The Director General

Maisons-Alfort, 4 June 2018

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the safety of feminine hygiene products

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 4 June 2018 shall prevail.

On 29 April 2016, ANSES received a formal request from the Directorate General for Health (DGS) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) to conduct an expert appraisal on the following issue: safety of feminine hygiene products.

1. BACKGROUND AND PURPOSE OF THE REQUEST

Feminine hygiene products are consumer products used by women from the age at which menstruation begins (12 years and 3 months on average), either during their periods to absorb menstrual flow or outside their periods (abnormal vaginal discharge, slight urinary tract leaks, etc.). There are two categories of feminine hygiene products on the market:

- internal feminine hygiene products designed to be inserted into the vagina to absorb menstrual flow during periods (tampons, menstrual cups). These can be disposable such as tampons, or reusable such as menstrual cups;
- external feminine hygiene products such as sanitary towels and panty liners. These can be disposable or reusable.

There are no specific regulations governing the composition, manufacture or use of feminine hygiene products. The safety requirements surrounding feminine hygiene products are defined by Directive (EC) No 2001/95/EC on general product safety. In the United States, the US Food and Drug Administration (FDA) has classified these products as medical devices and their marketing has been regulated since the late 1970s.

According to the formal request, "the main proven risk associated with the use of tampons is the occurrence of menstrual toxic shock syndrome" (TSS) due to a bacterial infection (*Staphylococcus aureus*). A case of TSS in the United States, in a young female model whose leg was amputated as a result of TSS, was behind a petition launched in France by Mélanie Doerflinger entitled "make the composition of Tampax brand tampons visible". In 2015, this petition was sent to the Ministry of Social Affairs and Health to raise the alert about the risks associated with the use of tampons.

In March 2016, *60 Millions de Consommateurs*[1] detected residues of toxic substances in intimate hygiene products (60 Millions de Consommateurs, 2016). This publication was picked up by the press and this issue has been the subject of numerous media communications.

On 29 April 2016, ANSES received a formal request to assess the safety of feminine hygiene products in terms of the risk of infection, allergy or intolerance and/or related to chemical action via dermal contact and contact with the mucous membranes. ANSES's expert appraisal was requested with the following aims:

- study the typical composition of feminine hygiene products;
- identify the regulated or non-regulated chemicals of concern liable to be present in these hygiene products, possibly in trace amounts;
- conduct a review of knowledge on the hazards presented by these substances, in particular through contact with the vaginal mucosa;
- assess the relevance of defining thresholds for the presence of these substances in feminine hygiene products, especially in view of the duration and mode of exposure;
- where appropriate, issue recommendations to encourage better control of manufacturing methods, composition and consumer information, particularly at European Union level.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

The expert appraisal fell within the sphere of competence of the Expert Committee (CES) on "Assessment of chemical risks of consumer items and products" from May 2016 to August 2017, and was then entrusted to the CES on "Assessment of chemical risks of consumer items and products 2". The methodological and scientific aspects of the work were presented to the two CESs between 26 May 2016 and 3 April 2018. It was adopted by the CES at its meeting on 3 April 2018.

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.
The experts' declarations of interests are made public via the ANSES website (www.anses.fr).

To obtain the opinions of the various stakeholders, a series of hearings took place between September 2016 and February 2018 with consumer groups (Federal Union of Consumers - UFC), companies and trade federations (Procter & Gamble, Johnson & Johnson, SCA Hygiene

[1] A magazine and website published by France's *Institut national de la consommation* (INC) whose main activities include gathering, producing, analysing and disseminating information, studies, surveys and tests on various consumer items and services

Products[2], Claripharm, Federation of Trade and Retail Companies - FCD, National Association of the Medical Technology Industry - SNITEM, French grouping of manufacturers of single-use products for hygiene, health and wiping or Group'Hygiene, the EDANA[3] professional federation) and public bodies (French National Consumer Institute - INC, National Reference Centre for Staphylococci).

To conduct this expert appraisal, ANSES compiled the available data, both institutional reports and scientific publications relating to the types of materials in these products, the chemical substances that may be found in these products, menstrual toxic shock syndrome and other disorders induced by feminine hygiene products (irritation, allergy, microtrauma, etc.). The literature search found only a few reports by public bodies[4] and a scarcity of scientific publications. In addition, the authors of most of the publications were employed by companies marketing feminine hygiene products. ANSES also took the grey literature into account, including the results of comparative tests carried out by consumer groups or institutions, particularly those behind the formal request (60 Millions de Consommateurs, 2016). Lastly, in 2016 the DGCCRF commissioned tests by the Joint Laboratory Service (SCL) to determine the substances found in feminine hygiene products.

Meanwhile, ANSES commissioned a survey on the use of feminine hygiene products and the perception of the risks in a sample of women representative of the French population (Opinion Way, 2017).

3. ANALYSIS AND CONCLUSIONS OF THE CES

The analysis and conclusions of the expert appraisal presented below relate in turn to the following points: use of feminine hygiene products and perception of the associated risks, microbiological risks and menstrual toxic shock syndrome (TSS) in particular, and lastly chemical risks (types of materials, presence of chemical substances, quantitative health risk assessment).

■ Use of feminine hygiene products and perception of the risks

A survey was carried out at ANSES's request by the research company Opinion Way, from 26 June to 4 July 2017, with a sample of 1065 menstruating women from 13 to 50 years of age, representative of the French female population (stratified based on criteria of age, SPC[5], regions and conurbation categories according to INSEE classifications), by means of an online questionnaire (Opinion Way, 2017). Its objectives were to collect information on women's feminine hygiene protection practices (types of protection used and conditions of use), the main factors determining their choices (criteria of choice, types and sources of information) and perceptions of the potential risks associated with their use.

The following points on the use of feminine hygiene products stood out among the survey's main results: external feminine hygiene products (towels and panty liners) are used by the majority of the women responding to the survey (91%), particularly respondents aged 13-24 years (33% exclusively use sanitary towels). Women over the age of 25 reported that they predominantly use internal feminine hygiene products such as tampons.

[2] Has since become Essity

[3] The European Disposables And Nonwovens Association or EDANA comprises companies in the nonwoven industry and provides recommendations that member companies undertake to follow

[4] The Danish EPA, the BfR (German Federal Institute for Risk Assessment), the OSAV (Swiss Federal Food Safety and Veterinary Office) and the US FDA (US Food and Drug Administration)

[5] Socio-professional category

In the 12 months prior to the date of the survey, 13% of respondents said they changed the type of protection, primarily to use menstrual cups. Nine percent of the surveyed women use them, mainly those in the 25-34 years age group.
In addition, while 21% of surveyed women only use sanitary towels, most respondents said they favoured the use of two different types of product (mainly tampons combined with towels or panty liners).

