DRAFT Analysis of the most appropriate regulatory management option (RMOA)

Hazardous chemicals in single use baby diapers

Authority: ANSES

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Cover Note

At EU level, baby diapers are subject to the general safety requirements defined by European legislation relating to consumer goods. There is no regulatory framework specific to babies' diapers in the EU. In 2019 ANSES has published a report on the risks related to the presence of hazardous substances in baby diapers and made recommendations for risk reducing measures.
This RMOA addresses the regulatory measures identified to address human health risks characterized with the hazardous substances or group of substances found in baby diapers on the EU market.

DISCLAIMER

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1 BACKGROUND- IDENTITY OF THE (GROUP OF) SUBSTANCES OF CONCERN

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 (EDANA, 2011). For example, in France, disposable diapers have been worn by over 95% of babies for almost 20 years (Group'Hygiène, 2015). Estimates of the total number of disposable diapers used by a baby before the age of toilet training range from 3800 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).

Following testings performed in France (INC, DGCCRF/SCL), single-use baby diapers have been reported as containing hazardous chemicals that may cause diseases to babies that are in direct contact with these articles. A report published in 2019 by the French Agency for environmental and health safety (ANSES[1]), 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 babies.

The chemicals analysis and the health risk assessment carried out by ANSES in 2019 are summarized below.

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

3 types of analysis were performed onto single-use baby diapers.The tests were conducted onto 23 products taking into account a wide range of products, including the best-selling commercial products on the French market, as well as retailers' own brands and "eco-friendly" diapers. The analysis performed were :

- Extraction of chemicals in shredded whole diapers or diapers parts using a solvent (scenario 1),
- Migration tests were carried out with whole diapers (scenario 2.2) and shredded whole diapers for single use in a urine simulant (scenario 2.1)[2].(SCL, 2019)

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

- In shredded **whole diapers** :
    - volatile organic compounds (naphthalene, styrene, toluene, dichlorobenzenes, p-isopropyltoluene, xylenes, chlorobenzene),
    - pesticides (hexachlorobenzene, quintozene and its metabolite pentachloroaniline, glyphosate and its metabolite AMPA),
    - formaldehyde,
    - dioxins, furans and DL-PCBs,
    - fragrances (benzyl alcohol, benzyl salicylate, coumarin, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), limonene, linalool, alpha-isomethyl ionone);

- in shredded **diaper parts**[3]:

[1] https://www.anses.fr/fr/system/files/CONSO2017SA0019Ra.pdf

[2] The urine simulant consisted of urea, creatinine, ammonium citrate, NaCl, KCl, $KHSO_4$, $MgSO_4$, $KH2PO_4$ and $KHCO_3$ in water (Colon *et al*., 2015).
These migration test 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.

[3] A diaper part refers to a component considered separately, such as the elastic bands, inner layer, absorbent pad, etc.

- dioxins, furans (in the outer layer, the inner layer and other parts, except the core),
- PAHs in the elastics (benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene).

Dioxins, furans and DL-PCBs, PAHs and formaldehyde were quantified or detected in the migration tests.

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

A quantitative risk assessment 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). In this study, the IER threshold was set at 10^{-6}, the most conservative value.

The details of the HQRA are available in the annex 3 and in the ANSES report (2019).

Table 1: Interpretation of the risk calculation results

Threshold effects	**HQ < 0.1**	**0.1 < HQ < 1**	**HQ > 1**
	No toxic effects are expected in the exposed population.	It is necessary to ensure that there are no other concomitant sources of exposure, to not risk exceeding 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.

Regarding the substances measured by **solvent extraction in shredded whole diapers (scenario 1)**, a risk calculation was undertaken using a refined scenario for all fragrances, dioxins, furans and DL-PCBs and their sums, as well as for three VOCs[4] and hexachlorobenzene.

It showed cases in which 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 out of the 19 analysed.

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

Regarding the substances quantified by **solvent extraction in certain diaper parts[5] (scenario 1)**, no health thresholds were being exceeded for PAHs or for 2,3,4,6,7,8 HxCDF, for children aged 0 to 36 months.

Regarding dioxins, furans and DL-PCBs and the sums of their quantities found by **extraction with a urine simulant in shredded whole diapers (scenario 2.1)**, a risk calculation was undertaken according to a refined scenario. It did not show any health thresholds being exceeded for children aged 0 to 36 months.

Regarding the substances found by **extraction with a urine simulant in whole diapers (scenario 2.2)**, a risk calculation was undertaken according to a refined scenario for 10 detected PAHs[6], formaldehyde, PCB-126, the sum of dioxins and furans, the sum of DL-PCBs and the sum of dioxins, furans and DL-PCBs[7], which were quantified. It highlighted the following, for children aged 0 to 36 months:

- ✓ the risk indicator (non-threshold carcinogenic effects) was exceeded for the 10 PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene);
- ✓ the health threshold[8] (threshold effects) was exceeded for six PAHs (benzo[b]fluoranthene, cyclopenta[c,d]pyrene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[a]pyrene, dibenzo[a,h]anthracene) and for PCB-126, the sum of DL-PCBs, and the sum of dioxins, furans and DL-PCBs.

The results of the above exposure calculations were limited to 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 dioxins and furans,
- 4 HAPs,
- formaldehyde.

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

Dioxins, furans, DL-PCBs and PAHs are ubiquitous substances that can be found, for example, in food and particularly in breast milk.

In the ANSES report, the scenario where chemicals have been found using a migration test in a whole diaper by urine simulant was considered as the most representative of the reality of use (scenario 2.2).

Moreover, the conclusion stated that there are no epidemiological data demonstrating an association between health effects and the wearing of diapers. However, hazardous chemicals have been found in these diapers. Based on the results of the tests and the literature data, a QHRA was undertaken for single-use baby diapers according to refined scenarios. 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 is not possible to rule out a health risk associated with the wearing of single-use diapers.**

Regarding the above conclusions of the ANSES report**, based on the results according to scenario 2.2, ANSES recommanded regulatory actions to be taken. In accordance with this scenario 2.2,** this RMOA covers numerous hazardous chemicals or hazardous groups of

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

chemicals detected or quantified in single use baby diapers on the EU market meaning the dioxins, furanes, DL -PCBs and the PAHs chemicals. As mentioned above the substances listed hereafter have their risk threshold exceeded:

- benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene;
- PCB-126, the sum of DL-PCBs, and the sum of dioxins, furans and DL-PCBs.

Moreover, some chemicals need to be monitored :

- formaldehyde,
- 4 HAPS,
- sum of quantified dioxins and furans.

Section 3 gives a more detailed description on the substances that are included in the scope of this RMOA and Annex 3 for a more detailed description of the QHRA performed in the ANSES report.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

In the EU, no specific regulation covers baby diapers, either for their composition, manufacture or placing on the market. The General Product Safety Directive (2001/95/EC, see section 5.2.4 for further details) is the only regulation to which these products are subject to. This Directive imposes several obligations on companies including the duty to market safe products for use under reasonably foreseeable conditions by consumers, to have at their disposal the corresponding dossier, to provide consumers with information about risks, to ensure the traceability of products, and to have a procedure for withdrawing products from the market.

At national level, Germany considers baby diapers as commodities and they are included in the German Food and Feed Code (LFGB). The German Federal Institute for Risk Assessment (BfR) has issued recommendations related to the materials used for the manufacture of baby diapers, in particular regarding:

- the materials used,
- maximum concentrations for acrylic acid,
- the use of scented oils and conditioning agents,
- the use of chemicals, plastic materials and dyes.

The French authorities[9], based on ANSES 2019 report, asked, in February 2019, the industry (and more specifically the distributors and the manufacturers) to take measures to remove hazardous chemicals that are present in their single use baby diapers. As a follow-up, industry were invited and agreed to take the following voluntary actions:

- To remove allergenic chemicals, especially in fragrances (deadline: 3 months)
- To identify and remove all the contamination sources possible due to hazardous chemicals, by an exhaustive analysis of their supply chain and process (deadline: 5 months) and the implementation of an action plan based on 2 axes:
    - Regarding raw materials: industry will complete a diagnosis of the quality of their supply chain. Based on this diagnosis, industry will have to take necessary measures like for exemple reinforced quality controls.
    - Regarding the process: industry will make a detailed audit of their manufacturing process to identify for each step, where hazardous chemicals are formed. On this basis, industry will have to take measures to modify their process.

[9] https://www.economie.gouv.fr/files/files/directions_services/dgccrf/presse/communique/2019/cp_securite_couches_engagements_08022019.pdf

- To inform the consumer regarding the articles compositions through their website (deadline: 3 months) and then through the labelling onto the packaging (deadline: 6 months).

Furthermore, there are a number of legislative acts or voluntary schemes that exist which are presented in the table below.

Table 2: Overview of current EU legislations and voluntary schemes on chemicals substances in baby diapers

Legal Act / Voluntary schemes	**Scope**
REACH Regulation(EU) 1907/2006	
Cosmetics Regulation (EU) 1223/2009	In particular for chemicals used in lotions.
Eu Ecolabel	Contains criteria that companies must comply with to label their baby diapers with EU Ecolabel
Nordic Swan Ecolabel	Contains criteria that companies must comply with to label their baby diapers with Nordic Swan Ecolabel
Oeko Tex Label	Contains criteria that companies must comply with to label their baby diapers with Oeko Tex Label
FSC Label	Contains criteria that companies must comply with to label their baby diapers regarding that the products are in particular sourced from sustainably managed forest
TCF, PCF SI Labels	Contains criteria that companies must comply with to label their baby diapers with these labels that certify that a product has been manufactured and bleached without any use of chlorine.
OK biobased Vinçotte Label	Contains criteria that companies must comply with to label their baby diapers with these labels that certify products based on their concentration of renewable raw materials.

The criteria that have to be fulfilled to get the voluntary scheme mark are detailed in the annex 2 .

In addition to current EU legislations or voluntary schemes presented in Table 2, France and Sweden have submitted in April 2019 a restriction proposal on skin sensitisers in textiles, leather, furs and hides articles that includes disposable baby diapers under Article 68.1 of Regulation EC N° 1907/2006 (REACH). However, this restriction proposal only covers skin sensitising substances and not all the substances identified as of concern by ANSES 2019 and in this RMOA (as detailed in Section 3).

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

This RMOA covers substances with or without a harmonised classification according the Annex VI of the CLP Regulation (Regulation EC 1272/2008).

The reason why some chemicals have been included in this RMOA is described in the sections 1 and 5.4. But as already mentionned, in the ANSES report published in 2019, the assessment of single use baby diapers showed health thresholds exceeded in realistic exposure scenario for infants between 0 to 36 months for various (groups of) chemicals considering single use baby diapers not being the only source of exposure to chemicals:

- The dioxins (namely 7 chemicals)
- The furans (namely 10 chemicals)
- The Polycholorobyphenyl dioxine-like (DL-PCBs) (12 chemicals)
- The PAHs (namely 17 substances)
- The formaldehyde.

3.1.1 Harmonised Classification in Annex VI of the CLP

Some chemicals of concern that are in the scope of this RMOA have an harmonised classification according to the Annex VI of the CLP. These classifications are detailed in the table below.

Table 3: Harmonised classifications for some of the chemicals in the scope of the RMOA

Chemicals	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)		
PAHs						
Benzo[a]anthracene	200-280-6	56-55-3	Carc. 1B Aquatic Acute 1 Aquatic chronic 1	H350 H400 H410	M=100	
benzo[b]fluoranthene	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[a]pyrene	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 %	-
dibenzo[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	

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 Note D

3.1.2 Self classification

For all the chemicals in the scope, meaning the chemicals belonging to the groups of dioxins, furans, PAHs, DL-PCBs, that are not in the Table 3, all the self classifications related to the health hazards are gathered in the table available in annex 5.

3.2 Additional hazard information

3.2.1 Reports from government authorities and research intitutes on hazardous chemicals found in baby diapers

Some reports from government authorities as well as some publications from the scientific literature were found regarding the scope of this RMOA and especially about the chemicals of concern that can be found in diapers. These reports and publications comfort the analysis results used in the QHRA in the ANSES report.

Here under are only described the reports and the scientific literature that are linked to the chemicals of concern in this RMOA, meaning : PAHs, dioxins, furans, DL-PCBs and formaldehyde.

3.2.1.1 Report from government authorities regarding chemicals contained in single use baby diapers

In 2009, the Danish Environmental Protection Agency published a report on the assessment of exposure of two-year-olds to chemical substances in consumer products (Danish EPA, 2009). The agency selected several consumer products including baby diapers. 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 precisely identified. 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. For all of the diapers, the table in Annex 2 summarises the chemicals detected, semi-quantified or quantified and the part of the diaper in which each chemical was found.

The Belgian Federal Public Service (VITO, 2018) screened four baby diapers in order to identify all of the compounds that could be extracted from a diaper.
In a second phase, 20 baby diapers of big-name brands, "store" brands and "bio" brands were analysed in order to screen for 17 PAHs, glyphosate and AMPA (aminomethylphosphonic acid), 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 with the exception of 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.

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, volatile organic compounds (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. 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, polycyclic aromatic hydrocarbons (**PAHs**) were screened for in several parts of three diapers of two different brands (LQ = 0.1 mg/kg). Benzo[a]anthracene (0.11-0.194 mg/kg) and chrysene (0.0182-0.104 mg/kg) 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 (industrial study, 2016).

3.2.1.2 Scientific literature regarding chemicals contained in single use baby diapers

In the **scientific literature**, some studies, quite old for most of them, have screened for the presence of **dioxins and furans** in disposable and reusable baby diapers (Wiberg *et al.,* 1989; Schecter *et al.,* 1998; DeVito and Schecter, 2002; Shin *et al.*, 2005). TEQs were calculated in these various studies, primarily using the WHO's toxic equivalency factors (TEFs), in order to express the overall toxicity of dioxin mixtures. This is because dioxins are generally found in mixtures containing several types of dioxins and dioxin-like compounds, each with a specific degree of toxicity.

