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Revision of EU Ecolabel criteria for Absorbent Hygiene Products

Technical report v. 1.0

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Contents

Abstract

This technical report is intended to provide the background information for the revision of the existing EU Ecolabel criteria for Absorbent Hygiene Products (Commission Decision 2014/763/EU). The study has been carried out by the Joint Research Centre (JRC). The work is being developed for the European Commission's Directorate General for the Environment.

The EU Ecolabel criteria for Absorbent Hygiene Products (AHP) set out in Decision 2014/763/EU were established in 2014. Commission Decision (EU) 2018/1590 prolonged their validity until 31 December 2022.

The main purpose of this technical report is to summarise the results of the preliminary analysis of the current criteria, to evaluate if any revision of the product groups scope is needed, and to discuss if the criteria are still appropriate and up-to-date, or if some of them should be revised, amended or removed; and finally, if any new criteria should be added.

This Technical Report addresses the requirements of the Regulation (EC) No 66/2010 (EC, 2010) for technical evidence to inform about the criteria revision, and sets the scene for the 1st Ad-Hoc Working Group (AHWG) meeting, scheduled for the 14th October 2021, and the following stakeholder consultation. This technical report is supported and complemented by the preliminary report, which is published in parallel with this technical report. The preliminary report includes an analysis of the product group scope and definition, a market analysis, and a technical analysis.

This technical report consists of the following key sections: Summary of the preliminary report (section 2), scope and definition (section 3), assessment and verification (section 4) and new criteria proposals (section 5). In this last section the rationale for each of the proposed criterion texts and assessment and verification texts are presented.

1 Introduction

The EU Ecolabel is a voluntary labelling policy that promotes the production and consumption of products with a reduced environmental impact over their life cycle, and is aimed at the products with a high level of environmental performance. Established in 1992, it has become a key policy instrument within the European Commission's Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP) Action Plan (see COM(2008) 397) and the Roadmap for a Resource-Efficient Europe (see COM/2011/0571). The Roadmap was designed to move the economy of Europe onto a more resource-efficient path by 2020 in order to become more competitive and to create growth and employment.

The EU Ecolabel also has links with other policy instruments, such as Green Public Procurement (GPP, see COM(2008) 400), the Eco-Management and Audit Scheme (EMAS) (see Regulation (EC) No 1221/2009 and Regulation (EU) No 2018/2026) and the Ecodesign Directive (see Directive 2009/125/EC).

Looking ahead, the EU Ecolabel is expected by the European Parliament to play an important role in the new Circular Economy Action Plan (CEAP), and will undoubtedly form an important part of the upcoming Green Claims Initiative. Both the CEAP and the Green Claims Initiative will be considered as important blocks of the EU Green Deal.

Methodology and sources of information

This Technical Report addresses the requirements of the Ecolabel Regulation No 66/2010 for technical evidence to inform about the criteria revision and sets the scene for the first Ad-Hoc Working Group meeting for the revision of EU Ecolabel criteria for Absorbent Hygienic Products product group.

The revision process takes the existing legal document (Commission Decision 2014/763/EU of 24 October 2014) as the starting point and seeks to analyse its validity, taking into account technological and economic changes in the European market, relevant legislative changes and improved scientific knowledge.

Bringing together the information in the associated Preliminary Report on the assessment of the current scope and criteria validity, on the market analysis and on the life cycle assessment (LCA) a proposal for a set of revised EU Ecolabel criteria is presented in this Technical Report. The entire life cycle of the product is considered, from the extraction of raw material through to production, use and disposal phase. The EU Ecolabel may define criteria that target environmental impacts from any of these life cycle phases, with the aim being to encompass the areas of greatest impact (life cycle hot spots).

An important part of the process for developing or revising EU Ecolabel criteria is the involvement of stakeholders through their consultation on draft criteria proposal and technical reports. This is carried out via Ad-Hoc Working Group meetings, conference calls, email exchanges, forum discussions and written comments submitted via an online platform. The criteria development process involves technical experts, non-governmental organisations (NGOs), Member State representatives and industry stakeholders.

The work of this Technical Report was carried by the Joint Research Centre, Seville (JRC Dir. B – Growth and Innovation).

2 Summary of Preliminary Report

This section provides a summary of the findings of the Preliminary Report (PR) for the revision of EU Ecolabel criteria for absorbent hygiene products (AHP) with a focus on the scope and on the key environmental aspects. The documents can be found on the BATIS platform and at the project website:

Product groups documents | Product Bureau (europa.eu)

2.1 Legal and Policy context

There are a number of relevant EU policy tools, Regulations and Directives that apply to this sector specifically and in an overarching manner as well. In fact, AHPs are not subject to sector-specific EU legislation. The main regulatory and policy framework relevant for the product group and the revision process are listed below:

- EU Ecolabel Regulation No 66/2010.
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (ECHA).
- Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).
- Regulation 2012/528/EC concerning the making available on the market and use of biocidal products.
- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.
- Waste Framework Directive 2019/1004/EC.
- Council Directive 96/62/EC on ambient air quality assessment and management.
- Directive 2009/28/EC16 for the promotion of the use of energy from renewable sources.
- Packaging and packaging waste Directive 2018/852/EC.
- Directive 2019/904/EC on the reduction of the impact of certain plastic products on the environment.
- Commission Implementing Regulation, of 17 December 2020, on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904.
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices of 12 July 1993 and later modification (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices).
- New EU forest strategy (COM/2021/572).
- The EU Action Plan for the Circular Economy.

2.2 Market analysis

Since Absorbent Hygiene Products can be classified in different ways, a revision of the market segmentation according to different sources was undertaken.

AHP are classified by means of PRODCOM data, Euromonitor data or using the EDANA[1] categorisation as informed in the Preliminary Report (PR). In the PR it was proposed to expand the scope to reusable menstrual cups. The products included under the scope of this AHP revision are shown in Table 1, where products covered by the existing EU Ecolabel criteria are marked in **bold**.

[1] EDANA is the Industry Association for nonwovens and related industries. EDANA's member companies are the AHPs manufacturers and their suppliers, covering the entire supply chain of the AHP manufacturing process, including testing and development facilities (https://www.edana.org/).

Table 1. Proposed product group segmentation to be used during the revision

Disposable Baby Diapers (single-use diapers or single-use nappies)
Disposable Sanitary Pads or Towels (single-use pads or towels)
Disposable Panty Liners (single-use panty liners)
Tampons (single-use)
Disposable Nursing Pads (breast pads)
Reusable Menstrual Cups

The market of analysed AHP products is primarily built on disposable options: baby diapers and feminine protection such as tampons, pads and panty liners, however reusable alternatives were also explored. Market data were mainly obtained from Euromonitor International, while data on relevant trends were collected from several resources, including scientific publications, reports and online references.

The main producers of disposable AHP in the past 10 years were Procter & Gamble (P&G) and Kimberly-Clark Corporation while principal brands for baby diapers are Pampers (from P&G) and Huggies (from Kimberly- Clark Corporation) whereas for feminine care pads are Always/Whisper (also from P&G) (Euromonitor, 2021).

The sales volume of AHP within the EU-27 and the UK (2010-2020) is dominated by baby diapers with nearly 57% of the market share, followed by feminine care pads (23%), panty liners (11%) and tampons (9%). Aggregated data for pads and panty liners represents over 34% of the market share, which is below worldwide average due to the higher tampons consumption in Europe (expresses in sales volume). The worldwide values of AHP sales volume are over 55% for baby diapers followed by feminine panty liners and pads (around 40%), whereas tampons' share of the total AHP market was about 5% for 2019 and 2020 (Euromonitor, 2021).

In terms of the geographical segmentation within the EU-27 and the UK, as AHP are generally articles of daily use, there is a good correlation between the population size of each country and the share of products sold in each of the countries (Euromonitor 2021, Eurostat 2021).

In general, the disposable options for baby diapers and feminine care products are rising as well as the demand of reusable products, however it seems reusable products will remain as niche product in the upcoming years.

Among reusable options, the menstrual cup has the highest Compound Annual Growth Rate (CAGR) predicted during 2020–2027. It has been reported that period underwear could experience a superior CAGR through the end of 2030. Consumer perception surveys on willingness to shift from disposable to reusable showed menstrual cups were the most used reusable option due to them being environmentally-friendly, comfortable and a good value for money as they can be used for five to ten years. A survey on reusable baby diapers showed the main attributes for the switch are related to 'value for money' and performance as 'leak protection' or 'soft materials for the baby skin'[2].

No comprehensive analysis of market data for reusable AHP alternatives has been found in the available literature. This makes the overall market estimation difficult as many products are produced by small manufacturers.

Lastly, market data for breast pads (reusable or disposable) were not found at this stage of the project.

[2] More information can be found in the Preliminary Report, PR.

2.3 Technical analysis

The sections below provide a summary of the findings from the preliminary report with a focus on the key environmental aspects.

2.3.1 Literature review of life cycle assessment studies

The AHPs within the scope of the EU Ecolabel have been subject to LCA studies for many years (Cordella et al. 2013, Mirabella et al. 2013, Arena et al. 2016, Mendoza et al. 2019, Hoffmann et al. 2020). Within the AHP group, baby diapers were the first products to be analysed in LCA studies (Cordella et al., 2013). In general, diapers are more often studied while feminine care products are only occasionally the subject of the LCA studies. Comparative LCA studies of different types of baby diapers were conducted within several objectives. For instance, scientific articles on LCA of baby diapers have compared single-use and reusable options, single-use diapers with improvement in design or end-of-life scenarios for the disposable options. On the other hand, only one peer-review study has been found on a full LCA of three menstrual products where disposable tampons and sanitary pads, and reusable menstrual cups were compared. Two other academic works on LCA based on a limited range of products were analysed. LCA studies on breast pads are not available at the moment[3].

The nature of the AHP group means that the highest environmental contributions or life cycle impacts are concentrated in the production stages, where electricity consumption and chemicals used in the process are highly significant (Cordella et al., 2015; Hoffman et al., 2020).

Differences are encountered whether single-use (disposable) products are compared with their correspondent reusable options. However, a limited number of scientific articles analyses the whole life cycle of the AHP that are addressed by the EU Ecolabel scope.

Therefore, how could the EU Ecolabel distinguish among the most environmentally friendly options without compromising product performance for the final users? With disposable options currently dominating the market, the focus of the criteria revision should be put on the following environmental hotspots: the choice of raw materials and their composition, the utilisation of renewable sources of energy and the promotion of recycled or bio-based materials, when possible, are considered as some particularly interesting ways to mitigate the life-cycle impacts.

The comparative LCA study of disposable and reusable baby diapers showed that for disposable options the production and consumption of raw materials had the highest environmental impacts while reusable baby diapers impacts were driven by consumer behaviour. For reusable diapers, temperature of washing and energy efficiency of the washing machine results in different outcomes whereas a reusable diaper system which optimises energy and water use has lower environmental impacts than single-use options (Hoffman et al., 2020).

Innovation seems to be a promising path to decrease the environmental impact of baby diapers. Several studies reported bio-based, glueless or different weights of material compositions as examples of more friendly options (Mirabella et al., 2013; Arena et al., 2016; Mendoza et al., 2019).

Assessment of the end-of-life scenarios is another option where biodegradation, pyrolysis, and composting might be of high potential for diaper recycling (Khoo et al., 2019). However, so far there has not been a consensus on what are the best methods for disposal of diapers or absorbent hygiene products. In fact, material recovery and recycling could require significant structural changes to the current waste management system. Thus said, at the moment there is not a well-implemented collection system across EU Member States for AHP[3]. There are examples of industrial sites for recycling of baby diapers in Italy (Fater company) and the UK (Knowaste company) (Dri et al., 2018). Although a competitive recycling project must fulfil several conditions which are currently difficult to address as explained in the PR.

Regarding disposable feminine care products, the most relevant environmental impacts in the sanitary pads are caused by the manufacturing of low-density polyethylene (LDPE) foil (Mazgaj at al., 2006). Tampons are more environmentally favourable due to the different product weights and compositions which include higher content of renewable raw materials such as cotton (Weir, 2015). It is worth noting that feminine care pads made of 100% cotton can also be found in the market. In the case of tampons, when the applicator is

[3] More information can be found in the Preliminary Report, PR.

removed from the study, the product reduces the impacts making them a better choice than a sanitary pad (Hait and Powers, 2019).

When compared to reusable feminine care products, waste prevention is one of the biggest environmental advantages. As an estimation, the use of a menstrual cup results in a reduction of 99% of the waste that would be generated using single-use products (UNEP, 2021).

All in all, LCA results are to be considered in conjunction with other sources of information on environmental aspects, particularly where gaps exist in the available LCA studies. Methods to be applied might differ among country or industrial prospects (UNEP, 2021).

2.3.2 LCA screening study

A study to assess environmental impacts of average disposable open baby diapers and sanitary towels using PEF methodology was performed. The detail information on the assessment is available in the Preliminary Report. The study aimed to find out the most relevant impacts categories, life cycle stages, processes and flows of selected AHPs. The results of the study served as a base to identify the environmental hotspots and define these areas of the product lifecycle that need to be specifically addressed by EU Ecolabel criteria for AHPs.

The functional unit of the study is one piece of an average product marketed in the European Union, in particular:

- An average open baby diaper based on data from four manufacturing companies
- An average feminine pad based on data from three manufacturing companies

The system boundary includes all life cycle stages from the raw material acquisition to the end of life while the EF 3.0 method, as implemented in SimaPro 9.1 software, was used in the study.

The environmental hotspots identified within the study are mainly from the production of raw materials while transportation of raw materials and packaging to the manufacturing site also contribute.

Raw material acquisition is always the most relevant life cycle stage, having contribution between 76% (Climate Change) and 102% (Resource Use - fossils) for baby diapers, and between 91% (Eutrophication, terrestrial) and 100% (Resource Use – fossils and Resource Use - minerals and metals) for sanitary towels. It is worth noting that Resource Use – fossils exceeds 100% due to negative values in the end of life. Distribution has typically contributions around 5%, but in Acidification and Eutrophication, terrestrial it is around 10%. The highest contribution of the transport is in all cases because of the train transport.

For baby diapers, Climate Change is the most relevant impact category with 26% share, followed by Resource Use – fossils (23%), Particulate Matter (9%), Photochemical Ozone Formation (8%), Acidification (7%), Eutrophication – terrestrial (5%) and Resource Use – minerals and metals (5%).

For sanitary towels or feminine pads, the most relevant impact category is Resource Use – Minerals and metals with 19% share, followed by Resource Use – fossils (17%), Climate Change (15%), Particulate Matter (8%), Photochemical Ozone Formation (7.5%), Acidification (6%), Eutrophication - terrestrial (5%) and Ecotoxicity - freshwater (5%).

The most relevant processes for baby diapers include PP granulates, kraft pulp (cellulose) and polyester resin (proxy for adhesives) used as raw materials, as well as acrylic acid and acetic acid used in SAP production. Also Electricity used in SAP production is among the most important processes in many impact categories, namely Climate Change (15%), Resource Use – fossils (15%), Particulate Matter (8%), Acidification (7%) and Eutrophication - terrestrial (3%). In addition, also LDPE granulates used for packaging can be identified among most relevant processes in some impact categories (Climate Change (6%), Resource Use – fossils (12%) and Photochemical Ozone Formation (3%)).

On the other hand, the most relevant processes for sanitary towels are PET and PP granulates, viscose, polyester resin (proxy for adhesives) and kraft pulp (cellulose) used as raw materials. In addition, also LDPE granulates used for packaging (Resource Use – fossils, Climate Change, Particulate Matter, Photochemical Ozone Formation, Acidification and Ecotoxicity - freshwater). In fact, it has the highest contribution for Resource Use – fossils (46%), Climate Change (30%) and Ecotoxicity - freshwater (38%), because the share of LDPE compared to the main product mass in sanitary towel is greater than for baby diapers. This also

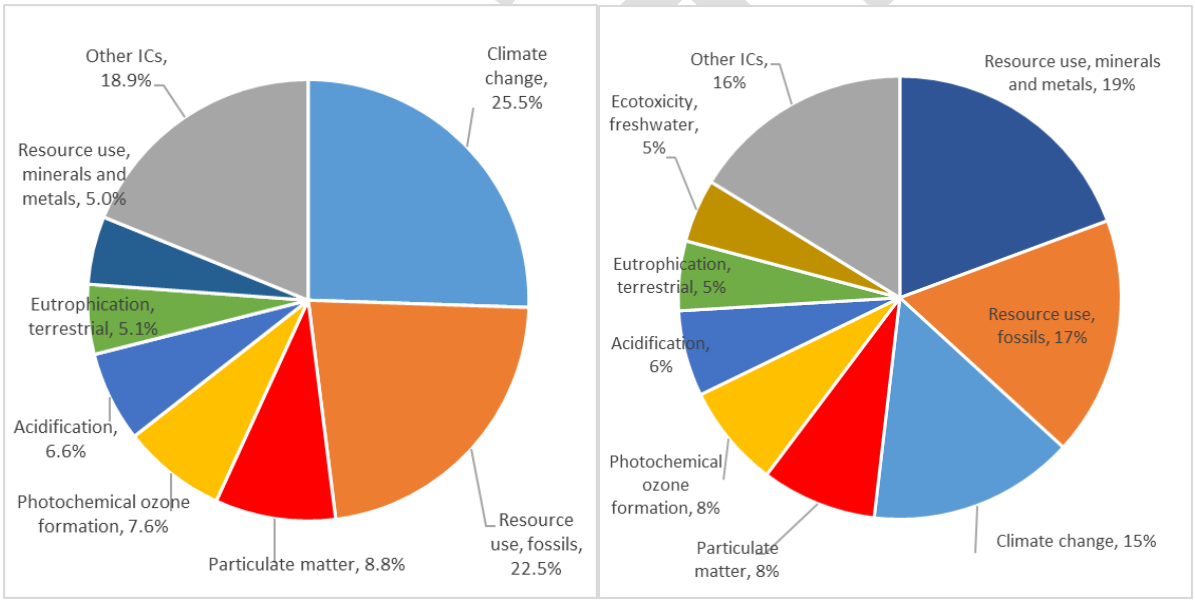
explains the presence of an additional impact category (Ecotoxicity) in the group of the most relevant ones for sanitary towels and the difference in the ranking of the other six.

For baby diapers, distribution by train has contributions of 46% (Particulate Matter), 58% (Photochemical Ozone Formation), 42% (Acidification), and 59% (Eutrophication - terrestrial), being the most relevant process in those impact categories. For sanitary towels train transport has contributions of 56% (Particulate Matter), 67% (Photochemical Ozone Formation), 51% (Acidification), and 68% (Eutrophication - terrestrial), being again the most relevant process in those impact categories.

Manufacturing and end of life (EoL) stages have only small share of impacts in almost all impact categories. Only in Climate Change impact of baby diapers end of life has 19% of contribution, because of emissions of the landfilling of the product. For sanitary towels this is not the case, because the mass of packaging is relatively high compared to the mass of the product itself, thus the credits received from EoL of packaging are partly compensating the impacts of the main product. Also, because of the credits from the packaging EoL, the End of Life stage has negative share in some impact categories, i.e. benefits from packaging EoL are bigger than impacts of the landfilling of main product.

A sensitivity analysis was performed in order to understand the impact of electricity choice (data collected from industry showed 100% renewable electricity used in the manufacturing). The analysis replaced the EU renewable electricity mix with the EF dataset 'Residual grid mix {EU-28+3} | AC, technology mix | consumption mix, to consumer | 1kV - 60kV' concluding without significant differences in the results in the majority of the impact categories. Only the Ionising Radiation impact category showed a significant difference because of nuclear energy in the average electricity mix. However, Ionising Radiation is not among the most relevant impact categories, so as a result, the main conclusions are not changed by using a different electricity mix.

Figure 1. Impact category (IC) contribution to the final weighted score for baby diapers (left figure) and sanitary towels (right figure)



3 Scope and definition

Existing scope: Absorbent Hygiene Products
1. The product group 'absorbent hygiene products' shall comprise baby diapers, feminine care pads, tampons and nursing pads (also known as breast pads), which are disposable and composed of a mix of natural fibres and polymers, with the fibre content lower than 90 % by weight (except for tampons). 2. The product group shall not include incontinence products and any other type of products falling under the scope of Council Directive 93/42/EEC.
Proposed scope: Absorbent Hygiene Products and Menstrual Cups
1. The product group 'absorbent hygiene products' shall comprise any sanitary article whose function is to absorb and retain human urine, faeces, sweat, menstrual fluid and milk - excluding textile products. 2. The product group 'menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body to retain and collect menstrual fluid, and usually made of medical-grade silicone, rubber, latex, or elastomer. 3. The product groups 'absorbent hygiene products' and 'menstrual cups' shall not include incontinence products and any other type of products falling under the scope of Council Directive 93/42/EEC amended by Regulation (EU) 2017/745.

Rationale for the proposed scope text

The current scope of the EU Ecolabel for absorbent hygiene products (AHP) lists down the disposable single use products that are covered by Commission Decision 2014/763/EU[4]. These are disposable baby diapers, feminine care pads, tampons and nursing pads.

However, the results of the preliminary questionnaire to stakeholders (carried out in December 2020) indicate that 57% of stakeholders (16 out of 28) are in favour of revising the current scope and definition of the product group. The feedback received after the EU Ecolabelling Board (EUEB) meeting confirmed the position of the majority of the stakeholders.

In general, stakeholders expressed that feminine care products such as 'pads/panty liners', 'tampons' or 'breast pads' and 'baby diapers' should be maintained in the scope.

In the cited preliminary questionnaire, over 80% of respondents (23 out of 28) would favour the expansion of the scope to incontinence products. Nevertheless, incontinence products might fall under Medical Devices Regulation (EU) 2017/745 if a manufacturer decides to CE mark their product and so indicate *that a device is in conformity with the applicable requirements set out in that Regulation and other applicable Union harmonisation legislation providing for its affixing*. Consultation with industry revealed that the incontinence products are usually declared as medical devices i.e. CE marked. Moreover, Article 2, point 2. of EU Ecolabel Regulation (EC) 66/2010 excludes from the scope of the scheme any type of medical devices. Conclusively, due to the regulatory requirements, **the expansion of the scope to cover incontinence products is not feasible**.

39% of the respondents to the preliminary questionnaire supported the inclusion in the scope of reusable alternatives for AHP such as: reusable menstrual cups, cloth baby diapers, cloth feminine care pads, reusable breast pads. However, at the EU Ecolabelling Board (EUEB) meeting held in November 2020, some of the EUEB members stated that while reusable alternatives serve the same purpose as single-use AHPs, their material composition is different, and inclusion in the textile product group should be preferred. This would

[4] Commission Decision of 24 October 2014 establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products. OJ L 320, 6.11.2014, p. 46–63

apply to reusable alternatives such as reusable feminine care pads, breast pads and baby diapers. Indeed, other Ecolabels such as the Austrian Ecolabel include reusable alternatives under their textile Ecolabel scope. Therefore, **the expansion of the scope to cover reusable textile AHP alternatives** (cloth baby diapers, cloth feminine care pads, reusable breast pads) **is not proposed** at this stage.

However, this is not the case for reusable menstrual cups, which are usually made of medical-grade silicone, rubber, latex, or elastomer, and whose market relevance is increasing (while still being a niche product in the market).

In addition to the opinion of the stakeholders gathered through the preliminary questionnaire, at the EUEB meeting in April 2021 EUEB members were asked about their opinion on the inclusion of menstrual cups in the revised scope. 80% of comments received were in favour of including reusable menstrual cups in the revised scope.

Based on the information included in the Preliminary Report (the results of the preliminary questionnaire, an overview of environmental labelling schemes and initiatives related to AHPs, a market analysis and a LCA literature review), and after applying a quantitative methodology, **it is proposed to expand the scope to cover also reusable menstrual cups** (more information in section 2.7 in the Preliminary Report).

Indeed, the EU Ecolabel Fitness check Report[5], which reviewed the implementation of the EU Ecolabel Regulation[6], concluded on the need to develop a more strategic approach for the EU Ecolabel. As the EU Ecolabel is part of a wider package of product policy instruments that contribute to the Circular Economy, its scope should be expanded to accommodate more environmentally friendly products, bundling of closely related product groups should be preferred, where appropriate.

As a result, **the following revised product group name is proposed**:

Absorbent Hygiene Products and Menstrual Cups

The inclusion of menstrual cups in the product group scope implies that existing criteria need to be further assessed in light of the validity for this type of product. Some of the criteria will not be relevant for reusable menstrual cups, some others will need to be revised, and some new ones will probably need to be added. However, at this stage of the revision process the validity of current EU Ecolabel criteria for reusable menstrual cups has not been evaluated in depth. The proposal of this first Technical Report aims at discussing with stakeholders about the inclusion of reusable menstrual cups in this product group scope.

Another important aspect is the product scope description for absorbent hygiene products (current Article 1 of Commission Decision 2014/763/EU[4]). EUEB members were consulted on the need to revise the wording of the product scope description for AHP. Following their feedback, **the following wording is proposed** at this stage of the revision process:

"An Absorbent Hygiene Product is any sanitary article whose function is to absorb and retain human urine, faeces, sweat, blood and milk - excluding textile products."

Points for discussion
• Do stakeholders agree on the inclusion of reusable menstrual cups in the product group scope? • Stakeholders' views on the new wording proposed for AHP is welcomed.

[5] Report from the Commission to the European Parliament and the Council on the review of implementation of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and the Regulation (EC) No 66/2010 of the parliament and of the Council of 25 November 2009 on the EU Ecolabel (COM(2017) 355).

