Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on
The following substances in single-use baby diapers

- The following polycyclic aromatic hydrocarbons (PAHs): benzo[c]fluorene, benz[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[e]acephenanthrylene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[def]chrysene, dibenz[a,h]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene, dibenzo[def,p]chrysene, naphtho[1,2,3,4-def]chrysene , benzo(r,s,t)pentaphene, dibenzo[b,def]chrysene
- The following polychlorinated dibenzo-p-dioxins (PCDDs): 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD, 1,2,3,4,7,8-HxCDD, 1,2,3,6,7,8-HxCDD, 1,2,3,7,8,9-HxCDD, 1,2,3,4,6,7,8-HpCDD, OCDD
- The following Polychlorinated dibenzofurans (PCDFs): 2,3,7,8-TCDF, 1,2,3,7,8-PeCDF, 2,3,4,7,8-PeCDF, 1,2,3,4,7,8-HxCDF, 1,2,3,6,7,8-HxCDF, 1,2,3,7,8,9-HxCDF, 2,3,4,6,7,8-HxCDF, 1,2,3,4,6,7,8-HpCDF, 1,2,3,4,7,8,9-HpCDF, OCDF
- The polychlorobiphenyls (PCBs) (DL-PCBs and NDL PCBs : PCB 81, PCB 77, PCB 123, PCB 118, PCB 114, PCB 105, PCB 126, PCB 167, PCB 156, PCB 157, PCB 169, PCB 189)
- Formaldehyde

ECHA/RAC/RES-O-0000007017-78-01/F
ECHA/SEAC/RES-O-0000007046-77-01/F

EC Numbers	CAS Numbers
n/a	n/a

Revision n. 5

21/12/2021

Change history

Revision n.	Reason for change	Date	Prepared by
5	**Background document**	**21/12/2021**	**Dossier submitter**

CONTENTS

TABLES

FIGURES

About this report

The preparation of this restriction proposal on hazardous chemicals in single-use baby diapers was initiated on the basis of Article 69(1) of the REACH Regulation.

The proposal consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information, analyzes and references underpinning the report.

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) (hereafter referred to as the Dossier Submitter) would like to thank the numerous stakeholders that made contributions to the call for evidence and from bilateral discussions leading to the development of this report.

This report has been reviewed for confidential information and any such information has been redacted.

Version 1.0 of this document was published on ECHA’s website on 9 October 2020.

Summary

Brief title: Restriction on formaldehyde, PAHs, dioxins, furans and PCBs in single-use baby diapers.

This restriction proposal aims at reducing health risk associated with the wearing of single-use baby diapers on children and infants under the age of three that are placed on the market and can contain polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and/or formaldehyde.

Ever since they were invented in the early 1930s, single-use baby diapers have continuously evolved to meet the expectations of modern life. Diapers are products made of several materials whose objectives are to absorb and retain the child's urine and faeces while keeping his/her skin clean and dry. Since the 1990s, single-use baby diapers have been used by more than 90% of families in most of the European Union countries. Estimates of the total number of single-use baby diapers used by a baby before the age of toilet training range from 3,800 to 4,800. These estimates vary depending on the age at which it is considered that children are fully toilet trained.

PAHs, formaldehyde, PCDD/Fs and "Dioxin-like PCBS" (DL-PCBs) have been detected and/or quantified in single-use baby diapers through realistic analytical tests using urine simulant.

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

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

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

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

chemicals at specified migration limits in single-use baby diapers placed on the market, but differ in which substances are covered.

The restriction options further assessed are the following:

- Restriction option 1 (RO1): Limiting concentrations of migration of formaldehyde, the sum of detected or quantified 17 PAHs, the sum of quantified PCDD/Fs and DL-PCBs, the sum of quantified PCBs .
- Restriction option 2 (RO2): Limiting concentrations of 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 considers these substances to have the potential to induce adverse effects in babies if present in single-use baby diapers that come in contact with the skin.

More information on the RMOs and the restriction options assessed is found in Sections 2.4 and 2.5.

Proposed restriction

On the basis of an analysis of the effectiveness, proportionality, practicality and monitorability of RO1 and RO2, and the impact assessment performed, the following restriction is proposed:

RAC and SEAC box

RAC and SEAC found that there is not a sufficient justification for a restriction.

Their evaluation of the restriction proposal is outlined in detail in the RAC and SEAC opinion.

Proposed Restriction: RO1

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 : o **Traditional baby diapers,** o **Diaper pants** or **training pants** for toilet-training the child, o **Night diapers**, , in order to help them with toilet training at night, o **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 migratein 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. 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.

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

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

Group of substances	Substance name	CAS Number	EC number
Formaldehyde	formaldehyde	50-00-0	200-001-8
PAHs	benzo[*c*]fluorene	205-12-9	205-908-2
	benz[*a*]anthracene	56-55-3	200-280-6
	cyclopenta[*c,d*]pyrene	27208-37-3	-
	Chrysene	218-01-9	205-923-4
	5-methylchrysene	3697-24-3	-
	benzo[*e*]acephenanthrylene	205-99-2	205-911-9
	benzo[*k*]fluoranthene	207-08-9	205-916-6
	benzo[*j*]fluoranthene	205-82-3	205-910-3
	benzo[*e*]pyrene	192-97-2	205-892-7
	benzo[*def*]chrysene	50-32-8	200-028-5
	dibenz[*a,h*]anthracene	53-70-3	200-181-8
	indeno[1,2,3-*c,d*]pyrene	193-39-5	205-893-2
	benzo[*g,h,i*]perylene	191-24-2	205-883-8
	dibenzo[*def,p*]chrysene	191-30-0	205-886-4
	naphtho[1,2,3,4-*def*]chrysene	192-65-4	205-891-1
	benzo(*r,s,t*)pentaphene	189-55-9	205-877-5
	dibenzo[*b,def*]chrysene	189-64-0	205-878-0
PCDDs	2,3,7,8-tetrachlorodibenzo[*b,e*][1,4]dioxin; 2,3,7,8-TCDD	1746-01-6	217-122-7
	1,2,3,7,8-pentachlorodibenzo-*p*-dioxin; 1,2,3,7,8-PeCDD	40321-76-4	-
	1,2,3,4,7,8-hexachlorodibenzo-*p*-dioxin; 1,2,3,4,7,8-HxCDD	39227-28-6	-
	1,2,3,6,7,8-hexachlorodibenzo-*p*-dioxin; 1,2,3,6,7,8-HxCDD	57653-85-7	-
	1,2,3,7,8,9-hexachlorodibenzo-*p*-dioxin; 1,2,3,7,8,9-HxCDD	19408-74-3	-
	1,2,3,4,6,7,8-heptachlorodibenzo-*p*-dioxin; 1,2,3,4,6,7,8-HpCDD	35822-46-9	-
	octachlorodibenzo-*p*-dioxin; OCDD	3268-87-9	-
PCDFs	2,3,7,8-tetrachlorodibenzofuran; 2,3,7,8-TCDF	51207-31-9	-
	1,2,3,7,8-pentachlorodibenzofuran; 1,2,3,7,8-PeCDF	57117-41-6	-
	2,3,4,7,8-pentachlorodibenzofuran; 2,3,4,7,8-PeCDF	57117-31-4	-
	1,2,3,4,7,8-hexachlorodibenzofuran; 1,2,3,4,7,8-HxCDF	70648-26-9	-
	1,2,3,6,7,8-hexachlorodibenzofuran; 1,2,3,6,7,8-HxCDF	57117-44-9	-
	2,3,4,6,7,8-hexachlorodibenzofuran; 2,3,4,6,7,8-HxCDF	60851-34-5	-
	1,2,3,7,8,9-hexachlorodibenzofuran; 1,2,3,7,8,9-HxCDF	72918-21-9	-
	1,2,3,4,6,7,8-heptachlorodibenzofuran; 1,2,3,4,6,7,8-HpCDF	67562-39-4	-
	1,2,3,4,7,8,9-heptachlorodibenzofuran; 1,2,3,4,7,8,9-HpCDF	55673-89-7	-

	octachlorodibenzofuran; OCDF	39001-02-0	-
PCBs	All the PCBs (DL and NDL are included in the scope of the restriction)		

A transitional period of 24 months after its entry into force is proposed.

Summary of the justifications:

The restriction proposal is based on the following considerations:

- Substances whose hazard profile suggests that exposure may cause adverse effects should not be present in single-use baby diapers placed on the market for children and infants.
- The quantitative health risk assessments of substances that can be found in single-use baby diapers, on the basis of reasonable exposure estimates, demonstrate the need to take action.
- The risk identified with all the chemicals and the sums of groups of chemicals is preferably managed by setting concentration limits.
- The migration limits should aim at preventing adverse effects in children and infants likely to be associated to the exposure to chemicals contained in single-use baby diapers for several reasons.

Identified hazards and risk

The chemical substances within the scope of this restriction proposal have the potential to cause adverse effects in individuals exposed to the substances *via* the skin through single-use baby diapers.

Oral Human Health Reference Values (HRVs) corrected with the oral bioavailability are used as reference values (internal Derived No Effect Level/ Derived Minimum Effect level i.e. DNEL/DMEL) from which migration limits for chemical substances in single-use baby diapers are derived. The Dossier Submitter considers that the HRVs apply to the entire population regardless of age, including children.

Prolonged skin contact with single-use baby diapers is expected over the day. Migration of hazardous substances from inner layers to outer parts of such articles cannot be formally excluded. The assessment of the exposure to chemical substances released by single-use baby diapers in urine simulant would ideally be based on presence in single-use baby diapers and information on migration of the substance to skin during use. The parameters needed to perform the assessment of exposure to chemicals were, for most of them, available to the Dossier Submitter that's why the Dossier Submitter has performed a quantitative exposure assessment based on available data and justified assumptions when needed. The risk is, then, assessed by using a quantitative approach.

The resulting proposed migration limits are shown in the table below. More information and details on hazard, exposure and risk assessments are found in sections 1.2.5 and 1.2.6 and Annex B.

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 PCDD/Fs and DL-PCB **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**	**0.023 ng_{TEQ} / kg of diaper**

1: TEQ from WHO 2005

For all the chemicals in the scope of the restriction proposal, the migration limits are far below the highest concentrations found in single-use baby diapers at point of sale. Hence, lowering the migration limits of these chemicals in single-use baby diapers to the ones proposed here above, is considered to significantly reduce the risk. The migration limits proposed are thus considered to adequately protect infants and children.

It is acknowledged that the restriction proposal calls for an explanation of the under process REACH Annex XVII restriction on skin sensiters in textile, leather, fur and hide as ar as formaldehyde and benzo[def]chrysene(BaP) are concerned. The skin sensitisers in textile, leather, fur and hide restriction aims at restricting the content of formaldehyde and benzo[def]chrysene in, among other articles, single-use baby diapers. It will be enforced through a dedicated analytical method. This restriction deals with the skin sensiting properties of formaldehyde and benzo[def]chrysene only. On the other hand, the current restriction proposal on single-use baby diapers aims at restricting formaldehyde and BaP in relation to their extractible part from diapers according to the most realistic conditions of exposure, which are different from those of the use of textile by stating a migration limit. It will be enforced through a different analytical method, and will protect from all the adverse effects of these substances and not only the skin sensitization.

Justification that action is required on a Union-wide basis

The 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 for two reasons:

a) exposure takes place in all Member States, and
b) to ensure the free movement of goods within the Union.

Effectiveness of the proposed restriction in reducing the identified risks

The proposed restriction is effective because it is targeted to the exposure that causes the risk, it is capable of reducing the identified risk in a reasonable period of time, and it is considered to be proportionate to the risk. The proposed restriction will reduce the risks to human health to an acceptable level from January 2024.

Proportionality of the proposed restriction to the risks

The Dossier Submitter does not expect major critical economic impacts that would be unaffordable by the supply chain and of a nature to threaten industry activities, neither in EEA31 nor outside. The total testing costs for EU diapers manufacturers are estimated to 0.6-80 million €/year with a medium estimate of 35 million€ / year (net present value, discounted at 4% over 10 years from 2024), corresponding to 0.01%-1.10% of the annual diapers market revenue with a medium estimate of 0.5%. Some overlapping is likely with testing costs already borne by industry due to their current testing routine. Among different explored technical solutions to reduce contamination of diapers, the cost of switching to total-chlorine free (TCF) pulp for the whole market was assessed to 5-25 million €/year with a medium estimate of 15 million€/ year (net present value, discounted at 4% over 10 years from 2024), corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%.

Positive economic impacts for the supply chains are possible, given a potential increased level of confidence of consumers in single-use baby diapers products as a result of the restriction proposal. Additionally, some extra-profits could arise for more 'eco-friendly by presentation' and safer raw materials suppliers such as current TCF pulp EU company 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 proposed restriction will bring benefits to society due to the avoided health impacts of adverse effects on babies' health even though their magnitude could not be accurately assessed. Potentially very severe, variable and latent diseases affecting their quality of life over their lifetime are expected to be avoided in babies at older ages and in their adulthood such as cancers, suspected endocrine disruption, reprotoxic effects, etc. Given the widespread use of single-use baby diapers, the Dossier Submitter considers that the proposed restriction is expected to prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their diapers every year. Due to uncertainties and a lack of data, the benefits could not be quantified but a break even analysis was performed by the Dossier Submitter to evaluate proportionality of the proposal.

Based on the cost assesssment and the break-even analysis carried out by the Dossier Submitter, the proposed restriction is considered affordable and proportionate.

Practicality and monitorability

The proposed restriction (RO1) is considered to be practicable because it is implementable, enforceable and manageable. It is also possible to monitor.

Without a validated method and scientifically sound thresholds, concerns were expressed that it might be difficult for industry to comply with the restriction and that it might result in a disruption of the market, the supply of diapers for babies and create unwarranted legal liabilities. Moreover, concerns were also raised about the migration levels the restriction will require that will be below current LOQ. The

development of relevant test methods to determine the presence of substances at trace level and to check that the amount of possible trace impurities in products does not exceed the defined limit values are currently ongoing.

Due to the absence of harmonized analytical method, the enforcement costs are uncertain. For illustrative purposes, the annualized net present value of total enforcement costs was assessed, based on ECHA's average estimate, and would amount to 45,000€/ year (discounted at 4% from 2024).

In conclusion, the Dossier Submitter considers that a transitional 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.

The proposed restriction can be monitored by Member States surveillance programs and compliance controls as well as by manufacturers, importers and distributors of single-use baby diapers articles who will have the obligation to place on the market compliant articles.

The table below presents the comparison of restriction options assessed in this restriction proposal.

Table 3 : Comparison of restriction options

	Risk reduction capacity	Proportionality	Practicality	Monitorability
Restriction Option 1 (restriction proposed)	**+++**	**+++**	**+**	**+**
Restriction Option 2	**+++**	**++(+)**	**+**	**+**

Overall, the 2 restriction options assessed are considered to be proportionate by the Dossier Submitter. Depending on whether the measures and technical solutions implemented under RO1 would be sufficient to already remove congeners from the diapers, benefits associated with RO2 are expected to be similar to RO1. Regarding the testing and enforcement costs, there is some uncertainty whether the costs associated to RO2 would be similar or higher than the costs associated to RO1 (for more details please refer to section 2.5). Practicality and monitorability of both restriction option are not expected to be significantly different.

Report

1. The identified problem

1.1. Scope

1.1.1. Introduction

Ever since they were invented in the early 1930s, single-use baby diapers have continuously evolved to meet the expectations of modern life. Diapers are products made of several materials whose objectives are to absorb and retain the child's urine and faeces while keeping his/her skin clean and dry.

Since the 1990s, single-use baby diapers have been used by more than 90% of families in most of the European Union (EDANA, 2011). For example, in France, single-use baby diapers have been worn by over 95% of babies for almost 20 years (Group'Hygiène, 2015). Estimates of the total number of single-use baby diapers used by a baby before the age of toilet training range from 3,800 to 4,800. These estimates vary depending on the age at which it is considered that children are fully toilet trained (between 2.5 and three years old).

1.1.2. Background information

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. In 2019, the French Agency for environmental and health safety (ANSES) has 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)[2].

Information on chemicals in single-use diapers for infants and children

Following chemical analysis performed in France (INC, DGCCRF/SCL[3]), single-use baby diapers have been reported as containing hazardous chemicals that may impair health of babies wear/use these articles. A report published in 2019 by ANSES, describes how chemicals analysis have been performed and how a health risk assessment performed on chemicals found in these diapers has raised some concerns about potential risk for infants and children.

The chemicals analysis provided to ANSES on single-use baby diapers:

Three types of analysis were performed onto single-use baby diapers. The tests were conducted onto 23 diapers taking into account a wide range of products, including the best-selling commercial products on the French market, as well as

[2] https://www.anses.fr/fr/system/files/CONSO2017SA0019Ra.pdf
[3] INC : Institut National de la Consommation
DGCCRF : General Directorate for Competition Policy, Consumer Affairs and Fraud Control
SCL : Service Commun des Laboratoires

retailers' own brands and "eco-friendly by presentation" ones. The chemical analyses were performed by:

- Solvent extraction of chemicals in aliquots of shredded whole diapers or diapers parts,
- Migration tests carried out with urine simulant onto whole diapers and shredded whole diapers [4].

The substances quantified or detected at least once in single-use baby diapers sold in France were:

- From the **migration tests in whole diapers and shredded whole diapers with a urine simulant**:
  - PCDD/Fs and DL-PCBs, PAHs and formaldehyde
- From **solvent extractions in shredded whole diapers:**
  - volatile organic compounds (VOCs) (naphthalene, styrene, toluene, dichlorobenzene, p-isopropyltoluene, xylene, chlorobenzene),
  - pesticides (hexachlorobenzene, quintozene and its metabolite pentachloroaniline, glyphosate and its metabolite AMPA),
  - formaldehyde,
  - PCDD/Fs and DL-PCBs,
  - fragrances (benzyl alcohol, benzyl salicylate, coumarin, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), limonene, linalool, alpha-isomethyl ionone);
- From **solvent extractions in shredded diaper parts**[5]:
  - PCDD/Fs (in the outer layer, the inner layer and other parts, except the core),
  - PAHs in the elastic bands (benzo[e]acephenanthrylene, benz[a]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene).

Summary of ANSES health risk assessment on chemicals contained in baby diapers (2019):

A quantitative health risk assessment (QHRA) was performed for each of the substances detected or quantified. Regarding risk characterisation, depending on the type of effect:

- a Hazard Quotient (HQ) was calculated for substances with a threshold effect,
- an Individual Excess Risk (IER) was calculated for substances with a no-threshold effect (carcinogenic effect).

[4] The urine simulant consisted of urea, creatinine, ammonium citrate, NaCl, KCl, $KHSO_4$, $MgSO_4$, KH_2PO_4 and $KHCO_3$ in water (Colon *et al*., 2015).
Migration test using urine simulant from a whole diaper do not follow a standard. The method is detailed in the article at the following link https://www.chimie-experts.org/Documentation/Articles-a-paraitre.
[5] A diaper part refers to a component considered separately, such as the elastic bands, inner layer, absorbent core, etc.

The details of the QHRA are available in the ANSES report (2019). **In the ANSES report, the scenario where chemicals have been found using a migration test in a whole diaper by using urine simulant was considered as the most representative scenario of the reality of use.**

In the table below are gathered the risk interpretations according to the calculation results of the HQ and the IER. In the ANSES study, IER threshold was set at 10^{-6}.

Table 4 : Interpretation of the risk calculation results

Threshold effects	**HQ < 0.1**	**0.1 < HQ < 1**	**HQ > 1**
	No toxic effect is expected in the exposed population.	It is necessary to ensure that there are no other concomitant sources of exposure, in order to not risk to exceed the TRV by combining intakes from all the sources of exposure to these substances.	The occurrence of a risk cannot be ruled out, although it is not possible to predict its likelihood of occurrence in the exposed population.
No-threshold effects	**IER < 10^{-7}**	**10^{-7} < IER < 10^{-6}**	**IER > 10^{-6}**
	The number of expected cancer cases is less than one out of 10 million exposed people.	The number of expected cancer cases is between one out of one million and one out of 10 million exposed people.	The number of expected cancer cases is greater than one out of one million exposed people.

In ANSES, 2019 it is stated : "*There is no epidemiological data demonstrating an association between health effects and the wearing of diapers. However, hazardous chemicals have been found in these single-use baby diapers. Based on the results of the tests and the literature data, a QHRA was undertaken for single-use baby diapers according to realistic scenarios.*

*Regarding the substances measured by **solvent extraction in shredded whole diapers**, a risk calculation was undertaken according to a realistic scenario for all fragrances, PCDD/Fs and DL-PCBs and their sums, as well as for three VOCs[6] and hexachlorobenzene.*

In some cases, the health threshold was exceeded for infants aged 0-12 months inclusive, for two fragrances (hydroxyisohexyl 3-cyclohexene carboxaldehyde or Lyral® and butylphenyl methylpropional or Lilial®) detected in one of the diaper products analysed.

[6] 1,2,3-trichlorobenzene; 1,2,4-trichlorobenzene; 1,3,5-trimethylbenzene

*In **solvent extraction in shredded specific diaper parts (elastics parts)**, only PAHs and 2,3,4,6,7,8 HxCDF were quantified but no health threshold were being exceeded for children aged 0 to 36 months.*

*Regarding PCDD/Fs and DL-PCBs and the sums of their quantities found by **migration with a urine simulant in shredded whole diapers**, a risk calculation was undertaken according to a realistic scenario. It did not show any health thresholds being exceeded for children aged 0 to 36 months.*

*Regarding the substances found by **migration using a urine simulant in whole diapers**, a risk calculation was undertaken according to a realistic scenario for 10 detected PAHs[7], formaldehyde, PCB-126, the sum of PCDD/Fs, the sum of DL-PCBs and the sum of PCDD/Fs and DL-PCBs[8], which were quantified. It highlighted the following, for children aged 0 to 36 months:*

- *the IER (non-threshold carcinogenic effects) was exceeded for the 10 PAHs (benzo[g,h,i]perylene, benzo[e]acephenanthrylene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[def]chrysene, dibenz[a,h]anthracene);*
- *the health threshold[9] (threshold effects) was exceeded for six PAHs (benzo[e]acephenanthrylene, cyclopenta[c,d]pyrene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[def]chrysene, dibenz[a,h]anthracene) and for PCB-126, the sum of DL-PCBs, and the sum of PCDD/Fs and DL-PCBs.*

In the ANSES report, the results of the above exposure calculations were limited to single-use baby diapers exposure, excluding other possible exposure sources (environmental, dietary, other consumer products). The possibility of cumulative exposure through various exposure routes leading to an increase in the estimated risks could not be ruled out, especially for substances found in baby diapers whose HQ was between 0.1 and 1, such as:

- *sum of PCDD/Fs,*
- *formaldehyde.*

It means that the chemicals cited above can be a group of substances with potential risks.

PCDD/Fs, DL-PCBs and PAHs are ubiquitous substances that can be found, for example, in food and particularly in milk.

*The analysis of the sources for uncertainties and their impact on the result of the QHRA lead ANSES to consider the set of hypothesis as reasonably conservative. This QHRA showed cases of the health thresholds being exceeded for several substances. **Therefore, to date and in the current state of knowledge, it was***

[7] For detected substances, the concentration used in the risk calculations was the value LQ/2.
[8] Classifications of these substances and sector-specific regulations are available in Annex 5.
[9] TRVs established based on developmental effects for PAHs and reprotoxic and developmental effects for dioxins, furans and DL-PCBs (Annex 1)

not possible to rule out a health risk associated with the repeated wearing of single-use diapers.

Regarding the above conclusions of the ANSES report, ***based on the results according to the scenario with urine simulant extraction on a whole diaper, ANSES recommended regulatory actions to be taken. "***

All the above statements and these results have since been confirmed by analysis of 31 new items performed in 2019 by SCL.

1.1.3. Composition of single-use baby diapers

Single-use baby diapers consist of several superimposed layers (ANSES, 2019) (Figure 2).

- A **topsheet** in contact with the baby's skin. It captures urine and enables it to be transferred to the core of the inner layer while limiting moisture in contact with the buttocks in addition to leakage. The polyolefin topsheet is a porous nonwoven[10]. The hydrophobic nature of the polyolefins is primarily what enables the absorbent material to rapidly absorb urine. Lotion may be added to the topsheet. It acts as a barrier against moisture and as a skin conditioning agent helping reduce skin irritation and prevent skin problems.

- An **acquisition layer** is sometimes added to absorb liquid and transfer it to the core.

- A **core**, which captures, absorbs and retains urine, is made of wood cellulose fibres (fluff pulp[11]) and superabsorbent polymer (SAP or sodium polyacrylate). The cellulose fibres are intended to absorb urine and distribute it through the core, while SAP is intended to trap liquids. For certain diapers, the core takes the form of absorbent channels that help distribute urine .

