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Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products)

Final Technical Report: Final criteria

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Contents

Abstract

This Science for Policy Report aims to provide a technical basis for the revision process of the EU Ecolabel criteria for Absorbent Hygiene Products. The set of criteria currently in force was adopted in 2014 (Commission Decision 2014/763/EU). The revised EU Ecolabel criteria are set to cover a wider scope, as for the first time they include a set of criteria targeting reusable menstrual cups. The product group has been enlarged thus to cover 'absorbent hygiene products' and 'reusable menstrual cups'.

To support the revision process, a first version of this report was produced as a working document, and was updated and complemented as the revision developed. That document provided the rationale for the revised criteria proposal and summarised the research and the outcome of three stakeholder consultations, which were crucial to develop revised criteria that are able to pinpoint the best environmental products available on the market while taking into account the state of the art of the sector.

After a revision process lasting 30 months, this is the final version of the report which supports the final criteria for absorbent hygiene products and reusable menstrual cups.

1 Introduction

The objective of this project is to revise the existing EU Ecolabel criteria (Commission Decision 2014/763/EU[1]) for absorbent hygiene products. The criteria were adopted for the first time in 2014 and the Decision currently in force is valid until the end of December 2023.

This technical report is intended to provide background information for the revision of the existing EU Ecolabel criteria for absorbent hygiene products. The study has been carried out by the European Commission's Joint Research Centre (JRC), Unit B.5 – Circular Economy and Sustainable Industry. The work has been developed for the European Commission's Directorate General for Environment.

The EU Ecolabel is the official voluntary labelling scheme of the EU that promotes the production and consumption of products (goods and services) with a reduced environmental impact over their life cycle, and is aimed at 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).

The EU Ecolabel was mentioned as having an important role in the new Circular Economy Action Plan (CEAP) from March 2020.

The EU Ecolabel was also mentioned in the Chapeau Communication on making sustainable products the norm. This Communication accompanies a package of measures proposed in the CEAP and adopted on 30 March 2022[2], including: a proposal for the Ecodesign for Sustainable Products Regulation, an EU strategy for sustainable and circular textiles, a proposal for a revised Construction Products Regulation, and a proposal for empowering consumers in the green transition. The Communication mentions the EU Ecolabel as an important tool whose criteria will be developed in synergy with future Ecodesign measures.

This technical report addresses the requirements of EU Ecolabel Regulation No 66/2010 and its main purpose is to summarise the results of the preliminary analysis of the current criteria and to discuss if the criteria are still appropriate and up-to-date or if they should be revised, amended or some of them removed; and finally, if any new criteria should be added. This technical report provides elements supporting the revised EU Ecolabel criteria for absorbent hygiene products and for new EU Ecolabel criteria for reusable menstrual cups.

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.

This technical report is supported and complemented by the Preliminary Report[3] published in September 2021. The preliminary report includes analyses of the scope and definition, market analysis, and technical analysis. In the preliminary report, the results of a life cycle assessment (LCA) for different products under the scope of the EU Ecolabel criteria were presented for the identification of the environmental hotspots. The LCA was carried out by JRC Unit D.3 – Land Resources and Supply Chain Assessments.

A first draft of the technical report (TR1.0)[4] was presented at the first Ad-hoc Working Group meeting (AHWG1), which took place online in October 2021. The discussions and comments received are included in this technical report, and form the basis for the further research done to justify the latest modifications of the criteria proposal.

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1 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) https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32014D0763

2 https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en

3 More information can be found in the Preliminary Report. Draft document available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2021-09/Absorbent%20Hygiene%20Products_Draft%20Preliminary%20report_FINAL.pdf

4 Technical Report 1, TR1.0, of the current revision process (2021). Draft document available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2021-09/Absorbent%20Hygiene%20Products_Draft%20Technical%20report%201_FINAL.pdf

A second technical report (TR2.0[5]) was discussed in the second Ad-hoc Working Group meeting (AHWG2) in May 2022. And a third version of the report (TR3.0[6]) was published in October 2022 taking into consideration the feedback received during and after the second Ad-hoc Working Group meeting, as well as further research.

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) studies (performed using the Product Environmental Footprint method), as well as the feedback from stakeholders, a final proposal for a set of revised EU Ecolabel criteria is presented in this technical report. The entire life cycle of the products is considered, from the extraction of raw material through production, transport and use, to the disposal phase. The EU Ecolabel criteria address the environmental impacts from any of these life cycle phases, with the aim being to encompass the areas of greatest impact (life cycle hotspots). The EU Ecolabel criteria shall be based on the best products available on the EU market in terms of environmental performance, and they shall correspond to the best 10-20% of the products available on the EU market in terms of environmental performance.

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

This final technical report is structured as follows:

- Introduction (Chapter 1): this section describes the goal of the project and the structure of the document.
- Summary of the Preliminary Report (Chapter 2): this section summarises the main findings from the Preliminary Report, especially with respect to market analysis and technical analysis, including an overview of the results of the LCA.
- Scope and definition (Chapter 3): this section reports the conclusions obtained regarding the scope definition and the key aspects related to the product groups of 'absorbent hygiene products' and 'reusable menstrual cups'.
- Assessment and verification (Chapter 4): this section includes information on the type of documentation required to show compliance with the criteria that shall be provided by applicants and approved by competent bodies.
- Criteria proposal for absorbent hygiene products (Chapter 5): this section presents the final EU Ecolabel criteria for the 'absorbent hygiene products' product group as well as the technical rationale for the structure and content of the individual criteria.
- Criteria proposal for reusable menstrual cups (Chapter 6): this section presents the final EU Ecolabel criteria for the 'reusable menstrual cups' product group as well as the technical rationale for the structure and content of the individual criteria.
- Impact of changes to the criteria (Chapter 7): this section consists of a summary of the main changes proposed for the revised criteria, their expected impact for the environmental and for resource circularity.

A table of all comments received during the consultation period since October 2021, together with responses and explanations on how they have been addressed in this final report, has been published as a separate document.

[5] Technical Report 2, TR2.0, of the current revision process (2022). Draft document available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/Technical%20Report%202_0.pdf

[6] Technical Report 3, TR3.0, of the current revision process (2022). Draft document available at: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents

2 Summary of the Preliminary Report

2.1 Legal and policy context

This section provides a summary of the findings of the Preliminary Report (PR)[2] for the revision of the EU Ecolabel criteria for absorbent hygiene products (AHP) with a focus on the scope and on the key environmental aspects.

AHP are not subject to sector-specific EU legislation. However, there are a number of relevant EU policy tools, Regulations and Directives that apply to this sector, including:

- 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 (Directive 2019/1004/EC);
- Council Directive 96/62/EC on ambient air quality assessment and management;
- Directive 2009/28/EC 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 (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;
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and later modifications (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;
- Communication from the European Commission on EU Policy Framework on biobased, biodegradable and compostable plastics;
- Proposal for a revision of EU legislation on Packaging and Packaging Waste.

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. In the following paragraphs, unless otherwise stated, data are from Euromonitor International[7].

AHP are classified by means of PRODCOM data, Euromonitor data or using the EDANA[8] categorisation. In the PR and TR1.0 it was proposed to use the product categorisation shown in Table 1, where products covered by the existing EU Ecolabel criteria are marked in **bold**.

[7] Euromonitor International: Tissue and Hygiene industry edition 2021. Data purchased.

[8] EDANA is the Industry Association for nonwovens and related industries. EDANA's member companies are the AHP 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 categorisation to be used during the EU Ecolabel revision process

Disposable Baby Diapers (single-use diapers/nappies)
Disposable Sanitary Pads or Towels (single-use pads/towels)
Disposable Panty Liners (single-use panty liners)
Tampons (single-use)
Disposable Nursing Pads (breast pads)
Disposable Adult Incontinence Products
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) and for feminine care pads Always/Whisper (also from P&G).

The sales volume of AHP within the EU-27 and the UK (2010-2020) is dominated by baby diapers with nearly 57% of the sales share, followed by feminine care pads (23%), panty liners (11%) and tampons (9%). Aggregated data for pads and panty liners represent over 34% of the market share, which is below the worldwide average due to the higher tampons consumption in Europe (expressed in sales volume). The worldwide values for 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% in 2019 and 2020.

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[9].

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

Among the 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 good value for money as they can be used for 5 to 10 years. A survey on reusable baby diapers showed the main attributes for the switch are related to 'value for money' and performance such as 'leak protection' or 'soft materials for the baby skin'[10].

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) could not be found.

[9] Eurostat PROD COM List. 2019: https://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=PRD_2019&StrLanguageCode=EN&IntPcKey=45169040&StrLayoutCode=HIERARCHIC (accessed 02/08/2021).

[10] More information can be found in the Preliminary Report

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 AHP within the scope of the EU Ecolabel have been subject to LCA studies for many years (Cordella et al., 2013[11], Mirabella et al., 2013[12], Arena et al., 2016[13], Mendoza et al., 2019[14], Hoffmann et al., 2020[15]). Within the AHP group, baby diapers were the first products to be analysed in LCA studies[11]. In general, diapers are more often studied while feminine care products are only occasionally the subject of LCA studies. Comparative LCA studies of different types of baby diapers were conducted with several objectives. For instance, scientific articles on LCA of baby diapers have compared single-use and reusable options, and 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[16].

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[17, 15].

Differences are encountered when single-use (disposable) products are compared with their corresponding reusable options. However, a limited number of scientific articles analyse the whole life cycle of the AHP that are addressed by the EU Ecolabel scope. 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, the washing temperature and energy efficiency of the washing machine result in different outcomes whereas a reusable diaper system which optimises energy and water use has lower environmental impacts than single-use options[15].

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 environmentally friendly options[12, 13, 14].

Assessment of the end-of-life scenarios is another option, for example scenarios where biodegradation, pyrolysis and composting might be of high potential for diaper recycling[18]. However, so far there has not been a consensus on what the best methods for disposal of diapers or absorbent hygiene products are. In fact, material recovery and recycling could require significant structural changes to the current waste management system. That said, at the moment there is not a well-implemented collection system across EU Member States for AHP[19]. There are examples of industrial sites for recycling of baby diapers in Italy (Fater

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[11] Cordella, M, Wolf, O, Schulz, M, Bauer, I, Lehmann, A, Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products"). Preliminary Report – Final. European Commission, Joint Research Centre, 2013. Available here

[12] Mirabella, N.; Castellani, V and Sala, S., 'Life cycle assessment of bio-based products: a disposable diaper case study', International Journal of Life Cycle Assessment, Vol. 18, Springer, 2013, pp. 1036–1047. https://doi.org/10.1007/s11367-013-0556-6

[13] Arena, U., Ardolino, F. and Di Gregorio, F., 'Technological, environmental and social aspects of a recycling process of post-consumer absorbent hygiene products', Journal of Cleaner Production, Vol. 127, Elsevier, 2016, pp. 289-301. https://doi.org/10.1016/j.jclepro.2016.03.164

[14] Mendoza, J. M. F., Popa, S. A., D'Aponte, F., Gualtieri, D., Azapagic, A., 'Improving resource efficiency and environmental impacts through novel design and manufacturing of disposable baby diapers', Journal of Cleaner Production, Vol. 210, Elsevier, 2019, pp. 916-928. https://doi.org/10.1016/j.jclepro.2018.11.046

[15] Hoffmann, B. S., Morais, J. de S. and Fonseca Teodoro, P., 'Life cycle assessment of innovative circular business models for modern cloth diapers', Journal of Cleaner Production, Vol. 249, No 10, Elsevier, 2020, pp. 119364. https://doi.org/10.1016/j.jclepro.2019.119364

[16] More information can be found in the Preliminary Report

[17] Cordella, M., Wolf, O., Schulz, M., Bauer, I., Lehmann, A., 'Evolution of disposable baby diapers in Europe: life cycle assessment of environmental impacts and identification of key areas of improvement', Journal of Cleaner Production, Vol. 95, Elsevier, 2015, pp. 322-331. https://doi.org/10.1016/j.jclepro.2015.02.040

[18] Khoo, S. C., Phang, X. Y., Ng, C. M., Lim, K. L., Lam, S. S. and Ma, N. L., 'Recent technologies for treatment and recycling of used disposable baby diapers', Process Safety and Environmental Protection, Vol. 123, Elsevier, 2019, pp. 116-129. https://doi.org/10.1016/j.psep.2018.12.016

[19] More information can be found in the Preliminary Report

company) and the UK (Knowaste company)[20]. Nevertheless, a competitive recycling project must fulfil several conditions which are currently difficult to address.

Regarding disposable feminine care products, the most relevant environmental impacts in sanitary pads are caused by the manufacturing of low-density polyethylene (LDPE) foil[21]. Tampons are more environmentally favourable due to the different product weights and compositions which include a higher content of renewable raw materials such as cotton[22]. 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 removed from the study, the product reduces the impacts, making them a better choice than a sanitary pad[23].

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[24].

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 depending on the country or industrial prospects.

2.3.2 LCA screening study (using the PEF methodology) of absorbent hygiene products

A study to assess environmental impacts of average disposable baby diapers and sanitary towels using the PEF methodology[25] was performed. The detailed information on the assessment is available in the Preliminary Report. The study aimed to find out the most relevant impact categories, life cycle stages, processes and flows of selected AHP. The results of the study served as a basis to identify the environmental hotspots and define the areas of the product life cycle that need to be specifically addressed by EU Ecolabel criteria for AHP[26].

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.

In accordance with the PEF method, the study was submitted to third-party verification. The overall opinion of the third-party verification was: "The study is technically performed correctly, but little attention is paid to the influence of representativeness of the data on the conclusions". Based on this feedback, the LCA screening study was reviewed by the JRC, additional analysis was performed, and the study was resubmitted to the third party. The final opinion of the third-party verification was the following: "The study is technically

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20 Dri M., Canfora P., Antonopoulos I. S., Gaudillat P., Best Environmental Management Practice for the Waste Management Sector, JRC Science for Policy Report, EUR 29136 EN, Publications Office of the European Union, Luxembourg, 2018, ISBN 978-92-79-80361-1, doi:10.2760/50247, JRC111059.

21 Mazgaj, M., Yaramenka, K. and Malovana, O., 'Comparative Life Cycle Assessment of Sanitary Pads and Tampons', 2006, GROUP 6, Royal Institute of Technology Stockholm.