The results of the investigation highlighted a **lack of hygiene measures**, particularly regarding washing hands, either before changing the feminine hygiene product (39% of women do not wash their hands at all) or afterwards (6% do not wash their hands at all, 35% just rinse them in water).

Concerning the perception of the risks associated with the use of feminine hygiene products, 81% of respondents felt that at least one type of product entailed a risk (mainly tampons), but few of them were aware of these risks. The risk of infection and "vaginal problems" (irritation, ulceration, dryness, pruritus, etc.) was regarded as common to all feminine hygiene products while menstrual toxic shock syndrome (TSS) was cited only for tampons and menstrual cups. Menstrual cups were perceived by the surveyed women to be the least risky feminine hygiene products.

All the respondents clearly expressed a desire for information on all these points (symptoms, composition, hygiene and use). At the same time, in principle the surveyed women considered health professionals to be trustworthy, key sources of information.

- **Microbiological risk**

The main documented risk associated with wearing feminine hygiene products (tampons, menstrual cups) is menstrual toxic shock syndrome (TSS) which although rare, can have serious consequences when it occurs. It is caused by a toxin, Toxic Shock Syndrome Toxin-1 (TSST-1), produced by a bacterium, *Staphylococcus aureus or S. aureus*. The development of menstrual TSS is associated with the following three conditions: vaginal colonisation by a strain of TSST-1-producing *S. aureus*, transfer of a sufficient quantity of TSST-1 through the vaginal epithelium to cause the disorder, and the absence or inadequacy of anti-TSST-1 antibodies.
External feminine hygiene products (towels, panty liners) have never been implicated in menstrual TSS.
The risk of developing menstrual TSS increases with the time that internal feminine hygiene products are worn. It also increases with the use of feminine hygiene products whose absorption capacity is higher than necessary (Barataud *et al.*, 2018).
The recommendations contained in the instructions for the use of internal feminine hygiene products advocate wearing them for no more than between 4 to 8 hours. These recommendations appear to be partly or completely disregarded by most women using tampons, according to the results of the survey, which showed that 79% of women respondents reported keeping their tampon for the entire night without changing it, and that nearly 30% of women do not change their menstrual cup for a whole day (2% for tampons).

The National Reference Centre (NRC) for Staphylococci (Lyon) has identified an average of 20 cases of menstrual TSS every year since 2010. These cases come from spontaneous reports by clinicians or microbiologists for diagnostic or epidemiological purposes. It should also be noted that there is currently no mandatory reporting of cases of TSS. According to the NRC, under-reporting to the NRC cannot therefore be ruled out. The NRC for Staphylococci and the French Public Health Agency are therefore currently working to estimate the incidence of this disease (results are expected in mid-2018).
In the United States, the number of cases of menstrual TSS has fallen sharply since the peak observed in the early 1980s (CDC, 1990), associated with the use of highly absorbent tampons, in particular the tampon Rely®. A link was established between TSS and the composition of this

tampon (polyurethane foam and cross-linked carboxymethyl cellulose). A regulation classifying tampons according to their absorption capacity was subsequently drawn up and companies reviewed the composition of their tampons.

The assumption of a link between the risk of menstrual TSS and the composition of these products or the presence of residual chemicals was put forward by the experts. However, no evidence in the scientific literature or in the results of this expert appraisal can currently confirm or refute this assumption.

- **Irritation, intolerance, allergy, microtrauma**

Symptoms of irritation, intolerance, allergy and even microtrauma are described with the use of feminine hygiene products. Although there are no epidemiological data available, these symptoms have been reported by the users themselves, by gynaecologists, by manufacturers through their system for monitoring marketed products, and in some articles in the literature.

- **Chemical risks**

The CES studied the potential chemical risks induced by feminine hygiene products, associated with the types of materials in the tampons, sanitary towels, panty liners and menstrual cups. It then carried out a quantitative health risk assessment (QHRA).

  - **Types of materials used in feminine hygiene products**

The data relating to the types of materials used in feminine hygiene products came primarily from manufacturers and trade federations.

In general, disposable feminine hygiene products are composed of macromolecular materials that can be classified into three categories:

- Products of natural origin derived from cotton: cellulose-type materials that also undergo a chemical treatment during the manufacturing processes. This treatment can be simple (this is the case with bleaching, which does not alter the structure), but may be more complex, such as the one used to produce viscose, which modifies the structure of the polymer chains.
- Synthetic products such as polyolefins (polyethylenes and polypropylenes), used in tampons, towels and panty liners. There are very different manufacturing processes that confer specific properties to these polymers; these processes differ from each other by the nature of the polymerisation initiators and/or catalysts, of which traces are found in the finished material.
- Superabsorbent products (SAPs), found only in external feminine hygiene products (panty liners and towels).

Menstrual cups are composed of thermoplastic elastomer or medical-grade silicone, but small ring compounds may be present due to secondary polymerisation mechanisms and can easily be extracted from the final material.

The experts emphasise the fact that the materials used in the manufacture of feminine hygiene products are poorly documented and that the hearings with the representatives of the product manufacturers did not enable them to be precisely characterised. The same lack of information was noted for the description of processing aids such as glues for example, or intentionally added substances (fragrances, inks, etc.).

- **Screening for chemical contamination: tests on shredded disposable feminine hygiene products**

In 2016, the National Consumer Institute (INC) and the Joint Laboratory Service (SCL) conducted tests on shredded feminine hygiene products, particularly tampons, towels and panty liners, in order to screen for the presence of chemical substances. Solvent extraction was used to extract as many chemical substances as possible. The substances quantified or detected at least once in the feminine hygiene products sold in France, in the tests conducted by the INC and the SCL in 2016 were:

- External feminine hygiene products: butylphenyl methylpropional or BMHCA (Lilial®), polycyclic aromatic hydrocarbons (PAHs) (benzo[a]pyrene, benzo[c]fluorene, chrysene, cyclopenta[c,d]pyrene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[g,h,i]perylene, benzo[e]pyrene, indeno[1,2,3-c,d]pyrene, dibenzo[a,h]anthracene), pesticides (glyphosate and its metabolite aminomethylphosphonic acid (AMPA), lindane, hexachlorobenzene, quintozene and its metabolite, pentachloroaniline) and di-n-octyl phthalate (DnOP);
- Tampons: dioxins and furans (1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,4,6,7,8-HpCDF and OCDF) and DnOP.