- A system for retaining urine and faeces inside the diaper, consisting of:

    - An impermeable **backsheet**, serving as a leakproof barrier for the diaper. It traps moisture within the material. It is usually made of polyolefins. This backsheet can have various designs (textile, print designs, etc.). It can be made breathable to maintain the skin in good condition. Small inclusions in the polyethylene film create holes that are small enough to allow movements of water vapour and air while retaining urine within the diaper (Counts *et al.*, 2014 and 2017).

[10] According to EDANA, a nonwoven is a manufactured sheet, web or batt of directionally or randomly orientated fibres, bonded by friction, cohesion or adhesion.
[11] Chemical pulp made from long-fibre wood. For more details please see Annex A.1.

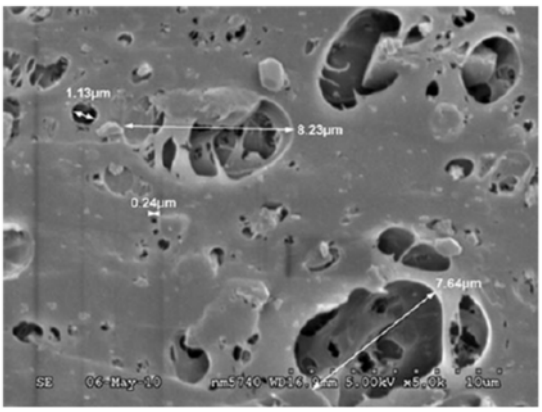

Figure 1: Detailed view of the micropores of a breathable backsheet (Counts et al., 2014)

- **Leak guards** that provide added protection against urine and faecal leakage. They are made of a hydrophobic nonwoven.
- **Elastics** that provide added protection against leakage by adapting to the baby's shape.

- The fastening system, which can be opened and closed several times. There are two different systems: adhesive and self-fastening systems.
  - **Ear tabs** enabling the diaper to be fitted to the baby's waist by adjusting the position of the fasteners.
  - **Fasteners** that attach to the ear tabs to close the diaper. The adhesive materials used are made of thermoplastic polymers. They are covered so as to never come into contact with the baby's skin.

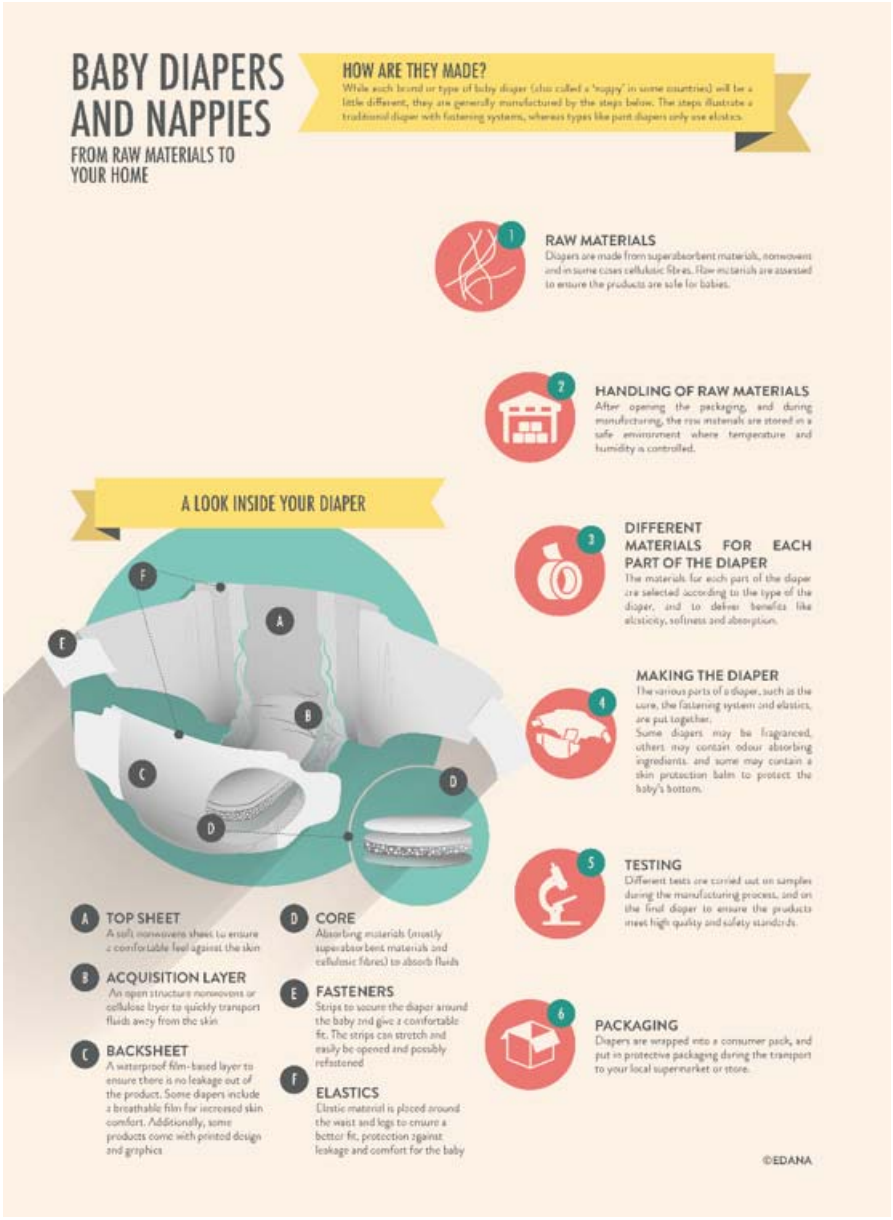

Figure 2 : Sectional diagram of a single-use baby diaper[12] (source : EDANA)

Some single-use baby diapers feature a wetness indicator that changes colour when exposed to urine. This indicator contains a pH-activated component. For more details, please see Annex A.1.

12 https://www.edana.org/docs/default-source/absorbent-hygiene-products/diapers-and-nappies-infographic.pdf?sfvrsn=8c8d06c_2

1.1.4. Chemical substances detected or quantified in single-use baby diapers for children and infants

A detailed overview of single-use baby diapers manufacturing process is provided in Annex A.3 of this restriction proposal. Various governments or agencies published reports pointing out the presence of hazardous chemicals in single-use baby diapers. These studies were not taken into account in the risk assessment for this restriction proposal (indeed it was a too old study or no health risk assessment performed in the other studies).

In 2009, the Danish Environmental Protection Agency (Danish EPA) published a report on the assessment of exposure of two-year-old babies to chemical substances in consumer products (Danish EPA, 2009). Five single-use diapers from various sources were analysed (range of prices, popular brands, organic/non-organic brands). Several diaper parts were studied. Aliphatic hydrocarbons and polymers were found but not individually identified. All of the five tested diapers contained antioxidants. Similarly, very low levels of formaldehyde were detected but not quantified in three diapers and more specifically in the printed backsheet and the acquisition layer.

The Belgian Federal Public Service of Health, Food Chain Safety and Environment (VITO, 2018) screened four baby single-use diapers in order to identify all of the compounds that could be extracted from a diaper. Levels of esters, heavy alcohol, alkanes and siloxanes were observed, but with "no risks to health". In a second phase, 20 baby single-use diapers of big-name brands, "store" brands and "bio" brands were analysed in order to screen for 17 PAHs, glyphosate and AMPA, pesticides, phthalates (DEHP, DBP, DMP, DINP), parabens, isothiazolinones, phenolic compounds, PFOA, BTEX and dioxins and furans. Only the inner surface in contact with babies' skin was analysed after shredding. SAP was removed before extraction. The concentrations of most of the detected chemicals were below the limit of quantification. Some chemicals were quantified but at concentrations below 1 mg/kg. Dioxins and furans (2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDF) were quantified in eight products. Toxic equivalent quantity (TEQ) values for the sum of dioxins and furans ranged from 0.16 to 0.61 ng $_{TEQ}$/kg. However, VITO considers it to be safe in baby diapers since the concentrations found are low.

In 2018, the Swiss Federal Food Safety and Veterinary Office (FSVO), in collaboration with the Fédération Romande des Consommateurs (FRC), a Swiss consumer association, also carried out tests with 21 single-use diapers available on the Swiss market. One hundred and fourteen chemicals were screened for in shredded diapers: dioxins and furans, PAHs, perfluorinated substances, glyphosate and AMPA, phthalates, VOCs and solvent residues. Dioxins and furans (1,2,3,4,6,7,8-HpCDD, OCDD and 1,2,3,4,6,7,8-HpCDF) were quantified in one product. PAHs (naphthalene, anthracene and pyrene) were quantified in 17 out of 19 diapers. Lastly, DIBP was quantified in one product. The FSVO concluded that baby diapers do not contain chemicals likely to pose health risks for infants or toddlers (FSVO, 2018; FRC, 2018). It should be noted that these conclusions were drawn without conducting a QHRA.

As part of tests undertaken by a company, PAHs were screened for in several parts of three diapers of two different brands. Benz[a]anthracene and chrysene were quantified in two diapers, more particularly in the elastics for the first diaper and in the front and rear parts for the second diaper (confidential industrial study; 2016).

1.1.5. Scope of the restriction

The intention of this restriction proposal is to minimise health risk associated with the wearing of single-use baby diapers on children and infants.

1.1.5.1. Articles covered by the restriction

This restriction proposal covers **all finished disposable (single-use) baby diapers which are placed on the market for the children and infants**.

No official "classification" of the different "types" of disposable diapers exists, but, to help the implementation of the restriction proposal, the Dossier Submitter has detailed the various "types" of disposable diapers included in the dossier by using the wording of the industry. Thus, the disposable articles covered by the restriction proposal are the following:

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

Swimming diapers are articles used when children are engaging in water activities. These diapers are made of an absorbent material that does not swell up in water and are not intented to be wore by children all day but only while the children are in the water. These articles are single-use ones and are part of the diapers that children will wear until they will be fully toilet trained. Consequently the Dossier Submitter chose to add these articles are parts of the articles covered by the restriction proposal.

As stated above, the restriction proposal is intended to protect babies and children that will wear single-use baby diaper until they will be fully toilet trained, which appears to be, most of the time, by the time they will turn 3 years old.

Despite the fact that some of them will need to wear a little bit more longer single-use baby diapers, the Dossier Submitter performed its risk assessment for babies and children under the age of 3.

Nevertheless, single-use baby diapers are put onto the market with categories of weight and not age, so even if the Dossier Submitter performed its risk assessment

for the 0-6 months old children, all the babies and children that will need to wear signle use baby diapers until they will be fully toilet trained are included in the scope.

1.1.5.2. Articles not covered by the restriction

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

Re-usable diapers: Unlike single-use baby diapers, re-usable 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 incontinence persons while keeping their skin dry. Incontinence diapers are regulated by the regulation EU 2017/745 (Medical Devices) and fulfil the following definition: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

No analytical tests were performed onto re-usable diapers in ANSES, 2019, so no health risk assessment was performed. Moreover, **re-usable diapers** are made in different materials compared to single-use baby diapers. Indeed, most of them are made in textile and washed, so other contaminants can be on these articles that are not due to the article itself but no data are available, to the Dossier Submitter, regarding these possible contaminants. All these reasons led the Dossier Submitter to not include re-usable diapers in the scope of the restriction proposal.

Regarding **incontinence diapers**, in ANSES, 2020, a health risk assessment was performed using different parameters values (ANSES, 2020) ; the conclusion was that some risks were demonstrated but with high uncertainties due to a lack of data and very few articles tested. Moreover, these types of diapers are already regulated as medical devices. All these reasons led the Dossier Submitter to not include incontinence diapers in the scope of the restriction proposal.

1.1.5.3. Chemical substances covered by the restriction

Based on composition and migration analysis, risk assessment was performed for compounds that have been detected or quantified. This restriction proposal therefore covers the hereafter chemical substances for which a health risk has been demonstrated.

- The Polycyclic aromatic hydrocarbons (PAHs) : Benzo[c]fluorene, Benz[a]anthracene, Cyclopenta[c,d]pyrene, Chrysene, 5-Methylchrysene, Benzo[e]acephenanthrylene, Benzo[k]fluoranthene, Benzo[j]fluoranthene, Benzo[e]pyrene, Benzo[def]chrysene, Dibenz[a,h]anthracene, Indeno[1,2,3-c,d]pyrene, Benzo[g,h,i]perylene, Dibenzo[def,p]chrysene, Naphtho[1,2,3,4-def]chrysene , Benzo(r,s,t)pentaphene, Dibenzo[b,def]chrysene

- The following Polychlorinated dibenzo-p-dioxins (PCDDs): 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD, 1,2,3,4,7,8-HxCDD, 1,2,3,6,7,8-HxCDD, 1,2,3,7,8,9-HxCDD, 1,2,3,4,6,7,8-HpCDD, OCDD

- The following Polychlorinated dibenzofurans (PCDFs): 2,3,7,8-TCDF, 1,2,3,7,8-PeCDF, 2,3,4,7,8-PeCDF, 1,2,3,4,7,8-HxCDF, 1,2,3,6,7,8-HxCDF, 1,2,3,7,8,9-HxCDF, 2,3,4,6,7,8-HxCDF, 1,2,3,4,6,7,8-HpCDF, 1,2,3,4,7,8,9-HpCDF, OCDF

- The total polychlorobiphenyls (PCBs) (NDL-PCBs and DL-PCBs: PCB 81, PCB 77, PCB 123, PCB 118, PCB 114, PCB 105, PCB 126, PCB 167, PCB 156, PCB 157, PCB 169, PCB 189),

- Formaldehyde.

Justification for inclusion of substances

According to the comments received from the consulted stakeholders during earlier stages of the assessment, none of these substances are intentionally added to single-use baby diapers during the manufacturing process, but they are rather residues or contaminants. Indeed, these chemicals have been found in various studies performed in Europe these last few years (please see section 1.1.4). Moreover, in ANSES 2019, the health thresholds have been exceeded when a quantitative health risk assessment was performed (ANSES, 2019). Therefore, the Dossier Submitter suggests to include all the above mentioned chemicals to discard from european market all articles that contain hazardous chemicals above a calculated concentration limit and hereby reduce health impact.

1.1.5.4. Chemical substances not covered by the restriction

Neither skin sensitising substances (except for the ones included in the scope of the restriction proposal) nor fragrances are included in the scope of this restriction proposal. Indeed skin sensitising substances could be restricted in the REACH restriction that is currently adopted by ECHA's committees. Moreover, all skin sensitising substances were not searched in the various analysis performed, so the

Dossier Submitter is not able to include this group of substances in this restriction proposal.

Regarding fragrances, some of these chemicals have been detected or quantified in the French SCL studies but only by solvent extraction through a whole shredded diaper considered not to be the most realistic analysis. Indeed, this solvent extraction method was used as a screening method, using extreme conditions, to know what group of substances might be present in a single-use baby diaper. Moreover, the substances found through this extraction method can be located in parts of the diaper that are not in contact with the skin, so it is less relevant than an urine extraction method. Nevertheless, the QHRA performed in ANSES (2019) showed health risks thresholds exceeded.

As fragrances are used voluntarily in only some rare diapers and can be easily removed, the Dossier Submitter decided to not include fragrances in the scope of the restriction proposal.

To conclude, no skin sensitising substances (except for the ones included in this restriction proposal) nor fragrances will be included in the present restriction proposal.

Eventually, even if some other chemicals have been detected or quantified in the various analysis performed by ANSES (2019) (VOC, pesticides, etc.) the QHRA showed no threshold being exceeded. In conclusion, the Dossier Submitter, decided to not include these groups of substances in the restriction proposal.

1.2. Hazard, exposure / emissions and risk

1.2.1. Identity of the substance(s), and physical and chemical properties

As explained in section 1.1 of this restriction proposal, the scope is limited to formaldehyde, the sums of PAHs, PCCD/Fs, DL-PCBs and PCBs.

More details about these chemicals are provided in Annex B.5.

1.2.2. Justification for grouping

Formaldehyde has a harmonised classification for carcinogenicity, mutagenicity and skin sensitization according to CLP Regulation. This chemical has been quantified in most of the diapers investigated so children and infants can be exposed while wearing single-use diapers. Furthermore, formaldehyde has been restricted in toys, in other articles and will be restricted for its skin sensitization property in single-use baby diapers according to the on-going restriction proposal according to REACH.

PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action. Children and infants exposed to single-use baby diapers containing PAHs will not be exposed to a single PAH but inevitably be exposed to several PAHs and complex mixtures.

The PAHs addressed in 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).

Finally, PCDD/Fs and DL-PCBs have for most of them a self-classification and have been quantified in single-use baby diapers implying potential exposure for children and infants wearing these articles. Numerous studies on the hazards of these chemicals are available (please refer to Annex B).

In conclusion, the Dossier Submitter decided to include all these substances in the scope of the restriction proposal.

1.2.3. Classification and labelling

Some chemicals of concern that are in the scope of the restriction proposal have a harmonised classification according to the Annex VI of the CLP. These classifications are detailed in the table below.

Table 5 : Harmonized classifications for some of the chemicals in the scope of the restriction proposal

Chemicals	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)		
PAHs						
Benz[*a*]anthracene	200-280-6	56-55-3	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	M=100	
Benzo[e]acephenanthrylene	205-911-9	205-99-2	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	-	-
Chrysene	205-923-4	218-01-9	Muta. 2 Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H341 H350 H400 H410	-	-
Benzo[*k*]fluoranthene	205-916-6	207-08-9	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	-	-
Benzo[*j*]fluoranthene	205-910-3	205-82-3	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	-	-
Benzo[*e*]pyrene	205-892-7	192-97-2	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	-	-
Benzo[def]chrysene	200-028-5	50-32-8	Skin Sens. 1 Muta. 1B Carc. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H 317 H 340 H350 H360FD H400 H410	Carc. 1B; H350: C ≥ 0,01 %	-

Dibenz[*a,h*]anthracene	200-181-8	53-70-3	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	Carc. 1B; H350: C ≥ 0,01 % M=100	
Dibenzo[def,p]chrysene*	205-886-4	191-30-0	CArc. 1B Muta.2	H350 H341	Carc. 1B; H350: C ≥ 0,001 %»	
Formaldehyde						
Formaldehyde	200-001-8	50-00-0	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1 Muta. 2 Carc. 1B	H301, H311 H331 H314 H317 H341 H350	Skin Irrit. 2; H315: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0,2 % Skin Corr. 1B; H314: C ≥ 25 %	Note B[13] Note D[14]

[13] Some substances are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In part 3 with Note B have a general designation of the following type " nitric acid…%". In case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

[14] Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It's in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words "non-stabilised".

For all the chemicals in the scope, meaning the chemicals belonging to the groups of PCDD/Fs, PAHs, DL-PCBs, that are not in Table 5, all the self classifications related to the health hazards are gathered in the Table 6.

Table 6 : Self-classification (health hazards) of chemicals included in the restriction proposal

Chemicals	EC No	CAS No	Self classification
PAHs			
Benzo[g,h,i]perylene	205-883-8	191-24-2	Not classified or No self classification related to health hazard
5-Methylchrysene		3697-24-3	Acute Tox 4; H302 Eye Dam 1; H318 Carc. 2; H 351 Carc. 1B; H350 Not classified
Indeno[1,2,3-cd]pyrene	205-893-2	193-39-5	Carc. 2; H351 Not classified
Naphtho[1,2,3,4-def]chrysene	205-891-1	192-65-4	Eye Dam.1; H318 Carc. 2; -H351 Muta. 2; H341 Carc. 1B; H350 Not classified
Benzo(r,s,t)pentaphene*	205-877-5	189-55-9	Carc.2; H351 Carc.1B; H350 Not classified
Dibenzo[b,def]chrysene*	205-878-0	189-64-0	Muta. 2; H341 Carc. 1B; H350 Not classified Carc. 2; H351
Cyclopenta[c,d]pyrene	-	27208-37-3	Not classified or No self classification related to health hazard
Benzo[c]fluorene	205-908-2	205-12-9	No self classification related to health hazard
DL-PCBs[15], PCDD/Fs			
2,3,7,8 TCDD	217-122-7	1746-01-6	Acute Tox. 1; H300 Eye Irrit. 2; H319
1,2,3,7,8 PeCDD	-	33 423-92-6	Acute Tox. 3; H301
1,2,3,4,7,8 HxCDD	-	39227-28-6	Acute Tox. 3; H301 Eye Irrit. 2; H319 STOT SE. 3; H335 Muta. 2; H341
1,2,3,6,7,8 HxCDD	-	57653-85-7	Acute Tox. 3; H301 Eye Irrit. 2; H319
1,2,3,7,8,9-HxCDD	-	19408-74-3	Acute Tox 4 H 302
1,2,3,4,6,7,8-HpCDD	-	35822-46-9	Eye Irrit. 2; H319 STOT SE 3; H335 Muta. 2; H341
OCDD	-	3268-87-9	No self classification
2,3,7,8 TCDF	-	51207-31-9	Acute Tox. 1; H300
1,2,3,7,8 PeCDF	-	57117-41-6	Acute Tox. 1; H300
2,3,4,7,8 PeCDF	-	57117-31-4	Acute Tox. 1; H300 Eye Irrit. 2; H319 STOT SE 3; H335 Carc. 1A; H350 STOT RE 2 ; H373
1,2,3,4,7,8 HxCDF	-	70648-26-9	Acute Tox. 3; H301 Eye Irrit. 2; H319

[15] DL-PCB are classified as 1 by IARC.

1,2,3,6,7,8 HxCDF	-	57117-44-9	Acute Tox. 1; H300
2,3,4,6,7,8 HxCDF	-	60851-34-5	Acute Tox. 3; H301 Eye Irrit. 2; H319
1,2,3,7,8,9-HxCDF	-	72918-21-9	Acute Tox. 3; H301 Eye Irrit. 2; H319 STOT SE 3; H 335 Muta. 2; H 341
1,2,3,4,6,7,8 HpCDF	-	67562-39-4	Acute Tox. 3; H301 Eye Irrit. 2; H319
1,2,3,4,7,8,9 HpCDF	-	55673-89-7	Acute Tox. 1; H300
OCDF	-	39001-02-0	Acute Tox. 1; H300
PCB 81	-	70362-50-4	STOT RE 2; H373
PCB 77	-	32598-13-3	STOT RE 2; H373
PCB 123	-	65510-44-3	STOT RE 2; H373 Not classified
PCB 118	-	31508-00-6	STOT RE 2; H373
PCB 114	-	74472-37-0	STOT RE 2; H373 Not classified
PCB 105	-	32598-14-4	Acute Tox. 4; H302 STOT RE 2; H373
PCB 126	-	57465-28-8	STOT RE 2; H373 Not classified
PCB 167	-	52663-72-6	STOT RE 2; H373 Not classified
PCB 156	-	38380-08-4	STOT RE 2; H373 Not classified
PCB 157	-	69782-90-7	STOT RE 2; H373 Not classified
PCB 169	-	32774-16-6	STOT RE 2; H373 Not classified
PCB 189	-	39635-31-9	STOT RE 2 – H373 Not classified
NDL-PCBs (non exhaustive list –examples of NDL PCBs included)			
PCB 28		7012-37-5	STOT RE2, H 373 Acute Tox 4, H 302 Acute Tox 4, H 312 Acute Tox 4, H332
2,2′,3,5′-Tetrachloro-1,1′-biphenyl ; PCB 44		41464-39-5	STOT RE2, H 373
2,2′,4,5′-Tetrachloro-1,1′-biphenyl; PCB 49		41464-40-8	Not Classified
PCB 52	-	35693-99-3	STOT RE2, H 373
2,3′,4,4′-Tetrachloro-1,1′-biphenyl; PCB 66		32598-10-0	Not Classified
2,4,4′,5-Tetrachloro-1,1′-biphenyl; PCB 74		32690-93-0	Not Classified
2,2′,3,4,5′-Pentachloro-1,1′-biphenyl; PCB 87		38380-02-8	Not Classified
2,2′,4,4′,5-Pentachloro-1,1′-biphenyl; PCB 99		38380-01-7	Not Classified
PCB 101	-	37680-73-2	STOT RE2, H 373
2,3,3′,4′,6-Pentachloro-1,1′-biphenyl; PCB 110		38380-03-9	STOT RE2, H 373
2,2′,3,3′,4,4′-Hexachloro-1,1′-biphenyl; PCB 128		38380-07-3	STOT RE2, H 373 Not Classified
PCB 138	-	35065-28-2	STOT RE2, H 373
2,2′,3,4′,5,5′-Hexachloro-1,1′-biphenyl; PCB 146	-	51908-16-8	Not Classified
2,2′,3,4′,5′,6-Hexachloro-1,1′-biphenyl; PCB 149	-	38380-04-0	STOT RE2, H 373
2,2′,3,5,5′,6-Hexachloro-1,1′-biphenyl; PCB 151	-	52663-63-5	STOT RE2, H 373
PCB 153	-	35065-27-1	STOT RE2, H 373

2,3,3′,4,4′,6-Hexachloro-1,1′-biphenyl; PCB 158	-	74472-42-7	Not Classified
2,2′,3,3′,4,4′,5-Heptachloro-1,1′-biphenyl; PCB 170	-	35065-30-6	STOT RE2, H 373 Not Classified
2,2′,3,3′,4,5,5′-Heptachloro-1,1′-biphenyl; PCB 172	-	52663-74-8	Not Classified
2,2′,3,3′,4,5′,6′-Heptachloro-1,1′-biphenyl; PCB 177	-	52663-70-4	Not Classified
2,2′,3,3′,5,5′,6-Heptachloro-1,1′-biphenyl; PCB 178	-	52663-67-9	Not Classified
PCB 180	-	35065-29-3	STOT RE2, H 373 Not Classified
2,2′,3,4,4′,5′,6-Heptachlorobiphenyl (PCB 183)	-	52663-69-1	Not Classified
2,2′,3,4′,5,5′,6-Heptachloro-1,1′-biphenyl; PCB 187	-	52663-68-0	STOT RE2, H 373 Not Classified
2,2′,3,3′,4,4′,5,5′-Octachloro-1,1′-biphenyl; PCB 194	-	35694-08-7	STOT RE2, H 373 Not Classified
2,2′,3,3′,4,4′,5,6-Octachloro-1,1′-biphenyl; PCB 195	-	52663-78-2	Not Classified
2,2′,3,3′,4,4′,5,6′-Octachloro-1,1′-biphenyl; PCB 196	-	42740-50-1	Not Classified
2,2′,3,3′,4,5,5′,6′-Octachloro-1,1′-biphenyl; PCB 199	-	52663-75-9	Not Classified
2,2′,3,4,4′,5,5′,6-Octachloro-1,1′-biphenyl; PCB 203	-	52663-76-0	Not Classified
2,2′,3,3′,4,4′,5,5′,6-Nonachloro-1,1′-biphenyl; PCB 206	-	40186-72-9	STOT RE2, H 373 Not Classified
decachloro-1,1'-biphenyl; PCB 209	218-115-1	2051-24-3	STOT RE2, H 373

*: these 2 chemicals have adopted RAC opinions that deal with harmonised classification as Muta.2; H 341 and Carc.1B; H350

1.2.4. Hazard assessment

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

1.2.4.1. General information on the hazard of PAHs

Given the targeting of this restriction proposal, only mutagenicity and carcinogenicity were addressed (see section 1.2.3. for the individual classification of the substances included).For more details, please refer to Annex B.5.1.