[6] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27, 30.1.2010, p. 1–19

Existing definitions
(1) 'Cellulose pulp' means a fibrous material mainly composed of cellulose and obtained from the treatment of lignocellulosic materials with one or more aqueous solutions of pulping and/or bleaching chemicals. (2) 'Optical brightener' and 'fluorescent whitening agent' mean any additives used with the only purpose of 'whitening' or 'brightening' the material. (3) 'Plastic materials', also referred to as 'Plastics', means synthetic polymers to which additives or other substances may have been added which can be moulded and used as main structural component of final materials and articles. (4) 'Synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by: - A polymerisation process such as poly-addition or poly-condensation or by any other similar process of monomers and other starting substances; - Chemical modification of natural or synthetic macromolecules; - Microbial fermentation. (5) 'Super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass.
Proposed definitions
For the purposes of this Decision, the following definitions shall apply: (1) 'Cellulose pulp' means a fibrous material mainly composed of cellulose and obtained from the treatment of lignocellulosic materials with one or more aqueous solutions of pulping and/or bleaching chemicals. (2) 'Optical brightener' and 'fluorescent whitening agent' mean any additives used with the only purpose of 'whitening' or 'brightening' the material. (3) 'Plastic materials', also referred to as 'Plastics', means synthetic polymers to which additives or other substances may have been added which can be moulded and used as main structural component of final materials and articles. (4) 'Synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by: - A polymerisation process such as poly-addition or poly-condensation or by any other similar process of monomers and other starting substances; - Chemical modification of natural or synthetic macromolecules; - Microbial fermentation. (5) 'Super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass; (6) 'Substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012([7]) or (EC) No 1107/2009([8]) of the European Parliament and of the Council;

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20210610
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

(7) 'Primary packaging', also known as sales packaging, means packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;

(8) 'Secondary packaging' means grouped packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics.

(9) 'Transport packaging', also known as tertiary packaging, means packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers.

(10) 'Additional packaging' means any component (with protective or hygienic function) of the absorbent hygiene product that is removed before the use of the product, e.g. the individual wrap or film where some products are contained within the primary packaging (mainly for tampons and sanitary pads), the release liner or paper in baby diapers and sanitary pads, or the applicator for tampons. The additional packaging can also be the cloth bag were menstrual cups are usually sold with.

(11) 'Recycled content' means the amount of an item (by area, length, volume or mass) sourced from post-consumer and/or post-industrial recycled material.

(12) 'Recyclability capacity' means the amount (mass or percentage) of an item available for recycling.

Rationale for the proposed definitions

Where possible, the proposed revised definitions are based on EN or ISO standards or EU legislation. When this was not possible, the terminology used in industry documentation was consulted and used as the basis.

The following definitions were added: substances identified to have endocrine disrupting properties primary packaging, secondary packaging, transport packaging, additional packaging, recycled content, and recyclability capacity.

The definition of substances identified to have endocrine disrupting properties is added because it is used in sub-criterion 6.3. this definition is aligned with the one used in the recently voted EU Ecolabel for Cosmetic products and animal care products.

The definitions added are in line with Directive 94/62/EC[9] on packaging and packaging waste. Primary, secondary and transport packaging are defined in the Article 3 of that Directive while additional packaging is proposed to be defined taking into consideration the needs of the final product. The proposal also accommodates definitions established by other ecolabels such as the Nordic Swan or the Blue Angel[10].

[9] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJ L 365, 31.12.1994, p. 10–23

[10] More information is provided in the proposal for the revised criterion 9 (Product and its packaging)

4 Assessment and verification

Current assessment and verification
The specific assessment and verification requirements are indicated within each criterion. Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant or his supplier or both. Competent Bodies shall preferentially recognise tests which are accredited according to ISO 17025 and verifications performed by Bodies which are accredited under the EN 45011 standard or an equivalent international standard. Where appropriate, test methods other than those indicated for each criterion may be used if the Competent Body assessing the application accepts their equivalence. Where appropriate, Competent Bodies may require supporting documentation and may carry out independent verifications. As pre-requisite, the product shall meet all respective legal requirements of the country (countries) in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.
Proposed assessment and verification
Specific assessment and verification requirements are indicated within each criterion. Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate. Competent Bodies shall preferentially recognise attestations that are issued by Bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by Bodies that are accredited in accordance with the relevant harmonised standard for Bodies certifying products, processes and services. Where appropriate, test methods other than those indicated for each criterion may be used if the Competent Body assessing the application accepts their equivalence. Where appropriate, Competent Bodies may require supporting documentation and may carry out independent verifications. Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to Competent Bodies, together with supporting information to enable verification of continued compliance with the criteria. As pre-requisite, the product must meet all respective legal requirements of the country (countries) in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

Rationale behind the General Assessment and Verification

The assessment and verification text appearing at the beginning of the Annex generally refers to the different types of evidence (e.g. declarations, test reports) that are considered relevant proof of compliance for criteria. This text is necessary in order to establish the framework and general rules for verification procedures so that they do not need to be repeated in every individual assessment and verification text.

Each EU Ecolabel criterion text is followed by specific assessment and verification requirements stating which type of evidence should be provided to the Competent Body that is assessing the application. It is important to clarify here that, when evidence is required from the supply chain, it is possible for the evidence to be

submitted directly by the supplier to the Competent Body (this may be important when the proof requires information that may be commercially sensitive).

When evidence is required from tests or analyses, these should preferentially be carried out by laboratories that are accredited in accordance with relevant harmonised (ISO or EN) standards. However, this may not always be possible and in some cases it may be satisfactory to accept evidence from in-house testing or testing by third parties that are only accredited with relevant national standards. The same situation applies to test reports.

When a test method is specified in the assessment and verification text for a particular EU Ecolabel criterion, this method should be followed unless the applicant can demonstrate to the Competent Body that they have used another method that produces equivalent results. In such cases, the justification for equivalence must be clearly demonstrated and the Competent Body should share this knowledge with other Competent Bodies.

Even in cases where evidence is provided exactly in accordance with the specific assessment and verification text for a particular EU Ecolabel criterion, it must be understood that the Competent Body reserves the right to request further information, to visit the site and even to consider independent means of testing and verification. If the applicant objects to such actions, this could potentially jeopardise the award of the EU Ecolabel.

For any criteria that relate to supplied chemicals or materials, it is understood that suppliers can change with time, that one supplier can supply multiple different types and grades of chemical/material and that, even for a given supplier and given chemical/material, variations in time are possible depending on the upstream supply chain and other factors. Consequently, any significant changes in the supplied chemicals/materials must be communicated to the Competent Body and supported by any relevant evidence (e.g. supplier declarations) to demonstrate ongoing compliance with EU Ecolabel criteria.

The final paragraph in the general assessment and verification text has been inserted in order to make it clear that non-compliance of the EU Ecolabel product with all applicable legal requirements of the country or countries in which the product is placed on the market may result in the full or partial revocation of the EU Ecolabel licence.

4.1 Summary of changes proposed for the overall structure of the current EU Ecolabel criteria for Absorbent Hygiene Products

In order to add the clarity to the applicability of the criteria, as well as to simplify the structure of the document the structural changes that are included in Table 2 are proposed to be introduced.

Table 2 Changes of the criteria structure that are proposed to be introduced

	Current criteria	Proposed changes to the revised criteria	
1	Product Description	Product Description	**1**
2	Fluff Pulp	Fluff Pulp	**2**
2.1	Sourcing	Sourcing	**2.1**
2.2	Bleaching	Bleaching	**2.2**
2.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**2.3**
2.4	Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production	Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production	**2.4**
2.5	Emissions of CO2 from production	Emissions of CO_2 from production	**2.5**
3	Man-made cellulose fibres	Man-made cellulose fibres	**3**
3.1	Sourcing	Sourcing	**3.1**
3.2	Bleaching	Bleaching	**3.2**
3.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**3.3**
3.4	Production of fibres	Production of fibres	**3.4**
4	Cotton and other natural cellulosic seed fibres	Cotton and other natural cellulosic seed fibres	**4**
4.1	Sourcing	Sourcing	**4.1**
4.2	Bleaching	Bleaching	**4.2**
4.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**4.3**
5	Plastic materials and superabsorbent polymers	Production of polymers	**5**
5.1	Production of synthetic polymers and plastic materials		
5.2	Additives in plastic materials	Moved to criterion 7.3 (Specific restrictions)	
5.3	Superabsorbent polymers	Moved to criterion 7.3 (Specific restrictions)	
6	Other materials and components	REMOVED (individual sub-criteria moved)	
6.1	Adhesive materials	Moved to criterion 7.3 (Specific restrictions)	
6.2	Inks and dyes	Moved to criterion 7.3 (Specific restrictions)	
6.3	Fragrances	Moved to criterion 7.3 (Specific restrictions)	
6.4	Lotions	Moved to criterion 7.3 (Specific restrictions)	
6.5	Silicone	Moved to criterion 7.3 (Specific restrictions)	
6.6	Nanosilver particles	Moved to criterion 7.3 (Specific restrictions)	
7	Hazardous substances and mixtures	Excluded and restricted substances	**6**
7.1	Hazardous substances and mixtures	Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council	**6.1**
7.2	Restrictions on Substances of Very High Concern (SVHCs)	Restrictions on Substances of Very High Concern (SVHCs)	**6.2**

	Current criteria	Proposed changes to the revised criteria	
7.3		Specific restrictions - NEW	**6.3**
8	Material efficiency in the manufacturing	Material efficiency in the manufacturing	**7**
		Packaging - NEW	**8**
9	Guidance on the product disposal	Guidance on the packaging and product disposal	**9**
10	Fitness for use and quality of the product	Fitness for use and quality of the product	**10**
11	Social aspects	Corporate Social Responsibility with regard to Labour Aspects	**11**
12	Information appearing on the EU Ecolabel	Information appearing on the EU Ecolabel	**12**

5 Criteria proposals

This chapter analyses proposals for the criteria revision. Each criterion is analysed within a separated sub-chapter. In order to better visualise changes that have been introduced, these are marked in blue across the document.

5.1 CRITERION 1: Product description

Existing criterion 1: Product description
A description of the product and packaging shall be provided (product name, classification, functionalities) together with information on all of the following characteristics: — the total weight of the product and packaging, — the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers. Information on the weight of the product shall be also displayed in the packaging **Assessment and verification**: The applicant shall provide a sample of the product and a report including the technical description and the weight of the product and of each component, material and additive used.
Proposed criterion 1: Product description
A description of the product and packaging shall be provided ~~(product name, classification, functionalities)~~ together with information on all of the following characteristics: — the total weight of the product and packaging, — the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers. ~~Information on the weight of the product shall be also displayed in the packaging~~ **Assessment and verification**: The applicant shall provide a technical description of the product that shall include information on the weight of the product and of each component, material and additive used in the final product.

Rationale for the proposed criterion text

Stakeholders were consulted through an online questionnaire on whether to maintain criterion 1 in the EU Ecolabel criteria for Absorbent Hygiene Products (AHP). The EU Ecolabelling Board (EUEB) members claimed that due to the fact that an Absorbent Hygiene product is made of many different materials, which represent a complex supply chain each, this criterion should not be withdrawn. Indeed, criterion 1 plays an important role providing product information which is helpful for the Competent Bodies during the verification of Absorbent Hygiene Products applications.

Nonetheless, several stakeholders have brought up the irrelevance of displaying information about the product weight on the packaging. Additionally, it could constitute a considerable burden for most applicants to change the packaging's design in the case that the weight of the product may vary. This has been confirmed by EUEB Members.

Accordingly, **it is proposed to maintain criterion 1, withdrawing the requirement for displaying the weight of the product on the packaging**.

Rationale behind the proposed assessment and verification text

The assessment and verification is proposed to be simplified. Sending the product to a Competent Body as an additional proof of compliance is considered as of limited value, given that Competent Bodies due to the obvious technical constrains will most probably not check the materials weight content.

Points for discussion
• In your opinion, should criterion 1 be maintained, or withdrawn?

5.2 CRITERION 2: Fluff Pulp

Existing criterion 2.1: Sourcing
All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent. A minimum of 25 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. The certification Bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme. **Assessment and verification**: The applicant shall obtain from the pulp manufacturer(s) valid, independently certified chain of custody certificates demonstrating that wood fibres have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.
Proposed criterion 2.1: Sourcing
All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent. A minimum of ~~25~~ 70 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. The certification Bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme. **Assessment and verification**: The applicant shall provide the Competent Body with a declaration of compliance supported by a valid, independently certified chain of custody certificate from the manufacturer of EU Ecolabel graphic paper and for all virgin fibres used in the product or production line. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification. The applicant shall provide audited accounting documents that demonstrate that at least 70 % of the materials allocated to the product or production line originate from forests or areas managed according to sustainable forestry management principles that meet the requirements set out by the relevant independent chain of custody scheme and/or originate from recycled materials. If the product or production line includes uncertified virgin material, proof shall be provided that the content of uncertified virgin material does not exceed 30 % and is covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

<u>Rationale for the proposed criterion text</u>

This criterion aims to ensure that that wood sources used in EU Ecolabel absorbent hygiene products are managed in an environmentally, socially, and economically viable manner. The proposed revised criterion also accommodates the horizontal approach applied across several EU Ecolabel product groups for addressing wood fibre sourcing.

In the previous revision of the criteria[11], 100% of the fibres were proposed to be covered by a chain of custody certification in the previous Technical Report for Absorbent hygiene products. In addition, it was highlighted that the EU Ecolabel should not allow more than 30% of uncertified material and that 100% should be the target to respect by 2020 as required in the EU Biodiversity Strategy[12].

The global industrial roundwood production in 2019 was 2021 million m^3 (FAOSTAT-Forestry database, 2020). The magnitude of European forest certification as compared with the industrial roundwood production was examined within the revision of EU Ecolabel criteria for Graphic paper, tissue paper, and tissue paper products. Considering the total productive forest areas in each Member State, it was estimated (Kowalska et al., 2019) that approximately 62 % of all productive forest area in Europe is Forest Stewardship Council (FSC) or Programme for the Endorsement of Forest Certification Schemes (PEFC) certified. If actual industrial roundwood is also factored into the calculation, the estimated certified industrial roundwood rises to 73.2%. The Sustainability Report published by the Confederation of European Paper Industries (CEPI) indicates that (CEPI, 2019):

- *90.4% of forests owned or managed by the European pulp and paper industry are forest management certified.*
- *More than 90% of the pulpwood used is sourced from the EU.*
- *83.2% of pulp purchased by the European pulp and paper industry is certified.*
- *70.7% of wood, woodchips or residues from saw mills we purchase come from forests that are certified.*

Altogether, the above information can be considered as the starting point for a discussion on the right ambition level for a minimum content of sustainable forest management (SFM) certified fibre used to manufacture EU Ecolabel product.

In the preliminary stakeholder questionnaire (December, 2020), 46% of the respondents indicated the need to change criterion 2.1. The vast majority requested an increase in the ambition level for the minimum SFM-certified fibres content. This could help to horizontally harmonise the requirement on the sustainable forestry across various paper-based EU Ecolabel products. In this sense, the EU Ecolabel criteria for Graphic paper, tissue paper, and tissue paper products[13], as well as the EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bags products[14] require a minimum of 70% pulp fibres to be covered by the valid Sustainable Forestry Management (SFM) certificate schemes. It shall be noted that in the EU Ecolabel criteria for Graphic paper, tissue paper, and tissue paper products FSC-certified virgin materials, PEFC-certified virgin materials, and recycled fibre are considered equivalent to each other in terms of complying with the minimum 70% content of certified fibre. Additionally, other Ecolabels such as the Blue Angel[15] requires that the 100% of wood fibre used for fluff pulp production must be sourced from the SFM certified areas (FSC 100% or 100% PEFC) but also allows FSC Mix Credit certified fluff pulp. In Nordic Swan[16], a minimum of 70% by weight of all wood raw materials must come from SFM certified forestry, such as FSC or the PEFC.

One stakeholder provided the following comment "*It has been brought to our attention that the criteria for AHPs is comprehensively focused on pulp. The substantial focus on fluff pulp only among all materials that constitute a diaper today is considered inconsistent considering the percentage of pulp in a diaper (around 15 g or 23% of a baby diaper is fluff pulp* (Kakonke et al., 2019)*)*".

On a different note, some stakeholders showed an interest, in shifting to a mass balance/credit principle for FSC/PEFC instead of a percentage system. Indeed, some Absorbent Hygiene Product producers indicate that the mass balance/credit principle for FSC/PEFC is generally used, as opposed to the percentage system.

[11] Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products"), Technical Report – Draft v.2, available at: Microsoft Word - Technical Report_v2.4.doc (europa.eu)

[12] EU biodiversity strategy for 2030, available at: https://op.europa.eu/en/publication-detail/-/publication/31e4609f-b91e-11eb-8aca-01aa75ed71a1

[13] Commission Decision (EU) 2019/70 of 11 January 2019 establishing the EU Ecolabel criteria for graphic paper and the EU Ecolabel criteria for tissue paper and tissue products (OJ L 15, 17.1.2019), p. 27–57.

[14] Commission Decision (EU) 2020/1803 of 27 November 2020 establishing the EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bag products, (OJ L 402, 1.12.2020), p. 53–72.

[15] Criterion 3.4.1 for sourcing of fluff pulp in Sanitary Products (Origin of the fluff pulp), (version 2, January 2021).

[16] Nordic Ecolabelling for Sanitary Products, Criterion 2.2.4 Wood materials (version 6.8, 14 June 2016 - 30 June 2024).

The credit system allows manufacturers to store "credit" into a credit account when they use inputs of post-consumer reclaimed material, pre-consumer reclaimed paper fibre or FSC certified material (either FSC 100%, FSC Mix Credit, or FSC Mix XX %) within the same product groups. A manufacturer can mix eligible inputs together based upon product groups, and then sell the "credit" amount that is in their inventory as FSC-certified with a label of FSC Mix and a claim of FSC Mix Credit. The credit system works so that the volume being sold as FSC Mix Credit is only as much as the volume of credit going into the system. If a manufacturer runs out of "credits" in their account they can no longer sell products as FSC certified, but they are able to sell their remaining stock as Controlled Wood only to other FSC certified customers.[17] According to stakeholder feedback, in the credit system, the producers source a specific amount of certified and controlled wood fibres to allocate them to the equivalent amount of wood fibres used for certified products. Therefore, the indication of 25% certified fibres content that is required by the currently valid criterion 2.1, would not be relevant in such cases as the amount of certified fibres used in the AHP should correspond to the amount of FSC or PEFC-certified fibre that was used in the production.

The inclusion of secondary fibre for fluff pulp manufacturing is not proposed at this stage. As a matter of fact, due to the sanitary aspect and to the prolonged skin contact with the AHP products, which are often intended for young children, the use of recycled materials in the Nordic Swan ecolabelled products is not allowed (Nordic Swan, 2021). However, the use of recycled materials in the packaging and in the release paper is addressed and recommended by the abovementioned scheme (see Section 5.9). As in the case of the EU Ecolabel for paper products, any recycled fibre must be covered by FSC-recycled claims, PEFC-recycled claims and/or EN 643 delivery notes. It needs to be further discussed with stakeholders if the use of recycled materials as product filling is feasible and if it meets the legal requirements and sanitary constrains. This aspect is important as it has direct implications on the EU goal of a circular economy.

As mentioned earlier in this section, various stakeholders asked for an alignment with EU Ecolabel for graphic paper, tissue paper, and tissue products[13].

Criterion 3 of Commission Decision (EU) 2019/70 establishes that:

- the fibre raw material may consist of recycled fibres or virgin fibres.
- any virgin fibres must not originate from GMO species.
- all fibres shall be covered by valid chain of custody certificates issued by an independent third-party certification scheme (e.g. FSC, PEFC or equivalent), or be covered by delivery notes of paper for recycling in accordance with EN 643
- at least 70 % of the fibre material allocated to the product or production line shall originate from forests or areas managed according to sustainable forestry management principles that meet the requirements set out by the relevant independent chain of custody scheme and/or originate from recycled materials.

A direct reference to criterion 3 of Commission Decision (EU) 2019/70 would imply that recycled fibres can be used in AHP, contrary to current practice in other ecolabelling schemes. However, since FSC-certified virgin materials, PEFC-certified virgin materials, and recycled fibre are considered equivalent, the minimum 70% of certified fibres could be either of virgin or of secondary origin. This possibility (but not obligation) of using recycled fibres might trigger innovation and changes in the product manufacturing philosophy. It might boost the use of RCF fibre for these paper based components of the final product that do not stay with the close contact with the body i.e. internal filling.

Therefore, at this stage of the revision process **it is proposed that the threshold of 25% is increased to 70%**.

[17] FSC- Forest Stewardship Council. Chain of Custody FAQs. Available at: https://us.fsc.org/preview.fsc-coc-faq.a-446.pdf

Points for discussion
• Should FSC Mix Credit be used instead of FSC Mix %? Could both be considered? • Do you agree with the proposed ambition level for fluff pulp? • Should the requirement on sustainable fibre sourcing be harmonised with other EU Ecolabel criteria for paper based products, e.g. EU Ecolabel for graphic paper, tissue paper, and tissue paper products? • Could recycled fibre be used in a final product? If yes, for which components? If not, which are the reasons behind?

Rationale behind the proposed 'assessment and verification'

During the preliminary questionnaire (December 2020), one stakeholder mentioned that the verification requirements should be clarified. Moreover, various stakeholders strongly suggested alignment with the EU Ecolabel criteria for graphic paper, tissue paper, and tissue paper products.

At this stage of the revision process it is proposed to improve the verification of this requirement by harmonising, to the extent possible, the wording with Criterion 3 (Fibres – conserving resources, sustainable forest management) of EU Ecolabel criteria for graphic paper, tissue paper, and tissue products, removing the reference to recycled fibres.

Existing criterion 2.2: Bleaching
The pulp used in the product shall not be bleached with the use of chlorine gas. The total amount of AOX emissions from pulp manufacturing shall not exceed 0,170 kg/ADT. **Assessment and verification**: The applicant shall provide a declaration from the pulp manufacturer that chlorine gas was not used and a test report showing compliance with the AOX limit value. ISO 9562 or the equivalent EPA 1650C shall be accepted as test methods, accompanied by detailed calculations showing compliance with this requirement, together with related supporting documentation. The supporting documentation shall include an indication of the measurement frequency. AOX shall only be measured in processes where chlorine compounds are used for the bleaching of the pulp. Measurements shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant. The measurement period shall be 12 months of production. Measurements shall be taken on a monthly basis from representative composite samples (24 hours composite). For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.
Proposed criterion 2.2: Bleaching
This criterion refers to elemental chlorine free (ECF) pulp. The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl_2) gas. The ~~total amount~~ ~~annual average of~~ AOX emissions from the production of each pulp each used in EU Ecolabel absorbent hygienic product shall not exceed ~~0,170~~ 0,140 kg/ADt. **Assessment and verification**: The applicant shall provide a declaration from the pulp manufacturer that elemental chlorine (Cl_2) gas was not used. The declaration shall be supported by a test report ~~showing compliance with the AOX limit value~~ using ISO 9562 test methods. Equivalent methods ~~shall~~ may be accepted as test methods, accompanied by detailed calculations showing compliance with this

requirement, together with related supporting documentation.

The applicant shall provide a declaration of compliance with this criterion, supported by a list of the different ECF pulps used in the pulp mix, their respective weightings and their individual amount of AOX emissions, expressed as kg AOX/ADt pulp.

The supporting documentation shall include an indication of the measurement frequency. AOX shall only be measured in processes where chlorine compounds are used for bleaching the pulp. AOX does not need to be measured in the effluent from non-integrated paper production or in the effluents from pulp production without bleaching or where bleaching is performed with chlorine-free substances.

Measurements of AOX emissions to water shall be taken on unfiltered and unsettled samples at the effluent discharge point of the mills' wastewater treatment plant. In cases where mill effluent is sent to a municipal or other third-party wastewater treatment plant, unfiltered and unsettled samples from the mill effluent sewer discharge point shall be analysed and the results multiplied by a standard removal efficiency factor for the municipal or third-party wastewater treatment plant. The removal efficiency factor shall be based on information provided by the operator of the municipal or other third-party wastewater treatment plant.

Information on the emissions shall be expressed as the annual average from measurements taken at least once every 2 months. In case of a new or rebuilt production plant, measurements shall be based on at least 45 subsequent days of stable running of the plant. They shall be representative of the respective campaign.

In case the applicant does not use any ECF pulp, a corresponding declaration to the Competent Body is sufficient.

~~The supporting documentation shall include an indication of the measurement frequency. AOX shall only be measured in processes where chlorine compounds are used for the bleaching of the pulp.~~

~~Measurements shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant.~~

~~The measurement period shall be 12 months of production. Measurements shall be taken on a monthly basis from representative composite samples (24 hours composite).~~

~~For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.~~

Rationale for the proposed criterion text

This criterion aims at minimising negative effects on the environment and on human heath from emissions occurring during the production of fluff pulp. This refers especially to emissions related to the use of chlorine gas as the main pulp bleaching agent until the early '90s, causing the discharge of significant amounts of the dioxin and furan chemical families into watercourses.

During the questionnaire on criteria validity conducted in December 2020, 32% of respondents indicated the need to revise the limit for the total amount of AOX emissions from pulp manufacturing, especially with respect to the limit for the total amount of AOX emissions from pulp manufacturing.

The parameter 'AOX' refers to a sum of all Absorbable Organic Halogens in the waste water. The pulp and paper industry might generate AOX emission by cause of reaction between residual lignin from wood fibres and chlorine compounds (chlorine dioxide) used during the ECF bleaching process.

In line with Kowalska et al. (2019) it is then reasonable to assume that reporting AOX should ahead of all target elemental chlorine free (ECF) pulps.