It should be noted that the use of certain pesticide substances that were quantified in the tested products is prohibited in the European Union (EU): lindane and quintozene since 2000 and hexachlorobenzene since 2004. Glyphosate, whose use is authorised in the EU, was quantified in some products.

According to the information provided by the manufacturers, the substances detected or quantified in feminine hygiene products by the SCL or the INC had not been added intentionally, except for Lilial®, which is a fragrance. They either resulted from contamination of raw materials or finished products, or were formed during the manufacturing processes (e.g. bleaching, glueing). Today, the cellulose used in these products is no longer bleached by elemental chlorine. However, certain processes using chlorinated agents such as chlorine dioxide, for example, are still used and may be responsible for the formation of dioxins and furans.
Environmental contamination may be responsible for the presence of certain substances such as dioxins and furans in feminine hygiene products. However, concerning the presence of PAHs in feminine hygiene products, another assumption made by the experts concerned the high-temperature conditions during assembly or packaging of the feminine hygiene products.

- **Quantitative health risk assessment associated with the substances detected or quantified in disposable feminine hygiene products**

Initially, a quantitative health risk assessment (QHRA) for the chemicals detected or quantified in tampons, panty liners and towels was carried out according to a maximalist approach ("worst-case" scenario). In the event that risks were identified for certain chemicals, the choices of toxicity reference values (TRVs) and exposure parameters were refined with assumptions that were more "realistic" ("refined" scenario).

- **Identification of hazards**

The CES decided not to produce full toxicological profiles for the different substances detected or quantified in the feminine hygiene products but rather to investigate whether the substances 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 view of the proximity of these products to the genital organs, classifications or databases used to identify potential endocrine-disrupting (ED) effects were also consulted[6].

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

For each chemical, the TRVs established by national, European and international agencies were identified, focusing on those developed for a chronic duration of exposure, the duration regarded as most relevant in view of the context of the formal request. Considering the close contact of the feminine hygiene products with the external genitalia and vaginal mucosa, the use of dermal TRVs seemed appropriate. However, because no TRVs were available for this route of exposure, a search for TRVs by the oral route was carried out.

For PAHs and dioxins and furans, only the TRVs for the "leaders"[7] 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 the leader.

Initially, in line with the "worst-case" approach, the most disadvantageous TRV was used regardless of how it had been established (Table 1 and Table 2).

Where there was no TRV, the critical doses selected by national, European and international agencies were identified.

[6] Classification of the European Commission (BKH, 2000 and 2002; DHI, 2007), of the US EPA and the Illinois EPA and presence on the TEDX (The Endocrine Disruption Exchange Inc) and SIN (Substitute It Now) lists.
[7] Reference congeners with the highest toxicity

Table 1: Summary of threshold TRVs and critical doses selected for conducting the QHRA according to a worst-case scenario

Substance	Type of TRV	Organisation (year)	Value	Target organ/critical effect
Pesticides				
Hexachlorobenzene	Chronic	ATSDR (2015)	$7 \cdot 10^{-5}$ mg/kg/d	Hepatotoxicity
Quintozene	Chronic	US EPA (1987)	$3 \cdot 10^{-3}$ mg/kg/d	Liver tumours
Quintozene + pentachloroaniline	Chronic	EC (2000)	10 µg/kg/d	Not indicated
Glyphosate	Chronic	US EPA (1987)	0.1 mg/kg/d	Development/ nephrotoxicity
Glyphosate + metabolites including AMPA	Chronic	JMPR (2016)	0-1 mg/kg	Carcinogenicity/salivary gland
Lindane	Chronic	RIVM (2001)	$4 \cdot 10^{-5}$ mg/kg/d	Immunotoxicity
Other				
Di-n-octyl phthalate	Subchronic	ATSDR (1997)	0.4 mg/kg/d	Hepatotoxicity
PAHs				
Benzo[a]pyrene → Application of TEFs* for PAHs	Chronic	US EPA (2017)	$3 \cdot 10^{-4}$ mg/kg/d	Developmental toxicity
PCDD/F + DL-PCB				
2,3,7,8 TCDD → Application of TEFs* for dioxins and furans	Chronic	US EPA (2012)	0.7 pg/kg/d	Reproductive and developmental toxicity
Fragrance				
BMHCA (Lilial®)	Chronic	SCCS (2017)	NOAEL: 5 mg/kg/d	Systemic effects and maternal toxicity

* TEF: Toxic Equivalency Factor

Table 2: Summary of non-threshold TRVs selected for conducting the QHRA according to a worst-case scenario

Substance	Organisation (year)	Value	Target organ/critical effect
Pesticides			
Hexachlorobenzene	OEHHA (2011)	$1.8\ (mg/kg/d)^{-1}$	Liver tumours
Lindane	US EPA (1997)	$1.3\ (mg/kg/d)^{-1}$	Liver tumours
PAHs			
Benzo[a]pyrene → Application of TEFs for the different PAHs	OEHHA (2009)	$12\ (mg/kg/d)^{-1}$	Gastrointestinal tumours

Then, whenever the TRV was found 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 was established (Annex 4).

- **Exposure assessment**

The formulation of exposure scenarios is designed to characterise the exposure of women of childbearing age (13 to 50 years) to the chemicals previously identified in feminine hygiene products.

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

The daily exposure dose (DED, expressed in mg/kg/d) is calculated according to the following formula:

$$DED = \frac{C \times W \times F \times T \times Abs}{BW}$$

where C: concentration of the substance found in the product (mg/kg), W: average weight of a feminine hygiene product (kg), F: frequency of use (number/day), T: transfer to the skin (%), Abs: fraction absorbed by the skin or mucosa (%), BW: body weight of a woman of childbearing age (kg).

For dioxins and furans and PAHs, exposure and risks were assessed globally for the substance class as well as for each congener taken in isolation.

The CES selected the following values for each exposure parameter to calculate the DED according to a "worst-case" scenario and subsequently according to a "refined" scenario (Table 3).

