheless, RAC has identified significant uncertainties related to the PAH analyses performed by DGCCRF/INC and SCL (described in section 3.1.3. and *"Key elements underpinning the RAC conclusions"* below), due to which the risk for babies from exposure to PAH substances in single-use diapers cannot be reliably characterised at present.

PCDDs/Fs/DL-PCBs. In contrast to the Dossier Submitter's calculation, RAC's sensitivity analysis showed RCRs below 1 for indirect exposure, direct exposure, and for the sum of RCRs for indirect and direct exposure. Allocation factor to the RCR could be justified for this group of substances, as discussed in *"Key elements underpinning the RAC conclusions"* in this section. However, RAC considers that the precise value of the allocation factor (i.e., 10%) is not sufficiently justified by the Dossier Submitter and points out that RCRs from mother's milk are two orders of magnitude higher than from diapers (EFSA, 2018). Considering uncertainties related to analyses performed by DGCCRF/INC and SCL (section 3.1.3 above), and the fact that the contribution of diapers to PCDDs/Fs/DL-PCBs exposure is negligible compared to

exposure from human milk, RAC concludes that presently available evidence is not reliable enough to justify a restriction for this group of substances.

NDL-PCBs were not analysed by DGCCRF/INC and SCL in diaper samples, therefore the risk has not been characterised.

Overall, RAC concludes that due to the high level of uncertainties related to the exposure assessment and risk characterisation of the substances in the scope of this restriction proposal, **the EU-wide risk for babies and infants wearing single-use diapers has not been demonstrated for the substances in the scope of the Annex XV dossier.**

For **formaldehyde**, RAC concludes that risk of skin sensitisation is a more appropriate assessment endpoint in diapers than the systemic effects proposed by the Dossier Submitter and that exposure to formaldehyde via diapers would be likely to be 20 times below reported elicitation thresholds for sensitisation. RAC also notes that as formaldehyde has a harmonised classification as a skin sensitiser it would be restricted in single-use diapers by means of the proposed restriction on skin sensitisers in textiles under REACH. As such, no further action for formaldehyde would appear to be necessary.

For **PCDD/Fs** and **DL-PCBs**, RAC has undertaken a sensitivity analysis of the Dossier Submitter's exposure assessment using more realistic conditions of use and concludes that risks for the endpoints assessed by the Dossier Submitter would be unlikely to occur from the wearing of single-use baby diapers because the assumptions used by the Dossier Submitter (and their inherent uncertainties) would tend to result in significant overestimates of exposure and risk. Nevertheless, RAC notes that the size of the allocation factor used for risk characterisation is a critical uncertainty in determining whether a risk would occur for certain sub-populations (i.e. formula-fed infants) and that the Dossier Submitter did not assess the potential for risks via all potentially relevant endpoints (i.e. via endocrine disruption). Therefore, it is not possible to conclude that there are no potential risks from these substances in single-use diapers based on the available assessment.

For **PAHs**, RAC concluded that the available analytical data are of insufficient quality for a reliable exposure assessment, which means that risks cannot be reliably characterised.

For **NDL-PCBs**, there are no analytical data upon which to base an assessment. Therefore, similar to PAHs, RAC cannot conclude whether NDL-PCBs in diapers pose a risk or not.

In order to address the highlighted uncertainties and enable a reliable risk assessment in an updated restriction proposal, several aspects could be considered:

- The simulated urine extraction method clearly has potential (above solvent extraction) but needs standardising with more realistic exposure assumptions;
- Suitable low and consistent limits of detection and quantification are needed for the analysis of the substances of concern and should include method validation within the range to be analysed and appropriate analytical and extraction method blanks;
- Realistically, further measurement campaigns showing consistent results would be needed to provide a strong basis upon which to base a risk assessment in support of a restriction proposal;

- Further investigations do not necessarily apply only to the substances in the scope of this restriction proposal but also to other hazardous substances, including fragrances, VOCs and pesticide residues;
- The use of allocation factors would need to be carefully justified.

RAC considers that the time required to obtain this information will be determined by:

a) the development of more sensitive analytical methods, bearing in mind the very low levels of derived DN(M)ELs for PAHs as well as PCDDs/Fs and PCBs set by the Dossier Submitter's restriction proposal and;
b) the standardisation of the simulated urine extraction method.

The potential consequences of inaction while this information is being generated are difficult to predict. The very limited human data available do not indicate an increased risk from testicular carcinoma in adult life associated with single-use diaper wearing during infancy (e.g., Møller, 2002), but they are not considered sufficient to conclude that there is no risk regarding carcinogenic effects of PAHs in single-use baby diapers. Similarly, there is generally a lack of human data on endocrine-disrupting effects of environmental contaminants (such as PCDDs/Fs/DL-PCBs) at very low levels of exposure.

RAC, however, thinks that the implementation of EDANA´s Stewardship Programme[26] for all manufacturers/importers of diapers in the EU/EEA could alleviate somewhat the potential consequences of inaction until the aforementioned information is generated. But, as discussed above, RAC has not evaluated this scheme in detail.

Key elements underpinning the RAC conclusion(s):

Considering 95th percentile of measured concentrations of substances in 51 diaper samples (SCL 2018, 2019), frequency of diapers' change (7.98), diaper weight (0.0231 kg), skin absorption (0.5) and baby's body weight (5.2 kg) for the class of age from zero to six months, the Dossier Submitter calculated daily exposure dose (DED) and RCR values ("DS" – "RCR 10%", Tables RCR1 - 3).

$$DED_{0\text{-}6} = (C_{diaper} \times F \times W \times Abs_{skin}) / BW$$

$$RCR_{0\text{-}6} = DED / DNEL$$

RAC notes that the sensitivity analyses were provided by the Dossier Submitter to address the uncertainties related to the frequency of diaper change considered in the exposure scenario. However, the sensitivity analyses were not performed by the Dossier Submitter regarding the rewet factor.

[26] https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products

Sensitivity analysis by RAC:

1) using the same 95th percentile values which were used by the Dossier Submitter in their analysis;
2) applying a rewet factor of 0.66% (as a realistic worst-case value from the PERMID method described by Dey et al., 2016), instead of 35% extracted urine simulant volume applied by the Dossier Submitter;
3) applying 2 instead of 7.98 diaper changes, in order to stay within the range of expected daily urinary output of babies during the first year of life (i.e., 400 to 600 mL per 24h);
4) adding direct transfer of 4.3% (as a realistic worst-case value from the PERMID method described by Dey et al., 2016) for substances for which data for solvent extraction from shredded diaper parts were available in the ANSES report (2019; Table 55). Only diaper parts that could be in direct contact with baby's skin were considered (e.g., top sheet, elastic parts; Rai et al., 2009)[27].

In the calculations performed by RAC, the volume of urine simulant per day was not corrected to more realistic values, i.e., volume of urine simulant in these calculations is 2 to 3 times higher than it is normally expected for two months to 12 months old babies. This more conservative approach allows for other uncertainties, e.g., for potential variability of rewet factor or uncertainty whether the urinary simulant extraction of the substances in the scope of this restriction proposal follows a linear function or whether the extraction capacity is reduced over time.