Brief overview of technical aspects and market situation

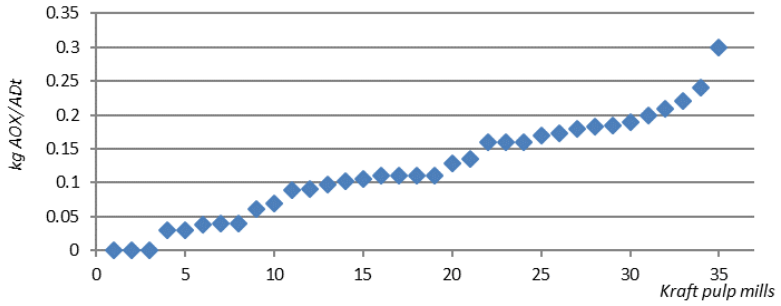
The Technical Report for EU Ecolabel criteria for graphic paper, tissue paper and tissue paper products (Kowalska et al, 2019), indicates that the shift from the use of elemental chlorine (CL_2) towards the ECF and total chlorine free (TCF) bleaching processes within the last 20 years has been driven by the objective of decreasing the discharge of chlorinated organic matter (AOX). However, from the market perspective, the

Biermann's Handbook of Pulp and Paper *(2018)* states that *'ECF pulp, bleached with chlorine dioxide, continues to grow and is now dominating the market. [...]'*[18]. In particular, ECF bleaching accounts for 93.9% while the use of TCF only represents 4.7%.

The vast majority of AOX emission comes from the first ClO_2 bleaching stage in the ECF process[19]. Moreover, Zhu et al. (2016)[20] explained that more than 97% of the AOX is produced during the first 5 minutes of the bleaching sequence, and the reaction rate is primarily determined by the initial amount of lignin in the pulp and ClO_2 dosage.

A reduction of AOX has been achieved, among others, thanks to the replacement of molecular chlorine by chlorine dioxide, and the use of chlorine free bleaching chemicals such as molecular oxygen (O_2), hydrogen peroxide (H_2O_2), ozone (O_3) or peracetic acid (CH_3CO_3H). Prevention of AOX formation could be achieved by an alternate use of bleaching sequences with reduced content of chlorine based bleaching agents i.e. chlorine dioxide, or using TCF bleaching. It is also important to notice that wood species (and so the initial kappa number[21]) should be taken into account when proposing AOX emission threshold (Shur et al., 2015). Stakeholders indicated that many pulp producing companies in Europe can meet a value of 0.08 kg AOX/ADt and thus, are clearly below the BAT limit[22] of 0.2 kg/ADT for AOX emissions. The yearly AOX emissions average for bleached kraft pulp at the point of discharge, i.e. after waste water treatment vary between undetectable and 0.3 kg AOX/ADt of bleached pulp – see Figure 2 (Shur et al., 2015).

Figure 2. AOX emission levels for bleached Kraft pulp



Source: Shur et al., 2015

One aspect that may possibly constrain the availability of resources is that in 2015 80% of all fluff pulp is produced in North America[23].

Overview of other Ecolabelling schemes

Concerning limits set in other Ecolabels, in the Nordic Swan Ecolabel for Sanitary Products[24], the resulting total amount of AOX (from the production of cellulose pulp) and organically bound chlorine (OCl) (in the finished fibre) must not exceed 0.15 kg/ADt of fibre pulp in wastewater from the fibre pulp production. In the Blue Angel Ecolabel criteria for AHPs (version 2), the AOX must be measured in the wastewater. The annual average for the measured AOX emissions to waste water must not exceed a value of 0.12 kg/ADt. Still, in the

[18] Bajpai, P. *Biermann's Handbook of Pulp and Paper. Raw Material and Pulp Making*, Third Edition, Volume 1, Elsevier, 2018, https://doi.org/10.1016/C2017-0-00513-X.

[19] Tuula, L., Ville, T., Susanna, K. Annastina, J., and Tapani, V., 'The effect of process variables in chlorine dioxide prebleaching of birch kraft pulp. Part 2. AOX and OX Formation', Journal of Wood Chemistry and Technology, Vol. 30, No 1, 2010, pp. 19-30.

[20] Zhu, H., Yao S., Jiang, L., Wang, S., and Qin, C., 'Kinetics of AOX formation', BioResources, 1194, 2016, pp. 8820-8830.

[21] Kappa number is a key test method for determining the level of lignin in a sample.

[22] 2014/687/EU: Commission Implementing Decision of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board. OJ L 284, 30.9.2014, p. 76–126

[23] Smithers PIRA (2015) The future of global fluff pulp to 2020. http://www.smitherspira.com/industry-market-reports/paper/the-future-of-fluff-pulp-to-2020

[24] Nordic Swan. Nordic Ecolabelling for Sanitary Products. Version 6.8 • 14 June 2016 - 30 June 2024. Available at: https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=023 (accessed 27/08/2021).

Blue Angel ecolabel (version 2) a total chlorine free (TCF) process is preferred for the bleaching of the fluff pulp, although an elemental chlorine free (ECF) process is also permitted.

It is relevant to stress that the EU Ecolabel for graphic paper, tissue paper and tissue paper products does not consider an average AOX value of all incoming pulps, but allocate requirements on each pulp stream present in the pulp mix used in a final product. This ensures that the AOX emission is not mathematically diluted, and that each incoming pulp meets the requirement.

Brief analysis of the influence of bleaching process on the presence of polyhalogenated organic compounds in a final product

In 2018 ANSES (ANSES, 2018) undertook a study on the presence of chemicals in 23 single-use baby diapers and performed a human health risk assessment. Among the substances covered by the analysis are dioxins, furans, PCBs, formaldehyde, and polycyclic aromatic hydrocarbons, which might potentially be present in a final product. The analysis results highlighted the presence, among other substances, of dioxins, furans and dioxin-like polychlorinated biphenyls (DL-PCBs), in a final product, as follows:

- DL-PCBs were quantified in all the diapers at concentrations ranging from 16.98 to 1404.98 ng/kg of diaper,
- dioxins were quantified in 17 of the 19 analysed samples,
- furans were quantified in 14 of the 19 analysed samples.

The study concluded that the presence of polyhalogenated organic compounds seems to be due to contamination of the raw materials or manufacturing processes. As a result, ANSES recommends '*to limit the presence of chlorinated dioxins and furans, the bleaching phases for materials could be undertaken without any chlorinated agents (such as chlorine dioxide, sodium or calcium hypochlorite, etc.). Techniques are available to achieve this, such as the use of dioxygen and hydrogen peroxide'.*

It needs however to be stressed that ANSES study also recognises that *'the precise nature of the materials which single-use baby diapers are made of 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'*. In this sense, it is not possible to assess neither the origin of pulp nor the nature or performance of the bleaching process used. Given that, as indicated by market analysis, the vast majority of fluff pulp is externally sourced, it is not possible to ensure if the bleaching process was conducted in line with the BATs conclusions and therefore meeting the requirement of Commission Implementing Decision 2014/687/EU (EC, 2014)[25]: Last but not least, the lack of data on the AOX emission from the bleaching process of pulps used to manufacture products that were analysed by ANSES does not enable the correlation of the AOX emission levels with the presence of polyhalogenated organic compounds in pulp.

Given this, a regulatory management option analysis (RMOA) was published in July 2019 concluding that the existing regulatory measures are insufficient to address these risks and that the most efficient regulatory option is the introduction of a new restriction entry in Annex XVII of the REACH Regulation. This led to France submission of a restriction proposal to ECHA on substances found in nappies on the 9th of October 2020[26].

The scientific community appears having polarised opinions as to the ECF bleaching, magnitude of the AOX contamination and the overall list of possible precursors of dioxin formation in ECF pulp bleaching process (Axegard, 2019). Ahtiainen et al., (2000)[27] found that debarking wastewaters and black liquor were even more toxic than bleaching wastewater. In this line, Verta et al., (1996) and Berry et al. (1993) suggested that the possible presence of dioxines in the effluents might also be a result of the presence of other than ClO_2 precursors. All in all, bleaching with chlorine dioxide was demonstrated to be a source of dioxin in pulp mill effluence, on one hand (Axegard, 2019). On the other hand, ECF bleaching effluents were also been proven non-detection of any 2,3,7,8-TCDD and 2,3,7,8-TCDF in several research studies (Bajpai, 2018; Axegård and Bergnor 2011; Pryke et al. 2006; Takagi et al. 2007; Nakamata and Ohi 2003; Luthe and Berry 1996).

Field studies, research and chemical analysis over the last two decades have shown that treated wastewater from well-managed pulp and paper mills using ECF bleaching is virtually free of dioxin and persistent

[25] Commission Implementing Decision of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board. OJ L 284, 30.9.2014, p. 76–126.

[26] France restriction proposal on substances used in single-use nappies. Available at: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5 (accessed 10/09/2021).

[27] J. Ahtiainen, T. Nakari, M. Ruoppa, M. Verta, E. Talka (2000), Toxicity screening of novel pulp mill wastewaters in Finnish pulp mills. In: Persoone G., Janssen C., De Coen W. (eds) New Microbiotests for Routine Toxicity Screening and Biomonitoring. Springer, Boston, MA. https://doi.org/10.1007/978-1-4615-4289-6_35

bioaccumulative substance, and studies comparing ECF and TCF effluents confirmed the absence of significant differences in biological effects in the aquatic environment (Bajpai, 2018). Axegard (2019) in the scientific review on influence of ECF bleaching on the PCDD/Fs formation concludes that: '*Replacing elemental chlorine with chlorine dioxide (with levels of elemental chlorine contamination of 0.3% or less in the chlorine dioxide) in pulp bleaching eliminates the formation of 2,3,7,8-TCDD and 2,3,7,8-TCDD during the bleaching process with chlorine dioxide*'.

In January 2021, ECHA organised a webinar consultation on proposed restriction of substances present in single-use baby diapers. The event gathered a number of comments with regards to the limits proposed by ANSES. For instance, it was noted that the limits proposed are below the current Limits of Quantification (LOQ). Therefore, an appropriate analytical method was proposed and must be developed before entry into effect (estimated in 2024). Nevertheless, it shall be noted that a risk, with regards to the abovementioned substances, has been demonstrated by the Dossier Submitter and it is currently being evaluated by ECHA's scientific committees. At the same time, a number of uncertainties that surround the information presented in the restriction dossier should also be taken into account: lack of harmonized analytical method, few low-dose dermal studies, expert judgement for some parameters in the exposure assessment, lack of information regarding the possible sources of contamination and lack of data regarding the possible alternatives (ECHA, 2021).

This scientific debate falls out of the scope of the present study that aims at ensuring that the bleaching process meets the best practice requirements, and, as a minimum, is conducted in line with the rules established by the best available techniques (Suhr et al., 2015). This is supposed to ensure the non-detectable presence of polyhalogenated organic compounds in a final product.

There is no conclusive evidence, which would support setting requirements in the EU Ecolabel that promote TCF bleaching over ECF bleaching. Nevertheless, given the current preference of ECF bleaching among Industry, setting ambitious AOX reference values would be recommended at this point in order to further mitigate any possibility to release dioxins to the environment.

The AOX limit for each pulp stream established by EU Ecolabel for graphic paper, tissue paper, and tissue paper products (EC, 2019) is 0.17 kg/ADt. However, the specific use of AHPs requires a close contact of a product with the human body. Therefore, in light of all the above, at this stage of the revision process **it is proposed to lower the AOX limit to 0.14 kg/ADt**. This threshold may be realistic and achievable by companies, given that similar thresholds are set by Nordic Swan and Blue Angel, and is sufficiently ambitious. Moreover, for the further lowering the values, it is considered that the situation of not sufficient availability of fluff pulp that fulfils the EU Ecolabel criteria on AOX emissions for absorbent hygiene products may occur and that trade barriers could be created.

Additionally, it is proposed to wait for the Commission Decision on the restriction proposal of France before concluding on whether to limit further the AOX emissions and/or promote TCF over the use of ECF.

Points for discussion
• Do stakeholders agree to increase an ambition level by lowering the reference value to 0.14 kg AOX/ADt for each pulp in a pulp mix?

<u>Rationale behind the proposed 'assessment and verification'</u>

One respondent of the questionnaire expressed that the assessment and verification should be revised. Moreover, some stakeholders indicated that the criterion should be harmonised with the product group tissue and tissue paper products as far as possible.

At this stage of the revision process it is proposed to harmonise the text of the assessment and verification with the EU Ecolabel criteria for graphic paper and the EU Ecolabel criteria for tissue paper and tissue products (EC, 2019).

Existing criterion 2.3: Optical brighteners and colouring agents

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the pulp.

Assessment and verification: The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.

~~**Existing criterion 2.3: Optical brighteners and colouring agents**~~ [This criterion has been moved to Criterion 6.3(d)]

Rationale for the proposed criterion text

This criterion aims at minimising negative effects on the environment and on human heath from the usage of whitening and colouring agents.

The majority of respondents (95%) of the preliminary questionnaire did not express any opinion in respect to the possible revision of the sub-criterion 2.3, whereas 35% confirmed adequateness of the currently valid requirement.

Nevertheless, the possibility to change the structure (i.e. the order) of the criteria has been explored with the aim of grouping together those criteria banning specific substances. The intention is to improve the clarity of the criteria set. Therefore, **it is proposed to move this criterion to revised criterion 6.3 (d) – Inks and dyes**.

Existing criterion 2.4: Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production

The emissions to air and water from the pulp production shall be expressed in terms of points (P_{COD}, P_P, P_S, P_{NOx}). Points are calculated by dividing actual emission by the reference values reported in Table 1.

— None of the individual points P_{COD}, P_P, P_S, $P_{NO}X$, shall exceed 1,5.

— The total number of points (P_{total} = P_{COD} + P_P + P_S + P_{NOx}) shall not exceed 4,0.

For each pulp 'i' sourced, the related measured emissions (expressed in kg/air dried tonne — ADT) shall be weighted according to the proportion of pulp sourced (pulp 'i' with respect to air dried tonne of pulp) and summed together. The reference values for each pulp type used and for the paper production are given in the Table 1. Finally, the total emissions shall be divided by the total reference value as shown in the following formula for COD:

$$P_{COD} = \frac{COD_{total}}{COD_{ref,total}} = \frac{\sum_{i=1}^{n}[pulp_i \times COD_{pulp,i}]}{\sum_{i=1}^{n}[pulp_i \times COD_{ref,pulp,i}]}$$

Table 1

Reference values for emissions from different pulp types

	Reference values (kg/ADT)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Bleached chemical pulp (others than sulphite)	18,0	0,045(*)	0,6	1,6
Bleached chemical pulp (sulphite)	25,0	0,045	0,6	1,6
CTMP	15,0	0,01	0,2	0,3

(*) Net emissions of P are considered in the calculation. The P naturally contained in wood raw materials and in water can be subtracted from the total emissions of P. Reductions up to 0,010 kg/ADT shall be accepted

In case of a co-generation of heat and electricity at the same plant, the emissions of S and NOx resulting from electricity generation shall be subtracted from the total amount. The following equation shall be used to calculate the proportion of the emissions resulting from heat generation:

[MWh(heat) —MWh(heat)sold]/[MWh(heat) + 2 × MWh(electricity)]

Where,

— MWh(electricity) is the electricity produced at the co-generation plant,

— MWh(heat) is the useful heat produced in a cogeneration process,

— MWh(heat)sold is the useful heat that is used outside the pulp manufacturing plant.

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this criterion, together with related supporting documentation which shall include test reports using the following test methods:

— COD: ISO 6060, EPA SM 5220D or HACH 8000,

— P: ISO 6878, SM4500, APAT IRSA CNR 4110 or Dr Lange LCK 349,

— S(oxid.): EPA 8 or equivalent,

— S(red.): EPA 8, EPA 16A or equivalent,

— S content in oil: ISO 8754 or EPA 8,

— S content in coal: ISO 351 or EPA 8,

— NOx: ISO 11564 or EPA 7E.

The supporting documentation shall include an indication of the measurement frequency and the calculation of the points for COD, P, S and NOx. It shall include all emissions of S and NOx which occur during the production of pulp, including steam generated outside the production site, except those emissions related to the production of electricity.

Measurements shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall be taken into account.

Reported emission values for S to air shall include both oxidised and reduced S emissions (dimethyl sulphide, methyl mercaptan, hydrogen sulphide and similar emissions). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of measured, and shall be taken into account.

Measurements of emissions to water shall be taken on unfiltered and unsettled samples either after

treatment at the plant or after treatment by a public treatment plant.

The measurement period shall be 12 months of production. Measurements for COD and P shall be taken on a monthly basis and measurements for S and NOx on a yearly basis. Alternatively, continuous measurements can be accepted if they are verified by a third party at least once per year.

For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.

Proposed criterion 2.4: Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production

The emissions to air and water from the pulp production shall be expressed in terms of points (P_{COD}, P_P, P_S, P_{NOx}). Points are calculated by dividing actual emission by the reference values reported in Table 1.

— None of the individual points P_{COD}, P_P, P_S, P_{NOX}, shall exceed ~~1,5~~ 1,3.

— The total number of points ($P_{total} = P_{COD} + P_P + P_S + P_{NOx}$) shall not exceed 4,0.

For each pulp 'i' sourced, the related measured emissions (expressed in kg/air dried tonne — ADT) shall be weighted according to the proportion of pulp sourced (pulp 'i' with respect to air dried tonne of pulp) and summed together. The reference values for each pulp type used and for the paper production are given in the Table 1. Finally, the total emissions shall be divided by the total reference value as shown in the following formula for COD:

$$P_{COD} = \frac{COD_{total}}{COD_{ref,total}} = \frac{\sum_{i=1}^{n}[pulp_i \times COD_{pulp,i}]}{\sum_{i=1}^{n}[pulp_i \times COD_{ref,pulp,i}]}$$

Table 1

Reference values for emissions from different pulp types

	Reference values (kg/ADT)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Bleached chemical pulp (others than sulphite)	~~18,0~~ 16,0	~~0,045~~ 0,025([1]) 0,09 ([2])	~~0,6~~ 0,35	1,6
Bleached chemical pulp (sulphite)	~~25,0~~ 24,0	0,045	~~0,6~~ 0,75	1,6
CTMP	~~15,0~~ 16,0	~~0,01~~ 0,008	0,2	0,3

([1]) Net emissions of P are considered in the calculation. The P naturally contained in wood raw materials and in water can be subtracted from the total emissions of P. Reductions up to 0,010 kg/ADT shall be accepted

([2]) The higher value refers to mills using eucalyptus from regions with higher levels of phosphorous (e.g. Iberian eucalyptus).

In case ~~of a~~ where co-generation of heat and electricity occur at the same plant, the emissions of S and NOx resulting from on-site electricity generation ~~shall be~~ can be subtracted from the total amount. The following equation shall be used to calculate the proportion of the emissions resulting from heat generation:

~~[MWh(heat) – MWh(heat)sold]/[MWh(heat) + 2 × MWh(electricity)]~~

~~Where,~~

~~— MWh(electricity) is the electricity produced at the co-generation plant,~~

~~— MWh(heat) is the useful heat produced in a cogeneration process,~~

~~— MWh(heat)sold is the useful heat that is used outside the pulp manufacturing plant.~~

2 × (MWh(electricity))/[2 × MWh(electricity) + MWh(heat)]

The electricity in this calculation is the electricity produced at the co-generation plant. The heat in this calculation is the net heat delivered from the co-generation plant to the pulp/paper production.

Assessment and verification:

~~The applicant shall provide detailed calculations showing compliance with this criterion, together with related supporting documentation which shall include test reports using the following test methods:~~

~~— COD: ISO 6060, EPA SM 5220D or HACH 8000,~~

~~— P: ISO 6878, SM4500, APAT IRSA CNR 4110 or Dr Lange LCK 349,~~

~~— S(oxid.): EPA 8 or equivalent,~~

~~— S(red.): EPA 8, EPA 16A or equivalent,~~

~~— S content in oil: ISO 8754 or EPA 8,~~

~~— S content in coal: ISO 351 or EPA 8,~~

~~— NOx: ISO 11564 or EPA 7E.~~

~~The supporting documentation shall include an indication of the measurement frequency and the calculation of the points for COD, P, S and NOx. It shall include all emissions of S and NOx which occur during the production of pulp, including steam generated outside the production site, except those emissions related to the production of electricity.~~

~~Measurements shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall be taken into account.~~

~~Reported emission values for S to air shall include both oxidised and reduced S emissions (dimethyl sulphide, methyl mercaptan, hydrogen sulphide and similar emissions). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of measured, and shall be taken into account.~~

~~Measurements of emissions to water shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant.~~

~~The measurement period shall be 12 months of production. Measurements for COD and P shall be taken on a monthly basis and measurements for S and NOx on a yearly basis. Alternatively, continuous measurements can be accepted if they are verified by a third party at least once per year.~~

~~For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.~~

The applicant shall provide detailed calculations and test data showing compliance with this criterion, together with related supporting documentation that include test reports using the following continuous or periodical monitoring standard test methods (or equivalent standard methods that are accepted by the Competent Body as providing data of equivalent scientific quality): COD: ISO 15705 or ISO 6060; NOx: EN 14792 or ISO 11564; S(sulphur oxides): EN 14791 or EPA no 8; S(reduced sulphur): EPA no 15A,16A or 16B; S content in oil: ISO 8754; S content in coal: ISO 19579; S content in biomass: EN 15289; Total P: EN ISO 6878.

Rapid tests can also be used to monitor emissions as long as they are checked regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents. In the case of COD emissions, continuous monitoring based on analysis of total organic carbon (TOC) shall be accepted as long as a correlation between TOC and COD results has been established for the site in question.

The minimum measurement frequency, unless specified otherwise in the operating permit, shall be daily

for COD emissions and weekly for Total P emissions. In all cases, emissions of S and NOx shall be measured on a continuous basis (for emissions from boilers with a capacity exceeding 50 MW) or a periodic basis (at least once a year for boilers and driers with a capacity less than or equal to 50 MW each).

Data shall be reported as annual averages except in cases where:

— the production campaign is for a limited time period only,

— the production plant is new or has been rebuilt, in which case the measurements shall be based on at least 45 subsequent days of stable running of the plant.

In either case, data may only be accepted if it is representative of the respective campaign and a sufficient number of measurements have been taken for each emission parameter.

The supporting documentation shall include an indication of the measurement frequency and calculation of the points for COD, Total P, S and NOx.

Emissions to air shall include all emissions of S and NOx that occur during the production of pulp, including steam generated outside the production site, minus any emissions allocated to the production of electricity. Measurements shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall also be taken into account. Reported emission values for S to air shall include both oxidised and reduced S emissions. The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of measured, and shall be taken into account.

Measurements of emissions to water shall be taken on unfiltered and unsettled samples at the effluent discharge point of the mills' wastewater treatment plant. In cases where mill effluent is sent to a municipal or other third-party wastewater treatment plant, unfiltered and unsettled samples from the mill effluent sewer discharge point shall be analysed and the results multiplied by a standard removal efficiency factor for the municipal or third-party wastewater treatment plant. The removal efficiency factor shall be based on information provided by the operator of the municipal or other third- party wastewater treatment plant.

Rationale for the proposed criterion text

This criterion aims at minimising negative effects on the environment and on human heath from emissions occurring during the production of fluff pulp, especially in terms of emissions of COD and P to water and for emissions of S and NOx to air.

In the preliminary stakeholder questionnaire (December, 2020), 36% of respondents did not express any opinion in respect to the possible revision of sub-criterion 2.4, whereas 29% expressed the adequateness of the currently valid requirement. Only 28% of respondents to the questionnaire indicated the need to revise the sub-criterion, half of which expressed that minor changes are needed. The stakeholder comments focused on the need to adjust the limits, preferably harmonising the emission limit with the requirements set in the EU Ecolabel for tissue paper products according to Annex II to Commission Decision (EU) 2019/70.

Some stakeholders indicated that the AHP criteria related to pulp should not be fully based on the requirements set for the EU Ecolabel criteria for Graphic Paper, Tissue Paper and Tissue Products. They argued that although there are similarities in the manufacturing process of the pulps, the tree species used for fluff pulp are different compared to the ones used to produce the graphic and tissue paper. In fact, the Technical Report for the EU Ecolabel criteria for Graphic Paper, Tissue Paper and Tissue Products ([13]) states that: "*to a certain extent, for a given pulping technology, the type of wood used may influence the yield, the process setup and the emission levels*".

Brief overview of technical aspects

The conventional fluff pulp also known as or "comminution" pulp is mainly derived from bleached long fibre softwood kraft pulp (BSKP) such as different pine species. Over time, the global fluff pulp market has become increasingly centered on BSKP due to the grade's superior performance in absorbent hygiene

applications and relatively low production costs[28]. However, other raw materials and processes, such as softwood CTMP (chemi-thermomechanical pulps) and hardwood kraft pulps, are of growing technical and economic interest (Rebola et al., 2020).

The main difference to standard market pulp is the density (bulk) of the sheet after drying stage. For such products, the density is between 0.4–0.65 kg/cm³ (bulk from 1.54–2.5 cm³/kg). The paper product is usually stored on reels for further fluffing in a hammer mill/defibrator, which fibreizes the fluff pulp sheets into loose fibres by means of small hammers that rotate at high speed ([29-30]).

Table 3 below indicates the different limits (for different emissions) set by Nordic Swan, Blue Angel and EU Ecolabel criteria for graphic paper, tissue paper and tissue products.

Table 3. Comparison of COD, P, S and NOx limits for different type of material and for different ecolabelling schemes. ADT = air dry tonne

	Current EU Ecolabel criteria for AHP	Nordic Swan	Blue Angel	EU Ecolabel criteria for graphic paper, tissue paper and tissue products
individual points P_{COD}, P_P, P_S, P_{NOX}	1.5	1.5	1.5	1.3
total number of points (Ptotal = PCOD + PS + PNOx + PP)	4	4	5	4
Bleached chemical pulp (others than sulphite)				
CODref (kg/ADT)	18	Not found	18	16
Pref (kg/ADT)	0.045	Not found	0.03	0.025 (0.09[1])
Sref (kg/ADT)	0.6	Not found	0.6	0.35
NOxref (kg/ADT)	1.6	Not found	1.5	1.6
Bleached chemical pulp (sulphite)				
CODref (kg/ADT)	25	Not found	18	24
Pref (kg/ADT)	0.045	Not found	0.03	0.04
Sref (kg/ADT)	0.6	Not found	0.6	0.75
NOxref (kg/ADT)	1.6	Not found	1.5	1.6
CTMP				
CODref (kg/ADT)	15	Not found	18	16
Pref (kg/ADT)	0.01	Not found	0.03	0.008
Sref (kg/ADT)	0.2	Not found	0.6	0.2
NOxref (kg/ADT)	0.3	Not found	1.5	0.25 (0.7[2])

[1] The higher value refers to mills using eucalyptus from regions with higher levels of phosphorous (e.g. Iberian eucalyptus).