Animal data

In numerous animal studies, the carcinogenic effects of PAHs, as single compounds or as various complex PAH-containing mixtures to which humans may be exposed, were examined by various routes of exposure. Of the PAHs under evaluation, benzo[def]chrysene (or benzo[a]pyrene or BaP) is the best-studied PAH. It is carcinogenic by all routes tested in a number of animal species. The majority of carcinogenicity studies in experimental animals were conducted as skin painting studies and a limited number of studies following ingestion were available. Oral studies with pure BaP or PAH mixtures resulted in increased tumour incidences in the gastrointestinal tract, liver, and respiratory tract in rats and mice. Dermal exposure to relative low BaP or various PAH concentrations induced benign and malign skin tumours in various strains of mice. It is noted that experimental data on the combined carcinogenicity of these exact 17 PAHs under current evaluation are not available. However, most of the 17 PAHs under current evaluation have implicitly been tested as part of the PAH mixtures in the various studies.

Human data

No data is available on the carcinogenic effects of single PAHs in humans. Most of the human studies have addressed the carcinogenicity of PAH mixtures with BaP as marker compound. A considerable number of epidemiological studies have demonstrated that occupational exposure to soot, coal tar, and other PAH-containing mixtures is carcinogenic to humans. The main route of occupational exposure is inhalation in most industries. However, in many cases, skin exposure represents an important route. However, interpretation and comparison of these data is partly hampered due to differences in study design (case control versus cohort); differences in exposure measurements; not taking into account lifestyle factors; unawareness of co-exposure; and, incomplete data presentation. Nevertheless, despite these confounding factors, the majority of the epidemiological data on PAH-exposed workers, especially in coke ovens and aluminium smelters support a clear excess of lung cancer, and are highly suggestive of an excess of bladder cancer. Skin cancer in man is well known to have occurred following exposure to poorly refined lubricating and cutting oils.

Finally, some PAHs are covered by the Stockholm Convention in 2001 (meaning they are known to be Persistent Organic Pollutants and regulated as such).

1.2.4.2. General information on the hazard of PCDD/Fs and PCBs

Given the targeting of this restriction proposal, only effects observed following oral or dermal exposure were addressed. For more details, please refer to Annex B.5.2.

- PCDD/Fs

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.

The International Agency for Research on Cancer (IARC) has classified 2,3,7,8-TCDD on the basis of epidemiological data in humans and animal data as "carcinogenic to humans" (Group 1) (IARC, 1997 and 2012). 2,3,7,8-TCDD is associated with an increased risk of all types of cancer in humans. The other dioxins and the majority of furans belong to group 3 ("unclassifiable as to its carcinogenicity to humans"). For PCDF, 2,3,4,7,8-Pentachlorodibenzofuran is classified in Group 1 since 2012 by IARC and the other members

of the family are in Group 3. In addition, PCDD/Fs are considered as threshold carcinogens (JECFA, 2001).

The effects on reproduction and development are critical and have been extensively studied, especially in humans after the Seveso accident of 1976. An association between exposure to 2,3,7,8-TCDD during childhood/prepuberty and impaired sperm quality has been demonstrated, as well as immunotoxicity effects and impaired thyroid function in the offspring of exposed mothers (INERIS 2006, US-EPA 2012, EFSA 2018). These results indicate a period of pre- and post-natal sensitivity extending to puberty.

Finally, the genotoxicity of PCDD/Fs was analysed in the EFSA 2018 report. The genotoxicity of 2,3,7,8-TCDD has been studied intensively over the last decades. Evidence for the direct genotoxicity of 2,3,7,8-TCDD is negative or equivocal for a wide range of *in vitro* and *in vivo* parameters.

- PCBs

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).

According to IARC, PCBs were considered to be carcinogenic to humans (Group 1) in 2013 based on the selective determination of 12 most dangerous "Dioxin Like" congeners (PCBs : 77,81,105,114,118,1123,126,156,157,167,169,189) in relation to their Toxic Equivalency Factor (TEF). However, the carcinogenicity of PCBs cannot be attributed solely to DL-PCB. Indeed, PCB-NDLs ("Non Dioxin Like" PCBs) may play an important role in tumor promotion and progression. Like PCDD/Fs, PCBs are considered as threshold carcinogens (JECFA, 2001).

Reprotoxic effects of PCBs are also of concern. Links with altered sperm morphology and motility have been reported (Danish EPA 2014 ; ATSDR, 2000). In females of various species, effects include changes in estrus and reduced implantation rate in adult rats and/or their offspring, decreased conception in mice, and menstrual alterations and decreased fertility in monkeys (Danish EPA 2014). Changes in the menstrual cycle (changes in interval, duration and flow) have also been observed in women exposed to high doses of PCBs (ATSDR, 2000).

Finally, the results of *in vitro* and *in vivo* genotoxicity studies are generally negative and indicate that commercial PCB mixtures are not potent genotoxic (EFSA 2018). The literature on the genotoxic effects of PCBs in humans lacks data on the levels or even the presence of individual PCB congeners. Only a few recent studies have analysed a very small number of congeners and calculated correlations with biological effects (EFSA 2018; IARC 2016).

1.2.4.3. General information on the hazard of Formaldehyde

Given the targeting of this restriction proposal, only effects observed following oral or dermal exposure were addressed (see section 1.2.3. for the individual classification of the substances included). For more details, please refer to Annex B.5.3.

Aqueous solutions of formaldehyde (0.1% to 20%) were irritating to the skin of rabbits. Formaldehyde was sensitising in the guinea pig maximisation test and the local lymph node

assay with mice. Formaldehyde has an harmonised classification for skin corrosion (category 1B) and classification for skin sensitization (category 1).

Formaldehyde is a highly reactive gas that is absorbed quickly at the point of contact and is also produced by endogenous metabolism. It is rapidly metabolised. Repeated formaldehyde exposure caused toxic effects in the tissues of direct contact after oral or dermal exposure characterised by local cytotoxic destruction and subsequent repair of the damage. The typical locations of lesions in experimental animals were the stomach after oral administration and the skin after dermal application. The nature of the lesions depended on the inherent abilities of the tissues involved to respond to the noxious event and on the local concentration of the substance. Atrophy and necrosis as well as hyper- and metaplasia of epithelia may occur. The most sensitive NOAELs for morphological lesions were about 260 mg/L in drinking water (equivalent to 25 mg/kg b.w./day).

Formaldehyde has an harmonised classification for mutagenicity (category 2) based on genotoxic effects observed in vivo in somatic cells at the site of contact. In vivo at the site of contact in somatic cells, positive evidence in mutagenicity tests are available from induction of chromosomal aberrations in rats by inhalation at high dose (Dallas, 1992 cited in ECHA, 2012a) and of micronuclei in rats in the GI tract by oral route (Migliore, 1989 cited in ECHA, 2012a).

Formaldehyde has harmonised classification for carcinogenicity (category 1B). The classification is mainly based on nasal tumours (site of contact) observed in rats of both sexes exposed to formaldehyde at concentrations of 2 ppm and higher for ≥ 24 months. In 2012, ECHA concluded that :

- no valid information is available to conclude on formaldehyde's potential to cause skin tumours and tumours at distant sites and no conclusion on its carcinogenic potential *via* the dermal route can be drawn.
- no conclusion can be drawn for systemic carcinogenicity by the oral route;
- oral exposure to concentrations of 0.19% formaldehyde in drinking water consistently caused erosive-ulcerative lesions and (regenerative) hyperplasia in the limiting ridge area in three studies. The induction of benign tumours in the forestomach in Takahashi (1986) is considered equivocal by the RAC (ECHA,2012a).

There is no convincing evidence that formaldehyde would lead to reproductive effects in human or in experimental animals after oral or dermal exposure. Indeed, experimental or epidemiological studies do not highlight systemic effects of formaldehyde, especially reprotoxic ones, even at high doses.

1.2.4.4. The dose-response relationship

For each chemical, 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, the duration regarded as most relevant in view of the context of the formal request (please refer to Annex B.5). Taking into account the close contact of single-use baby diapers with the buttocks, the use of dermal HRVs seemed appropriate. For PAHs, several dermal slope factors/DMELs are available (see Annex B.5.1.11.1) Two dermal DMEL (10^{-6} risk level) were chosen to assess health risks: a DMEL of 0.004 ng/kg bw/d for PAH

mixture (BAuA, 2010, considering only dermal studies) and a DMEL of 0.006 ng/kg bw/d for BaP alone (derived from Knafal *et al.*, 2006) (most conservative DMEL). (Table 7).

However, for formaldehyde, PCDD/Fs and PCBs, since no HRVs were available for this route of exposure, a search for HRVs by the oral route was carried out.

After the selection of chronic oral HRVs (for threshold and/or no-threshold effects), corrections of HRVs will be made using the estimation of the relative bioavailability of each substance via oral route in order to establish the potential internal dose linked to the selected HRV. Internal DNEL is a better indicator to take into account the bioaccumulation of chemical (WHO, 2015). Afterward for risk characterisation, the internal DNEL will be compared with the estimation of the daily exposure dose (DED). This approach corresponds to a route-to-route extrapolation according to the REACH or IGHRC Guidances (ECHA, 2012b; IGHRC, 2006). Nevertheless, an oral route to dermal route extrapolation needs to consider the following statements: the route should not modify the metabolic profile of the substance and only systemic adverse effects should be considered. For PAHs, PCDD/Fs and PCBs, data on oral bioavailability are available and will be used to establish internal DNELs. For formaldehyde, information suggests good bioavailability following oral administration, it is assumed that its availability will not be superior to 50%. In that case, this value will be used.

A detailed analysis of the HRVs was conducted, considering the relevance of the choices made (critical effect, key study, critical dose, uncertainty factors) and the transparency of the way in which the HRV had been established.

For this health risk assessment, only children between the ages of zero and three years old were specifically targeted. The issue of the applicability of the identified HRVs to the population under three years of age was discussed. This is because these are generally established for the general population and for lifetime exposure. Applying them to this specific age group could therefore lead to uncertainties in terms of hazards when establishing the HRVs and also when calculating risks in comparison with exposure levels. **The Dossier Submitter considered that the HRVs apply to the entire population regardless of age, including children.** If there are data showing that children are more susceptible than adults to the effects of certain substances, these must be taken into account in the establishment of the HRV. If these data cannot be used to establish the HRV, an additional factor can be applied on a case-by-case basis to protect susceptible population groups. In the absence of data showing that children are particularly susceptible, the Dossier Submitter considered that the default intra-species uncertainty factor (UF_H) of 10 was sufficient to protect the entire population (ANSES, 2017a).

Moreover, the Dossier Submitter determined whether the selected HRVs could be applied to the population of children between zero and three years of age, who can be particularly susceptible to certain chemicals. To do so, the approach used for the infant Total Diet Study (iTDS, 0-3 years) (ANSES, 2016) was followed. Therefore a review of toxicological data specific to children taken into account in the establishment of each of these HRVs (perinatal and postnatal toxicity studies, developmental toxicity studies, reproductive toxicity studies conducted with several generations, etc.) was made.

For PAHs, only the HRVs of the reference compound, benzo[def]chrysene (BaP), were identified. Indeed, the toxicity of only a limited number of PAHs is currently known. Some PAHs, primarily those with a low molecular weight, induce systemic non-carcinogenic

threshold effects (mainly kidney, liver and blood disorders) for which HRVs have been established. Other PAHs, in particular those with a high molecular weight, appear to be carcinogenic and genotoxic. BaP was considered as a marker of PAH exposure and carcinogenic effects (WHO-IPCS, 1998). So the toxicity of other PAH was estimated based on toxic equivalency factors (TEFs)(the Dossier Submitter assumes this approach is better for monitorability) contrarily to EFSA's approach retained in the ECHA's restriction for PAHs in granules and mulches (see section B.5.1.8.4.).

For PCDD/Fs, only the HRVs of the reference compound, 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) (the most toxic congener), and those for total dioxins and furans were analysed. The toxicity of other compounds in this group was estimated based on TEFs used to express the toxicity of all congeners with the same mechanism of toxicological action compared to that of the reference compound.

The following table lists the chronic oral HRVs (threshold and no-threshold) selected after a critical analysis and the internal DNEL proposed for risk characterization after route to route extrapolation.

Table 7 : DNELs or DMELS used to conduct the risk characterization

Chemicals	Type of HRV	Organisation (year)	Value	Target organ/critical effect	Oral bioavailability (reference)	internal DNEL
Formaldehyde						
Formaldehyde	Oral Chronic	WHO/IPCS (2005)	TDI : 0.15 mg/kg b.w./day	Stomach irritation and nephrotoxicity	50% (default value)	0.075 mg/kg b.w./day
PCDD/Fs + DL-PCBs						
2,3,7,8-TCDD → Application of TEFs for PCDD/Fs and DL-PCBs	Oral Chronic	EFSA (2019)	TWI : 2 pg $_{TEQ}$/kg/week → $3 \cdot 10^{-10}$ mg/kg b.w./day	Fertility	100% MacLachlan, 1993)	0.3 pg/kg b.w./day
PCBs						
Total PCBs	Oral Chronic	WHO (2003)	TDI : 0.02 µg/kg b.w./day	Immunological and neurobehavioural effects	100% (MacLachlan, 1993)	0.02 µg/kg b.w./day
PAHs						
Benzo[def] chrysene Application of TEFs for PAHs	dermal carcinogenic	Knafla *et al.* (2006) for BMDL modelling	DMEL = 0.006 ng/kg bw/day – 10^{-6} risk level	Skin carcinoma	/	/
PAHs mixture	dermal carcinogenic	BAuA (2010)	DMEL = 0.004 ng/kg bw/day	Skin carcinoma	/	/

			– 10^{-6} risk level			

1.2.5. Exposure assessment

As already mentioned, since the 1990s, single-use baby diapers have been used by more than 90% of families in most of the European Union (EDANA, 2011). The frequent everyday use may lead to exposure of babies to chemicals. Most of the articles covered by the restriction are also used for prolonged periods of time and exposure occurs under occlusion, which increases the likelihood for substances to cross the skin and trigger diseases.

Hazardous chemical substances can intentionally or unintentionally remain in the final product following the manufacture of single-use baby diapers. They can be released through several mechanisms: from direct release of the substance from the articles, or released by diapers in urine during normal wear resulting in exposures of the babies.

Prolonged skin contact with single-use baby diapers is expected over the day. Migration of hazardous substances from inner layers to outer parts of such articles cannot be formally excluded. In addition, a tearing of the outer parts of the diapers may occur, leading to skin contact with the inner parts of the article.

Hence, the assessment of the exposure to chemical substances released by single-use baby diapers in urine simulant would ideally be based on presence in single-use baby diapers and information on migration of the substance to skin during use. The parameters needed to perform the assessment of exposure to chemicals were, for most of them, available to the Dossier Submitter (concentration in a urine simulant, frequency of use, body weight, diapers weight, skin absorption) that's why the Dossier Submitter has performed a quantitative health exposure assessment based on available data and justified assumptions when needed.

1.2.5.1. Exposure scenario

The assessment of exposure relies on the calculation of a daily exposure dose (DED), which is the quantity of a substance to which a population (children between zero and three years of age here) is exposed on a daily basis. The DED is expressed in mg/kg bw/day. The calculation of this DED requires the development of exposure scenario reflecting the population's habits and the selection of exposure variables from the available data or from hypotheses when the necessary data are not available.

The **dermal route of exposure was the one taken into account in this assessment, and more specifically exposure in the diaper area.** Until a child is toilet trained, this area is a warm, occlusive and moist environment with ideal kinetic conditions facilitating the percutaneous absorption of substances (ANSM, 2010; SCCS, 2018).

The **establishment of exposure scenario** aimed to characterise the exposure of infants and children, from birth to the completion of toilet training, to chemicals previously identified in single-use baby diapers.

The Dossier Submitter considers that a test with an extraction through a urine simulant is providing realistic estimates of the capacity of urine to extract a number of chemicals from

diapers (that are in direct contact of the skin or that can migrate from the outer part of the diapers to the parts of the diaper in direct contact with the skin). In this experimental protocol, synthetic urine was added to the diapers before being pressed out. The urine thus released from the diapers was then analysed (please refer to Annex E.8.). In these conditions, the doses contained in the urine recovered after pressing enabled quantities of chemicals in contact with a child's skin to be estimated. Taking into account the capacity of these chemicals to penetrate the skin, the Dossier Submitter was able to estimate realistic internal exposure doses.

The equation for the DED for each chemical individually is:

$$DED = (C_{diaper} \times W \times F \times Abs_{skin}) / BW \qquad \text{equation 1}$$

where :

- DED: daily exposure dose (mg/kg bw/day)
- C_{diaper}: concentration of the chemical extracted with a urine simulant from a whole diaper, in relation to the weight of the diaper taking into account the extracted simulant volume (mg/kg of diaper)
- 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)

As explained in section 1.2.4.4, cumulative exposure was taken into account for each group of substances. For PCDD/Fs and DL-PCBs, exposure was assessed using TEFs revised in 2005 by the WHO (Van den Berg *et al.,* 2006) and indicating the toxicity of all congeners having the same mechanism of toxicological action as the "Seveso" dioxin (2,3,7,8-TCDD), considered the most toxic. Exposure was therefore expressed in toxic equivalent quantities (TEQs). For PAHs, exposure was also assessed using TEFs. The TEFs used were the ones defined in the table available in the Annex B.9. Consequently, the calculation of the DED is then:

$$DED_{TEQ} = (C_{diaper} \times W \times F \times Abs\ skin \times TEF) / BW \qquad \text{equation 2}$$

1.2.5.2. Population to be included in the risk assessment

The age at which children are toilet trained varies considerably depending on the individual. By two and a half years of age, approximately 90% of girls and 75% of boys have complete bladder control (Stoppard, 1990 cited in UK Environment Agency, 2005a). The average child will stay dry at night at the age of 33 months (normal range from 18 months to eight years) (Green, 1998 cited in UK Environment Agency, 2005a).

In 2004, the UK Environment Agency undertook a study on the use of disposable and re-usable diapers. It showed that the average age out of diapers was 26.17 months (1,553 respondents). By the age of two and a half years, 95% of children are out of disposable diapers (UK Environment Agency, 2005b). However, some children continue wearing training pants and/or diapers at night for varying lengths of time.

Table 8 : Percentage of children wearing disposable diapers (all types) (UK Environment Agency, 2005b)

Age of child	Children wearing nappies (%)	Children not wearing nappies (%)
up to 6 months	100.0%	0.0%
6 to 12 months	95.7%	4.3%
12 to 18 months	82.8%	17.2%
18 to 24 months	45.6%	54.4%
24 to 30 months	17.6%	82.4%
30 to 36 months	4.8%	95.2%
36 to 42 months	1.8%	98.2%
42 to 48 months	0.4%	99.6%
48 to 54 months	0.1%	99.9%
54 to 60 months	0.1%	99.9%
60 to 66 months	0.1%	99.9%

In this restriction proposal, the health risk assessment was undertaken for children aged from birth to 36 months included. The population of interest was divided into six age groups in order to better take into account the weight evolution and psychomotricity developments of children between the ages of zero and 36 months involving the use of different diaper sizes and a daily frequency of use adapted to each age group.

1.2.5.3. Contact between single use baby diapers and skin

The dose per skin surface area is considered to be the most relevant dose metric for risk assessment of the chemicals of concern. Therefore, the area of the exposed skin is typically an important parameter to consider in such calculations. However, in single-use baby diaper exposure scenario the relationship between the diaper surface and surface of the exposed skin is 1:1, i.e. **the exposed skin area is 100% covered by the material**.

1.2.5.4. Exposure duration

It is generally agreed that it is not only the dose per skin area that is the determinant of the adverse effect but also that the duration of the exposure, i.e. the accumulated dose per skin area is important.

24 hours was selected as an **appropriate time frame** for accumulated dose when chemicals have **threshold effects** given that exposure is expected throughout the day until the child or the infant is fully toilet trained.

On the contrary, for chemicals with **non-threshold effect**s (carcinogenic ones), **3 years** corresponding to the time until that a child is fully toilet trained, is considered as the **appropriate time frame**.

1.2.5.5. Babies weight

Body weight depends on the age and sex of the individual and his/her physiological condition. During the diaper wearing period, the weight of a child varies. On average, it is 3.5 to 4 kg for a newborn, 10 kg for a one-year-old child, and 18 to 25 kg for a toddler (Rai *et al.*, 2009).

Companies consider an average body weight of 8 kg (Rai *et al*., 2009; Dey *et al.*, 2016a; EDANA). As part of a worst-case scenario, they recommend using the smallest body weight for newborns (Rai *et al.*, 2009).

Body-weight data from the 2013 BEBE-SFAE survey, on the eating habits and food consumption of children between the ages of zero and 36 months in metropolitan France, are also available. This study was conducted in the field by TNS-SOFRES for the French Association for Children's Food. Consumption data were collected from 1,188 mothers of children between the ages of 15 days and 36 months, meant to be a representative sample of the French population[16]. Body weights were recorded by the interviewer in the children's homes using a bathroom scale or recent weighing data (Table 9).

Table 9: Reported French body weights (girls and boys) – zero to 36 months (SFAE, 2013)

Age group (years)	Body weight (kg)						
	Min	Q.5	Q.25	Q.50	Q.75	Q.95	Max
0-6months exclusive	2.60	3.97	5.20	6.11	7.00	7.80	9.75
6-12 months inclusive	3.36	6.66	7.50	8.20	9.20	10.50	11.50
13-18 months inclusive	8.00	8.90	9.60	10.80	11.50	12.00	12.70
19-24 months inclusive	8.50	9.80	10.90	11.75	12.80	14.28	16.00
25- 30 months inclusive	10.00	11.00	12.00	13.00	14.50	16.80	18.50
31-36 months inclusive	9.88	11.00	12.00	14.00	15.00	17.57	20.00

In this restriction proposal, the Dossier Submitter chose to work with the Q25 of the body weight for each age group described in the BEBE-SFAE study (2013). The BEBE-SFAE study was retained for this restriction proposal because it is the only European study available that details sufficient data covering all classes between 0 and 36 months old .

The Dossier Submitter chose to retain, as a reasonable worst case, a Q25 of the body weight distribution for each class of age in order to be in line with the RIVM "General Fact Sheet" report about the general default parameters for estimating consumer exposure (RIVM, 2014).

1.2.5.6. Absorbed fraction by the skin

Dermal absorption depends on the specific physico-chemical properties of the chemical, the maturity of the skin tissue, the state of the skin (skin diseases) and the exposure conditions (occlusive or semi-occlusive conditions).