In 1989, Wiberg *et al.* measured levels of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) in baby diapers on the Swedish market that had or had not been bleached without chlorine (Table 4). The packaging of the diapers included the statement "chlorine-free" or "dioxin-free".

Table 4: Levels of PCDDs and PCDFs in baby diapers (Wiberg *et al*., 1989)

	TCDD equivalent*	**2,3,7,8-TCDF**	**2,3,7,8-TCDD**	**2,3,4,7,8-PeCDF**	**1,2,3,7,8-PeCDD**
Disposable diapers	1.0 pg/g	2.7 pg/g	0.54 pg/g	<0.2 pg/g	<0.3 pg/g

* calculated using "Nordic toxic equivalency factors" (1988)

** 1,2,3,7,8-PeCDF, 1,2,3,4,6,7,8-HpCDF, OCDF and OCDD were detected.

In 1998, Schecter *et al.* conducted a preliminary study on sanitary products including baby diapers of four different brands. Three of these were disposable diapers and one was a reusable cotton diaper. The authors quantified **PCDDs and PCDFs** (Table 5). The lowest concentrations were found in the cotton diaper.

Table 5: Concentrations of dioxins and furans in baby diapers (Schecter *et al*., 1998)

Diapers	**Measured levels (ppt)**			**Dioxin TEQ (ppt)**		
	PCDDs	**PCDFs**	**Sum**	**PCDDs**	**PCDFs**	**Sum**
Disposable - Brand E	3.9	1.8	5.6	0.005	0.064	0.069
Disposable - Brand F	2.2	0.5	2.7	0.005	0.010	0.015
Disposable - Brand G	1.8	0.5	2.3	0.004	0.010	0.014
Reusable diaper	2.6	0.2	2.7	0.005	0.001	0.006

De Vito and Schecter (2002) analysed four baby diapers, including three disposable diapers and one cotton diaper, all purchased in San Francisco. They screened for 17 PCDDs and PCDFs. Only five of the 17 dioxins were detected in the diapers (LD = 0.1 - 0.2 ppt). There were similar concentrations in the disposable and reusable diapers. Total PCDD/F concentrations in the diapers ranged from 1.8 to 3.7 pg/g, i.e. from 0.0042 pg $_{TEQ}$/g (cotton diaper) to 0.023 pg $_{TEQ}$/g (disposable diaper).

In a Korean study, Shin *et al.* (2005) screened for PCDDs and PCDFs in disposable diapers purchased in Korea, Japan, the United States and Germany (Shin *et al.*, 2005 – abstract; article in Korean). OCDD was quantified in four diapers (two Korean and two Japanese), with concentrations ranging from 0.0013 to 0.0058 pg $_{TEQ}$/g, and HpCDD in one Korean diaper (0.0163 pg $_{TEQ}$/g). HpCDD ($5.6 \cdot 10^{-3}$ pg $_{TEQ}$/g) and OCDD ($6\text{-}9 \cdot 10^{-4}$ pg $_{TEQ}$/g) were quantified in three diapers (two purchased in the USA and one in Germany) after six hours of extraction whereas HxCDD (10^{-4} pg $_{TEQ}$/g), OCDD ($4\text{-}6 \cdot 10^{-4}$ pg $_{TEQ}$/g) and OCDF ($9 \cdot 10^{-4}$ pg $_{TEQ}$/g) were found in four diapers (three American and one Japanese) after 24 hours of extraction.

3.2.2 Skin diseases associated to the wearing of baby diapers in infants

3.2.2.1 Diaper dermatitis

ANSES (2019) report indicates that diaper dermatitis is the most common skin disease in infants. There are different forms of diaper dermatitis which are related to the wearing of baby diapers. They are described below.

Irritative dermatitis

Irritative dermatitis is the most common form. Until a child is toilet trained, the diaper area is an occlusive, warm and moist environment due to prolonged contact between the baby's buttocks and faeces and/or urine. The available studies have shown that an increase in skin moisture, a high alkaline skin pH, the mixing of urine and faeces and the mechanical action of friction between the skin and diaper can cause irritative dermatitis to develop (Scheinfeld, 2005; Runeman, 2008*; Tüzün *et al.*, 2015; Atherton, 2016*; Bender and Faergemann, 2017*).

Other factors promote the occurrence of irritative dermatitis and can aggravate its symptoms; these include gastrointestinal diseases (e.g. diarrhoea), low diaper-changing frequency, the use of low-absorbency diapers (Counts *et al.*, 2014*; Helmes *et al.,* 2014*), inadequate cleansing, the administration of antibiotics that can disrupt the equilibrium of the intestinal flora, teething, the presence of micro-organisms on the epidermis, the use of unsuitable care products for this location, allergies to chemicals, etc. (Tüzün *et al.*, 2015; Atherton, 2016*).

Some studies, undertaken by companies, indicate that the presence of lotion in the topsheet helps facilitate the restoration of skin barrier function and reduce the severity of irritation and diaper dermatitis (Odio *et al.*, 2000*; Odio and Friedlander, 2000*; Erasala *et al.*, 2007*; Counts *et al.*, 2014*).

There have been reports of cases of irritative dermatitis related to the wearing of reusable diapers that disappeared with the use of single-use diapers (Harfmann *et al.*, 2017; Maruani *et al.,* 2013).

Allergic contact dermatitis

Much less common, allergic contact dermatitis can be caused by certain components in a diaper (Roul *et al.,* 1998; Larralde *et al.,* 2001; Belhadjali *et al.*, 2001; Onken *et al.*, 2011; Jacob *et al.*, 2012; Chiriac *et al.*, 2017; Yu *et al.*, 2016 and 2017). The main chemicals identified as causing allergic contact dermatitis are as follows:

- mercaptobenzothiazole (MBT), found in the rubber used in the elastics (Roul *et al.,* 1998; Onken *et al.*, 2011),
- cyclohexylthiophthalimide, used as a vulcanisation retarder in rubber (Belhadjali *et al.*, 2001),
- p-tert-butylphenol formaldehyde resin, found in glues (Belhadjali *et al.*, 2001),
- disperse dyes (Alberta *et al.*, 2005).

However, Evans *et al.* indicate that the colouring agents used are pigments and not disperse dyes (Evans *et al.*, 2014*).

Infectious dermatitis

Secondary infections, due primarily to bacteria (Staphylococci) or *Candida albicans*, are common when the skin of the diaper area has lesions (Šikić Pogačar *et al.,* 2017). Cases of severe diaper dermatitis, including confirmed *Candida albicans* infections, have been reduced by 50% in children wearing breathable diapers.

Diaper dermatitis prevalence over time

The prevalence of diaper dermatitis is estimated to be between 7% and 50%, depending on the country and hygiene practices, keeping in mind that many cases are not reported by doctors or parents and heal within a few days without any medical treatment. Its incidence peaks between the ages of nine and 12 months (Joran *et al.*, 1986 cited in Blume-Peytavi *et al.*, 2014*; Klunk *et al.*, 2014; Felter *et al.*, 2017*). The number and severity of cases of diaper dermatitis have sharply decreased with the emergence of disposable diapers and the use of superabsorbent polymers keeping the buttocks dry (Carr *et al.*, 2017* cited in Felter *et al.*, 2017*)..

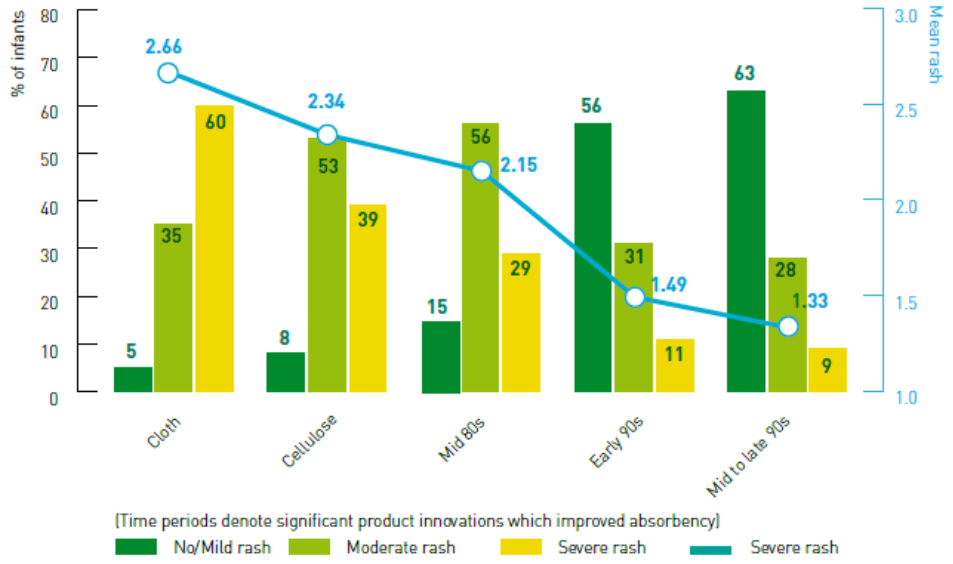

Figure 1: Change in case of diaper dermatitis since the introduction of single-use baby diapers (Group'Hygiène, 2015; EDANA, 2010)

3.2.2.2 Urinary tract infections

In a prospective case-control study, *Nuutinen et al.* (1996) did not find any association between the type of diaper used and the risk of developing a urinary tract infection (disposable with SAP: OR = 0.95; $CI_{95\%}$ = 0.62 – 1.46; without SAP: OR = 1.04; $CI_{95\%}$ = 0.69 – 1.57; reusable cotton: OR = 1.00; $CI_{95\%}$ = 0.46 – 2.16). Conversely, in a case-control study of 59 girls under the age of two years with a urinary tract infection and 59 controls matched for age, Fahimzad *et al.* observed that the use of diapers with SAP was significantly higher in the individuals with urinary tract infections (cases) than in the control individuals (62.71% vs 35.59%; OR = 3.29; p = 0.005) (Fahimzad *et al.*, 2010).

Sugimura *et al.* (2009) studied the association between daily diaper-changing frequency and urinary tract infections in 128 infants with a temperature of ≥ 38°C, including 32 with a urinary tract infection. Diaper-changing frequency was significantly lower in the children with a urinary tract infection compared to the others. The main bacteria isolated from the urine samples of the children with a urinary tract infection were *Escherichia coli* followed by *Klebsiella pneumonia* (Sugimura *et al.*, 2009).

3.2.3 Other risks likely to be associated with the wearing of baby diapers in infants

As described in section 1, with a refined scenario meaning a realistic scenario that is **the most representative of the reality of use, health thresholds were exceeded for various chemicals meaning PAHs, dioxins, furans DL-PCBs.**

Formaldehyde is also included in the scope of the RMOA considering single use baby diapers not being the only source of exposure to chemicals. Formaldehyde toxicity is described in a RMOA dealing with occupational exposure (to be published, see ANSES Opinion in French here: https://www.anses.fr/fr/system/files/REACH2017SA0072.pdf).

PAHs refers to a large class of organic substances that contain carbon and hydrogen atoms. PAHs are ubiquitous in the environment and the general population is exposed to measurable background levels (Chen *et al*., 2001).

Dioxins, furans and dioxin-like polychlorobenzyls (DL-PCBs) have a similar behavior in the body. In humans, data are almost exclusively for the 2,3,7,8-TCDD.

A brief description of the hazards linked to these chemicals are listed in the sections below. The toxicokinetic profile of the chemicals is described in Annex 6.

3.2.3.1 Genotoxicity

PAHs

As the majority of the studies carried out on PAHs are on the benzo(a)pyrene, genotoxicity is focused on this substance.The substances like benzo(a)pyrene with harmonised classification as mutagenic in category 1B can induce genetic abnormalities. DNA damage associated with aryl hydrocarbon receptor activation and induction of CYP450 induced by PAHs exposure has been suggested by numerous authors (Liamin *et al*., 2017). Benzo(a)pyrene genotoxicity is through its ultimate metabolite: the BPDE (benzo(a)pyrene-7,8-diol-9,10-epoxyde). The formation of DNA adducts is believed to be a key event in the mutagenicity and carcinogenicity of PAHs. Adducts may lead to misrepair and result in mutations (Borska *et al.*, 2014).

Dioxins, Furans and DL PCB

Dioxins, furans and DL-PCBs are considered as cancer promoters. It is a significant fact that dioxins, furans and DL-PCBs are non genotoxic substances, nevertheless they are known as carcinogenic. It is generally assumed that for nongenotoxic substances there exists a threshold level of exposure necessary to produce cancer effects.

3.2.3.2 Carcinogenicity

PAHs

PAHs are known carcinogens in humans, causing direct genotoxic effects, or indirectly through oxidative stress (Gammon & Santella, 2008). The International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the American Conference of Governmental Industrial Hygienists (ACGIH) and the CLP regulation have classified several PAH mixtures as carcinogenic to humans (cf Table 6).

Table 6: Identification table for the carcinogenicity of various PAHs from IARC, NTP, ACGIH and CLP

Chemical	CAS	IARC	NTP	ACGIH	CLP
Benzo(g,h,i)perylene	191-24-2	3	-	-	-
Benzo(b)fluoranthene	205-99-2	2B	R	A2	1B

Cyclopenta(c,d)pyrene	27208-37-3	2A	-	-	-
Chrysene	218-01-9	2B	-	A3	1B
5-methylchrysene	3697-24-3	2B	R	-	-
Benzo(k)fluoranthene	207-08-9	2B	R	-	1B
Benzo(j)fluoranthene	205-82-3	2B	R	-	1B
Benzo(e)pyrene	192-97-2	3	-	-	1B
Benzo(a)pyrene	50-32-8	1	R	A2	1B
Dibenz(a,h)anthracene	53-70-3	2A	R	-	1B

R: PAH reasonably anticipated to be human carcinogens by the NTP

No studies were found showing evidence of a direct association between human dermal exposure to individual PAHs and cancer induction. However, reports of skin tumors among individuals exposed to mixtures containing PAHs lend some qualitative support to their potential for carcinogenicity in human skin (ATSDR, 1995). IARC monography concluded that benzo(a)pyrene produces tumors in all species (mouse, rat, hamster, guinea pig, rabbit, newt, monkey) after several exposure routes (oral, dermal, inhaled…). Benzo(a)pyrene has both local and systemic carcinogenic effects and it is an initiator of skin cancer in mice. In several studies in which benzo(a)pyrene was applied to the skin of different strains of mice, benign (squamous cell papillomas and keratoacanthomas) and malignant (mainly squamouscell carcinomas) skin tumours were observed (IARC, 2012).