Regarding the allocation factor of 10% for the calculation of risk, RAC acknowledges that different exposure routes and sources (food, ambient air, cosmetic products, objects and toys) might contribute to the uptake of substances in the scope of the proposed restriction. However, RAC considers that the Dossier Submitter's approach to use an allocation factor of 10% for the calculation of risk is not sufficiently justified. The extent of the share depends on the substance, on the route which is considered in the exposure scenario (e.g., dermal route) and the approach chosen for the hazard assessment (e.g., dermal slope for PAHs). Thus, RAC considers that an allocation factor is not justified for formaldehyde and PAHs, for which local effects are the most relevant ones for this restriction proposal. For substances like PCDDs/Fs and PCBs for which systemic effects (reprotoxicity, immunotoxicity) were considered critical, an allocation factor is justified (Costopoulou et al., 2013; EFSA, 2017). However, in RAC's opinion, the Dossier Submitter has not provided sufficient documentary evidence regarding why an allocation of the total daily intake (TDI) to 10% from diapers reflects a reasonable level of exposure.

<u>Formaldehyde</u>

When a rewet factor of 0.66% was applied in RAC's sensitivity analysis, RCRs were well below 1, either with 2 or 8 diaper changes. Direct contact could not be calculated since there were

[27] INC and SCL calculated daily exposure dose (DED) according to formula DED = ($C_{shredded\ material}$ x W x F x T x Abs)/BW, where $C_{shredded\ material}$ is the highest concentration of the chemical extracted with a solvent from shredded diaper parts (mg/kg of the diaper); W is the average weight of the diaper part (kg); F is the frequency of use (12 per day); T is transfer to the skin (100%); Abs is fraction absorbed by the skin (100%); and BW is body weight of a child (2.6 kg). RAC recalculated these values using 8 instead of 12 diaper changes per day, body weight of 5.2 kg instead of 2.6 kg, and 50% absorption via the skin.

no data available in ANSES report for formaldehyde in diaper parts.

Table 11 Risk characterisation for formaldehyde, calculated by the Dossier Submitter and by RAC (sensitivity analysis)

Substance(s)	Rewet factor	95th percentile (mg/kg)	Frequency of diaper change/day	Diaper weight (kg)	Skin abs.	Body weight (kg)	DED (mg/kg bw/day)	DN(M)EL	RCR	RCR 10%
Formaldehyde										
DS	35%	1.77	8	0.0231	0.5	5.2	0.03132	0.075	**0.42**	**4.18**
	35%	1.77	2	0.0231	0.5	5.2	0.00785	0.075	**0.10**	**1.05**
Rapps										
Indirect contact	0.66%	0.033	8	0.0231	0.5	5.2	0.00059	0.075	**0.008**	**0.08**
	0.66%	0.033	2	0.0231	0.5	5.2	0.00015	0.075	**0.002**	**0.02**

DED = daily exposure dose; RCR 10% = RCR with 10% allocation factor applied; DS = Dossier Submitter

Regarding the allocation factor, the Dossier Submitter argues that an allocation of 10% of the TDI to the intake of formaldehyde (due to its carcinogenic effect) was used to derive a migration limit for formaldehyde in toys (Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC). However, this cannot be extrapolated to this restriction proposal as RAC is of the opinion that local effects, i.e., skin sensitisation, is probably the most sensitive critical effect following dermal exposure to formaldehyde. This critical effect has not been assessed by the Dossier Submitter.

Just as an illustration for a possible approach to risk characterisation based on skin sensitisation, RAC compared skin exposure to formaldehyde in diapers with the elicitation threshold for formaldehyde (20.1 µg/cm^2; Flyvholm et al., 1997) used in the proposed restriction on skin sensitisers in textiles (ECHA, 2020). RAC calculated skin exposure to formaldehyde in diapers as a ratio between:

- formaldehyde content extracted by urine simulant during 24h (based on 95th percentile of formaldehyde concentration measured in diaper samples by SCL and DGCCRF/INC), i.e., 326 µg/day;[28] and
- skin area in contact with diaper (287 cm^2) according to ECHA, 2017 and Boniol et al., 2008);

obtaining the value of: 326 µg/day / 287 cm^2 = 1.1 µg/cm^2.

This value is approximately 20 times lower than the elicitation threshold of 20.1 µg formaldehyde/cm^2. RAC considered that elicitation threshold value (Flyvholm et al., 1997) has been obtained in adults and not in infants, and that diaper dermatitis, a common problem in children, is considered to increase the risk for allergic sensitisation (e.g., Sweeney et al. 2021). Nevertheless, it is considered that the use of elicitation instead of induction dose (which is expected to be higher than elicitation dose) in the calculation, alleviates these uncertainties. RAC also points out that formaldehyde in single-use baby diapers is within the

[28] C_{diaper} (95th percentile) x frequency of diaper changes x diaper weight = 1.77 mg/kg x 7.98 x 0.023 kg = 0.326 mg/day

scope of the proposed restriction on skin sensitisers in textiles (ECHA, 2020).

PAHs

Even when applying a rewet factor of 0.66%, 2 diaper changes, and no allocation factor (since the local effect, i.e., skin tumorigenesis, was the critical effect) in RAC's sensitivity analysis, RCR was several orders of magnitude above 1 for indirect contact. For direct contact (PAHs were detected/quantified in elastic parts of diapers by solvent extraction; ANSES, 2019), RCR was also several orders of magnitude above 1. The sum of RCRs for direct and indirect exposure were approximately 4 orders of magnitude above 1.

Table 12 Risk characterisation for PAHs, calculated by the Dossier Submitter and by RAC (sensitivity analysis)

Substance(s)	Rewet factor/ Direct transfer	95th percentile (mg/kg)	Frequency of diaper change/day	Diaper weight (kg)	Skin abs.	Body weight (kg)	DED (mg/kg bw/day)	DN(M)EL	RCR
PAHs, sum	Rewet factor								
DS	35%	1.080	8	0.0231	0.5	5.2	0.01914	4.00E-09	4783815
	35%	1.080	2	0.0231	0.5	5.2	0.00480	4.00E-09	1198951
Rapps	Rewet factor								
Indirect contact	0.66%	0.020	8	0.0231	0.5	5.2	0.00036	4.00E-09	90209
	0.66%	0.020	2	0.0231	0.5	5.2	0.00009	4.00E-09	22609
	Direct transfer								
Direct contact	4.3%	0.141	8	0.00012007	0.5	5.2	1.3E-05	4.00E-09	3246

DED = daily exposure dose; DS = Dossier Submitter

Nevertheless, RAC recognises several significant uncertainties related to PAHs analyses performed by DGCCRF/INC and SCL, mainly described in section 3.1.3. above. In the sensitivity analysis, the 95th percentile was calculated based on the data from both sets of measurements (from 2018 and 2019). It should be stressed that in the analysis carried out in the year 2019, only 4 out of 32 samples had detectable level of one PAH (benzo[a]anthracene). Since the lowest LoD in 2019 analysis (100 ng/kg) is four orders of magnitude higher than the proposed migration limit for PAHs (0.023 ng/kg), it is not known whether the true quantity (if any) of non-detected PAHs were above or below the proposed migration limits.