22 Weir, C. S., In The Red: A private economic cost and qualitative analysis of environmental and health implications for five menstrual products. Master Thesis, Dalhousie University, 2015. Available at: https://cdn.dal.ca/content/dam/dalhousie/pdf/science/environmental-science-program/Honours Theses/2015/ThesisWeir.pdf (accessed 26/08/2021).

23 Hait, A. and Powers, S. E., 'The value of reusable feminine hygiene products evaluated by comparative environmental life cycle assessment', Resources Conservation and Recycling, Vol. 150, Elsevier, 2019, pp. 104422. https://doi.org/10.1016/j.resconrec.2019.104422

24 UNEP, 2021. Notten, P., Gower, A., Lewis, Y. Single-use menstrual products and their alternatives: Recommendations from Life Cycle Assessments. United Nations Environment Programme (UNEP), 2021. Available here (accessed 26/08/2021).

25 The Product Environmental Footprint (PEF) is a LCA-based method to quantify the environmental impacts of products (goods or services) that are more reproducible, comparable and verifiable, compared to existing alternative approaches. For the details of the methodology, see: https://eplca.jrc.ec.europa.eu/permalink/PEF_method.pdf

26 Sinkko T., Tosches D., Pérez-Camacho M.N., Faraca G. (2022). Screening LCA study: Absorbent Hygiene Products in Europe (Updated April 2022). Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/LCA%20screening%20study%20on%20AHP_update%20April%202022.pdf

performed correctly. Due to the character of the study, not all PEF reporting requirements could be fully met, but this makes no difference to the results. The limitations and representativeness of the conclusions are sufficiently explained, and the study finds and discusses the environmental hotspots in a way that they can be used for the goal."

While the revised version of the LCA screening study for AHP can be found in the supplementary document published together with this Second Technical Report, the next sections summarise the results of the LCA screening study on AHP, including the modifications performed after the third-party verification.

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

Raw material acquisition is always the most relevant life cycle stage, having a contribution of 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 at the end-of-life. Distribution typically has contributions around 5%, but in Acidification and Eutrophication – terrestrial it is around 10%. The highest contribution of the transport in all cases is because of the train transport.

For baby diapers, Climate Change is the most relevant impact category with a 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 a 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 related to the acquisition of raw material for the baby diaper include production of superabsorbent polymers (SAP), fluff pulp, and polypropylene (PP), low-density polyethylene (LDPE) and polyethylene terephthalate (PET) granulates. In particular, SAP which was assumed to have a 40% share of the all raw materials, and are thus identified as having the highest contributions in terms of the impacts. In addition to raw materials, waste landfilling (in Climate Change), train transportation of raw materials and packaging (in Particulate Matter, Photochemical Ozone Formation, Acidification and Eutrophication – terrestrial), ship transportation of fluff pulp from the US to Europe (in particulate Matter and Photochemical Ozone Formation), and lorry transportation of raw materials and in the product distribution phase (in Particulate Matter, Acidification and Eutrophication – terrestrial) are also identified among the most relevant processes for baby diapers in some impact categories. Results obtained are overall in line with the overview of published LCA studies.

Indeed, the raw material acquisition is also the main contributing life cycle stage in Cordella et al. (2015)[11] and Mendoza et al. (2019)[12]. However, in Hoffman et al. (2020)[15], the end-of-life is the life cycle stage that contributes the most with a 75% contribution in the Climate Change impact category due to emissions from landfilling, which are also identified as a hotspot in this study, but with lower importance. It has to be noted that results cannot be fully compared because of the differences in the definition of the functional unit (FU) and different characterisation method used in the different studies. For example, in Aumonier et al. (2008)[27] Climate Change impact is 568 kg CO_2-eq for 'one toilet trained child' or '4 550 used diapers', while Hoffman et al. (2020) obtained an impact of 1 236 kg CO_2-eq for the same functional unit. In Cordella et al. (2015) the overall CO_2-eq is 592 kg and in the present study the Climate Change impact is 410 kg CO_2-eq, if the impact is converted as a use of 4 550 diapers.

The most relevant processes related to the acquisition of raw material for the sanitary towel include production of viscose, fluff pulp, and PET, LDPE and PP granulates. Also, production of LDPE granulates and film extrusion of LDPE for packaging production were identified among the most relevant processes in some impact categories, mainly in Resource Use – fossils (17%), Climate Change (11% granulates, 6% extrusion) and Ecotoxicity – freshwater (14%). In the case of sanitary towels, LDPE packaging has the highest contribution in the most relevant processes compared to baby diapers, because of the higher share of

[27] Aumónier, S., Collins, M. and Garrett, P., An updated lifecycle assessment study for disposable and reusable nappies. Environmental Agency, England and Wales, 2008. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/291130/scho0808boir-e-e.pdf

packaging materials compared to the product mass in sanitary towels. This also explains the presence of an additional impact category (Ecotoxicity – freshwater) in the group of the most relevant ones for sanitary towels and the difference in the ranking of the other six. In addition to the raw materials and packaging production, train transportation of raw materials and packaging and lorry transportation of raw materials and in the product distribution phase are identified among the most relevant processes for sanitary towels in some impact categories. In contrast to baby diapers, waste landfilling was not identified among the most relevant processes, because of the smaller mass of the product compared to LDPE packaging, when the credits from packaging recycling compensate the emissions from the landfilling.

When comparing the results with other studies, Mazgaj at al. (2021)[21] observed that the process contributing most in sanitary towels is the production of the LDPE foil, while Hait and Powers (2019)[23] and Vilabrille Paz et al. (2020) (as cited in the United Nations Environment Programme report, UNEP (2021)[24]) found that manufacturing of raw materials contributed the most to the overall impact. According to Hait and Powers (2019), the raw materials contributing most in sanitary towel manufacturing are polyethylene (66% of Energy Resource Use and 34% of Climate Change impact) and absorbent fluff from softwood pulp (23% of Climate Change impact).

Distribution typically has contributions around 5%, but in Acidification and Eutrophication – terrestrial it is around 10%. The high contribution of the transport during distribution is in all cases mainly due to the transportation of product by lorry. In some impact categories train transportation was identified among the most relevant processes, which is the part of raw material (240 km) and packaging (280km) transportation scenario, which are taken from Zampori & Pant (2019)[28]. For baby diapers, train transportation 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 stages have only a small share of impacts in almost all impact categories. Only in the Climate Change impact of baby diapers does end-of-life have a 19% contribution, because of the emissions from the landfilling of the product. For sanitary towels, this is not the case because the mass of the packaging is relatively high compared to the mass of the product itself, thus the credits received from the end-of-life of the packaging (assumed to be partly recycled) partly compensate the impacts of landfilling the product. The credits from the end-of-life of the packaging (assumed to be partly recycled) also explain why the end-of-life stage has a negative share in some impact categories, i.e. benefits from the end-of-life of the packaging are bigger than the impacts of landfilling the 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 that there were no 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.

Moreover, because SAP production data were based on literature, and proved to be a hotspot of the system, the most relevant processes in the SAP production dataset were investigated further. It was noticed that electricity consumption has the highest share of the impacts in many impact categories. Thus the assumption of the electricity amount was also explored in the sensitivity analysis. In the absence of knowledge of the range of electricity consumption for SAP production, it was decided to test an arbitrary choice of -20%. The analysis showed that such a decrease in electricity consumption would have a very limited impact on the total results for baby diapers. Only in the case of Ionising Radiation is the impact decrease significant (11%), but, since Ionising Radiation is not among the most relevant impact categories for this model, the main conclusions would not be affected by a change in electricity consumption.

[28] Zampori, L. and Pant, R., Suggestions for updating the Product Environmental Footprint (PEF) method, EUR 29682 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-00653-4, doi:10.2760/265244, JRC115959.

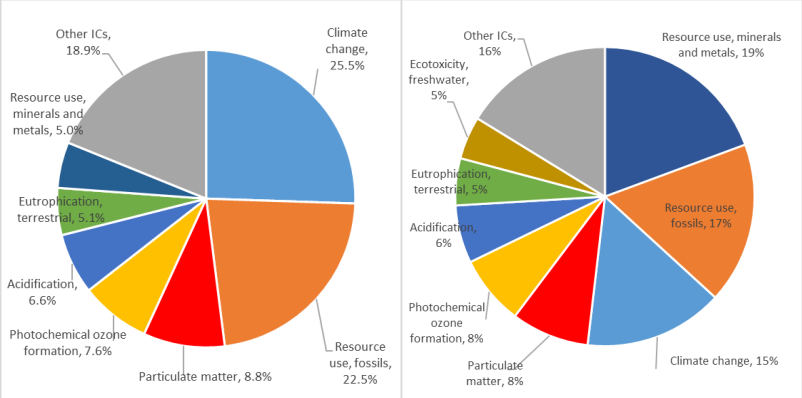

Figure 1. Impact category (IC) contribution to the final weighted score for baby diapers (left) and sanitary towels (right)

2.3.3 LCA screening study (using the PEF methodology) of reusable menstrual cups

A study to assess environmental impacts of average reusable menstrual cups using PEF methodology was performed[29]. The detailed information on the assessment is published as a separate document at the following webpage: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents

The study aimed to find out the most relevant impact categories, life cycle stages, processes and flows of selected reusable menstrual cups (RMC). The results of the study served as a basis to identify the environmental hotspots and define the areas of the product life cycle that need to be specifically addressed by EU Ecolabel criteria for RMC.

The functional unit (FU) of the study is *10 years of use of an average reusable menstrual cup produced and marketed in the EU*. The average product is defined using the average composition and weight of the products from companies providing data. Two separate cases were considered, in line with the two most common raw materials used for reusable menstrual cups: silicone and thermoplastic elastomer (TPE). Thus the FU is:

— 10 years of use of one reusable menstrual cup made from silicone, based on data from two manufacturing companies (three production sites);

— 10 years of use of one reusable menstrual cup made from TPE based on data from one manufacturing company (one production site).

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

In accordance with the PEF method, the study was submitted to third-party verification. The overall opinion of the third-party verification was: "The study is technically performed correctly and in line with PEF methodology. The results clearly describe the hotspots and where to focus when using the results for next steps in the development of ecolabel criteria. The conclusions properly address the limitations."

The most important impact categories for both products are: Water Use (24%), Climate Change (16%), Ecotoxicity – freshwater (15%), Particulate Matter (8%), Resource Use – fossils (7%), Eutrophication – marine (7%) and Acidification (4%).

The environmental hotspots identified within the study are mainly from the use phase, having contributions of between 98% (Acidification) and 99% (Ecotoxicity – freshwater) in the case of silicone cups, and 96% (Acidification) and 99% (Ecotoxicity – freshwater) in the case of TPE cups.

[29] Sinkko T., Pérez-Camacho M.N., Faraca G. (2022). Screening LCA study: Reusable Menstrual Cup in Europe. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/LCA%20screening%20study%20RMC_April%202022.pdf

Raw material acquisition has a share of around 1-2% in the case of silicone cups, and a little higher, 1-3%, in the case of TPE cups. The impacts of all other life cycle stages are negligible, manufacturing impacts being almost zero for all relevant impact categories.

In the case of Water Use, tap water used for the washing of hands and RMC is the most relevant process for both products, with more than 100% contribution (due to negative impacts for example from wastewater treatment when water is returned to the environment). In all other impact categories, soap production is the most relevant process, and often also the only relevant process. In the case of Climate Change, wastewater treatment after washing hands and RMC was identified as the second most relevant process, and in the case of Resource Use – fossils it was electricity used in households to sterilise the cup before the first use and between cycles.

As the use phase was identified as the most relevant life cycle stage with a 98-99% share of the impacts, the most relevant impact categories, phases, processes and flows are also analysed without the use phase. Water Use and Climate Change are still the two most important impact categories for both products, with shares of 24% and 14% (silicone cup), and 28% and 15% (TPE cup). When the use phase is excluded from the assessment, raw material acquisition is the most relevant life cycle stage for all impact categories and both products, with shares between 84% and 100% (silicone cup), and 80% and 100% (TPE cup).

In the case of silicone cups, cotton bag production is the most relevant process in the Water Use (92%), Climate Change (36%), Eutrophication – marine (80%), Particulate Matter (33%) and Ecotoxicity – freshwater (80%) impact categories, and the second most relevant in the Resource Use – fossils (32%) impact category. Silicone production is the most relevant process in the Resource Use – minerals and metals (95%) and Human Toxicity – non-cancer (95%) impact categories, which were not identified among the most relevant life cycle stages when analysing results with the use phase. In some impact categories (i.e. Climate Change, Resource Use – fossils and Particulate Matter), corrugated board used for packaging was also identified among the most relevant processes with a lower share (14%, 14% and 8%, respectively).

In the case of TPE cups, cotton bag production is again identified as the most relevant process in many impact categories, namely Water Use (97%), Climate Change (38%), Eutrophication – marine (77%), Ecotoxicity –freshwater (80%) and Acidification (41%), and the second most relevant in Resource Use – fossils (32%), Particulate Matter (34%) and Photochemical Ozone Formation (21%). Thermoplastic elastomer production is the most relevant process in the Resource Use – fossils impact category (36%), and among the most relevant processes in the Climate Change impact category (16%). Also, in the case of TPE cups, corrugated board packaging was identified among the most relevant processes in Climate Change (17%), Resource Use – fossils (16%), Particulate Matter (10%) and Photochemical Ozone Formation (11%). In addition, transport processes are among the most relevant processes in some impact categories, mainly train and lorry transport, which is due to the use of EF transport scenarios, which include train transport, while in the case of silicone cups, only lorry transport was reported by the companies.

A sensitivity analysis was performed in order to understand the impact of relevant parameters on the overall results of the study.

RMC lifetime

In the baseline scenario, the lifetime of silicone RMC was assumed to be 10 years, in line with the information from manufacturing companies. However, in some cases the lifetime can be shorter, and thus the impacts of this assumption were analysed by sensitivity analysis, considering the case of a 5-year lifetime for the silicone RMC, i.e. 2 cups would be needed during the 10-year period used in the study. Due to the high impacts occurring in the use phase, the impact of the assumption on the lifetime is very low. Only in the Resource Use – minerals and metals and Human Toxicity – non-cancer impact categories is the impact increase higher, between 6% and 7%. However, these impact categories are not identified among the most relevant impact categories when the use phase is included.