Dioxins, Furans and DL PCB

2,3,7,8-TCDD, 2,3,4,7,8-PCDF and PCB 126 are classified since 1997 group 1 by the IARC mainly based on studies in workers who have been exposed to industrial accidents and on evidence of carcinogenicity in animals. Dioxins, furans and DL-PCBs cause an excess of cancers without specific localization, the most cited according to the studies being lymphomas, myelomas, soft tissue sarcomas, lung and liver tumors. Carcinogenic effect is likely the result of their tumor promoting activity produced by activation of the aryl hydrocarbon receptor . There are several theories on the mechanism of action including the role of apoptosis inhibition of tumor precursor cells and induction of apoptosis (Chopra *et al.,* 2011).

3.2.3.3 Toxicity for reproduction and developmental effects

The substances with harmonised classification as reprotoxic 1B can harm fertility or the fetus.

Animal studies have shown adverse reproductive and developmental effects from PAHs exposure (Kim *et al*., 2013). PAH-DNA adducts have been found in fetal cord and maternal blood after maternal exposure to PAHs in ambient air. Studies show a dose-response relationship between exposure to PAHs during pregnancy and effects related to intrauterine growth restriction. A study of neonates showed that those with increased levels of PAH-DNA adducts had significantly lower birth weight, length and head circumference (WHO Guidelin for indoor air quality).

Several studies suggests that dioxins, furans and DL-PCBs decrease male and female fertility. Retrospective studies demonstrated a decreased male/female sex ratio in children born to males exposed to TCDD as well as an endocrine disrupting activity affecting semen quality in young males (Mocarelli *et al*., 2000). These observations and the fact that AhR activation may induce the estrogen signalling pathways make TCDD a possible endocrine disruptor (Sorg *et al.*, 2014).

3.2.3.4 Other effects

Immunosuppressive effects

The immunosuppressive effects of PAHs have mainly been investigated in studies using parenteral administration. It has been suggested that PAHs exert immune effects via the aryl hydrocarbon receptor. Observations in CYP1A1 knock-out mice have indicated that CYP1A1 may protect against immunotoxic effects by benzo(a)pyrene.

Dioxins shows a change in the number of lymphocytes and a decrease in reactions to certain allergens. These changes seem to decline several years after the stop of the exhibition. Animal studies have shown that the immune system is a target organ for dioxins. TCDD is a highly immunosuppressive agent that reduces the humorous and cellular pathway of the immune response. The mechanism of action is discussed but could be based on the induction of cell death of immune system cells (Vos *et al*., 1973).

Neurological effects

Environmental exposure to PAHs is correlated with learning and memorizing defects in adults and impaired neurodevelopment in children. Based on behavioral tests in mice neuro-toxicity is evaluated at 0.025mg / kg weight / day against 0.54mg / kg weight / day for carcinogenicity which suggests that the neurotox is more sensitive than cancer. It is possible that damage to DNA causes neurotoxicity and cancer depending on tissue (Chepelev *et al.,* 2015).

3.2.3.5 Conclusion

As shown here above, the chemicals of concern identified in the frame of this ROMA are associated with serious hazards. According to the available data, these chemicals may induce severe health effects, even if no disease linked to single use baby diapers have been reported for now in the litterature.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Origins of the chemicals in single use baby diapers

According to the data from the literature and the information provided during the hearings conducted for the assessment performed by ANSES, the chemicals detected or quantified in diapers are not intentionally added by the manufacturers, with the exception of fragrances. The majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination or be formed during manufacturing processes such as bleaching or bonding (e.g. DL-PCBs, furans and dioxins). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, processes using chlorinated agents such as chlorine dioxide, for example, are used and can be responsible for the formation of dioxins and furans. Regarding the presence of PAHs in single-use diapers, the ANSES (2019) report do not rule out PAH formation during the manufacture of these diapers due to the use of high temperatures for certain manufacturing processes (Abdel-Shafy and Mansour, 2016).

Contaminants were found both in "eco-friendly" diaper products and in other diaper products.

The concentrations of the quantified and/or detected chemicals extracted using solvents from shredded baby diapers were compared with those measured in food as part of the infant Total Diet Study (iTDS) (common foods[10]) (ANSES, 2016a). The routes of exposure to these sources are different, but comparing concentrations can enable contamination levels to be compared. For simplification purposes, the maximum concentration measured in diapers in the SCL (2017) or INC (2017 and 2018) studies was compared with the maximum concentration measured in

[10] Non-alcoholic beverages, dairy-based desserts, cream desserts and jellied milks, milk, vegetables (excluding potatoes), mixed dishes, fish, ultra-fresh dairy products, meat, poultry and game.

the iTDS study. The maximum concentration levels in diapers for dioxins and furans were always lower than those found in food. Conversely, the maximum concentration levels in diapers for DL-PCBs and glyphosate were always higher than those found in food. Lastly, the concentrations of PAHs detected in shredded baby diapers were higher than those found in food. (please refer to Annex 4).

4.2 Use of baby diapers [11]

As already mentioned, since the 1990s, single-use diapers have been used by more than 90% of families (around 70 000 births every year in France) in most European countries (EDANA, 2011). For example, **in France**, **disposable diapers have been worn by over 95% of babies** for almost 20 years (Group'Hygiène, 2015). Nonetheless, some parents choose to use reusable 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*).

In 1990, Shanon *et al.* published the results of a questionnaire-based study on diaper choices in 600 parents of young children under two years of age seen in a clinic or by paediatricians in Ottawa (Shanon *et al.*, 1990). Single-use diapers were used by 82.3% of the parents. Only 2.7% of the parents exclusively used reusable cloth diapers. The choice was driven by convenience for disposable diapers, rash prevention for disposable and reusable diapers, cost for diapers washed at home, and convenience for diapers washed by a diaper cleaning service.

In 2004, a study on diaper use (types of diapers used, number of diaper changes per day, age when children stop using diapers) was undertaken in the United Kingdom. Eight thousand households were surveyed between June 2002 and February 2003. Only those with a child who was in diapers or had worn diapers in the recent past (children under the age of 10) were interviewed (n=2096). Of these families, 94.1% used only single-use diapers, 1.5% only reusable diapers, 2.4% both types of diapers but primarily disposable diapers, and 2% both types of diapers but primarily reusable diapers (UK Environment Agency, 2005b). The people preferring reusable diapers considered they were more eco-friendly and less expensive and contained fewer chemicals. In some cases, they had also been recommended by friends or family members or donated by a family that no longer needed them.

In Belgium, a pilot programme was implemented in 2002 and then in 2005 to encourage parents to use reusable diapers for a period of 13 weeks. The parents were recruited in a maternity department. Seventy percent of the 436 women invited to take part in this programme declined. Only 23 participants (in 2002 or 2005) said they intended to continue using reusable diapers at the end of the 13 weeks, i.e. 5% of the women invited to participate. The main reasons for not wanting to continue were leakage, difficulty of use, extra work and cost (EDANA, 2010. Several other initiatives have been taken in France to promote reusable diapers (ADEME, 2012).

Diapering habits vary according to country, income level, family practices and cultural norms. Single-use diapers are used in most countries except for example in India and China, where reusable diapers are widely used. Diaper changing practices differ depending on the country. In Japan, for example, babies are changed while standing up rather than while lying on their back, which has resulted in babies in Japan frequently wearing training pants before they start toilet training. However, in Western Europe and North America, training pants are almost exclusively limited to the toilet-training period (Figure 2) (Thaman and Eichenfield, 2014*).

[11] Information taken from the ANSES 2019 Report

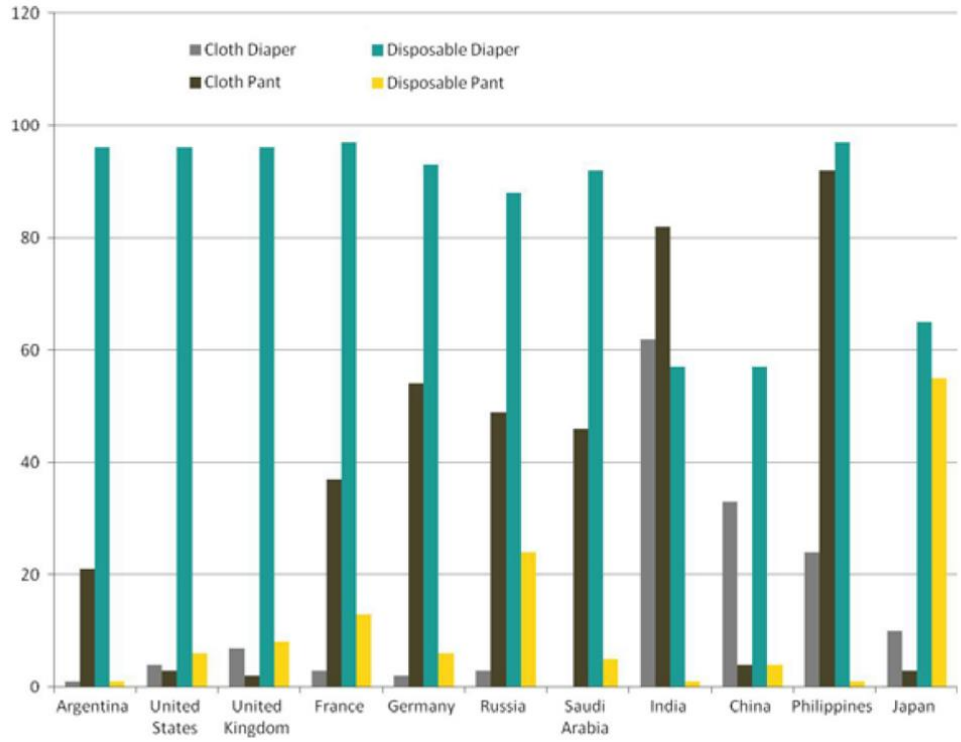

Figure 2: Use of the various types of diapers according to country in children between the ages of zero and 24 months (%) (Thaman and Eichenfield, 2014*)

- **Number of diapers used before toilet training**

Estimates of the number of disposable diapers used by a baby before toilet training range from 3800 to 4800. 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).

- **Diaper wearing time**

Younger babies are changed more frequently than older babies (10 times/day versus 4-5 times/day). The average diaper wearing time for an older baby is four hours during the day and 10 to 12 hours at night (Thaman and Eichenfield, 2014*). Indeed, as they reach one year of age, babies sleep an average of 14 to 15 hours per day, with most of their sleep occurring overnight (~10-12 hours).

4.3 Volumes regarding baby diapers

The ANSES report made various observations regarding the market of baby diapers in France and in some cases in the EU. They are primarily based on information from industry players.

In the ANSES study published in 2019, the issue of sales volumes for single-use baby diapers and training pants was addressed. It appeared that these figures were confidential and could not be used.

According to EDANA (European Disposables and Nonwovens Association), around 30 billion diapers and diaper pants are sold in the European Union (2015 figures) (Figure 3).

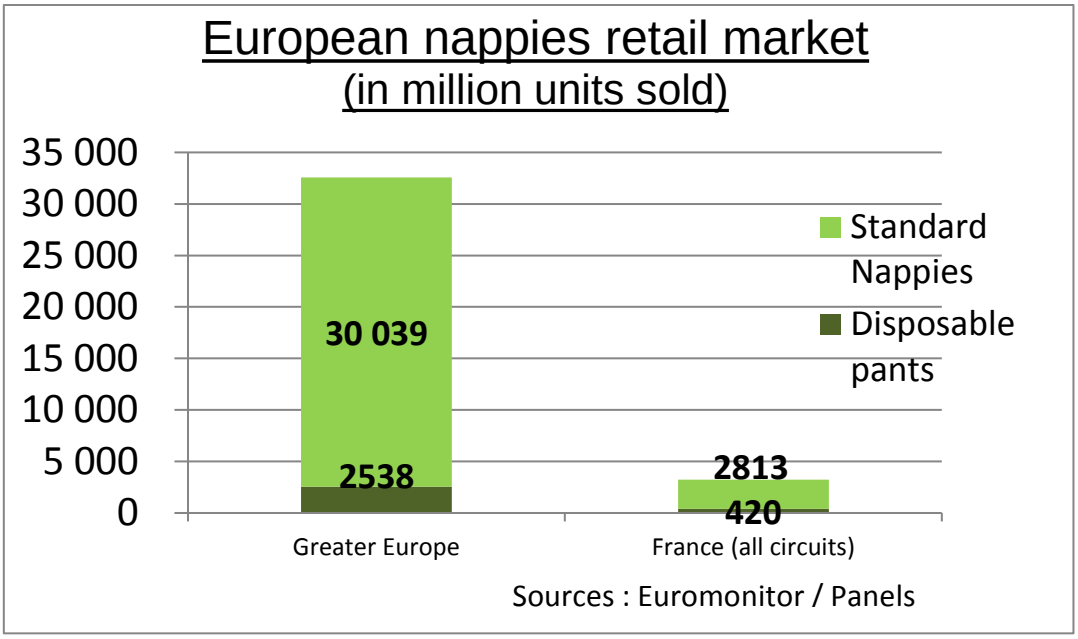

Figure 3: Sales volumes for baby diapers (ANSES, 2019)

As shown here, few market data are available at this time. If a restriction proposal appears to be the best regulatory management option analysis to deal with the hazardous chemicals in single use baby diapers, more data market would be needed in order to perform the impact assessment and the cost benefict analysis.