RAC considers that due to these uncertainties, the risk for babies from exposure to PAH substances in single-use baby diapers cannot be reliably characterised at present.

PCDDs/Fs/DL-PCBs

When applying a rewet factor of 0.66%, 2 diaper changes, and no allocation factor, RAC's sensitivity analysis showed RCRs below 1 for indirect exposure, direct exposure (furans were detected/quantified by solvent extraction in topsheet layer and other diaper parts, excluding the diaper core which is not in direct contact with baby's skin; ANSES, 2019), and for the sum of RCRs for indirect and direct exposure.

Table 13 Risk characterisation for PCDDs/Fs/DL-PCBs, calculated by the Dossier Submitter and by RAC (sensitivity analysis)

Substance(s)	Rewet factor/ Direct transfer	95th percentile (mg/kg)	Frequency of diaper change/day	Diaper/ diaper part weight (kg)	Skin abs.	Body weight (kg)	DED (mg/kg bw/day)	DN(M)EL	RCR
PCDD/Fs/DL-PCBs	Rewet factor								
DS	35%	3.1E-07	8	0.0231	0.5	5.2	5.53E-09	3.00E-10	18.4
	35%	3.1E-07	2	0.0231	0.5	5.2	1.38E-09	3.00E-10	4.6
Rapps									
Indirect contact	0.66%	5.9E-09	8	0.0231	0.5	5.2	1.04E-10	3.00E-10	0.35
	0.66%	5.9E-09	2	0.0231	0.5	5.2	2.61E-11	3.00E-10	0.09
	Direct transfer								
Direct contact	4.3%	5.5E-08	8	0.001-0.006	0.5	5.2	1.6E-10	3.00E-10	0.52
							Sum RCR for 8 changes =		0.87
							Sum RCR for 2 changes =		0.61
PCDD/Fs/DL-PCBs in breastfed infants with average human milk consumption (EFSA 2018)							3.29E-08	3.00E-10	110
PCDD/Fs/DL-PCBs in breastfed infants with high human milk consumption (EFSA 2018)							4.93E-08	3.00E-10	164
Mean exposure via infant formula (Infant TDS, ANSES 2016)							2.00E-10	3.00E-10	0.67

DED = daily exposure dose; DS = Dossier Submitter

Applying an allocation factor to the RCR could be justified for this group of substances, as discussed above. However, RAC considers that the precise value of the allocation factor (i.e., 10%) is not sufficiently justified by the Dossier Submitter. For example, allocation factor for diapers is expected to differ several orders of magnitude between breastfed infants and infants fed with infant formula (Table RCR3). Namely, according to EFSA report (2018), the RCR from mother's milk is two orders of magnitude higher than from diapers.

Considering the uncertainties related to analyses performed by DGCCRF/INC and SCL (described in section 3.1.3. above), and the fact that the contribution of diapers to PCDDs/Fs/DL-PCBs exposure is negligible compared to dietary sources, i.e., human milk, RAC concludes that presently available evidence is not substantial (or reliable) enough to justify a restriction proposal for this group of substances.

NDL-PCBs were not analysed by DGCCRF/INC and SCL in diaper samples, so the risk for these substances has not been characterised.

3.1.5. Uncertainties in the risk characterisation

Summary of proposal:

For all the chemicals in the scope of the restriction proposal, the migration limits are far below the highest limits found in single-use baby diapers at point of sale. Therefore, the Dossier Submitter concludes that the risks associated with these substances are not adequately controlled. Hence, lowering the concentrations of these chemicals in single-use baby diapers, so that they comply with the migration limits proposed, is considered to significantly reduce the risk. The limits proposed are considered to adequately protect infants and children under the age of three.

RAC conclusion(s):

RAC notes that none of the substances in the scope of the Annex XV dossier are intentionally added to diapers according to information provided by industry. Although a risk for babies has not been demonstrated for formaldehyde and PCDDs/Fs/DL-PCBs, and cannot be characterised for PAHs and NDL-PCBs, RAC is of the opinion that each of these substances should be kept to a level as low as possible/feasible[29] in single-use baby diapers, and preferably not be present at all. RAC notes that the POPs (Persistent organic pollutants) regulation already covers the unintentional presence of PCBs in all articles, including diapers, and, as such, no PCB content above the detection limit would be allowed.

Key elements underpinning the RAC conclusion(s):

According to information provided by industry in the consultation on the Annex XV report, e.g., comment #3165, "*formaldehyde, PCDD/Fs and DL-PCBs, PCBs and PAHs are not intentionally added"* to single-use baby diapers. They are impurities and according to information obtained during the consultation, there is no clear knowledge where these substances come from. According to comment #3162, a source of contamination could be raw materials, oils, glues, wetness indicator, pigments, etc. However, it is also noted that the source for PCCDs/Fs and PCBs are most likely from cellulose (comment #3208).

3.1.6. 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

Summary of proposal:

At EU level, baby diapers are subject to the general safety requirements defined by European legislation related to consumer goods. A European regulatory framework specific to babies' diapers does not exist. In 2019, ANSES published a report on the risks associated with the presence of hazardous substances in single-use baby diapers and made recommendations for risk reducing measures (ANSES, 2019).

There is no epidemiological data demonstrating an association between health effects and the wearing of diapers. However, hazardous chemicals have been found in single-use baby diapers. Based on the results of the tests and the literature data, a quantitative health risk assessment was undertaken for single-use baby diapers according to realistic scenarios. This assessment showed cases of the health thresholds being exceeded for several substances. Therefore, the Dossier Submitter concludes that it is not possible to rule out a health risk associated with the repeated wearing of single-use diapers and recommends regulatory actions to be taken.

RAC conclusion(s):

RAC is of the opinion that the EU-wide risk for babies and infants wearing single-use diapers has not been demonstrated for the substances in the scope of the proposed restriction.

[29] Feasibility refers in to technical (incl. analytical methods) and economic feasibility.

Nevertheless:

- for **PCDD/Fs and DL-PCBs**, RAC notes that the Dossier Submitter did not assess the potential for risks via all potentially relevant endpoints (i.e., via endocrine disruption) therefore, it is not possible to conclude that there are no potential risks from these substances in single-use diapers based on the available assessment (see section 3.1.4).

- for **PAHs**, RAC concludes that the available analytical data are of insufficient quality for a reliable exposure assessment, which means that risks cannot be reliably characterised (see section 3.1.4).

- for **NDL-PCBs**, there are no analytical data upon which to base an assessment. Therefore, similar to PAHs, RAC cannot conclude whether NDL-PCBs in diapers pose a risk or not (see section 3.1.4).

RAC acknowledges that there is no binding EU wide regulation which deals with migration limits of hazardous substances like formaldehyde, PAHs, PCDDs/Fs and PCBs in disposable baby diapers.