Table 3: Summary of the exposure parameters selected

Parameter	Worst-case scenario	Refined scenario
	Value (reference)	**Value (reference)**
Concentration	For quantified substances: highest concentration in each product (SCL, 2016; INC, 2016)	
	For detected substances: LQ (SCL, 2016; INC, 2016)	For detected substances: LQ/2 (SCL, 2016; INC, 2016)
Weight of a feminine hygiene product	Tampon: 6 g (without applicator) (OSAV, 2016)	/
	Panty liner: 1.5 g (Working Group of the European Commission organised for the development of Ecolabel criteria, 2012)	
	Towel: 10 g (Working Group of the European Commission organised for the development of Ecolabel criteria, 2012)	
Frequency of use	6/day (Opinion Way, 2017)	
Transfer of the substance to the skin	100%	20% corresponding to the percentage of transfer of a substance in direct contact with the skin/mucosa despite the fact that it is impossible to determine where the substances detected or quantified by the INC or the SCL were found, as they were screened for in shredded material (Woeller and Hochwalt, 2015)
Dermal absorption	Tampon: 100%	/
	Panty liner: 100% Towel: 100%	From literature data specific to the substances: - lindane: 10% - PAHs: 56%
Body weight	For threshold effects: - 30 kg (5th percentile of body weight for the 11-14 years age group) (SFAE, 2013) - 60 kg (adult) (WHO, 2017) For effects without a threshold: 60 kg (adult) (WHO, 2017)	

- **Risk characterisation**

No cases of the health thresholds being exceeded were observed according to the maximalist approach for threshold effects induced by dioxins and furans (1,2,3,4,6,7,8-HpCDD, OCDD, 2,3,7,8-TCDF, OCDF), chrysene and DnOP found **in tampons** (Annex 1). For chrysene, which has

carcinogenic effects without a threshold, the excess risk per unit corresponding to a risk of 10^{-6} was not found to have been exceeded[8].

Concerning the substances found in **sanitary towels and panty liners**, no cases of the health thresholds being exceeded were found according to the maximalist approach for threshold effects induced by glyphosate alone or associated with AMPA, lindane, PAHs (by congener or added together), Lilial®, hexachlorobenzene, quintozene alone or associated with pentachloroaniline, or DnOP. Similarly, the excess risk per unit corresponding to a risk of 10^{-6} was not found to have been exceeded for carcinogenic no-threshold effects induced by hexachlorobenzene and certain PAHs (panty liners: benzo[g,h,i]perylene and benzo[e]pyrene; towels: chrysene, cyclopenta[c,d]pyrene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[g,h,i]perylene, benzo[e]pyrene and indeno[1,2,3-c,d]pyrene) (Annexes 2 and 3).
For some PAHs (benzo[a]pyrene, cyclopenta[c,d]pyrene and benzo[k]fluoranthene in panty liners, and benzo[k]fluoranthene, benzo[c]fluorene and dibenzo[a,h]anthracene in towels), for the sum of the PAHs found in towels and panty liners and for lindane (quantified in one panty liner), a risk calculation according to a refined scenario was performed. This calculation showed no case of the excess risk per unit corresponding to a risk of 10^{-6} being exceeded for these same PAHs and the sum of the PAHs and lindane (Annex 4).

- **Conclusion**

An analysis of the uncertainties was carried out during the expert appraisal, focusing on:
- the context and formulation of the question,
- the body of knowledge,
- the method of assessing the health risks via identification of the hazards, choice of TRVs, estimate of the exposure and characterisation of the risks.

The analysis of the uncertainties revealed unknowns that may require specific studies to limit the overall uncertainty. However, the experts consider that this QHRA was mainly based on upper-bound hypotheses.

No cases of the health thresholds being exceeded were found by the dermal route for these chemicals detected or quantified in tampons, sanitary towels and/or panty liners. Nevertheless, the CES stresses that there are other sources of human exposure to these substances (environmental, food, consumer products) that were excluded from the scope of the expert appraisal. It cannot therefore comment on the potential risk associated with human exposure to certain substances, given all these sources of exposure. It highlights the resulting uncertainty as to whether or not there is in fact a risk, particularly associated with dioxins, furans and PAHs, which are all ubiquitous.

A number of substances found in these feminine hygiene products are suspected endocrine disruptors (Lilial®, PAHs, DnOP, lindane, hexachlorobenzene, quintozene, dioxins and furans). Other substances are regarded as known or suspected skin sensitisers (benzo[a]pyrene and quintozene have been classified as Skin Sensitiser Category 1 by the CLP Regulation, CLP classification proposals have been made by certain notifiers for Lilial® and DnOP). Moreover, it should be noted that the risk calculations performed did not take endocrine-disrupting and skin-sensitising effects into account. Even when TRVs are available, they cannot guarantee protection from these effects.

- **Additional tests**

The CES notes that the information available to ANSES on the composition of feminine hygiene products was insufficient for assessing the risks of menstrual cups. The CES therefore decided to

[8] 1 case for 1,000,000 people exposed

conduct material characterisation tests on these cups. Moreover, the CES also noted the lack of information on the composition of tampons and the physico-chemistry of materials, and commissioned additional tests. All the results will be covered in an addendum to the report and opinion.

Recommendations

On the basis of the above conclusions, the CES is issuing the following recommendations:

- **on the composition of feminine hygiene products and the chemical risk:**

  - The CES recommends better documenting the types of materials (cotton, viscose, etc.) used in these products and displaying this information on the packaging in order to inform users.

  - The CES recommends eliminating the use of all fragrances in the composition of the feminine hygiene products, particularly those with irritant and skin-sensitising effects, such as Lilial®, which was quantified in one panty liner product.

  - The following substances were found in feminine hygiene products:
    - pesticides whose use is prohibited in Europe, such as lindane, hexachlorobenzene and quintozene, were quantified in external feminine hygiene products (towels and panty liners);
    - pesticides authorised in Europe (glyphosate) were quantified in one panty liner;
    - PAHs were detected and quantified in external feminine hygiene products while this was the case for only one PAH (chrysene) and dioxins/furans in tampons. These dioxins/furans or PAHs could possibly come from the contamination of raw materials.

    However, despite the fact that the risk assessment related to the use of feminine hygiene products found that no health values had been exceeded, the CES recommends improving the quality of the raw materials. These feminine hygiene products can be contaminated even before manufacture. The CES recommends eliminating or reducing as far as possible the presence of hazardous chemicals, particularly those with CMR, endocrine-disrupting or skin-sensitising effects, in the materials used in feminine hygiene products. To do this, manufacturers could introduce more restrictive specifications and more systematic verifications.

  - Concerning the relevance of whether or not to determine thresholds for the substances in feminine hygiene products, the CES recommends setting a threshold for each of the chlorinated dioxins and furans that is of the same order of magnitude as the limit of quantification (LQ). Initially, the lowest LQ identified in this expert appraisal (0.2 ng/kg) could be proposed. This value was not determined on the basis of health considerations.

  - The CES recommends improving feminine hygiene product manufacturing processes in order to reduce as far as possible the presence of hazardous chemicals, such as dioxins and furans or PAHs, in the materials used in feminine hygiene products. To achieve this, certain industrial processes should be revised. To limit chlorinated dioxins and furans, the material bleaching phases could be carried out without elemental chlorine or chlorinated agents. Alternative techniques are available, such as the use of dioxygen and hydrogen peroxide. Nevertheless, an assessment of the residues produced by these processes should first be carried out.