4.4 European single use baby diapers actors

According to the hearings held during the ANSES expertise, it appears that the producers of single use baby diapers have their production lines based in Europe. These production lines can be only used by one producer or can be shared by different distributors.

However, through the hearings, it appears that some of the raw materials used to create the single use baby diapers can be imported from outside Europe.

4.5 Additional information related to volumes of chemicals

Formaldehyde is a very known used chemical, for various purposes, in Europe. According the ECHA's website :

- There is a high number of registration dossiers and uses,
- The tonnages are above 1 000 000 tons a year.

Dioxins, furans and DL-PCBs haven't a harmonised classification according to the CLP. On the ECHA's website, these chemicals are pre-registered for 1-10 tons.

For the PAHs that have a hamonised classification (for more information, please see the section 3.1.1) and according to ECHA's website, these chemicals are pre-registered for 1-10 tons. These chemicals are intented to be restricted or already restricted under REACH at EU level.

For the PAHs that are only self classified, they are pre-registered for 1-10 tons.

5 JUSTIFICATION FOR THE REGULATORY MANAGEMENT OPTION

5.1 Need for (further) regulatory management

Single use baby diapers can contain hazardous chemicals which may cause diseases in susceptible individuals. The QHRA performed by ANSES showed that health thresholds have being exceeded for several substances, after having applied a refined scenario and reasonably conservative assumptions.

The diseases 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 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 free of potential symptoms, babies 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 age of 3 .

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

5.2 Identification and assessment of regulatory management options

In its report, ANSES has analysed the current EU legislations on chemicals in single-use baby diapers and made recommendations for measures aiming at reducing the chemicals risks of various hazardous chemicals in baby diapers (ANSES, 2019).

The various chemical groups of concern mean that in terms of effectiveness, it is not possible to investigate thoroughly and address the substances one at a time. Instead, effective risk management of hazardous chemicals in single-use baby diapers requires assessment and regulation of those substances following a grouping approach. Below, possible regulatory management options (RMO) for the regulation of risks caused by chemicals in single-use baby diapers are presented. Possible scopes for regulatory measures are also discussed.

5.2.1 Restriction 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 goods.

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 RMOA, their classification or their hazard profiles, **the aim of a restriction would be to limit the content of the substances of concern identified in single-use baby diapers, not withstanding the reason for their presence in the finished article.** Indeed, as explained above, there are – at the current stage – only assumptions on the sources (raw material, manufacturing processes, …) 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 section 1 of this RMOA, 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, Dioxins, Furans, DL-PCBs, formaldehyde).

5.2.1.1 Substances to be included in a possible restriction of hazardous chemicals in single-use baby diapers

This RMOA assesses four alternative scopes regarding the substances that should be included in a potential restriction under REACH. The criteria for inclusion of substances in the proposed scopes differ in terms of hazard-related criteria and exposure-related criteria.

The four options considered in this section are in line with exposure scenarios developed in ANSES report (2019). More information is available in Annex 3. The four alternative scopes are related to the following refined scenarios:

	Exposure Scenario number	**QHRA results**
Option A	Scenario 2.2	Substances in red zone
Option B	Scenario 2.2	Substances in red and orange zones
Option C	Scenarios 1, 2.1 and 2.2	Substances in red zone
Option D	Scenarios 1, 2.1 and 2.2	Substances in red and orange zones

Option A :

The restriction will cover all the substances for which threshold have been exceeded according to the ANSES QHRA considering that the exposition to these substances is only due to single use baby diaper exposure and according to the most realistic exposure scenario.

The proposal will covers the substances with or without a harmonised classification but for whom a health threshold (HQ > 1 or IER> 10^{-6}) has been exceeded according to the most

realistic exposure scenario (extracting chemicals in a whole diaper through a urine simulant) meaning the following chemicals:

- Each of the following PAHs: benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene,
- PCB 126,
- The sum of the DL-PCBs,
- The sum of the dioxins, furans and DL-PCBs.

Option B :

Single use baby diapers are not the only source of exposure to chemicals for which reference values have been established and exposure via single-use diapers is certainly lower than exposures from other sources such as food or the air. Thus, it was chosen to limit to 10% of the TRV the share allocated to baby diapers for the calculation of threshold concentrations. Note that the same approach is used to establish thresholds for substances in toys (RIVM 2008, SCHER 2010a and 2010b). To get more information about the choice of the value of 0.1 for HQ and 10^{-7} for the IER, please refer to Table 1.

So the option B covers in addition to option A all the substances that have $0.1<HQ<1$ or $< 10^{-7}<IER<10^{-6}$ according to the most realistic exposure scenario (extracting chemicals in a whole diaper through a urine simulant).

Option B will include all the congeners of the family of the compounds described above, to be sure not to avoid a chemical that can be quantified at a greater concentration than the ones measured in the non-exhaustive analysis. So, the congeners to be included in option B are:

- Each of the following PAHs: benzo[c]fluorene, benzo[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene, 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,
- Each of the following Dioxins: 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,
- Each of the following 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, 1,2,3,7,8,9-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,
- Each of the following 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,
- The sum of the above dioxins and furans,
- The sum of the above DL-PCBs,
- The sum of the dioxins, furans and DL-PCBs.

Inclusion of substances in the proposal will not require assessment of the likelihood of presence in the single use baby diapers. Inclusion of substances will make sure that all the relevant substances are covered.

It has to be highlighted that in this option B, some substances that have been found in concentration implying a health threshold not exceeded in the analysis performed by ANSES can be found in other single use baby diapers with a greater concentration.

Option C :

The restriction will cover all the substances for which threshold have been exceeded according to the ANSES QHRA considering that the exposition to these substances is only due to single use baby diaper exposure whatever is the exposure scenario (meaning scenarios 1, 2.1 and 2.2 as detailed in Annex 3).

Option C will then comprises the following substances:

- Each of the following PAHs: benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene,
- Each of the following fragrances: hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®),
- The sum of dioxins and furans,
- PCB 126,
- The sum of the DL-PCBs,
- The sum of the dioxins, furans and DL-PCBs.

Option D :

The proposal will cover the substances for which threshold have been exceeded and the ones with $0.1<HQ<1$ or $< 10^{-7}<IER<10^{-6}$, whatever is the exposure scenario. Indeed, all the single use baby diapers have not been yet analysed so some of these substances can be found in greater concentration and then have health threshold exceeded. Moreover, the results of the ANSES exposure calculations were limited to exposure related to baby diapers, excluding other possible exposure sources (environmental, dietary, 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 or whose IER was around 10^{-7}. Finally, these materials are in contact with the skin of sensitive populations.

The option will cover all the substances for which threshold have been exceeded according to the ANSES QHRA (meaning $HQ>1$ or $IER >10^{-6}$) and the ones that have $0.1<HQ<1$ or $< 10^{-7}<IER<10^{-6}$.

Option D would include all the congeners of the family of the compounds described above, to be sure not to avoid a chemical that can be quantified at a greater concentration than the ones measured in the non-exhaustive analysis.

So, the congeners to be included in this option is :

- Each of the following PAHs: benzo[c]fluorene, benzo[a]anthracene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene, Indéno[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,
- Each of the following Dioxins: 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,
- Each of the following 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, 1,2,3,7,8,9-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,
- Each of the following 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,
- Each of the following VOCs: 1,2,3-trichlorobenzene, 1,2,4-trichlorobenzene
- Each of the following fragrances: coumarine, limonene, benzyl salicylate, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), alphamethyl ionone
- Formaldehyde,
- hexachlorobenzene
- The sum of the above DL-PCBs,
- The sum of the above dioxins, furans and DL-PCBs,
- The sum of the above dioxins and furans.

If this option of a possible scope for a restriction is considered as the most relevant, it has to be noted that all the exposure scenario are not the most realistic ones. Actually, the exposure scenario 1 and 2.1 are more screening scenario to detect if some chemicals are present in the single use baby diapers. On the contrary the exposure scenario 2.2 is still considered the most realistic exposure scenario.

Nonetheless, the analytical methods used for two out of the 3 exposure scenarios (meaning scenario 1 and 2.1) are well known according to analytical standards.

5.2.1.2 Challenges of a possible restriction

Articles to be included in a possible restriction

This RMOA does not provide a detailed proposal on what articles should be covered by a possible restriction. In case a restriction proposal would be developed subsequently to this RMOA, it should cover single-use baby diapers. It has to be understood that single use baby diapers may include various types of diapers like the diapers pants, diapers and baby swim pants. However baby swim pants do not have the same use, exposure frequency and manufacturing process as daily diapers pants and single-use baby diapers.

Depending on the child's age and body weight, various sizes and ranges of diapers are available (for newborns, for children who are becoming mobile, etc.). There are several models of single use baby diapers with different characteristics:

- Traditional diapers,
- Diaper pants or training pants for toilet-training the child,
- Swimming diapers, used when babies/children are engaging in water activities. These diapers are made of an absorbent material that does not swell up in water,
- Night diapers, intended for children over three years of age, in order to help them with toilet training at night.

During the elaboration of a restriction proposal, it should be carefully considered whether all those types of baby diapers should be covered.

Concentration limits

This RMOA does not provide a detailed proposal on concentration limits for a possible restriction. In case a restriction proposal would be developed subsequently to this RMOA, available detection methods and appropriate concentration limits must be thoroughly investigated.

Analyticals methods standards

As shown in this RMOA, there are no available standards or analytical methods. Indeed, the tests performed to demonstrate the presence of hazardous substances in single use baby diapers were built especially for this QHRA, when talking about extraction through a urine simulant in a whole baby diaper (meaning migration analytical methods).

That’s why, if a possible restriction is further assessed, the lack of harmonised analytical methods and standards will have to be taken into account as uncertainties and information from the industry will be useful to ensure that the one developed in the ANSES report is achievable. It may also have a concern regarding the enforcement due to the possible lack of analytical means.

On the other hand, if the scope of the restriction correspond to the option D desribed above, all the substances which have threshold exceeded whatever is the analytical method used, will have to be taken into account. This means, that the analytical methods using solvent (scenario 1), are well known.and so it would be easier, in terms of enforceability, to monitor the presence or not of the chemicals.

Alternatives

When fullfiling a restriction dossier, a section regarding the alternatives of the substances that are meant to be restricted must be developed. The aim of the ANSES report was not to propose alternatives to the chemicals of concern. While looking at these chemicals, it has to be taken into account that these chemicals are not intentionally used, except for the fragrances, but are residues, contaminants.

That's why, in a possible restriction dossier, the alternatives section will have to be taken into account. Because these substances are residues or contaminants and may be generated by the raw materials used or by the process, the objectives of the analysis if the alternatives won't be to find other safer chemicals but safer processes that won't generate chemicals of concern.

Human Health Impact assessment

When fullfiling a restriction dossier, an assessment of the health benefits expected from the restriction has to be performed.

For the time being, the evidence of adverse effects only comes from studies reported in the scientific literature (please refer to section 3) and no epidemiological studies are published showing health effects or pathologies for kids under the age of three while wearing single use baby diapers.

Therefore, the human health impact assessment will remain a challenge while elaborating a restriction dossier according to the REACH regulation.

5.2.2 Identification as substances of very high concern (SVHC) according to REACH Article 57 and subsequent authorisation

Hazardous chemicals of the present RMOA 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 authorization. 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 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 less than 0,1% in single use baby diapers. That will implies that these chemicals won't have to be notified according to the Authorization 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.

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

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

The major part of the substances that are of concern in this proposed RMOA 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 regulatory 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 regulatory management option is not appropriate to deal with the scope of this RMOA but can be a complementary measure of the restriction procedure according to REACH Regulation.

5.2.4 Other legislations

5.2.4.1 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 applied for the highly allergenic 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.

5.2.4.2 The Medical Device Regulation (EU) No 2017/745

As incontinence diapers are considered as medical device according to the regulation (EU) 2017/745[12] and due to the fact that single use baby diapers and incontinence diapers, are made the same way and have a similar composition, including single use baby diapers in this regulation could have been a regulatory 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,

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

- 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 regulatory 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.

5.2.4.3 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 chilcadre 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 regulatory management option is not appropriate to deal with the scope of this RMOA.

5.2.5 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.

5.2.6 Development of a specific guideline

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 toaddress critical information gaps, assessment of proposed future research actions and of research results.

So taking into account the fact that ANSES already performed an 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 regulatory management option consisting of developing a guide to the industry through SCCS can be considered as complementary measures before the most adequate regulatory management option will be put into force.

5.3 Conclusions on the most appropriate (combination of) regulatory management options

Several RMOs to address the risks identified in this RMOA from chemicals in single-use baby diapers have been discussed and considered by ANSES.

Based on available data, ANSES considers that the most efficient way to regulate hazardous chemicals in single-use baby diapers is to address chemicals at risks using relevant legal instruments available in REACH, namely a restriction under article 68.1. EU wide legally binding restriction in REACH will address the risk for all babies all over Europe and will impose equal conditions for the entire EU market and will make it easier for the companies to set demands on the suppliers.

ANSES considers 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 products as well as imported baby diapers and allows covering different types of hazard endpoints.

5.4 Conclusions on the most appropriate scope for restriction of hazardous chemicals in single-use baby diapers

The objective of this RMOA is to identify a RMO with the potential to sufficiently reduce the risks for babies under 3 years old wearing single-use baby diapers available on the EU market without causing a disproportionate burden on the EU diapers market. The ANSES 2019 report has been discussed at the Risk Management Expert Meeting (RiME+) in february 2019 and comments have been received from ECHA and Member States. Some comments were about on-going studies in other Member States or the choices of the exposure parameters.