[2] NOx emission value for non-integrated CTMP mills using flash-drying of pulp with biomass-based steam

Given **Table 3** above, at this stage of the revision process **it is proposed to harmonize the emission limits** for chemical oxygen demand (COD), sulphur (S), NOx, and phosphorous (P) **with those specified in Criterion 1(a) of Commission Decision 2019/70/EU** (EU Ecolabel criteria for graphic paper, tissue paper

[28] Rebola SM, Ferreira J, Evtuguin DV. Potential of bleached eucalyptus kraft pulp for applications in nonwoven fibrous fabrics. Journal of Engineered Fibers and Fabrics. January 2020. doi:10.1177/1558925020980146

[29] Check: https://www.andritz.com/products-en/pulp-and-paper/pulp-and-paper/pulp-production/kraft-pulp/pulp-drying-finishing/pulp-dewatering-fluff-applications

[30] Check: https://campenmachinery.com/airlaid/fibreization

and tissue paper products). Even considering the preferable use of softwood fibre in a final AHP. The pulping process used for manufacturing of fluff pulps is the same as used for manufacturing of graphic paper or tissue paper (mainly kraft and CTMP pulping techniques). The use of softwood fibre for pulp and paper manufacturing is also addressed by the scope of EU Ecolabel criteria for graphic paper, tissue paper and tissue paper products. Therefore, having in mind the need to apply integrated approach among different product groups, the harmonisation seems justified.

If necessary, considering the fluff pulp market situation, the magnitude of harmonisation should be further discussed with stakeholders during the upcoming 1st AHWG Meeting.

Points for discussion
• How can the reference values established by EU ecolabel criteria for graphic paper, tissue paper, and tissue paper products be adapted to the fluff pulp market situation?

Rationale for the assessment and verification text

Since a harmonisation with the more recent EU Ecolabel criteria for graphic paper, tissue paper and tissue products has been expressed by stakeholders, **the text of the assessment and verification is proposed to be adapted accordingly**.

Existing criterion 2.5: Emissions of CO2 from production

CO2 emissions from non-renewable energy sources shall not exceed 450 kg per tonne of pulp produced, including emissions from the production of electricity (whether on-site or off-site). Reference emission values according to Table 2 shall be used in the calculation of CO2 emission from fuels.

Table 2

Reference values for CO2 emissions from different energy sources

Fuel	CO2 fossil emissions	Unit
Coal	95	g CO2 fossil/MJ
Crude oil	73	g CO2 fossil/MJ
Fuel oil 1	74	g CO2 fossil/MJ
Fuel oil 2-5	77	g CO2 fossil/MJ
LPG	69	g CO2 fossil/MJ
Natural Gas	56	g CO2 fossil/MJ
Grid Electricity	400	g CO2 fossil/kWh

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this requirement, together with related supporting documentation.

The applicant shall provide data on the air emissions of carbon dioxide. This shall include all sources of non-

renewable fuels during the production of pulp, including the emissions from the production of electricity (whether on-site or off- site).

The measurement period shall be 12 months of production. Measurements shall be done on a yearly basis.

For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. Results have to be shown also after 12 months of production. The measurement shall be representative of the respective campaign.

The amount of energy from renewable sources ([31]) purchased and used for the production processes will not be considered in the calculation of the CO2 emissions: appropriate documentation that this kind of energy are actually used at the mill or are externally purchased shall be provided by the applicant.

Proposed criterion 2.5: Emissions of CO2 from production

CO2 emissions from non-renewable energy sources shall not exceed 450 kg per tonne of pulp produced, including emissions from the production of electricity (whether on-site or off-site). Reference emission values according to Table 2 shall be used in the calculation of CO2 emission from fuels.

Table 2

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Fuel oil 1	74	g CO2 fossil/MJ
Fuel oil 2-5	77	g CO2 fossil/MJ
LPG	69	g CO2 fossil/MJ
Natural Gas	56	g CO2 fossil/MJ
Grid Electricity	400	g CO2 fossil/kWh

Assessment and verification:

The applicant shall provide data and detailed calculations showing compliance with this criterion, together with related supporting documentation.

~~The applicant shall provide data on the air emissions of carbon dioxide. This shall include all sources of non-renewable fuels during the production of pulp, including the emissions from the production of electricity (whether on-site or off- site).~~

~~The measurement period shall be 12 months of production. Measurements shall be done on a yearly basis.~~

~~For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. Results have to be~~

[31] As defined in Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

~~shown also after 12 months of production. The measurement shall be representative of the respective campaign.~~

~~The amount of energy from renewable sources ([32]) purchased and used for the production processes will not be considered in the calculation of the CO2 emissions: appropriate documentation that this kind of energy are actually used at the mill or are externally purchased shall be provided by the applicant.~~

For each pulp used, the pulp manufacturer shall provide the applicant with a single CO2 emission value in kg CO2/ADt. The applicant shall also provide a single CO2 emission value for the relevant paper machine(s) used to produce EU Ecolabel fluff pulp.

The CO2 emission data shall include all sources of non-renewable fuels used during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

Emission factors for fuels shall be used in accordance with Annex VI of Regulation (EU) No 601/2012. For grid electricity, an emission calculation factor of 376 (kg CO2/MWh) shall be used in accordance with the Commission Delegated Regulation (EU) 2019/331 ([33]).

The period for the calculations or mass balances shall be based on the production over 12 months. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing the average value for its suppliers of electricity (contracting suppliers), in which case the applicant may use this value instead of the value quoted. The documentation used as proof of compliance shall include technical specifications that indicate the average value (i.e. copy of a contract).

The amount of energy from renewable sources purchased and used for the production processes counts as zero CO2 emission when calculating CO2 emissions. The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased.

Rationale for the proposed criterion text

This criterion aims at reducing the emissions of CO_2 from the fluff production.

A major part of the respondents (46%) did not express any opinion in respect to the possible revision of the sub-criterion 2.5, whereas 29% confirmed adequateness of the currently valid requirement. Only 21% of respondents indicated the need to revise the sub-criterion. The additional comments indicate that the limits should be evaluated and adjusted. Additionally, the categorization of the different pulps used in AHPs and the development of appropriate criteria for each was also mentioned.

In the newest version of the Nordic Swan[24] for Sanitary Products, the requirement for CO_2 emissions for the fluffing process remains with the same limit value (450 kg/ADT) as in the current EU Ecolabel criteria for absorbent hygiene products. In order to calculate the CO_2 emissions in relation to purchased electricity, Nordic Ecolabelling uses a factor of 385 g CO2/kWh. In the previous AHP Technical Report[11], it was stated that lowering the value below 450 kg/ADT could result in an insufficient availability of fluff pulp for absorbent hygienic products creating trade barriers at the same time.

In regards to CO_2 emission reference values, in 2017 the Nordic Ecolabelling's Criteria Group decided to introduce two adjustments and added specific CO_2 emission reference values for mechanical pulp (CTMP) for electricity (2000 kWh/ADT) and fuel (1000 kWh/ADT) and a requirement level for the emission of CO_2 (900 kg CO_2/ADT) for chemi-thermo-mechanical pulp (CTMP). For non-woven based on cellulose pulp (air-laid) the addition in reference values for air-laid process are increased from 1000 kWh/ADT for electricity and 1000 kWh/ADT for fuel to 4000 kWh/ADT for electricity and 4000 kWh/ADT for fuel.

[32] As defined in Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

[33] Commission Delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council. OJ L 59, 27.2.2019, p. 8–69.

No changes in the criteria text are proposed at this point as further information should be gathered on reference values for CO_2 emissions from different energy sources.

Rationale behind the proposed 'assessment and verification'

During the preliminary questionnaire, stakeholders asked to take into account the verification set for EU Ecolabel criteria for graphic paper, tissue paper and tissue products. Moreover, it has been specifically asked to revise the verification of the purchase of renewable energy.

Given the feedback, at this stage of the revision process **it is proposed to harmonise the assessment and verification with criterion 1(c) of Annex II of the Commission Decision (EU) 2019/70** (EU Ecolabel criteria for graphic paper, tissue paper and tissue products). The grid electricity reference value has been set according to the most updated value published in Article 22, point 3 of the Commission Delegated Regulation (EU) 2019/331 on free allocation rules. This is harmonised with the proposed revised criterion on CO2 emissions calculation under EU Ecolabel criteria for growing media and soil improvers (on going revision). .

Points for discussion
• Should the amount of CO_2 emissions from non-renewable energy sources per tonne of pulp produced be updated? • Should a categorization of the different pulps used be established and set up appropriate criteria for each? • We would like to call for stakeholders to provide input on the reference values for CO_2 emissions from different energy sources presented in Table 2.

5.3 CRITERION 3: Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

Existing criterion 3.1: Sourcing

(a) All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 25 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification Bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme.

(b) Dissolving pulp produced from cotton linters shall meet the criterion 4.1 for cotton (sourcing and traceability).

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this requirement, together with related supporting documentation.

(a) The applicant shall obtain from the pulp manufacturer(s) valid, independently certified chain of custody certificates demonstrating that wood fibres have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.

(b) The application shall provide evidence of compliance according to criterion 4.1 for cotton (sourcing and traceability).

Proposed criterion 3.1: Sourcing of man-made cellulose fibres

(a) All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 70 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification Bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme.

(b) Dissolving pulp produced from cotton linters shall meet the criterion 4.1 for cotton (sourcing and traceability).

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this requirement, together with related supporting documentation.

(a) The applicant shall obtain from the pulp manufacturer(s) valid, independently certified chain of custody certificates demonstrating that wood fibres have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.

(b) ~~The application shall provide evidence of compliance according to criterion 4.1 for cotton (sourcing and traceability).~~

Invoices shall be provided which document that 70% of certified fibres have been allocated to the

material they supply to the Absorbent Hygiene Product producer.

Rationale for the proposed criterion text

Stakeholders are invited to refer to the rationale explained under Section 5.2 – criterion 2.1, given the similarity between these two criteria.

At this stage of the revision process **it is proposed that the threshold of pulp fibres covered by Sustainable Forestry Management certificates is increased to 70%**.

Rationale behind the proposed 'assessment and verification'

During the preliminary questionnaire, stakeholders indicated a lack of clarity of section b) in the assessment and verification for criterion 3.1. According to some stakeholders, there should be no reference to the compliance method used in criterion 4.1 for cotton (sourcing and traceability). Instead, it was suggested to carry out the verification of this criterion through the provision of an invoice from the man-made cellulose producer which would confirm the allocation of 70% fibres with an independent third party certification scheme, to the material supplied to the Absorbent Hygiene Product producer.

It is proposed to require invoices as a proof of evidence for certified fibres.

Existing criterion 3.2: Bleaching
The pulp used to manufacture fibres shall not be bleached with the use of chlorine gas. The resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) shall not exceed either of the following: — 0,170 kg/ADT, if measured in the wastewater from pulp manufacturing (AOX), or — 150 ppm, if measured in the finished fibres (OCl). **Assessment and verification**: The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with either the AOX or the OCl requirement, using the appropriate test method: — ISO 9562 or the equivalent EPA 1650C for AOX, — ISO 11480 for OCl. Frequency of measurement for AOX shall be set in accordance with the criterion 2.2 for fluff pulp.
Proposed criterion 3.2: Bleaching of man-made cellulose fibres
The pulp used to manufacture man-made cellulose fibres shall not be bleached with the use of elemental chlorine (Cl_2) gas. The resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) shall not exceed either of the following: — ~~0,170~~ 0,150 kg/ADT, if measured in the wastewater from pulp manufacturing (AOX), ~~or~~ and — 150 ppm, if measured in the finished fibres (OCl). **Assessment and verification**: The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with either the AOX or the OCl requirement, using the appropriate test method: — ISO 9562 or the equivalent EPA 1650C for AOX, — ISO 11480 for OCl.

Frequency of measurement for AOX shall be set in accordance with the criterion 2.2 for fluff pulp.

Rationale for the proposed criterion text

According to the Nordic Swan[24], the industry standard for man-made cellulose fibres is ECF (elemental chlorine free) bleaching.

Less than 20% of stakeholders who responded to the preliminary questionnaire indicated the need to adjust the limits of the resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) used to manufacture man-made cellulose fibres. However, in order to harmonise with the Nordic Swan, **it is proposed to make compulsory both requirements** of criterion 3.2, i.e. to comply with the AOX emission limit in the wastewater and with the concentration (ppm) of OCl in the finished fibres.

Moreover, **it is proposed to tighten the AOX limit to 0,150 kg/ADT**.

Additional information on pulp bleaching process and related emissions can be found in Section 5.2.

Rationale behind the proposed 'assessment and verification'

No changes are proposed at this stage of the revision process.

Existing criterion 3.3: Optical brighteners and colouring agents
Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the fibres. **Assessment and verification**: The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.
~~**Revised criterion 3.3: Optical brighteners and colouring agents**~~ [This Criterion has been moved to Criterion 6.3 (d)]

Rationale for the proposed criterion text

The majority of respondents (97%) of the preliminary questionnaire either found the criterion adequate, or did not express any opinion in respect to its revision.

Nevertheless, as stated in Section 5.2 for sub-criterion 3.3, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 6.3 (d) – Inks and dyes**.

Existing criterion 3.4: Production of fibres
(a) More than 50 % of pulp used to manufacture fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by: — generating on-site electricity and steam, or — manufacturing chemical co-products. (b) The following limit values for the emission of sulphur compounds to air shall be respected in the viscose and in the modal fibres production process: *Table 3* **Viscose and modal fibres sulphur emission values**

Fibre type	Sulphur emissions to air — Limit value (g/kg)
Staple fibre	30
Filament fibre — Batch washing — Integrated washing	 40 170

Assessment and verification:

(a) The applicant shall make the fibres manufacturers to provide a list of pulp suppliers used to produce the fibres and the proportion they supply. Supporting documentation and evidence shall be provided that the required proportion of suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at related production sites.

(b) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.

Proposed criterion 3.4 : Production of man-made cellulose fibres

(a) More than 50 % of pulp used to manufacture man-made cellulose fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by:

— generating on-site electricity and steam, or

— manufacturing chemical co-products.

(b) The following limit values for the emission of sulphur compounds to air shall be respected in the viscose and in the modal fibres production process:

Table 3

Viscose and modal fibres sulphur emission values

Fibre type	Sulphur emissions to air — Limit value (g/kg)
Staple fibre	20
Filament fibre — Batch washing — Integrated washing	 40 170

Assessment and verification:

(a) The applicant shall make the fibres manufacturers to provide a list of pulp suppliers used to produce the fibres and the proportion they supply. Supporting documentation and evidence shall be provided that the required proportion of suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at related production sites.

(b) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.

Rationale for the proposed criterion text

This sub-criterion aims at minimising negative effects on the environment and on health due to resource consumption and emissions occurring during the production of viscose.

During the preliminary questionnaire, 15% of respondents indicated the need to revise the criterion, specifically pointing to adapting the limit threshold to Nordic Swan criteria. The background report to Nordic Swan criteria[24] explains that a tighter limit for sulphur emissions to air was set after discussions with license holders. Nevertheless, the background document also reports a possible slow uptake of the market, since the previous limit of 30 g/kg was already considered not achievable since it requires the use of a combination of different recycling technologies. Nordic Swan criteria set emission thresholds for only staple fibres, since this is the relevant fibre for the product group of absorbent hygiene products.

Given all the above, at this stage of the revision process **it is proposed to tighten the limit on sulphur emissions to air of 20 g/kg for staple fibres**. Stakeholders are invited to comment on the feasibility of this revised requirement.

The Nordic Swan criterion on man-made cellulose fibre also includes COD and zinc emission requirements to better address impacts of the production of these fibres. While these should also be considered within the on-going revision, they are not proposed to be added at this stage of the revision process.

Finally, a stakeholder indicated the need to set a requirement for carbon disulphide emission given that acid sulphite process is the preferred manufacturing way to produce viscose (Strunk, 2012).

Summary of technical reasons that support the proposed restriction

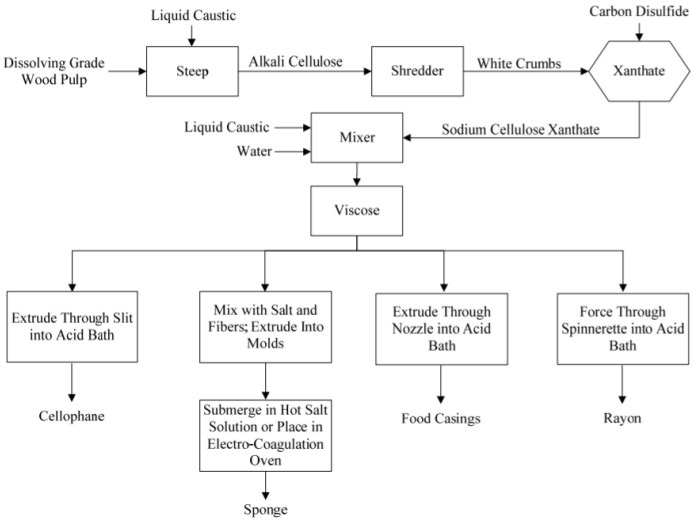
Prehydrolysis kraft pulping and acid sulphite pulping, are the two dominant commercial processes for the production of dissolving pulp (Duan et al., 2015). In the viscose process, sheets of dissolving-grade cellulose pulp are saturated with sodium hydroxide to convert the cellulose into alkali cellulose that partially oxidizes and degrades by aging in ambient air to target viscosity of 200–250 mL/g. Carbon disulphide (CS_2) is used in the xanthation phase of the viscose process, to dissolve alkali cellulose formed in the previous mercerisation phase. The cellulose xanthate is subsequently dissolved in sodium hydroxide solution to form viscose dope, and cellulose is regenerated in an acid spin bath by the action of sulphuric acid. (US EPA, 2011; Duan et al., 2015; Gondhalekar et al., 2018). The quantity of CS_2 used in the process ranges from 32 to 34% w/w of cellulose (Gondhalekar et al., 2018). Gaseous by-products formed during the regeneration of cellulose, including hydrogen sulphide (H2S) and CS_2, are off-gassed from the process equipment. Facilities control emissions of CS_2 (and simultaneously released H_2S) use hydrolysis, incineration, thermal oxidation, activated carbon adsorption, or a biofilter system, among others (US EPA 2011; Xia et al., 2019).

CS_2 (CAS: 75-15-0) according to the CLP harmonised classification and labelling causes damage to organs through prolonged or repeated exposure. It is a highly flammable liquid and vapour that causes serious eye irritation, and is also suspected of damaging fertility and the unborn child and causes skin irritation. Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is suspected of damaging fertility or the unborn child and is harmful if inhaled[34].

Releases of CS_2 from manufacturing facilities are almost exclusively to the atmosphere, but facilities may also transfer CS_2 to wastewater during feedstock unloading and storage. The exposure path is mostly confined to those engaged in technological processes in the viscose industry via respiratory or skin contact routes. The general population living near viscose plants may also be exposed to carbon disulfide emissions (US EPA 2011; WHO. 2005).

[34] Based on ECHA, for more information please check: https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.000.767

Figure 3. Simplified process flow diagram for the generic viscose process and regenerated cellulose products



Source: US EPA, 2011.

As to the current knowledge of the authors, due to the nature of viscose manufacturing process, the possible restriction should rather consider the best practice approach, and not the proposal of technology change. As previously stated, Nordic Swan sets a limit for sulphur emissions to air of 20 g/kg. Further feedback is expected from industry stakeholders in this respect. Similarly, the possible restrictions or monitoring requirements that specifically target CS_2 need to be further discussed with stakeholders.

Rationale behind the proposed 'assessment and verification'

No changes are proposed at this stage of the revision process.

Points for discussion
• Should COD and Zinc emission requirements for man-made cellulose fibres be included? • Should measurement frequency or test method be defined for sulphur emissions? • Should the specific requirement for carbon disulphide emission into air be added to this criterion?

5.4 CRITERION 4: Cotton and other natural cellulosic seed fibres

Existing criterion 4.1: Sourcing and traceability
(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (1), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton. (b) Cotton grown according to criterion 4.1(a) and used to manufacture absorbent hygiene product shall be traceable from the point of verification of the production standard. **Assessment and verification:** (a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin. (b) The applicant shall demonstrate compliance with the cotton content requirement for the annual volume of cotton purchased to manufacture the final product(s) and according to each product line on an annualised basis: Transaction records or invoices shall be provided that document the quantity of cotton purchased on an annual basis from farmers or producer groups, and the total weight of certified bales.
Proposed criterion 4.1: Sourcing and traceability of Cotton and other natural cellulosic seed fibres
(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (1), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton. (b) Cotton grown according to criterion 4.1(a) and used to manufacture absorbent hygiene product shall be traceable from the point of verification of the production standard. Tampon strings are exempted from complying with this requirement. **Assessment and verification:** (a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin. (b) The applicant shall demonstrate compliance with the cotton content requirement for the annual volume of cotton purchased to manufacture the final product(s) and according to each product line on an annualised basis: Transaction records or invoices shall be provided that document the quantity of cotton purchased on an annual basis from farmers or producer groups, and the total weight of certified bales. *(1) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91*

Rationale for the proposed criterion text

This sub-criterion aims at minimising the negative effects from the cultivation of cotton, which is one of the most intensive users of agrochemicals worldwide. The use of organic cotton reduces the emission of greenhouse gases and avoids the use of pesticides, which benefits both the environment and the health of farmers and local communities.

35% of the respondents to the preliminary questionnaire expressed the need to revise the criteria. One stakeholder mentioned that the requirement of organic cotton may counteract with the necessary strength requirements of some parts of the product, e.g. the removal cords in tampons.

Since the cord of the tampon comprises less than 3% by weight of the product, and given the majority of positive feedback from the preliminary questionnaire, **it is proposed to exempt the tampon string from complying with the criterion on cotton**. This is also in line with Nordic Swan requirements.

Rationale behind the proposed 'assessment and verification'

In the preliminary questionnaire, several respondents indicated that the adoption of cotton certification to sustainability aspects other than organic, may allow for a more holistic approach to sustainable cotton production. The Better Cotton Initiative (BCI) (Better Cotton, 2021) was proposed as an alternative scheme which has been adopted by the Textile Exchange for its global sustainable cotton goals.

Nonetheless, in 2013, the JRC (Dodd et al., 2013) reported that schemes such as BCI were not mature enough to be recognised by the EU Ecolabel. Concerns related to both, the criteria and the verification systems were raised. Additional consultation with stakeholders is needed in order to estimate the feasibility of including such scheme to certify cotton used in AHPs and in which terms.

Points for discussion
• Should BCI cotton certification be accepted as a proof of compliance? • Which are the certification schemes that could be considered equivalent, and could be specifically listed under the assessment and verification?

Existing criterion : 4.2: Bleaching
Cotton shall not be bleached with the use of chlorine gas. **Assessment and verification**: The applicant shall provide a declaration from the supplier that chlorine gas is not used.
Proposed criterion : 4.2: Bleaching of cotton and other natural cellulosic seed fibres
Cotton shall not be bleached with the use of chlorine gas. **Assessment and verification:** The applicant shall provide a declaration from the supplier that chlorine gas is not used.

Rationale for the proposed criterion text

This sub-criterion aims at minimising the negative effects on the environment caused by the use of chlorine (e.g. prevention of dioxine formation and other highly carcinogenic pollutants).

Only 14% of the respondents to the preliminary questionnaire reported that the sub-criterion needs revision, pointing to the consistency with the AOX limit in criterion 2.2, the possibility of adding a requirement on sulphide, and one on total chlorine free (TCF) bleaching process. Indeed, in the Blue Angel Ecolabel (criterion 3.5.2., version 2), a total chlorine free (TCF) bleaching process is permitted for the bleaching of cotton fibres.

While it is proposed to discuss these aspects at the 1st Ad-Hoc Working Group meeting, **no changes are proposed** at this stage of the revision process.

Rationale for the assessment and verification text

One stakeholder suggested to require the applicant to hand in a description of the bleaching process.

No changes are proposed at this stage of the revision process.

Points for discussion
• Should TCF be the only bleaching process allowed for cotton fibres? • Should a description of the bleaching process (if applicable) be provided by the applicant?

Existing criterion 4.3: Optical brighteners and colouring agents
Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the cotton. **Assessment and verification**: The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.
~~**Revised criterion 4.3: Optical brighteners and colouring agents**~~ [This criterion has been moved to Criterion 6.3 (d)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. The intention is to improve the clarity of the criteria set. Therefore, **it is proposed to move this criterion to revised criterion 6.3 (d) – Inks and dyes**.

5.5 CRITERION 5: Plastic materials and superabsorbent polymers

Existing criterion 5.1: Production of synthetic polymers and plastic materials
All plants producing synthetic polymers and plastic materials used in the product shall have implemented systems for: — water-saving (e.g. monitoring of water flow in a facility and circulating the water in closed systems), — integrated waste management plan to optimise prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions), — optimisation of energy efficiency and energy management (e.g. reuse of the steam generated during the manufacture of SAPs). **Assessment and verification**: The applicant shall provide a declaration of compliance with the requirement from the suppliers. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirement for each of the sites concerned.
Proposed criterion 5.1: Production of polymers
All plants producing synthetic polymers and plastic materials used in the product shall have implemented systems for: — water-saving (e.g. monitoring of water flow in a facility and circulating the water in closed systems), — integrated waste management plan to optimise prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions), — optimisation of energy efficiency and energy management (e.g. reuse of the steam generated during the manufacture of SAPs). **Assessment and verification**: The applicant shall provide a declaration of compliance with the requirement from the suppliers. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirement for each of the sites concerned.