- The CES recommends documenting the bleaching process and displaying this information on the packaging in order to inform users.

- **on the use of feminine hygiene products:**

  - The CES recommends improving information for women on good hygiene practices to reduce the risk of infection, by means of institutional communication.

  - The CES recommends increasing awareness among information relays such as health professionals, particularly general practitioners and gynaecologists, of the need to inform women about **hygiene practices**.

  - The CES recommends that each internal feminine hygiene product sold (tampon, menstrual cup) be systematically accompanied by a package leaflet with instructions for use and hygiene recommendations (on wearing time, washing menstrual cups between each use, etc.).

  - Due to misuses of internal feminine hygiene products, particularly tampons (wearing them during episodes of abnormal vaginal discharge, simultaneous wearing of two tampons, etc.), the CES recommends always using them in accordance with the manufacturers' recommendations.

- **on the microbiological risk (menstrual TSS):**

According to the survey by Opinion Way, women are keen for more information, particularly on the **symptoms of menstrual TSS**.

  - The CES recommends improving information for women on menstrual TSS by promoting the dissemination of information on this risk via health professionals (general practitioners, gynaecologists, nurses, school doctors and nurses, midwives, etc.) or more generally through information campaigns or dedicated internet pages.

  - Tampon manufacturers and some menstrual cup manufacturers currently inform users of the existence of menstrual TSS via the packaging and the instructions for use found in the packets, and issue recommendations on use, particularly regarding how long tampons and/or menstrual cups should be worn. The CES therefore recommends:

    - that all manufacturers improve user information on the existence of menstrual TSS by clearly indicating this risk on the packaging and instructions for use of internal feminine hygiene products (tampons and menstrual cups).
    - that users comply with the manufacturers' recommendations, particularly those regarding how long tampons and cups can be worn, wearing a tampon only during menstruation and using tampons with the lowest absorbency needed for their menstrual flow, in order to avoid wearing these products longer than the recommended time.
    - improving how key information (symptoms of menstrual TSS, wearing time, etc.) is displayed on the packaging – for example by creating a logo – and in the instructions for use.
    - that women who have already had menstrual TSS refrain from using internal feminine hygiene products (tampons and menstrual cups).

  - that external feminine hygiene products be used at night to reduce the risk of developing menstrual TSS, given the length of time they are worn.

- Given the seriousness of menstrual TSS, the CES recommends developing information for health professionals – particularly those working in emergency and intensive care – in order to improve diagnosis, and in particular advocates following the recommendations of the NRC for Staphylococci[9].

- The CES recommends encouraging physicians and hospital services to report cases of TSS, particularly menstrual TSS, to the NRC for Staphylococci.

- **on the acquisition of knowledge:**

To assess the risk presented by substances added intentionally by manufacturers to feminine hygiene products, or substances contaminating these products that are impossible to eliminate, the CES recommends:

- conducting studies to obtain substantiated scientific information on the transfer of substances from the material to the skin/mucous membranes;
- obtaining data on:
  - the transfer of substances through the vaginal mucosa,
  - the possible link between the presence of micro-lesions and the transfer of *Staphylococcus aureus* through the vaginal mucosa;
- developing TRVs for the mucocutaneous route;
- conducting an *ex-vivo* study of bacterial growth and screening for chemical substances in the blood from used feminine hygiene products after having first taken blood samples from the women who wore these products, in order to determine their concentrations.

- **on the establishment of new regulations:**

The existing regulatory system governing the composition, use and manufacture of feminine hygiene products as defined in the Directive on general product safety is insufficient, due to the presence of hazardous chemicals in these products. The CES recommends developing a more restrictive regulatory framework to limit the presence of these substances. This regulatory framework could involve a restriction procedure for each type of article according to the REACh Regulation (Annex XVII). The substances identified in this expert appraisal could be used as a basis for a list of substances to be included in this regulatory measure.
The CES also recommends developing standards to regulate the tests to be performed (e.g. choice of materials to use, their biocompatibility, etc.). These standards could be based on regulations currently in force for medical devices and food contact materials.
Due to the rapid growth in the market for menstrual cups, the CES recommends increasing market surveillance (type of materials, contaminants, etc.).

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

This expert appraisal sought to:

[9] Barataud *et al.*, 2018

- assess the safety of feminine hygiene products in terms of the risk of infection, allergy or intolerance and/or related to chemical action via dermal contact and contact with the mucous membranes,
- study the composition of feminine hygiene products,
- identify the regulated or non-regulated chemicals of concern liable to be present in these products,
- conduct a review of knowledge on the hazards presented by these substances,
- conduct a quantitative health risk assessment (QHRA) for these substances.

The French Agency for Food, Environmental and Occupational Health & Safety endorses the CES's conclusions and recommendations.

Two main risks associated with feminine hygiene products were analysed in the expert appraisal: firstly, the infectious risk essentially related to menstrual toxic shock syndrome (TSS) and secondly, the chemical risk in the short term (allergy, intolerance, etc.) and long term (e.g. cancer).

The expert appraisal also highlighted the results of a survey commissioned by ANSES on women's practices regarding the use of feminine hygiene products and their perceptions of the risks. In view of the results of this survey, ANSES stresses the need to improve information for women on hygiene measures, particularly washing hands, before and after changing the feminine hygiene product.
ANSES therefore recommends improving information for women about good practices when using internal feminine hygiene products (tampons, menstrual cups) and draws the attention of public authorities to the need to provide better information and training for health professionals to enable them to disseminate the good hygiene practices to be adopted when using feminine hygiene products, from the time menstruation first begins.

With regard to the microbiological risk, ANSES insists on the seriousness of menstrual TSS, which is the main documented microbiological risk associated with the use of internal feminine hygiene products (tampons and menstrual cups). ANSES underlines the fact that TSS is not related to the materials used in the composition of these feminine hygiene products. Work is under way at the instigation of the National Reference Centre for Staphylococci and the French Public Health Agency that should help estimate the incidence of this disease.

With regard to manifestations of irritation, intolerance, allergy or microtrauma associated with chemical substances and materials, the expert appraisal noted the scarcity of studies and the absence of epidemiological data. These effects are reported by the users themselves, by gynaecologists and by manufacturers through their system for monitoring marketed products. **ANSES recommends conducting a study on the adverse short- and medium-term health effects associated with the articles used.**

Regarding the medium- and long-term chemical risk, ANSES stresses the fact that the expert appraisal was based on a very small number of studies on feminine hygiene products published in the scientific literature.