For TPE cups, a 4-year lifetime was assumed in the baseline, i.e. 2.5 cups would be needed during the 10-year period. An alternative case was studied in the event that the lifetime would be 3 years (3.33 cups) or 5 years (2 cups). Also, in the case of TPE cups, the lifetime assumption has only a marginal impact, less than 1% in most of the impact categories. Only in the case of Human Toxicity – cancer and Photochemical Ozone Formation is the change around 2% when the lifetime is increased or decreased.

RMC replacement interval

In the baseline scenario, it was assumed that, due to hygienic and safety reasons, the cup is changed and washed every 8 hours, i.e. 3 times per day. However, some manufacturers suggest that a cup can be worn up to 12 hours consecutively, i.e. changed and washed only 2 times per day. As the use phase was the predominant phase in all impact categories, the importance of this assumption was analysed by sensitivity analysis. Increasing the silicone RMC use time from 8 to 12 hours has a significant impact in all impact categories, between 33% (Ozone Depletion and Land Use) and 16% (Ionising Radiation). In the case of TPE cups, the highest decrease can be noticed in Resource Use – minerals and metals, and Ozone Depletion (33%), and the lowest in Resource Use – fossils (15%).

3 Scope and definition

This section presents the proposed changes to the existing name, definitions and scope of the EU Ecolabel criteria.

Final proposal for product group name
Absorbent hygiene products and reusable menstrual cups

Final proposal for product group scope:
1. The product group 'absorbent hygiene products' shall comprise any article whose function is to absorb and retain human fluids such as urine, faeces, sweat, menstrual fluid or milk, excluding textile products. 2. The product group 'reusable menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body whose function is to retain and collect menstrual fluid, and made of silicone or other elastomers. 3. The product groups 'absorbent hygiene products' and 'reusable menstrual cups' shall not include products falling under the scope of Regulation (EU) 2017/745.

Final proposal for definitions	
(1)	'additives' means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;
(2)	'biobased plastic' means a plastic manufactured from biobased raw materials as feedstock for its production. While conventional plastics are made from fossil resources (oil and natural gas), biobased plastics are made from biomass. The biomass currently originates mainly from plants grown specifically to be used as feedstock to substitute fossil resources, such as sugarcane, cereal crops, oil crops or non-food sources like wood. Other sources are organic waste and by-products, such as used cooking oil, bagasse and tall oil. Plastics can be fully or partially made from biobased feedstock. Biobased plastics can be both biodegradable and non-biodegradable;
(3)	'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;
(4)	'component' means one or several materials and chemical products that together fulfil a desirable function in the absorbent hygiene product, such as an absorbent core, adhesives, or an outer barrier film;
(5)	'composite packaging' means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;
(6)	'grouped packaging', also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;
(7)	'impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg);

(8) ‘ingoing substance’ means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;

(9) ‘man-made cellulose fibres’, also known as regenerated fibres, means fibres produced from the raw material cellulose which include viscose, modal, lyocell, cupro and triacetate;

(10) ‘materials’ mean the materials constituting different components of an absorbent hygiene product, such as fluff pulp, cotton or polypropylene (PP);

(11) ‘packaging’ means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:

(a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;

(b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;

(c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc;

(12) ‘plastic materials', also referred to as ‘plastics’, means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council , to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;

(13) ‘polymer’ means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a ‘monomer unit’ means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC) No 1907/2006;

(14) ‘product unit’ means the smallest item that can be used by the consumer and that fulfils the product’s function;

(15) ‘recyclability’ means the amount (mass or percentage) of an item available for recycling;

(16) ‘recycled content’ means the amount of an item (by area, length, volume or mass) that is sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or to the packaging in this case;

(17) ‘recycling’ means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council , any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;

(18) ‘sales packaging’, also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;

(19) ‘separate component’, also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of absorbent hygiene products, it is any component with protective or hygienic function that is removed before the use of the product, e.g. the individual wrapping or film where some absorbent

hygiene products are contained within the sales packaging (mainly for tampons and sanitary pads), the release liner and paper in baby diapers and sanitary pads, or the applicator for tampons;

(20) 'substances identified to have endocrine disrupting properties', also referred to as endocrine disruptors, 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 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1107/2009 of the European Parliament and of the Council , or Regulation (EC) No 1272/2008 of the European Parliament and of the Council ;

(21) 'super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass;

(22) 'synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by:

(a) a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;

(b) chemical modification of natural or synthetic macromolecules;

(c) microbial fermentation.

Rationale for the proposed scope text

The current scope of the EU Ecolabel for absorbent hygiene products (AHP), in Commission Decision 2014/763/EU[30], lists the disposable single-use products that are covered by the EU Ecolabel: disposable baby diapers, feminine care pads, tampons and nursing pads. In addition, the current scope states that adult incontinence products are not covered by Commission Decision 2014/763/EU, because they fall under the Medical Devices Regulations, and are therefore excluded according to Article 2.2 of the EU Ecolabel Regulation[31].

Considering the general interest expressed by stakeholders to revise the current scope of the product group, the scope section was modified to a more general wording indicating the *function* of the products under the scope, rather than listing the products themselves. The new proposal of the scope is: "*The product group 'absorbent hygiene products' shall comprise any article whose function is to absorb and retain human fluids such as urine, faeces, sweat, menstrual fluid or milk - excluding textile products*".

The new wording was in general welcomed by all stakeholders.

During the revision process, the issue of whether additional product groups could be added to the product scope was studied. The discussions focused in particular on reusable products made of textiles, reusable menstrual cups and adult incontinence products.

Reusable AHP made of textiles: The analysis carried out in the Preliminary Report did not suggest the inclusion of reusable textile AHP alternatives (cloth baby diapers, cloth feminine care pads, reusable breast pads). In addition, it was considered that such reusable alternatives have a material composition which is fundamentally different to disposable AHP, and rather similar to that of textiles, for which a dedicated set of EU Ecolabel criteria exists[32]. Other Ecolabels such as the Austrian Ecolabel also include reusable alternatives under their textile ecolabel scope. It was therefore proposed that reusable AHP made of textiles are proposed to be considered during the revision of the EU Ecolabel criteria for textile products.

Reusable menstrual cups: The analysis carried out in the Preliminary Report suggested the inclusion of reusable menstrual cups (RMC). The stakeholders were generally in favour of this inclusion. Different

[30] 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. https://op.europa.eu/s/w8jj

[31] 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. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010R0066

[32] Commission Decision (EU) 2017/1392 of 25 July 2017 amending Decision 2014/350/EU establishing the ecological criteria for the award of the EU Ecolabel for textile products. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32017D1392.

materials are possible constituents for RMC: medical-grade silicone, rubber, latex or elastomer. Several companies manufacturing RMC were consulted, all of them using silicone or thermoplastic elastomers (TPE); it was not possible to consult companies manufacturing RMC made of latex and rubber. Therefore, as no relevant information could be found for RMC made of rubber or latex that could enable the proposal of criteria for RMC made of such materials, at this stage it is proposed that the product group scope includes only reusable menstrual cups made out of silicone or TPE. Indeed, silicone and TPE represent the largest part of the RMC market, with silicone being by far the main material used currently, and TPE being expected to grow rapidly due to the lower price, easier manufacturing process and a better fit for use, despite having a lower durability compared to silicone RMC. The product scope was proposed to be as follows: "*The product group 'reusable menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body to retain and collect menstrual fluid, and made of silicone or other elastomers*[33]".

As a result, the EU Ecolabel criteria for "absorbent hygiene products" and for "reusable menstrual cups" (two product groups) are proposed to be organised in two legal annexes:

- Annex I: EU Ecolabel criteria for awarding the EU Ecolabel to absorbent hygiene products, and
- Annex II: EU Ecolabel criteria for awarding the EU Ecolabel to reusable menstrual cups.

Adult incontinence products: The inclusion or not of adult incontinence products was discussed extensively with stakeholders during the revision process. Incontinence products *might* fall under Medical Devices Regulation (MDR) (EU) 2017/745 when the manufacturer demonstrates the intention of covering a medical purpose. In the event that the product then falls under the MDR, it shall go through a process showing conformity with the MDR requirements and bear the CE marking, which in fact indicates '*that the device is in conformity with the applicable requirements set out in that Regulation and other applicable Union harmonisation legislation providing for its affixing*'. With a CE mark, products can move freely within the Union and be put into service in accordance with their intended purpose. However, there is no incompatibility between the CE mark and the EU Ecolabel. Indeed, Regulation (EC) No 765/2008[34] setting out the requirements for accreditation and market surveillance of products states that '*other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation*'. The market volume of adult incontinence products in the EU was studied (Figure 2), illustrating an increase in all EU countries except for Croatia.

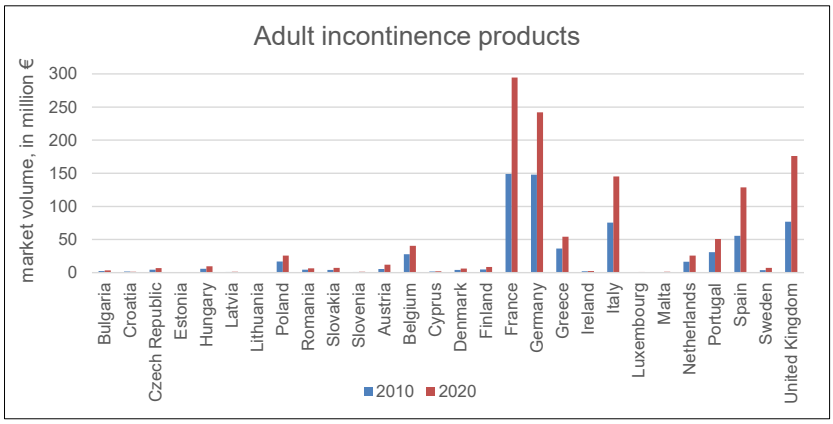

Figure 2. Market volume of adult incontinence products in the EU (in million EUR) for the years 2010 and 2020

Source: Euromonitor International.

Unfortunately, information on the share of incontinence products not registered as medical devices could not be retrieved. Consultation with industry revealed that incontinence products are usually declared as medical devices i.e. CE marked, but not always. Therefore, the share of incontinence products not registered as

[33] Because several types of TPEs exist depending on the chemical structures of the base polymers or polymer blends, it is proposed not to explicitly mention TPE in the product group scope other elastomers

[34] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

medical devices is estimated by the JRC to be small or very small. This means that the scope of action of the EU Ecolabel is expected to be limited. Nevertheless, documents such as the Green Deal and the Circular Economy Action Plan clearly show the commitment of the Commission to reduce the environmental impact of as many products as possible. This is confirmed by the recent proposal for an Ecodesign for Sustainable Products Regulation[35], which aims at making sustainable products the norm in the EU. This policy framework confirms and strengthens the role of the EU Ecolabel to identify the leader products on the market from an environmental point of view. The fact that the EU Ecolabel is promoted in green public procurement could increase the market penetration of products with reduced environmental impacts.

Incontinence products' composition is very similar to that of some absorbent hygiene products included in the EU Ecolabel scope. For example, incontinence products are registered under the same PRODCOM code as baby napkins (code 17.22.12.30 – "Napkins and napkin liners for babies and similar sanitary articles of paper pulp, paper, cellulose wadding or webs of cellulose fibres, (excluding toilet paper, sanitary towels, tampons and similar articles))". Similarly, EDANA considers baby and adult incontinence products as part of the same "diapers" category. The inclusion of adult incontinence products in the EU Ecolabel scope does not require changes to the proposed set of revised criteria.

Some stakeholders commented during the process that obliging manufacturers to choose between the CE marking of conformity with the MDR and the EU Ecolabel for environmental excellence may create distortions in the market, as it would look like the consumer had to choose between safety and environmental performance. Given the expected low percentage of incontinence products not registered as medical devices, the risk of a distortion of the market is very low. Moreover, the EU Ecolabel is a voluntary label and the inclusion of incontinence products in its scope would be a signal that more and more products should take environmental considerations into account, but it will take time before benefits can be seen. Finally, some stakeholders opposed the inclusion of incontinence products because of the risk of confusion for competent bodies who would not know whether a product is infringing Article 2 of the EU Ecolabel Regulation. This risk would be avoided by requiring potential applicants to declare in the application form that their incontinence product is not registered as a medical device. This aspect will be taken into account when preparing the User Manual and the application form.

In light of the information above, adult incontinence products (that are not registered as medical devices) are proposed to be kept in the scope of the EU Ecolabel.

Other products: wet wipes, cotton swabs and make-up remover wipes are not included in the scope of the EU Ecolabel. Indeed, their function is not to absorb and retain human fluids, but rather to clean parts of the human body. Moreover, these are single-use products that are not essential to use, and whose utilisation by society should not be fostered via the EU Ecolabel.

[35] Proposal for Ecodesign for Sustainable Products Regulation, https://environment.ec.europa.eu/publications/proposal-ecodesign-sustainable-products-regulation_en

4 Assessment and verification

Final proposal for the assessment and verification

The EU Ecolabel criteria target the best absorbent hygiene products on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

Assessment and verification requirements

For the EU Ecolabel to be awarded to a specific product, the product shall comply with each requirement. The applicant shall provide a written confirmation stating that all the criteria are fulfilled.

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 awarded shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product shall meet all respective legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The following information shall be provided together with the application for the EU Ecolabel:

(a) a description of the product, together with the weight of the individual product units and the total weight of the product;

(b) a description of the sales packaging, together with its total weight, if applicable;

(c) a description of the grouped packaging, together with its total weight, if applicable;

(d) a description of the separate components, together with their individual weight;

(e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

Rationale behind the proposed 'assessment and verification'

The assessment and verification text appearing at the beginning of the legal Annex generally refers to the different types of evidence (e.g. declarations, test reports) that the competent body shall recognise as 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. Such text is included at the beginning of the legal Annex for all EU Ecolabel new or revised criteria. The proposed text is valid for both Annex I on AHP and Annex II on RMC.

The text highlights that 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 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 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.

The main additions that were made to this section during the revision process were the following:

- To clarify in the text that any significant changes in the supplied chemicals/materials must be communicated to the competent body and supported by relevant evidence (e.g. supplier declarations) to demonstrate ongoing compliance with EU Ecolabel criteria. Indeed, especially for 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.
- To clarify that the applicant must submit information on the product composition and its packaging (moving it from current criterion 1 in force). Some competent bodies expressed their concern because this criterion was important to ensure that applicants submit all relevant documentation; however, moving the requirement to the Assessment and Verification ensures the legal obligation for the applicant.