[16] Excluding highly vulnerable populations, based on the following criteria: the baby's age and sex, the mother's occupation, and the family's socio-professional category and region/metropolitan area

Until a child is toilet trained, the diaper area is a warm, occlusive and moist environment with ideal kinetic conditions facilitating the percutaneous absorption of substances. This environment supports the development of skin diseases. Diaper dermatitis is one of the most common skin disorders in neonates and infants, with a prevalence between 7 and 50% (Šikić Pogačar *et al*., 2018). However, the real incidence of diaper dermatitis might be higher because physicians and parents do not report many cases of diaper dermatitis as they usually resolve after a few days without the need for medical treatment (Šikić Pogačar *et al*., 2018; Blume-Peytavi *et al*., 2014). Even though it rarely causes problems for longer periods of time (typically 2-4 days), it causes considerable distress to both infants and parents at the same time. Incidence peaks is reported in infants between 6 and 12 months who are weaning off breast milk and beginning to consume solid foods (Blume-Peytavi *et al.,* 2014; Burdall *et al.,*2019; Carr *et al*., 2020; Cohen, 2017; Odio and Thama, 2014; Ersoy-*Evans et al.,* 2016).

Nonetheless, despite the potential risks associated with the occlusive nature of this environment, a significant decrease in the incidence and severity of diaper dermatitis has been observed over the past few years (ANSM, 2010). This improvement may result likely from these different factors:

- Improved design and greater use of modern superabsorbent nappies. According to Burdall *et al*. (2019): "The inclusion of super-absorbent gels (reducing skin moisture),
- petrolatum-based lotions (improving skin integrity), and breathable outer layers (reducing local humidity) into thinner diapers with a better fit to the body's contour has seemingly led to a reduction in the presence of erythema and severity of diaper dermatitis."
- Improved design of wipes,
- Improved use of barrier emollients,
- Improved general skin care of infants (Atherton, 2016: Burdall *et a*l., 201; Odio and Thaman, 2014).

However, even with these advances, diaper dermatitis persists around the world, with prevalence rates estimated to be as high as one-fourth of diaper users at any given time although more typically reported to be in the 8–12% range (Odio and Thaman, 2014). The wearing of diapers continues to contribute to the development of skin diseases in the buttocks area that can affect dermal absorption. In that case, skin penetration can be increased. Stamatas *et al.* (2011) compared skin barrier function in infants with dermatitis, considering areas of lesional skin, non-lesional skin and control skin (skin on the outer thigh). Barrier function was similar for the non-lesional and control skin (transepidermal water loss (TEWL)[17] 47 ± 29 g/m²/hr vs 48 ± 30 g/m²/hr). The lesional skin showed higher TEWL (104 ± 67 g/m²/hr) than the non-lesional skin and control skin, indicating that skin with erythema can be vulnerable due to loss of stratum corneum, resulting in increased TEWL (Stamatas *et al.,* 2011). Skin conditions such as contact dermatitis and diaper rash can potentially increase the dermal penetration of substances depending on their physico-chemical characteristics and the degree of skin damage. For example, skin compromised by diaper rash or by mechanical or chemical damage has shown variable penetration properties, with slightly higher dermal penetration compared to normal skin (Gattu and Maibach, 2011 cited in Dey *et al.*, 2016a).

[17] Transepidermal water loss refers to a mixed phenomenon of passive diffusion and water vapour loss as a result of sweating. When the skin is damaged, transepidermal water loss is increased. On the other hand, it returns to normal baseline values when the skin barrier is restored. The value of transepidermal water loss measured with an evaporimeter is expressed as a mass of evaporated water per unit area of skin per unit of time (g/m²/hr).

Conversely, other studies indicate that compromised skin does not necessarily result in increased dermal penetration (McCormack *et al.*, 1982 cited in Dey *et al.*, 2016a; Dey *et al.*, 2015).

At European level, the Scientific Committee on Consumer Safety (SCCS) recommends using a default absorption rate of 50%. However, the buttocks area has its own particular conditions: wearing of diapers, uncontrolled urination and defecation, and diseases that can damage the skin. Modern diaper technology has shown increasing compatibility with the skin, leading to a reduction in the frequency and severity of diaper dermatitis. That said, diaper dermatitis cannot be completely avoided and may have an impact on the dermal absorption of substances. Thus, the potential impact of irritation on the dermal absorption of chemicals should be taken into account in the final quantitative risk assessments of products intended to be used on the buttocks (SCCS, 2018).

It should be noted that for the assessment of cosmetics intended for children under three years of age, the ANSM recommends applying a worst-case scenario, i.e. 100% topical penetration, when calculating margins of safety for products likely to be applied to the buttocks (ANSM, 2010).

Even though the frequency of diaper dermatitis has decreased due to the use of diapers with increasing skin compatibility, diaper dermatitis cannot be completely avoided and may have an impact on the dermal absorption of chemicals. In addition, direct contact with damaged skin may increase the skin sensitisation concern.

Thus, the Dossier Submitter assumed a mucocutaneous absorption rate of 50% to calculate exposure (SCCS, 2018).

1.2.5.7. 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.

The population of interest was divided into six age groups in order to better take into account the rapid weight evolution and psychomotricity development of children between the ages of zero and 36 months involving the use of different diaper sizes and a daily frequency of use adapted to each age group.

Based on the available data described in Annex B.9, the daily frequency of use, the Dossier Submitter used the data from a study undertaken in 2002-2003 in the United Kingdom in more than 2,000 households with a child who was in diapers or had worn diapers in the recent past, due to the robustness of this study.

Table 10 : Frequency of use for children between 0-3 years old (UK environment agency, 2005b)

Parameter	Age groups	Value Refined Approach	Reference
Frequency of use	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	

1.2.5.8. Baby diaper weights

The literature data available for this parameter are summarised in the annex B.9. It should be noted that the weight of a single-use baby diaper depends on its size.

The population of interest was divided into six age groups in order to better take into account the rapid weight evolution and psychomotricity development of children between the ages of zero and 36 months involving the use of different diaper sizes and a daily frequency of use adapted to each age group. Based on the weight of a diaper, the Dossier Submitter considered the most recent data available from a European industrial association.

Table 11 : Reported diapers weight (Group'Hygiène 2019)

Parameter	Age groups	Value	Reference
Weight of a diaper by age group	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	

The Dossier Submitter would like to underline that the weight of premature babies single-use diapers are not taken into account in the weight of a diaper by age group due to lack of available data.

1.2.5.9. Conclusion on exposure to hazardous chemicals in single use baby diapers

The values of the parameters used by the Dossier Submitter to perform the exposure assessment (and calculate the DED) are gathered in the Table 12 .

Table 12: 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	
Dermal absorption rate (Abs $_{skin}$)	50%		SCCS (2018)
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	

Dermal exposure can be assessed by actual measurements of the chemical deposited onto the skin. This exposure concentration is then compared to a presumed safe exposure level (reference dose, derived no effect level) to conclude on the risk.

For most substances in the scope of this restriction proposal specific concentrations in urine simulant (i.e migration concentrations) and most of the valuable parameters are available which allow the Dossier Submitter to perform quantitative substance-specific exposure assessments (see Annex B.10.2).

A realistic precautionary quantitative approach for exposure assessment is thus proposed in the present restriction proposal.

1.2.6. Risk characterisation

RAC box

RAC reached different conclusions than the Dossier Submitter concerning the risk characterisation of the restriction proposal. RAC undertook a sensitivity analysis using more realistic conditions of use and concluded that either the RCRs were below 1 or that the risks could not be reliably characterised because of the lack of a reliable exposure assessment.

The details of the RAC evaluation are reported in the RAC opinion, together with the justification for the conclusions on the characterisation of risks.

The Dossier Submitter proposes that substances of concern should be restricted in the whole single-use baby diapers based on the risk from exposure to substances classified with regard to their hazards with consideration to the exposure assessment as described in 1.2.4 and Annex B.10. Given that most of the approximated 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 (see annex B for more details).

The purpose of the risk characterisation is to assess the likelihood that the health effects are avoided when wearing single use baby diapers containing the substances of concern.

The RMOA finalised by Anses in 2019, **concluded that restriction under REACH Article 68.1 to be the most appropriate RMO to address the risk from chemicals in single-use baby diapers. Such an option enables regulation of groups of substances at once, applies to EU manufactured products as well as imported baby diapers and allows covering different types of hazard endpoints.**

However some challenges have been highlighted like:

- The chemicals to be included in the scope;
- The articles to be included in the scope;
- The limit of concentrations that must not be exceeded taking into account that substances in single use baby diapers are the only way of exposure to these chemicals or on the contrary are only a part of the daily exposure;
- The capacity to demonstrate the applicability of the enforcement of the proposal regarding analytical methods that would be needed to achieve the safe levels;
- The human health benefits of such a restriction will have to be demonstrated;
- The availability of suitable (technically and economically feasible) alternatives.

Risk characterisation enables the expected risk in a population to be quantified, taking into account exposure to the substance in question and its effects (toxicity). Risk characterisation is the final QHRA phase and consists in calculating the expected risk level for the chosen type of effect, based on the calculation of:

- a risk characterisation ratio (RCR) for substances with a threshold effect,
- an individual excess risk (IER) for substances with a no-threshold effect (carcinogenic effect).

For substances with a threshold effect, meaning formaldehyde, PCDD/Fs and DL-PCBs and for substances with a no-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 (DED) 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 $DMEL_{dermal}$.

$$RCR = DED/DNEL_{in} \text{ or } DMEL_{dermal} \qquad \textbf{equation 3}$$

The numerical value of the RCR is interpreted as follows: an RCR greater than 1 means that the toxic effect may occur, without it 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.

The possibility of cumulative exposure through other sources (environmental, food, *etc*.) leading to an increase in the total DED cannot be ruled out, meaning that the exposure to

these chemicals is likely not limited to diapers only. **Therefore the Dossier Submitter decided to limit the share allocated to baby diapers to 10 % of the DNEL / DMEL**.(see Annex B.10.2.1)

1.2.6.1. Equation to derive migration limits in single-use baby diapers

To reduce the risk for children and infants from exposure to substances of concern in single use baby diapers, the exposure to a chemical substance migrated from the article should not lead to a RCR higher than 1. As explained before, as various exposure sources leading to an increase in the estimated risks could not be ruled out, **the Dossier Submitter decided to limit the share allocated to baby diapers to 10 % of the RCR.**

Thelimits in single use baby diaper were calculate using the following equation:

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

equation 4

With:

- $DNEL_{in}$: internal DNEL (mg/kg bw/d)
- $DMEL_{dermal:}$ dermal DMEL (mg/kg bw/d)
- BW: body weight of a child (kg)
- 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}**:** concentration limit of the chemical extracted (I.e. that migrated) with a urine simulant from a whole diaper, in relation to the weight of the diaper taking into account 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 concentration 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:

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

equation 5

An example of calculation is available in the Annex B.10.2.1.1

The Dossier Submitter would like to indicate that even if the risk assessments are performed while using concentrations of chemicals measured through a dedicated analytical method were urine simulant are added to the parts of the diapers that are in contact with the skin (to be the more realistic), chemicals can migrate from the other parts of the diapers (due to urine simulant, the sweat or to the ability itself of the chemicals to migrate). In conclusion, the limits proposed by the Dossier Submitter here after will be applicable for the whole diaper, all the sizes of the diapers available on the market and all the category of ages(explanations given in Annex B and in 1.2.6 of the main report)**and refer to migration limits.**

1.2.6.2. Derivation of migration limit for formaldehyde

Formaldehyde has been found in most of the analyzed single-use baby diapers (ANSES, 2019). A $DNEL_{in}$ of 0.075 mg/kg bw/d was retained (see section 1.2.4). For infants between 0 to 6 months old, a frequency of use of 7.98; a diaper weight of 23.1 g and a body weight of 5.2 kg were used. No TEF is needed for formaldehyde.

The migration limit of formaldehyde in single-use baby diapers ensuring that the 10% of the $DNEL_{in}$ is not exceeded is (using equation 5):

Migration limit (mg/kg diaper) = 1 X 0.1 x 0.075 X 5.2 /(0.0231 X 7.98 X 50%) = **0.42 mg/kg**

The Dossier Submitter proposes a migration limit of **0.42 mg/kg** for formaldehyde in single-use baby diapers.

As explained in section 1.2.6.1. this limit is proposed to cover all the category of ages and all the sizes of diapers available on the market.

1.2.6.3. Derivation of a migration limit for PCDD/Fs and DL-PCBs.

Various PCDD/Fs and DL-PCBs have been quantified in single-use baby diapers. In the Annex B.10, the risk evaluation has shown cases of risk ratios higher than 0.1 for some of the congeners. The Dossier Submitter would like to underline the hereafter statements:

- When laboratories perform analysis onto diapers, they search for each congener,
- All PCDD/Fs and DL-PCBs were not quantified in each diaper but could be found in some of them leading, when performing the QHRA to risk ratios higher than 0.1 (see Annex B.10). These risk assessments showed that risks exist for the chemical groups quantified in single-use baby diaper.
- Moreover, these chemicals have similar toxicological profiles meaning that hazards for each congener can be evaluated by using TEF.

All these statements lead the Dossier Submitter, in terms of regulatory management, to restrain the sums of the quantified PCDDs, PCDFs and DL-PCBs.

To define the migration limit for the sum of quantified PCDD/Fs, DL-PCBs and according to the equations 4 and 5, the Dossier Submitter followed the approach described here under.

A $DNEL_{in}$ of 0.3 pg/kg bw/d has been retained (See Annex B.5). For infants between 0 to 6 months old, a frequency of use of 7.98; a diaper weight of 23.1 g and a body weight of 5.2 kg were used.

The migration limit of **the sum of DL-PCBs, PCDD/Fs** in single-use baby diapers ensuring that 10% of the $DNEL_{in}$ is not exceeded is then:

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

The Dossier Submitter proposes a migration limit of **0.0017ng_{TEQ}/kg** in single-use baby diapers.

As explained in section 1.2.6.1. this limit is proposed to cover all the category of ages and all the sizes of diapers available on the market.

DL-PCBs can be found in such articles and as it is commonly known (please refer to Annex B) that when DL-PCBs can be quantified, NDL-PCBs are likely to co-exist. Even if these chemicals have not been searched in single-use baby diaper by the SCL (no reason was provided by the laboratory for this choice), they have been quantified in similar articles, that is to say in incontinence diapers (UFC Que Choisir, 2019). **Consequently, the Dossier Submitter, chose to add these chemicals to the restriction proposal and to restrain the sum of the PCBs.**

To determine the migration limit, the Dossier Submitter used the same equation (equation 5) and the same values for the parameters like for the calculation of the limit of the sum of the above PCDD/Fs, DL-PCBs except for the $DNEL_{in}$. Indeed, the $DNEL_{in}$ that has to be used can't be the same as the one used above (meaning 0.3 pg/kg bw/d) due to the fact that the toxic action mode of PCBs is not the same as the one for DL-PCBs. Consequently, and after a literature search and exchange with toxicological experts, the Dossier Submitter, retained a TDI of 0.02 µg/kg/d (WHO, 2002b) for the PCBs. In the table below are gathered all the information needed to determine the $DNEL_{in}$.

Table 13 : DNEL used to define a migration limit for PCBs

Chemical	Type of HRV	Organisation (year)	Value	Target organ/critical effect	Oral bioavailability	internal DNEL
PCBs	Oral chronic	WHO (2002b)	TDI = 0.02 µg/kg/day	immunological and neurobehavioral effects	100%	2.10^{-5} mg/kg/day

The migration limit of **the sum of PCBs** in single-use baby diapers ensuring that 10% of the $DNEL_{in}$ is not exceeded is then:

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

The Dossier Submitter proposes a migration limit of **112 ng/kg** of diaper. As explained in section 1.2.6.1. this limit is proposed to cover all the category of ages and all the sizes of diapers available on the market.

The migration limit of each sum of the quantified PCDDs, PCDFs, DL-PCBs and PCBs, in single-use baby diapers ensuring the safety of children and infant is:

Table 14 : Migration limit not to be exceeded in diapers

Chemical	Migration limit
Sum of the quantified PCDDs, PCDFs and DL-PCBs in **TEQ**	**0.0017 ng_{TEQ}/kg of diaper**
Sum of the quantified total PCBs	**112 ng/kg of diaper**

As explained in section 1.2.6.1. these limits are proposed to cover all the category of ages and all the sizes of single-use baby diapers available on the market.

1.2.6.4. Derivation of a migration limit for the PAHs

As for PCDD/Fs and DL-PCBS, various PAHs have been detected in single-use baby diapers. In the Annex B.10, the risk evaluation has shown cases of risk ratios higher than 0.1 for some of the congeners and for the sum of the detected PAHs. The Dossier Submitter would like to underline the statements hereafter:

- When laboratories perform analysis onto diapers, they search for each congener,
- All PAHs are not detected in each diaper but can be found in some of them leading, when performing the QHRA, to risk ratios higher than 0.1 (see annex B.10). These risk assessments showed that risks exist for the chemical groups detected in single-use baby diaper.
- Moreover, these particular PAHs (carcinogenic ones[18]) have similar toxicological profiles meaning that hazards for each congener can be evaluated by using TEF.

All these statements lead the Dossier Submitter, in terms of regulatory management, to restrain **the sum of the detected or quantified PAHs (benzo[c]fluorene, benz[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[e]acephenanthrylene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[def]chrysene, dibenz[a,h]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene, dibenzo[def,p]chrysene, naphtho[1,2,3,4-def]chrysene , benzo(r,s,t)pentaphene, dibenzo[b,def]chrysene)**

A $DMEL_{dermal}$ of 0.004 ng/kg bw/d has been retained (please see Annex B.5).

The migration limit not to be exceeded to ensure that infant and children under the age of 3 exposed to PAHs in single-use baby diapers is calculated according to the equation 4 .

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**

For the sum of the detected or quantified PAHs, the migration limit in single-use baby diapers ensuring the safety of children and infant is 0.023ng_{TEQ}/kg of diaper.

1.2.6.5. Conclusion on the risk

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 (as indicated in section 1.2.4 and Annex B). Therefore, the risks associated with these substances are not adequately controlled. Hence, lowering the concentrations of migration of these chemicals in single-use

[18] benzo[c]fluorene, benz[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenz[a,h]anthracene, Indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene, Dibenzo[a,l]pyrene, Dibenzo[a,e]pyrene, Dibenzo[a,i]pyrene, Dibenzo[a,h]pyrene

baby diapers to the ones proposed here under, is considered to significantly reduce the risk. The limits proposed are considered to adequately protect infants and children.

The calculated limits in single-use baby diapers proposed by the Dossier Submitter are the following ones:

Table 15: Migration limits not to be exceeded in single use baby diaper

Substance / group of substances	**Proposed migration limit**
Formaldehyde	
Formaldehyde	**0.42 mg / kg of diaper**
PCDDs/PCDFs/DL-PCBs	
Sum of the quantified PCDD/Fs and DL-PCB **in TEQ**	**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**	**0.023 ng_{TEQ} / kg of diaper**

An uncertainty analysis has been performed in Annex F. This analysis shows that by increasing one parameter at a time (weight of a diaper, frequency of use or skin absorption), the limit in single-use baby diaper will decrease. Conversely, an increase of the internal DNEL or DMEL or the baby body weight will result in an increase of the migration limit. Finally, all the DNELs and DMELs used for the risk assessment were derived on the basis of oral studies, which represents a significant source of uncertainty for assessing the health impacts of a generated risk associated with cutaneous exposure. A sensitivity analysis is also available in annex of this restriction proposal.

1.3. Justification for an EU wide restriction measure

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.

Single-use baby diapers can contain hazardous chemicals which may cause adverse effects in susceptible individuals (in older ages and in their adulthood). The QHRA performed by the Dossier Submitter showed that risks have been demonstrated for several substances, after having applied a realistic scenario and reasonably conservative assumptions.

The health effects that may be caused by the use of single-use baby diapers may have a significant impact on a person's quality of life, partly because some of the chemicals have CMR and suspected ED properties and because it is a massively adopted practice to use these articles before three years of age, without widely accepted alternatives.

Moreover, to be protected, children and infants should not wear single-use baby diapers containing hazardous substances at a level that can not be demonstrated as safe.

Based on the available scientific literature, it is impossible to estimate how many people in the EU would suffer from diseases that could be attributed to the regular wearing of single use baby diapers until the full acquisition of toilet-training.

It has been admitted that children and infants' sensitivity to chemical exposure is higher than adults identifying children as a vulnerable group in risk assessment procedures. This higher sensitivity to chemical exposure is explained by particularities in their behaviour, activities and physiological characteristics and parameters. Indeed, children and infants in the first years after birth are facing to particular situations of exposure leading them to be disproportionally exposed to chemicals when compared to adults thus affecting the rate of contact, the exposure-uptake relationship and the fate of chemicals. Moreover, they have immature barriers and metabolic pathways of chemicals, and have in opposition an extra metabolic rate to fuel growth and development. Then, their early developmental processes are easily disrupted which could result in some disorders in systems that continue to mature after birth (e.g., the central nervous, immunologic, reproductive, and endocrine systems) and consequently in adverse effects in childhood and in adult life[19].

Considering all the elements described above, **the Dossier Submitter considers that there is a need for risk management.**

1.4. Baseline

This restriction covers substances specified in section 1.1.4 that may be present in single-use baby diapers at points of sale within EEA31. A list of articles relevant for the scope is provided in section 1.1.4.

The baseline, the "business as usual" scenario, is defined as the current and predicted future use of these substances in the articles covered without the proposed restriction and is described as follows:

- The geographical boundaries for the assessment are the countries of EEA31.

- Regarding pending legislative changes of relevance, and as already mentioned above: BaP and formaldehyde will also be the subject of a restriction proposal from Sweden and France, which suggests a concentration limit for textiles, leather fur and hide articles including single-use baby diapers. The proposal is targeted at the skin sensitising properties of formaldehyde and BaP. In some cases certain single-use baby diapers can meet the concentration limit proposed in Sweden and France's restriction but they would be taken off the market in order to comply with this restriction on single-use baby diapers. Some impacts for these diapers may thus occur. However, at this stage, it is difficult to predict them. The Dossier Submitter would like to underline

[19] National Research Council. Pesticides in the Diets of Infants and Children, Washington (DC): National Academies Press; 1993.

Philip J. Landrigan and Lynn R. Goldman. Children's vulnerability to toxic chemicals: a challenge and opportunity to strengthen health and environmental policy. Health Aff (Millwood). 2011 May;30(5):863-70.

that no overlapping is expected betwenn the skin sens in textiles restriction and the single-use baby diaper's proposal due to the fact that in the current proposal, **it is a migration limit that is proposed while in the skin sens in textile restriction, it is a concentration limit i.e a content limit**. In conclusion, the two restrictions do not have the same objective.

- **Concurrently,** voluntary actions from diapers industry as well as labels exist. These schemes are part of the baseline. As explained in section 2.2., if properly implemented and monitored, voluntary agreements can be effective and businesses can help to achieve public policy aims. Since they are not regulatory schemes, their efficiency is however difficult to measure. Nevertheless, these actions demonstrate that diaper industry is willing to improve their processes and end products and has already implemented actions for these purposes.

- As shown in Annex A, the single-use baby **diapers consumption** in the EU has been constantly grown since the 1980s and has rapidly increased during the last decade. Based on EU statistics, a part of the diapers production involving chemical substances occurs outside the EU. Based on these trends, it is assumed that the production of single-use baby diapers will keep on growing in the future or at least stay as it is now, and the part of manufacturing occurring outside EU is assumed to remain real, encouraged by low-paid workforce and less stringent workers regulation in the field of textiles in particular.

- The Dossier Submitter has insufficient information to define the actual number of children and infants that wear single-use baby diapers in Europe. As a best-informed guess, the Dossier Submitter assumes that 90% of the European children and infants wear only single-use baby diapers (EDANA, 2011). Nonetheless, some parents choose to use re-usable diapers. The choice of diaper type is influenced by family members as well as by income disparity and methods of access to information (Thaman and Eichenfield, 2014). According to Eurostat, around 5.2 million babies are born in EU28 every year[20], i.e. there are currently about 16 million babies and infants between 0 and 3 years old in EU28. It is reasonably assumed that all babies and infants in Europe share similar skin properties and similar diapering time until 3 years old (except some extreme cases of late toilet-training or physiological deficiencies). Therefore, it is assumed that around 14.5 million babies and infants in Europe are exposed to the chemicals targeted in this restriction proposal *via* their single-use diapers and thus are potentially at risk.

As a result of these above asumptions, it is assumed that diseases linked to the chemicals of concern in single-use baby diapers, will steadily increase over time.

[20] Average over 2008-2018 retrieved on June the 9th from: https://ec.europa.eu/eurostat/databrowser/view/tps00204/default/table?lang=en

2. Impact assessment

2.1. Introduction

The Dossier Submitter evaluated a number of other EU-wide and national legislative and voluntary measures. Following an assessment of the current Member States' national legislation and an assessment of the substances in single-use baby diapers that can present a risk to human health, one restriction option (RO) is proposed, although 2 are comprehensively analysed in the dossier (see section 2.2.1 and sections 2.4 to 2.7). The impacts of the restriction proposed were assessed and (when possible) monetised (please see section 2.4).