The results of tests carried out by the Joint Laboratory Service (SCL) and by the National Consumer Institute (INC) demonstrated the presence of various chemical substances (PAHs, dioxins and furans, DnOP, Lilial®, pesticides) in feminine hygiene products. Among these substances, some are added intentionally (Lilial®) while others, according to the available data, result from the contamination of raw materials or manufacturing processes (e.g. PAHs, dioxins and furans, pesticides).

Based on the results of these tests, ANSES conducted a quantitative assessment of the health risks by the dermal route. It concluded that there is no health risk in tampons, sanitary towels and/or panty liners, whether these chemicals were detected or actually quantified.

However, ANSES recommends eliminating or reducing as far as possible the presence in feminine hygiene products of these substances, particularly those with CMR, endocrine-disrupting or skin-sensitising effects.

In addition, within the framework of the REACH Regulation, ANSES is supporting a project to restrict the presence of CMR substances in feminine hygiene products. This project is being examined by the European Commission.

A lack of information on the materials in tampons and menstrual cups was noted by the experts. Additional material characterisation tests are therefore currently being conducted at the request of ANSES and will give rise to a complementary expert appraisal.

Dr Roger Genet

KEYWORDS

Protection intime, sécurité, tampon, serviette hygiénique, protège-slip, coupe menstruelle, syndrome de choc toxique, évaluation quantitative de risques sanitaires, EQRS

Feminine hygiene products, sanitary towels, panty liners, pads, tampons, cup, safety, toxic shock syndrome, risk assessment

ANNEX 1: CALCULATIONS OF DEDS AND RISKS FOR TAMPONS ACCORDING TO THE WORST-CASE APPROACH

Substance	Nb of samples detected/ quantified	Concen-tration (mg/kg)	Body weight (kg)	DED (mg/kg bw/d)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	Hazard quotient	ERU $(mg/kg/d)^{-1}$	IER
Dioxins and furans										
1,2,3,4,6,7,8-HpCDD	Quantified in 5 products	$3.85 \cdot 10^{-7}$	60	$2.31 \cdot 10^{-10}$	0.01	$2.31 \cdot 10^{-12}$	TRV for TCDD $7 \cdot 10^{-10}$	$3.3 \cdot 10^{-3}$	**Carcinogen with a threshold**	
			30	$4.62 \cdot 10^{-10}$		$4.62 \cdot 10^{-12}$		$6.6 \cdot 10^{-3}$		
OCDD	Quantified in 8 products	$3.90 \cdot 10^{-6}$	60	$2.34 \cdot 10^{-9}$	0.0003	$7.02 \cdot 10^{-13}$		10^{-3}		
			30	$4.68 \cdot 10^{-9}$		$1.40 \cdot 10^{-12}$		$2.01 \cdot 10^{-3}$		
2,3,7,8-TCDF	Quantified in 4 products	$9.60 \cdot 10^{-8}$	60	$5.76 \cdot 10^{-11}$	0.1	$5.76 \cdot 10^{-12}$		$8.23 \cdot 10^{-3}$		
			30	$1.15 \cdot 10^{-10}$		$1.15 \cdot 10^{-11}$		$1.65 \cdot 10^{-2}$		
1,2,3,4,6,7,8-HpCDF	Quantified in 4 products	$7.70 \cdot 10^{-8}$	60	$4.62 \cdot 10^{-11}$	0.01	$4.62 \cdot 10^{-13}$		$6.6 \cdot 10^{-4}$		
			30	$9.24 \cdot 10^{-11}$		$9.24 \cdot 10^{-13}$		$1.32 \cdot 10^{-3}$		
OCDF	Quantified in 6 products	$6.88 \cdot 10^{-7}$	60	$4.13 \cdot 10^{-10}$	0.0003	$1.24 \cdot 10^{-13}$		$1.77 \cdot 10^{-4}$		
			30	$8.26 \cdot 10^{-10}$		$2.48 \cdot 10^{-13}$		$3.54 \cdot 10^{-4}$		
Sum of quantified dioxins and furans in TEQ*	At least 1 dioxin and/or furan quantified in all 10 tampons tested	$9.94 \cdot 10^{-9}$	60			$5.97 \cdot 10^{-12}$		$8.52 \cdot 10^{-3}$		
			30			$1.19 \cdot 10^{-11}$		$1.7 \cdot 10^{-2}$		
Phthalates										
DnOP	Detected in 1 product	120	60	$7.2 \cdot 10^{-2}$			0.4	0.18		
			30	0.144				0.36		
PAHs										
Chrysene	Detected in 1 product	$5 \cdot 10^{-3}$	60	$3 \cdot 10^{-6}$	0.01	$3 \cdot 10^{-8}$	TRV for BaP $3 \cdot 10^{-4}$	10^{-4}	12	$4.78 \cdot 10^{-8}$
			30	$6 \cdot 10^{-6}$		$6 \cdot 10^{-8}$		$2 \cdot 10^{-4}$		