With regard to formaldehyde, RAC refers, however, to its opinion on the proposed restriction on skin sensitisers in textiles, leather, fur and hide articles (skin sensitising substances in textiles – ECHA, 2020) which would very likely address the risk of this substance to induce allergic effects in the population addressed by the restriction proposal if adopted. According to RAC, systemic effects of formaldehyde via the dermal route are highly unlikely.

Key elements underpinning the RAC conclusion(s):

The potential risks associated with EU manufactured or imported single-use baby diapers articles containing the chemicals of concern need to be addressed on a Union-wide basis since exposure takes place in all Member States.

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

Summary of proposal:

For the purposes of this restriction proposal, several risk management options (RMOs) for the regulation of hazardous chemicals in single-use baby diapers have been identified and analysed (REACH restriction options under Article 69, introduction of labelling requirements, Identification as SVHC according to REACH Article 57 and subsequent authorisation, harmonised classification of substances under CLP (EC) No 1272/2008, development of a specific EU product legislation covering single-use baby diapers and voluntary actions. The Dossier Submitter concluded that none of these RMOs was appropriate to control the risk. Therefore, several restriction options under REACH were explored: in total two restriction options were analysed. The following REACH restriction options were considered by the Dossier Submitter:

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

- Restriction option 2 (RO2): Limiting 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.

RAC conclusion(s):

RAC concurs with the Dossier Submitter that possible health risk associated with substances in the scope of the proposed restriction and repeated wearing of single-use diapers by babies and children under the age of three could not be completely ruled out so far (especially from cancerogenic PAHs and substances with endocrine disrupting properties, i.e. PCDDs/Fs/DL-PCBs) due to the uncertainties described in sections 3.1.4. and 3.1.5. above.

RAC acknowledges that there is no binding EU wide regulation which deals with concentration/migration limits of hazardous substances like formaldehyde, PAHs, PCDDs/Fs and PCBs in disposable baby diapers.

With regard to formaldehyde, RAC refers, however, to its opinion on the Annex XV dossier on skin sensitisers in textiles, leather, fur and hide articles (skin sensitising substances in textiles – ECHA,2020) which would very likely address the risk of this substance to induce allergic effects in the population addressed by the restriction proposal if adopted. Systemic effects of formaldehyde via the dermal route are highly unlikely according to RAC.

Key elements underpinning the RAC conclusion(s):

The potential risks associated with EU manufactured or imported single-use baby diapers articles containing the chemicals of concern need to be addressed on a Union-wide basis since exposure takes place in all Member States.

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, traded between Member States and also imported from outside Europe. As such, any action aiming to reduce the exposure of children to hazardous substances in single-use diapers should be taken on a Union-wide basis.

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, RAC and SEAC support the view that any necessary action for the substances in the scope of the restriction proposal should be taken at EU level.

However, RAC has concluded that uncertainties in the risk assessment are such that a risk has not been demonstrated for formaldehyde and PCDDs/Fs/DL-PCBs and cannot be characterised for PAHs and NDL-PCBs. 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 concludes 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.

As stated before, the available human and animal data provides very limited information for the assessment of health risks from the hazardous chemicals present in baby diapers. RAC notes that it is very difficult (and therefore very unlikely) that associations will be found in epidemiological data to demonstrate such a health risk for babies/children posed by the substances in the scope of this restriction proposal. Hazardous substances in modern diapers are mostly at very low levels, while health effects like cancer, adverse reproductive effects, mutagenicity effects, genotoxic effects and endocrine effects are complex, multifactorial adverse effects, mostly with a long latency period. These factors demand very large sample size to obtain adequate statistical power, and there is still an issue of uncontrolled/unrecognised confounding factors. Lack of human evidence, therefore, cannot exclude the risk, especially regarding non-threshold effects, such as genotoxic carcinogenicity or endocrine disruption. Consequently, it is necessary to keep these substances to a level as low as possible/feasible in such articles, and preferably not be present at all. RAC notes that the POPs (Persistent organic pollutants) regulation already covers the unintentional presence of PCBs in all articles, including diapers, and, as such, no PCB content above the detection limit would be allowed.

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

Scope including derogations

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 children,
- 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.

Justification for the opinion of RAC

RAC conclusion(s):

RAC agrees in principle with the Dossier Submitter that a restriction under REACH would be the most appropriate risk management option to address a risk to babies wearing single-use baby diapers.

However, since the risk from formaldehyde PCDDs/Fs and DL-PCBs has not been demonstrated and cannot be reliably characterised for PAHs and NDL-PCBs, RAC is of the opinion that it has not been demonstrated that a restriction is justified.

In the meanwhile, the existing EDANA Stewardship Programme for Absorbent Hygiene Products[30] - a voluntary action by industry - could ensure a standard throughout the EU/EEA in dealing with impurities/contaminants. However, RAC does not see this as a substitute for a restriction under REACH should a risk be adequately demonstrated. This programme may help to further reduce the concentration of the substances in the scope of the Annex XV dossier – but also of other substances like phthalates, organotins, metals - in all single-use diapers put on the European market. As indicated by industry, whilst 85% of European manufacturers comply with the requirements of this programme, a number of producers do not. In addition, RAC points out that products imported to the EU may not be addressed by the Stewardship Programme at all.

The POPs (Persistent organic pollutants) regulation covers the unintentional presence of PCBs in all articles, including diapers. As such, no PCB content above the detection limit is permitted. RAC, therefore, considers that there is a concern related to the proposed restriction being counter to the objectives of the existing POPs regulation.

With regard to the articles covered by the scope, RAC considers that this is clear but it is not possible to support either of the two proposed restriction options (RO1 or RO2) due to the uncertainties and shortcomings related to the exposure assessment and risk characterisation.

RAC notes that no derogations were requested during the commenting period, probably since the same "base material" might be used for all the different diapers included in the scope of the restriction proposal.

Key elements underpinning the RAC conclusion(s):

RAC is of the opinion that based on the information in the Annex XV dossier and its Annex, none of the assessed RMOs would be more efficient than a restriction under REACH if the

[30] https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products/the-edana-absorbent-hygiene-product-stewardship-programme-codex

substances in the scope of the proposed restriction pose a health risk for babies and children.

Below, RAC briefly describes why the other RMOs mentioned by the Dossier Submitter are not considered to be more efficient than a restriction under REACH:

Introduction of labelling requirements for disposable baby diapers containing formaldehyde, PAHs, PCDDs/Fs and PCBs:
RAC considers that labels on disposable diapers might not be an appropriate measure to reduce a health risk for babies and children because labels would not require manufacturers to reduce the concentration of the substances in single-use diapers.

Identification as SVHC according to REACH Article 57 and subsequent authorisation:
The Authorisation process in the EU applies to the use of a chemical during its incorporation into an article rather than the use of the article itself. Since the substances in the scope of the proposed restriction are not intentionally added, Authorisation is not considered to be an appropriate RMO by RAC.

Harmonised classification of substances under CLP (EC) No 1272/2008:
Although harmonised classification is an important tool to "identify" substances of high concern, it would not itself reduce exposure of babies and children to the substances in the scope of the proposed restriction. Therefore, RAC does not consider classification to be an appropriate RMO concerning impurities in disposable baby diapers.