5 Criteria proposal for absorbent hygiene products

5.1 Summary of changes proposed for the overall structure of the current EU Ecolabel criteria for absorbent hygiene products

In order to add clarity to the applicability of the criteria, as well as to simplify the structure of the document, some structural changes were proposed during the revision process, in particular with respect to grouping together the requirements related to the presence of chemicals in AHP, moving the criterion on product description to the general assessment and verification (see Chapter 4), adding new criteria and sub-criteria, and changing the order of the criteria to have first the criteria related to the manufacture of the product or its components, and then the criteria on its packaging. In this final TR, minor structural changes are proposed as criterion 5 on compostability is deleted and sub-criterion 4.2 on biobased plastic materials is set as criterion number 5. Table 2 below summarises the changes and illustrates the changes proposed.

Table 2. Changes of the criteria structure proposed during the revision process

Current criteria (Commission Decision 2014/763/EU)		Final revised criteria	
1	Product Description	Product Description	**-**
2	Fluff Pulp	Fluff Pulp	**1**
2.1	Sourcing	Sourcing of fluff pulp	**1.1**
2.2	Bleaching	Bleaching of fluff pulp	**1.2**
2.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**7.3 (d)**
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 of fluff pulp	**1.3**
2.5	Emissions of CO2 from production	Emissions of CO_2 from production of fluff pulp	**1.4**
		Energy use from production - NEW	**1.5**
3	Man-made cellulose fibres	Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)	**2**
3.1	Sourcing	Sourcing of man-made cellulose fibres	**2.1**
3.2	Bleaching	Bleaching of man-made cellulose fibres	**2.2**
3.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**7.3 (d)**
3.4	Production of fibres	Production of man-made cellulose fibres	**2.3**
4	Cotton and other natural cellulosic seed fibres	Cotton and other natural cellulosic seed fibres	**3**
4.1	Sourcing	Sourcing and traceability of cotton and other natural cellulosic seed fibres	**3.1**
4.2	Bleaching	Bleaching of cotton and other natural cellulosic seed fibres	**3.2**
4.3	Optical brighteners and colouring agents	Moved to criterion 7.3 (Specific restrictions)	**7.3 (d)**
5	Plastic materials and superabsorbent polymers	Production of synthetic polymers and plastic materials	**4**
5.1	Production of synthetic polymers and plastic materials	~~Production of synthetic polymers and plastic materials~~ set as 4	**4.1**
		Biobased plastic materials – NEW	**5**
5.2	Additives in plastic materials	Moved to criterion 7.3 (Specific restrictions)	**7.3 (e)**
5.3	Superabsorbent polymers	Moved to criterion 7.3 (Specific restrictions)	**7.3 (g)**
6	Other materials and components	REMOVED (individual sub-criteria moved)	

Current criteria (Commission Decision 2014/763/EU)		Final revised criteria	
6.1	Adhesive materials	Moved to criterion 7.3 (Specific restrictions)	**7.3 (f)**
6.2	Inks and dyes	Moved to criterion 7.3 (Specific restrictions)	**7.3 (d)**
6.3	Fragrances	Moved to criterion 7.3 (Specific restrictions)	**7.3 (b)**
6.4	Lotions	Moved to criterion 7.3 (Specific restrictions)	**7.3 (c)**
6.5	Silicone	Moved to criterion 7.3 (Specific restrictions)	**7.3 (h)**
6.6	Nanosilver particles	Moved to criterion 7.3 (Specific restrictions)	**7.3 (a)**
7	Hazardous substances and mixtures	Excluded and restricted substances	**7**
7.1	Hazardous substances and mixtures	Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council	**7.1**
7.2	Restrictions on Substances of Very High Concern (SVHCs)	Substances of Very High Concern (SVHCs)	**7.2**
7.3		Other specific restrictions – NEW	**7.3**
8	Material efficiency in the manufacturing	Material efficiency in the manufacturing of the final product	**6**
		Packaging - NEW	**8**
9	Guidance on the product disposal	Guidance on the use and on the disposal of the product and of the packaging	**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**

5.2 CRITERION 1 for Absorbent Hygiene Products: Fluff Pulp

5.2.1 Sub-criterion 1.1 – Sourcing of fluff pulp

Annex I: Final proposal for sub-criterion 1.1: Sourcing of fluff pulp
This criterion applies to fluff pulp that represents ≥ 1% w/w of the final product. **1.1. Sourcing of fluff pulp** All (100%) fluff pulp suppliers shall hold valid chain of custody certificate issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. A minimum of 70 % of the wood raw materials used for the production of the fluff pulp 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 the wood raw materials, including any virgin wood material, shall be controlled wood 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 the chain of custody and/or the Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme. **Assessment and verification**: The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificates for the suppliers of all (100%) fluff pulp used in the product. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification. In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70 % of the wood raw materials used for the production of the fluff pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel license. Competent bodies shall check the accounting documents again twelve months after the awarding of the EU Ecolabel license. If the fluff pulp is used in an air-laid material, then the air-laid material supplier shall allocate credits to the air-laid delivered to the product, providing invoices to support the number of credits allocated. For the remaining proportion of wood raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30 % and that it is controlled wood 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.

Rationale for the proposed criterion text

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

This criterion focuses on the production of fluff pulp. Fluff pulp is a type of chemical pulp characterised by its bulk and water absorbency features, used as a direct input in various end-use products that require strong absorption qualities, such as diapers and feminine care products, but not for paper products. Although the weight of fluff pulp in AHP has gradually decreased in favour of super absorbent polymers (SAP)[36], the key

[36] Kakonke, G., Tesfaye, T., Sithole, B. and Ntunka, M., 'Review on the Manufacturing and Properties of Nonwoven Superabsorbent Core Fabrics used in Disposable Diapers', International Journal of Chemical Sciences, Vol. 17, Issue 1, Trade Science Inc., 2019.

function of the fluff pulp is to acquire and distribute the fluids in the core layer (so that it can be stored in the SAP)[37].

The most important fibre properties for the final quality of an AHP are the length of the fibres, the width of the fibres and the thickness of the wall of the fibres. The longer, the wider and the thicker they are, the stiffer the fibres, the higher the absorption capacity in the AHP, and the more they allow the structure of the fluff pulp in the AHP to maintain its shape and thickness when wet and under pressure[38].

This is why fluff pulp is made mainly from softwood, such as southern yellow pine, which contains long cellulosic fibres (2–5 mm) with good absorptivity and the mechanical strength of air-laid formulations, although they are difficult to defiberise and produce dust[38,39]. Short-fibre (around 1 mm) hardwood fluff pulps are an attractive alternative to softwood pulps though their applicability to air-laid formulations is much less studied[40].

In general, the production process to produce fluff pulp is very similar to the one used to produce paper products, differing mainly in the last steps of the process.

Depending on the production process used for the separation of the fibres, wood pulp can be either mechanical or chemical. Mechanical pulp is produced by weakening and separating fibres from wood via mechanical grinding or refining. Mechanical pulp is generally used for lower grade papers, such as newsprint and catalogues, since the fibres' strength and the age resistance of the resulting pulp are lower than that of chemical pulp. Chemical pulp is produced either by using acid to extract the lignin from wood chips in large pressure vessels ("sulphite process") or by being cooked, bleached and dried ("kraft process").

Pulp (mechanical or chemical) can then be bleached or unbleached. The goal of bleaching the pulp is to remove all of the residual lignin, which lightens and whitens the pulp.

More than 90% of all fluff pulps are fully bleached chemical pulps, of which more than 90% are kraft (sulphate) pulps, the remaining being chemical sulphite pulps or chemi-thermomechanical pulps (CTMP). The following paragraphs describing the pulp production processes are based on the Best Available Techniques Reference Document (BREF) for the Production of Pulp, Paper and Board[41].

In the chemical kraft (sulphate) process, the fibres are liberated from the wood matrix in the cooking step: the lignin in the wood is removed by dissolving it into a cooking chemical solution at a high temperature in a digester. Part of the hemicellulose is dissolved as well in the cooking. In this process, the active cooking chemicals (white liquor) are sodium hydroxide (NaOH) and sodium sulphide (Na_2S). Sodium sulphate is added in the recovery cycle to compensate for chemical losses. As a result of chemical reactions in the cooking stage, chromophoric groups of the residual lignin are formed, causing the pulp to become darker in colour than the original wood. This is why normally bleaching is carried out.

After cooking, the pulp contains both fibres and spent cooking liquor (black liquor, containing inorganic chemicals and a large amount of organic substances). The black liquor is removed from the pulp in the subsequent washing step and is led to the chemical recovery system, where cooking chemicals and energy are recovered. Modern systems normally recover at least 99% of the chemicals applied in the cooking step. Washing can be carried out in various types of washing equipment, e.g. vacuum drum washers, wash presses, diffusers or wire-type washers.

The pulp is then screened with pressure screens and centrifugal separation in order to separate knots and fibre bundles from the main pulp stream. Rejects from screening are either removed from the process, mechanically treated and returned to the screening, or are directly recycled to the digesters.

After screening, the pulp can be further delignified with oxygen and then washed again, before the bleaching step. The purpose of bleaching chemical pulp is to obtain a certain pulp quality with respect to brightness,

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[37] Rebola S.M., Ferreira J. and Evtuguin D.V., Potential of bleached eucalyptus kraft pulp for applications in nonwoven fibrous fabrics, 2020, Journal of Engineered Fibers and Fabrics, volume 15, doi: 10.1177/15589250209801

[38] Schlusaz M., Reis Milagres F., Biernaski F. A., Meister Sommer S., Fluff pulp performance improved by alternative pine species, 2019, Conference paper for the 19PEERS Conference. Available at: https://www.tappi.org/content/Events/19PEERS/19PEE09.pdf

[39] Dillen J.R., Dillén S., Hamza M.F., Pulp and Paper: Wood Sources, Reference Module in Materials Science and Materials Engineering, Elsevier, 2016, https://doi.org/10.1016/B978-0-12-803581-8.09802-7.

[40] Young D and Barlow F. Past, present and future of the global fluff pulp market. Nonwovens World 2007; 16: 51–56.

[41] Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

brightness stability, cleanliness and strength. Indeed, cooking and oxygen delignification cannot remove all the lignin and, to achieve high brightness, it is necessary to remove or oxidise the remaining lignin and impurities in the pulp.

After bleaching, there is generally a final screening of pulp. The final step is the drying of the pulp for subsequent transportation.

The chemical sulphite process is very similar to the kraft process, and it differs mainly in terms of the cooking step, which in the EU predominantly uses magnesium sulphite. The production of sulphite pulp is much smaller than the production of kraft pulp because the strength properties of the pulps are generally not as good as those of kraft pulp. No new sulphite pulping plants have been built in the EU for decades.

In the CTMP process, the lignin in the wood is pre-softened with chemicals, prior to the mechanical stage of defibrating wood chips between metal refiner discs.

The pulp production processes described above are valid for paper pulp as well as for fluff pulp. However, the process for fluff pulp differs in terms of web formation, wet pressing and drying (the density is different, with pulp for fluff pulp having a density of 0.4–0.65 kg/cm³), as well as in terms of packaging for transport, with pulp for paper products being transported in the form of rolls while the pulp for fluff pulps is in reels[42,43,44]. The pulp fibres in reels are then transported to the manufacturer of the final product, where they are dry-defiberised into fluff pulp. Indeed, absorbent product manufacturing includes air or vacuum units to form a fluff pulp pad on an air-permeable screen or wire. Also in this case, long fibres are preferred: the longer the fibres, the higher the efficiency of the process and the lesser the waste[38].

During the revision process, the market for fluff pulp was investigated.

The fluff pulp market relies on wood fibres from softwood, due to their preferred properties in terms of absorption applications when compared to hardwood fibres. This implies that the production of fluff pulp takes place mainly in the areas where softwood species grow. Different values can be found according to different sources, but they all agree that the market for fluff pulp production is dominated by US actors, with mills located especially in the south-east US area (data found ranges between 75% and 85% of world fluff pulp production, 2018-2019 data[45]). The remaining part of the fluff pulp production market is in Canada, South America (Brazil and Argentina), and the EU. The EU production volume is estimated to account for ~5% of global production[46]. The major actors in the EU are located in Sweden and Finland. Spain is also investing in new capacity for fluff pulp production[47].

In terms of certification schemes to demonstrate the sustainable sourcing of pulp fibres, the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC) are the two most prominent private schemes worldwide, with a total area of certified forests of 435.5 million ha in 2020 (both schemes, after correcting for double-certified forest areas)[48]. Looking at production forest area, 39% of it is certified[49]. North America and Europe represent around 85% of certified forests (2017 data).

In addition, it should be mentioned that, currently, the regulatory framework with respect to forestry-related products in the EU is being revised. The 'New EU Forest Strategy for 2030'[50] defines the priorities of European forest management in the coming years, promoting the reuse and recycling of long-lived wood-based materials, without however setting binding requirements for the industries. At the time of writing this report, the Commission has proposed a Regulation on land use, forestry and agriculture, which should set an

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

[43] https://campenmachinery.com/airlaid/fibreization

[44] European Commission, 2018, Case M.8951 - SUZANO PAPEL E CELULOSE / FIBRIA CELULOSE, C(2018) 8166 final

[45] RISI Fastmarkets, 2019.

[46] Schlusaz M., Reis Milagres F., Biernaski F. A., Meister Sommer S., Fluff pulp performance improved by alternative pine species, 2019, Conference paper for the 19PEERS Conference. Available at: https://www.tappi.org/content/Events/19PEERS/19PEE09.pdf

[47] https://www.risiinfo.com/industry-news/ence-to-invest-in-fluff-pulp-and-dp-bhkp-swing-line-at-navia-mill-pontevedra-investment-plans-on-ice/

[48] UNECE/FAO Forest Products Annual Market Review, 2013-2014, UNITED NATIONS PUBLICATION, ISBN 978-92-1-117081-8, available at: https://unece.org/DAM/timber/publications/FPAMR-2014-final.pdf

[49] Kraxner F., Schepaschenko D., Fuss S., Lunnan A., Kindermann G., Aoki K., Dürauer M., Shvidenko A., See L., Mapping certified forests for sustainable management – A global tool for information improvement through participatory and collaborative mapping, Forest Policy and Economics 83, 2017, https://doi.org/10.1016/j.forpol.2017.04.014

[50] COM(2021) 572 final, New EU Forest Strategy for 2030

overall EU target for carbon removal by natural sinks[51]. Finally, the European Commission recently proposed a Regulation to contrast EU-driven deforestation and forest degradation[52].