Rationale for the proposed criterion text

Plastics represent a significant share of the weight of AHPs, either as a component of the product or as packaging.

Overall, 25% of the respondents to the preliminary questionnaire indicated the need to revise this criterion. One stakeholder expressed to remove this criterion. Indeed, apart for the lack of clarity of the sub-criterion, "the bullet points are not relevant for all polymer or plastic production processes. An AHP may consist of 10 different plastic materials with several polymer granulate suppliers and to get detailed info from the producers is an impossible task".

Another stakeholder mentioned that the use of a % organic or PCR (Post Consumer Recycled) material could be introduced. This has been addressed in the new criterion 8 on "Product and its packaging".

Finally, one stakeholder mentioned that it would be relevant to explore the use bioplastics and biopolymers and plastic free solutions.

In the previous revision process[11], a criterion promoting the use of synthetic polymers based on renewable materials was considered. However, at the end the promotion of bio-polymers was not recommended. The potential benefits of non-biodegradable bio-based polymers such as BioPE and BioPET have been explored in the new Preliminary Report for Absorbent Hygiene Products. Currently there bio-based polymers are not

mentioned by the current EU Ecolabel criteria. The Nordic Swan sets a requirement for bio-based polymers like PLA and bioPE to be part of the outer layer of an AHP. There is the requirement for certification of raw materials for bio-based polymers when they constitute more than 20% of the total weight of the product (Nordic Swan, 2021).

The environmental benefits of bio-based polymers over fossil ones have not been clearly demonstrated. For example, Pré Sustainability[35] indicated impacts in terms of nitrous oxide, in fossil fuels used to produce the fertilisers and in land use changes. Moreover, the economic situation of bio-based polymers is not clear yet. Therefore, the use of bio-based polymers is not proposed to be incentivised at this stage of the revision process. However, as criterion 5.1 refers to general environmental practices that can be carried out in the production of bio-based polymers, **it is proposed to change the name of criterion 5.1 into "*production of polymers*"**, in order to allow for the inclusion of different types of polymers under one criterion.

Rationale behind the proposed 'assessment and verification'

No changes are proposed at this stage of the revision process.

Existing criterion 5.2: Additives in plastic materials
(a) 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. (b) Additives used in plastics in concentration above 0,10 % by weight shall not be classified with any of the below listed hazard statements, in accordance with the classification rules in Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1): — carcinogenic, mutagenic or toxic for reproduction, categories 1a, 1b and 2 (H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df), — acutely toxic, categories 1 and 2 (H300, H310, H330, H304), — toxic to specific target organs (STOT), category 1: (H370, H372), — hazardous to the aquatic environment, categories 1 and 2 (H400, H410, H411). **Assessment and verification**: (a), (b) The applicant shall provide a declaration of compliance with the requirements from the suppliers. A list of added substances shall be also provided, including concentrations and related H statements/R phrases, supported by safety data sheets. In order to facilitate follow-up and monitoring of the documentation provided, a random sample of suppliers may be examined. The supplier shall provide access to production facilities, warehouses and similar installations. Confidentiality applies to any documentation and information submitted and shared.
Proposed criterion 5.2: Additives in plastic materials [This criterion has been moved to Criterion 7.3 (d)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (d) – Further restrictions applying to plastic materials**.

[35] Pré Sustainability (2015) Bio-based products are always better than fossil fuel-based products: myth or not? Available at: https://pre-sustainability.com/articles/bio-based-products-are-always-good-myth-or-not/

Existing criterion 5.3: Superabsorbent polymers
(a) Acrylamide (CAS number: 79-06-1) shall not be intentionally added to the product. (b) 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. (c) 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. **Assessment and verification:** (a) The applicant shall provide a declaration of non-use of the substance. (b) The applicant shall provide a declaration from the supplier documenting the composition of the super absorbent polymer(s) used in the product. This shall be done by means of product safety data sheets which specify the full name and CAS number and the residual monomers contained in the product classified in accordance with the requirement and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The methods used for the analyses shall be described and the names of the laboratories used for analysis shall be stated. (c) The applicant shall provide a declaration from the supplier specifying the quantity of water-soluble extracts in the superabsorbent polymer(s). Recommended test methods are ISO 17190 and WSP 270. The methods used for the analyses shall be described and the analysis laboratories shall be stated.
~~**Proposed criterion 5.3: Superabsorbent polymers**~~ [This criterion has been moved to Criterion 7.3(g)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (g) – Superabsorbent polymers**.

5.6 CRITERION 6: Other materials and components

Existing criterion 6.1: Adhesive materials
Adhesive materials shall not contain any of the following substances: — Colophony resins (CAS numbers 8050-09-7, 8052-10-6, 73138-82-6), — Diisobutyl phthalate (DIBP, CAS number 84-69-5), — Diisononyl phthalate (DINP, CAS number 28553-12-0), — Formaldehyde (CAS number 50-00-0). This requirement shall not apply if those substances are not intentionally added to the material or to the final product, and are present in the adhesive materials in concentrations below 100 ppm (0,010 % by weight). For formaldehyde, the maximum limit for the content of formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. Hotmelt adhesives shall be exempted from this requirement. **Assessment and verification**: The applicant shall provide a declaration from the supplier that the requirements have been fulfilled. Safety data sheets may be used as proof. Test results for formaldehyde shall be provided, with the exception of hotmelt adhesives.
~~**Proposed criterion 6.1: Adhesive materials**~~ [This criterion has been moved to Criterion 7.3(f)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (f) – Further restrictions applying to adhesives**.

Existing criterion 6.2: Inks and dyes
The product and any homogeneous part of it shall not be dyed. Derogations to this requirement shall apply to: — tampon strings, packaging materials and tapes, — titanium dioxide in polymers and viscose, — materials that are not directly in contact with the skin may be dyed if the dye fulfils specific functions (e.g. reducing visibility of the product through white or light coloured clothing, showing landing zones of tapes, indicating the wetness). Inks and dyes used shall also comply with Criterion 7 on excluded or limited substances or mixtures. **Assessment and verification**: The applicant shall provide and shall make suppliers to provide a declaration that the requirements have been fulfilled. In case dyes are used, their presence shall be justified by indicating the specific function provided.
~~**Proposed criterion 6.2: Inks and dyes**~~ [This criterion has been moved to Criterion 7.3(d)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (d) – Inks and dyes**.

Existing criterion 6.3: Fragrances
(a) Products marketed as designed and intended for children as well tampons and nursing pads shall be fragrance-free. (b) Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer. (c) Any fragrance used shall also comply with Criterion 7 on excluded or limited substances or mixtures regardless of the concentration in the final product. (d) Fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety ([36]) as well as the fragrances whose presence, in accordance with Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ([37]), is required to be indicated in the list of ingredients shall not be used. (e) 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 Consumer and are not restricted by Criterion 6.3 (c) and (d) shall additionally be named. **Assessment and verification**: The applicant shall provide a declaration of compliance for all the requirements laid down in points (a) to (e), supported by a declaration of the fragrance manufacturer, if appropriate. The list of fragrances used and visual evidence that information has been added to the packaging shall be also provided, when fragrances are used.
~~**Proposed criterion 6.3: Fragrances**~~ [This criterion has been moved to Criterion 7.3(b)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (b) – Fragrances**.

Existing criterion 6.4: Lotions
(a) 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. (b) Any lotion used in products other than feminine care pads, tampons and nursing pads shall comply with Criterion 6.3 on fragrances and Criterion 7 on excluded or limited substances or mixtures regardless of their concentration in the final product.

[36] SCCS Opinion on Fragrance allergens in cosmetic products adopted in June 2012 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

[37] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

(c) The following substances shall not be used: triclosan, parabens, formaldehyde and formaldehyde releasers.

Assessment and verification:

The applicant shall provide a declaration of compliance supported by a declaration of the lotion manufacturer, if appropriate. Visual evidence that information has been added to the packaging shall be also provided, when lotions are used.

~~Proposed criterion 6.4: Lotions~~ [This criterion has been moved to Criterion 7.3(c)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (c) – Lotions**.

Existing criterion 6.5: Silicone

(a) Where components of the product are treated with silicone, the manufacturer shall ensure that employees are protected from the solvents.

(b) Neither octamethyl cyclotetrasiloxane D4 (CAS 556-67-2) nor decamethyl cyclopentasiloxane D5 (CAS 541-02-6) shall be present in chemical products used in the silicone treatment of components. This requirement shall not apply where D4 and D5 are not intentionally added to the material or to the final product, and where D4 and D5 are present in the silicone in concentrations below 100 ppm (0.01 % by weight).

Assessment and verification:

(a) The applicant shall provide information on the method used for the treatment of silicone and documentation attesting that employees are protected.

(b) The applicant shall provide a declaration from the supplier that this requirement has been fulfilled.

~~Proposed criterion 6.5: Silicone~~ [This criterion has been moved to Criterion 7.3(h)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (h) – Silicone**

Rationale behind the proposed 'assessment and verification'

Minor wording clarifications are proposed at this stage of the revision process.

Existing criterion 6.6: Nanosilver particles

Nanosilver particles shall not be intentionally added to the product or to any homogeneous part or material of it.

Assessment and verification: The applicant shall provide a declaration and shall make suppliers to provide a declaration that this requirement has been fulfilled.
~~**Proposed criterion 6.6:**~~ [This criterion has been moved to Criterion 7.3(a)]

Rationale for the proposed criterion text

As previously mentioned, it is proposed to change the structure (i.e. the order) of the criteria, with the aim of grouping together those criteria banning specific substances. Therefore, **it is proposed to move this criterion to revised criterion 7.3 (a) – Specified excluded substances**.

5.7 CRITERION 6: Excluded and restricted substances

This criterion aims at minimising the use during the production process and presence in a final AHP product of substances and mixtures that have hazardous properties. Current criteria 7.1 and 7.2 are directly linked to the requirements given in Article 6(6) of the EU Ecolabel Regulation (EC) No 66/2010, which states:

'*the EU Ecolabel may not be awarded to goods containing:*

- Substances or preparations/mixtures meeting the criteria for classification as toxic hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008, and

- Substances of Very High Concern, as referred to in Article 57 of Regulation (EC) No 1907/2006'.

The identification of potential sources of hazard is based on a list of hazard classes, categories and hazard statements codes that are grouped based on the CLP classification and labelling rules and harmonised across different EU Ecolabel product groups (see Table 4 of the criteria). The list generally refers to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

In this first Technical Report it is proposed to have a revised structure of the horizontal hazardous substance criteria 7.1 and 7.2., following the general recommendations of the 1st and 2nd EU Ecolabel Chemicals Task Forces (EC, 2018).

In order to correctly match the intention of Articles 6(6) and 6(7) of the EU Ecolabel Regulation, the criterion 7.1 and 7.2 only need to focus on the final product and not on hazardous substances and mixtures potentially used during the production process. At this stage of the revision, it is proposed to add a new sub-criterion 7.3 which sets down specific restrictions in defined circumstances, targeting the possible use of specific group of chemicals during the production process, such as biocidal active substances, APEOs, phthalates, PAHS, formaldehyde and organotins.

5.7.1 Criterion 6.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Existing criterion 7.1: Hazardous substances and mixtures

The EU Ecolabel may not be awarded if the product or any article of it, as defined in Article 3(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (1), or any homogenous part of it contain substances or mixtures meeting the criteria for classification with the hazard statements or risk phrases specified in table 4, in accordance with Regulation (EC) No 1272/2008 or Council Directive 67/548/EEC (2), nor they contain substances or mixtures referred to in Article 57 of Regulation (EC) No 1907/2006, unless they have been specifically derogated from.

The most recent classification rules adopted by the Union shall take precedence over the listed hazard classifications and risk phrases. Applicants shall therefore ensure that any classifications are based on the most recent classification rules.

The hazard statements and the risk phrases in table 4 generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

Substances or mixtures which change their properties through processing and thus become no longer bioavailable or undergo chemical modification in a way that removes the previously identified hazard are exempted from criterion 7.1. This shall include, for instance, modified polymers and monomers or additives, which become covalently bonded within plastics.

Concentration limits for substances or mixtures which may be or have been assigned the hazard statements or risk phrase listed in table 4, meeting the criteria for classification in the hazard classes or categories, and for substances meeting the criteria of Article 57 (a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined they shall prevail over the generic ones.

Table 4

Hazard statements and respective risk phrases

Hazard Statement (1)	Risk Phrase (2)
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22

H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
H317 (Sub-category 1A): May cause allergic skin reaction (trigger concentration ≥ 0,1 % w/w) (3)	R43
H317 (Sub-category 1B): May cause allergic skin reaction (trigger concentration ≥ 1,0 % w/w) (3)	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42

Notes

(1) In accordance with Regulation (EC) No 1272/2008.
(2) In accordance with Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the clas- sification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).
(3) In accordance with Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011, p. 1).

Assessment and verification:

The applicant shall provide the bill of materials of the product, including a list with all articles and homogeneous part of it.

The applicant shall screen the presence of substances and mixtures that may be classified with the hazard statements or risk phrases reported in this criterion. The applicant shall provide a declaration of compliance with this criterion for the product, any article of it or any homogenous part of it.

Applicants shall select the appropriate forms of verification. The main forms of verification are set out as follows:

— homogenous parts and any associated treatments or impurities (e.g. superabsorbent polymer layer): safety data sheets shall be provided for the materials composing that part of product and for substances and mixtures used in the formulation and treatment of the materials remaining in the final part above a cut-off limit of 0,10 % w/w unless a lower generic or specific concentration limit applies in accordance with the Article 10 of Regulation (EC) No 1272/2008,

— chemical recipes used to impart a specific function to the product or to components of the product (e.g. glues and adhesives, dyes): safety data sheets shall be provided for substances and mixtures used in the

assembly of the final product or substances and mixtures applied to components of the product and remaining in the components of the product.

That declaration shall include related documentation, such as declarations of compliance signed by the suppliers, on the non-classification of the substances, mixtures or materials with any of the hazard classes associated to the hazard statements or risk phrases referred in table 4 in accordance with Regulation (EC) No 1272/2008, as far as this can be deter- mined, as a minimum, from the information meeting the requirements listed in Annex VII to Regulation (EC) No 1907/2006.

The information provided shall relate to the forms or physical states of the substances or mixtures as used in the final product.

The following technical information shall be provided to support the declaration of classification or non-classification for each substance and mixture:

(i) for substances that have not been registered under Regulation (EC) No 1907/2006 or which do not yet have a harmonised CLP classification: information meeting the requirements listed in Annex VII to that Regulation;

(ii) for substances that have been registered under Regulation (EC) No 1907/2006 and which do not meet the requirements for CLP classification: information based on the REACH registration dossier confirming the non-classified status of the substance;

(iii) for substances that have a harmonised classification or are self-classified: safety data sheets where available. If these are not available or the substance is self-classified then information shall be provided relevant to the substances hazard classification in accordance with Annex II to Regulation (EC) No 1907/2006;

(iv) in the case of mixtures: safety data sheets where available. If these are not available then calculation of the mixture classification shall be provided according to the rules under Regulation (EC) No 1272/2008 together with information relevant to the mixtures hazard classification in accordance with Annex II to Regulation (EC) No 1907/2006.

Safety data sheets (SDS) shall be completed in accordance with the guidance set out in Section 2, 3, 9, 10, 11 and 12 of Annex II to Regulation (EC) No 1907/2006 (requirements for the compilation of safety data sheets). Incomplete SDS shall require supplementing with information from declarations by chemical suppliers.

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI to Regulation (EC) No 1907/2006. The sharing of relevant data across the supply chain is strongly encouraged.

First proposal for criterion 6.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([38])

Unless derogated in Table X, the final product, and any component articles therein, shall not contain substances or mixtures in concentrations greater than 0,10% (weight by weight) that are assigned any of the following hazard classes, categories and associated hazard statement codes, in accordance with Regulation (EC) No 1272/2008:

- Group 1 hazards: Category 1A or 1B carcinogenic, mutagenic and/or toxic for reproduction (CMR): H340, H350, H350i, H360, H360F, H360D, H360FD, H360Fd, H360Df.
- Group 2 hazards: Category 2 CMR: H341, H351, H361, H361f, H361d, H361fd, H362; Category 1 aquatic toxicity: H400, H410; Category 1 and 2 acute toxicity: H300, H310, H330; Category 1 aspiration toxicity: H304; Category 1 specific target organ toxicity (STOT): H370, H372; Category 1

[38] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

skin sensitisation H317; Category 1 respiratory Sensitization H334.

- Group 3 hazards: Category 2, 3 and 4 aquatic toxicity: H411, H412, H413; Category 3 acute toxicity: H301, H311, H331; Category 2 STOT: H371, H373.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement.

***Assessment and verification**: the applicant shall provide a list of all relevant chemicals used in their production process, together with the relevant safety data sheet or chemical supplier declaration and any relevant declarations from component article suppliers.*

Any chemicals containing substances or mixtures with restricted classifications under Regulation (EC) No 1272/2008 shall be highlighted. The approximate dosing rate of the chemical, together with the concentration of the restricted substance or mixture in that chemical (as provided in the Safety Data Sheet or supplier declaration) and an assumed retention factor of 100%, shall be used to estimate the quantity of the restricted substance or mixture remaining in the final product.

Since multiple products or potential products using the same process chemicals may be covered by one license, the calculation only needs to be presented for each chemical for the worst-case product or component article covered by the EU Ecolabel license (e.g. the most heavily printed component article when screening for inks with restricted classifications).

Justifications for any deviation from retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a restricted hazardous substance or mixture must be provided in writing to the Competent Body.

For any restricted substances or mixtures that exceed 0.10% (weight by weight) of the final product, or of relevant component articles therein, a relevant derogation must be in place and proof of compliance with any relevant derogation conditions must be provided

Rationale for the proposed criterion text

Legal basis

Criterion 6.1 (together with criterion 6.2) represent the practical implementation of the requirements set out in Articles 6(6) and 6(7) of the EU Ecolabel Regulation. These Articles place clear restrictions on the possible presence of hazardous substances being present in EU Ecolabel products, helping to thus ensure that the EU Ecolabel is only awarded to the least environmentally impacting products.

The term "toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR)" from Article 6(6) was translated into specific CLP hazard categories by the EU Ecolabel Chemicals Task Force and resulted in the Group 1, Group 2 and Group 3 hazards as listed in the criterion proposal.

In this first TR, **it is proposed to remove any reference to risk phrases** (e.g. R45, R50, etc.) when mentioning the classification of substances and mixtures because these were linked to the Dangerous Substances Directive (67/548/EEC) which was repealed by the CLP Regulation of June 2015. When the existing AHP criteria were developed, risk phrases were still be used in parallel with hazard statements as part of a transition period. Now that the transition is complete, reference is exclusively made to hazard statements and classes (e.g. H350, H400, etc.).

Screening process

In reality, it is not possible to verify the “presence” of all possible restricted hazardous substances in a product or component part. An EU Ecolabel Chemicals Task Force was set up to define a practical implementation of the requirements of Articles 6(6) and 6(7). A screening process for all chemicals used that may end up in the final product has been defined, which follows the steps illustrated below.

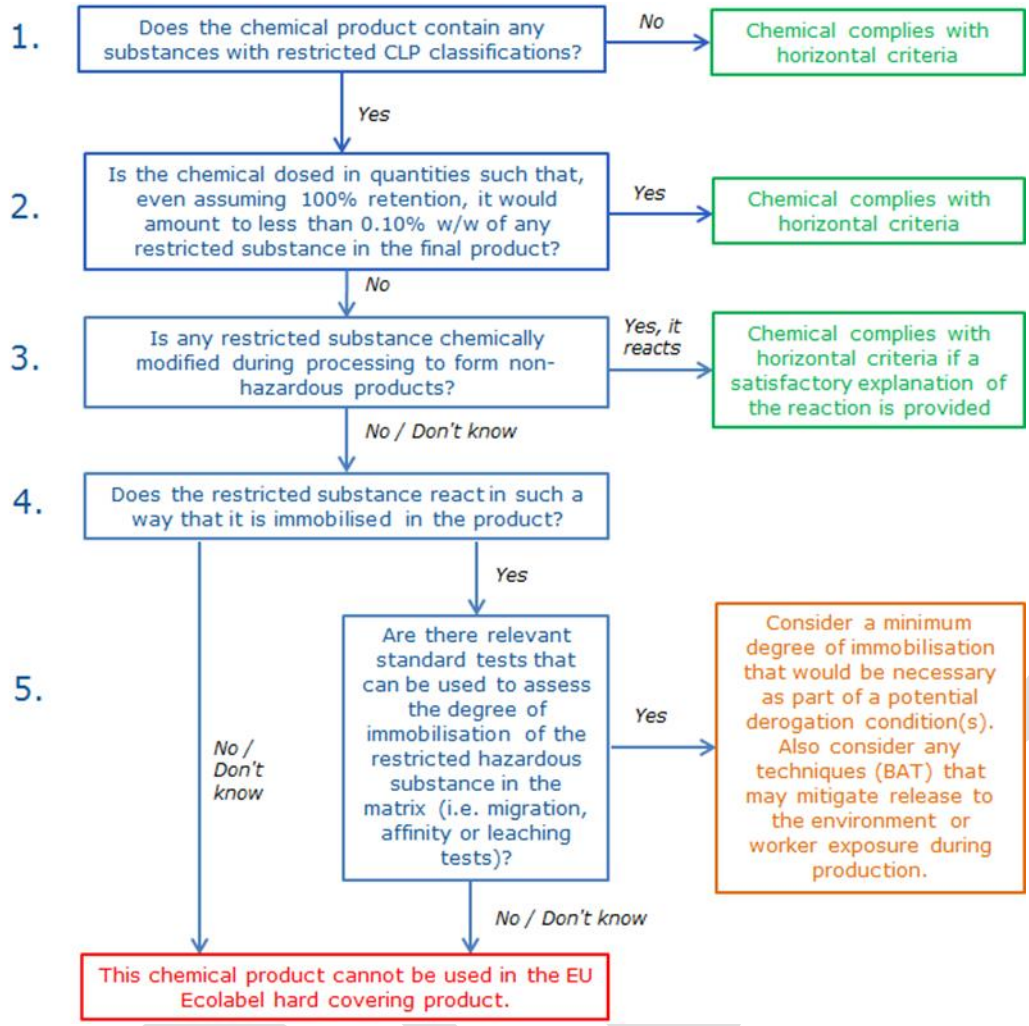


Figure 4. Flow chart for checking compliance with CLP restrictions and potential need for derogations.

Screening process

The precise wording and structure of the horizontal hazardous substance restrictions has varied considerably with different EU Ecolabel product groups. Although necessary differences still exist in the wording depending on whether the product group is a simple article, complex article or a mixture, the wording has gradually evolved to a more consistent and harmonised text.

In this sense, with AHP being examples of complex articles, it is proposed to closely align the wording of the revised criterion with that of the recently adopted EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bag products (Commission Decision (EU) 2020/1803). This leads to the removal of some parts of the currently valid criterion that were more like a guidance rather than requirements. These parts are proposed to be explicitly described in the User Manual for Absorbent Hygiene Products.

Derogations

No derogations have been in place for the currently valid criterion 6.1 and no derogation requests have been received so far from industry.

Granting derogation is ruled by the provision of the EU Ecolabel Regulation and certain conditions must be met before a substance can be placed on the derogation list. Namely only:

-when it is not technically feasible to substitute these substances or use alternative materials or designs without losing the performance or functionality that they impart to the product,

-or in the case that use and resulting presence of the hazardous substance or mixture in products results in a significantly higher overall environmental performance for the production process or product when compared with other goods of the same category that do not use the hazardous substance or mixture in question.

In this first TR, no derogations are proposed. Nevertheless, industry is asked to submit official derogation requests in case a potential need for derogation is identified. The derogation request must be duly substantiated with data, according to the template in Appendix I. The derogations received will be evaluated during the revision process.

Points for discussion
• Is there any additional clarifications needed about the proposed wording? • AreIs there any derogation requests foreseen? (note: titanium dioxide is now a pigment that would require derogation if used in quantities >0.1% of the treated article or component part; See criterion 6.3).

Rationale behind the proposed 'assessment and verification'

The current version of the assessment and verification outlines the documentation that the applicant shall submit to prove compliance with this sub-criterion.

As the basis for demonstrating compliance with sub-criterion criterion 6.1, the applicant should provide a list of all the relevant chemicals used together with appropriate documentation (safety data sheet and/or a declaration from the chemical supplier). As a minimum, all process chemicals used by the applicant in the end product must be screened. This is to reduce the risk of possible misinterpretation of the legal text as to the level of detail that is necessary to determine the hazard classifications of the substances and mixtures in chemicals used. Accordingly, under the current formulation of criterion 6.1. The cut-off value of the screening of the product's composition for hazards shall be 0.10% w/w.

The basis for all information related to criteria 6.1. is a REACH compliant Safety Data Sheet (SDS). If a hazardous substance is present in a product above a certain trigger concentration that is related to the hazards it presents, it must be listed in Section 3 of the SDS. If the whole chemical itself is classified, then this information will be present in Section 2 of the SDS.

When the SDS reveals the presence of restricted hazardous substances, its use has to be quantified by estimating the total quantity of the substance added and dividing this by the total production volume of the EU Ecolabel product. This will provide a final product concentration that assumes that all added substance remains in the final product and none of it reacts to form different products. This initial assumption can then be multiplied by factors that account for degrees of chemical reaction and any losses due to washing out of substances or so on.

Since not all chemicals have an SDS, in these cases, the supplier of the chemical product would be required to provide a declaration to the applicant or Competent Body about the presence and concentrations of any substances or mixtures with restricted CLP hazards listed in criterion 6.1.