Other legislation:
Legislations like the General Product Safety Directive (EC) No 2001/95 apply to disposable baby diapers. However, since such a general regulation neither includes maximum concentration limits for any impurities nor regulate specific (concentration/migration) limits of hazardous substances, it is insufficient to address the identified risk.

RAC notes that a specific product regulatory framework for baby diapers, which tackles concentration/migration limits for hazardous substances, has not been developed or implemented in the EU. RAC considers that a restriction under REACH might result in lower administrative burden than the development of a specific EU product regulation in respect to specific migration/concentration limits.

RAC acknowledges that the POPs regulation addresses PCB impurities in diapers.

Voluntary actions:
A review of 47 studies on voluntary agreements between governments or government bodies and individual businesses or industry groups concluded that, if properly implemented and monitored, voluntary agreements can be effective (Bryden and al., 2013). Although RAC considers that the effectiveness of voluntary agreement in general is highly uncertain and therefore this option, in absence of complementary legislation, is usually not feasible in terms of risk management, RAC points out that according to comment #3165 (industry) EDANA member companies have adhered to the guidance values set in the EDANA Stewardship Programme. However, RAC notes that it has not evaluated the migration limits in the EDANA Stewardship Programme or how effectively the member companies have implemented these limits, since such an evaluation is not within the remit of the current evaluation.

Justification for the opinion of SEAC

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 to be justified since these 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 REACH restriction, such as classification and labelling, identification as SVHC and subsequent authorisation, use of legislations other than REACH, development of specific product legislation 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.

Based on SEAC's assessment, RO1 would have been the most appropriate out of the two ROs considered to address an identified risk. However, since RAC concluded that a risk had not been demonstrated, SEAC considers that RO1 is not an appropriate measure.

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

Key elements underpinning the SEAC conclusion(s):

A. Scope

Substances covered by the proposed restriction

In 2019, the French Agency for Food, Environmental and Occupational Health and 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 reduction 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. With the exception of total PCBs, only the substances that were detected in single-use diapers and which the Dossier Submitter concluded to pose a health risk are covered by the proposed restriction. Although total PCBs were not analysed in single-use baby diapers their likely presence was extrapolated from findings in adult incontinence diapers. Even though incontinence diapers are excluded from the scope (see later in the opinion), SEAC finds this approach to be 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 conditions of the restriction, including the table of substances, the intended scope of the proposed restriction (RO1) was initially not clear in relation to PCBs. During opinion development the Dossier Submitter indicated that all PCBs are indeed intended to be within the scope of RO1. SEAC therefore suggests simplifying and clarifying the conditions of the restriction to reflect this better[31] if the Commission pursue the restriction proposal despite RAC's conclusions.

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:

- **Traditional baby diapers**,
- **Diaper pants** or **training pants** for toilet-training children,
- **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 that this covers all types of single-use diapers worn by infants and children 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 infants and children 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. However, the Forum raised concerns regarding this specificity since they note that 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.

Articles derogated

Reusable diapers were excluded from the scope because the Dossier Submitter did not perform chemical analysis and, as a result, 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

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

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. As such, SEAC agrees with the Dossier Submitter that this type of product should not be subject to the conditions of the proposed restriction.

Interaction with other (proposed) restrictions and regulations.

Four (proposed) restrictions were 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 via entry 72 of Annex XVII on CMRs in textiles with a concentration limit of 1 mg/kg. However, given that entry 72 of Annex XVII derogates single-use textiles, there is no overlap with the proposed restriction on single-use baby diapers.

Proposed restriction on skin sensitising substances[32]

This potential overlap is relevant for formaldehyde and benzo[e]pyrene since both restriction 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) realistic conditions of exposure are very different 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 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[33]. 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

[32] 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

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

consumer articles[34]

This proposal for a restriction targets articles produced with the intentional use of formaldehyde or formaldehyde releasing substances. 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.

Transition period.

The Dossier Submitter considers that a transition period of 24 months will provide sufficient time for manufacturers, laboratories and other economic operators in the supply chain to adapt to the requirements of this restriction (implementation of alternative feedstock/processes, depletion of stock, development of a standard analytical method).

Considering the uncertainty related to how industry would or could even react to address the potential risk identified by the Dossier Submitter[35], the uncertainty related to the sources of the contaminants and/or to the alternatives (see cost section), SEAC cannot conclude on the suitability of a transition period of 24 months.

During the consultation on the SEAC draft opinion, comments (#978 and 980) were received regarding the suitability of the transition period. These comments expressed doubts that instrument sensitivity would become substantially better in 24 months given the fact that mature state-of-the-art methodologies are currently being applied. The consultation on the SEAC draft opinion did not provide sufficient information to address the uncertainties mentioned above.

B. Risk management option analysis (RMOA)

i. <u>Discarded risk management options</u>

- 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 option on the basis that the process is long. While this may be true, the same could be

[34] 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

[35] SEAC notes that this is a risk that could not be demonstrated for formaldehyde and PCDD/Fs/DL-PCBs and could not be characterised for PAHs and NDL-PCBs, according to RAC.

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 require 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 the GPSD is not sufficient 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 SEAC 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 when the REACH restriction process is specifically designed to handle this type of issue efficiently.

  As such SEAC agrees that this risk management option 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.

ii. RO1 (proposed restriction) versus RO2

Based on the discussion on discarded risk management options 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 17 detected or quantified 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 restriction options are assessed according to their risk reduction capacity, proportionality, practicality and monitorability. It is stated that there are no significant differences between the two restriction options 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 that RO1 is not an appropriate measure.

In relation to RO2:

- 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)[36], 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 substance migration 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[37] 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.

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

3.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

RO1 (the proposed restriction covering formaldehyde, the sum of 17 detected or quantified PAHs, the sum of quantified PCDD/Fs and DL-PCBs, and the sum of quantified PCBs) is considered to be the most effective restriction option in terms of risk reduction capacity. The migration limits proposed are deemed to adequately protect children and infants against adverse effects caused by the chemicals of concern. It is considered that RO1 would protect at least 90% of European babies (i.e., 14.5 million babies) from being exposed to hazardous chemicals contained in their diapers every year within the EEA31. The lack of harmonised analytical method may be an issue. However, and due to current research by industry to put in place a harmonised analytical method, the Dossier Submitter is confident that this will be in place before the end of the transitional period proposed (24 months).

RAC conclusion(s):

RAC notes that the effectiveness in reducing the risks cannot be assessed due to the

[36] 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.

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

uncertainties related to the exposure/risk characterisation.

Since RAC considers that for formaldehyde local effects, i.e., skin sensitisation, is more relevant than systemic effects (as pointed out in section 3.1.2.), these effects would be very likely covered by the proposed restriction on skin sensitising substances in textiles.

Key elements underpinning the RAC conclusion(s):

RAC notes that the substances in the scope of the restriction proposal are known to cause health effects like cancer, adverse reproductive effects, mutagenicity effects, genotoxic effects, endocrine effects and skin sensitisation. Therefore, it is necessary to keep these substances to a level as low as possible/feasible in such articles, and preferably not be present at all. RAC notes that the POPs (Persistent organic pollutants) regulation already covers the unintentional presence of PCBs in all articles, including diapers, and, as such, no PCB content above the detection limit would be allowed. However, given that a risk from these substances in single-use diapers was not demonstrated it is not possible to evaluate the effectiveness of the proposed restriction.