ANSES considers restriction under REACH Article 68.1 to be the most appropriate RMO.

Restriction enables regulation of groups of substances, may apply to imported articles and may cover all types of hazard endpoints. Nevertheless, the Member State that might be in charge of this restriction dossier will have to face some challenges highlighted like:

- **The chemicals to be included in the scope, meaning the chemicals described above or others that can be included in the families of the substances.**
- **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 must be developed.**
- **The human health benefits of such a restriction will have to be demonstrated,**
- **The availability of suitable (technically and economically feasible) alternatives.**

ANSES considers that all the substances that have been detected or quantified in the ANSES 2019 report through the most relevant scenario (scenario 2.2), meaning the migration tests from a whole diaper by a urine simulant, and with a $0.1 < HQ < 1$, $HQ > 1$, $10^{-7} < IER < 10^{-6}$ and $IER > 10^{-6}$ should be a criteria for inclusion in a possible restriction. This means formaldehyde, DL-PCBs, Dioxins, Furans and PAHs (those mentioned in section 3) and their sums. This corresponds to option B discussed in section 5.2.1.1.

5.5 References

Alberta. L, Sweeney SM, Wiss K.(2005). Diaper Dye Dermatitis. Pediatrics.. 2005 Sept, 116 : 450 – 452

ANSES, French Agency for Food, Environmental and Occupational Health & Safety. January 2019. "Safety of footwear and textile clothing."

Atherton DJ. (2016). Understanding irritant napkin dermatitis. Int J Dermatol. 2016 Jul;55 Suppl 1:7-9.

ATSDR, A. f. T. S. a. D. R. (1995). Toxicological profile for polycyclic aromatic hydrocarbons.

Belhadjali H, Giordano-Labadie F, Rance F, Bazex J. (2001). "Lucky Luke" contact dermatitis from diapers: a new allergen? Contact Dermatitis. 2001 Apr;44(4):248.

Bender JK, Faergemann J, Sköld M. (2017). Skin Health Connected to the Use of Absorbent Hygiene Products: A Review. Dermatol Ther (Heidelb). 2017 Sep;7(3):319-330.

Blume-Peytavi U, Hauser M, Lünnemann L, Stamatas GN, Kottner J, Garcia Bartels N. (2014). Prevention of diaper dermatitis in infants--a literature review. Pediatr Dermatol. 2014 Jul-Aug;31(4):413-29.

Borska, L., Andrys, C., Krejsek, J., Palicka, V., Chmelarova, M., Hamakova, K., . . . Fiala, Z. (2014). Serum level of antibody against benzo[a]pyrene-7,8-diol-9,10-epoxide-DNA adducts in people dermally exposed to PAHs. J Immunol Res, 2014, 834389. doi:10.1155/2014/834389

Chen, B. H., & Chen, Y. C. (2001). Formation of polycyclic aromatic hydrocarbons in the smoke from heated model lipids and food lipids. Journal of Agricultural and Food Chemistry, 49(11), 5238-5243. doi:10.1021/jf0106906

Chepelev, N. L., Moffat, I. D., Bowers, W. J., & Yauk, C. L. (2015). Neurotoxicity may be an overlooked consequence of benzo[a]pyrene exposure that is relevant to human health risk assessment. Mutat Res Rev Mutat Res, 764, 64-89. doi:10.1016/j.mrrev.2015.03.001

Chiriac A, Birsan C, Podoleanu C, Chiriac AE, Stolnicu S. (2017). Pragmatic management of (suspected allergic) diaper dermatitis. Contact Dermatitis. 2017 Feb;76(2):129-130.

Chopra, M., & Schrenk, D. (2011). Dioxin toxicity, aryl hydrocarbon receptor signaling, and apoptosis-persistent pollutants affect programmed cell death. Crit Rev Toxicol, 41(4), 292-320. doi:10.3109/10408444.2010.524635

Chu, I. Dick, D. Bronaugh, R. Tryphonas, L. Skin reservoir formation and bioavailability of dermally administered chemicals in hairless guinea pigs. Food Chem Toxicol. 0278-6915 (Print) 0278-6915

Cohen B. (2017). Differential Diagnosis of Diaper Dermatitis. Clinical Pediatrics. 2017,Vol 56(5S) : 16S – 22S

Counts JL, Helmes CT, Kenneally D, Otts DR. (2014). Modern Disposable Diaper Construction: Innovations in Performance Help Maintain Healthy Diapered Skin. Clin Pediatr (Phila). 2014 Aug;53(9 suppl):10S-13S.

Danish EPA. (2009). Survey and health assessment of the exposure of 2 year-olds to chemical substances in consumer products. Survey N°102, 2009. København, Denmark : Danish EPA, 327p.

Directive 2001/95/CE du Parlement européen et du Conseil du 3 décembre 2001 relative à la sécurité générale des produits

DeVito MJ, Schecter A. (2002) Exposure assessment to dioxins from the use of tampons and diapers. Environ Health Perspect. 2002 Jan;110(1):23-8

EDANA. (2010). Quality of Life and Absorbent Hygiene Products. Avril 2010. Bruxelles, Belgique: EDANA, 13 p.

Erasala GN, Merlay I, Romain C. (2007). Evolution des couches à usage unique et amélioration de l'état cutané du siège des enfants. Arch Pediatr. 2007 May;14(5):495-500. Epub 2007 Apr 24.

Evans EB, Helmes CT, Kirsch T, Ruble KM. (2014). Colors in Disposable Diapers: Addressing Myths. Clin Pediatr (Phila). 2014 Aug;53(9 suppl):20S-22S.

Fahimzad A, Taherian M, Dalirani R, Shamshiri A. (2010). Diaper type as a risk factor in urinary tract infection of children. Iran J Pediatr. 2010 Mar;20(1):97-100.

Felter SP, Carr AN, Zhu T, Kirsch T, Niu G. (2017). Safety evaluation for ingredients used in baby care products: Consideration of diaper rash. Regul Toxicol Pharmacol. 2017 Nov;90:214-221.

Gammon, M. D., & Santella, R. M. (2008). PAH, genetic susceptibility and breast cancer risk: An update from the Long Island Breast Cancer Study Project. European Journal of Cancer, 44(5), 636-640.

Group'Hygiene. (2015). La couche bébé à usage unique. 14p.

Harfmann K, Chen AY, Witman P. (2017). Bullous diaper dermatitis with cloth diaper use. Pediatr Dermatol. 2017 Nov;34(6):e309-e312.

Helmes CT, O'Connor R, Sawyer L, Young S. (2014). Disposable Diaper Absorbency: Improvements via Advanced Designs. Clin Pediatr (Phila). 2014 Aug;53(9 suppl):14S-16S.

IARC, I. A. f. R. o. C. (2012). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. In (Vol. 100F).

Ishii, Satoko Katagiri, Ritsuko Kataoka, Toshiyuki Wada, Mitsuhiro Imai, Shigeo Yamasaki, Kanji. (2014) Risk assessment study of dioxins in sanitary napkins produced in Japan. 0273-2300

FRC. (2018). Couches-culotte. Au sec et en sécurité. Frc miuex choisir. 2018 octobre :112 : 16-17.

Kim, K.-H., Jahan, S. A., Kabir, E., & Brown, R. J. C. (2013). A review of airborne polycyclic aromatic hydrocarbons (PAHs) and their human health effects. Environment International, 60, 71-80.

Klunk C, Domingues E, Wiss K. (2014). An update on diaper dermatitis. Clin Dermatol. 2014 Jul-Aug;32(4):477-87.

Jacob SE, Herro EM, Guide S, Cunningham B, Connelly EA. (2012). Allergic contact dermatitis to Pampers Drymax. Pediatr Dermatol. 2012 Sep-Oct;29(5):672-4.

Lagier L, Mazereeuw-Hautier J, Raffin D, Beneton N, Lorette G, Maruani A; Société française de dermatologie pédiatrique. (2015). Les dermites du siège du nourrisson. Ann Dermatol Venereol. 2015 Jan;142(1):54-61; quiz 53, 62.

Larralde M, Raspa ML, Silvia H, Lamas F. (2001). Diaper dermatitis: a new clinical feature. Pediatr Dermatol. 2001 Mar-Apr;18(2):167-8.

Liamin, M., Boutet-Robinet, E., Jamin, E. L., Fernier, M., Khoury, L., Kopp, B., . . . Sparfel, L. (2017). Benzo[a]pyrene-induced DNA damage associated with mutagenesis in primary human activated T lymphocytes. Biochem Pharmacol, 137, 113-124.

Maruani A, Lorette G, Barbarot S, Potier A, Bessis D, Hasselmann C, Mazereeuw-Hautier J; Groupe de Recherche de la Société Française de Dermatologie Pédiatrique. (2013). Re-emergence of papulonodular napkin dermatitis with use of reusable diapers: report of 5 cases. Eur J Dermatol. 2013 Apr 1;23(2):246-9.

Mocarelli, P. Gerthoux, P. M. Ferrari, E. Patterson Jr, D. G. Kieszak, S. M. Brambilla, P. Vincoli, N. Signorini, S. Tramacere, P. Carreri, V. Sampson, E. J. Turner, W. E. Needham, L. L. (2000) Paternal concentrations of dioxin and sex ratio of offspring. Lancet. 01406736 (ISSN)

Moody, R. P., Nadeau, B., & Chu, I. (1995). In vivo and in vitro dermal absorption of benzo[a]pyrene in rat, guinea pig, human and tissue-cultured skin. J Dermatol Sci, 9(1), 48-58.

Moody, Richard P. Joncas, Julie Richardson, Mark Chu, Ih (2007). Contaminated Soils (I): In Vitro Dermal Absorption of Benzo[a]Pyrene in Human Skin. Journal of Toxicology and Environmental Health, Part A, 1528-7394

Odio M, Friedlander SF. (2000). Diaper dermatitis and advances in diaper technology. Curr Opin Pediatr. 2000 Aug;12(4):342-6. Review. Odio MR, O'Connor RJ, Sarbaugh F, Baldwin S. (2000). Continuous topical administration of a petrolatum formulation by a novel disposable diaper. 2. Effect on skin condition. Dermatology. 2000;200(3):238-43.

Odio M, Thaman L. (2014). Diapering, diaper technology, and diaper area skin health. Pediatr Dermatol. 2014 Nov;31 Suppl 1:9-14.

Onken AT, Baumstark J, Belloni B, Ring J, Schnopp C. (2011). Atypical diaper dermatitis: contact allergy to mercapto compounds. Pediatr Dermatol. 2011 Nov-Dec;28(6):739-41.

Philipp R, Hughes A, Golding J. (1997). Getting to the bottom of nappy rash. ALSPAC Survey Team. Avon Longitudinal Study of Pregnancy and Childhood. Br J Gen Pract. 1997 Aug;47(421):493-7.

Roul S, Ducombs G, Leaute-Labreze C, Taïeb A. (1998). 'Lucky Luke' contact dermatitis due to rubber components of diapers. Contact Dermatitis. 1998 Jun;38(6):363-4.

Runeman B. (2008). Skin interaction with absorbent hygiene products. Clin Dermatol. 2008 Jan-Feb;26(1):45-51.

Scheinfeld N. (2005). Diaper dermatitis: a review and brief survey of eruptions of the diaper area. Am J Clin Dermatol. 2005;6(5):273-81.

Schecter A.J., Papke O., Marquardt S. (1998). Dioxins and Dibenzofurans in USA Sanitary Products: Tampons, Sanitary Napkins, Disposable and Cloth Diapers, and Incontinence Pads, Organohalogen Compd. 36, 281—284 (1998).

Schwarz, M., & Appel, K. E. (2005). Carcinogenic risks of dioxin: mechanistic considerations. Regul Toxicol Pharmacol, 43(1), 19-34. doi:10.1016/j.yrtph.2005.05.008

Shin JH, Ahn YG, Seo JJ. (2005). Determination of PCDD/Fs in Disposable Diaper for Infant. Journal of the Korean Society of Clothing and Textiles 2005,29(6):814-824

Sorg, Olivier (2014). AhR signalling and dioxin toxicity. Toxicology Letters. 0378-4274

Sugimura T, Tananari Y, Ozaki Y, Maeno Y, Tanaka S, Ito S, Kawano K, Masunaga K. (2009). Association between the frequency of disposable diaper changing and urinary tract infection in infants. Clin Pediatr (Phila). 2009 Jan;48(1):18-20.

Tüzün Y, Wolf R, Bağlam S, Engin B. (2015). Diaper (napkin) dermatitis: A fold (intertriginous) dermatosis. Clin Dermatol. 2015 Jul-Aug;33(4):477-82.

Van den Berg M, Birnbaum LS, Denison M, De Vito M, Farland W, Feeley M, Fiedler H, Hakansson H, Hanberg A, Haws L, Rose M, Safe S, Schrenk D, Tohyama C, Tritscher A, Tuomisto J, Tysklind M, Walker N, Peterson RE. (2006). The 2005 World Health Organization reevaluation of human and Mammalian toxic equivalency factors for dioxins and dioxin-like compounds. Toxicol Sci. 2006 Oct;93(2):223-41. VITO (2018). Monitoring of the Belgian market with regard to organic residues in baby nappies. Part 2 : target analyses.119p.

VanRooij, J. G., De Roos, J. H., Bodelier-Bade, M. M., & Jongeneelen, F. J. (1993). Absorption of polycyclic aromatic hydrocarbons through human skin: differences between anatomical sites and individuals. J Toxicol Environ Health, 38(4)

Vos, J. G., Moore, J. A., & Zinkl, J. G. (1973). Effect of 2,3,7,8-tetrachlorodibenzo-p-dioxin on the immune system of laboratory animals. Environ Health Perspect, 5, 149-162. doi:10.1289/ehp.7305149

Weber, L. W., Zesch, A., & Rozman, K. (1991). Penetration, distribution and kinetics of 2,3,7,8-tetrachlorodibenzo-p-dioxin in human skin in vitro. Arch Toxicol, 65(5), 421-428.