* Maximum concentration retained in a tampon

ANNEX 2: CALCULATIONS OF DEDS AND RISKS FOR PANTY LINERS ACCORDING TO THE WORST-CASE APPROACH

Substance		Nb of samples detected/quantified	Concen-tration (mg/kg)	Body weight (kg)	DED (mg/kg/d)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	HQ	ERU $(mg/kg/d)^{-1}$	IER
PAHs											
Benzo[a]pyrene		Detected in 1 product	$5 \cdot 10^{-3}$	60	$7.50 \cdot 10^{-7}$	1	$7.50 \cdot 10^{-7}$	TRV for BaP $3 \cdot 10^{-4}$	$2.5 \cdot 10^{-3}$	TRV for BaP 12	$1.08 \cdot 10^{-5}$
				30	$1.50 \cdot 10^{-6}$		$1.50 \cdot 10^{-6}$		$5 \cdot 10^{-3}$		
Cyclopenta[c,d]pyrene		Quantified in 2 products and detected in 1	$8.9 \cdot 10^{-3}$	60	$1.34 \cdot 10^{-6}$	0.1	$1.34 \cdot 10^{-7}$		$4.45 \cdot 10^{-4}$	TRV for BaP	$1.44 \cdot 10^{-6}$
				30	$2.67 \cdot 10^{-6}$		$2.67 \cdot 10^{-7}$		$8.9 \cdot 10^{-4}$		
Benzo[k]fluoranthene		Quantified in 2 products	$1.04 \cdot 10^{-2}$	60	$1.56 \cdot 10^{-6}$	0.1	$1.56 \cdot 10^{-7}$		$5.2 \cdot 10^{-4}$	TRV for BaP	$2.25 \cdot 10^{-6}$
				30	$3.12 \cdot 10^{-6}$		$3.12 \cdot 10^{-7}$		$1.04 \cdot 10^{-3}$		
Benzo[g,h,i]perylene		Quantified in 2 products and detected in 2	$1.17 \cdot 10^{-2}$	60	$1.76 \cdot 10^{-6}$	0.01	$1.76 \cdot 10^{-8}$		$5.85 \cdot 10^{-5}$	TRV for BaP	$1.9 \cdot 10^{-7}$
				30	$3.51 \cdot 10^{-6}$		$3.51 \cdot 10^{-8}$		$1.17 \cdot 10^{-4}$		
Benzo[e]pyrene		Quantified in 2 products	$9.7 \cdot 10^{-3}$	60	$1.46 \cdot 10^{-6}$	0.01	$1.46 \cdot 10^{-8}$		$4.85 \cdot 10^{-5}$	TRV for BaP	$1.73 \cdot 10^{-8}$
				30	$2.91 \cdot 10^{-6}$		$2.91 \cdot 10^{-8}$		$9.7 \cdot 10^{-5}$		
Sum of PAHs (TEQ)*	Minimum**	/	$2.13 \cdot 10^{-3}$	60			$3.2 \cdot 10^{-7}$		$1.07 \cdot 10^{-3}$	TRV for BaP	$3.47 \cdot 10^{-6}$
				30			$6.39 \cdot 10^{-7}$		$2.13 \cdot 10^{-3}$		
	Maximum***	/	$7.13 \cdot 10^{-3}$	60			$1.07 \cdot 10^{-6}$		$3.57 \cdot 10^{-3}$	TRV for BaP	$1.16 \cdot 10^{-5}$
				30			$2.14 \cdot 10^{-6}$		$7.13 \cdot 10^{-3}$		
Pesticides											
Glyphosate		Quantified in 1 product	$3.75 \cdot 10^{-2}$	60	$5.63 \cdot 10^{-6}$			0.1	$5.63 \cdot 10^{-5}$		
				30	$1.13 \cdot 10^{-5}$				$1.13 \cdot 10^{-4}$		
Glyphosate + AMPA*		Quantified in 1 product	0.188	60	$2.81 \cdot 10^{-5}$			1	$2.81 \cdot 10^{-5}$		
				30	$5.63 \cdot 10^{-5}$				$5.63 \cdot 10^{-5}$		
Lindane		Quantified in 1 product	$4.2 \cdot 10^{-2}$	60	$6.30 \cdot 10^{-6}$			$4 \cdot 10^{-5}$	0.158	1.3	$6.67 \cdot 10^{-6}$
				30	$1.26 \cdot 10^{-5}$				0.315		

* Highest amount quantified in one panty liner; *** Only quantified substances taken into account; *** Only detected and quantified substances taken into account

Substances	Nb of samples detected/quantified	Concentration (mg/kg)	Body weight (kg)	DED (mg/kg/d)	Critical dose (mg/kg/d)	MOE	Ref MOE	Ref MOE/ MOE
Lilial®	Quantified in 1 product	10	60	$1.50 \cdot 10^{-3}$	5	3330	100	$3 \cdot 10^{-2}$
			30	$3.00 \cdot 10^{-3}$		1670		$6 \cdot 10^{-2}$

ANNEX 3: CALCULATIONS OF DEDS FOR SANITARY TOWELS (WORST-CASE APPROACH)

Substance		Nb of samples detected/ quantified	Concentration (mg/kg)	Body weight (kg)	DED (mg/kg bw/d)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV (mg/kg/d)	Hazard quotient	ERU $(mg/kg/d)^{-1}$	IER effects
PAHs											
Chrysene		Quantified in 1 product	$5.1 \cdot 10^{-3}$	60	$5.1 \cdot 10^{-6}$	0.01	$5.1 \cdot 10^{-8}$	TRV for BaP $3 \cdot 10^{-4}$	$1.7 \cdot 10^{-4}$	TRV for BaP	$8.13 \cdot 10^{-8}$
				30	$1.02 \cdot 10^{-5}$		$1.02 \cdot 10^{-7}$		$3.4 \cdot 10^{-4}$		
Cyclopenta[c,d]pyrene		Quantified in 1 product and detected in 1	$5.1 \cdot 10^{-3}$	60	$5.1 \cdot 10^{-6}$	0.1	$5.1 \cdot 10^{-7}$		$1.7 \cdot 10^{-3}$	TRV for BaP	$8.13 \cdot 10^{-7}$
				30	$1.02 \cdot 10^{-5}$		$1.02 \cdot 10^{-6}$		$3.4 \cdot 10^{-3}$		
Benzo[b]fluoranthene		Detected in 1 product	$5 \cdot 10^{-3}$	60	$5 \cdot 10^{-6}$	0.1	$5 \cdot 10^{-7}$		$1.67 \cdot 10^{-3}$	TRV for BaP	$7.97 \cdot 10^{-7}$
				30	10^{-5}		10^{-6}		$3.33 \cdot 10^{-3}$		
Benzo[c]fluorene		Detected in 1 product	$5 \cdot 10^{-3}$	60	$5 \cdot 10^{-6}$	20	10^{-4}		0.33	TRV for BaP	$1.59 \cdot 10^{-4}$
				30	10^{-5}		$2 \cdot 10^{-4}$		0.67		
Benzo[j]fluoranthene		Detected in 2 products	$5 \cdot 10^{-3}$	60	$5 \cdot 10^{-6}$	0.1	$5 \cdot 10^{-7}$		$1.67 \cdot 10^{-3}$	TRV for BaP	$7.97 \cdot 10^{-7}$
				30	10^{-5}		10^{-6}		$3.33 \cdot 10^{-3}$		
Benzo[k]fluoranthene		Quantified in 1 product and detected in 1	$8.2 \cdot 10^{-3}$	60	$8.2 \cdot 10^{-6}$	0.1	$8.2 \cdot 10^{-7}$		$2.73 \cdot 10^{-3}$	TRV for BaP	$1.31 \cdot 10^{-6}$
				30	$1.64 \cdot 10^{-5}$		$1.64 \cdot 10^{-6}$		$5.47 \cdot 10^{-3}$		
Benzo[g,h,i]perylene		Quantified in 1 product and detected in 3	$9.8 \cdot 10^{-3}$	60	$9.8 \cdot 10^{-6}$	0.01	$9.8 \cdot 10^{-8}$		$3.27 \cdot 10^{-4}$	TRV for BaP	$1.56 \cdot 10^{-7}$
				30	$1.96 \cdot 10^{-5}$		$1.96 \cdot 10^{-7}$		$6.53 \cdot 10^{-4}$		
Benzo[e]pyrene		Quantified in 1 product and detected in 2	$5.8 \cdot 10^{-3}$	60	$5.8 \cdot 10^{-6}$	0.01	$5.8 \cdot 10^{-8}$		$1.93 \cdot 10^{-4}$	TRV for BaP	$9.25 \cdot 10^{-8}$
				30	$1.16 \cdot 10^{-5}$		$1.16 \cdot 10^{-7}$		$3.87 \cdot 10^{-4}$		
Indeno[1,2,3-cd]pyrene		Detected in 2 products	$5 \cdot 10^{-3}$	60	$5 \cdot 10^{-6}$	0.1	$5 \cdot 10^{-7}$		$1.67 \cdot 10^{-3}$	TRV for BaP	$7.97 \cdot 10^{-7}$
				30	10^{-5}		10^{-6}		$3.33 \cdot 10^{-3}$		
Dibenzo[a,h]anthracene		Detected in 2 products	$5 \cdot 10^{-3}$	60	$5 \cdot 10^{-6}$	1	$5 \cdot 10^{-6}$		$1.67 \cdot 10^{-2}$	TRV for BaP	$7.97 \cdot 10^{-6}$
				30	10^{-5}		10^{-5}		$3.33 \cdot 10^{-2}$		
Sum of 17 PAHs (TEQ)*	Minimum**	/	$1.49 \cdot 10^{-3}$	60			$1.49 \cdot 10^{-6}$		$4.95 \cdot 10^{-3}$	TRV for BaP	$2.37 \cdot 10^{-6}$
				30			$2.97 \cdot 10^{-6}$		$9.91 \cdot 10^{-3}$		
	Maximum ***		$1.06 \cdot 10^{-1}$	60			$1.06 \cdot 10^{-4}$		0.354	TRV for BaP	$1.69 \cdot 10^{-4}$
				30			$2.12 \cdot 10^{-4}$		0.707		