5.7.2 Criterion 6.2: Restrictions on Substances of Very High Concern (SVHCs)

Existing criterion 7.2: *Restrictions on Substances of Very High Concern (SVHCs)*
No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list provided for in Article 59(1) of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogeneous part of the product in concentrations > 0.10 % by weight.

Assessment and verification:

Reference to the latest list of substances of very high concern shall be made on the date of application. The applicant shall provide a declaration of compliance with criterion 7.2, together with related documentation, including declarations of compliance signed by the material suppliers and copies of relevant SDS for substances or mixtures in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits shall be specified in the safety data sheets in accordance with Article 31 of Regulation (EC) No 1907/2006 for substances and mixtures.

First proposal for criterion 6.2: Restrictions on Substances of Very High Concern (SVHCs)

All ingoing chemicals used in the production process by the applicant and any supplied materials that form part of the final product shall be covered by declarations from suppliers that they do not contain, in concentrations greater than 0.10% (weight by weight), substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[39] that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation. No derogation from this requirement shall be granted.

Assessment and verification

The applicant shall provide a declaration that the product has been produced using supplied chemicals or materials that do not contain any SVHC in concentrations greater than 0.10% (weight by weight). The declaration shall be supported by safety data sheets of process chemicals or appropriate declarations from chemical or material suppliers.

The list of substances identified as SVHCs and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

Reference to the list shall be made on the submission date of the EU Ecolabel application.

Rationale for the proposed criterion text

As with criterion 6.1, sub-criterion 6.2 is directly linked to Articles 6(6) and 6(7) of the EU Ecolabel Regulation (EC) No 66/2010, which effectively states that no substances of very high concern (SVHC) can be present in EU Ecolabel products. The practical interpretation of this requirement for the majority of EU Ecolabel products that are articles has been to set a limit of 0,1 % (weight by weight) in the final product or in any component part therein.

When attempting to demonstrate compliance, it is necessary to screen for the presence of SVHCs in process chemicals used by the applicant and in component articles supplied to the applicant.

Since absorbent hygiene products may include separable product parts or components, it is worth mentioning here that the 0.1% threshold for SVHC and CLP restrictions should apply to the individual component level, not simply the weight of the entire complex article (final product). This is in line with the European Court of Justice ruling on case 106/14 in September 2015 regarding communication requirements on SVHCs. The 0.1% limits should apply to any component that can be considered an individual article in itself.

The 0.10% limit is particularly useful for SVHC declarations since it aligns perfectly with communication requirements that are stipulated in the REACH Regulation. The SVHCs are restricted to 0.10% at the level of ingoing materials and substances, and not at the level of the final product. This more stringent approach is possible without any major increase in assessment and verification difficulties thanks to the communication requirements set out by REACH (specifically in Articles 7(2) and 33 of REACH):

[39] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- Article 7(2) of REACH requires importers or producers to notify ECHA if a SVHC is present in articles they import or produce in concentrations exceeding 0.1% (w/w) and add up in total to more than 1 tonne of a particular SVHC per actor per year.
- Article 33 of REACH is even more relevant, since any recipient (i.e. a business-to-business transaction) or consumer (business-to-consumer transaction) must, upon request, be informed within 45 days of the presence of any SVHC present in the article(s) they have purchased if the concentration of the SVHC exceeds 0.1% (w/w). The weak point of Article 33 is that this communication requirement is only triggered by a specific request and only if the answer is positive (i.e. that there is a SVHC present at a level >0.1% w/w). There is no obligation to respond if no SVHC is present at a level >0.1% w/w, even if it is simply to confirm that there is no issue.

An important point to note is the recent shift towards placing SVHC restrictions on ingoing chemicals instead of the final product. This goes beyond the requirements laid out in the EU Ecolabel Regulation but is considered as a powerful signal to the chemical industry to find alternatives to SVHCs.

However, this increased ambition level creates some potentially unforeseen issues with criterion 7.2. With the currently valid criterion, if an SVHC is present in an ingoing chemical, its use is not necessarily prohibited because it could only be chemically modified to be no longer present in the final product. Furthermore, because the list of SVHCs is dynamic, when a particular substance becomes an SVHC in the future, it can take time for both chemical producers and applicants to find alternative, SVHC-free chemicals that carry out any equivalent function.

Consequently, a close consultation is needed with chemical suppliers to AHP producers in order to understand better about the potential presence of SVHCs in process chemicals (both today and in the near future).

Rationale behind the proposed 'assessment and verification'

As mentioned in mentioned in the rationale for sub-criterion 6.1, the starting point for demonstrating compliance with sub-criterion 6.2 is a list of all the relevant process chemicals used together with appropriate documentation (SDSs and/or a declaration from the chemical supplier). As a minimum, all process chemicals used by the applicant must be screened.

For supplied component articles, it is not necessary to present a list of the chemicals used, but the supplier must declare that the article does not contain any SVHC in concentrations greater than 0.10% (weight by weight). In case the supplied article is itself a complex article, then the declarations shall state compliance with the 0.10% limit for each separate part of the supplied component article.

No content-wise changes have been introduced, however **the text has been aligned with corresponding criterion from the EU Ecolabel for printed paper, stationery paper, and paper carrier bags**.

5.7.3 Sub-criterion 6.3: Specific restrictions - NEW

In the Commission Decision Absorbent Hygiene Products (2014/763/EU), specific chemical restrictions were not sufficiently grouped along the text. In order to simplify the structure of the criteria set, a new criterion (7.3) that collects specific restrictions on substances is proposed. This criterion 6.3 groups requirements already existing in current criteria in force (but under a different criterion number), as explained in previous sections of this Technical Report. Newly proposed requirements were also added to sub-criterion 6.3.

First proposal for criterion 6.3: Specific restrictions
6.3(a) Specified excluded substances The following substances shall not be present in the product, regardless of the concentration, neither as part of the product, as part of any mixture included in the product, nor as impurities: i. 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT); ii. Acrylamide shall not be intentionally added to superabsorbent polymers.

iii. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]. Sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole are allowed;
iv. Formaldehyde and formaldehyde releasers [2];
v. Methylisothiazolinone (MIT)
vi. Nanosilver
vii. Nitromusks and Polycyclic musks;
viii. Organotin compounds used as a catalysts in the production of silicone polymers
ix. Parabens;
x. Phthalates [3];
xi. Substances identified to have endocrine disrupting properties;
xii. Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects;
xiii. Triclosan.

Notes:

[1] Substance name = "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals

[2] This exclusion relates to the use of formaldehyde and formaldehyde releasers in lotions. Their use in adhesives is regulated according to sub-criterion 7.3 (f)

[3] DIBP and DINP may be allowed if used in adhesive formulations at a maximum concentration of 0.010% weight by weight of the adhesive formulation

6.3(b) Fragrances

(i) Products marketed as designed and intended for children as well as tampons and nursing pads shall be fragrance-free.

(ii) Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

(iii) Fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety ([40]) as well as the fragrances restricted by the criteria 7.1 and 7.2 shall not be used.

(iv) The use of fragrances shall be indicated on the product packaging.

6.3(c) 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.

6.3(d) Inks and dyes

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the pulp used in products.

The product ~~homogeneous part of~~ and any component part thereof shall not be dyed. Derogations to this requirement shall apply to:

[40] Table 13-1 of SCCS Opinion on Fragrance allergens in cosmetic products adopted in June 2012 http://ec.europa.eu/health/scientific_committees/ consumer_safety/docs/sccs_o_102.pdf

— tampon strings, packaging materials and tapes,

— titanium dioxide in polymers and viscose,

— materials that are not directly in contact with the skin may be dyed if the dye fulfils specific functions (e.g. reducing visibility of the product through white or light coloured clothing, showing landing zones of tapes, indicating the wetness).

~~Inks and dyes used shall also comply with Criterion 7 on excluded or limited substances or mixtures.~~

6.3(e) Further restrictions applying to **plastic materials**

(a) Contents of lead, cadmium, hexavalent chromium and related compounds shall be lower than 0.01 % weight by weight (100 ppm) of the mass of each plastic material and synthetic polymer used in the product.

(b) Additives used in plastics in concentration above 0,10 % weight by weight shall not be classified with any of the below listed hazard statements, in accordance with the classification rules in Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1):

— carcinogenic, mutagenic or toxic for reproduction, categories 1a, 1b and 2 (H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df),

— acutely toxic, categories 1 and 2 (H300, H310, H330, H304),

— toxic to specific target organs (STOT), category 1: (H370, H372),

— hazardous to the aquatic environment, categories 1 and 2 (H400, H410, H411).

6.3(f) Further restrictions applying to adhesives

The following substances shall not be added to adhesives used in Absorbent Hygiene Products according to the thresholds listed below:

— Colophony resins: Adhesives shall not contain more than 0.01% (weight by weight) colophony resin. Modified colophony derivatives that are not classified as sensitizers, e.g. rosin esters, are allowed;

— Formaldehyde: the content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. The threshold for formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Hotmelt adhesives shall be exempted from this requirement.

6.3(g) Super absorbent polymers (SAP)

(i) Superabsorbent polymers used in the product shall contain a maximum of 1 000 ppm residual monomers that are classified with the H-codes reported in sub-criterion 6.1. For sodium polyacrylate this limit applies to the sum of unreacted acrylic acid and cross linking agents.

(ii) Superabsorbent polymers used in the product shall, 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.

6.3(h) Silicone

(i) ~~Where components articles of the product are treated with silicone, the manufacturer silicone supplier shall ensure that employees are protected from the solvents~~. Solvent-based silicone coatings must not be used.

(ii) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture in concentrations above 800 ppm (0,08 % by weight). ~~chemical products used in the silicone treatment of components. This requirement shall not apply where D4 and D5 are not intentionally added to the~~

~~material or to the final product, and where D4 and D5 are present in the silicone in concentrations below 100 ppm (0,01 % by weight).~~

Assessment and verification:

The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers whenever relevant; and the following supporting evidence:

To demonstrate compliance with sub-criteria 6.3(a), 6.3(e), 6.3(f) and 6.3(g), the applicant shall provide:

(i) safety data sheets (SDS) of any substance/mixture and their concentration in the final product;

(ii) a written confirmation that sub-criteria 6.3(a), 6.3(e), 6.3(f) and 6.3(g) are fulfilled.

To demonstrate compliance with sub-criterion 6.3(b), the list of fragrances used and visual evidence that information has been added to the packaging shall be provided, when fragrances are used.

To demonstrate compliance with sub-criterion 6.3(c), visual evidence that information has been added to the packaging shall be provided, when lotions are used.

To demonstrate compliance with criterion 6.3(d), in case dyes are used, their presence shall be justified by indicating the specific function provided.

To demonstrate compliance with sub-criterion 6.3(f), the applicant shall also provide test results for formaldehyde.

To demonstrate compliance with sub-criterion 6.3(g), the applicant shall also provide a declaration from the supplier documenting the composition of the super absorbent polymer(s) used in the product and the quantity of water-soluble extracts in the superabsorbent polymer(s). The SDSs shall specify the residual monomers contained in the product and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The methods used for the analyses shall be described and the names of the laboratories used for analysis shall be stated.

To demonstrate compliance with sub-criterion 6.3(h), the applicant shall provide a declaration from the silicone supplier with information on the method used to manufacture the silicone. Moreover, the applicant shall provide a declaration from the silicone supplier that requirement (ii) has been fulfilled

The above evidence may also be provided directly to competent bodies by any supplier in the applicant's product supply chain.

Rationale of the proposed criterion text

Criterion 6.3 is proposed to be newly added to the revised criteria for Absorbent Hygiene Products.

This criterion aims at simplifying the structure of current criteria in force, gathering in it all requirements concerning chemical substances and compounds.

Criterion 6.3 is subdivided into eight sub-requirements:

- *6.3(a) Excluded substances*
- *6.3(b) Fragrances*
- *6.3(c) Lotions*
- *6.3(d) Ink and dyes*
- *6.3(e) Further restrictions applying to plastic materials*
- *6.3(f) Further restrictions applying to adhesives*
- *6.3(g) Super absorbent polymers*
- *6.3(h) Silicone*

5.7.3.1 Sub-criterion 6.3(a) Excluded substances

This criterion lists the substances and compounds that shall not be present in the product, regardless of the concentration, in any form, not even as impurities (which are defined according to what stated in Section 3).

Some of the substances listed under 7.3(a) are already excluded in current criteria in force, although in a different criterion. They were gathered here to improve the readability and the clarity of the criteria.

Some other substances are here newly proposed to be banned in the revised criteria set. Further details on the substances and their rationale are given below.

Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives

APEOs and its derivatives are a large group of different substances commonly used in products containing polymers, e.g. adhesives, but also in: binders, dispersants, thickeners, siccatives, anti-foaming agents, pigments, waxes, etc.

APEOs have a number of problematic environmental and health properties (Environmental Agency, 2002). They are not readily degradable according to standardised tests for ready degradability, they tend to bioaccumulate, they have been found in high concentrations in waste sludge. Degradation products of APEO, alkylphenols and APEO with one or two ethoxy groups are very toxic to aquatic organisms and certain alkylphenols are suspected of being endocrine disruptors (Ye et al., 2014; Toor and Sikka, 2017). Ultimately, the last products of biodegradation of APEOs are 4-nonylphenol (NP) and 4-tert-octylphenol (OP), which are identified as endocrine-disrupting compounds (Zhang et al., 2003; Brian et al., 2007).

As per Regulation (EC) No 552/2009, the use of Nonylphenol and Nonylphenol Ethoxylate in concentrations higher than 0.1% has been restricted as per entry 46 of Annex XVII to the REACH Regulation in cleaning products, the processing of textiles and leather and in a number of other specified uses. Both of these compounds have been added to the ECHA Authorisation List (Annex XIV to REACH) as per Regulation (EU) 2017/999, which means that they cannot be used unless they are specifically authorised.

Although NPE and OPE do not possess any of the hazards that would qualify them to be listed as Substances of Very High Concern (SVHCs), which is a normal prerequisite before being placed on the Authorisation List, there are concerns that their degradation products (including NP and OP) are toxic to fish and aquatic species and their use can also result in degradation products with estrogenic activity being released to the aquatic environment. The criteria for EU Ecolabel printed paper, stationery paper and paper carrier bag products are very much in line with the general idea of moving away from the use of APEOs altogether. The EU Ecolabel criteria for cosmetic products and animal care products (Faraca et al., 2021) also set a ban on APEOs and other alkyl phenol derivatives.

The Nordic Swan bans the use of APEOs and substances that release alkylphenols on degradation, however allowing the use of sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole. These are antioxidants that can be defined as APEOs and alkylphenol derivatives that can be contained in some adhesives on the market. Antioxidants are essential for the quality of the glue. It has also been found that less PAH is formed in this adhesive compared to corresponding adhesives. The exception is however limited to antioxidants which are used in small amounts. The exception does not allow the use of substances known to be harmful for health and environment such as nonylphenol ethoxylates.

In this first proposal **it is proposed to include a ban on APEOs and other alkyl phenol derivatives**, with the exception of sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole.

Nitromusks and Polycyclic musks

Nitromusks and polycyclic musks are already banned by current criteria in force, specifically in criterion 6.3 (d) on fragrances. The requirement is proposed to be moved to the revised criterion 7.3 (a) to improve the clarity of the criteria set.

Formaldehyde and formaldehyde releasers

Formaldehyde and formaldehyde releasers are already banned by current criteria in force, specifically in criterion 6.4 (c) on lotions. The requirement is proposed to be moved to the revised criterion 7.3 (a) to improve the clarity of the criteria set.

Parabens

Parabens are already banned by current criteria in force, specifically in criterion 6.4 (c) on lotions. The requirement is proposed to be moved to the revised criterion 6.3 (a) to improve the clarity of the criteria set.

Triclosan

Triclosan is already banned by current criteria in force, specifically in criterion 6.4 (c) on lotions. The requirement is proposed to be moved to the revised criterion 6.3 (a) to improve the clarity of the criteria set.

Acrylamide

Acrylamide is already banned by current criteria in force, specifically in criterion 5.3 (a) on superabsorbent polymers. The requirement is proposed to be moved to the revised criterion 6.3 (a) to improve the clarity of the criteria set.

Phthalates

Phthalates are a large group of chemicals used as plasticisers, in adhesive formation, or to help dissolve other materials/substances. Some phthalates are inscribed on the EU's priority list of substances that should be investigated more closely for endocrine disruption (EC, 2021) and some have already been identified as endocrine disruptors.

Some phtalate compounds are also listed on the List of substances included in Annex XIV of REACH ("Authorisation List") due to their classification as a toxic for reproduction (Article 57c). These are: DEHP (bis-(2-ethylhexyl)phtalate), DBP (dibutylphtalate), BBP (benzylbutylphtalate), DIBP (diisobutylphtalate), DPP (dipentylphtalate), , DiPP(diisopentylphtalate), N-pentyl-isopentylphatlate, bis(2-methoxyethyl) phthalate and 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP). The limitation of the use of DEHP, DBP, BBP, DINP (diisononylphthalate), DIDP (diisodecylphthalate) and DNOP (di-n-octylphthalate) are also regulated by REACH Appendix XVII. Phthalates are also included in the "Substitute It Now!" List (Chem Sec, 2021).

Since phthalates are a large group of chemicals, with many substances with proven properties of concern, and since they are banned (as a group) in Nordic Swan ecolabel, **it is proposed to include a ban on all phthalates**. This is also in line with the recommendation of the EU Chemicals Strategy, which suggests to address chemicals by family or groups.

Organotin compounds

Organotin compounds are regulated under Annex XVII, point 20 of REACH. Subsection 6a states that dioctyltin (DOT) must not appear at more than 0.1% weight by weight of tin in feminine hygiene products, for example. A report from 2005 written by Risk & Policy Analysts Limited (RPA), on behalf of the European Commission (EC, 2005), states that organotin compounds have been reported in products that include diapers and feminine hygiene products. According to the report, organotin has historically been used as a catalyst in polymer production, as a stabiliser in polymers and as a biocide in various products.

Both Nordic Swan and Blue Angel ecolabels have a restriction on organotin compounds used as catalysts in the production of silicone polymers. **It is therefore proposed to add the same exclusion** as a requirement of sub-criterion 6.3 (a) also in the EU Ecolabel.

Isothiazolinones

Isothiazolinonesare strong sensitizers, producing skin irritations and allergies and may pose ecotoxicological hazards. Therefore, their use is restricted by EU legislation (BPR, Regulation (EU) 528/2012) (Silva et al., 2020)

Isothiazolinone derivatives are widely used as preservatives or biocides in household and industrial products, with several of them contained in cosmetic products. Using MI (CAS no.: 2682-20-4) as a stand-alone preservative at increased concentrations (up to 100 ppm) in cosmetics has resulted in dramatic sensitization rates in Europe and beyond. In fact, the Committee for Risk Assessment concluded in 2016 that MI should be recognized as a skin sensitizer in the 1A, H317 Category ('may cause an allergic skin reaction') with a specific concentration limit of 0.0015% (15 ppm). Other isothiazolinones, including benzisothiazolinone (BIT; CAS 2634-33-5; 1,2-benzisothiazolin-3-one) and octylisothiazolinone (OIT; CAS 26530-20-1; 2- octyl-1,2 thiazol-3-one), may also provoke allergic skin reactions in humans (Herman et al., 2018).

In the previous criteria development, a preliminary screening of chemicals found nanosilver as the only biocide used in AHPs. However, the Belgium Federal Public Service Health, Food Chain Safety and Environment (VITO) has detected compounds of MIT (CAS 2682-20-4; 2-Methyl-4-isothiazolin-3-one) and CMIT (CAS 26172-55-4; 5-chloro-2-methyl-4-isothiazolin-3-one) in samples of a tampon and a sanitary pad, respectively.

In general, isothiazolinone biocides present high volatility and are sensitive to thermal and pH conditions. Benzisothiazolinone (BIT) has been described as being hydrolytically stable, presenting a half-life of more than 30 days in the environment. BIT may be transported through soil and reach surface water, and it can still retain its biocidal qualities for 3 months when exposed to sunlight (Silva et al., 2020).

The preservative CMIT is banned in the Blue Angel criteria for absorbent hygiene products. This fact shows that it is possible to manufacture absorbent hygiene products without its use. Also, MIT is banned in the EU Ecolabel criteria for Tissue Paper and Tissue Products. Finally, the recently released EU Ecolabel criteria for cosmetic products and animal care products ban all isothiazolinones.

In this first technical report **it is proposed**, as a first step, **to introduce a ban on the preservatives MIT and CMIT**.

Substances identified to have endocrine disrupting properties

Endocrine disruptors (EDs) are defined as 'an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations'[41] Close to 800 chemicals are known or suspected to be capable of interfering with hormone receptors, hormone synthesis or hormone conversion. However, only a small fraction of these chemicals has been investigated in tests capable of identifying over endocrine effects in intact organisms.

Substances can be identified to have endocrine disrupting properties after a full evaluation process for endocrine disruption as regulated in three different EU legislations: the Plant Protection Products Regulation (PPPR), the Biocidal Products Regulation (BPR) or REACH (the Candidate- and Authorization Lists). In REACH, substances with identified endocrine disrupting effects are considered under Article 57, as substances which should be included in Annex XIV (i.e. List of substances subject to authorisation). Article 57 states the following: "substances — such as those having endocrine disrupting properties (...) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) [of the article 57 of REACH] and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59". Identified endocrine disruptors include some 20 compounds, including 12 phenols, five phthalates and one paraben.

One single list with legal validity compiling all identified EDs does not exist in the EU. Six EU Member States (Belgium, Denmark, France, Netherlands, Spain and Sweden) have joined efforts with the aim to compile all information about regulated EDs in EU in order to improve knowledge about EDs, increase transparency, coherence and consistency, as well as coordination across different legislative areas. They created a single repository for identified as well as suspected EDs[42]. List I of this repository gathers together all identified EDs

[41] Definition provided in 2002 by the International Programme on Chemical Safety, a joint programme of various United Nations Agencies, including the World Health Organisation.

[42] Endocrine Disruptors (EDs) Lists. Available at: https://edlists.org/ (accessed 10/09/2021).

in EU, whether evaluated via PPPR, BPR or REACH. While this list can be useful as a reference, it cannot be referred to by EU Ecolabel criteria.

Therefore, it is proposed to include a ban of identified EDs without referring to this list, but rather referring to the individual evaluation processes that are in place under PPPR, BPR and REACH.

Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects

Next to compounds with identified disrupting properties, there are compounds which are suspected to have endocrine disrupting properties, but for which a full evaluation process has not been carried out yet.

Over the years, many organisations have published lists of 'suspected EDs'. To make clarity, DG Environment commissioned a series of studies in order to develop a coherent approach to establish a list of priority substances for further evaluation of their role in endocrine disruption. From a total of 564 chemicals that had been suggested by various organisations or in published papers or reports as being suspected EDs, 146 were considered likely to be either persistent in the environment or produced at high volumes. Of these, however, in a first assessment clear evidence of endocrine disrupting activity was noted for only 66 (assigned Category 1 using the criteria adopted in the study). A further 52 chemicals showed some evidence suggesting potential activity (Category 2). In total 118 substances were categorised in the first exercise of priority setting[43]. Of the 66 chemicals in Category 1, humans were considered likely to be exposed to 60. More info on the work on the priority list can be found on the dedicated website[44].

Given all the above, **it is proposed to add a ban on the substances identified as Category 1 or 2** on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects. This is also in line with the criteria in Nordic Swan ecolabelling.

Points for discussion
• Are absorbant hygiene products ever treated with biocidal active substances for a certain product functionality? • Are absorbant hygiene products every treated with substances that themselves contain biocidal active substances for other purposes (e.g. as in-can preservatives) which could lead to them being present as residuals in the final product?

5.7.3.2 Sub-criterion 6.3(b): Fragrances

Rationale of the proposed criterion text

Only minor wording changes are proposed at this stage of the revision process.

Points for discussion
• Should a tighter threshold limit be set for individual hazardous substances present in fragrances applied in feminine pads and panty-liners? • Should the use of fragrances not be permitted in the EU Ecolabel AHP product?

[43] Annex 13: Towards the establishment of a priority list of substances related to endocrine disruption. Available at: https://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_13.pdf (accessed 10/09/2021).

[44] Substances are of concern. Available at: https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm (accessed 10/09/2021).

5.7.3.3 Sub-criterion 6.3(c): Lotions

Rationale for the proposed criterion text

According to the preliminary stakeholder questionnaire (December, 2020) the vast majority of stakeholders supported the exclusion of lotions from the presence in EU Ecolabel AHP product.

No changes are proposed at this stage of the revision process.

5.7.3.4 Sub-criterion 6.3(d): Inks and dyes

Rationale for the proposed criterion text

No major changes have been included in the new criterion text.

The phrase 'the product and any homogeneous part of it' has been substituted by 'any part thereof' in line with the most recently voted article: Hard Coverings (EC 2021/476).

It is important to note that titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm is now classified as Cat 2 carcinogenic[45]. Titanium dioxide is widely used as a white pigment in many products. At this stage of the revision process, it is important to gather data from stakeholders on how titanium dioxide is used and in what concentration, in order to know if a derogation would be needed to be considered. Moreover, data on alternative pigments that can be used to give a white colour are welcome.

Points for discussion
• In what concentration is TiO2 used? Are there alternatives used for TiO2 used as a pigment?

5.7.3.5 Sub-criterion 6.3(e): Further restrictions applying to plastic materials

Rationale for the proposed criterion text

In this first Technical Report **it is proposed to remove the exception granted on additives** used in plastics in concentration above 0,10 % (previous criterion 5.2 clause b), as the rationale behind is not clear.

Apart from this, **no other content-wise changes are proposed** to this sub-criterion at this stage of the revision process.