2.2. Risk management options

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. It was concluded that none of these RMOs was appropriate to control the risk (see sections 2.2.2 to 2.2.8, and Annex E.1). Therefore several restriction options under REACH were explored: in total two restriction options were analysed.

2.2.1. REACH Restriction options according to REACH Article 69

Substances in single-use baby diapers for which the manufacture, use or release on the market cause an unacceptable risk at the EU level can be restricted and included in Annex XVII of REACH. The restriction may apply to a substance, as such, or to one included in a mixture or an article. The restriction may also apply to substances in imported baby diapers.

Restriction under REACH may be designed in different ways in order to reach the highest possible risk reducing effect without having a disproportionate economic impact on the EU market.

A restriction proposal under REACH has to meet the REACH Annex XV requirements aiming at tackling a risk by reducing the exposure to the hazardous substance down to a safe level, otherwise at removing it. For this purpose, a restriction proposal may have several forms such as limiting the concentration or the migration of a substance in one specific article to protect consumers and users.

Submitting a REACH restriction to address a particular risk requires the following preliminary conditions:

- First of all, the Dossier Submitter has to be sure that the substance(s) of concern and the risks targeted can be legally addressed under the REACH restriction procedure. In those circumstances, REACH restrictions may cover a wide range of situations. Regarding the substances covered by the scope of this restriction proposal, their classification or their hazard profiles, **the aim of a restriction would be to limit the migration of the substances of concern identified in single-use baby diapers, not-withstanding the reason for their presence in the finished article** (In the present restriction proposal, the substances of concern are not intentionally used in the single-use baby diapers). Indeed, as explained below, there are – at the current

stage – only assumptions on the sources (raw material, manufacturing processes, etc.) of the chemicals of interest for this restriction.

- Then, the scope of the restriction has to be defined precisely, including the substance as well as the definitions of the consumer article targeted. This requirement is important to ensure the effectiveness, the enforceability and the monitorability of the restriction but also its consistency with other existing pieces of legislations which may cover the same or close field. This capacity highly depends on the quality of the information provided in the registration dossiers. More details are available in section 5.4.

- Last, an "unacceptable" risk has to be demonstrated. This "unacceptability" is not strictly defined in the REACH technical guidances or the legal text but it implies that the argumentation has to be scientifically-based and the risk robustly demonstrated, such as described in the Guidance on Annex XV Restrictions. The proposal submitted by the Member State (or ECHA) has thus to include a hazard and exposure assessment as well as a risk characterisation. Although a certain level of uncertainty might remain (if highlighted and treated) in the demonstration, the analysis has to be as precise as possible and supported by evidences. To that respect, depending on the quality of the information provided in the registration dossier, this capacity may be hindered or made easier. As shown in this restriction proposal, after performing a QHRA having applied a refined scenario, realistic worst-case assumptions and considering single use baby diapers not being the only source of exposure to chemicals, health thresholds have been exceeded for hazardous chemicals (PAHs, PCDD/Fs, DL-PCBs, formaldehyde).

A restriction proposal recently adopted by ECHA's committees on skin sensitisers in textiles, leather, fur and hide articles ("skin sens. in textiles").

It is acknowledged that the restriction proposal calls for an explanation of the under process REACH Annex XVII restriction on skin sensiters in textile, leather fur and hide as ar as formaldehyde and benzo[def]chrysene are concerned. The skin sensitisers in textile, leather, fur and hide restriction aims at restricting the content of formaldehyde and benzo[def]chrysene in, among other articles, single-use baby diapers. It will be enforced through a dedicated analytical method. This restriction deals with the skin sensiting properties of formaldehyde and benzo[def]chrysene only. In the Annex D, more explanations are given about two others restrictions (PAHs in mixtures and articles and Formaldehyde and formaldehyde releasers) and their possible overlap with the present restriction proposal.

An overview of two restriction options (RO) that have been considered are presented in Table 16 below, including a brief description of the option and the Dossier Submitter's considerations with respect to risk reducing capacity, proportionality to the risk and practicability.

Table 16 : Overview of possible restriction options (ROs)

Restriction option	Description	Considerations with respect to risk reduction capacity, proportionality to the risk and practicability
RO1	In this RO, formaldehyde, the sum of the sum of detected or quantified 17 PAHs and the sum of quantified PCDD/Fs, DL-PCBs and the sum of quantified PCBs are covered.	This option is assessed further in the impact assessment section, defined as RO1. This is the proposed restriction option.

	Migration limits based on a QHRA approach are set.	It is considered as efficient in reducing the risk, as well as proportionate, affordable, monitorable and enforceable.
RO2	This RO has a broader scope than RO1. It covers the same chemicals as RO1 and also all the congeners of the PAHs, all the congeners of the PCDD/Fs, and DL-PCBs. The conditions of the restriction and migration limits are unchanged compared to RO1.	This option is further assessed in the impact assessment section, defined as RO2. Depending on whether the measures and technical solutions implemented under RO1 would be sufficient to already remove congeners from the diapers, benefits associated with RO2 are expected to be similar as RO1. There is some uncertainty whether the testing and enforcement costs associated to RO2 would be similar or higher than the costs associated to RO1 (a higher number of substances would have to be tested and monitored (not quantified) but it may be possible that costs would not be higher in case congeners and substances would be tested simultaneously without additional testing burden). RO2 is also considered proportionate (but whether it is similarly proportionate as RO1 is somehow uncertain). Practicality and monitorability of RO2 are not expected to be significantly different from RO1.

2.2.2. Introduction of labelling requirements

Harmonised classification of substances according to the CLP regulation entails requirements, such as labelling.

The substances that are of concern in this proposed restriction are residues or contaminants and are part of chemicals groups with a hazard profile well known, even if all the chemicals do not have a harmonised classification yet.

The proposal of harmonised classification is possible for a group of substances, but requires a long process before inclusion in the ATP.

Therefore, this risk management option does not seem to be the appropriate way to deal with the issue of hazardous chemicals in single-use baby diapers.

In the case of risk management of hazardous substances in baby diapers, harmonised classification of substances may aid the implementation of other regulations. A harmonised classification can for example be a tool to help define which substances should be covered by a possible restriction proposal (e.g. DL-PCBs, PAHs etc.).

In conclusions, this risk management option is not appropriate to deal with the scope of this restriction proposal but can be a complementary measure of the restriction procedure according to REACH Regulation.

The main costs caused by the implementation of a labelling restriction would be:

- labelling costs,
- information campaign costs,
- costs of compliance and control by importers and retailers, and

- authority enforcement costs.

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 concentration. This relative cost reduction may be partially offset by the costs of labelling and information. The costs of compliance and control within the diapers articles supply chains and the authority enforcement costs are likely to be similar to the costs in the ban alternative.

2.2.3. Identification as SVHC according to REACH Article 57 and subsequent authorisation

Hazardous chemicals of the present restriction proposal may be identified as SVHC, according to REACH article 57 and put on the candidate list. Once listed on the Annex XIV, the substances may not be used or placed on the market without authorisation. The prioritisation for inclusion in Annex XIV from the candidate list doesn't need to be risk-based but mainly hazard-based (triggered by SVHC identification). Priority is driven by several criteria that are set by Article 58 of REACH and implemented by ECHA following a methodology that has been agreed by the Member States Committee (MSC).

In case substances in Annex XIV are used in articles and pose a risk to human health or the environment, ECHA considers whether these substances may be also restricted on Annex XVII (Restriction) of REACH, according to REACH article 69.2.

In addition, SVHC identification and the authorisation system are designed for risk management of one substance 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. It can not be ruled out that single-use baby diapers are imported from outside the EU.

Identification of substances as SVHC may lead to an improved consumer information as it entails information requirements under REACH Article 33. On request from the consumers, the supplier of the article has to provide information if the article contains more than 0.1% of an SVHC substance. But, according to the analysis reported in the ANSES report and in the literature, hazardous chemicals that are of concern are found at concentrations far lower than 0.1% in single-use baby diapers. That will implies that these chemicals won't have to be notified according to the authorisation procedure.

In conclusion, this regulatory management option is not appropriate to manage the risks due to the hazardous chemicals to be considered for single-use baby diapers.

2.2.4. Harmonised classification of substances under CLP (EC) No 1272/2008

Harmonised classification of substances according to the CLP regulation entails requirements, such as labelling.

All of the substances that are of concern in this restriction proposal are residues or contaminants and are part of chemicals families with a hazard profile well known, even if all the chemicals do not have a harmonised classification yet.

The proposal of harmonised classification is possible for a group of substances, but requires a long process before inclusion in the ATP.

Therefore, this risk management option does not seem to be the appropriate way to deal with the issue of hazardous chemicals in single use baby diapers.

In the case of risk management of hazardous substances in single-use baby diapers, harmonised classification of substances may aid the implementation of other regulations. A harmonised classification can for example be a tool to help define which substances should be covered by a possible restriction proposal (e.g. DL-PCBs, PAHs, etc.).

In conclusion, this risk management option is not appropriate to deal with the scope of this restriction proposal.

2.2.5. Other legislations

2.2.5.1. The General Product Safety Directive (GPSD) (EC) No 2001/95

The GPSD requires all consumer products to be safe when placed on the European market. The GPSD sets a number of requirements that needs to be met by producers (and importers) and distributors in order to secure consumer safety, including taking appropriate action to avoid risks, e.g. by withdrawing a dangerous product from the market or warning the consumers of a specific danger concerning a certain product.

However, the regulation concerns actions made towards specific products that unexpectedly pose a risk under normal or reasonably foreseeable conditions of use and not towards a more general hazard. 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 (rapid intervention). 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. This type of procedure does not happen very often. It was previously applied for the highly irritant chemical substance dimethyl fumarate (DMF), which is now regulated under REACH Annex XVII.

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.

To conclude, the GPSD seems not to be protective enough regarding the numerous hazardous chemicals that can be found in single-use baby diapers and that are of concern.

2.2.5.2. The Medical Device Regulation (EU) No 2017/745

As incontinence diapers are considered as medical devices according to the regulation (EU) 2017/74521 and due to the fact that single-use baby diapers and incontinence diapers are

[21] From May, 26th of 2020, directive 93/42/EEC applying to medical devices until this date.

made the same way and have a similar composition, including single use baby diapers in this regulation could have been a risk management option.

However, according to this regulation a medical device means any instrument, apparatus, software, implant, reagent, material or other article intended to be used by the manufacturer, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Considering that acquisition of toilet training by children is not a disease, a single-use baby diaper can not be considered as a medical device because it is an article not used to achieve a function that the human body could not achieve anymore.

In conclusion, the risk management option consisting in including single-use baby diapers as medical devices can not be an option to regulate the risks due to hazardous chemicals in these articles.

2.2.5.3. Childcare articles

A definition of "childcare articles" was inserted by the 22nd amendment of Council Directive 76/769/EEC, (which was repealed by REACH, Annex XVII) *via* the Directive 2005/84/EC of the European Parliament and of the Council. Directive 76/769/EEC was amended so that the following definition for childcare articles was added in its Article 1(3)c: "childcare article" means any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. Hence the intention of the legislator was to use this definition for the purpose of all the restriction provisions and thereby this to be applicable for the entire Directive 76/769/EEC. Therefore, the same definition appears in entries 51 and 52 of Annex XVII, providing an indication of what should be generally considered as a "childcare article" in the context of all Annex XVII (to REACH) provisions.

So single-use baby diapers can be considered as childcare articles regarding the above definition.

This definition does not imply any limitation regarding the chemicals to be used excepted for the phthalates that are restricted in childcare articles under REACH.

In conclusion, this risk management option is not appropriate to deal with the scope of this restriction proposal.

2.2.6. Development of a specific EU product legislation covering single-use baby diapers

Today, the regulation of hazardous chemicals in single-use baby diapers is only driven by the General Product Safety Directive (2001/95/EC).

Consequently, a specific single-use baby diapers act would have the advantage of imposing uniform requirements on chemicals in single-use baby diapers and on the development and dissemination of relevant information in the supply chain. However, the development of a specific single-use baby diaper regulation is possible on 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 in that act.

2.2.7. Voluntary actions

The Scientific Committee on Consumer Safety (SCCS) provides the Commission with opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and services (e.g. tattooing, artificial sun tanning). These opinions should also include when relevant, identification of research needs to address critical information gaps, assessment of proposed future research actions and of research results.

So taking into account the fact that ANSES already performed a QHRA on single-use baby diapers and showed health thresholds exceeded for some hazardous chemicals, asking SCCS to develop an opinion on these chemicals could be a management option.

This opinion could be then sent to the industry as a guide to ensure safer single use baby diapers.

However this guide won't be mandatory for the industry and won't include enforcement measures for the authorities to control if single-use baby diapers put onto the market will follow the recommendations.

In conclusion, the risk management option consisting of developing a guide to the industry through SCCS can be considered as complementary measures before the most adequate risk management option will be put into force.

2.2.8. Conclusion on the most appropriate risk management option

The alternative RMOs presented above have been discussed after the publication of the ANSES' RMOA, and then carefully considered by the Dossier Submitter. Given current conditions, the Dossier Submitter believes that the most efficient way to regulate the substances of concern in single-use baby diapers is to address them as a group and using relevant legal instruments available in REACH. EU-wide legally binding regulatory measures in REACH will impose equal conditions for the entire EU market and will make it easier for the companies to set demands on the suppliers.

The Dossier Submitter considers restriction under REACH Article 69.1 as the most appropriate RMO. Restriction enables regulation of groups of substances, may apply to imported articles and may cover all types of hazard endpoints.

Two restriction options were analysed in the framework of the elaboration of this restriction proposal. Both are considered are similarly proportionate to mitigate the risk.

2.3. Restriction scenario(s)

In response to the proposed restriction option (RO1), actors in the supply chain and society as a whole are expected to react as follows:

- Single-use baby diapers industry in the EEA31 will in some cases incur increased costs due to this restriction (compliance costs) and it may be anticipated that some of these costs may be pushed down the supply chain to the distributors and finally to the consumers. However, the Dossier Submitter considers that this potential increase (if any) would likely be limited given the very high level of price competition on the single-use baby diapers market currently within EEA31. Even though extra costs would be borne by diapers industry due to the restriction, these extra costs are expected to be absorbed by the upstream supply chain. For more details please refer to section 2.4.

- Consumers are not expected to decrease their consumption since demand on this market seems to be quite inelastic driven by the need for a baby to wear a diaper for convenience and toilet-training reasons.

- Since the 2019 ANSES' risk assessment and French RMOA have been published, industry claimed to have made considerable efforts to further control and tests their raw materials, products and manufacturing process all along their supply chain. Consequently, they seem to already have started implementing some preventive measures.

- The actors in the supply chain (including distributors) in the EEA31 will have to deplete single-use baby diapers in stock prior to the entry into force of the restriction. This can induce a forced sale, but it can be anticipated that this can be combined with already planned sales. The way existing stocks would be depleted in the supply chain (gradually – business as usual speed - , depletion of stock until the entry into force of this restriction or forced sale) depends on the capacity of the transitional period to allow such a depletion. The Dossier Submitter considers that the proposed transitional period of 24 months would provide sufficient time to the supply chain to adapt and to gradually deplete existing stocks.

- The analysis of alternatives performed shows that technically and economically feasible technical solutions exist. Difficulties are however expected from a technical and/or economical standpoint regarding the analytical feasibility for testing and monitoring capacity of the restriction. For now, no standardised analytical method exists using an extraction by urine simulant in a whole diaper. Considering that companies, laboratories but also EU enforcement services will have to build this new

analytical method, even define a CEN standard, the transitional period of 24 months is considered by the Dossier Submitter as necessary.

- Enforcement authorities in the EU Member States shall put the necessary measures for control in place. This would also include, as already mentioned, the development of standardised testing methods for the substances of concern.

2.4. Assessment of restriction option 1 (restriction proposed)

SEAC box

SEAC found it difficult to reach a conclusion on the possible socio-economic impacts associated with the proposed restriction due to the uncertainties related to e.g. the contamination sources, the feasibility of reducing or eliminating the contamination and what industry would do in the restriction scenario.

The details of the SEAC evaluation are reported in the SEAC opinion.

2.4.1. Economic impacts

The economic impacts expected from the restriction proposed largely depend on the way industry is likely to react to the new obligations enforced by the restriction and the measures they will implement to reduce contamination of their products to meet the legal concentration limits. From the information collected, industry has identified possible sources of contamination and has drawn some possible leads of technical and substitution solutions. The solutions foreseen by industry are overall converging, therefore their implementation is considered likely by the Dossier Submitter. However the exact industry reactions cannot be anticipated and remain to some degree uncertain.

The economic impacts presented in this restriction proposal correspond to the overall compliance costs of reducing or removing the contaminants targeted in this restriction proposal in finished products onto the single-use baby diapers industry due to the substitution and technical changes assessed above and considered as likely. These costs are based on the information collected from the stakeholders consulted during the preparation of this restriction proposal (for further details about this consultation, please see Annex G.) and during the consultation of the Annex XV report, and are assessed qualitatively or quantitatively. Economic impacts on industry include direct costs of removing or reducing contaminants from raw materials, manufacturing process and other steps in the supply chain (section 2.4.1.1) as well as testing costs (section 2.4.1.2). Testing costs for control authorities are also assessed (section 2.4.1.2) as well as economic impacts on consumers (section 2.4.3.1).

According to the information collected from industry and additional literature research and experts consultations performed by the Dossier Submitter, and as detailed in Annex E.2.1.2.6, the Dossier Submitter is of the view that:

- Raw materials is one of the possible source of contamination given that:

  - Some of them are produced with temperatures above temperatures considered as "safe" (SAP, non-wovens and elastic films in particular);
  - Some raw materials may contain residues from combustion (cellulose);
  - Some others are reported to contain contaminants and hazardous chemicals (glues, pigments and wetness indicator);
  - Cellulose pulp manufacturers may adopt TCF bleaching processes to limit production of chlorinated dioxins and furans. The Dossier Submitter does not have any study available to compare the levels of chlorinated products in pulp and single-use baby diapers to be sure that the searched levels of chlorinated products are similar. It is therefore necessary to undertake assays on cellulose derivatives. Eventually the Dossier Submitter would like to underline that the choice of a bleaching process may not be as clear as it seems to reduce the presence of the chlorinated chemicals (PCDD/Fs and DL-PCBs);
  - As a conclusion, in order to comply with the migration limits proposed in this restriction proposal in the finished products (section B.10.2.2), the raw materials used to manufacture single-use baby diapers should be better selected and further tested and controlled. The development of stricter specifications for raw materials should be also implemented. The raw materials which do not have any technical function, are not necessary to manufacture a single-use baby diapers and are possible sources of contamination, may be removed and no longer be used.

- Manufacturing process is another possible source of products contamination. As the substances subject to this restriction are not intentionally used as "ingredients" for diapers during the manufacturing process, reformulations using alternative substances is not a viable option for diapers manufacturers. However, different technical measures could be implemented to further reduce contamination of products:

  - Even though processing temperatures usually should not exceed 180°C – 200°C under normal conditions of manufacturing, and despite suppliers recommend similar temperatures applications for their raw materials (e.g. glues), it cannot be excluded that higher temperatures and over-heating may occur at certain critical points of the manufacturing process (e.g. during transitional paces of a heating press while starting and maintaining temperatures). Involontary incidents can not be excluded. Excessive temperatures cannot be discarded as one of the possible causes of contamination of the products during the manufacturing process and should be further controlled.
  - Regarding glues as potential sources of contamination during the process, as mentioned in Annex A.1, some diapers manufacturers now produce so-called 'glueless' baby diapers based on alternative bonding technologies. This innovation could be of interest in terms of human health protection and it would worth investigating further. However, to the Dossier Submitter knowledge, these diapers are produced by only one company in Europe that did not provide any information during the preparation of this restriction proposal in spite of Dossier Submitter's requests. The Dossier Submitter is therefore not in a position to recommend this technology as a possible solution to glues contamination. For more details about "glueless" diapers, please see Annex E.2.2.2.2.

- Additionally to further reducing and controlling temperatures, diaper manufacturers should make all possible efforts to improve in general their manufacturing processes to minimize presence of chemical substances (PCDD/Fs, DL-PCBs, formaldehyde, PAHs) in products.

- Air contamination may also be a possible cause since the contaminants targeted in this restriction proposal are natural contaminants. Further air filtration, air controls and higher frequency of dust clean-up should be carried out following the best practices.

- No conclusion can be made on the impact of transport and storage as a possible source of contamination even if it is not formally excluded that some of the pollutants could reach the finished products in the time interval between manufacture and consumer purchase (during transport and/or storage for instance).

2.4.1.1. Costs of removing or reducing contaminants in products

2.4.1.1.1. Substitution costs related to raw materials used

Moving to totally chlorine-free (TCF) pulp

As presented in Annex A.1, currently two bleaching processes are used:

- the ECF (elemental chlorine free) method, which uses chlorine dioxide; this is the most commonly process used worldwide to bleach cellulose (95% of cellulose producers) (Counts *et al.*, 2017).
- the TCF (totally chlorine free) method, which uses hydrogen peroxide, oxygen or ozone is used by 5% of cellulose producers (Counts *et al.*, 2017).

During the preparation of this restriction proposal, the single-use baby diapers industry have been extensively consulted and challenged by the Dossier Submitter on the bleaching issue and types of pulps (additionally to Dossier Submitter's own investigation and literature research). As presented in Annex E.2, comparison of the two processes allows for the following overview:

- PCDD/Fs have been quantified in single-use baby diapers and may be assumed to come from cellulose bleaching and/or residues of combustion in cellulose
- PCDD/Fs are possibly assumed to come from bleaching but given the types of PCDD/Fs detected (specific congeners 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) which are highly chlorinated, some manufacturers state that it is more likely that they are produced rather from combustion than bleaching.
- Still, bleaching TCF process seems to allow for reduction of highly chlorinated dioxins in pulp but is reported to still contain traces of PCB.
- ECF process with chlorine dioxide seems to reduce the quantity of chlorinated products in pulp but does not eliminate them (*"ECF bleaching is capable of reducing 2,3,7,8-TCDD and 2,3,7,8-TCDF to undetectable levels" ;* JRC, 2015*)*. The Dossier Submitter does not have any study available to compare the levels of chlorinated products in pulp and single-use baby diapers to be sure that the searched levels of chlorinated products are similar. It is therefore necessary to undertake assays on cellulose derivatives. Eventually the Dossier Submitter would like to underline that the choice

of a bleaching process may not be as clear as it seems to reduce the presence of the chlorinated chemicals (PCDD/Fs and DL-PCBs).
- Likewise, it may be assumed that DL-PCBs may come from chlorine process: it is reported by diapers industry that bleaching ECF process seems to less generate PCBs than TCF but leads to traces of highly chlorinated dioxins.

As explained in E.2.2.1.1, 5% of the manufacturers have already chosen TCF pulp over ECF pulp for a long time (Counts *et al.*, 2017). From the publication of the ANSES' 2019 expertise and the French RMOA, a few companies have informed the Dossier Submitter that they have substituted from ECF pulp to TCF pulp already or are about to do it. Most of them however seem to make this move more by precaution than based on chemicals-contamination evidence. Some other diapers manufacturers are more skeptical about the benefit of moving from ECF to TCF pulp to reduce contaminants in the pulp and thus the final products due to the trade-off between the presence PCBs vs dioxins, the environmental impact (higher energy- and raw materials-consumption of TCF process) as well as differences in cost and performance. From the information the Dossier Submitter could gather on TCF pulp supply, in Europe there seems to be only one supplier of TCF pulp for an application in single-use baby diapers on the EU market currently (see Annex E.2.3.1). The impact of moving to TCF pulp from single-use baby diapers manufacturers on the TCF market will depend on the capability of the TCF pulp suppliers to adapt and to the elasticity of TCF pulp market to demand. A massive move to TCF pulp would affect dramatically the demand upward on TCF market: if the availability of TCF (currently low) would remain the same (due to unavailability of supply, scarcity of raw materials to make TCF pulp, incapacity of the sole EU supplier to adapt, or other factors) then the price of TCF pulp may increase and the extra-cost for baby diapers manufacturers may get significant. On the contrary, it may be also possible that new TCF suppliers may enter the market and price would actually decrease. An increase in demand may generate additional profits to the current TCF pulp producer in Europe and it may also be a market opportunity for other pulp companies to enter and widen this market. It may also happen that some current ECF pulp producers would diversify their portfolio by partly supplying TCF pulp while keeping on supplying ECF pulp, since fluff pulp production line in mills is not locked to one market or one specific hygiene product category. Fluff pulp end-uses encompass a wide range of absorbent hygiene products besides baby diapers, as well as pulp fibre for production of many other products for home and hygiene purposes. It is also not known to what extent current ECF pulp suppliers may adapt and supply TCF pulp instead after the entry into force of the restriction. The Dossier Submitter does not have information on supply of TCF from outside EU that could be imported within the EU market to complement domestic supply and to help meet the higher demand. As impacts from the switching to TCF pulp, industry reports:

- In a worst-case situation, if supply cannot meet demand, a quick shortage of TCF pulp globally because there is not enough TCF available to convert all ECF products into TCF. Industry considers that several years would be necessary to develop such a capacity and to move to TCF pulp. This may lead to the unavailability of single-use baby diapers for consumers;
- Time needed to switch to TCF products is reported by industry to be at least 2 years with extra-investments associated. These extra-investments may represent more than 1-1.5 million€ (one-shot cost) per single-use diapers manufacturing company depending on the number of sites according to industry. These investments are

presented as necessary in order to manage and treat several types of pulp on one single site;
- Technically, since performance and treatment efficiency are lower with TCF fluff (more TCF pulp is needed to supply the same level of performance of the finished product and TCF pulp is claimed to be more complicated to treat), extra-costs may be expected due to the use of a higher quantity of raw material and more transport (and environmental impacts associated). However those costs have not been provided by industry and the Dossier Submitter has no information at hand allowing a quantification;
- More dust would be generated during the manufacturing process of diapers that would require additional challenges in terms of further air filtration and staff safety (the Dossier Submitter has no more information available regarding why more dust can be generated);
- Finally, moving to TCF pulp would impact the final price of baby diapers (for further details, see section 2.4.3.1).