Pesticides										
Hexachlorobenzene	Quantified in 1 product	$2 \cdot 10^{-3}$	60	$2 \cdot 10^{-6}$			$7 \cdot 10^{-5}$	$2.86 \cdot 10^{-2}$	1.8	$4.11 \cdot 10^{-7}$
			30	$4 \cdot 10^{-6}$				$5.71 \cdot 10^{-2}$		
Quintozene	Quantified in 1 product	$2.1 \cdot 10^{-2}$	60	$2.1 \cdot 10^{-5}$			$3 \cdot 10^{-3}$	$7 \cdot 10^{-3}$		
			30	$4.2 \cdot 10^{-5}$				$1.4 \cdot 10^{-2}$		
Quintozene + pentachloroaniline*	Quantified in 1 product	$4 \cdot 10^{-2}$	60	$4 \cdot 10^{-5}$			10^{-2}	$4 \cdot 10^{-3}$		
			30	$8 \cdot 10^{-5}$				$8 \cdot 10^{-3}$		
Phthalate										
DnOP	Detected in 1 product	120	60	0.12			0.4	0.3		
			30	0.24				0.6		

* Highest amount quantified in 1 towel; *** Only quantified substances taken into account; *** Only detected and quantified substances taken into account

ANNEX 4: DED AND RISK CALCULATIONS FOR PAHS AND THE SUM OF PAHS IN PANTY LINERS AND TOWELS, AND LINDANE IN TOWELS ACCORDING TO THE REFINED APPROACH

Substance		Nb of samples detected/quantified	Concentration (mg/kg)	LQ/2	DED (mg/kg/d)	TEF	DED toxic equivalent (mg_{TEQ}/kg/d)	TRV $(mg/kg/d)^{-1}$	IER effects without a threshold
Panty liners									
Benzo[a]pyrene		Detected in 1 product	$5 \cdot 10^{-3}$	$2.5 \cdot 10^{-3}$	$4.2 \cdot 10^{-8}$			TRV for BaP 1 **	$3.78 \cdot 10^{-8}$
Cyclopenta[c,d]pyrene		Quantified in 2 products and detected in 1	$8.9 \cdot 10^{-3}$	/	$1.5 \cdot 10^{-7}$	0.1	$1.5 \cdot 10^{-8}$		$1.35 \cdot 10^{-8}$
Benzo[k]fluoranthene		Quantified in 2 products	$1.04 \cdot 10^{-2}$	/	$1.75 \cdot 10^{-7}$	0.1	$1.75 \cdot 10^{-8}$		$1.57 \cdot 10^{-8}$
Sum of PAHs (TEQ)*	Minimum	/	$2.13 \cdot 10^{-3}$	/			$3.58 \cdot 10^{-8}$		**Sum of PAHs (TEQ)***
	Maximum		$7.13 \cdot 10^{-3}$	/			$1.2 \cdot 10^{-7}$		
Lindane		Quantified in 1 product	$4.2 \cdot 10^{-2}$	/	$1.26 \cdot 10^{-7}$			1.1 ***	$1.33 \cdot 10^{-7}$
s									
Benzo[k]fluoranthene		Quantified in 1 product and detected in 1	$8.2 \cdot 10^{-3}$	/	$9.18 \cdot 10^{-7}$	0.1	$9.18 \cdot 10^{-5}$	TRV for BaP 1 **	$1.22 \cdot 10^{-8}$
Benzo[c]fluorene		Detected in 1 product	$5 \cdot 10^{-3}$	$2.5 \cdot 10^{-3}$	$2.8 \cdot 10^{-7}$	20	$5.6 \cdot 10^{-6}$		$7.44 \cdot 10^{-7}$
Dibenzo[a,h]anthracene		Detected in 2 products	$5 \cdot 10^{-3}$	$2.5 \cdot 10^{-3}$	$2.8 \cdot 10^{-7}$	1	$2.8 \cdot 10^{-7}$		$3.72 \cdot 10^{-8}$
Sum of PAHs*	Minimum	/	$1.49 \cdot 10^{-3}$	/			$1.66 \cdot 10^{-7}$		**Sum of PAHs***
	Maximum		$1.06 \cdot 10^{-1}$	$5.3 \cdot 10^{-2}$			$5.94 \cdot 10^{-6}$		

* Highest amount quantified
** TRV for benzo[a]pyrene from the US EPA (2017) based on gastrointestinal tumours
*** TRV for lindane from the OEHHA (2009) based on liver tumours