5.7.3.6 Sub-criterion 6.3(f) Further restrictions applying to adhesives

Rationale for the proposed criterion text

This sub-criterion presents specific requirements for substances that are used in the production of adhesives in AHP. This sub-criterion was previously criterion 6.1 in current criteria in force.

Colophony or rosin

Colophony or rosin is a substance obtained from trees and is used in a wide variety of applications including (food contact) packaging, tape, labels, etc. It is formed by reacting Rosin, which is an acid, with polyfunctional alcohols like glycerol and pentaerythritol. These reaction products are substances in their own right, with their own chemical names and CAS numers, including:

[45] https://echa.europa.eu/it/brief-profile/-/briefprofile/100.033.327

- Resin acids and Rosin acids, esters with pentaerythritol, CAS 8050-26-8

- Resin acids and Rosin acids, esters with glycerol, CAS 8050-31-5

The use of the term 'colophony resins' seem to create confusion. By using the word "resins" applicants may interpret that any derivative of rosin must not be used. However, the intention of this criterion is not to allow the use of rosin and those rosin reaction products that are classified as skin sensitizers, which are the so-called *adducted rosin esters*.

The Nordic Ecolabelling for Sanitary Products Version 6.7 states in section 7: "Adhesives/binders must not contain phthalates or colophony rosin. Modified colophony derivatives that are not classified as sensitizing are allowed."

As a result, in line with the Nordic Ecolabel for Sanitary Products, it is proposed to include in this criterion that a maximum concentration of 0.1% shall be applied for colophony. Modified colophony derivatives that are not classified as sensitizers, e.g. rosin esters, are allowed.

Formaldehyde

Formaldehyde (CAS number 50-00-0) shall not be added to adhesives, used for the manufacturing of Absorbent Hygiene Products, however, the criterion 6.1 included a clause which indicated that *this requirement shall not apply if those substances are not intentionally added to the material or to the final product, and are present in the adhesive materials in concentrations below 100 ppm (0,010 % by weight).* We would like to request stakeholders to provide additional information on the need to have this exception, and how would be possible to carry out such verification.

According to the information contained in the User Manual for Absorbent Hygiene Products (EC, 2021): '*The content of formaldehyde in adhesives can be determined using derivatisation and analysis with GC-MSD (Gas chromatography-mass spectrometry) or HPLC (high performance liquid chromatography) with UV detection. A relevant standard method could be ISO EN 16000-3:2011 for formaldehyde, or CEN/TS 16516 which includes formaldehyde with the testing regime'.*

However, it is important to note that the measurement of formaldehyde is not an easy task and actual results can depend on how the test is performed. Some parameters are not standardised and differences in performing the tests may lead to different results. Since the publication of the last criteria set, CEN/TS 16516 has been formally published as an EN standard and is considered to provide a tighter definition of testing variables that can help with the aim of achieving more consistent results between different laboratories than with ISO 16000, even though both methods are very similar.

Points for discussion
• Are the formaldehyde test methods correct? If not, which ones are? • Is there any experience with testing of formaldehyde emissions during polymer dispersion? It may be possible that results are highly variable depending on sampling protocols and perhaps further guidance is needed for applicants.

5.7.3.7 6.3(g) – Superabsorbent polymers (SAPs)

Rationale of the criterion text

This criterion corresponds to current criterion 5.3 in the EU Ecolabel criteria in force.

No major changes are proposed at this stage of the revision process.

Points for discussion

- We request stakeholders to please provide data on which residual monomers are used in the production of SAPs, and at which concentration

5.7.3.8 6.3(h) – Silicone

Rationale of the criterion text

This criterion corresponds to current criterion 6.5 in the EU Ecolabel criteria in force.

This criterion was discussed at length with silicone suppliers and release liner manufacturers at the beginning of the revision process. A range of opinions were expressed both about the ambition level and the precise formulation of the text. Some important points to highlight are described below.

Silicones (or polysiloxanes) are used primarily to achieve a grease- or water-repellent effect as a coating on materials or as an additive in materials. When they are used to produce release liners, silicone coating adheres to the material to be treated in the form of a thin layer, especially to low-porosity and smooth paper substrates. There are release liners which use different types of substrates (papers, films, and combinations), many different types of silicone coatings, and at a wide range of weights/amounts.

From the chemical point of view, silicones refer to compounds of 'siloxanes' (Si-O-Si) which have reacted with methyl chloride (Müller Rochow synthesis)[46]. The typical structure of silicones or polydiorganosiloxanes consists of an 'inorganic' backbone built up of alternating silicon and oxygen atoms where the other two bonds of the silicon atoms are occupied with organic groups (preferably methyl groups). Their primary ingredient is silica or quartz sand.

The first part of the sub-criterion refers to the issues emerging from the use of solvent-based silicones.

During the preliminary questionnaire, one stakeholder expressed that solvent-based silicones shall not be used. In fact, both Nordic Swan and Blue Angel ecolabels set a requirement prohibiting their use.

Given that both ecolabelling schemes have licenses that can comply with such a requirements, **it is proposed to ban the use of solvent-based silicone coatings**.

The second part of this sub-criterion refers to the presence of the cyclosiloxanes D4 and D5 in the silicone treatment used to coat the release liner.

During the preliminary questionnaire, stakeholders clearly stated the confusion of the current criterion and the difficulty of interpret it right. The current requirement refers to presence of the cyclosiloxanes "in the chemical products used in the silicone treatment of components". Some stakeholders interpreted it as the presence of the cyclosiloxanes in the silicone mixture before curing, which leads to the current limit of 100ppm to be considered currently technically impossible. Other stakeholders interpreted the requirement as adding D4/D5 to the release liner (material or final product), which, according to the industry, does not happen. Finally, a third interpretation is that

Nordic Swan and Blue Angel also set a requirement on the cyclosiloxanes. The wording used by Blue Angel is as follows: "*The chemicals used in the silicone treatment must not contain either D4, D5 or D6. This requirement is considered to be fulfilled if D4, D5 and D6 are not intentionally added to the material or if the product and the concentrations found in the silicone are less than 800 ppm (proportion by mass) of the adhesive strip*". While Nordic Swan states the following: "*D4, D5 and D6 must not form part of the product. The requirement does not apply to D4, D5 and D6 contained as impurities*", which are defined as "*residual products from the raw material production in the silicone mixture (like the silicone emulsion's coating bath) or in the finished cured silicone in concentrations below 800 ppm (0.08% by weight, 800 mg/kg)*"

It is understood that it is the word silicone (in the current EU Ecolabel criteria) that creates confusion as it could refer to the silicone as supplied by a chemical supplier, or to the silicone mixture generated by the release liner manufacturer which includes cross linking agents or even the cured silicone onto the release liner. Thus, **it is proposed to add the reference to "silicone mixture"**. "Silicone mixture" is a liquid composition of two or more silicone raw materials, and may also contain other non-silicone crosslinking agents. The release liner manufacturers (customers of the chemical suppliers) usually buy different raw

[46] https://www.wacker.com/cms/en-us/products/product-groups/silicones/silicones.html

materials from the silicone supplier (silicone formulation) and mix them in-house, obtaining the so-called "silicone mixtures". It is also the release liner manufacturer the one responsible for the curing process of such mixture when applied on their article.

Another potential issue is that both silicone suppliers and release liner manufacturers confirmed that it is not common to measure the concentration of siloxanes on the release liner. Typically, the concentration of siloxanes in the release liner can be done through a calculation. Some manufacturers use approximately 0,5 g/m^2 to 1 g/m^2 silicone coating applied to papers of 30 g/m^2 to 50 g/m^2. Staying with dry weight and taking the worst case scenario (1 g/m^2 coating per 30 g/m^2 paper), 800 ppm in the coating would mean there are 26 ppm of siloxanes in the release liner.

It shall be noted that almost all cyclics are being removed in a final distillation step done by the silicone suppliers. As a matter of fact, a small content of residual cyclics remain in the silicone raw materials for technical/chemical reasons, which cannot be reduced further without disproportional technical effort. This means that having below 800 ppm of D4, D5 and D6 in the silicone mixture is not feasible nowadays for most part of the industry. The 800 ppm threshold applies to the sum of all three cyclics.

As also Blue Angel sets the same threshold, **it is proposed to increase the limit of the cyclosiloxanes D4 and D5 to 800 ppm.**

Finally, Dodecamethylcyclohexasiloxane **D6** (CAS 540-97-6) **is proposed to be added to the cyclics D4 and D5 that shall not be present in the silicone mixture in concentrations over 800 ppm**. This decision is in line with the Nordic Swan Ecolabel and the Blue Angel.

5.7.4 Assessment and verification

Rationale to the proposed criterion text

As sub-criterion 6.3 is proposed to be newly added to the revised criteria for AHP in order to gather together all requirements related to chemical substances, a new assessment and verification text is needed. Given the similarities of all the sub-requirements (6.3(a), 6.3(b), etc.) in terms of documentation to verify compliance, and with the aim of keeping the text clear and concise, it is proposed to have one single assessment and verification valid for all requirements under 6.3. This approach is also in line with the "chemicals criterion" of the most recently voted ecolabel product group (Cosmetic and Animal care products).

5.8 CRITERION 7: Material efficiency in the manufacturing

Existing criterion 8: Material efficiency in the manufacturing
The quantity of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed: — 10 % by weight of the end products for tampons, — 5 % by weight of the end products for all the other products. **Assessment and verification**: The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy. Calculations shall be shown in accordance with ISO 14025 and the applicant shall present all of the following parameters concerning: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of. The net waste shall be calculated as the difference between the amount of waste produced and the amount of waste recovered.
Proposed criterion 7: Material efficiency in the manufacturing
The quantity of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed: — 10 % by weight of the end products for tampons, — 5 % by weight of the end products for all the other products. **Assessment and verification**: The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy. Calculations shall be shown in accordance with ISO 14025 and the applicant shall present all of the following parameters concerning: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of. The net waste shall be calculated as the difference between the amount of waste produced and the amount of waste recovered.

Rationale for the proposed criterion text

In line with the Circular Economy Action Plan 2020, the design and production phases are among the key drivers to achieve circular economy objectives, and ensure that the resources used are kept within the EU economy for as long as possible (EC, 2020). Waste reduction, lower resource consumption and less

environmental impacts are general objectives of the Green Deal[47] in relation to sustainable product manufacture. To this end, the reduction of the thresholds of the quantity of waste generated during the manufacture and packaging of AHP is expected in order to meet policy requirements.

According to the questionnaire from December 2020, some stakeholders proposed to modify the thresholds to stricter values. In order to shed more light within this criterion, the Competent Bodies (CBs) were asked in July 2021 to clarify the percentage of total waste generated in the production of the final AHP and the main sources of waste generation at the manufacturing sites reported by licence holders. Only three responses were received, indicating a maximum of 5% by weight of the end products for baby diapers and 3.3% for feminine care pads were reported.

At this stage of the revision process, it is not possible to tighten the waste generation thresholds. Therefore, **no changes are proposed**. The feedback from stakeholders will be crucial to develop the proposal for the maximum acceptable quantity of waste generated during the manufacture and packaging of the products (% w/w).

Rationale behind the proposed 'assessment and verification'

The 'assessment and verification' means of criterion 8 are proposed to be maintained while changes to the thresholds of waste production (not reused within the manufacturing process or that is not converted into materials and/or energy) are expected.

Points for discussion
• What should be the threshold values for the quantity of waste generated during the end-product manufacture and packaging for each AHP? • Industry and CBs are strongly invited to submit relevant data in order to correctly shape this criterion. • Which are the main sources of waste generated during the product manufacturing stages?

[47] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS The European Green Deal COM/2019/640 final

5.9 CRITERION 8: Packaging - NEW

Proposed criterion 8: Packaging
The primary packaging must contain information on the packaging and product composition specifying the weight of the packaging and product and of each component as requested in criterion 1. The primary packaging of feminine care products such as sanitary towels or pads and tampons must comply with the marking requirements according to the Article 7 of Directive (EU) 2019/904 of the EU Parliament and the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment[48] whose harmonised marking specifications must follow the rules laid down by Annex I of the Commission Implementing Regulation, of 17 December 2020 (Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment)[49]. The additional packaging must include the marking specifications also in the case of sanitary towels or pads. Primary packaging, secondary, and additional packaging shall include x % of recycled content in their composition, and it must be recyclable. **Assessment and verification**: The applicant shall submit a signed declaration of compliance specifying the product composition, supported by manufacturer documentation, including the composition of the packaging (primary, secondary and additional). The applicant shall provide a sample of the primary packaging by submitting either a sample itself or a primary packaging photo (where information requested appears clearly). The applicant shall submit a signed declaration of compliance specifying the percentages of recycled content and recyclability capacity in the packaging where the test methods used must be notified. Invoices demonstrating the purchase of the recycled material must be provided.

Rationale for the proposed criterion text

This criterion aims at the introduction of certain percentages of recycled content and recyclable components in the packaging of AHPs (primary, secondary and additional packaging), in order to support the EU's goal of a circular economy.

Usually the packaging of AHPs can be primary (sales packaging) and secondary packaging as defined in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste[50]. An additional packing where the product is individually wrapped is considered sometimes such as in the case of feminine care pads or tampons. The additional packaging is also the release liner or paper (in baby diapers and sanitary pads) or the applicator for tampons. The additional packaging can also be the cloth bag were menstrual cups are usually sold with.

[48] Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019L0904&qid=1627652000930 (accessed 10/09/2021).

[49] Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R2151 (accessed 10/09/2021).

[50] Directive 94/62/EC European Parliament and of the Council of 20 December 1994 on packaging and packaging waste. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20180704&from=EN (accessed 10/09/2021)

Packaging makes an important contribution to the overall life cycle impact of a product. Impacts from packaging come mainly from the material used (derived from resources and energy used for producing packaging materials) (see Section 4.3 of the Preliminary Report).As mentioned in Section 3, definitions for primary, secondary and transport packaging are defined in the Article 3 of the consolidated version of the Directive 94/62/EC on packaging and packaging waste (European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste). Additional packaging, recycled content and recyclability capacity have also been included in the definitions in Section 3.

As a matter of comparison with other Ecolabels in the market, the Nordic Swan and the Blue Angel both consider the primary or sales packaging. However, secondary packaging is not mentioned in the Nordic Swan while the Blue Angel called it repackaging. Transport packaging is mentioned in both the Nordic Swan and the Blue Angel whereas additional packaging is only addressed in the Nordic Swan where it is called additional component. The Blue Angel touched upon the additional packaging as an individual package item part of the whole packaging criterion which would be revised in the future update of the ecolabel.

The packaging criterion shall address three main items: (1) incorporation of product and packaging composition; (2) incorporation of new marking requirements; and (3) recycled content and recyclability capacity in the composition of primary, secondary, and additional packaging.

(1) Incorporation of product composition:

As regards as the inclusion of the full product composition in the primary packaging, this modification was proposed by stakeholders in the questionnaire from December 2020.

(2) Incorporation new marking requirements:

From 3 July 2021, according to Directive (EU) 2019/904, EU Member States shall, through their national legislation, ensure that certain single-use products containing plastic bear a marking on the packaging or product itself, with a view to reducing the impact of these products on the environment. In the case of AHP, sanitary towels (pads), tampons and tampon applicators are among the products whose marking will have to follow rules laid down by the Commission Implementing Regulation, of 17 December 2020, on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 (Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment).

The Directive (EU) 2019/904 tackled the top ten SUP (single used products) items most commonly found in marine litter of which baby diapers are outside the list. Sanitary towels (pads), tampons and tampon applicators are included in such list.

(3) Recycled content in the composition of primary, secondary, and additional packaging.

The vast majority of sanitary products are individually packaged (additional packaging) before being contained in a single pack (primary packaging) usually made of paperboard/cardboard.

In the case of AHPs, the packaging phase has not been highlighted as a key environmental hotspot through the LCA literature review, however the specific LCA screening analysis reported the relevancy of LDPE granulates used for packaging. As there is a clear aim to the alignment with other Ecolabels of reference, it seems appropriate to address product packaging. For instance, the Nordic Swan requirements are stimulating the use of recycled materials in the product packaging.

Since sanitary products come into close contact with the body and many of the products are intended for young children, the use of recycled materials is prohibited (Nordic Swan Background document version 6.8, 2021). However, the EU Ecolabel aims to promote the use of recycled materials in the packaging (primary, secondary and additional) which are all removed from the products before use, and thus does not come into contact with the user. In fact, using recycled paperboard, cardboard or plastic in the packaging of AHPs allows for extracting value from waste and avoids a significant amount of raw materials and energy use that would otherwise be used in the production of virgin fossil fuel based raw material.

Considerations regarding recycled content and recyclability of the packaging are specified in other ecolabels such as the Nordic Swan and the Blue Angel.

The Blue Angel considers recyclability aspects in the primary or sales packaging and in the repackaging (or secondary packaging) while only allows recycled content in the repackaging.

The Nordic Swan does not allow recycled material in the sanitary product (e.g. in cotton, paper and fluff) with the exception of recycled plastic. However recycled material is allowed in additional components (or additional packaging), e.g. in tape or release paper that shall be removed before use and in primary packaging. Recyclability percentages are not mentioned.

Table 4 to **Table 7** summarise the aspects on recycled content and recyclability for the final product and the different types of packaging considered in the Blue Angel and the Nordic Swan ecolabels. The third column of each table provides potential information to be added to this criterion for the EU Ecolabel:

It is proposed that the **final product will not have any content of recycled materials** either be recyclable.

Table 4. Sanitary product and recycled content/recyclability comparison in Ecolabels.

Item	Blue Angel[51]	Nordic Swan[52]	Proposed for EU Ecolabel
Sanitary product (final product)	There is no mention to recycled content either recyclability percentages. Other materials: any bio-based plastics present in the product must be sourced from sustainable cultivation. Certification systems.	Recycled material is not allowed in the sanitary product (e.g. in cotton, paper and fluff) with the exception of recycled plastic. Different requirements depending if recycled plastic constitutes ≥1.0 weight-%, or ≥20.0 weight-%. Other materials: one of three requirements (a, b or c) must be fulfilled in relation to renewable material or recycled material	Non recycled content is allowed in the final product. No recyclability capacity assessed in the final product.

[51] Blue Angel. The German Ecolabel. Nappies, feminine hygiene and incontinence products (absorbent hygiene products, AHP) DE-UZ 208 Version 3 (06/2021): Additions to 3.6.2 and 3.13. Available at: https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20208-202101-en%20Criteria-V3.pdf (accessed 27/08/2021).

[52] Nordic Swan. Nordic Ecolabelling for Sanitary Products. Version 6.8 • 14 June 2016 - 30 June 2024. Available at: https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=023 (accessed 27/08/2021).

Table 5. Primary packaging comparison in Ecolabels.

Item	Blue Angel	Nordic Swan	Proposed for EU Ecolabel
Primary packaging	Primary or sales packaging: packaging that is typically offered to the end consumer with the goods as a sales unit.	Primary packaging: it means the packaging around the sanitary products and additional components as sold in retail outlets or directly to the customer. Primary packaging does not include transport packaging, information sheet and additional components.	Primary packaging as in Directive 94/62/EC on packaging and packaging waste
	No recycled material. Recyclability of the packaging must be ≥95%. Other materials: any bio-based plastics present in the packaging must be sourced from sustainable cultivation. Certification systems. Composite packaging or coating of the paper/cardboard with plastics or metals are not permitted. It is only permitted to use unmixed plastic without any coating.	Recycled material is allowed. Different requirements depending if recycled plastic constitutes ≥1.0 weight-%, or ≥20.0 weight-%. If the primary packaging makes up more than 1.0% of the weight: different requirements if packaging is made of cardboard/carton or plastic. For recycled plastic, there is a requirement on recycled plastic. Other materials: one of three requirements (a, b or c) must be fulfilled in relation to renewable material or recycled material	Issues to discuss with stakeholders: - % of recycled materials? - % of recyclability? - % other materials? E. g. Primary packaging should be 100% recyclable and sourced from recycled cardboard or plastics.

Table 6. Secondary packaging comparison in Ecolabels.

Item	Blue Angel	Nordic Swan	Proposed for EU Ecolabel
Secondary packaging	Repackaging or secondary packaging Packaging that contains a certain number of sales units (consisting of the goods and their sales packaging) and which is typically offered to the end consumer as a "bulk pack".	No repackaging mentioned.	Secondary packaging as in Directive 94/62/EC on packaging and packaging waste.
	Any bio-based plastics present in the packaging must be sourced from sustainable cultivation. Certification systems. Recyclability of the packaging: 95%. Composite packaging or coating of the paper/cardboard with plastics or metals are not permitted. It is only permitted to use unmixed plastic without any coating. Repackaging should be avoided or preferably consist of paper and cardboard and have several requirements on recycled fibres, virgin fibres and recycled plastic.	N/A	Items to discuss with stakeholders: - % of recycled materials? - % of recyclability? - % other materials? E. g. Secondary packaging should be 100% recyclable and sourced from recycled cardboard or plastics.

Table 7. Transport packaging comparison in Ecolabels.

Item	Blue Angel	Nordic Swan	Proposed for EU Ecolabel
Transport packaging	Transport packaging Packaging that facilitates the handling and transport of goods to avoid direct contact with the goods and any transport damage. This packaging is typically not passed on to the end consumer.	Transport packaging contains and protects the packs of sanitary products during transport to stores and consumers.	Transport packaging as in Directive 94/62/EC on packaging and packaging waste.
	Applicant to provide information on the design of the business-to-business transport packaging	No information requested.	Items to discuss with stakeholders: - % of recycled materials? - % of recyclability? - % other materials? Example: when possible transport packaging should be 100% recyclable and sourced from recycled cardboard or plastics.

Table 8. Additional packaging comparison in Ecolabels.

Item	Blue Angel	Nordic Swan	Proposed for EU Ecolabel
Additional packaging	Named as additional component. No definition.	Additional component: components belonging to the hygiene product that are removed before use of the product. Examples include release paper, a plastic film around a tampon or a sanitary towel or an applicator for tampons.	Additional packaging (such as the individual wrap or film where tampons or pads are contained within the primary packaging)
	It appears on future aspects to revise.	Recycled plastic is allowed. Chemicals to avoid if recycled plastic constitutes ≥1.0% in weight. If the additional component makes up more than 1.0% of the weight: different requirements if packaging is made of cardboard/carton or plastic. Other materials: one of three requirements (a, b or c) must be fulfilled in relation to renewable material or recycled material.	Items to discuss with stakeholders: - % of recycled materials? - % of recyclability? - % other materials?

<u>Rationale behind the proposed 'assessment and verification'</u>

As per the questionnaires sent to stakeholders in December 2020, many comments expressed that a sample of packaging would not be needed as far as a clear photograph is provided.

Information on full composition must be provided as it was also highlighted by stakeholders in the December 2020 questionnaire.

Recyclability and recycled content of packaging are to be discussed.

The Nordic Swan and the Blue Angel requests the explanation of the description of the procedure for determining the recycled material content but do not specify the test methods.

The Blue Angel specifies that the recyclability of the packaging '*must be determined in accordance with the currently valid version of the 'Minimum standard for determining the recyclability of packaging subject to system participation" from the Zentrale Stelle Verpackungsregister (*Central Agency Packaging Register from Germany – ZSVR*); the recyclability should be expressed in percent. It can also be determined based on a method that complies with the minimum criteria in the minimum standard from the ZSVR and also verifies this compliance'* (Blue Angel, 2021).

It is worth noting that regarding the verification of recycled content in packaging, there are guidelines such as the standard EN 15343 for Plastics recycling traceability and assessment of conformity and recycled content and the ASTM D5663 - 97 for Validating Recycled Content in Packaging Paper and Paperboard (ASTM, 1997).

Regarding test methods on recyclability, Cepi provides a test method to assess the recyclability of paper and board products in their so called document 'Harmonised European laboratory test method to produce parameters enabling the assessment of the recyclability of paper and board products in standard paper and board recycling mills (Cepi recyclability laboratory test method)' Version 1, December 2020 (CEPI, 2020). According to the EN13430, verifying a product recyclability as defined in such standard involves validating the mass composition of the product and the suitability for recycling (CTP, 2021).

As set in the Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste: *'Bio-based recyclable packaging and compostable biodegradable packaging could represent an opportunity to promote renewable sources for the production of packaging, where shown to be beneficial from a life-cycle perspective'*[53].

There are companies that verify the recyclability and also examples of recyclability certificate as voluntary schemes as for instance 'Recyclable Certificate' (Sello Reciclabilidad, 2021). Also there are certification schemes on recycled content such as the Global Recycled Standard (GRS) that sets requirements for third-party certification of recycled content (GRS, 2020).

The recyclability capacity can be of use for cardboard and paper packaging used for primary and secondary packaging in AHP, however it is a matter to be discussed with stakeholders.

Points for discussion
• Should product and packaging composition be shown on the primary packaging? • Which % of recycled plastic/cardboard should be set in the primary/secondary/additional packaging? • Should there be a requirement on recyclability of plastic/cardboard in the primary/secondary/additional packaging? How to demonstrate it? • Should there be a requirement on content of bio-material in the primary/secondary/additional packaging, similar to Nordic Swan and Blue Angel? • Should there be any banned substances in primary/secondary/additional packaging?

[53] Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018L0852&from=EN (accessed 10/09/2021).

5.10 CRITERION 9: Guidance on the product disposal

Existing criterion 9: Guidance on the product disposal
The producers shall write or indicate through visual symbols on the packaging: — that the product must not be flushed into toilets, — how to dispose the product correctly. **Assessment and verification**: The applicant shall provide a sample of the packaging.
Proposed criterion 9: Guidance on the packaging and product disposal
~~The producers shall write or indicate through visual symbols on the packaging.~~ The primary packaging must contain information on the guidance of the primary packaging, the additional packaging and the product disposal. The following information shall be written or indicated through visual symbols on the primary packaging: — that the primary packaging, the additional packaging and the hygiene used product must not be flushed into toilets, and — ~~how to dispose the product correctly.~~ that the hygiene used products should be disposed of within the household waste. — that the primary packaging and additional packaging should be disposed of within the recyclable waste. **Assessment and verification**: The applicant shall provide a high resolution image of the primary packaging (where information regarding disposal appear clearly).