All in all, it is difficult to estimate the overall cost of moving from ECF pulp to TCF pulp given that the availability of TCF pulp is today rather low and could change over time driven by stricter regulation such as this restriction proposal. Nevertheless, **the diapers manufacturers consulted during the preparation of this restriction proposal still provided (rough) estimate of this extra (annual) cost that would be between 200,000€ and 400,000€ per single-use diapers procuding company (based on difference in pulp costs) i.e. between 950,000€-5,700,000€ for the whole EU manufacturing market plus extra (one-shot) investment of €1-1.5 million per company (due to technical treatment challenge of TCF fiber compared to ECF fiber) (please refer to Table 17).**

In relative terms, according to the companies consulted, moving from ECF cellulose to TCF cellulose would represent an extra (annual) cost of at least 17% (under current market conditions) for them, due to the higher costs of TCF cellulose and given the current low availability of TCF on the EU market.

This cost increase is uncertain and includes extra cost of purchasing (more expensive) TCF pulp, extra cost due to technical treatment challenge of TCF fiber, and extra cost due to additional FSC certification (since TCF is only available as certified under FSC certification- no more information is available to the Dossier Submitter regarding this link between TCF fiber and extra costs). The magnitude of this costs depends on the size of their market and their manufacturing volume. **Some companies indicate that the extra-cost of moving to TCF pulp would represent between +1% and +2% of their current costs per products range.** From those estimates, the Dossier Submitter considers that switching to TCF pulp may be economically feasible, at least for big companies and provided that they have sufficient time to operate this move. Diaper industry reports that where large companies may be able to offset to a certain extent such investments due to high diaper production volumes, this offset may be less likely for those producers with a smaller production volume such as SMEs. As a consequence, SMEs might have more difficulties to move to TCF pulp depending on the capability of the TCF pulp market to increase its supply while controlling the price increase of TCF pulp to a sustainable level for them.

Total costs of moving to TCF pulp for EU diapers manufacturing companies was assessed by the Dossier Submitter to 5-25 million €/year with a medium estimate of 15 million€/ year (corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%). This cost corresponds to the annualized net present value discounted at 4% over 10 years from 2024 (for more details please refer to Table 17). For sensitivity analysis purposes, if it is assumed for the low scenario that no diapers manufacturers would switch to TCF pulp, this costs would thus be 0-25 million €/year.

The Dossier Submitter does not have further information to anticipate about the evolution of TCF pulp market in case industry would massively move to this raw material as a consequence of this restriction and can not judge about any potential shortage of finished products and the actual impacts of the costs. In order to tackle potential adverse effects on the market (prohibitive costs increase and shortage), the transitional period recommended in this restriction proposal, meaning 24 months, is of utmost importance in order to take TCF market situation and availability into account and give sufficient time to suppliers to adapt. During the public consultation, industry confirms 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.

In conclusion, and as explained in Annex E.2.2.1.1, based on the information at hand, it is difficult for the Dossier Submitter to have a clear-cut conclusion about the better capability of TCF pulp to address the health concerns targeted in this restriction proposal over ECF pulp. Within all the possible solutions to reduce contamination in single-use baby diapers identified, moving to TCF pulp could be an option but given the uncertainties associated to its benefits to human health, its availability in the future and its economic feasibility especially for SMEs, the Dossier Submitter can not strongly recommend this substitution without reservation. Nevertheless, if industry decided to switch to TCF pulp (some have already done it), the information presented above, in particular regarding economic impacts expected would be useful to anticipate the possible costs associated. However, this switch would not substitute to the proposed restriction and should only be seen as a complementary approach based on private decisions.

Substitution of types of glues used

As presented in Annex E.2.1.2.1, several diapers manufacturers consulted reported that glues may contain PAHs traces (especially resins from glues as well as construction and elastic glues; see Annex E.2.1.2.1). Glues used to assemble the different parts of a single-use baby diapers are generally hot melt adhesives, i.e. thermoplastic adhesives in solid form, designed to be melted by a heating element to provide it with adhesion properties. The main resins used in hot-melt adhesives are ethylene-vinyl acetate copolymer, polyamides, polyolefins (mainly polyethylene) and polyesters. Glues can also be copolymer rubber (e.g. SBR, EPDM) and starch (for more details, see Annex A.1). Unfortunately the exact composition of any of these glues could not be obtained from suppliers due to confidentiality and business secret.

According to the experts and chemists consulted by the Dossier Submitter, glues are not expected to be the source of contamination *per se*, but they could be when heated during the

manufacturing process if temperatures exceed 200°C. During the public consultation, some industry claimed that if a too hot temperature is used while using hotmelt adhesives, this will not result in PAHs formation but instead in a reduction in performance of the adhesive.

Based on those findings, substitution of glues used to manufacture single-use baby diapers is not considered as a solution to reduce contamination of finished products and may not be necessary. As a consequence, there is no substitution cost associated assessed.

Removal or substitution of wetness indicator

As explained in Annex A.1, a wetness indicator is a common feature in many single-use baby diapers and toilet training pants. It is a feature that reacts to exposure of liquid as a way to discourage the wearer to urinate in the training pants, or as an indicator for parents that a diaper needs changing. Many diapers that contain a wetness indicator seem to use a chemical called bromophenol blue (CAS 115-39-9). Bromophenol blue is a pH indicator, it changes colour depending on the surrounding acidity or alkalinity. In diapers, bromophenol blue appears yellow when the diaper is dry, but the slightly alkaline pH of urine causes its colour to change to blue when the diaper is wet. Other patents suggest that some other diapers use chemicals that are sensitive to moisture as indicators, though it is unclear how these compounds cause a colour change to appear. **The Dossier Submitter does not have information about other pH indicators available on the market that would be also used for this function as wetness indicators in single-use baby diapers (see Annex E.2.3.2).**

Moreover, as indicated in Annex E.2.1.2.1, one diaper manufacturer indicated that wetness indicator can contain PAH even though wetness indicator is not in contact with the baby skin and no PAH has been detected in their finished products. For this manufacturer, the detection of PAH in the wetness indicator used has led to the replacement with a non-detectable PAH-level wetness indicator. **The Dossier Submitter does not have further information neither about this substitute nor about the cost of substituting it.** The company did not provide evidence from chemical analysis about the fact that the new wetness indicator presents a non-detectable PAH-level.

Regardless of substitution cost due to the replacement of wetness indicators, as explained in Annex E.2.2.1.3., the acceptability of using such a material in the finished products may be questioned given that wetness indicators do not have essential technical function to manufacture a single-use baby diaper and are only used for parents' convenience reasons. If they are possible source of contamination, they could be basically removed from the diapers without impeding the absorbing function of the diapers.

On this basis, the Dossier Submitter considers that wetness indicators may no longer be used in the single-use baby diapers if they are possible sources of contamination and given that they do not meet any essential technical function in single-use baby diapers. In terms of economic impacts, the removal of wetness indicators to the products may negatively affect manufacturers' sales and profits since this feature may stand for a competitive advantage for them. The Dossier Submitter does not have information allowing to confirm and quantify any loss in profit. 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 wetness indicators from their products would represent cost savings for manufacturers due to fewer materials to purchase and process.

Removal or substitution of pigments

Single-use baby diapers may be colored onto their external sheets to make them more attractive and fancy.

As indicated in Annex E.2.1.2.2., according to one company, a green pigment used in aesthetic printing may be the source of OCDF and OCDD in external sheet and external film: in 2018 the green pigment was reformulated and more than 10,000 modifications related to improved raw materials were implemented. These changes are pretended to now allow for non- detectable levels of PCDD/Fs. **The Dossier Submitter has no knowledge about neither details about this reformulation, nor about whether the other manufacturers carried out the same change or what was the cost associated (see Annex E.2.3.3.).**

Similarly to the wetness indicators, and regardless of substitution cost due to the replacement of this type of pigment, as explained in Annex E.2.2.1.4., the acceptability of using pigments in the finished products may be questioned given that pigments do not have essential technical function to manufacture a single-use baby diaper. They are only used for aesthetic reasons and may be considered as marketing assets only. If they are possible source of contamination, they may be removed from the diapers without impeding the absorbing function of the diapers.

On this basis, the Dossier Submitter considers that pigments may no longer be used in the single-use baby diapers given that they are possible sources of contamination and they do not meet any essential technical function in single-use baby diapers. In terms of economic impacts, the removal of pigments may negatively affect manufacturers' sales and profits since this feature may stand for a competitive advantage for them. The Dossier Submitter does not have information allowing to confirm and quantify any loss in profit. 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 pigments from their products would represent cost savings for manufacturers due to fewer materials to purchase and process.

Overall better selection and control of raw materials: moving to best practices

As explained in Annex E.2.3., beyond the identification of particular raw materials used in single-use baby diapers as potential contamination sources, the Dossier Submitter is of the view that overall, diapers industry from upstream to downstream should be particularly careful about the raw materials used and present in the diapers they produce, supply and sell by a stricter and better selection of raw materials upstream by suppliers. Moreover, manufacturers should reduce the level of contamination downstream in the finished products (provided that the manufacturing process and other steps in the supply chain are concurrently also further controlled, see next sections). More stringent regulations on single-use baby diapers such as this restriction proposal are expected to re-think and trigger best selection

and manufacturing practices towards safer and more eco-friendly raw materials. Industry reports that overall, stricter selection and controls on raw materials would cause fewer compliant raw materials eligible to be used in the baby diapers manufacturing and higher prices for those. However, this statement has been provided in broad terms without costs specification or quantification. Moreover, **the costs of moving to these best practices are difficult to estimate due to the high number of raw materials at stake but the manufacturers consulted indicate that stricter chemical quality requirements from suppliers would reduce the variety of sources of raw materials and would entail extra costs due to increasing tests to be carried out to select compliant raw materials (for more details about these tests, please see section 2.4.1.2). Availability of those fewer compliant raw materials may also decrease and their prices increase. The Dossier submitter does not have further information allowing for a quantification of these costs.**

2.4.1.1.2. Mitigation costs related to manufacturing process

Further controlling temperatures and general improvement on the process

As a good practice, diapers manufacturers indicate that they perform regular temperature controls on their production lines (automatically and/or by operators) in order to avoid e.g. temperatures above 200°C, uncontrolled combustion and potential generation of undesired contaminants such as PAHs.

However, as indicated above and in Annex E.2.1, despite temperatures controls already carried out on the manufacturing equipment so that they do not exceed 180°C – 200°C under normal conditions of manufacturing, it cannot be excluded that very high temperatures and over-heating may occur at certain critical points of the manufacturing process (e.g. during transitional paces of a heating press while starting and maintaining temperatures). Involontary incident can not thus be excluded. Excessive (above 200°C) temperatures cannot be discarded as one of the possible causes of contamination of the products during the manufacturing process and should be further controlled. These controls should be targeted primarily on hot points such as the ones involving in gluing and thermo-welding operations.

The cost of further controlling process temperatures has not been communicated by diapers manufacturers. None of them consider that temperatures may be a cause of contamination during the production of single-use baby diapers, therefore they do not see the need for further controlling or reducing them. In case they would have to still implement stricter and more regular controls on their production lines, extra costs may be expected due to more frequent lines monitoring and maintenance. 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 significant due to the fact that those controls are already done routinely by the diapers manufacturers.

Additionally to further controlling temperatures, diaper manufacturers should **improve in general their manufacturing processes** to minimize presence of chemical substances (PCDD/Fs, DL-PCBs, formaldehyde, PAHs) in products by further controls on each step of the manufacturing process from the reception of raw materials to their circulation indoor to the packaging (solutions related to indoor air and packaging are developed herebelow). These

further controls would imply higher testing costs and more regular audits on the production lines which are analyzed further in section 2.4.1.2.

Moving to fluffless diapers

Up to now, the majority of the cores of single-use baby diapers are made of a mix of fluff pulp and SAP. After last developments and new SAP generations this fluff function has become less and less important. Therefore a goal for all hygiene absorbent product producers is to eliminate usage of fluff and obtain a core made of SAP only. Please refer to Annex E.2.2.2.3 for further explanations.

The Dossier Submitter has not assessed the cost of moving to fluffless diapers due to a lack of data. Moreover, experts consulted during the elaboration of this restriction proposal stated that a higher pollution process compared to the process currently used can occur.

2.4.1.1.3. Mitigation costs related to packaging changes

As explained in Annex E.2.3.3., 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 diapers packaging to make them more "air contaminant-proof" during storage and transport. The purpose of vent holes is to eject air more easily during the packaging of baby diapers. An illustrative picture of vent holes is provided in Annexe E.2.3.3.

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

2.4.1.1.4. Other mitigation costs due to changes and measures to remove contaminants

Further decontamination of indoor air

As explained in Annex A.2.2.4.1, producing in clean rooms is considered unfeasible by manufacturers and absolute filtration cannot be reasonably guaranteed. Based on their own air analysis at production site, a very few companies consulted recognize that further indoor air filtration may be achieved through generalizing central air filtration systems to reduce as far as possible (not eliminate) the presence of outside air pollutants indoor. During the preparation of the proposal, these companies did however not communicated precise estimate of extra-cost due to e.g. additional investment nor any economic feasibility concern associated with further air filtration. They only broadly reported that the needed investments would amount *in the millions euros per production plant*. During the public consultation, industry indicated that providing specific cost estimates is difficult as the actual engineering and cost will be site dependent and influenced dramatically by the level of filtration required, the fan capacity required for the site's size etc. Industry confirmed that experience installing systems in several sites shows the cost is in the millions of Euros range per site for a new installation. However, they specified that upgrading the filtration level in existing systems can be equally expensive as fan and ducting systems generally also need to be upgraded to cope with

additional pressure drop. One member company shared a cost of over 5 million Euros for a filtering system upgrade for a medium sized manufacturing site. This cost is considered by the Dossier submitter only illustrative and cannot be computed in order to get a total cost for the whole market.

In sum, the Dossier Submitter does not have further information allowing for a quantification or specification of these costs. Should implementing further filtration would imply to re-invest in total different air decontamination systems or simply to adjust the system on the spot is uncertain. As a collateral consequence, further filtration would have positive impacts on workers health.

Nevertheless, as also indicated in Annex E.2.1.1., as a good and best practice, air filtration and dust management systems are in principle in place at production site to help reduce levels of airborne pollutants. Materials are covered in protective packaging materials until they are delivered to the production line to be used. Indoor air is centrally filtered to guarantee certain air quality (blockage of pesticides and reduction of other potential chemical traces such as PCDD/Fs, PCB from outdoor air). Example of air filter used is also provided in Annex E.2.1.1. Therefore, all manufacturing sites are expected to currently already follow good or best practice in terms of indoor air filtration and most of the companies consulted during the preparation of the dossier do not seem to consider this technical measure as the most relevant and cost-efficient to achieve the decontamination goals set by the restriction proposal. During the public consultation, industry re-stated that hygiene levels in most production sites is already very good.

Additionally, diapers industry is currently investigating solutions to further isolate the supply chain from the environmental elements. **They report development and significant capital investment to achieve this but do not provide any cost estimate.**

2.4.1.2. Testing and control costs

In this section, the associated administrative costs for testing and enforcement that will be incurred by industry and enforcement authorities in order to ensure compliance with the restriction are assessed. Indeed, additionally and concurrently to the technical changes and substitution, the diapers industry would implement to comply with the restriction, companies would have to control and test their raw materials, products and manufacturing lines in order to ensure compliance. After the entry into force of the restriction, the enforcement authorities will also have to test finished products to ensure that they are compliant with the concentrations limits proposed.

Regarding diapers industry, companies consulted report further costly and time-demanding purity/analytical testing of raw materials and finished products.

From the publication of ANSES 2019 and 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). The companies consulted during the preparation of the restriction thus report the testing costs that would be expected if the present restriction would be adopted, based on the costs already borne since 2019 (analytical costs, record-keeping/work process verification, costs for enforcement / market review). Testing costs claimed to occur by industry in case of a restriction vary from one

company to the other, depending on the volumes of their products range and size. From the information collected:

- **The extra analysis cost to test raw materials seem to be the highest and would range from 50,000€ to 200,000€ per year per single-use diapers manufacturing company depending on their size, monitoring strategy and production volume, i.e 600,000€-80,000,000€ for the whole EU manufacturing market (please refer to Table 18).** This cost range was provided by industry to the Dossier Submitter without details and was claimed to include the cost charged by laboratories as well as internal extra staff to supervise chemical analysis and controls. Companies report that up to 35 materials enter in the composition of a single-use baby diaper and each must be tested. According to the laboratories, the testing cost may vary from 1,000€ (no specific method indicated) to 3,000€ (method with urine simulant, confirmed by industry during the public consultation) per material tested. One company reports that, to this cost, must be added +3,000€ for white values (performed on 1 out of 5 materials tested; i.e. on up to 7 raw materials). Some companies indicate that such costs would represent +300% extra cost compared to current testing costs. Companies also indicate that these costs do not include internal and indirect costs such as staff in charge of managing analysis, procurement costs, etc. The information collected by the Dossier Submitter is provided by the manufacturers of single-use baby diapers themselves and not the suppliers of raw materials (the suppliers of raw-materials consist of an unknown number from inside and outside EU and they are hardly identifiable). How these costs would be shared and split between suppliers of raw materials and manufacturers of single-use baby diapers is not known. Whether part of these testing costs are already borne and internalized by companies (triggered by the publication of Anses's risk assessment and the French RMOA) or whether whole or part of them are only attributable to this restriction remains unclear. Some overlapping cannot be excluded.

- **The extra analysis cost to test finished products would range from 50,000-200,000€ per year per diapers manufacturing company depending on their size and their production volume, i.e. between 240,000€-23,000,000€ for the whole EU manufacturing market (please refer to Table 18).** Again, this cost range was provided by industry to the Dossier Submitter without details. Some companies indicate that such costs would represent +25%-50% extra cost per year compared to current testing costs. Accredited laboratories charge at least 1,000€ (no specific method indicated) per product tested for all the substances of concern in this proposal. It has to be noted that these costs are claimed to be estimated based on current non harmonized analytical methods. These costs might somehow not totally reflect the actual testing costs expected from the restriction (see further below for more details).

- **Other testing and control costs are reported such as costs of audits at production site: one company estimate at around 20,000€ per year chemical analysis on the process;** companies report a cost of at least 1,000€ per process step analyzed.

- **Finally, some companies indicate expenses already spent for extra chemical analysis (all included) and extra audits at around € 5 million over 2 years.**

This cost is hardly interpretable due to lack of specifications. Moreover, if these costs have been already borne by industry they can not be attributable to this restriction.

Moreover, diapers manufacturing industry consider that this further testing will create delays in production of diapers and increased inventories due to the need for a positive release system following receipt of impurity test results. No cost data has been provided associated to these impacts.

The Dossier Submitter also investigated the frequency of tests performed by diapers industry along the supply chain. The information collected is based on consultation carried out during the preparation of this proposal through direct communications with companies as well as additional information collected through the public consultation carried out on this proposal. Regarding the frequency of tests:

- Information from diapers manufacturers is contrasted: some report much higher frequency of tests on finished products than others (between once a month and twice a year at the end of production line); During the public consultation, industry reported much higher frequency on weekly basis.

- As far as distributors are concerned they are more numerous than manufacturers and are of various sizes and business models (online and physical shops, small and big retailers) but are not expected to be impacted significantly by testing costs. Distributors report no testing of raw materials and only testing frequency on finished products around once a year on average;

- As one could expect, the testing on raw materials seem to be mostly carried out by the raw materials suppliers themselves with a reported frequency of about once a month. Diapers manufacturers also test raw materials received from their suppliers but, according to the information collected, to a lesser frequency. Some diapers manufacturers indicated a quarterly testing on raw materials; others indicated every two year testing. During the public consultation, industry then reported much higher frequency on weekly basis. Given the fact that diapers manufacturing companies do not seem to test raw materials themselves routinely but rely on their suppliers instead (and mainly further test raw materials when changing suppliers), the Dossier submitter considers this weekly frequency overestimated.

- In general, it seems that small companies show lower frequency than big companies. This situation may be due to SMEs lower capacity to bear the level of these costs and/or their lower capacity to organize, manage and coordinate these tests.

Additionally to testing costs incurred by European market actors on diapers industry, testing costs might be also incurred to some single-use baby diapers importers to test the presence of chemicals in the scope in their products. This will induce some costs for the importing companies. No further information is available on those.

To the Dossier Submitter’s knowledge, in general, companies would commission standard laboratories for testing the levels of the concerned substances. It is assumed that only a minority of companies would invest money in in-house laboratory devices.

Regarding the overall magnitude of the testing costs for the companies, it has to be noted that all the costs and test frequency reported are not based on harmonized analytical methods (using urine simulant but instead using solvent extraction on a shredded diaper) and this might cause some difficulties to compare and interpret them. The Dossier Submitter may expect some economies of scale in testing practices and costs since some chemicals in the scope of the present restriction are also classified as skin sens. under CLP Regulation and thus fall under the scope of the restriction on skin sensitizing substances (formaldehyde, benzo[def]chrysene). In the skin. sens. in textile restriction under REACH, which covers single-use baby diapers, formaldehyde is proposed to be restricted at 30 mg/kg from an solvent extraction while in this restriction proposal, the limite proposed is **0.42 mg/kg** with an urine simulant extraction from a whole diaper. It is acknowledged that the restriction proposal calls for an explanation of the under process REACH Annex XVII restriction on skin sensiters in textile, leather fur and hide as ar as formaldehyde and benzo[def]chrysene are concerned. The skin sensitisers in textile, leather, fur and hide restriction aims at restricting the content of formaldehyde and benzo[def]chrysene in, among other articles, single-use baby diapers. It will be enforced through a dedicated analytical method. This restriction deals with the skin sensiting properties of formaldehyde and benzo[def]chrysene only.

Moreover, as already explained, since 2019 the companies of diapers industry have been already testing, on voluntary basis, the substances targeted in the scope of the present restriction. **While these additional tests stand for extra-cost for them, they cannot be attributable to this restriction and can be considered as affordable.**

Nevertheless, due to the lack of harmonized analytical methods and the challenges of measuring very low concentration limits such as proposed herein (lower than the LoD/LoQ) (see Annex E8), the testing costs may be actually somehow higher than reported during the consultation by the Dossier Submitter. If the transitional period of 24 months recommended allowed to implement a harmonized analytical method with very low LoD, this issue might be solved. **This is a source of uncertainty.**

<u>Refinement of the testing cost assessment made by the Dossier Submitter</u>

Since the testing costs reported by industry are only based on claims without substantiation, the Dossier Submitter refined their estimate of the testing costs for diapers manufacurers based on different information collected on testing cost per raw material and finished product, frequency and number of product ranges and raw materials tested with a low/medium/high approach:

- The testing cost of raw materials for diapers manufacturers are estimated based on the following assumptions:
    - Frequency: quaterly to weekly (again weekly being considered as overestimated)
    - Cost per raw material tested: from €1000 to €3000
    - Number of raw materials tested: from 15 to 35
- The testing cost of finished products for diapers manufacturers are estimated based on the following assumptions:
    - Frequency: monthly to weekly
    - Cost per finished product tested: from €1000 to €3000
    - Number of products ranges tested: from 2 to 10

Based on this further assessment, the total testing costs for diapers manufacturers (whole EU market) is thus estimated to 0.6-80 million€ / year with a medium estimate of 35 million€/year (annualized net present value discounted at 4% over 10 years from 2024), corresponding to 0.01%-1.10% of the annual diapers market revenue with a medium estimate of 0.5% (for more details please refer to Table 18).

Regarding enforcement costs for authorities, they are administrative costs incurred by Member States' enforcement agencies to ensure that economic actors on the EU-28 market comply with EU regulations. By evaluating data reported from European studies on inspection/enforcement costs of REACH restrictions (ECHA, 2018c), ECHA assessed the administrative burden of enforcement for new restriction proposals. ECHA concluded that based on data reported by Member States, the average administrative cost of enforcing a restriction is approximately €55,600 per year.