With regard to formaldehyde, RAC points out that formaldehyde in single-use baby diapers is within the scope of the proposed restriction on skin sensitisers in textiles (ECHA, 2020), see section 3.1.4. *"Key elements underpinning the RAC conclusion(s)".*

3.3.2. Socio-economic impact

Justification for the opinion of SEAC

3.3.2.1. 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 obligations introduced by the restriction including the measures they will implement to reduce contamination of their products to meet the conditions of the restriction, 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 14 Costs of substitution / technical changes and adaptations likely to reduce contamination (from Background Document)

Type of economic impacts		Costs	Other economic impacts (benefits and others)	Uncertainties
	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	• Shortage of TCF pulp (low availability) and finished products	++ (time needed to adapt > 2 years)

Substitution/better selection of raw materials		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)	• Extra-profit for TCF pulp suppliers	
	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 %. (annualised 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 also quantified industry testing costs associated with the proposed restriction, 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 the costs appear to be attributable 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 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 15 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[38] • €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[39] • ≥€1 000 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		+
TOTAL[40] 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%)**			

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

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

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

	(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 analysed possible sources of contaminants, but it is not clear whether these are the actual sources of contamination. 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 would 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. An industry association comment (#978) in the consultation on the SEAC draft opinion states that the average PAH levels in air are 1.16 – 5.95 ng_{TEQ}/m^3 in urban locations. The daily inhaled PAH dose by a child of less than 6 months is 3.9 – 20.1 ng_{TEQ} per day. The comment argues that a child that is less than six months old and uses six diapers a day would have a daily dose of 0.0027 ng_{TEQ} per day.

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 would eliminate or reduce the substances in scope and therefore whether industry would take these measures to comply with a restriction as proposed by the Dossier Submitter.

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 industry would pass on additional costs to them. The Dossier Submitter believes that competition in the market is sufficiently strong that industry could not pass the costs down to consumers. However, industry has indicated that the restriction could result in 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 the total costs, nor of 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 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 17 detected or quantified 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 focused 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 to the proposed restriction:

- The single-use baby diapers industry in the EEA30 would 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 would 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 identified possible sources of contamination and identified some possible technical and substitution solutions. Different industry players have overall proposed similar solutions, and the Dossier Submitter thus finds it likely that the implementation of these solutions 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. Removing and reducing contaminants

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 may be one of the solutions to reduce or remove contaminants.

Several comments to the consultation on the Annex XV report (e.g. #3165 and 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.

Raw materials

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. Most of them seem to have made this transition based on precautionary reasoning rather 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 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 16. 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 16 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 would 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 16 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 the scope of the proposal restriction 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 diapers with 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 reduce contaminants. An industry association (#3165) states 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 refers to several studies indicating that dioxins and furans are present in the environment. For example, DeVito & Schecter (2002) 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 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) 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 also brings attention to the fact 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 state 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[41])[42].

SEAC notes that there is no evidence that a switch to TCF pulp would reduce the concentration of dioxins and furans in diapers. 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 also notes that there are several studies that suggest 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 within the scope of the restriction, 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 and the costs of a change are quantified in a reasonable manner, but it is not clear whether a change would reduce the presence or 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 above 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 associated substitution costs.

SEAC notes that comments submitted in the consultation on the Annex XV report (#3162 and #3165) argue that the conditions for PAH formations from glues are never fulfilled in the diaper manufacturing process. These comments explain that the formation of PAH requires temperatures of 350 – 1 200°C. The production lines for diapers use temperatures of 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 would lead to PAH contamination. The comments also state that if temperatures somehow were to reach 200°C

[41] https://www.xe.com/currencyconverter/convert/?Amount=6000000000&From=JPY&To=EUR
[42] https://technology.risiinfo.com/company/daio-paper

(well below the 350°C required for PAH generation), the 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. Any 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 the 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 while this substance seems to be used in wetness indicators, it is not known whether it is the cause of the presence of PAHs.

The Dossier Submitter stated that regardless of the substitution costs associated with 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.

The Dossier Submitter states that if the wetness indicators are one of the possible sources of contamination of the diaper, one option could be to not use wetness indicators in diapers. According to the Dossier Submitter, removing the wetness indicator would not affect the diaper's basic function as an 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, 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 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 was stated that for new-born and small sizes used at hospitals, the 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 and #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 and environmental impacts from greater frequency of diaper changes and would 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. Finally, SEAC notes that the potential costs of removing wetness indicators are not quantified.

Pigments

The external parts of single-use baby diapers may be coloured/patterned 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 it 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 it 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 baby 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 more for them). Therefore, SEAC concludes that, overall, some loss of profits could be reasonably expected, although it is not possible to quantify them 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 that it is 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 is 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 diaper industry from upstream to downstream should be particularly careful about the raw materials that are used and present in the diapers that they produce, supply and sell; by applying stricter 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 develop any cost estimates, it is currently not possible for SEAC to assess the costs.

An industry association (#3165) submitted information in the consultation on the Annex XV report informing that the EDANA stewardship programme for absorbent hygiene products has been 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 is 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 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 diapers 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 diaper 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 to keep the temperature below 200°C, and thus it is not likely that the temperatures would exceed 350°C, which is required to generate 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 diaper cores are made of a mix of fibres (generally fluff) and superabsorbent polymer (SAP). The former represents the matrix to stabilise 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 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 substances in scope are ubiquitous 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. Indoor air is centrally filtered to guarantee certain air quality (filtering pesticides and other potential chemical traces such as PCDD/Fs, PCB from outdoor air).

The Dossier Submitter states that producing diapers in clean rooms is considered infeasible and absolute filtration cannot be reasonably guaranteed. Nevertheless, based on industry's own air analysis at production sites, some companies recognise the necessity of air filtration to reduce as far as possible (not eliminate) the presence of outside air pollutants. These companies did, however, not communicate precise estimates of extra costs related to e.g. additional investment nor any economic feasibility concern associated with further air filtration. Industry only broadly reported that the investments are estimated to amount "in the million euros per production plant". The Dossier Submitter does not have further information allowing 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 at manufacturing sites would result in less contamination of the diapers. SEAC recognises 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. SEAC notes that comment #978 in the consultation on the SEAC draft opinion states that PAH in ambient air can contaminate baby diapers to levels that would exceed the proposed concentration limits, independently of any possible actions by manufacturers.

- <u>Packaging changes</u>

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 to cause any extra cost.

An industry association (#3165) states in the consultation on the Annex XV report that the implication in the dossier 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 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 that the levels discussed in the restriction proposal are similar to environmental background levels.