After three stakeholder consultations, **the SFM threshold was increased from 25% to 70%**. This represents a good compromise between the availability of the market and the objective of sustainably managed forests contributing to a wealthy environment, economy and society, as well as being a step in the direction of 100% SFM certified fibres. FSC and PEFC are mentioned in the Assessment and Verification as certification schemes accepted as means of verification; however, other schemes can be accepted if deemed equivalent.

In this sense it is also important to point out that, in the context of the Deforestation Regulation, certification (e.g. via schemes such as FSC and PEFC) does not equate to compliance with the soon-to-be-adopted Regulation requirements. While certification can help operators to meet requirements, gaps and weaknesses exist and most scheme standards have gaps in their legality definitions[53]. In this respect, the new EU Forest Strategy for 2030 mandates the Commission to develop a voluntary certification scheme for closer to nature forestry, subject to an impact assessment. The voluntary certification will build on the Commission guidelines in preparation for closer to nature forestry. At this stage, it is expected that the guidelines will be finalised by the end of 2022, while the work on the closer to nature certification should start in 2023.

Moreover, while it would have been very pertinent to make sure that EU Ecolabel criteria comply with deforestation-free requirements, the upcoming Regulation on deforestation will be binding in requiring operators and traders placing a wood or its derivate product on the EU market to perform due diligence to ensure that their products are deforestation-free, applying also to EU Ecolabel products.

The possibility of setting requirements on recycled fibres was also analysed during the revision process. Recycling of fibres is a very mature market which has an established supply chain. In the context of AHP, recycled materials in general (and thus recycled fibres for the fluff pulp) are not common. Indeed, no producers (to our knowledge) currently include recycled fibres in their products due to the sensitivity of the products. This is especially true for baby diapers, which have very high product safety measures. Recycled fibres are not even used close to product layers in contact with the skin, because of the risk of migration. In light of this, it is not proposed to set a requirement on the presence of recycled fibres in fluff pulp.

[51] COM/2021/554 final, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2018/841 as regards the scope, simplifying the compliance rules, setting out the targets of the Member States for 2030 and committing to the collective achievement of climate neutrality by 2035 in the land use, forestry and agriculture sector, and (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review

[52] Proposal for a Regulation of the European Parliament and of the Council on the making available on the Union market as well as export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010, COM(2021) 706 final

[53] Report: Study on Certification and Verification Schemes in the Forest Sector and for Wood-based Products, https://op.europa.eu/en/publication-detail/-/publication/b67b91af-efcd-4b46-87c6-c4f4d23448b8/language-en/format-PDF/source-search

5.2.2 Sub-criterion 1.2 – Bleaching of fluff pulp

Annex I: Final proposal for sub-criterion 1.2: Bleaching of fluff pulp
The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl2) gas. In the case of elemental chlorine free (ECF) pulp, the average annual adsorbable organically bound halogens (AOX) emissions, expressed in kg/air dried tonne (ADt), from the production of each pulp used in EU Ecolabel products shall not exceed 0,140 kg/ADt. **Assessment and verification**: The applicant shall provide a declaration of compliance with this criterion, supported by a test report performed using the ISO 9562:2004 test method, including the AOX emissions relative to the ECF bleached pulp, expressed as kg AOX/ADt pulp. In case different pulp quality grades are used, the applicant shall provide the individual AOX emission corresponding to each pulp. Equivalent methods may be accepted as test methods if considered equivalent by a third-party, and shall be accompanied by detailed calculations showing compliance with this requirement and related supporting documentation. Measurements of AOX emissions shall be taken on unfiltered and unsettled samples at the effluent discharge point of the mills' wastewater treatment plant. In cases where the 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 AOX emissions shall be expressed as the annual average from at least 12 measurements taken at least every month. 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. 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 (ECF bleaching). AOX does not need to be measured in the effluent from pulp production without bleaching or where bleaching is performed with chlorine-free substances. The applicant shall also provide a declaration from the pulp manufacturer that elemental chlorine (Cl2) gas was not used. In case the applicant does not use any ECF pulp, a corresponding declaration is sufficient.

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 1990s, which caused the discharge of significant amounts of the dioxin and furan chemical families into watercourses.

Bleaching is the production step that aims to obtain a certain pulp quality with respect to brightness, brightness stability, cleanliness and strength. More than 90% of all fluff pulps are fully bleached chemical pulps[54]. The bleaching step involves the addition of different chemical compounds in order to remove or oxidise the lignin and impurities in the pulp. Indeed, the cooking and oxygen delignification steps (occurring in the kraft and sulphite production processes) remove parts of the lignin and other impurities, but not all; therefore, a bleaching step is often required. A brief overview of the technical aspects and the market situation of bleaching was given in TR1.0 and TR2.0, together with a brief analysis of the influence of the bleaching process on the presence of polyhalogenated organic compounds in a final product.

[54] Rebola S.M., Ferreira J. and Evtuguin D.V., Potential of bleached eucalyptus kraft pulp for applications in nonwoven fibrous fabrics, 2020, Journal of Engineered Fibers and Fabrics, volume 15, doi: 10.1177/15589250209801

The two main types of bleaching methods in use in Europe in the kraft process are elemental chlorine free (ECF), i.e. when no molecular or gaseous chlorine is dosed in the bleaching, and totally chlorine free (TCF) bleaching. All ECF mills use chlorine dioxide (ClO_2) in the bleaching sequences and in a few cases also ozone (O_3), alkali for the extraction of the dissolved lignin, and peroxide (H_2O_2) and oxygen (O_2) for the reinforcement of the extraction stages. TCF bleaching does not use chlorine dioxide (ClO_2), but instead uses oxygen (O_2), ozone (O_3) or peracetic acid (CH_3CO_3H) and peroxide (H_2O_2) with alkali for lignin extraction.

The criterion refers to the parameter 'AOX', which refers to the sum of all Adsorbable Organic Halogens in the wastewater. It is the measure of the total amount of halogens (chlorine, bromine and iodine) bound to dissolved or suspended organic matter in a wastewater sample. For pulp, paper and paperboard wastewaters, essentially all of the organic substances measured as AOX are chlorinated compounds that result from the bleaching of pulps with chlorine and chlorinated compounds such as chlorine dioxide and hypochlorite. AOX emissions form when chlorine compounds are added during bleaching. The vast majority of AOX emission comes from the first ClO_2 bleaching stage in the ECF process[55], while TCF bleaching is not relevant in terms of AOX emissions. AOX provides information about the quantity of chlorinated organic compounds in wastewater, and thus contains a broad mix of compounds that have different chemical properties[56]. Minimising AOX emissions will usually have the effect of also reducing the generation of chloroform, 2,3,7,8-TCDD, 2,3,7,8-TCDF, and chlorinated phenolic compounds[57].

The AOX limit was decreased from 0.17 kg AOX/ADt fluff pulp (in the current Commission Decision) to 0.14 kg AOX/ADt fluff pulp.

[55] Tuula, L., Ville, T., Susanna, K. Annastina, J., and Tapani, V. 2010. The effect pf process variables in chlorine dioxide prebleaching of birch kraft pulp. Part 2. AOX and OX Formation. Journal of Wood Chemistry and Technology 30 (1)

[56] Paper Task Force, White Paper No. 5, Environmental comparison of bleached kraft pulp manufacturing technologies, 1995, Environmental Defense Fund. Available at: https://businessdocbox.com/82128310-Green_Solutions/Paper-task-force-white-paper-no-5-environmental-comparison-of-bleached-kraft-pulp-manufacturing-technologies.html

[57] US EPA, Pulp paper permit guidance, 2000. Available at: https://www.epa.gov/sites/default/files/2015-10/documents/pulp-paper_permit-guidance_2000.pdf

5.2.3 Sub-criterion 1.3 – Emissions of COD and phosphorus to water and of sulphur compounds and NOx to air from the production of fluff pulp

Annex I: Final proposal for criterion 1.3: Emissions from fluff pulp production to water (chemicl oxygen demand (COD) and phosphorus (P)), and to air (sulphur compounds (S) and NOx)

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

— None of the individual points P_{COD}, P_P, P_S, and P_{NOx} shall exceed 1,5.

— The sum of the 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/ADt) shall be weighted according to the proportion of pulp sourced (pulp 'i' with respect to air dried tonne of pulp 'i') and summed together. The reference values for each pulp type used 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.
CTMP = chemi-thermomechanical pulp; NSSC = neutral sulphite semi-chemical pulp

	Reference values (kg/ADt)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Integrated mills				
Bleached chemical pulp (others than sulphite)	16,0	0,030([1]) 0,05([2])	0,6	1,5
Bleached chemical pulp (sulphite)	24,0	0,03	0,6	1,5
Unbleached chemical pulp	6,5	0,02	0,6	1,5
Unbleached chemical pulp (only UKP-E quality)	6,5	0,035	0,6	1,5
CTMP	15,0	0,01	0,2	0,3
NSSC	11	0,02	0,4	1,5
Non-integrated mills([3])				
Converting process	1	0,001	0,15	0,6

([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 and southern U.S. pine species from regions with higher levels of phosphorus and applies until 31 December 2026. From 1 January 2027, the limit of 0,03 kg P/ADt shall apply also to mills using eucalyptus and southern U.S. pine species from regions with higher levels of phosphorus.

([3]) For non-integrated mills, the raw material pulp(s) shall comply with the values listed for integrated mills, to which the emissions resulting from the conversion process should be added.

Assessment and verification:

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: COD: ISO 15705 or ISO 6060; Total P: EN ISO 6878; NOx: EN 14792, ISO 11564, or EPA Method 7e; S(sulphur oxides): EN 14791, EPA Method no. 6C or 8; S(reduced sulphur): EPA no. 15A, 16A, 16B or 16c; S content in oil: ISO 8754; S content in coal: ISO 19579; S content in biomass: EN 15289. Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an independent third-party shall be accepted. Rapid tests can also be used to monitor emissions as long as they are done regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents.

In the case of COD measurements, 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 for COD measurements and for total P emissions shall be weekly. Emissions of S and NOx shall be measured at least twice per calendar year (separated by four to six months).

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.

Measurement results shall be representative of the respective campaign and a sufficient number of measurements shall have been taken place for each emission parameter. The supporting documentation shall include the measurement frequency and the calculation of the points for COD, Total P, S and NOx.

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 the 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.

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. In cases where co-generation of heat and electricity occur at the same plant, the emissions of S compounds and NOx resulting from on-site electricity generation shall be subtracted from the total amount. The proportion of the emissions resulting from electricity generation shall be calculated as:

$$2 \times (\text{MWh(electricity)})/[2 \times \text{MWh(electricity)} + \text{MWh(heat)}]$$

In this calculation, 'electricity' is the electricity produced at the co-generation plant, and 'heat' is the net heat delivered from the co-generation plant to the pulp production.

Measurements of S compounds and NOx 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 compounds shall include both oxidised and reduced S emissions (SO2 and total reduced sulphur (TRS) – measured as S). 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 being measured, and shall be taken into account.

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.

During the revision process, all emission thresholds were reassessed and, in general, made stricter compared to the current Commission Decision in force. Moreover, new thresholds were created for pulp types that were

previously not specified, i.e. unbleached pulps, CTMP (chemical thermomechanical pulp) and NSSC (neutral sulphite semi-chemical).

During the revision process, the limits for P were the topic of many discussions in terms of their ambition level.

Nutrients like P originate mainly from the wood although the biological treatment of the effluent from the fluff pulp plant may require the addition of nutrients. Studies at kraft pulp mills have shown that P discharges mainly come from the bleach plant. The prospects for reducing P discharges from the process are mainly dependent on the possibilities of further processing the condensate and further delignifying the pulp in the closed part of the process. Data collected for the derivation of the BAT-AELs for the production of pulp, paper and board show yearly average P values between 0.003 kg P/ADt and 0.08 kg P/ADt (after biological wastewater treatment), with the majority of mills achieving values below 0.04 kg P/ADt. The average across mills is around 0.03 kg P/ADt, which is the same value as the BAT-AEL set by the BREF. The EU Ecolabel proposal was set at 0.03 kg P/ADt for all eucalyptus species.

However, wood from Iberian eucalyptus contains higher levels of phosphorus compared to other forest species used for pulp production in Europe and elsewhere. Even though no or little phosphorus is added as a nutrient in the biological treatment plant, the level in discharged effluents is much higher compared to other production sites using non-eucalypt forest species (assuming that no flocculants are added for phosphorus removal). For eucalyptus pulp mills using wood from regions with higher levels of phosphorus, the average level discharged with the effluent is up to 0.12 kg tot-P/ADt[58]. The BAT-AEL for eucalyptus pulp is 0.11 kg P/ADt. The BAT-AELs refer to Iberian eucalyptus because they focus on the EU only. However, eucalyptus from other regions (e.g. from Brazil) also has the same high-P characteristics[59,60]. As Brazilian eucalyptus was already allowed in EU Ecolabel graphic paper products, it was proposed in previous drafts of this sub-criterion to state that all eucalyptus species must be compliant with the 0.09 kg P/ADt level.