Rationale for the proposed criterion text

This criterion aims at providing the user with the correct information in order to dispose of the waste product and packaging in the most appropriate way.

At the preliminary questionnaire (December 2020), only 14% of the respondents indicated the need of revising this criterion. Therefore, the changes proposed mainly focus on improving the clarity of the criterion.

The vast majority of sanitary products are individually packaged (additional packaging) before being contained in a single pack (primary packaging). Therefore, it is proposed that the indication of not flushing into the toilet does not only refer to the product, but to the packaging as well.

As current waste management systems in Member State do not consider the recycling or any other type of valorisation of used absorbent hygiene products, it is proposed to include the indication that these products should be disposed of within the household waste.

Finally, a third sentence is proposed to indicate that the primary packaging (which is normally made out of cardboard or plastic) should be disposed of within the recyclable waste. More precise indications are not possible at this stage given the variation in product used as well as in waste management systems across MSs.

Rationale behind the proposed 'assessment and verification'

The current assessment and verification requires the applicant to provide a sample of the packaging.

As a result of the preliminary questionnaire sent to stakeholders in December 2020, some stakeholders expressed that a sample of packaging would not be needed as far as a clear photograph is provided.

Therefore, **it is proposed to require a photograph of the primary packaging** as a proof of compliance. The photo should clearly show the indications displayed on the primary packaging.

Points for discussion
• Should the requested disposal information appear in primary packaging?

5.11 CRITERION 10: Fitness for use and quality of the product

Existing criterion 10: Fitness for use and quality of the product

The efficiency/quality of the product shall be satisfactory and at the least equivalent of products already on the market. Fitness-for-use shall be tested with respect to the characteristics and parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Table 5

Characteristics and parameters describing the fitness for use of the product to be tested

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (*)	Consumer panel test (Leakage occurs in less than 5 % of the product uses)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1. Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	No method recommended
	T2. Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	No method recommended

(*) Panty liners without a core intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

Assessment and verification:

A test report shall be provided for in-use and technical tests describing test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems, no matter if internal or external.

Tests shall be conducted for the specific type and size of products applying for the EU Ecolabel. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design. Special care shall be taken regarding sampling, transport and storage of the products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or

packaging.

Information on testing shall be made available to Competent Bodies under the respect of confidentiality issues. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the products tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. Clear guidelines on the use of test results shall be provided.

Additional guidelines for user tests.

— Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).

— Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.

— The recommended number of testers shall be at least 30. All the individuals participating to the survey shall be current users of the specific type/size of product tested.

— When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1.

— A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age, countries and genders shall be clearly stated.

— Sick individuals and those with a chronic skin condition should not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.

— For skin dryness, fit and comfort and overall performance, 80 % of the consumers testing the product shall rate the performance as satisfactory, which could for instance mean that a rate above 60 is assigned by the consumer (on a quantitative scale from 1 to 100) or that the product has been assessed as good or very good (among five qualitative options: very poor, poor, average, good, very good). For absorption and leakage protection, leakage shall occur in less than 5 % of the products tested.

— The results shall be statistically evaluated after the user trial has been completed.

— External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

Additional requirements for technical tests.

— Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.

— A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation.

Weight, dimensions and design features of the product shall be described and provided in accordance with criterion 1.

Proposed criterion 10: Fitness for use and quality of the product

The efficiency/quality of the product shall be satisfactory and at the least equivalent of products already on the market. Fitness-for-use shall be tested with respect to the characteristics and parameters reported in Table 5. Performance thresh- olds shall be matched, where these have been identified.

Table 5

Characteristics and parameters describing the fitness for use of the product to be tested

	Testing practice required (performance threshold)

Characteristic		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (*)	Consumer panel test ~~(Leakage occurs in less than 5 % of the product uses)~~ (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers and feminine care pads
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1. Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	~~No method recommended~~ As for baby diapers and feminine care pads
	T2. Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	~~No method recommended~~ As for baby diapers and feminine care pads

(*) Panty liners ~~without a core~~ intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

Assessment and verification:

A test report shall be provided for in-use and technical tests describing test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems, no matter if internal or external.

Tests shall be conducted for the specific type and size of products applying for the EU Ecolabel. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design. Special care shall be taken regarding sampling, transport and storage of the products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

Information on testing shall be made available to Competent Bodies under the respect of confidentiality issues. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the products tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. Clear

guidelines on the use of test results shall be provided.

Additional guidelines for user tests.

— Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).

— Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.

— The recommended number of testers shall be at least ~~30~~ 100 (for products that are not specifically designed for one gender). When products are specifically designed for one gender at least 30 test subjects should be included. All the individuals participating to the survey shall be current users of the specific type/size of product tested.

— When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1.

— A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age, countries and genders shall be clearly stated.

— Sick individuals and those with a chronic skin condition should not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.

— For all in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, which could for instance mean that a rate above 60 is assigned by the consumer (on a quantitative scale from 1 to 100) or that the product has been assessed as good or very good (among five qualitative options: very poor, poor, average, good, very good). ~~For absorption and leakage protection, leakage shall occur in less than 5 % of the products tested.~~

— The results shall be statistically evaluated after the user trial has been completed.

— External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

Additional requirements for technical tests.

— Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.

— A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation.

— Technical tests recommended for nursing pads are the same as for baby diapers and for feminine care pads.

Weight, dimensions and design features of the product shall be described and provided in accordance with criterion 1.

Rationale for the proposed criterion text

The quality of products awarded with the EU Ecolabel is an important aspect of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendlier but poor in performance/inefficient. For that reason performance tests should address all important characteristics and functions of the product.

At the preliminary questionnaire (December 2020), 25% of the respondents indicated the need for revision.

The following changes are proposed at this stage:

- Panty liners derogation from requirement U1

Each panty liner has a core or insert with varying levels of absorbency. Industry recommends to derogate all panty liners for daily usage from the in-use test, U1- absorption and leakage protection, without specifying

the construction as a precise definition of the core is missing. **This derogation is proposed to be included in the revised criterion.**

- Threshold for in-use test, U1-absorption and leakage protection

Regarding the in-use test, U1-absorption and leakage protection for all products (baby diapers, feminine care pads, tampons and nursing pads), industry recommendations specify that when performing these tests a percentage rating is recommended as well, e.g. a > 80% satisfaction criterion which usually covers the so-called 'Top 2 Boxes' in a 5-box ranking that ranges from extremely dissatisfied to extremely satisfied. It is to be preferred over e.g. a general < 5% leakage rate. This is because the leakage rate and the consumer perception about leakage varies between the product categories. For all feminine hygiene products a 5% leakage rate is low. Tampons for example have to leak once their capacity is reached. Leakage is driven by product performance and consumer behaviour (wear time). Industry recommends strongly against prescribing a special protocol for panellists, especially regarding wear times / changing frequency etc. This is prone to drive failures and non-acceptance on a high level.

- For these reasons, it is proposed that the **performance threshold in the testing practice required for in-use tests type U1**- absorption and leakage protection, should be a **consumer panel test where 80 % of the consumers testing the product shall rate the performance as satisfactory** (instead of a leakage occurrence in less than 5 % of the product uses).Nursery pads technical tests, T1 and T2

The only reference available from the Kenya Bureau of Standards (KEBS, 2021) specified technical test methods for baby diapers and feminine care pads are also valid for nursery pads (Kenya Standard, 2017). Therefore, the technical tests recommended are the same for these three product categories.

It is proposed to apply the **same technical test methods** for baby diapers, feminine care pads, and nursery pads.

- Technical tests T1 on absorption and leakage protection

Industry commented that technical tests such as on absorbency, absorption rate and rewet can be applied to baby diapers and feminine hygiene products. Certified laboratories that perform such technical performance tests cannot refer to standardized test methods, with the exception of the syngina test for tampons. Laboratories use their own test procedures. However, some stakeholders provided a recommendation for a test method for in-use tests on absorption and leakage protection.

Besides, EDANA has developed guidelines for testing feminine hygiene products and baby diapers:

- Guidelines for testing baby diapers (EDANA, 2016)
- Guidelines for testing feminine hygiene products (EDANA, 2018)

Both guidelines also include examples of questions to be addressed for a standardized questionnaire.

Minimum performance requirements are very important as this is a major dimension assessed by consumer organisations. In order to achieve this, some stakeholders requested that for instance the tests that baby diapers shall undergo need to be very explicit because laboratories propose different methodologies. To cite an example, the use of prototypes for testing is expensive and that is maybe the reason why some laboratories propose other methods. However, other tests are not always accepted by those who test their own models using prototypes or the so-called dummies/mannequins.

In the EDANA Guidelines for the Testing of Baby Diapers (EDANA, 2016), there is no listed test methods for absorption and leakage protection. However, in the EDANA Guidelines for Testing Feminine Hygiene Products (EDANA, 2018), the test method for Absorption rate/time of penetration is listed as NWSP 070.7.R0 (15) Repeated Liquid Strike-Through Time (Simulated Urine) which last update seems to be NWSP 070.7.R2 (20) according to the last update on the EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021). There are not listed test methods for leakage protection.

In conclusion, it has been suggested by some stakeholders to define in detail the test method to apply for technical tests on absorption and leakage protection. To this end, **listing the technical test methods for absorption and leakage protection shall be further discussed with stakeholder during the AHWG Meeting**.

- Biocompatibility tests

In addition, biocompatibility tests (ISO 10993 family) could be performed for AHPs in order to understand the effects of these products on the human body. In relation to this matter, a section on tests for biocompatibility is assessed in the menstrual cups Section 4.2.4 in the Preliminary Report. According to information shown in the PR, the recommended biocompatibility tests for baby diapers, feminine care pads, tampons and nursery pads could be cytotoxicity (ISO 10993-5), sensitization and irritation (ISO 10993-23:2021) and intracutaneous reactivity (ISO 10993-10). While this needs to be discussed, at this stage of the revision process is not proposed to add them.

The addition of biocompatibility tests in the section of in-use tests should be further discussed in the First Ad-Hoc Working Group meeting.

- Specification on aerobic microorganism content in tampons

In the EDANA Guidelines for the Testing of Baby Diapers (EDANA, 2016) it is specified that '*due to the dry nature of the materials and considering their final use, baby diapers have very low numbers of microorganisms and do not support microbial growth. Therefore, there is no need to prescribe specific microbiological tests for these products*'. In the EDANA Guidelines for Testing Feminine Hygiene Products (EDANA, 2018), it is mentioned that '*some testing organisations have carried out tests on feminine hygiene for microbial contamination. [..] The low water activity value of these products and their raw materials will therefore mitigate the risk of microbial growth and survival. In addition, manufacturers' adherence to Good Manufacturing Practices (GMP), use of high quality materials and the highly-automated manufacturing process under which these products are produced minimise the possibility of microbial contamination during production. They also comply with any local regulatory requirements where relevant when evaluating the potential presence of any microbial growth in feminine care products and their raw materials*'. The EDANA Code of Practice for tampons placed on the European market does not provided information on this test either (EDANA, 2020). All in all, there is not a current specification on microbiological test for any AHP in these references.

However in the Nordic Swan Ecolabel, there is a requirement for tampons to contain as a maximum of 1,000 aerobic microorganisms per gram of product and the tampon producer to provide a description of the test for detection of aerobic microorganisms and a statement on the test results.

In order to fulfil the highest standards, it would be recommended to add a requirement on aerobic microorganism content in EU Ecolabel tampons.

The addition of a requirement for tampons on aerobic microorganism content in EU Ecolabelled tampons should therefore be discussed.

<u>Rationale behind the proposed 'assessment and verification'</u>

The recommendations published by EDANA for tests (EDANA 2016, 2018) should be taken into account when carrying out the application tests. These recommendations indicate that at least 100 test subjects should be used for products that are not specifically designed for one gender. For products that are specifically designed for one gender at least 30 test subjects should be included. Therefore, **it is proposed to raise the minimum amount of consumers tested to 100 persons for products not specifically designed for one gender.** The limit for products specifically designed for one gender has not changed (30 persons).

The applicant shall document the test protocol (laboratory test(s) or consumer test) that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the functions claimed on the product label or packaging.

Recommendation from industry regarding the in-use test, U1-absorption and leakage protection are behind the change in thresholds, thus aiming to percentage rating. For so, to comply with this criterion **all in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance)**, **shall report 80% of the consumers testing the product performance as satisfactory.**

Technical tests recommended for nursing pads are harmonised with a reference from the Kenya Bureau of Standards, which specified these methods for nursery pads. Thus meaning that the **same test methods used for baby diapers and feminine care pads (either in-use or technical tests) can be applied to nursing pads.**

Points for discussion

• For the in-use tests, absorption and leakage protection is the performance threshold modification appropriate?
• For nursey pads, the same methods than for baby diapers and feminine care pads are recommended, is this appropriate?
• Stakeholders' views are welcomed on :
  o Addition of biocompatibility tests (ISO).
  o Addition of specification about aerobic microorganism content in tampons.
  o Acceptance of in-house test methods.

5.12 CRITERION 11: Social aspects

Existing criterion 11: Social aspects
Applicants shall ensure that the fundamental principles and rights at work as described in the International Labour Organisation's (ILO) Core Labour Standards, the UN Global Compact and the OECD Guidelines for Multi-National Enterprises shall be observed by production sites along the supply chain used to manufacture the licensed product(s). For the purpose of verification, the following ILO Core Labour Standards shall be referred to: 029 Forced Labour 087 Freedom of Association and Protection of the Right to Organise 098 Right to Organise and Collective Bargaining 100 Equal remuneration 105 Abolition of Forced Labour 111 Discrimination (Employment and Occupation) 138 Minimum Age Convention 155 Occupational safety and health 182 Elimination of the Worst Forms of Child Labour These standards shall be communicated to production sites along the supply chain used to manufacture the final product. **Assessment and verification**: The applicant shall demonstrate third party verification of compliance, using independent verification or documentary evidence, including site visits by auditors during the Ecolabel verification process for production sites in the supply chain for the licensed products. This shall take place upon application and subsequently during the license period if new production sites are introduced.
Proposed criterion 11: Social aspects Corporate Social Responsibility with regard to Labour Aspects
Requirements in this criterion shall apply to the final absorbent hygiene product assembly site. ~~Applicants shall ensure that the fundamental principles and rights at work as described in the International Labour Organisation's (ILO) Core Labour Standards, the UN Global Compact and the OECD Guidelines for Multi-National Enterprises shall be observed by production sites along the supply chain used to manufacture the licensed product(s). For the purpose of verification, the following ILO Core Labour Standards shall be referred to:~~ ~~029 Forced Labour~~ ~~087 Freedom of Association and Protection of the Right to Organise~~ ~~098 Right to Organise and Collective Bargaining~~ ~~100 Equal remuneration~~ ~~105 Abolition of Forced Labour~~ ~~111 Discrimination (Employment and Occupation)~~ ~~138 Minimum Age Convention~~ ~~155 Occupational safety and health~~ ~~182 Elimination of the Worst Forms of Child Labour~~ ~~These standards shall be communicated to production sites along the supply chain used to manufacture~~

~~the final product.~~

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy, the UN Global Compact (Pillar 2), the UN Guiding Principles on Business and Human Rights and the OECD Guidelines for Multinational Enterprises, the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the ILO's fundamental conventions and the supplementary provisions below have been respected at the final AHP assembly site for the product.

Fundamental conventions of the ILO:

(i) Child Labour:

— Minimum Age Convention, 1973 (No 138);

— Worst Forms of Child Labour Convention, 1999 (No 182).

(ii) Forced and Compulsory Labour:

— Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention;

— Abolition of Forced Labour Convention, 1957 (No 105).

(iii) Freedom of Association and Right to Collective Bargaining:

— Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87);

— Right to Organise and Collective Bargaining Convention, 1949 (No 98).

(iv) Discrimination:

— Equal Remuneration Convention, 1951 (No 100);

— Discrimination (Employment and Occupation) Convention, 1958 (No 111).

Supplementary provisions:

(v) Working Hours:

— ILO Hours of Work (Industry) Convention, 1919 (No 1).

(vi) Remuneration:

— ILO Minimum Wage Fixing Convention, 1970 (No 131);

— Living wage: The applicant shall ensure that wages paid for a normal working week shall always meet at least legal or industry minimum standards, are sufficient to meet the basic needs of personnel and provide some discretionary income. Implementation shall be audited with reference to the SA8000 guidance on 'Remuneration'.

(vii) Health & Safety:

— ILO Safety in the use of chemicals at work Convention, 1981 (No 170);

— ILO Occupational Safety and Health Convention, 1990 (No 155).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

The audit process shall include consultation with external stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. The applicant shall publish the aggregated results and key findings from the audit online in order to provide evidence of their supplier's performance to interested consumers.

Assessment and verification:

~~The applicant shall demonstrate third party verification of compliance, using independent verification or documentary evidence, including site visits by auditors during the Ecolabel verification process for production sites in the supply chain for the licensed products. This shall take place upon application and~~

~~subsequently during the license period if new production sites are introduced.~~

The applicant shall provide a declaration of compliance together with copies of certificates and a supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled.

The third-party site audit shall be carried out by private auditors qualified to assess the compliance of the AHP industry supply chain with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective[54] and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a national authority.

Certificate(s), not dated more than 12 months prior to the application, from schemes or processes that audit compliance with the applicable principles of the listed fundamental ILO conventions, together with the supplementary provisions on working hours, remuneration and health and safety, shall be accepted.

Rationale for the proposed criterion text

The EU Ecolabel Regulation 66/2010, Art 6.3. specifies that: '*EU Ecolabel criteria shall be determined on a scientific basis considering the whole life cycle of products. In determining such criteria, the following shall be considered: (…) e) where appropriate, social and ethical aspects, e.g. by making reference to related international conventions and agreements such as relevant ILO standards and codes of conduct*'.

The aim of the criterion is to set guidelines to ensure that the minimum labour standard requirements have been fulfilled by companies applying for the EU Ecolabel, independently from national laws.

At the preliminary questionnaire (December 2020), 25% of the respondents indicated the need for revision. In particular, stakeholders indicated a lack of clarity.

In order to improve the clarity of the criterion, the criterion text is proposed to be harmonised with the EU Ecolabel for footwear (European Commission, 2016)[55].

Respondents to the questionnaire (December 2020) highlighted the need to clarify the scope of this criterion, i.e. for which tier production chain the social aspects requirement should apply.

This criterion verification refers to the final Absorbent Hygiene Product assembly site.

Rationale behind the proposed 'assessment and verification'

According to the questionnaire from December 2020, some stakeholders mentioned that the '*lack of clarity on required/acceptable documentation leads to a high administrative burden both for applicant and for suppliers to compile a 'Body of evidence' and also that legal requirements/regulations/documentation vary across countries/regions/industries'*. Also '*checking compliance for every single supplier is a very high burden for the applicant/supplier and the CB*'.

In addition, stakeholders were asked to explain how they carry out the evaluation of the compliance with the social requirements of Criterion 11. Overall, the responses revealed the existence of different ways of verification, as follows:

- Two ways of verification: (1) knowledge of national law - to verify that the listed ILO standards are fulfilled (later been replaced by SA8000 certification) or (2) third-party certification - showing compliance with the ILO standards;
- Confirmation by each supplier, BSCI Certificate or SA8000 Certificate or confirmation by third party;
- Applicant provides SMETA - Sedex members ethical trade audit or Code of conduct (public declaration), also from his suppliers. Not much costs or burden with fulfilling the criterion. Production site visit of applicant during assessment process.

[54] ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.
[55] Commission Decision (EU) 2016/1349 of 5 August 2016 establishing the ecological criteria for the award of the EU Ecolabel for footwear https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D1349&from=EN

Stakeholders also informed that they did not perceive high economic burden for meeting the criterion nor they encountered problems gathering information from suppliers or manufacturing sites.

When it comes to other labels or awards relevant to Absorbent Hygiene Products, the following have been listed by respondents as containing best practice social criteria:

- The Blue Angel has risk-based approach with more clarity and accepts other certifications (e.g. GOTS) as evidence.
- The Verisk Maplecroft social risk assessment system.
- UN Global Compact, amfori BSCI.
- The Nordic Swan explains that *'the licensee shall ensure compliance with all applicable local laws and provisions at all production facilities […], e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits. The product must also fulfil relevant product-specific requirements laid down by the authorities'.*

Looking at the evidence, criterion 11 should only apply to the production site of the final AHP product.

For each production site where final AHPs are assembled, applicants must provide not only the **declaration of compliance, but also copies of other certificates (not dated >12 months) and supporting audit reports.**

The documentation must be certified by private auditors qualified to assess the compliance of the AHP industry supply or by labour inspector(s) appointed by a national authority.

Points for discussion
• Should the criterion verification refer to the final Absorbent Hygiene Product assembly (manufacturing site)? • Should the criterion welcome a non-exhaustive list of acceptable proofs (Sustainability reports, Corporate policies, ISO-certificates) as well?

5.13 CRITERION 12: Information appearing on the EU Ecolabel

Existing criterion 12: Information appearing on the EU Ecolabel
The EU Ecolabel logo shall be applied on the packaging of the product. Box 2 of the EU Ecolabel shall contain the following text: — 'Reduced impacts from consumption of resources', — 'Restricted use of hazardous substances', — 'Performance and quality tests satisfied'. The following text should moreover appear on the packaging: 'For more information on why this product has been awarded the EU Ecolabel, please visit http://ec.europa.eu/environment/ecolabel/'. **Assessment and verification**: The applicant shall provide a declaration of compliance with the requirement and visual evidence.
Proposed criterion 12: Information appearing on the EU Ecolabel
The optional EU Ecolabel logo shall be applied on the primary packaging of the product. The optional label with box shall contain the following text: ~~— 'Reduced impacts from consumption of resources',~~ ~~— 'Restricted use of hazardous substances',~~ — 'Product designed to reduce environmental impact', — 'Verified performance'. The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf **Assessment and verification**: The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The photograph provided must be a high resolution image of the product packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

Rationale for the proposed criterion text

Information about the EU Ecolabel on the product helps to inform the consumer on the environmental preference of this product and make easy the environmentally friendly decision. For this reason, this criterion is included in all EU Ecolabels.

According to the feedback received from the December 2020 questionnaires, 43% of stakeholders considered that the criterion is adequate and does not need to be changed. In general, stakeholders requested the update of the existing statements that appear on the primary packaging as it has been proposed.

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the EU Ecolabel product may be displayed in the optional label with text box. The guidelines for the use of the optional label with text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website (logo_guidelines.pdf (europa.eu)).

Finally, the wording of the criterion has been changed to harmonise with the most recently voted product group (Cosmetic products and animal care products).

Rationale behind the proposed 'assessment and verification'

Clarification about the visual evidence has been added allowing applicants to send a high resolution image of the primary packaging instead of the product itself. Besides the statement to appear have been redefined.

Points for discussion
• Are the proposed statement facts appropriate or should they be modified?

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List of abbreviations and definitions

AHWG	Ad-Hoc Working Group Meeting
AOX	Adsorbable Organic Halogen
BAT	Best Available Technology
BAT-AELs	BAT-associated emission levels
BPA	Bisphenol-A
BREF	Best Available Techniques Reference Document
CLP	Classification, Labelling and Packaging
CO_2	Carbon dioxide
CTP	Computer to Plate
DIBP	Diisobutyl phthalate.
DIPN	Diisopropylnaphthalene.
EMAS	Eco Management and Audit Scheme
EN	European Norm
EU	The European Union
EUEB	The European Union Eco-labelling board
FSC	Forest Stewardship Council
GMO	Genetically modified organism
IPPC	Integrated Pollution Prevention and Control
ISO	International Standardisation Organisation
LCA	Life Cycle Assessment
NGO	Non-governmental organizations
NOx	Nitrogen Oxides
PEFC	Programme for the Endorsement of Forest Certification
PAH	Polycyclic aromatic hydrocarbons.
PBT	Persistent Bioaccumulative Toxic
PP	Printed paper products
PVC	Polyvinyl chloride
PUR	Polyurethane

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RSB	Roundtable on Sustainable Biomaterials
SETAC	Society of Environmental Toxicology and Chemistry
SO_2	Sulphur Dioxide
TOC	Total organic carbon, expressed as C (in water or in gases)
TVOC	Total volatile organic carbon, expressed as C (in air).
VOCs	Volatile Organic Compounds
vPvB	Very persistent, very bioaccumulative

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ANNEX I. Substitution information and Derogation request form

Stakeholders should fulfil to communicate the derogation from of substances that cannot be replaced and are not able to comply with article 6 (6) of the EU Ecolabel Regulation.

1. Common information requirements

To be treated as confidential?	☐Yes ☐No

Contact name	
Organisation	
Email	
Telephone No.	
Supplementary documents attached	

1a. Chemical substance name(s)	
1b. CAS, EC or Annex VI numbers	
1c. Current EU regulatory status	
1d. CLP Classifications from the EU Ecolabel hazard listing	
1e. Proportional contribution to final product classification (for mixture ingredients)	
1f. Existing scientific evidence and risk assessments relating to the substance	

1g. Functional need and significance to the final product	
1h. Typical concentration in the final product and specific components or articles	

2. Additional information required for <u>derogation requests</u>

2a. The relevance of the hazard classification(s) along the life cycle of the product (e.g. manufacturing, use, disposal)	
2b. Market availability of alternatives and the potential for substitution	

3. Additional information required about <u>substitutes</u>

3a. Comparative evaluation of environmental performance	
3b. The relevance of the hazard substitution along the life cycle of the product (e.g. manufacturing, use, disposal)	
3c. Compliance with product performance and functional requirements	
3d. Market diffusion and technical maturity	

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