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 alternatives to reduce or remove contaminants 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, their 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'[43] 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 minimise 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, crematoria 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. According to 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 stated that "background" amounts of dioxins/furans can regularly be detected in the laboratory water of accredited laboratories that specialise 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. Comment #978 in the consultation on the SEAC draft opinion stated that PAH in ambient air can contaminate baby diapers to levels that would exceed proposed concentration limits, independently of any possible actions by manufacturers. The Dossier Submitter has indicated that part of the contamination could be background contamination, but at the same time the Dossier Submitter argues 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 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.

[43] 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.

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

The diaper 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 diaper 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 would 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 years 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
- Number of products tested: from 2 to 10

Based on these assumptions, the annual testing costs for finished diapers would be in the range of €0.24 – €23 million /year for the whole EU diapers manufacturing market. The central estimate is €4.8 million /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 – 1 050 million /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 billion /year and the testing costs would hence represent 0.01 – 1.1 % of the market revenue, with the central estimate at 0.5 %.

Comment #975 in the consultation on the SEAC draft opinion gave additional information about testing costs for spin finishes. The comment argued that all batches would need to be tested and that there would be between 1 500 and 2 000 batches per year with a total analytical cost of €4.5 – 6 million and a total additional storage and freight cost of €2.3 – 3million per year. The cost calculations are not thoroughly explained. It is not clear what this would mean for the frequency of testing. Furthermore, SEAC would assume that the testing cost of spin finishes are already included in the Dossier Submitter's testing cost estimation.

Several comments in the consultation on the Annex XV report (#3162, 3163, 3166, 3168, 3169) stated that the proposed limits are below today's possible analytical limits of detection and quantification, 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 stated that due to the extremely low limit values requested, the testing costs will be significantly higher than the current testing costs. They stated 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 are to measure these values, as unwanted cross-contamination needs to be avoided.

SEAC finds it possible that testing costs for these limits might be higher than the current testing costs. The comments did not provide any estimates of how much higher the testing costs could be. As the comments are 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) stated 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 in the consultation on the Annex XV report pointed out that the 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, this 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 stated 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 would result in a need for frequent testing, and an inability to place products on the market for an undefined period of time leading to even higher testing costs and supply disruption. The comments provided some estimations of the testing costs, although parts of the estimations are confidential, and thus not possible to refer to. The estimations assumed detects and the costs of testing through the whole supply chain, but there was 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 the current methods. This implies that the testing costs could be higher than estimated. SEAC also recognises 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 consultations 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 harmonised 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 17 Total costs

	Annualised 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 consultations 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 consultations have not shown feasible measures but have 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 in the consultation on the Annex XV report 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 as those tested by the Dossier Submitter. 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). The comments argue that laboratories have been working for two years but have not been able to replicate the 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 do not 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 all congeners of DL-PCBs, which means that a migration limit would also be defined for each congener. The conditions of the restriction are otherwise unchanged compared to RO1.

The Dossier Submitter expects that measures and technical solutions implemented by 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 harmonised analytical method with urine simulant would equally allow measuring chemicals as well as their congeners. An industry association (#3165 in the consultation on the Annex report) 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, PCDD/F/DL-PCBs) required by RO2 already must be done to calculate sum-TEQ values. The association judges that – given the existence of suitable, routine tests – the Dossier Submitter's estimate of up to €3 000 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 must 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 hence 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.

3.3.2.2. 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 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 scope show severe hazard profiles:

- Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity and skin sensitisation 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 scope have a harmonised classification or a self-classification for carcinogenicity under the CLP Regulation. Furthermore, two of them also have a harmonised classification for mutagenicity and one is additionally classified as reprotoxic and skin sensitiser. 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, variable 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 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 on the Annex XV report 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 references to several studies by various governments or agencies regarding the presence of hazardous chemicals in single-use baby 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 dioxin-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 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 recognises that comments in the consultation on the Annex XV report (#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 on the Annex XV report 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.

3.3.2.3. 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 (€0.44-€1 per month) as rather low and that it should be affordable for consumers. However, if realistically estimated, the upper bound of the price increase may be considered as rather significant especially for low-income 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 of age, 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 by the Dossier Submitter 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 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 manufacturers, there are also implications for 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 consumers or borne by industry.

According to the Dossier Submitter, industry reports that a price increase for consumers is likely. Industry has indicated a possible price increase in the range of 2% to 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 would 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 that competition is driven by price and notes that e.g. the performance of the diaper may also be a driver. SEAC notes that, on the other hand, oligopolistic markets make it easier for 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 a price increase of single-use baby diapers might have a significant effect on the purchasing power of low-income families.

Social impacts

According to industry stakeholders 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 considers 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 or eco-friendly 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.

3.3.2.4. Overall proportionality

Summary of proposal:

The Dossier Submitter argues that the proposed restriction will bring benefits to society due to the avoided adverse effects on babies' health even though the magnitude of these health impacts 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 to the supply chain and of a nature to threaten industry activities, neither in EEA30 nor outside. The Dossier Submitter considers it

possible that there may be positive economic impacts for the supply chains, given a potential increased level of consumer confidence 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 exposure and risk assessments 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 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. On the cost side, it is 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. In Annex I to the Background Document it also assesses a break-even analysis made by the Dossier Submitter during the opinion development.

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

The uncertainties and shortcomings described in sections 3.1.3 and 3.1.4 do not allow RAC to conclude that a risk has been demonstrated; in its absence, the full implementation of the EDANA programme aimed at limiting the use of hazardous substances may contribute to further reduce any potential risk. However, RAC does not see this as any substitute for a restriction under REACH should the risk be adequately demonstrated.

For SEAC, 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.

During the opinion development the Dossier Submitter carried out a break-even analysis to give a better understanding of the proportionality. The analysis does not affect SEAC's discussion on proportionality and it is therefore presented (together with SEAC's evaluation of it) in Annex I of the Background Document.

Proportionality discussion for different scenarios

There are several uncertainties regarding the proposed restriction, which have implications for the proportionality discussion. In this section, SEAC 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 by SEAC:

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 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 means that single-use baby diapers generally do not contain the substances in scope above the proposed migration limits, then this means that industry may not need to implement 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 do not 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/level of detection 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 consultations have not shown feasible measures but have 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 the 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.

3.3.3. 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 of testing and the monitoring capacity of the proposed restriction. For now, no standardised analytical method exists using an extraction by urine simulant in a whole diaper. Considering that companies, laboratories and also EU enforcement services will have to build this new analytical method, and even define a CEN standard, the transitional period of 24 months is considered by the Dossier Submitter as necessary.

RAC and SEAC conclusion(s):

RAC concludes that the following issues should be considered to ensure the practicality of the proposed restriction:

- the LoQ of available analytical methods should be below the limit values of the restriction for all substances in scope; and
- the development of a standardised analytical methodology.

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

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

- Bringing the migration limits in line with the Forum recommendations.

SEAC considers that the practicality and enforceability of RO2 is less than RO1 due to the application of individual migration limits for 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[44]

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 at the age of 0-36 months. It should be noted that single-use baby diapers seem to be categorised by baby weight rather than baby age. While correlation tables between median baby weight and age exist, diaper weight categories for older babies do not correspond directly 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. However, SEAC notes that this might reduce the risk of specialised, but undefined, single-use diaper products not being within the scope of the proposed 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 intended to be within the scope of the restriction since chemicals can migrate from different parts of the diapers (due to urine simulant, sweat or the ability itself of the chemicals to migrate) to skin. The proposed restriction requires compliance to be checked through a specific analytical method mimicking realistic 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 within the conditions of the restriction and aligning the scope to it would negate this unclarity.