This value is estimated based on numbers of controls over the period 2010-2014 reported by Member States (reporting under REACH art. 117 / CLP art.46). The calculation is based on an average cost per control (inspection) and an average number of controls per restriction. ECHA notes that while the average enforcement costs may remain fairly similar over time, as they are driven by budgetary constraints, the costs for individual restrictions would likely vary. It is often the practice that enforcement campaigns focus on newer restrictions or high-risk restrictions considered a priority by Member States, and fewer resources are allocated to restrictions industry is already familiar with.

For the purpose of the current assessment, the value of €55,600 per year should be seen as only illustrative in terms of the order of magnitude of the cost. It might be possible that enforcement cost can be reduced when some of these costs are shared with the enforcement costs associated with other interlinked REACH restrictions and other regulations. To this respect, like for testing costs from companies, the Dossier Submitter may expect some economies of scale in testing practices and costs since some chemicals in the scope of the present restriction are also classified as skin sens. Under CLP Regulation and thus fall under the scope of the restriction on skin sensitizing substances (formaldehyde, benzo[def]chrysene). As already mentioned, it has to be noted that due to the lack of harmonized analytical methods and the challenges of measuring very low limits such as proposed herein (lower than the LoD/LoQ) (see Annex E8), these enforcement costs might somehow not totally reflect the actual costs expected from the restriction (see further below for more details).

For illustrative purposes, the annualized net present value of total enforcement costs was assessed, based on ECHA's average estimate, and would amount to 45,000€/ year (discounted at 4% from 2024) (please also refer to Table 19).

Nevertheless, due to the lack of harmonized analytical methods and the challenges of measuring very low migration limits such as proposed herein (lower than the current LoD/LoQ), the enforcement costs may be actually higher than the average cost of REACH restrictions (for more details, please refer to Annex E). The enforcement and testing costs remain overall unclear. Again, it the transitional period of 24 months recommended would allow to implement a harmonized analytical method with very low LoD, this issue may be solved. **This is a source of uncertainty.**

2.4.1.3. Conclusion on the costs

As explained above, the economic impacts expected from the restriction proposed largely depend on the way industry is likely to react to the new obligations enforced by the restriction and the measures they will implement to reduce contamination of their products to meet the legal concentration limits.

Regarding substitution and technical changes costs, from the information collected, industry has identified possible sources of contamination and has drawn some possible leads of technical and substitution solutions. Overall, the exact industry reactions cannot be anticipated and remain to some degree uncertain. The compliance costs assessment has been performed by the Dossier Submitter assuming that the implementation of these solutions are likely and based on information provided by industry. The costs reported by industry are overall converging but show some uncertainties and discrepancies: some expected costs 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. Moreover, some reported costs might present some overlapping between extra-costs already borne due to new measures implemented as a voluntary response from industry since ANSES' expertise and French RMOA have been published and extra-costs specifically attributable to this restriction proposal. In general, the costs reported by industry are broad estimations due to uncertainties about the restrictions conditions that would actually enter into force and the evolution of the market (such as raw materials and TCF pulp markets). The substitution and technical changes and adaptations costs assessed are summarized in Table 17. **Due to uncertainties, these costs are not considered as an actual estimate of the expected costs of the restriction proposal but are provided as an indication of possible economic impacts industry would cope with in case of a restriction and depending on the technical solutions companies would opt for to make their finished products compliant.**

Table 17: Costs of substitution / technical changes and adaptations likely to reduce contamination

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 single-use diapers manufacturing company (> +17% per year; +1% and +2% of current costs per products range) i.e. between 950,000€-5,700,000€ for the	• Shortage of TCF pulp (low availability) and finished products	++ (time needed to adapt > 2 years)

Substitution/better selection of raw materials		whole EU manufacturing market[22] • 1-1.5 million€ (extra-investments due to technical treatment challenge of TCF fiber) per single-use diapers manufacturing company • 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 million €/year with a medium estimate of 15 million€/ year (corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%) (annualized net present value calculated based on 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 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 (therefore that between 0% and 100% of the diapers manufacturers would switch to TCF pulp), this costs would thus be 0-25 million €/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)		

[22] Based on: 10-15 manufacturing companies and the assumption that between 50%-100% would switch to TCF pulp.

		• Higher costs due to more tests (see below)		
Technical measures on the manufacturing process	Further control of temperatures	• more frequent lines monitoring and maintenance (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		

Whatever the technical or substitution solutions companies would opt for, they would have to make sure that their finished products are compliant before being used by end consumers. Testing costs and test frequency along the supply chain have been assessed by the Dossier Submitter based on information provided by industry and experts and are summarized in Table 18. These testing costs are rather uncertain and show discrepancies: some or part of them seem to be already borne and internalized by companies and can not be attributable to the restriction itself (tests already performed routinely), others lack specifications on what they exactly include. Overall the magnitude of testing costs depend on the companies' size and manufacturing volume (e.g. range of products to be tested). Moreover, all the costs and test frequency reported are not based on harmonized analytical methods (meaning migration though a whole diaper using urine simulant) and this might cause some difficulties to compare and interpret them. Indeed, most of the manufacturers perform analysis by using methods that are not representative of the real exposure (e.g. solvent extraction though a shredded diaper). Without a validated method and scientifically sound thresholds, it will be difficult or even impossible for industry to comply with the restriction and that it may result in a disruption of the market. Hence, the absence of a validated method combined with the challenge for sensitive detection and quantification limits prone to unintended contamination during product pick-up, transport, sample preparation etc.. This is a source of uncertainty.

Due to these uncertainties and to the current lack of harmonised analytical methods, these costs are not considered as an actual estimate of the expected testing costs of the restriction proposal but are provided as an indication of possible testing costs industry would cope with in case of a restriction.

Table 18 : Annual Testing costs expected from industry

Type of tests	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€ per year per company (+300% extra cost); i.e. between 600,000€-80,000,000€ for the whole EU manufacturing market[23] • 1,000-3,000€ charged by laboratories per material tested; up to 35 materials to test	• Raw materials suppliers : once a month • Manufacturers: from quarterly testing to every 2 year (if no change in supplier)	• Delays in production of diapers and increased inventories	++
Extra analysis cost to test raw materials for EU diapers manufacturers (based on Dossier Submitter further assessment)	0.6-82 million€/year with a medium estimate of 41 million €/year	• quaterly to weekly		+
Extra analysis cost to test finished products for EU diapers manufacturers (based on industry claims)	• 100,000-200,000€ per year per company (+25%-50% extra cost); i.e. between 240,000€-23,000,000€ for the whole EU manufacturing market[24] • >1,000€ charged by laboratories per product tested	• Manufacturers: between once a month and twice a year at the end of production line • Distributors : once a year on products samples in shops	• Delays in production of diapers and increased inventories	**++**
Extra analysis cost to test finished products for EU diapers manufacturers (based on Dossier Submitter further assessment)	0.24-23 million€/year with a medium estimate of 4.8 million €/ year	• monthly to weekly		**+**

[23] Based on: 10-15 manufacturing companies; 15-35 materials tested and a testing frequency from 4 to 52 times a year (which is considered very conservative estimates by the Dossier Submitter, in particular the upper bound).

[24] Based on : 10-15 manufacturing companies; 2-10 products ranges tested and a testing frequency from 12 to 52 times a year (which is considered very conservative estimates by the Dossier Submitter, in particular the upper bound).

TOTAL testing costs for diapers manufacturers (raw materials + finished products)	**0.6-80 million €/year with a medium estimate of 35 million€ / year (corresponding to 0.01%-1.1% of the annual diapers market revenue with a medium estimate of 0.5%)** (annualized net present value calculated based on 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, they are somehow uncertain. Whether these costs will converge to the ECHA's average estimate of 55,600€ enforcement costs per restriction per year in total or whether the costs would be higher/lower remains uncertain.

For illustrative purposes, the annualized net present value of total enforcement costs was assessed, based on ECHA's average estimate and would amount to 45,000€/ year (discounted at 4% from 2024).

There may be some economies of scale in testing practices and costs in connection with the restriction on skin sensitizing substances in textile, leather, furs and hides. However, there may be extra-costs due to the lack of harmonized analytical methods and the challenges of measuring very low limits such as proposed herein (lower than the LoD/LoQ), Sufficient time through the transitional period may allow to implement a harmonized analytical method with very low LoD and reduce unclarity and uncertainty to this respect.

Summary of the costs

The total costs expected from the restriction proposed are summarized in the table below and are estimated to **6-100 million €/year with a medium estimate of 50 million€/ year (annualized net present value, discounted at 4% over 10 years from 2024).**

Table 19 : Summary of the total costs expected from the restriction proposed

	Annualized net present values of the costs (discounted at 4% over 10 years from 2024)
Total costs of moving to TCF pulp for EU diapers manufacturing companies	5-25 million €/year with a medium estimate of 15 million€/ year (corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%)
Total testing costs for diapers manufacturers (raw materials + finished products)	0.6-80 million €/year with a medium estimate of 35 million€ / year (corresponding to 0.01%-1.10% of the annual diapers market revenue with a medium estimate of 0.5%)

Total enforcement costs	45,000€/ year
GRAND TOTAL	**6-100 million €/year with a medium estimate of 50 million€/ year**

For sensitivity analysis purposes, if it is assumed for the minimum scenario that no diapers manufacturers would switch to TCF pulp (therefore that between 0% and 100% of the diapers manufacturers would switch to TCF pulp), the cost of switching would thus be 0-25 million €/year and the grand total cost would be 0.7-100 million€/year with a medium estimate of 50 millions€/year.

2.4.2. Human health impacts

Single-use baby diapers can contain hazardous chemicals that may cause risks in older ages and in their adulthood. As demonstrated above, the QHRA performed by the Dossier Submitter showed that health thresholds are exceeded for the substances in the scope under realistic and reasonably conservative assumptions (see Annex B.10). As a consequence, this proposal aims at protecting babies from developing adverse effects due to the exposure to these chemicals at older ages or in their adulthood by restricting these chemicals.

2.4.2.1. Incidence, prevalence and attributable fraction

It is difficult to estimate the incidence and prevalence of adverse effects in babies likely to be associated to the exposure to chemicals contained in single-use baby diapers for several reasons.

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

Secondly, all DNEL/DMEL 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 assess 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 actually 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 oral route which is a source of uncertainty to assess actual human health impacts of a risk generated through dermal exposure.

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

2.4.2.2. Adverse effects from chemical contamination of single use baby diapers

As presented in section 1.2 above and in Annex B, all chemicals in the scope show very severe hazards profiles.

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

PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action. The vast majority of the PAHs in the scope have a harmonised or a self classification for carcinogenicity under the CLP regulation. Furthermore, two of them have also a harmonised classification for mutagenicity and one is additionally classified as reprotoxic and skin sensitizer. Eventually, 2 of them have adopted RAC opinions that deal with harmonised classifications for mutagenicity and carcinogenicity .

PCDD/Fs and PCBs show hazardous properties for fertility, carcinogenicity and for some of them mutagenicity properties.

Moreover, PAHs, formaldehyde and some PCDD/Fs and PCBs are suspected endocrine disruptors (see sections B.5.1.10, B.5.2.10 and B.5.3.10).

By being exposed to these chemicals through their diapers, children and infants may thus develop very severe, various and latent diseases, such as:

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

Given that the chemicals in the scope have CMR and ED properties and in the view of the severity of the diseases likely to be developed by babies at older ages or in their adulthood, the health effects likely to be caused by single use diapers may have a significant impact on their quality of life. Protecting them is all the more important that single-use baby diapers is a massively adopted practice before three years of age, without widely accepted alternatives.

2.4.2.3. Health benefits expected from the restriction

As explained in the baseline section, the Dossier Submitter has insufficient information to define the actual number of babies and infants who wear single use baby diapers in Europe. It is assumed that 90% of the European babies and infants wear single use baby diapers (EDANA, 2011; Shanon *et al.*, 1990). According to Eurostat, around 5.2 million babies are

born in EU28 every year[25], i.e. there are currently about 16 million babies and infants between 0 and 3 years old in EU28. It is reasonably assumed that all babies and infants in Europe share similar skin properties and similar diapering time until 3 years old (except some extreme cases of late toilet-training or physiological deficiencies). Therefore, it is assumed that around 14.5 million babies and infants in Europe are exposed to the chemicals targeted in this restriction proposal *via* their single use baby diapers and thus are potentially at risk.

Although the exact number of babies who might develop adverse effects cannot be computed due to the above-mentioned reasons, given the severity, the variability and the latency of the effects of concern, the Dossier Submitter considers that the proposed restriction is expected to have positive health impacts since it will prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their single-use baby diapers every year. When it cannot be determined to what extent illness or disease will actually occur, the risk assessment undertaken can be used as a proxy of the health impacts as it has been done in past restriction proposals scrutinized by ECHA committees. In this restriction proposal, the risk assessment showed that for some substances in the scope RCR and IER are high, even very high (for example, and as explained in Annex B.5, the calculated RCR for formaldehyde is 0.54). The output from risk assessment are an imperfect proxy of health impacts but such high values reflect plausible risks. Finally, the Dossier Submitter would like to emphasize that these babies represent particularly vulnerable sub-population as well as future generations that should be protected also based one equity and distributional considerations.

Table 20. **Break-even analysis performed by the Dossier Submitter**

In order to get a better understanding of the proportionality of this restriction proposal the Dossier Submitter carried out a break-even analysis focusing on the annual impacts associated with the proposal. The analysis aims at illustrating and putting into perspective the health benefits that would be required for the proposal to break even, i.e. to generate more benefits than costs.

Among the different health endpoints covered by the proposal (skin tumors, impacts on fertility and other reprotoxic effects, endocrine disrupting effects, skin sensitization, such as listed in the Human Health Impact Assessment Section 2.4.2.2. of the Main report), the break-even analysis used avoided skin cancer cases as a proxy for benefits, considering the other endpoints too uncertain and vague to be "translated" into precise and valuable diseases. Moreover, cancer cases were used for illustrative purposes because the required data are readily available.

Taking into consideration the fact that the Dossier Submitter in its cost assessment only estimated the cost for EU diapers manufacturers (cost of switching to TCF pulp as a feasible technical solution to reduce contamination, and testing costs of raw materials and finished products to comply with the restriction), the break-even analysis was thus performed on these costs (provided in Table 19).

Therefore, the break-even analysis does not fully account for the expected benefits and economic impacts of the restriction proposal but only a part of them.

For the purpose of the break-even analysis, the Dossier Submitter estimated the welfare of an avoided skin cancer derived from different sources in order to obtain information on the number of

[25] Average over 2008-2018 retrieved on June the 9th from: https://ec.europa.eu/eurostat/databrowser/view/tps00204/default/table?lang=en

skin cancer cases that would need to be avoided in the 14.5 million babies potentially exposed to chemicals of concern (as future adults, most of diseases being latent).

For skin cancers, the Dossier Submitter monetised DALYs[26]/case (0.59-0.65) using the VSLY[27] to calculate a welfare proxy for one case of skin cancer of around €120,000-160,000 with a mean of €140,000 (based on the total number of DALYs for those diseases in the EU in 2019 divided by the total number of skin cancer cases in the EU in 2019). These values are based on the use of prevalence and DALYs numbers for both malignant skin melanomas and non-melanoma skin cancers, derived from the results of the Global Burden of Disease Study 2019[28] (GBD, 2019).

As shown in the table below, 49-630 cancer cases would have to be avoided each year for the restriction proposal to break even. To put these values into perspective, the Dossier Submitter calculated the skin cancers incidence that would have to be observed among the EU population exposed (14.5 million babies) each year for the proposal to break even and compared this with the skin cancers incidence rate actually observed in the EU according to GBD, 2019. This means that for the restriction proposal to break even, 49-630 skin cancer cases would have to be avoided among these 14.5 million individuals, i.e. 3.4-43.4 in 1 million would have to suffer skin cancer. According to GBD 2019, in 2019, the incidence rate of skin cancers (including both malignant skin melanomas and non-melanoma skin cancers) in the EU was 960-1400 in 1 million[29]. BEA incidence compared to actual incidence represents 0.4%-3.1%. This means that the current incidence would need to decrease by 0.4%-3.1% in order for the proposal to break even.

	Annualized costs (based on Grand total of the costs from Table 19)	value of an avoided skin cancer case	number of skin cancers cases to be avoided each year to break even	number of EU population exposed (babies exposed each year, i.e future adults likely to suffer from skin cancers)	**skin cancers incidence among EU population exposed (14.5 million babies i.e future adults likely to suffer from skin cancers) to break even (in 1 million)**	actual skin cancers incidence rate according to GDP 2019	**actual skin cancers incidence rate according to GDP 2019 (converted to incidence in 1 million, based on EU27 population of 447 million people)**	**BEA incidence compared to actual incidence (%)**

[26] Disability Adjusted Life-Years

[27] The VSLY (Value of Statistical Life-Year) is based on ECHA's reference "Value of Statistical Life" (VSL) in the context of cancer of €3.5-5 million (ECHA, 2017). Using standard annuitization the VSLY can be derived as follows: VSLY = r*VSL/(1-(1+r)^-LE) = 0.04*VSL/(1-(1.04)^-35) = €190,000-230,000 for individuals with an average remaining life expectancy of 35 years and for a discount rate of 4 %. See also ECHA (2017), Willingness-to-pay values for various health endpoints associated with chemicals exposure

[28] http://ghdx.healthdata.org/gbd-results-tool?params=gbd-api-2019-permalink/c066fee2c7b3dbfe2f6fcec7d3f235e6

[29] http://ghdx.healthdata.org/gbd-results-tool?params=gbd-api-2019-permalink/79e45c464a4d45a713063225195bd6df

min	≈6,000,000 €	121 576 €	49	14 500 000	3.4	429 837	962	0.4%
mean	≈50,000,000€	143 375 €	349	14 500 000	24.1	534 018	1 195	2.0%
max	≈100,000,000€	158 745 €	630	14 500 000	43.4	628 967	1 407	3.1%

Given the relatively low range of 0.4%-3.1%, this break even analysis tends to confirm that the restriction proposal is proportionate.

For the sake of sensitivity analysis, the Dossier Submitter made vary :

- From the one hand, the number of babies potentially exposed to chemicals of concern from diapers to -70% the number estimated in the main assessment (i.e. 4.5 million vs 14.5 million). In that case, for the restriction proposal to break even, 11-140 in 1 million skin cancer cases would have to occur among these 4.5 million individuals. This means the current incidence would need to decrease by 1.1-9.9% in order for the proposal to break even.
- From the other hand, the level of the expected costs of the restriction to +50% higher the costs estimated in the main assessment (assuming no overlapping of testing costs attributable to the restriction compared to the testing burden already borne by industry through their routine practices) i.e. €9-150 million /year. In that case, for the restriction proposal to break even, 74-945 skin cancer cases would have to be avoided among the 14.5 million individuals, i.e. 5.1-65.2 in 1 million would have to suffer skin cancer. This means that the current incidence would need to decrease by 0.5-4.6% in order for the proposal to break even.

2.4.3. Other impacts, practicability and monitorability

2.4.3.1. Impact on consumers

Annex A presents the life cycle of a single-use baby diaper with associated costs. All in all, each step of the life cycle of a single-use baby diaper represents a cost which composes the unit cost of the finished product. Based on the information collected, the following figure provides the composition of this unit cost.

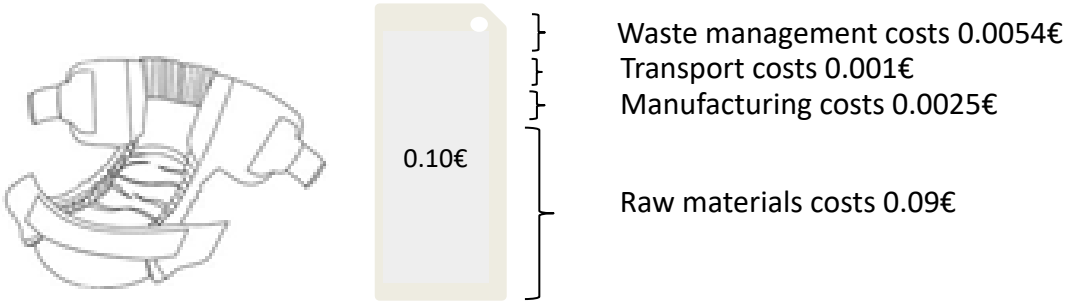

Figure 3 : Estimated unit cost of a single-use baby diaper in the EU (Source: own elaboration based on Mendoza et al., 2019)

As indicated in *Figure 3*, raw materials cost stand for around 90% of the unit cost of a single-use baby diaper (0.09€ out of 0.10€ being the estimated unit cost).

Moreover, as indicated in Annex A.2.2. the average unit price of a single-use baby diaper in the EU currently ranges from 0.20€ to 0.30€.

Whether the extra-costs on diapers industry due to the present restriction such as estimated in the sections above would be passed on the consumers is uncertain. How much of the extra-costs would be passed on the consumers is also uncertain. Nevertheless, due to investments and higher controls and tests that would be required by the restriction proposed in terms of mitigation and monitoring measures (better air filtration systems at production site, stricter analytical tests on the production chain, on finished products as well as on raw materials, quarantine of raw materials before use, etc.), industry reports that a potential increase of prices for consumers due to increased costs is likely.

Some companies indicate a likely price increase of +2% per SKU (stock-keeping unit, which corresponds in that case to a diapers pack). Conservative estimates suggest that price increases of at least 10% would be required to implement the systems necessary to comply with strict limits such as recommended in this proposal with low probability of being able to technically deliver. A higher increase is claimed likely for smaller companies. In the case of a massive move of the diapers market to TCF pulp, industry considers that the price increase would be even higher. **In conclusion, between +2% and 10% of price increase per SKU at point of sale is expected according to industry. 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.**

If one assumes that the price increase estimated by industry would actually occur after the entry into force of the restriction on the market, one can estimate the expected price increase as a conservative approach as follows:

- At production site, the production price of a single-use baby diaper is estimated at 0.10€. As a consequence, an impact on price of +2% to +10% would represent an extra-cost from 0.002€ to 0.01€ and **would increase the production price at 0.102€ to 0.11€ per single-use baby diaper**. The Dossier Submitter considered this increase per unit as low.
- At point of sale, the price of a single-use baby diaper is estimated at 0.20€ and 0.30€ (see Annex A.2.2.). If the selling price would increase of +2% to +10% as claimed by industry, this would represent an extra-cost from 0.004€ to 0.03€ per unit and would increase the selling price at 0.204€ to 0.33 € per single-use baby diaper. As an illustration, this would correspond to a price increase 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 price increase as rather low at any baby's age and should be affordable for consumers (0.44€-1€ per month). However, if realistically estimated, the upper bound of the price increase may be considered as rather significant especially for the low incomes families and might be less affordable (3.30€-7.50€ per month). Nevertheless, if the whole diapering period is taken into account, as the number of diapers used decrease while babies grow, the price increase burden would be higher for families of newborns in the very first months after birth, then would be much lower. In any case, any price increase would only be temporarily borne by consumers since after 3 years old, most kids stop wearing diapers.

Again, this expected price increase has been indicated as a rough estimate by industry without evidence and is largely uncertain. This estimate is rough and would depend on the capacity of each market actor from upstream to absorb whole or part of the extra-costs before the products reach the consumers. The difference between the unit cost of a diaper at production site and the unit selling price is rather important and is a factor of 2 or 3 (0.10€ vs 0.20€-0.30€): this difference covers own production costs and internal expenses of diapers manufacturers as well as some profit margin. The magnitude of this profit margin has not been communicated by industry and is not known by the Dossier Submitter. As a consequence of higher costs borne by diapers industry (raw materials suppliers and diapers manufacturers), one may expect that extra-costs may be entirely passed on the consumers so that the price increase would be the highest. Alternatively, the extra-costs may be spread and partially passed on each segment of the supply chain down to the consumers, so that the price increase would be moderate. In order to soften the selling price increase and to maintain a certain level of competitive advantage on the market, diapers industry may also decide to absorb most of the extra-costs.