Wester, R. C. Maibach, H. I. Bucks, D. A. Sedik, L. Melendres, J. Liao, C. DiZio, S. (1990) Percutaneous absorption of [14C]DDT and [14C]benzo[a]pyrene from soil. Fundam Appl Toxicol. 0272-0590

Wiberg K., Lundström K., Glas B., Rappe C. (1989). PCDDs and PCDFs in consumer'paper products. Chemosphere, 19(1-6) :735-740 (1989).

Yu J, Treat J, Brod B. (2017). Patch Test Series for Allergic Perineal Dermatitis in the Diapered Infant. Dermatitis. 2017 Jan/Feb;28(1):70-75.

Yu J, Treat J, Chaney K, Brod B. (2016). Potential Allergens in Disposable Diaper Wipes, Topical Diaper Preparations, and Disposable Diapers: Under-recognized Etiology of Pediatric Perineal Dermatitis. Dermatitis. 2016 May-Jun;27(3):110-8.

Annex 1: Detected, semi-quantified or quantified chemicals in tested baby diapers by Danish EPA (Danish EPA, 2009[13])

- Table 1 : Detected, semi-quantified or quantified chemicals in tested baby by Danish EPA (2009)

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	VoInner waist lining	Frontal print	All parts of the diaper (not in the filling material)
Diaper with strech closure. Print on the front side of diaper. Junio/5 11-25 kg	Latex free. Contains no lotion or fragrance -Contains: Cellulose, bleached without chlorine, polypropylene, polyethylene, polyurethane, synthetic rubber.		2,4-di-tert-butylphénol = 14 µg/g BHT = 100 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 480 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 180 µg/g Irgafos 168 oxydized = 200µg/g	2,4-di-tert-butylphénol = 19µg/g BHT = 29 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 1000 µg/g Irgafos 168 oxydized = 180 µg/g	BHT = 18 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 430 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 92 µg/g Irgafos 168 oxyized = 98 µg/g	BHT = 25 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 130 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 100 µg/g Irgafos 168 oxydized = 81µg/g	2.4-bis (1,1-dimethylethyl)-phenol BHT Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
Trouser diaper, print on the front side of diaper. 13.20 kg	-Anti leak technology - All-round soft fit	Irganox 245 = 160 µg/g	2,4-di-tertbutylphenol = 14 µg/g BHT = 9 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 1200 µg/g	No sterch closure	BHT = 7 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 890 µg/g Irgafos 168 oxydized = 61 µg/g	2,4-di-tert-butylphenol = 8 µg/g BHT = 7 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 960 µg/g	2.4-bis (1,1-dimethylethyl)-phénol BHT Tris(2,4-ditert-butylphenyl) phosphite

[13] https://mst.dk/service/publikationer/publikationsarkiv/2009/okt/survey-and-health-assessment-of-the-exposure-of-2-year-olds-to-chemical-substances-in-consumer-products/

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	VoInner waist lining	Frontal print	All parts of the diaper (not in the filling material)
			Irgafos 168 oxydized = 180µg/g			Irgafos 168 oxydized = 160µg/g	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
Diaper with strech closure. Print on the front and back sides of the diapers. Junior 11-25 kg	- Non-stop fit - Stretch & Hold - Contains: Petrolatum, stearyl alcohol, paraffinum liquidum, aloe barbadensis extract.		2,4-di-tert-butylphenol = 8 µg/g BHT = 11 µg/g 1-Octadecanol = 4800µg/g Tris(2,4-ditert-butylphenyl) phosphite = 550 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 280 µg/g Irgafos 168 oxydized = 240 µg/g	Limonene = 42 µg/g 2,4-di-tert-butylphénol = 11 µg/g BHT = 9 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 300 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 500 µg/g	BHT = 8 µg/g Naugard Tris(2,4-ditert-butylphenyl) phosphite = 550 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 55 µg/g Irgafos 168 oxydé = 67 µg/g	2,4-di-tert-butylphenol = 8 µg/g BHT = 10 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 430 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 150 µg/g Irgafos 168 oxydized = 140µg/g	Limonene 2.4-bis (1,1- dimethylethyl)-phenol BHT 1-Octadecanol Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
Diaper with strech closure. Print on the front side of diaper. Junior 12-22. Kg	Fragrance and lotion free		2,4-di-tert-butylphenol = 7 µg/g BHT = 8 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 560 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-	Limonène = 60 µg/g 2,4-di-tert-butylphenol = 10 µg/g BHT = 10 µg/g 13-Docosenamide = 82 µg/g	Tris(2,4-ditert-butylphenyl) phosphite = 380 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 50 µg/g Irgafos 168 oxydized = 180 µg/g	Limonene = 41 µg/g Caprolactame = 610 µg/g 2,4-di-tert-butylphenol = 7 µg/g BHT = 6 µg/g	Limonene Caprolactame 2.4-bis (1,1-diméthyléthyl)-phénol BHT

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	VoInner waist lining	Frontal print	All parts of the diaper (not in the filling material)
			hydroxyphenyl)propionate = 76 µg/g Irgafos 168 oxydized = 150µg/g	Tris(2,4-ditert-butylphenyl) phosphite = 210 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 480 µg/g Irgafos 168 oxydizedé = 89µg/g		Isobutyle palmitate = 210 µg/g sobutyle stearate = 560 µg/g Octadecyle oleat = 210 µg/g	Isobutyle palmitate isobutyle stearate Octadecyle oleate 13-Docosenamide Tris(2,4-ditert-butylphenyl) phosphite Irganox 1076 Formaldehyde
Diaper with strech closure. Print on the front side of diaper.	- 100% free of chlorine - Contains over 50% “renewable resources”. - Compostable packaging. - Dermatologically and clinically tested - Breathable foil 100% biodegradable		Limonene = 140 µg/g Dilactide = 160 µg/g 2,4-di-tert-butylphénol = 6 µg/g BHT = 8 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 260 µg/g Phthalate containing a long a alkyl chain = 170 µg/g Irgafos 168 oxydized = 130µg/g	Limonene = 210 µg/g 2,4-di-tert-butylphénol = 25 µg/g BHT = 41 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 830 µg/g Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate = 62 µg/g Irgafos 168 oxydized = 100µg/g	Limonene= 33 µg/g Dilactide = 220 µg/g BHT = 10 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 220 µg/g Phthalate containing a long alkyl chain = 100 µg/g Irgafos 168 oxydized = 41 µg/g	Limonène = 92 µg/g Caprolactame = 240 µg/g Palmitate d’isobutyle = 1200 µg/g Tris(2,4-ditert-butylphenyl) phosphite = 390 µg/g	Limonene 3.6-Dimethyl-1.4-dioxan-2.5-dione Caprolactame 2.4-bis (1,1-diméthyléthyl)-phénol BHT Isobutyl stearate Tris(2,4-ditert-butylphenyl) phosphite Octadecyl 3-(3,5-di-tert-butyl-4-

Baby diaper description	Information stated on the packaging or product	Filling material	Elastic rim	Strech closures	VoInner waist lining	Frontal print	All parts of the diaper (not in the filling material)
							hydroxyphenyl)propionate Phthalates containing a long alkyl chain Ester

Annex 2: Voluntary scheme criteria

EcoLabel[14]

- The pulp used to manufacture fibres shall not be bleached with the use of chlorine gas.
- Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the cotton.
- Plastic materials ans superabsorbent polymers
    - Contents of lead, cadmium, hexavalent chrome and related compounds shall be lower than 0,01 % (100 ppm) of the mass of each plastic material and synthetic polymer used in the product,
    - Additives used in plastics in concentration above 0,10 % by weight shall not be classified with any of the listed hazard statements (CMR, Acute Tox 1 or 2, STOT cat 1, hazardous for the aquatic environment cat 1 and 2).
- Superabsorbent polymers:
    - Acrylamide shall not be intentionnaly added,
    - Superabsorbent polymers used in the product may contain a maximum of 1 000 ppm residual monomers that are classified with the H-statements reported in criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent total of unreacted acrylic acid and cross linkers,
    - Superabsorbent polymers used in the product may, as a maximum, contain 10 % (weight/weight) of water-soluble extracts and these shall comply with criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.
- Adhesive materials shall not contain colophany resins, DIBP, DINP, Formaldehyde. This requirement shall not apply if those substances are not intentionnaly added to the amterial or the final product and are present in the adhesive mateirals in concentrations below 100ppm.

- The product and any homogeneous part of it shall not be dyed.(derogation shall apply to tampon strings, packaging material and tapes, titanium dioxide in polymers and viscose, materials not directly in contact with the skin may be dyed if the dye fulfils specifi functions).

- Fragrances :
    - Products marketed as designed and intended for children as well tampons and nursing pads shall be fragrance-free.
    - Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of IFRA.
    - Any fragrance used shall also comply with Criterion 7 on excluded or limited substances or mixtures regardless of the concentration in the final product.
    - Fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety as well as the fragrances whose presence, in accordance with Annex III to Regulation (EC) No 1223/2009 is required to be indicated in the list of ingredients shall not be used. Further the use of nitromusks and polycyclic musks is not allowed.
    - The use of fragrances shall be indicated on the product packaging. Further, fragrances and/or ingredients of the fragrance mixtures that are identified as established contact allergens in humans by the Scientific Committee on Consumerand are not restricted by Criterion 6.3 (c) and (d) shall additionally be named.

[14] https://www.ecolabels.fr/trouver-un-produit-ou-service-ecolabellise/

- Lotions
    - Lotions shall not be used in feminine care pads, tampons and nursing pads. The use of lotions in other products shall be indicated on the packaging.
    - Any lotion used in products other that feminine care pads, tampons and nursing pads shall comply with criterion6.3 on fragrances and criterion 7 on excluded or limited substances and mixtures regardless or their concentration in the final product.
    - Triclosan, parabens, formaldehyde, formaldehyde releasers shall bot be used.
- Neither D4 nor D5 shall be present in chemical products used in silicone treatmen of components. This requirement shall not apply where D4 and D5 are not intentionnaly added to the material or to the final product and where D4 and D5 are present in the silicone in concentration beloww 100 ppm.
- Nanosilver particles shall not be intentionnaly added to the product or to any homogeneous part or material of it.
- The EU Ecoloabel may not be awarded if the product or any article of it, or any homogeneous part of it contain substances or mixtures meeting the cirteria for classification with the hazard statements or risks phrases[15].

Nordic Swan[16]

The criteria that diapers have to fulfill in order to get the Nordic Swan Ecolabel are :

- Description of the product and material composition,
- Chemicals products and their classification,
- Chemicals substances, CMR,
- Other excluded substances: Substances on the Candidate List, Organotin compounds, phthalates, APEO, Halogenated organic compounds, Flame retardants, PBT/VPvB, endocrine disruptors, preservatives that are bioaccumulative, antibacterial agents.
- Indicate if silicone treatment of the whole or part of the product is used.
- Adhesives/binders used in the composition of the product and additional components are required,
- Fragrance, scents, lotion, skin care and/or moisturing preparations must not be added,
- No odour control substances,
- No medicament and antibacterial agents can be added.
- Products must not be dyed (except for tampon strings).
- Material/component that are not directly in contact with the skin may, however, be dyed if the dye has a special function,
- Printing inks used in a product or the components of the ink must fulfill a Nordic Swan document.
- Recycled material is not allowed in sanitary product with the exception of recycled plastic,
- Requirements regarding cellulose based pulp/fluff/air-laid are needed.
- Cotton must not be bleached with the aid of chlorine gas.
- The cotton must be organically cultivated or cultivated in the transitionary phase to organic production.
- Chlorine gas must not be used to bleach cellulose pulp or cellulose fibre.
- Sanitary products, additional components and their packaging must not be halogen-based,
- According to the amount of polymer in the article, some chemicals must not be present.
- Polyurethane/Elastane require a closed process when using isocyanate in the production, organotin compounds shall not be used, PUR foam and thermoplastic PUR must fulfill EU ECOLABEL requirements,

[15] H300, H301, H304, H310, H311, H330, H331, H340, H341, H350, H350i, H360F, H360D, H360FD, H360fD, H360Fd, H361f, H361d, H361fd, H362, H370, H371, H372, H373, H400, H410, H411, H412, H413, EUH059, EUH029, EUH031, EUH032, EUH070, H317 1A et 1B et H334

[16] http://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=023

- For superabsorbent polymers, acrylamide must not be used as a monomer, and SAP may as a maximum contain 10%w of water soluble extracts.
- Requirements are needed for non woven parts.
- Procedure requirements are needed.

Annex 3: THE QHRA performed in the ANSES report (2019)

ANSES first studied the possible chemical risks associated with the types of materials contained in single-use baby diapers. It then undertook a quantitative health risk assessment of the chemicals found in diapers[17].

- **Types of materials used in babies' diapers**

The data relating to the types of materials used in baby diapers came primarily from manufacturers and trade federations.

Regarding the **composition of baby diapers**, macromolecular materials can be broken down into two main categories:

- Products of natural origin, derived from wood cellulose, which all undergo chemical treatment (bleaching). The exact nature of these cellulose products, which influences their physicochemical properties, was not provided as part of this formal request.
- Synthetic products such as polyolefins (polyethylenes and polypropylenes) and superabsorbent polyacrylates (sodium polyacrylate or SAP-SuperAbsorbent Polymer). There are very different manufacturing processes that provide these polymers with specific properties, but these processes differ by the nature of the polymerisation initiators and/or catalysts, of which traces can be found in the finished material. SAP is contained in all single-use diapers.

It should be noted that the precise nature of the materials with which single-use baby diapers are made could not be determined through the hearings that were held. The same lack of information was noted for the description of processing aids such as glues, and for intentionally added substances (fragrances, inks, etc.).