[44] In the Background Document the Dossier Submitter does not give any indication of which marker PCBs could or should be used to check compliance

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 a lack of clarity regarding how the migration limit is set up for PCCD/Fs and DL-PCBs. The proposed restriction wording, as amended in the Background Document, 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 corresponding to 1) the sum of all categories of substances together (PCCDs+PCDFs+DL-PCBs) or 2) 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 the migration of DL-PCBs must also be counted toward total PCB migration. The Dossier Submitter does not consider this double counting since different health reference values (HRVs) were used to propose migration limits. RAC has agreed with this approach. However, SEAC and RAC 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 18 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	0.023 ng/kg (0.000000023 mg/kg)*	no
Dioxins, furans & DL-PCBs	From 0.002 to 1 ng/kg regarding the test sample	From 0.002 to 1 ng/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 1 700 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 1 700 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 that the availability of a standardised analytical method was not a prerequisite to conclude that a proposed restriction is enforceable.

However, the Dossier Submitter discussed analytical methods that differ from other studies looking at these types of products (solvent extraction[45] 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[46]. 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 discussed by the Dossier Submitter (see Appendix: SCL methodology study at the end of the Background Document). This option would not ensure harmonised enforcement throughout the Union but could afford companies and enforcement agencies to adapt quickly to scientific progress.

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

[46] 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.

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[47]

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 with regard to enforceability compared to RO1, due to the large number of substances within scope.

3.3.4. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The implementation of this restriction proposal will imply testing and control costs for industry and authorities (see the section on costs for more information). Nevertheless, for the time being, no harmonised 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 stakeholders define, before the end of the transitional period, a harmonised analytical method. In conclusion, to enable the monitoring of the results of the implementation of the proposed restriction, a harmonised analytical method should be developed during the transitional period.

RAC and SEAC conclusion(s):

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

Since RO2 is considered to be less appropriate than RO1 in regard 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. Please refer to that section of the opinion for a more in-depth discussion. The conclusions for this section can be found above.

[47] 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 is not usable to perform the daily exposure dose calculation. The daily exposure dose calculation could have been done if data on surface weight was 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 50% 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 monetised 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 harmonised test method is available for now.

RAC conclusion(s):

In the following table the uncertainties/shortcomings recognised by RAC are listed:

Table 19 Main uncertainties and shortcomings concerning the Annex XV dossier

Part of the underlying assessment	Identified uncertainty			Priority	Summary of contribution to uncertainty about results of the assessment
	No.	Description of uncertainty	Input/ Methodology		

Exposure assessment	1	Uncertainties and shortcomings concerning the analytical method (see section 3.1.3, D)	I/M	Very high	>30%
	2	Use of the exposure variables in the daily exposure dose calculation, particularly the disparity in the "rewet" factor (baby's urine refluxed from a diaper)	M	High	15% (approximately two orders of magnitude overestimation)
	3	It is not clear why PAHs concentrations in diapers (including LoDs/LoQs) are orders of magnitude lower in 2019 compared to 2018 analysis performed by SCL and DGCCRF/INC	I/M	High	10%
	4	Lacking assessment of direct exposure - especially regarding extraction of lipophilic substances which could come into direct contact with baby's skin	M	Medium	5-10%
Risk characterisation	5	For PAHs, the lowest LoD is orders of magnitude higher than the proposed migration limits - it is not known how many samples were above/below the proposed limits	M	High	10%
	6	Allocation factor should not be used for the calculation	M	High	10%

		of risk (to account for aggregate exposure from different exposure routes) for the local dermal effects (formaldehyde and PAHs); for other effects (PCDD/Fs and PCBs), the value of an allocation factor of 10% is not sufficiently justified by the Dossier Submitter			
	7	A cumulative risk assessment (exposure to a mixture of substances present in diapers and from other sources relevant for children up to three years of age) was not presented in the Annex XV dossier.	I	Medium	5%
Hazard assessment	8	Uncertainties related to epidemiological study in Russian children (stated in section 3.1.2, "Key elements underpinning the RAC conclusion(s)") - overestimation of the DNEL expected	M	High	10%
	8	Local skin sensitisation of formaldehyde was not assessed	I	Low	<1% Skin sensitising effects very likely addressed in the REACH restriction concerning skin sensitisers in textiles.

	9	Limited information on dermal toxicity for PCDDs/Fs/DL-PCBs	I	Low	<5%
	10	Health risk assessment is based on studies using a limited set of PCB mixtures, so when the pattern of PCB congeners is different from the commercial mixtures, another approach could be preferable; however, NDL-PCBs have not been analysed in diapers, so the pattern of congeners is unknown	M	Low	<5%

RAC is of the opinion that the following information (by the Dossier Submitter or other bodies) would be needed to address the identified (main) uncertainties concerning the exposure:

- Detailed information about
    - sample preparation;
    - analytical quality control and assurance information (including the use of blank samples) for analytical data.

In addition, if the risks of substances in single-use baby diapers are reconsidered in the future (i.e., not as part of the opinion development on this Annex XV dossier) the following topics should be elaborated in order to minimise the uncertainties:

- appropriate rewet factor;
- evaluation of direct exposure;
- reproducibility and relevance (to reasonably foreseeable conditions of use) of urine simulant extraction methodology;
- justification for the use of (and value for) an allocation factor.

According to industry, further reduction of the LoD/LoQ for the substances included in the scope of the restriction proposal, particularly for PAHs, would require several years (certainly much longer than the two years proposed as transitional period).

However, as previously mentioned, RAC notes that a methodologically different approach could also be used to deal with hazardous substances in single-use baby diapers in a restriction proposal.

Key elements underpinning the RAC conclusion(s):

Key elements concerning the different topics are already described in the respective sections above.

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 monetised 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 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 the 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 whether TCF pulp has a better capability than ECF pulp to address the health concerns targeted in this restriction proposal. 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 it 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 existing systems.

Economic Impacts/testing and enforcement costs: From the publication of ANSES 2019 and the French RMOA reports, companies on the single-use baby 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 internalised 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 harmonised analytical methods and the challenges of measuring very low migration limits such as those proposed (lower than the current LoD/LoQ) (see Annex E8 of the Background Document), the testing costs may be higher than reported during the consultation by the Dossier Submitter. This is a source of uncertainty.

Regarding enforcement costs for authorities. 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 sensitising substances in textile, leather, furs and hides. However, there may be extra costs due to the lack of harmonised analytical methods and the challenges of measuring the very low migration limits proposed (lower than the current LoD/LoQ).

Economic impacts/consumers: Industry claims between +2% and 10% price increases at point of sale because 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, the 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 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 possible sources of substance contamination have been discussed but none of them have been possible to confirm. Given that comments in the consultation on the Annex XV report

have provided evidence that industry has 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.

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