As mentioned above for the case of eucalyptus pulp, the P naturally contained in the wood plays an important role for the discharge of P to wastewater, and for compliance with emission limits. Phosphorus found in the wood chips is divided between the black liquor and the pulp fibre in the digester. Approximately 50% of the phosphorus found in wood ends up in the pulp fibre, but the range is 35-70%[61]. According to the data shared by stakeholders, loblolly pine is the primary species used in fluff pulp production in the US, and other species typically used are: slash pine (Pinus elliottii Engelm.), longleaf pine (Pinus palustris Mill.), shortleaf pine (Pinus echinate Mill.), pond pine (Pinus serotine), Virginia pine (Pinus virginiana), sand pine (Pinus clausa), spruce pine (Pinus glabra) and white pine (Pinus strobes). The average content of the P naturally occurring in such wood species is 0.054 kg P/t dry wood (average based on four types of wood studied between 1965 and 2006 from a variety of geographical locations within the southern United States). Converting this value into phosphorus content on a final air-dried product basis leads to an average P content of 0.125 kg P/ADt fluff pulp, which is much higher than the EU Ecolabel emission limit, and more similar to the case of eucalyptus pulp. The conversion[62] was obtained by considering a pulp production yield of 48% (based on the range of 45-55% given by the FAO[63]). Wastewater treatment is the phase were supplemental P is added. For the pulp sector in the US, wastewater treatment is mainly performed by activated sludge treatment (AST) and aerated stabilisation basins (ASBs), with ASB being more common and representing 53% of wastewater treatment technology for the pulp sector. Nearly all mills operating AST require the use of supplemental phosphorus, which is disposed of in the form of solids however. ASBs on the contrary require

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58 Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

59 Mekonnen M.M. & Hoekstra A.Y., 2018, Global anthropogenic phosphorus loads to freshwater and associated grey water footprints and water pollution levels: A high resolution global study. Water Resources Research, 54, 345–358. https://doi.org/10.1002/2017WR020448

60 G.K. MacDonalda, E.M. Bennetta, P.A. Potterc, and N. Ramankuttyd, 2011, Agronomic phosphorus imbalances across the world's croplands, www.pnas.org/cgi/doi/10.1073/pnas.1010808108

61 Judd, M.C., Stuthridge, T.R., Hunter, R.G., Morgan, K.B. 1997. In-mill sources of wastewater constituents from integrated pulp and paper processing. APPITA. 60(6):469-473.
Järvinen, R., Välttilä, O. 1998. A practical method for studying NPEs in a kraft mill. Proceedings of the 1998 International Chemical Recovery Conference. Tappi Press. 107-116.
Slade, A.H., Nicol, C.M., Grigsby, J. 1999. Nutrients within integrated bleached kraft mills: sources and behaviour in aerated stabilization basins. Water Science & Technology. 40(11-12):77-84.

62 (0.054 kg/t dry wood) * (1 t dry wood/0.48 t oven-dried pulp) * (1 t oven-dried pulp/0.9 t ADt pulp)

63 FAO, ITTO and United Nations. 2020. Forest product conversion factors. Rome. https://doi.org/10.4060/ca7952e

less supplemental phosphorus (owing to internal recycling of phosphorus), but dispose of it in the effluent. To account for this, the EU Ecolabel threshold for Iberian eucalyptus in previous drafts (0.09 kg P/ADt) was set to apply also to loblolly pine.

In the last stage of the revision process, following comments from some stakeholders, the available data on the P emissions from fluff pulp production were reviewed again to ensure that only the best plants can meet the EU Ecolabel criteria. Combining the data available in the BREF (which focus on Iberian eucalyptus, see Figure 6 on page 52 of Technical Report 2[64]) and the data shared by stakeholders on southern pine (see also the discussion on pages 51-54 of Technical Report 2), it was finally proposed to set:

- until 31 December 2026, a P limit of 0.05 kg P/ADt for eucalyptus and southern pine species;

- from 1 January 2027, a P limit of 0.03 kg P/ADt for eucalyptus and southern pine species (the same as all other species).

Indeed, the BREF indicates an average emission of ~0.07 kg P/ADt for eucalyptus mills, whereas data from stakeholders indicate an average emission for the period 2018-2020 for 15 mills (out of the 19 producing fluff pulp between EU and North America) of 0.068 kg P/ADt. It should therefore be feasible to meet a P threshold of 0.05 kg P/ADt until 1 January 2028. This solution is proposed as a compromise to find a good balance between the availability of fluff pulp, the P naturally contained in the wood, and the time that industry needs to invest in modern technologies that are capable of reducing emissions.

During the revision process, the discussion around the limits for COD, P, S compounds and NOx was held having in mind that, in contrast to the paper pulp process, fluff pulp production occurs at integrated pulp mills. However, in later stages of the revision process stakeholders informed of the fact that fluff pulp production also occurs at non-integrated mills, even if with a relatively low production capacity. Indeed, it is estimated that fluff pulp production at non-integrated mills represents around 2% of worldwide capacity, and around 25% of European capacity.

A non-integrated process is more similar to the paper production process than the one for fluff pulp, as the mill buys market pulps as raw materials from one or more supplier(s). The market pulp(s) are then dissolved, mixed (in the event that more pulps are used), and dried to obtain the fluff pulp rolls that are transported to the AHP production site, where the fluff pulp is defibrated (or '*fluffed*'). Non-integrated mills can provide special fibre mixtures and tailor-made grades for specific applications that can be chosen and adapted according to the function and characteristics of the final product. However, the configuration of this process implies that emissions occur twice: one time when the market pulp is produced (i.e. from the wood raw material to the market pulp), and a second time when the fluff pulp is produced (i.e. the conversion process, from the market pulp to the fluff pulp). Therefore, in this last stage of the revision process it is proposed to create reference values for the emissions of COD, P, S compounds and NOx to apply only to the conversion process (from market pulp to fluff pulp) taking place at non-integrated mills.

According to the information received from stakeholders, totally unbleached fluff pulp is currently produced only via a non-integrated process. Because the pulp is unbleached, this means that no chemicals are used to bleach the pulp, which is instead washed several times in order to remove the lignin from the wood material. To be used in AHP applications, the unbleached pulp must be as clean as possible and have good absorbency, which is not inherent to unbleached pulp due to the high amount of residual lignin. Only a few qualities can meet such properties; UKP-E is the purest possible unbleached pulp quality and is therefore suitable for hygiene product applications designed for intimate areas.

Unbleached pulp has a niche but growing market for AHP applications, especially as a response to the consumers' worries after the publication of the ANSES study which could detect dioxins in selected final products. While the detection of dioxins in the ANSES study was likely to be caused by trace contamination, there has been consumer demand for unbleached products. Therefore, also in line with the Chemicals Strategy for Sustainability, new thresholds have been set for unbleached pulp of a UKP-E grade.

[64] https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/Technical%20Report%202__0.pdf

5.2.4 Sub-criterion 1.4 – Emissions of CO_2 from production

Annex I: Final proposal for sub-criterion 1.4: Emissions of CO_2 from fluff pulp production

CO2 emissions from the production of fluff pulp shall not exceed the values presented in Table 2, including emissions from the production of electricity (whether on-site or off-site). CO_2 emissions shall include all sources of energy used during the production of pulp.

Reference emission values according to Table 3 shall be used in the calculation of CO_2 emission from energy sources. If needed, CO_2 emission factors for other energy sources can be found in Annex VI to Commission Implementing Regulation (EU) 2018/2066[65], whereas the CO_2 emission factors for grid electricity should be in line with Commission Delegated Regulation (EU) 2019/331[66].

Table 2. Limit values for different types of pulp. CTMP: chemical thermomechanical pulp

Integrated mills	
Chemical and semi-chemical pulp	400 kg CO_2/ADt
CTMP	900 kg CO_2/ADt
Non-integrated mills	
Converting process([1])	95 kg CO_2/ADt

([1]) The raw material pulp(s) for non-integrated mills shall comply with the values listed for integrated mills, to which the emissions resulting from the conversion process should be added.

Table 3. Reference values for CO_2 emissions from different energy sources

Fuel	CO_2 emissions	Unit	Reference
Coal	94.6	g CO_2 fossil/MJ	Regulation 2018/2066
Crude oil	73.3	g CO_2 fossil/MJ	Regulation 2018/2066
Fuel oil 1	74.1	g CO_2 fossil/MJ	Regulation 2018/2066
Fuel oil 2-5	77.4	g CO_2 fossil/MJ	Regulation 2018/2066
LPG	63.1	g CO_2 fossil/MJ	Regulation 2018/2066
Natural Gas	56.1	g CO_2 fossil/MJ	Regulation 2018/2066
Grid Electricity	376	g CO_2 fossil/kWh	Regulation 2019/331

Assessment and verification:

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

For each pulp used, the pulp manufacturer shall provide the applicant with a single CO_2 emission value in kg

[65] Commission Implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012, C/2018/8588 (OJ L 334, 31.12.2018, p. 1).

[66] 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).

CO_2/ADt.

The CO_2 emission data shall include all sources of energy sources used during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

When calculating CO_2 emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO_2 emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001 of the European Parliament and of the Council[67]. The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

The period for the calculations and/or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. 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 the grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing the specific value for its suppliers of electricity (contract for specified electricity or certified electricity). In this 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 (e.g. copy of a contract).

Rationale for the proposed criterion text

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

The main changes applied during the revision process were:

- to set the reference value for electricity purchased from the grid from 400 g to 376 g CO_2 fossil/kWh;
- to set a tighter limit value for chemical and semi-chemical pulp (down from 450 g) of 400 kg CO_2/ADt, based on the anonymous data received by stakeholders and competent bodies and on available information in the literature[68];
- to set a new limit for CTMP pulp at 900 kg CO_2/ADt;
- to set a new limit value for the conversion process taking place at non-integrated mills, similar to that mentioned for sub-criterion 1.3, based on industry data shared with the JRC;
- to mention in the Assessment and Verification that in order to count as zero-CO_2 emission sources, the biomass used for energy needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Renewable Energy Directive.

[67] Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (recast) (OJ L 328, 21.12.2018, p. 82).

[68] Rodrigo Buitrago-Tello, Richard A. Venditti, Hasan Jameel, Yuan Yao, and Darlene Echeverria, , 2022, Carbon Footprint of Bleached Softwood Fluff Pulp: Detailed Process Simulation and Environmental Life Cycle Assessment to Understand Carbon Emissions, ACS Sustainable Chem. Eng. 10, 28, 9029–9040, https://doi.org/10.1021/acssuschemeng.2c00840

5.2.5 Sub-criterion 1.5 – Energy use from production - NEW

Annex I: Final proposal for sub-criterion 1.5: Energy consumption for fluff pulp production

The energy consumption for the pulp production shall include both the electricity consumption and the fuel consumption for heat production and shall be expressed in terms of points ($P_{electricity}$ and P_{fuel}). The following limits and reference values shall apply:

— $P_{electricity} < 1,5$;

— $P_{fuel} < 1,5$;

— The sum of points ($P_{total} = P_{electricity} + P_{fuel}$) shall not exceed 2,5.

Calculation of electricity consumption points:

$$P_{electricity} = \frac{\sum_{i=1}^{n}[pulp_i \times E_{pulp,i}]}{\sum_{i=1}^{n}[pulp_i \times E_{ref,pulp,i}]}$$

Where:

$E_{pulp,i}$ = internally produced electricity + purchased electricity – sold electricity;

$E_{ref,pulp,i}$ as in Table 4.

$E_{pulp,i}$ shall be expressed in kWh/ADt and calculated for each pulp i used in the final product.

Calculation of fuel consumption points:

$$P_{fuel} = \frac{\sum_{i=1}^{n}[pulp_i \times F_{pulp,i}]}{\sum_{i=1}^{n}[pulp_i \times F_{ref,pulp,i}]}$$

Where:

$F_{pulp,i}$ = internally produced fuel + purchased fuel – sold fuel – 1,25 × internally produced electricity;

$F_{ref,pulp,i}$ as in Table 4.

$F_{pulp,i}$ shall be expressed in kWh/ADt and calculated for each pulp i used in the final product.

The amount of fuel used to produce the sold heat shall be added to the term 'sold fuel' in the equation above.

In case of a mix of pulps, the reference value for electricity and fuel consumption for heat production shall be weighted according to the proportion of each pulp used (pulp 'i' with respect to air dry tonne of pulp), and added together. The energy consumed when mixing the pulps as well as the energy used in the converting process shall be added as well.

Table 4 Reference values for electricity and fuel

Pulp grade	**$E_{ref,pulp}$ kWh/ADt**	**$F_{ref,pulp}$ kWh/ADt**
Integrated mills		
Chemical and semi-chemical pulp	800	5400
CTMP pulp	1800	900
Non-integrated mills ([1])		
Converting process	250	1800

(1) for non-integrated mills, the raw material pulp(s) shall comply with the values listed for integrated mills, to which the energy used during the conversion process should be added.

Assessment and verification:

The applicant shall provide the total electricity and fuel consumption, together with the calculations and related supporting documentation showing compliance with this criterion.

The applicant shall calculate all energy inputs, divided into heat/fuels and electricity used during the production of the pulp. If a mix of fluff pulps is used, the energy must be proportionally calculated to each fluff pulp. Energy used in the transportation of the raw materials is not included in the energy consumption calculations. The period for the calculations or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. 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.

Total electricity consumption E_{pulp} includes the net imported electricity coming from the grid and the internal generation of electricity measured as electric power. Electricity used for wastewater treatment shall not be included.

Total fuel consumption F_{pulp} includes all purchased fuels, the heat energy recovered by incinerating liquors and waste from on-site processes (e.g. wood waste, sawdust, liquors, etc.), as well as the heat recovered from the internal generation of electricity. However, the applicant only needs to count 80 % of the heat energy from such sources when calculating the total heat energy.

Where steam is generated using electricity as the heat source, the heat value of the steam shall be calculated, then divided by 0,8 and added to the total fuel consumption.

Rationale of the proposed criterion text

The pulp and paper industry is the fourth largest industrial user of energy and the second industrial electricity consumer in Europe[69]. The energy required for paper production is comparable to that of cement or steel[70], and in 2020 it was estimated to represent 4% of total EU consumption.

During the revision process, stakeholders commented that the criteria for fluff pulp production should not only focus on CO_2 emissions, but should include measures oriented to also reduce the energy use. For this reason, it was proposed to add a new sub-criterion setting specific limits on the consumption of electricity and fuel during the production of fluff pulp.

The structure of the criterion is in line with the EU Ecolabel criteria for tissue, tissue paper and tissue paper products[71]. However, the limit values and the reference values were aligned with the Nordic Swan criteria for sanitary products[72]. Indeed, the manufacture and fluffing process for fluff pulp consume more energy than the one for tissue products, as the product needs to be dried to 95% dry matter content; and this was taken into account in the Nordic Swan limits. In this way it is intended to strengthen the harmonisation between different schemes, while setting ambitious but achievable limits for companies.

69 CEPI (2021) Fit for 55' package: how to unleash the European pulp and paper industry's decarbonisation potential?, Position paper

70 Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L. (2015) Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control)

71 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. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019D0070

72 Nordic Ecolabelling for Sanitary Products, Version 6.8, 14 June 2016 - 30 June 2024. https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=023

5.3 CRITERION 2 for Absorbent Hygiene Products: Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

5.3.1 Sub-criterion 2.1 – Sourcing of man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

Annex I: Final proposal for sub-criterion 2.1: Sourcing of man-made cellulose fibres

This criterion applies to man-made cellulose fibres that represent ≥ 1% w/w of the final product.