Nonetheless, certain stages of the manufacturing processes appear to use silica, a percentage of which is in nanoparticle form. The CES reiterates that declaration in the national R-Nano registry is required for any substance with nanoparticle status, whether it is produced, imported or distributed in France, as is, contained in a mixture without being bound to it, or contained in a material intended to release it under normal conditions of use.

- **Chemicals identified in baby diapers/Chemical contamination**

In 2016, 2017 and 2018, the French National Consumer Institute (INC) and the Joint Laboratory Service (SCL) conducted tests on shredded whole diapers and shredded diaper parts, in order to screen for the presence of chemicals. Solvent extraction was used to extract as many chemicals as possible from 23 products for the INC (2017, 2018) and SCL (2017). The tests were conducted with the best-selling commercial products on the French market, as well as with retailers' own brands and "eco-friendly" diapers.

The following classes of substances were screened for:

- By the INC: pesticides, PAHs, dioxins and furans, fragrances and volatile organic compounds (VOCs), heavy metals, nonylphenol, octylphenol and nonylphenol monoethoxylates,
- By the SCL: pesticides, PAHs, dioxins, furans and DL-PCBs ("dioxin-like" polychlorinated biphenyls), phthalates, organotins, VOCs, fragrances and azoic dyes.

[17] https://www.anses.fr/en/system/files/CONSO2017SA0019EN.pdf -
ANSES, French Agency for Food, Environmental and Occupational Health & Safety. 2018. "Safety of footwear and textile clothing."

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

- in shredded **whole diapers**:
    - volatile organic compounds (naphthalene, styrene, toluene, dichlorobenzenes, p-isopropyltoluene, xylenes, chlorobenzene),
    - pesticides (hexachlorobenzene, quintozene and its metabolite pentachloroaniline, glyphosate and its metabolite AMPA),
    - formaldehyde,
    - dioxins, furans and DL-PCBs,
    - fragrances (benzyl alcohol, benzyl salicylate, coumarin, hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral®), butylphenyl methylpropional (Lilial®), limonene, linalool, alpha-isomethyl ionone),

- in shredded **diaper parts**[18]:
    - dioxins, furans (in the outer layer, the inner layer and other parts, except the core),
    - PAHs in the elastics (benzo[b]fluoranthene, benzo[a]anthracene, indeno[1,2,3-c,d]pyrene, benzo[g,h,i]perylene).

The SCL also carried out **migration tests with whole diapers and shredded whole diapers for single use in a urine simulant**[19]. Dioxins, furans and DL-PCBs, PAHs and formaldehyde were quantified or detected.

Regardless of the test, the detected and/or quantified chemicals were the same overall. However, due to the use of analytical methods of varying precision, for the same diaper product, the same substance could be detected in one test and quantified or not detected in another.

It should be noted that, of the pesticides found in these products, the majority are currently prohibited in the EU (lindane and quintozene since 2000, hexachlorobenzene since 2004), with the exception of glyphosate which is authorised in France and the EU.

According to the data from the literature and the information provided during the hearings, the chemicals detected or quantified in diapers by the SCL or INC are not intentionally added by the manufacturers, with the exception of fragrances. The majority of the chemicals detected or quantified in diapers can either be the result of raw-material contamination (e.g. pesticides) or be formed during manufacturing processes such as bleaching or bonding (e.g. DL-PCBs, furans and dioxins). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, processes using chlorinated agents such as chlorine dioxide, for example, are used and can be responsible for the formation of dioxins and furans. Regarding the presence of PAHs in single-use diapers, the experts do not rule out PAH formation during the manufacture of these diapers due to the use of high temperatures for certain manufacturing processes (Abdel-Shafy and Mansour, 2016).

Contaminants were found both in "eco-friendly" diaper products and in other diaper products.

- **Quantitative health risk assessment of substances detected or quantified in single-use baby diapers**

A quantitative health risk assessment (QHRA) was undertaken for the chemicals detected or quantified in baby diapers. ANSES used the QHRA approach formalised in 1983 by the US National Research Council (NRC, 1983). This approach is divided into four separate steps: identification of hazards, description of the dose-response relationship, assessment of exposure, and characterisation of risks.

[18] A diaper part refers to a component considered separately, such as the elastic bands, inner layer, absorbent pad, etc.

[19] The urine simulant consisted of urea, creatinine, ammonium citrate, NaCl, KCl, $KHSO_4$, $MgSO_4$, $KH2PO_4$ and $KHCO_3$ in water (Colon *et al.*, 2015).

An analysis of uncertainties was carried out during the expert appraisal. It focused on:

- the context and formulation of the question,
- the body of knowledge,
- the method of assessing health risks via the identification of hazards, choice of toxicity reference values (TRVs), estimation of exposure and characterisation of risks.

The QHRA was based on the various analyses undertaken by the SCL and the INC:

- Solvent extractions in shredded whole diapers or diaper parts (SCL, 2017; INC, 2017 and 2018; Group'Hygiène, 2018[20]),
- Extractions with a urine simulant in shredded whole diapers (SCL, 2017),
- Extractions with various urine simulants in whole diapers (SCL, 2018; Group'Hygiène, 2018[21]).

The QHRA was first undertaken using a "worst-case" scenario in order to rapidly eliminate substances posing no health risks. In cases when the TRV was exceeded, a "realistic" approach (a scenario whose parameters intend to replicate the actual conditions of use commonly encountered) was implemented.

- **Hazard identification**

As part of its hazard identification approach, ANSES investigated whether the substances found in diapers were covered by harmonised classifications according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) and according to the carcinogenicity classification of the International Agency for Research on Cancer (IARC).

In light of the proximity of these products to the reproductive organs, ANSES also consulted classifications and databases with the aim of identifying potential endocrine-disrupting (ED) effects[22].

- **Description of the dose-response relationship**

A toxicity reference value (TRV) is a toxicological index that, when compared with exposure, is used to qualify or quantify a risk to human health. A distinction is made between "threshold" TRVs, used for substances that, above a certain dose, cause damage whose severity is proportional to the absorbed dose (direct non-genotoxic carcinogenic and non-carcinogenic effects); and "no-threshold" TRVs, or excess risk per unit (ERU), used for substances for which direct genotoxic or carcinogenic effects can appear irrespective of the dose received and the likelihood of their occurrence. These TRVs are defined as an increase in the likelihood, compared to an unexposed subject, of an individual developing the disease if he/she is exposed over his/her entire lifetime to a unit dose of the substance.

At first, for each chemical, the TRVs established by national, European and international agencies were identified, with a focus on those developed for a chronic duration of exposure (repeated and/or long-term exposure, generally associated with low or moderate dose levels), the parameter regarded as most relevant in view of the context of the formal request. Considering the close contact of baby diapers with the buttocks, the use of dermal TRVs seemed the most appropriate. However, since no TRVs were available for this route of exposure, a search for TRVs by the oral route was carried out.

[20] Confidential tests
[21] Confidential tests
[22] Classifications of the European Commission (BKH, 2000 and 2002; DHI, 2007), the US EPA and the Illinois EPA and inclusion on the TEDX (The Endocrine Disruption Exchange Inc) and SIN (Substitute It Now) lists.

For PAHs and dioxins and furans, only the TRVs for the reference compound[23] were identified, namely benzo[a]pyrene and 2,3,7,8-tetrachlorodibenzo-para-dioxin or TCDD (the most toxic congener). The toxicity of other compounds in the same class was estimated from toxic equivalency factors (TEFs) used to express the toxicity of all congeners with the same toxicological mechanism of action compared to that of the leader.

When there was no TRV (p-isopropyltoluene, benzyl salicylate, butylphenyl methylpropional or Lilial®, hydroxyisohexyl 3-cyclohexene carboxaldehyde or Lyral®**,** alpha-isomethyl ionone), the critical doses selected by national, European and international agencies were identified and a critical dose was selected.

The experts considered that the TRVs 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 TRV (ANSES, 2017). First using a worst-case approach, ANSES considered, by default, that the TRVs applied to children between 0 and 36 months of age, and the most disadvantageous TRV was used regardless of how it had been established.

Then, whenever the risk analysis undertaken according to the "worst-case" scenario found the TRV to have been exceeded, the experts decided to conduct a more detailed analysis of the TRV considering the relevance of the choices made (critical effect, key study, critical dose, uncertainty factors) and the transparency of the manner in which it had been established (Annex 2).

ANSES discussed the applicability of the selected TRVs to the population of children aged 0 to 36 months, who can be particularly susceptible to certain chemicals. The CES thus chose the approach used for the infant Total Diet Study (iTDS, 0-36 months) (ANSES, 2016b) and the QHRA on the mouthing of plastic toys containing phthalate substitutes (ANSES, 2016). ANSES therefore reviewed the toxicological data specific to children taken into account in the establishment of each of these TRVs (studies of perinatal and postnatal toxicity, studies of developmental toxicity, reproductive studies conducted with several generations, etc.).

- **Exposure assessment**

Refined exposure scenarios were developed in order to characterise the exposure of children between 0 and 36 months of age inclusive to the chemicals previously identified in baby diapers.

The dermal route of exposure was the one taken into account in this assessment, and more specifically exposure via the buttocks.

The daily exposure dose (DED, expressed in mg/kg/day) was calculated using a deterministic approach according to the following formula:

For solvent extractions (shredded whole diapers or diaper parts)

$$\mathbf{DED = (C_{shredded\ material} \times W \times F \times T \times Abs) / BW}$$ [scenario 1]

For extractions in shredded diapers with a urine simulant:

$$\mathbf{DED = (C_{shredded\text{-}material\ simulant} \times W \times F \times R \times Abs) / BW}$$ [scenario 2.1]

For extractions in whole diapers with a urine simulant:

$$\mathbf{DED = (C_{diaper\ simulant} \times W \times F \times Abs) / BW}$$ [scenario 2.2]

- DED: daily exposure dose (mg/kg/day)
- $C_{shredded\ material}$: concentration of the chemical extracted with a solvent from shredded whole diapers and diaper parts (mg/kg of diaper)

[23] Reference congeners with the highest toxicity.

- $C_{shredded\text{-}material\ simulant}$: concentration of the chemical extracted with a urine simulant from shredded whole diapers (mg/kg of diaper)
- $C_{diaper\ simulant}$: 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 or of the diaper part (kg)
- F: frequency of use (number/day)
- T: transfer to skin (%)
- R: reflux ratio (%[24])
- Abs: fraction absorbed by the skin (%)
- BW: body weight of a child (kg)

It should be noted that the DED that seemed the most realistic from these various analyses was that calculated from the extractions in whole diapers with a urine simulant (scenario 2.2), since:

- the capacity to extract substances from diapers to urine was not modelled but was observed during the experiment. This avoided the need to use the default skin transfer value T of 7%;
- quantities of substances were only measured in urine actually coming out of the diapers after pressing, which avoided the need to use the modelled reflux ratio R parameter.

ANSES used the following values for each exposure parameter to calculate the DED according to a "worst-case" scenario and subsequently using a "refined" approach (Table 2).

[24] The reflux ratio corresponds to the transfer of the substance into body fluids by extraction or solubilisation, followed by migration to the surface layer and release onto the skin under pressure.

Table 2: Summary of the parameters used to assess exposure according to the worst-case scenario and the refined scenario

Parameter	Worst-case scenario	Refined scenario		
Concentration (mg/kg)	For quantified substances: highest concentration in each diaper For detected substances: LoQ (SCL, 2016 and 2018; INC, 2016 and 2018)	For quantified substances: highest concentration in each diaper For detected substances: LoQ/2 (SCL, 2016 and 2018; INC, 2016 and 2018)		
Weight of a diaper (W) (g)	24 g (size 1) (Krause *et al.*, 2006*; Rai *et al.*, 2009)	0-6 months exclusive	24 g	Krause *et al.* (2006)* Rai *et al.* (2009)*
		6-12 months inclusive	33 g	
		13-18 months inclusive	33 g	
		19-24 months inclusive	40 g	
		25-30 months inclusive	40 g	
		31-36 months inclusive	45 g	
Frequency of use (F) (number of diapers per 24 hrs)	12/day (Ishii *et al.*, 2015)	0-6 months exclusive	7.98	UK Environment Agency, 2005 (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	4.7	
Transfer of the substance to the skin (T)	100%	7% (Odio *et al.*, 2000)*		
Dermal absorption (Abs)	100% (ANSM, 2010)			
Reflux ratio (R)	100%	1.32% (Dey *et al.*, 2016)* for scenario 2.1		
Body weight (BW) (kg)	2.6 kg (SFAE, 2013)	0-6 months exclusive	3.9 kg	(SFAE, 2013)
		6-12 months inclusive	7 kg	
		13-18 months inclusive	8.4 kg	
		19-24 months	9.2 kg	

		25-30 months inclusive	10 kg	
		31-36 months inclusive	11.4 kg	

For the refined scenarios, the experts underline that for the skin transfer and reflux ratio parameters, the only available data were those published in the literature by manufacturers.

Regarding dermal absorption, the experts chose to retain the value used for the worst-case scenario (100%), considering that diaper dermatitis could not be reasonably excluded and that it was likely to impact the dermal absorption of the chemicals.

Characterisation of risks

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). In this study, the acceptable risk was set at 10^{-6}, the most conservative value.

Threshold effects	HQ < 0.1	0.1 < HQ < 1	HQ > 1
	No toxic effects are expected in the exposed population.	It is necessary to ensure that there are no other concomitant sources of exposure, to not risk exceeding 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.

For substances for which no TRV could be identified, the CES calculated a margin of exposure (MOE[25]).

Regarding the substances measured by **solvent extraction in shredded whole diapers (scenario 1)**, a risk calculation was undertaken using a refined scenario for all fragrances, dioxins, furans and DL-PCBs and their sums, as well as for three VOCs[26] and hexachlorobenzene.