As shown in Annex A.2.2.1, EU single-use baby diapers manufacturing market is oligopolistic (it counts a low number of manufacturers (10-15) with some big leaders and some SMEs and a high number of consumers). Under such circumstances, industrial economics teaches that companies show a certain degree of interdependence and must be careful about their decisions on production and prices. Companies of the sector may decide altogether to pass all costs increases onto the final consumers. On the opposite, they may compete in trying to maintain a certain level of low price to keep their consumers and possibly capture extra consumers from competitors. In order to maintain a certain level of low price, companies would thus have to absorb whole or part of their costs increase. Although the manufacturers are not very numerous on the single-use baby diapers sector, competition on this mass consumption market is high. Competition is particularly fierce between retailers and distributors. Competition on price in particular has been increasing for a few years, driven by alternative cheaper distribution channels (such as online shops), new brands and new competitors, etc.; the decrease in European birth rate making market situation worse. As reported in Annex A.2.2.1, the trend for the unit price of single-use baby diapers is slightly decreasing (Businesscoot, 2020). Demand on this market seems to be quite inelastic to price driven by the need for a baby to wear a diaper for convenience and toilet-training reasons. However, if consumers have the choice among similar baby diapers at different prices, they are likely to go for the cheapest. If all companies would adopt the same strategy in terms of price increase/costs absorption, the restriction should not affect the sales volumes for each. On the contrary if their strategy is heterogeneous or discrepent, one can expect that some

companies may lose market shares on the benefit of others. For instance, it may be the case of SMEs that may not afford absorbing all extra-costs. During the preparation of this proposal, SMEs have been contacted. These companies provided information on the extra-costs they may cope with but did not raise major concern about the affordability of these extra-costs. Products and quality differenciation (such as more eco-friendly, organic, or innovative diapers brands) may offset somehow price increases for some companies that would capture some niche consumers who would opt for better quality and/or better environmental footprint. However, again given the high level of price competition on the diapers market currently, one can not assume that it would actually and largely be the case. **Given all these findings, the Dossier Submitter considers most likely that the price increase for consumers (if any) will be low.**

As a conclusion, consumers may be impacted by the restriction proposed. However, the magnitude of this impact is uncertain. Although the upper bound of the price increase estimated by industry may be considered as rather significant especially for the low incomes families and might be less affordable (3.30€-7.50€ per month and per baby), this price increase is rough, highly uncertain and maybe overestimated. Furthermore, price increase (if any) would be only borne temporarily by families until the baby is toilet-trained around 3 years old: if the whole diapering period is taken into account, as the number of diapers used decrease while babies grow, the price increase burden would be higher for families of newborns in the very first months after birth, then would be much lower. As a consequence, over the diapering period (3 years on average), **this increase incurred per single-use baby diaper (if any) is considered overall low and affordable by the Dossier Submitter**. This conclusion is strengthened by competition considerations since competition on diapers market is fierce and largely driven by price that must remain low. **Therefore, the restriction is considered affordable for consumers.**

Additionnally to the impacts on consumption price, the restriction may have some impact on consumers surplus. The removal of wetness indicators or pigments may to some extent reduce the utility that consumers get from the purchase of baby diapers that contain such features. For instance, wetness indicators are used in diapers primarily for new-borns to provide guidance for parents (nd for midwives and nurses in hospitals for new borns and small sizes babies) as to when a diaper needs to be changed. This supports inexperienced parents in learning a changing behaviour that helps avoid rashes on the new-borns' skin. Nevertheless, the Dossier submitter does not consider relevant to assess further this potential loss of consumer surplus from wetness indicator or pigments. One the one hand, such assessment has not been considered relevant because the main functionality (absorption) of the baby diaper would not be affected by the removal of these (potentially toxic) materials. On the other hand, and more generally, the Dossier Submitter considers that the use of such 'non essential' materials in consumption products may be questioned in the light of the current reflexion on 'essential societal uses' ongoing within the EU Chemicals Strategy for Sustainability and the European Green Deal[30].

[30] https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1839

2.4.3.2. Social impacts

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

2.4.3.3. Distributional impacts

The restriction proposal is expected to generate distributional impacts.

Regarding risk reduction capacity, given the widespread use of single-use baby diapers, the Dossier Submitter considers that the proposed restriction is expected to prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their diapers every year. In the general population, babies represent particularly vulnerable sub-population.

Regarding industry, SMEs may have more difficulties to comply with the restriction because the extra-costs due to additional investments and preventive measures to reduce contamination of raw materials and finished products might be relatively more significant for them (such as the move to TCF pulp depending on the evolution of TCF pulp market and price to a sustainable level for them or the selection of more expensive compliant raw materials). 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. As a consequence, one may expect that SMEs might hardly absorb the extra-costs and might pass them down onto the consumers. However, as indicated in Annex A, single-use baby diapers market is mostly dominated by big manufacturing companies and the number of SMEs is minor. Most of those differentiate their products on this market by specificities (eco-friendly materials, 'organic' diapers, etc.) which may somehow prevent them from major changes to be done due to the compliance to this restriction. Furthermore, during the preparation of this proposal, SMEs have been contacted. These companies provided information on the extra-costs they may cope with but did not raise major concern about the affordability of the costs attributable to the compliance to this restriction.

As far as distributors are concerned they are more numerous than manufacturers and are of various sizes and business models (online and physical shops, small and big retailers) but are not expected to be impacted significantly.

Regarding consumers, in case diapers industry passes down their extra-costs onto them, they may cope with higher price of single-use baby diapers at point of sales. As explained above, this price increase reported by industry is highly uncertain and considered unlikely by the Dossier Submitter. In case of a price increase however, low incomes families may be more impacted. Nevertheless, this impact would be only occur temporarily by families until the baby is toilet-trained.

2.4.3.4. Practicality

As explained in Annex E.8, without a validated method and scientifically sound thresholds, some companies expressed their concern that it will be difficult for industry to comply with the restriction and that it may result in a disruption of the market, the supply of diapers for babies and create unwarranted legal liabilities.

Moreover, some companies raised concerns about the levels the restriction will require that will be below current LoQ. Eventually, one company stated that the concentrations of PCDD/Fs quantified can regularly be detected in laboratory water of accredited laboratories that specialize in dioxin/furan analyses. (please refer to Annex E.8)

EDANA indicated that they have proposed the development of relevant test methods to determine the presence of substances at trace level and to check that the amount of possible trace impurities in products does not exceed the defined limit values. During the public consultation, various stakeholders stated that it would not be possible to develop such an analytical method while others are confident to be able to develop it before the end of 2021.

In conclusion, the Dossier Submitter is confident that a harmonised analytical method will be in place before the end of the transitional period proposed (24 months).

2.4.3.5. Monitorability

As already explained in sections 2.4.1.2 and 2.4.1.3, the implementation of this restriction proposal will imply testing and controls costs for industry and authorities. Extra costs may be expected from the companies to develop an analytical method that will allow them to control the amount of the chemicals of concern. Moreover, from authorities' point of view, costs may not be so high if some of these costs are already covered by enforcement costs of other REACH restrictions. Nevertheless, by the time being, no harmonized analytical method is available based on urine simulant although EDANA is currently working on the establishment of guidelines for all Absorbent Hygiene Products (AHPs) with a common analytical method that may help the stakeholders defining, before the end of the transitional period, a harmonized analytical method.

In conclusion, to enable the monitoring of the results of the implementation of the proposed restriction, a harmonized method should be developed during the transitional period.

2.4.4. Proportionality

SEAC box

SEAC reached different conclusions than the Dossier Submitter concerning the proportionality of the restriction proposal. SEAC undertook a scenario analysis to consider the key uncertainties and information gaps related to the proposed restriction. It concluded that for none of the scenarios is there any evidence demonstrating that the restriction would be proportionate.

The details of the SEAC evaluation are reported in the SEAC opinion, together with the justification for its conclusion on proportionality.

The proposed restriction is considered proportionate for the following reasons.

The risk of negative economic impacts on companies in single-use baby diapers industry is to some extent uncertain but according to the information collected and the impacts assessed, the Dossier Submitter does not expect major critical economic impacts that would be unaffordable. The total extra testing costs for EU diapers manufacturers are estimated to 0.6-80 million €/year with a medium estimate of 35 million€ / year (annualized net present value,

discounted at 4% over 10 years from 2024), corresponding to 0.01%-1.10% of the annual diapers market revenue with a medium estimate of 0.5%.

Some overlapping is considered likely with testing costs already borne by industry due to their current testing routine. Since the 2019 ANSES' risk assessment and French RMOA have been published, industry claimed to have made considerable efforts to further control and tests their raw materials, products and manufacturing process all along their supply chain. Consequently, they seem to already have started implementing some preventive measures involving extra-investments and extra-costs. Among different explored technical solutions to reduce contamination of diapers, the cost of switching to total-chlorine free (TCF) pulp for the whole market was assessed to 5-25 million €/year with a medium estimate of 15 million€/ year (net present value, discounted at 4% over 10 years from 2024), corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%.

The companies consulted provided information on these extra costs and additionnal burden expected from the compliance to this restriction. However it remains to some extent uncertain whether part of these costs are already borne and internalized by companies or whether whole or part of them are only attributable to this restriction. Regarding testing costs, while additional tests implemented voluntarily since 2019 stand for extra-cost for industry, they cannot be attributable to this restriction and can be considered as affordable. Uncertainties however exist related to the achievability to the very low concentration limits proposed herein (below the current LoD/LoQ) given the lack of harmonized analytical methods based on urine simulant in a whole diaper. The testing costs might be higher than reported. If the transitional period of 24 months recommended would allow to implement a harmonized analytical method with lower LoD, this issue may be solved.

The total costs expected from the restriction proposed are summarized in the table below and are estimated to **6-100 million €/year with a medium estimate of 50 million€/ year (annualized net present value, discounted at 4% over 10 years from 2024).**

Furthermore, the risk of increased competition from outside the EU seems limited: EU domestic manufacturing market is oligopolistic, well settled and there is little competition from outside EU according to the Dossier Submitter's knowledge. No company consulted during the preparation of this proposal raises this concern. No risk of profit losses for the EU economy is therefore to be expected.

As indicated in Annex A.2 some single-use baby diapers are imported as finished products from outside EEA31 (e.g. Vietnam). In some European overseas territories, up to 50% of diapers are imported from Asia (e.g. Vietnam, China, South Korea, Malaysia, etc.) and other countries (e.g. South Africa, USA). Regarding imported raw materials used in diapers manufacturing, most raw materials come from EU but some raw materials come from outside EU. The amount of imported finished products and raw materials is not available to the Dossier Submitter's knowledge. It cannot be excluded that some impacts may occur outside EEA31 to some companies supplying raw materials or finished single-use baby diapers in Europe due to the restriction. However, due to a lack of data and information, the magnitude of these impacts cannot be assessed.

Positive economic impacts for the supply chains are possible, given a potential increased level of confidence of consumers in baby diapers products as a result of the restriction proposal. These products being specifically purchased for babies, consumers are particularly sensitive

to trust, image and reputation. Additionally, one can expect extra-profits for more 'eco-friendly' and safer raw materials suppliers such as current TCF pulp EU company 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. As explained above, the price increase assessed was reported by industry, not substantiated and is considered highly uncertain. In case of a price increase this would be only borne temporarily by families until the baby is toilet-trained (3 years on average). Based on market structure considerations and the competition on diapers market being high and mainly driven by price, the Dossier Submitter considers consumers price increase unlikely and if any, likely to be low and affordable to consumers.

The proposed restriction will bring benefits to society due to the avoided health impacts of adverse effects on babies' health even though their magnitude could not be assessed. Potentially very severe, variable and latent diseases affecting their quality of life over their lifetime are expected to be avoided in babies at older ages and in their adulhood such as cancers, suspected endocrine disruption, reprotoxic effects, etc. Given the widespread use of single-use baby diapers, the Dossier Submitter considers that the proposed restriction is expected to prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their diapers every year. The Dossier Submitter emphasizes that these babies represent particularly vulnerable sub-population as well as future generations that should be protected also based one equity and distributional considerations. Contaminants in their diapers are undesired chemicals which are not intentionally added by producers and which do not meet any technical function in the products. They should thus be reduced as much as possible. Although the benefits could not be quantified, a break-even analysis was performed by the Dossier Submitter to evaluate proportionality of the proposal.

Considering the above elements, the Dossier Submitter considers that the proposed restriction will bring health benefits and is not expected to have major economic impacts that would be of a nature to threaten industry activities. Finally, the break even analysis carried out by the Dossier Submitter tends to confirm that the proposed restriction is proportionate.

Therefore, the Dossier Submitter concludes that the proposed restriction is affordable and proportionate.

2.5. Assessment of restriction option 2

Restriction Option 2 (RO1 and all the congeners of PAHs, DL-PCBs, furans and dioxins)

This RO has a broader scope than RO1. It covers the same chemicals as RO1 but also all the congeners of the PAHs, all the congeners of the PCDD/Fs and DL-PCBs which means that a migration limit would also be defined for each congener.

Regarding the expected costs of removing contaminants from RO2, they are expected to be similar to RO1 since the measures and technical solutions implemented by industry in order

to remove the chemicals covered by RO1 should be in principle also efficient in removing their congeners covered by RO2 without additional efforts. No contradictory information has been received by the Dossier Submitter. Therefore, the risk reduction capacity (i.e. benefits) from RO2 is expected to be similar to RO1 since the measures implemented under RO1 would collaterally address the concern raised by congeners.

Regarding the testing and enforcements costs, there is some uncertainty whether the costs associated to RO2 would be similar or higher than the costs associated to RO1 (a higher number of substances would have to be tested and monitored (not quantified) but it may be possible that costs would not be higher in case congeners and substances would be tested simultaneously without additional testing burden). According to some information received during the public consultation, having the congeners in the scope of RO2 would not impact the analytical practicalities and a harmonized analytical method with urine simulant would equally allow measuring chemicals as well as their congeners. Some companies confirm that from a testing point of view RO1 and RO2 are largely indistinct in practicality and in cost. Nevertheless, some contradictory information indicates that testing costs associated to RO2 would be higher. Therefore, without more substantiated information, the Dossier Submitter cannot provide a clear-cut conclusion on the costs of RO2 comparatively to RO1 and some uncertainty remains.

Overall, RO2 is considered proportionate but whether it is similarly proportionate as RO1 is somehow uncertain.

Practicality and monitorability are not expected to be significantly different from RO1.

2.6. Comparison of restriction options

The restriction option RO1 would be the most efficient in terms of risk reduction capacity.

Table 21 : Comparison of restriction options

	Risk reduction capacity	Proportionality	Practicality	Monitorability
Restriction Option 1 (restriction proposed)	**+++**	**+++**	**+**	**+**
Restriction Option 2	**+++**	**++(+)**	**+**	**+**

Overall, the 2 restriction options further assessed are considered to be proportionate by the Dossiers Submitter. Benefits associated with RO2 are expected to be similar as RO1. There is some uncertainty whether the costs associated to RO2 would be similar or higher than the costs associated to RO1. RO2 is considered proportionate but whether it is similarly proportionate as RO1 is somehow uncertain. Practicality and monitorability of both options are not expected to be significantly different.

3. Assumptions, uncertainties and sensitivities

Please see Annex F.

4. Conclusion

Ever since they were invented in the early 1930s, single-use baby diapers have continuously evolved to meet the expectations of modern life. Diapers are products made of several materials whose objectives are to absorb and retain the child's urine and faeces while keeping his/her skin clean and dry. Since the 1990s, single-use diapers have been used by more than 90% of families in most of the European Union.

In 2019, the French Agency for environmental and health safety (ANSES) has published a report on the risks associated with the presence of hazardous substances in baby diapers and made recommendations for risk reducing measures. Therefore, the Dossier Submitter proposes that PAHs, formaldehyde, PCDD/Fs, PCBs should be restricted in these materials. The Dossier Submitter bases the restriction proposal on the risk from exposure to PAHs, formaldehyde, PCDD/Fs and PCBs. The identified risks need to be addressed on a Union-wide basis to achieve a harmonised high level of protection of human health and free movement of goods within the Union.

The risk management option analysis (RMOA), finalised by ANSES in 2019, and the French expertise published by ANSES in 2019, concluded that a community-wide ban of placing single-use baby diapers that contain PAHs, formaldehyde, PCDD/Fs and PCBs on the market, was the most appropriate RMO. The risk is proposed to be managed by setting migration limits for these chemicals in single-use baby diapers.

As the amount of available information needed to perform the assessment of exposure to chemicals were available, the Dossier Submitter sets the migration limits using a quantitative approach. The proposed limits are shown in *Table 22* below.

Table 22 : Proposed migration limits for the substances in the restriction scope

Substance / group of substances	**Proposed migration limit**
Formaldehyde	
Formaldehyde	**0.42 mg / kg of diaper**
PCDD/Fs/DL-PCBs	
Sum of the quantified PCDD/Fs and DL-PCB **in TEQ**	**0.0017 ng_{TEQ} / kg of diaper**
Sum of the quantified PCBs	**112 ng / kg of diaper**
PAHs	
The sum for the detected or quantified PAH **in TEQ**	**0.023 ng_{TEQ} / kg of diaper**

It is acknowledged that these substances covered by the scope are not intentionally used in single-use baby diapers. However, for substances that the Dossier Submitter considers as relevant for single-use baby diapers, the suggested limits are far below the highest

approximated concentrations in the materials at point of sale. Hence, lowering the limits of these chemicals in single-use baby diapers to the ones proposed, is considered to significantly reduce the risk for infants anduntil they will be fully toilet-trained. The migration limits proposed are thus considered to adequately protect infants and children.

It is acknowledged that the restriction proposal calls for an explanation of the under process REACH Annex XVII restriction on skin sensiters in textile, leather fur and hide as ar as formaldehyde and benzo[def]chrysene are concerned. The skin sensitisers in textile, leather, fur and hide restriction aims at restricting the content of formaldehyde and benzo[def]chrysene in, among other articles, single-use baby diapers. It will be enforced through a dedicated analytical method. This restriction deals with the skin sensiting properties of formaldehyde and benzo[def]chrysene only.

To identify the most appropriate measure to address the risk targeted here, two restriction options under REACH were assessed (the restriction proposed, RO1, and another restriction option RO2). To decide which one of these options that is the most beneficial from a societal perspective, RO1 and RO2 were assessed against the criteria of risk reduction capacity, proportionality, practicality and monitorability. The conclusions of this assessment are the following:

Risk reduction capacity

RO1 (the proposed restriction covering formaldehyde, the sum of detected or quantified 17 PAHs, the sum of quantified PCDD/Fs and DL- PCBs, the sum of quantified PCBs) is considered to be the most efficient restriction option in terms of risk reduction capacity. The concentration limits proposed are deemed to adequately protect children and infants under the age of 3 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).

In comparison, RO2 (covering all the substances from RO1 and all the congeners of PAH, PCDD/Fs and DL-PCBs) would provide an equal risk reduction capacity since the measures implemented under RO1 would in principle collaterally address the concern raised by congeners.

Proportionality

The two restriction options assessed are considered to be proportionate by the Dossier Submitter.

The costs of compliance associated with RO1 (the proposed restriction) are not considered unaffordable to industry and not disproportionate and it is not expected to have major economic impacts that would be of a nature to threaten industrial activities. Uncertainty remains due to lack of information about what exact reactions industry would have and what exact technical solutions they would opt for to comply with the restriction. Regarding the

testing and enforcements costs of RO2, there is some uncertainty whether the costs associated to RO2 would be similar or higher than the costs associated to RO1 (a higher number of substances would have to be tested and monitored (not quantified) but it may be possible that costs would not be higher in case congeners and substances would be tested simultaneously without additional testing burden). Contradictory information has been received from public consultation in this respect. Therefore, there is some uncertainty whether the costs associated to RO2 would be similar or higher than the costs associated to RO1.

Regarding substitution and technical changes costs from the restriction option proposed, from the information collected, industry has identified possible sources of contamination and has drawn some possible leads of technical and substitution solutions. The costs reported by industry are overall converging but show some uncertainties and discrepancies. Moreover, some reported costs might present some overlapping between extra-costs already borne due to new measures implemented as a voluntary response from industry since ANSES' expertise and French RMOA have been published and extra-costs specifically attributable to this restriction proposal. In general, the costs reported by industry are rough estimations due to uncertainties about the restrictions conditions that would actually enter into force and the evolution of the market (such as raw materials and TCF pulp markets). The substitution and technical changes and adaptations costs assessed are summarized in Table 17. Among different explored technical solutions to reduce contamination of diapers, the cost of switching to total-chlorine free (TCF) pulp for the whole market was assessed to 5-25 million €/year with a medium estimate of 15 million€/ year (net present value, discounted at 4% over 10 years from 2024), corresponding to 0.07%-0.30% of the annual diapers market revenue with a medium estimate of 0.2%.

Due to uncertainties, these costs are not considered as an actual estimate of the expected costs of the restriction proposal but are provided as an indication of possible economic impacts industry would cope with in case of a restriction and depending on the technical solutions companies would opt for to make their finished products compliant**.**

Testing costs and test frequency along the supply chain have been assessed by the Dossier Submitter. These testing costs are rather uncertain and show discrepancies. Overall the magnitude of testing costs depend on the companies' size and manufacturing volume. Moreover, all the costs and test frequency reported are not based on harmonized analytical methods and this might cause some difficulties to compare and interpret them. Indeed, most of the manufacturers perform analysis by using methods that are not representative of the real exposure (e.g. solvent extraction though a shredded diaper). Without a validated method and scientifically sound thresholds, it might be difficult or even impossible for industry to comply with the restriction and that it may result in a disruption of the market. Hence, the absence of a validated method combined with the challenge for sensitive detection and quantification limits prone to unintended contamination during product pick-up, transport, sample preparation etc. would present a major barrier for compliance and enforcement. This is a source of uncertainty.

The total testing costs for EU diapers manufacturers are estimated to 0.6-80 million €/year with a medium estimate of 35 million€ / year (net present value, discounted at 4% over 10 years from 2024), corresponding to 0.01%-1.10% of the annual diapers market revenue with a medium estimate of 0.5%.

Due to these uncertainties and to the current lack of harmonised analytical methods, these costs are not considered as an actual estimate of the expected testing costs of the restriction proposal but are provided as an indication of possible testing costs industry would cope with in case of a restriction.

Regarding enforcement costs for authorities, they are somehow uncertain. The estimation of 55,600€ per restriction per year in total (in 2014 values) provided by ECHA should only be seen as an indication of the magnitude of the enforcement costs, since a variation in costs is observed for different restrictions. It might be possible that enforcement cost can be reduced when some of these costs are shared with the enforcement costs associated with other interlinked REACH restrictions and other regulations. To this respect, like for testing costs from companies, the Dossier Submitter may expect some economies of scale in testing practices and costs since some chemicals in the scope of the present restriction are also classified as skin sens. Under CLP Regulation and thus fall under the scope of the restriction on skin sensitizing substances (formaldehyde, benzo[def]chrysene). Nevertheless, due to the lack of harmonized analytical methods and the challenges of measuring very low concentration limits such as proposed herein,the enforcement costs may be actually higher than the average cost of REACH restrictions. The enforcement and testing costs remain overall unclear. Again, it the transitional period of 24 months recommended would allow to implement a harmonized analytical method with very low LoD, and this issue may be solved.

Due to the absence of harmonized analytical method, the enforcement costs are uncertain. For illustrative purposes, the annualized net present value of total enforcement costs was assessed, based on ECHA's average estimate, and would amount to 45,000€/ year (discounted at 4% from 2024).

As a whole, the total costs expected from the restriction proposed are estimated to 6-100 million €/year with a medium estimate of 50 million€/ year (annualized net present value, discounted at 4% over 10 years from 2024).

Positive economic impacts for the supply chains are also expected, given a potential increased level of confidence of consumers in baby diapers products as a result of the restriction proposal. Additionally, some extra-profits for more 'eco-friendly' and safer raw materials suppliers such as current TCF pulp EU company 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.

Regarding human health benefits, the Dossier Submitter considers that the expected benefits should be significant and comparable between RO1 and RO2 (although the exact number of babies who might develop adverse effects cannot be computed). Given the severity, the variability and the latency of the effects of concern, the Dossier Submitter considers that the proposed restriction is expected to have positive health impacts since it will prevent 90% of European babies (i.e. 14.5 million babies) from being exposed to hazardous chemicals contained in their single-use baby diapers every year. When it cannot be determined to what extent illness or disease will actually occur, the risk assessment undertaken can be used as a proxy of the health impacts as it has been done in past restriction proposals scrutinized by ECHA committees. In this restriction proposal, the risk assessment showed that for some substances in the scope RCR and IER are high, even very high (for example, and as explained in Annex B.5, the calculated RCR for formaldehyde is 0.54). The output from risk assessment

are an imperfect proxy of health impacts but such high values reflect plausible risks. Finally, the Dossier Submitter would like to emphasize that these babies represent particularly vulnerable sub-population as well as future generations that should be protected also based one equity and distributional considerations. Although the benefits could not be quantified, a break even analysis was performed by the Dossier Submitter that tends to confirm that the proposal is proportionate.

In conclusion, the Dossier Submitter therefore considers that the proposed restriction is affordable and proportionate.

Practicality and monitorability

RO1 is considered overall practicable and monitorable. Even if a validated method is not available, some development of relevant test methods to determine the presence of substances at trace level and to check that the amount of possible trace impurities in products does not exceed the defined limit values are currently under consideration. The Dossier Submitter believes that a transitional period of 24 months will provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction. Overall, RO1 is thus considered implementable, enforceable and manageable.

RO1 can be monitored by Member State surveillance programs and compliance controls as well as manufacturers, importers and distributors of single use baby diapers articles who will have the obligation to place compliant articles on the market.

Practicality and monitorability of RO2 are expected to be similar to RO1.

Overall conclusion

In conclusion, being effective (protective, proportionate and affordable), practical and monitorable, RO1 is considered to be the most appropriate RMO to address the risk for human health from exposure to PAHs, PCDD/Fs, PCBs and formaldehyde in single use baby diapers on a Union-wide basis.