2.1. Sourcing of man-made cellulose fibres

All (100%) dissolving pulp suppliers shall hold valid chain of custody certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent.

A minimum of 70% of the raw materials used for the production of the dissolving pulp 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 raw materials used for the production of the dissolving pulp shall be controlled wood 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 the chain of custody and/or Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

Dissolving pulp produced from cotton linters shall meet criterion 3.1 for cotton (sourcing and traceability).

Assessment and verification:

The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the suppliers of all (100%) dissolving pulp used in the product. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.

In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70% of the raw materials used for the production of the dissolving pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel license. Competent bodies shall check the accounting documents again twelve months after the awarding of the EU Ecolabel license.

If man-made cellulose fibres are used in an air-laid or other nonwoven materials, the air-laid or other nonwoven material supplier or the air-laid or other nonwoven material producer shall allocate credits to the air-laid or other nonwoven materials delivered to the product, providing invoices to support the number of credits allocated.

For the remaining proportion of raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30% and that it is controlled material 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.

Rationale for the proposed criterion text

This criterion aims to ensure that wood raw materials used for the manufacture of man-made cellulose fibres (MMCF) used in EU ecolabelled absorbent hygiene products are managed in an environmentally and socially viable manner.

Man-made cellulose fibres, also known as regenerated cellulose fibres are produced by the chemical sulphite pulping process, more specifically by the dissolving pulp process. By far, the most common MMCF is viscose fibre[73].

The sulphite process can be differentiated from the chemical pulping technology (i.e. with regards to the pH of the process or the chemical base used) and according to the products manufactured (i.e. paper pulp or viscose pulp). According to the Best Available Techniques Reference Document (BREF) for the Production of Pulp, Paper and Board, the pulp grades can be divided into three main groups: pulp for papermaking (acid bisulphite, magnefite pulp), dissolving pulp for textile production and speciality pulp for chemical applications[74]. The so-called dissolving pulp process for textile production is the process also used for the MMCF used in AHP.

Dissolving pulp manufacturing is similar to the manufacturing of sulphite pulp used for paper manufacturing; the same chemicals are used with the chemicals and energy recovery system operating in a similar way. However, major differences are found in the cooking and bleaching steps. In dissolving pulp manufacturing, the aim is to achieve a low viscosity, i.e. a short molecule chain in the cellulose, which is adjusted in the cooking and bleaching (as explained in the BREF on the production of pulp, paper and board). Dissolving pulp requires longer fibres, a higher level of quality control and more feedstock than paper pulp. It is produced using eucalyptus or beech and bamboo in western Europe and China respectively.

In general, dissolving sulphite pulp involves a combination of delignification and finishing. An example summarised in the BREF for production of pulps explains how in the Lenzing plant (Austria), for the manufacturing of viscose, the delignification of hardwood (beech) brings down the kappa number before bleaching (TCF). The three bleaching stages (oxygen and peroxide with alkaline extraction followed by ozone and then peroxide again) bring the kappa number down to reach a cellulose content of over 90%. The major sources of water pollution are the bleach plant and the condensates from the evaporation plant, where acetic acid and furfural are recovered as valuable products.

There are four main methods used to produce MMCF at an industrial scale: (i) the viscose process, which is applied to produce viscose and modal fibres; (ii) the lyocell process used to produce lyocell fibres (e.g. Tencel); (iii) the cuprammonium process in which cupro is manufactured; and (iv) the acetate process which is applied to produce cellulose acetate fibres[75].

During the revision process, the market for MMCF was studied. In 2020, the production volume of MMCF was around 6.5 million tonnes, which represents a market share of about 6% of the total fibre production volume and an 8% decrease with respect to 2019 due to COVID-19[76]. However, the market is projected to reach 8.5 million tonnes by 2027, growing at a CAGR of 4.3% over the analysed period (2020-2027)[77]. Main producers of MMCF are China, India, the US, Japan and South Africa. European production of MMCF is concentrated in Germany and Austria.

Textile Exchange reports a clear growth of the MMCF market, the global production volume of which has more than doubled in the last 30 years (from 3 million tonnes in 1990 to 6.5 million tonnes in 2020)[76]. The majority of MMCF being produced corresponds to viscose (with a market share of around 80% or 5.2 million tonnes manufactured in 2020). Acetate had a market share of around 13% (0.9 million tonnes), lyocell around 4% (production volume of 0.3 million tonnes), modal 3% (0.2 million tonnes) and cupro 0.2%. The MMCF are primarily produced from wood while less than 1% is currently made from recycled fibres (and currently not considered for AHP applications).

According to data received from competent bodies from their license holders, MMCF are used in feminine care only (menstrual pads, tampons and panty liners). Percentages of MMCF vary within the products from around 10% to 30%.

In terms of market share, the two most significant Sustainable Forestry Management Systems are those operated by the Forestry Stewardship Council (FSC) and the Programme for the Endorsement of Forestry

[73] European Man-made Fibres Association https://www.cirfs.org/

[74] Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

[75] Shen, L and M.K.Patel, Life cycle assessment of man-made cellulose fibres, Utrecht University, Lenzinger Berighte 88 (2010) 1-59.

[76] Preferred Fiber & Materials Market Report 2021 Textile Exchange, https://textileexchange.org/

[77] Cellulosic Man-Made Fibers - Global Market Trajectory & Analytics. April 2021. Available at: www.researchandmarkets.com

Certification (PEFC). During the previous revision of the AHP EU Ecolabel criteria in 2014, the percentage of SFM-certified MMCF was aligned with the recently voted EU Ecolabel criteria for Textiles to a value of 25% and in line with the proposal for fluff pulp[78]. A publication in relation to the market share of FSC and/or PEFC certification for MMCF reports an increment to around 55-60% of all MMCF in 2020[79]. Moreover, European producers of MMCF report the utilisation of wood that is certified according to FSC and PEFC standards[80,81]. For instance, a MMCF manufacturer outside Europe claimed that over 75% of all their wood-based raw material is sourced from FSC or PEFC (including SFI) certified forests in 2021[82], while other manufacturers show commitments to sustainable sourcing with certifications already in place (no information on percentages achieved)[83].

As explained in the rationale for fluff pulp, it should be mentioned that, currently, the regulatory framework with respect to forestry-related products in the EU is being revised. The 'New EU Forest Strategy for 2030'[84] defines the priorities of European forest management in the coming years, promoting the reuse and recycling of long-lived wood-based materials, without however setting binding requirements for the industries. At the time of writing this report, the Commission has proposed a Regulation on land use, forestry and agriculture, which should set an overall EU target for carbon removal by natural sinks[85]. Finally, the European Commission recently proposed a Regulation to contrast EU-driven deforestation and forest degradation[86].

After three stakeholder consultations, **the SFM threshold was increased from 25% to 70%**. This represents a good compromise between the availability of the market and the objective of sustainably managed forests contributing to a wealthy environment, economy and society, as well as being a step in the direction of 100% SFM certified fibres. FSC and PEFC are mentioned in the Assessment and Verification as certification schemes accepted as means of verification; however, other schemes can be accepted if deemed equivalent.

In this sense it is also important to point out that, in the context of the Deforestation Regulation, certification (e.g. via schemes such as FSC and PEFC) does not equate to compliance with the soon-to-be-adopted Regulation requirements. While certification can help operators to meet requirements, gaps and weaknesses exist and most scheme standards have gaps in their legality definitions[87]. In this respect, the new EU Forest Strategy for 2030 mandates the Commission to develop a voluntary certification scheme for closer to nature forestry, subject to an impact assessment. The voluntary certification will build on the Commission guidelines in preparation for closer to nature forestry. At this stage, it is expected that the guidelines will be finalised by the end of 2022, while the work on the closer to nature certification should start in 2023.

Moreover, while it would have been very pertinent to make sure that EU Ecolabel criteria comply with deforestation-free requirements, the upcoming Regulation on deforestation will be binding in requiring operators and traders placing a wood or its derivate product on the EU market to perform due diligence to ensure that their products are deforestation-free, applying also to EU Ecolabel products.

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78 Cordella, M. and Wolf, O., Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products") Technical Report – final. European Commission, Joint Research Centre, 2014. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/contentype/product_group_documents/1581682328/Technical%20Report%20AHP%20-%20final.pdf

79 Preferred Fiber & Materials Market Report 2021 Textile Exchange, https://textileexchange.org/

80 Lenzing Group, Responsible wood and pulp sourcing https://www.lenzing.com/sustainability/production/resources/wood-and-dissolving-wood-pulp

81 Kelheim Fibres GmbH, RESPONSIBLE EXPLOITATION OF WOOD https://kelheim-fibres.com/en/sustainability/wood-fibres/

82 Sappi Group sustainability report, 2021 https://cdn-s3.sappi.com/s3fs-public/2021-Sappi-Group-Sustainability-Report-5.pdf

83 Sateri Group, Sustainability and Certifications https://www.sateri.com/sustainability/certifications/

84 COM(2021) 572 final, New EU Forest Strategy for 2030.

85 COM/2021/554 final, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2018/841 as regards the scope, simplifying the compliance rules, setting out the targets of the Member States for 2030 and committing to the collective achievement of climate neutrality by 2035 in the land use, forestry and agriculture sector, and (EU) 2018/1999 as regards improvement in monitoring, reporting, tracking of progress and review.

86 Proposal for a Regulation of the European Parliament and of the Council on the making available on the Union market as well as export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010, COM(2021) 706 final

87 Report: Study on Certification and Verification Schemes in the Forest Sector and for Wood-based Products, https://op.europa.eu/en/publication-detail/-/publication/b67b91af-efcd-4b46-87c6-c4f4d23448b8/language-en/format-PDF/source-search

5.3.2 Sub-criterion 2.2 – Bleaching of man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

Annex I: Final proposal for sub-criterion 2.2: Bleaching of man-made cellulose fibres
This sub-criterion does not apply to totally chlorine free (TCF) bleached pulp. 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 AOX and organically bound chlorine (OCl) shall not exceed the following: — 0,140 kg/ADt, measured in the wastewater from pulp manufacturing (AOX); and — 150 ppm, measured in the finished man-made cellulose 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 (if possible) showing compliance with both the AOX and the OCl requirements, using the appropriate test method: — For AOX: ISO 9562 or the equivalent EPA 1650C; — For OCl: ISO 11480. Frequency of measurement for AOX shall be set in accordance with the criterion 1.2 for fluff pulp. In case the applicant could not provide the actual value of AOX level measured in the wastewater from pulp manufacturing, a corresponding declaration of compliance signed by the pulp manufacturer, in accordance with the exposed requirement, shall be provided. In case the applicant does not use any ECF pulp, a corresponding declaration is sufficient.

Rationale for the proposed criterion text

This sub-criterion aims at minimising negative effects on the environment and on human heath from emissions occurring during the production of man-made cellulose fibres; specifically, this sub-criterion sets requirements for ECF (elemental chlorine free) bleaching of the pulp used for MMCF.

In the current criteria in place (from 2014), applicants are requested to comply with either one of the limits, i.e. AOX or OCl. In early discussions for the current revision, it was proposed to make **both** requirements **compulsory** and to **tighten the AOX** limit in line with the fluff pulp sub-criterion.

The sub-criterion refers to the parameter 'AOX' as a sum of all Adsorbable Organic Halogens in the wastewater. It is the measurement of the total amount of halogens (chlorine, bromine and iodine) bound to dissolved or suspended organic matter in a wastewater sample.

According to the Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board[88], in European sulphite pulp mills, bleaching is carried out without the use of molecular chlorine (Cl_2). Except for two pulp mills that manufacture elemental chlorine free (ECF) pulp, all sulphite mills in Europe for dissolving pulp are totally chlorine free (TCF) pulp mills. For ECF bleached sulphite pulp, chlorine dioxide (ClO_2) is used as a bleaching chemical in one or more bleaching stages combined with the application of hydrogen peroxide in other bleaching stages.

[88] Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

The Lenzing Group Sustainability Report from 2019[89] indicates that their two dissolving wood pulp mills (sulphite process) in central Europe are equipped with the totally chlorine free (TCF) bleaching process. On the other hand, Lenzing reports that other European mills, as well as South African and US mills where the pulping process is either kraft or sulphite, bleaching is performed via the elemental chlorine free (ECF) process. There are no data on values of AOX/OCl reported.

The BAT Reference Document for the Production of Pulp, Paper and Board also provides data on the AOX emissions for European dissolving wood pulp plants, with a figure of 0.0015 kg AOX/ADt (data only for one mill shown in Tables 4.9 and 4.10 and in Figure 4.28 of the referenced document).

The parameter 'OCl' (organically bound chlorine) is a measure of chlorine compounds in a material or product; it can be decreased by improving delignification during pulping, with a proper washing of the pulp before bleaching, using substitutes for chlorine or avoiding over chlorination (by efficient mixing of chlorine added to pulp or using several smaller additions of chlorine to avoid localised high chlorine concentrations)[90].

As the majority of MMCF is produced in the Asia or North America, their AOX emissions should also be examined. However, a US data analysis could not be performed due to the lack of public data. Sateri Fibre Co.[91] conducted an EU BAT Assessment in 2021[92] and, although it was stated that '*There were no gaps identified against EU BAT in the data for the assessment period between June 2020 to May 2021*', AOX or OCl data were not made public or reported in their Sustainability Report for 2020[93].

The AOX limit was decreased from 0.17 kg AOX/ADt (in the current Commission Decision) to **0.14 kg AOX/ADt** while OCl was kept **< 150 ppm**.

[89] Lenzing Group, Sustainability Report (2029), available at: https://www.lenzing.com/?type=88245&tx_filedownloads_file%5bfileName%5d=fileadmin/content/PDF/04_Nachhaltigkeit/Nachhaltigkeitsberichte/EN/NHB_2019_EN.pdf

[90] Pratima Bajpai, Chapter 15 - Environmental Impact, Editor(s): Pratima Bajpai, Biermann's Handbook of Pulp and Paper (Third Edition), Elsevier, 2018, Pages 325-348, ISBN 9780128142387, https://doi.org/10.1016/B978-0-12-814238-7.00015-5

[91] https://www.sateri.com/

[92] https://www.sateri.com/wp-content/uploads/2021/08/eu-bat-assessment-report-en-sjs-2021.pdf

[93] https://www.sateri.com/wp-content/uploads/2021/08/sateri-sustainability-report-2020-en.pdf

5.3.3 Sub-criterion 2.3 – Production of man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

Annex I: Final proposal for sub-criterion 2.3: Production of man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

(a) More than 50 % of dissolving 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:

(i) generating on-site electricity and/or steam, or

(ii) manufacturing chemical co-products.