[25] The MOE was calculated as the ratio of the No Observed Adverse Effect Level in animals to the value of the daily exposure dose: MOE = Critical dose / DED

[26] 1,2,3-trichlorobenzene; 1,2,4-trichlorobenzene; 1,3,5-trimethylbenzene

It showed cases in which 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 out of the 19 analysed.

Regarding the substances quantified by **solvent extraction in certain diaper parts[27] (scenario 1)**, no cases of the health threshold being exceeded were found for PAHs or for 2,3,4,6,7,8 HxCDF, for children aged 0 to 36 months.

Regarding dioxins, furans and DL-PCBs and their sums found by **extraction with a urine simulant in shredded whole diapers (scenario 2.1)**, a risk calculation was undertaken according to a refined scenario. It did not show any cases of the health threshold being exceeded for children aged 0 to 36 months.

Regarding the substances found by **extraction with a urine simulant in whole diapers (scenario 2.2)**, a risk calculation was undertaken according to a refined scenario for 10 detected PAHs[28], formaldehyde, PCB-126, the sum of dioxins and furans, the sum of DL-PCBs and the sum of dioxins, furans and DL-PCBs[29], which were quantified. It highlighted the following, for children aged 0 to 36 months:

- ✓ cases in which the risk indicator (no-threshold carcinogenic effects) was exceeded for the 10 PAHs (benzo[g,h,i]perylene, benzo[b]fluoranthene, cyclopenta[c,d]pyrene, chrysene, 5-methylchrysene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[e]pyrene, benzo[a]pyrene, dibenzo[a,h]anthracene);
- ✓ cases in which the health threshold[30] (threshold effects) was exceeded for six PAHs (benzo[b]fluoranthene, cyclopenta[c,d]pyrene, benzo[k]fluoranthene, benzo[j]fluoranthene, benzo[a]pyrene, dibenzo[a,h]anthracene) and for PCB-126, the sum of DL-PCBs, and the sum of dioxins, furans and DL-PCBs.

The results of the above exposure calculations were limited to exposure related to baby diapers, excluding other possible exposure sources (environmental, dietary, 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 (orange column), such as:

- sum of dioxins and furans
- formaldehyde.

Dioxins, furans, DL-PCBs and PAHs are ubiquitous substances that can be found, for example, in food and particularly in breast milk.

The risk calculations performed did not take endocrine-disrupting or skin-sensitising effects into account. However, a number of the substances are possible EDs[31] or are classified as known or suspected skin sensitisers[32]. These skin-sensitising effects were confirmed by data from the literature.

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[27] Plastic parts and outer layer

[28] For detected substances, the concentration used in the risk calculations was the value LQ/2.

[29] Classifications of these substances and sector-specific regulations are available in Annex 5.

[30] TRVs established based on developmental effects for PAHs and reprotoxic and developmental effects for dioxins, furans and DL-PCBs (Annex 1)

[31] Naphthalene, styrene, toluene, 1,4-and 1,3-dichlorobenzene, m-xylene + p-xylene, hexachlorobenzene, quintozene, glyphosate, benzyl salicylate, Lilial, PAHs, dioxins, furans and DL-PCBs (BKH, DHI, SIN List, TEDX List); note that these classifications were not analysed by ANSES as part of this expert appraisal.

[32] BaP, formaldehyde, quintozene, linalool, limonene and Lyral® classified as skin sensitisers according to the CLP Regulation; 1,2,3 trichlorobenzene, Lilial®, alpha-isomethyl ionone, benzyl salicylate and coumarin self-classified under the REACh Regulation

- **Conclusions**

There are no epidemiological data demonstrating an association between health effects and the wearing of diapers. However, hazardous chemicals have been found in these diapers. Based on the results of the INC and SCL tests and the literature data, a quantitative health risk assessment was undertaken for single-use baby diapers according to refined scenarios considered to be realistic. This QHRA showed cases of the health thresholds being exceeded for several substances. Therefore, to date and in the current state of knowledge, it is not possible to rule out a health risk associated with the wearing of single-use diapers.

Annex 4: Comparison of the levels of chemicals in baby diapers and in baby food

Chemicals	Diaper part	Max in diapers (mg/kg)	Max from the iTDS (mg/kg)	iTDS/diaper concentration ratio
PAHs				
Benzo[g,h,i]perylene	Whole diaper	0.1*	$3.5 \cdot 10^{-5}$	$3.5 \cdot 10^{-4}$
Benzo[b]fluoranthene		0.1*	$1.44 \cdot 10^{-4}$	$1.44 \cdot 10^{-3}$
Benzo[a]anthracene		0.1*	$8.4 \cdot 10^{-5}$	$8.4 \cdot 10^{-4}$
Indeno[1,2,3-c,d]pyrene	Plastic part	1.2	$2.3 \cdot 10^{-5}$	$1.91 \cdot 10^{-5}$
Dioxins and furans				
1,2,3,6,7,8-HxCDD	Whole diaper	$1.32 \cdot 10^{-7}$	$1.68 \cdot 10^{-5}$	127
1,2,3,4,6,7,8-HpCDD	Whole diaper	$1.03 \cdot 10^{-6}$	$2.61 \cdot 10^{-5}$	25.33
	Topsheet	$6.09 \cdot 10^{-7}$		42.86
OCDD	Whole diaper	$2.15 \cdot 10^{-6}$	$3.33 \cdot 10^{-4}$	154.88
	Topsheet	$2.69 \cdot 10^{-6}$		123.79
1,2,3,6,7,8-HxCDF	Whole diaper	$4.42 \cdot 10^{-8}$	$3.05 \cdot 10^{-5}$	690.04
2,3,4,6,7,8-HxCDF	Whole diaper	1.07210^{-7}	$2.13 \cdot 10^{-5}$	199.06
	Backsheet	$5.01 \cdot 10^{-7}$		42.51
1,2,3,4,6,7,8-HpCDF	Whole diaper	$1.54 \cdot 10^{-6}$	$6.42 \cdot 10^{-5}$	41.68
	Other parts	$1.93 \cdot 10^{-7}$		332.64
1,2,3,4,7,8,9-HpCDF	Whole diaper	$2.62 \cdot 10^{-7}$	$8.7 \cdot 10^{-6}$	33.2

Annex 5: Self classifications according to the CLP for the chemicals included in the scope of this RMOA

Table 7: Self classifications according to the CLP for the chemicals included in the RMOA

Chemicals	EC No	CAS No	Self classification
PAHs			
benzo[g,h,i]perylene	205-883-8	191-24-2	Not classified
cyclopenta[c,d]pyrene		27208-37-3	-
5-methylchrysene	681-936-2	3697-24-3	Acute Tox 4-H302 Eye Dam 1-H318 Carc 2-H 351 Carc 1B-H350 Not Classified
Benzo[c]fluorene	205-908-2	205-12-9	
Indeno[1,2,3-cd]pyrene	205-893-2	193-39-5	Carc 2-H351 Not Classified
Dibenzo[a,l]pyrene*	205-886-4	191-30-0	Eye Dam 1-H318 Carc 1B-H350 Not Classified
Dibenzo[a,e]pyrene	205-891-1	192-65-4	Eye Dam.1-H318 Carc 2-H351 Muta 2-H341 Carc 1B-H350 Not classified
Dibenzo[a,i]pyrene*	205-877-5	189-55-9	Carc 2-H351 Carc 1B-H350 Not classified
Dibenzo[a,h]pyrene*	205-878-0	189-64-0	Muta 2-H341 Carc 1B-H350 Not classified Carc 2-H351
DL-PCBs, dioxins, furans			
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	809-099-2	33 423-92-6	Acute Tox 3–H301
1,2,3,4,7,8 HxCDD	694-767-4	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	694-811-2	57653-85-7	Acute Tox 3 – H301 Eye irrit 2 – H319
1,2,3,7,8,9-HxCDD	694-810-7	19408-74-3	Acute Tox 4 H 302
1,2,3,4,6,7,8-HpCDD	694-835-3	35822-46-9	Eye Irrit 2 – H319 STOT SE 3 – H335 Muta 2 – H341
OCDD	694-813-3	3268-87-9	Acute Tox 1 – H300
2,3,7,8 TCDF	694-829-0	51207-31-9	Acute Tox. 1 – H300
1,2,3,7,8 PeCDF	694-762-7	57117-41-6	Acute Tox. 3 – H301 Eye Irrit. 2 – H319 STOT SE 3 – H335 Muta. 2 – H341
2,3,4,7,8 PeCDF	694-761-1	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	694-812-8	70648-26-9	Acute Tox. 3 – H301 Eye Irrit. 2 – H319
1,2,3,6,7,8 HxCDF	694-837-4	57117-44-9	Acute Tox. 1 – H300
2,3,4,6,7,8 HxCDF	694-831-1	60851-34-5	Acute Tox. 3 – H301 Eye Irrit. 2 – H319

1,2,3,7,8,9-HxCDF	694-765-3	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	694-815-4	67562-39-4	Acute Tox. 3 – H301 Eye Irrit. 2 – H319
1,2,3,4,7,8,9 HpCDF	694-836-9	55673-89-7	Acute Tox. 1 – H300
OCDF	694-806-5	39001-02-0	Acute Tox. 1 – H300
PCB 81	690-324-4	70362-50-4	STOT RE 2 – H373
PCB 77	634-804-3	32598-13-3	STOT RE 2 – H373
PCB 123	690-284-8	65510-44-3	STOT RE 2 – H373 Not classified
PCB 118	621-375-2	31508-00-6	STOT RE 2 – H373
PCB 114	690-296-3	74472-37-0	STOT RE 2 – H373 Not classified
PCB 105	634-808-5	32598-14-4	Acute Tox. 4 – H302 STOT RE 2 – H373
PCB 126	682-346-8	57465-28-8	STOT RE 2 – H373 Not classified
PCB 167	690-199-6	52663-72-6	STOT RE 2 – H373 Not classified
PCB 156	620-601-7	38380-08-4	STOT RE 2 – H373 Not classified
PCB 157	690-279-0	69782-90-7	STOT RE 2 – H373 Not classified
PCB 169	682-345-2	32774-16-6	STOT RE 2 – H373 Not classified
PCB 189	690-157-7	39635-31-9	STOT RE 2 – H373 Not classified

*: these 3 chemicals have adopted RAC opinions that deal with harmonised classifications as Muta.2 H 341 and Carc.1B H350

Annex 6: Toxicokinetic profiles of Dioxins, furans and dioxin-like polychlorobenzyls (DL-PCBs)

Data is scare regarding toxicokinetics for PAHS or dioxins/furans/DL PCBS when describing human data or human skin.

PAHs

PAHs are lipophilic compounds that are absorbed from the lungs following inhalation, the gastrointestinal tract following ingestion and the skin following dermal exposure. Several studies show good absorption of PAHs through the skin (Moody *et al*., 2007; Chu *et a*l., 1996) An in-vivo interspecies study of skin absorption shows at 48-hour, an absorption of 14C-benzo(a)pyrene (8-13ug/cm² of skin) in acetone of : 95% +/- 9.6% in rat, 43% +/- 8.7% in a 50-year-old man, and 23% +/-5.3% in a 32-year-old man (Moody *et al*., 1995). A study of skin absorption in volunteers exposed to coal tar showed absorption rates between 0.036 and 0.135 L/hour depending on anatomical sites for 45-minute exposure, suggesting that 20-56% of the dose would be absorbed in 6 hours (VanRooij *et al*., 1993). Finally a study of human corpse skin showed that 23.7 +/- 9.7% of the applied dose of 14C-benzo(a)pyrene penetrated the skin (Wester *et al*., 1990).

PAHs are rapidly distributed throughout the body by all routes of exposure. Fatty tissues tending to show higher amounts of PAHs. They are metabolized into a wide variety of compounds by the action of CYP450 and epoxide enzymes. Metabolites of PAHs are generally excreted as conjugates of GSH, glucuronic acid or sulphate in the urine, faeces and via biliary excretion.

Dioxins, Furans and DL PCB

The toxicokinetic differences between dioxins, furans and DL-PCBs appear to stem mainly from variability in fat affinity, rate of metabolism and solubility. Dermal absorption seems to be very low compared to oral absorption.

In-vitro absorption of 3H-TCDD through human corpse skin was studied at concentrations of 65 and 6.5ng/cm². The vehicle used was acetone to simulate exposure to TCDD in the form of dust or volatile solvent, or mineral oil to simulate the situation of industrial accidents. Penetration was assessed after 30,100,300 and 1000 min. The vehicle plays an important role in skin penetration. Acetone allows TCDD to penetrate strongly into the free-surface slats of the stratum corneum but little into the lower layers while mineral oil slows skin penetration by competing with the lipophilic constituents of the stratum corneum. For intact skin and acetone as a vehicle, the penetration rate in the dermis and epidermis was between 6 and 170 pg/h/cm^2 while the penetration rate in the dermis was between 100 and 800 pg/h/cm2. With mineral oil as a vehicle, the penetration rate was 5 to 10 times lower (in the dermis: 20 to 220 pg/h/cm^2; in the dermis and epidermis: 1.4 to 18 pg/h/cm^2) (Weber *et al*., 1991). Several studies have evaluated skin exposure to dioxins in absorbent hygiene products such as sanitary napkins, tampons and baby diapers (Ishii *et al.* 2014; DeVito *et al*., 2002). For baby diapers, the wood pulp used in the absorbent mattress is a mixture of large organic fibers, so it is likely that the dioxins are strongly linked to these fibers and therefore not absorbed easily (DeVito *et al.,* 2002).

Metabolism and passive fecal excretion are the two routes of elimination for these products. The metabolites are eliminated in the bile.

Because the environmental exposure of PAHs, dioxins, furans and DL-PCBs is multiple, the skin pathway is a route of exposure for humans not to be overlooked for these substances.