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

Table 5. Viscose and modal fibres emission values

Fibre type	Sulphur emissions to air — Limit value (g /kg)	Zinc emissions to water — Limit value (g/kg)	COD emissions to water — Limit value (g/kg)	SO_4^{2-} emissions to water — Limit value (g/kg)
Staple fibre	20	0,05	5	300
Filament fibre				
— Batch washing	40	0,10	5	200
— Integrated washing	170	0,50	6	250

Note: Limit values are expressed as annual average. All values are expressed as g of pollutant/kg of product.

Assessment and verification:

(a) The applicant shall provide supporting documentation and evidence that the required proportion of dissolving pulp suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at the related production sites. The list of such dissolving pulp suppliers shall also be provided.

(b) In relation to test methods:

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

(ii) Sulphur emissions to air: use method defined in EN 14791, EPA no. 8, 15A, 16A or 16B or DIN 38405-D27.

(iii) Zinc emissions to water: use method defined in EN ISO 11885.

(iv) COD measurements in water: use method defined in ISO 6060, DIN ISO 15705, DIN 38409-01 or DIN 38409-44.

(v) SO_4^{2-} (sulphates) emissions to water: use method defined in ISO 22743.

(vi) Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an

independent third-party shall be accepted.

(vii) The detailed documentation and test reports shall include an indication of the measurement frequency for S, Zn, COD and SO_4^{2-}. The minimum measurement frequency, shall be weekly for COD, S, Zn and SO_4^{2-}, in addition to any measurements stipulated in the regulatory requirements.

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 man-made cellulose fibres.

In the current sub-criterion in force, limitations to **sulphur emissions to air** are the only possible limitation to a fast uptake by the market.

As a result of the investigations during the revision process, thresholds for emissions to water of Zn, COD and SO_4^{2-} were set.

According to the Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board[94], in sulphite pulp mills producing dissolving pulp, a number of aspects differ from the pulping for papermaking regarding consumption and emission levels:

- the wood input is generally higher (around 2.6 bone dry tonnes of wood/ADt of pulp is used in a mill due to the lower yield);
- the dosage of NaOH is also higher in order to achieve purified pulp with a high alpha-cellulose content;
- the usage of second-hand caustic from the viscose plant is common; and
- in relation to the energy balance, the pulp mill generates its own energy, delivering the excess to the viscose fibres mill.

The emissions to water in dissolving pulp mills can originate from different processes, mainly washing losses, effluents from the bleach plant and condensates from the evaporation plant, while major point sources for emissions to air are the recovery boiler, the bark or biomass boiler and other steam blocks for steam production; however, potential releases of emissions to air from a number of processes are also to be taken into account.

Emissions for staple and filament fibres

This sub-criterion sets requirements for staple and filament fibres. It is worth noting that Best Available Techniques or BAT only exist for staple fibres, as explained in the BREF for the Production of Polymers[95]. As explained in this document, about 85% of the total viscose fibre production is produced as staple fibres while about 15% is produced as filament fibres. The main difference between staple and filament is the length of the fibres. As the BREF states, staple fibres are cut into short pieces of approximately 4 cm after the spinning bath, which are later spun into textile yarns or processed into nonwoven products (as for AHP). On the other hand, filament yarns are spun into endless fibres, which can be used immediately.

The reference values used for the new proposed requirements for staple fibres are taken from Table 13.13 (page 302) from the cited Production of Polymers BREF. In this case, from the range of emissions provided for sulphur, Zn, COD and SO_4^{2-}, the highest value is taken as the cited table shows the BAT-associated emission and consumption levels for the production of viscose staple fibres.

In the case of filament fibres, there are no BAT-associated emission levels. The reference values used for the proposal are taken from the lower values summarised in Table 11.2 (page 208) on emission and consumption data for viscose staple fibre production.

94 Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

95 European Commission (2007) Reference document on best available techniques in the production of polymers. Available at: https://eippcb.jrc.ec.europa.eu/reference/production-polymers.

Metal emissions

Sulphite pulp mills have emissions of cadmium, chromium, copper, nickel, lead and zinc to water. For AHP, only a requirement for zinc emissions is relevant, as in Nordic Swan and Blue Angel.

A copper requirement would be relevant for the production of cupro fibre; however, a Nordic Swan background report indicates that cupro fibre is mainly used as a replacement for silk with no special relevance for AHP.

The indicated values for Zn emissions to water in viscose production (Table 5 in sub-criterion 2.3) are taken from the Production of Polymers BREF. Table 13.13 has been used for the requirement for viscose staple fibres. In contrast, viscose filament fibres emission levels are indicated in Table 11.2 of the cited BREF.

COD emissions

According to the Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board[96], COD emissions from sulphite pulp mills producing dissolving pulp are slightly higher from the pulping for papermaking.

As for Zn and sulphur emissions, the indicated values for COD emissions in viscose production (Table 5 in sub-criterion 2.3) are from the Production of Polymers BREF. Table 13.13 has been used for the requirement for viscose staple fibres while viscose filament fibres emission levels are indicated in Table 11.2 of the cited BREF.

Sulphur and sulphate emissions

From bilateral meetings with industry, it was found that carbon disulphide is already counted with the sulphur emissions to air, thus carbon disulphide (CS_2) to air cannot be measured separately.

Therefore, the sulphur emissions accounted for in Table 5 of sub-criterion 2.3 relate to SO_2, SH_2 and CS_2 emissions to air. Looking at Table 13.13 from the Production of Polymers BREF, it is indicated which BAT-associated emission level for the production of viscose staple fibres shall be reached. In the case of viscose filament fibres, emission levels are indicated in Table 11.2 of the same BREF. The sulphate emissions to water are also taken from the tables referred to.

[96] Suhr M., Klein G., Kourti I., Gonzalo M.R., Giner Santonja G., Roudier S., Delgado Sancho L., Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), 2015, available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf

5.4 CRITERION 3 for Absorbent Hygiene Products: Cotton and other natural cellulosic seed fibres

5.4.1 Sub-criterion 3.1 – Sourcing and traceability of cotton and other natural cellulosic seed fibres

Annex I: Final proposal for sub-criterion 3.1: Sourcing and traceability of cotton and other natural cellulosic seed fibres

This criterion applies to cotton and other natural cellulosic seed fibres that represents ≥ 1% w/w of the final product.

(a) All cotton and other natural cellulosic seed fibres shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007[97] and Regulation (EU) 2018/848 of the European Parliament and of the Council[98], the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the European Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton and other natural cellulosic seed fibres grown according to criterion 3.1(a) and used to manufacture absorbent hygiene product shall be traceable.

Tampon strings are exempted from complying with this requirement.

Assessment and verification:

(a) The organic content of cotton and/or other natural cellulosic seed fibres 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 and Regulation (EU) 2018/848, the US NOP or equivalent legal obligations set by other trade partners of the European Union. Verification shall be provided on an annual basis and for each country of origin.

(b) The applicant shall demonstrate compliance with the material content requirement for the annual volume of cotton and/or other natural cellulosic seed fibres purchased to manufacture the final product(s) and according to each product line, on an annualised basis. Transaction records or invoices documenting the quantity of cotton and/or other natural cellulosic seed fibres purchased on an annual basis from farmers or producer groups, and the total weight of certified bales shall be provided.

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 cultivation 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.

This criterion has not changed much compared to the Commission Decision currently in force. The main changes were the exemption of the tampon string from complying with the criterion on cotton, as the requirement on organic cotton may counteract the necessary strength requirements of the removal cords. This change is also in line with Nordic Swan requirements.

[97] 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 (OJ L 189, 20.7.2007, p. 1).

[98] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, PE/62/2017/REV/1 (OJ L 150, 14.6.2018, p. 1).

5.4.2 Sub-criterion 3.2 – Bleaching of cotton and other natural cellulosic seed fibres

Final proposal of sub-criterion 3.2: Bleaching of cotton and other natural cellulosic seed fibres
Cotton and other natural cellulosic seed fibres shall be bleached only using TCF technologies. This sub-criterion shall not apply to cotton linters used to produce dissolving pulp. **Assessment and verification:** The applicant shall provide a declaration from the supplier of cotton and/or other natural cellulosic seed fibres that TCF technologies are 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 the formation of dioxins and other highly carcinogenic pollutants).

Cotton, like all natural fibres, has some natural colouring matter, which confers a yellowish brown colour to the fibre. The purpose of bleaching is to remove this colouring material and to confer a white appearance to the fibre. As discussed in TR2.0 for the case of fluff pulp, many bleaching techniques exist depending on the material that needs to be bleached, the desired level of brightness and the environmental impacts related to the process. For cotton, the situation is different to that of fluff pulp, and oxygen peroxide (H_2O_2) is widely used as a bleaching agent, due to the fact that the effects of effluents on the environment are minimal[99] (as it decomposes to O_2 and H_2O), it is colourless and non-corrosive. It is also a very selective bleaching agent, causing less textile fibre damage compared to other bleaching systems, and tends to be less aggressive on fabric dyes, detergent enzymes and optical brighteners[100]. The main drawback of H_2O_2 is that, in order to be effective, alkaline conditions and suitably elevated temperatures of about 50 °C, but normally around 90-100 °C, are needed[101]. While practically all cotton produced is bleached, about 80-90% of all cotton fabrics are bleached with hydrogen peroxide[88,102,103].

The main change during the revision process is thus that only total chlorine free (TCF) technologies are allowed.

[99] P. Bajpai, Chapter Five - Hydrogen Peroxide Bleaching, In: Environmentally Benign Approaches for Pulp Bleaching (Second Edition), Elsevier, edited by P. Bajpai, 2012, ISBN 9780444594211, https://doi.org/10.1016/B978-0-444-59421-1.00005-3

[100] J. B.St. Laurent, F. de Buzzaccarini, K. De Clerck, H. Demeyere, R. Labeque, R. Lodewick, L. van Langenhove, B.1.I - Laundry Cleaning of Textiles, In: Handbook for Cleaning/Decontamination of Surfaces, Elsevier Science B.V., edited by I. Johansson and P. Somasundaran, 2007, ISBN 9780444516640, https://doi.org/10.1016/B978-044451664-0/50003-6

[101] Chapter 6: BLEACHING OF TEXTILES. Available here

[102] Evonik Industries AG, Mild bleaching agents and disinfectants: Hydrogen Peroxide and Peracetic Acid - Textile and laundry. Available at: https://active-oxygens.evonik.com/en/markets/textile

[103] Fibres2Fashion, Problems in Bleaching For Cotton Textile Material, available at: https://www.fibre2fashion.com/industry-article/7071/problems-in-bleaching-for-cotton-textile-material

5.5 CRITERION 4 for Absorbent Hygiene Products: Production of synthetic polymers and plastic materials

Annex I: Final proposal for criterion 4: Production of synthetic polymers and plastic materials

This criterion applies to each synthetic polymer and plastic material that represents ≥ 5% w/w of the final product and/or of the packaging.

Manufacturing facilities producing synthetic polymers and plastic materials used in the final product shall have systems for the implementation of:

(a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);

(b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and, recovery of waste fractions that cannot be prevented (including energy recovery);

(c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

Assessment and verification:

The applicant shall provide a declaration of compliance with the criterion from the suppliers of synthetic polymers and plastic materials used in the final product and/or the packaging. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/ or ISO 50001 for water, waste and energy plans.

If waste management is outsourced, the sub-contractor shall provide a declaration of compliance with this criterion as well.

Applicants registered with EU Eco-Management and Audit Scheme (EMAS) and/or certified according to ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme shall be considered as having fulfilled these requirements if:

(a) the inclusion of water, waste and energy management plans for the production site(s) is documented in the company's EMAS environmental statement; or

(b) the inclusion of water, waste and energy management plans for the production site(s) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme.

Rationale for the proposed criterion text

The aim of this criterion is to set general environmental practices that are carried out in the production of polymers and plastic materials, i.e. plans and/or measures aligned with water, waste and energy savings that shall be taken into account at the manufacturing sites of such polymers and plastic materials used in AHP and/or packaging. Indeed, plastics represent a significant share of the weight of AHP, either as a component of the product or as packaging.

In the previous revision process[104], a criterion promoting the use of synthetic polymers based on renewable materials was considered. Renewable materials are usually biomass from plants and in this case polymers are referred to as biobased. In relation to biodegradation, it is worth noting that some polymers derived from petrochemical sources can be biodegradable, while not all biobased polymers will biodegrade[105]. However, in the previous revision the promotion of non-biodegradable biobased polymers was not recommended**.** The rationale for the inclusion of biobased plastic materials will be explained within criterion 5.

After three stakeholder consultations, it is proposed to change the name of this criterion to 'production of synthetic polymers and plastic materials' in order to allow for the inclusion of different types of polymers under one criterion, while criterion 5 is related to 'biobased plastic materials'. Nevertheless, it is worth noting that biobased plastic materials also have to fulfil criterion 4.

The **variety of synthetic polymers and plastic materials** that can be used in AHP and/or the packaging include, among others, polyethylene (PE), polypropylene (PP), polyester (PET), polystyrene (PS), polyamide (PA), ethylene vinyl acetate (EVA) and polyether/polyurethane (e.g. elastane, spandex, foam)[106]. Given that there are many types of synthetic polymers and plastic materials that could be used in these products whose manufacturing processes are very different from each other, it is possible that normally this requirement is not event relevant. Therefore, it is proposed that this criterion shall apply to synthetic polymers and plastic material that represents **≥ 5% w/w of the final product and/or of the packaging**.

Discussions during the three stakeholder consultations were focused on whether this criterion is needed and can be fulfilled and, specifically, whether or not water is used in the production of polymers and plastic materials for AHP and/or packaging. More **details on the procedures to be included in the water, waste and energy plans** for sites producing synthetic polymers and plastic materials used in the final AHP and/or packaging were added.

The composition of absorbent hygiene products has seen an evolution in recent years. While disposable AHP were initially made from cellulose and cotton[107], recent developments evolved from the reduction of the content of natural wood fibres towards the inclusion of more synthetic polymers and plastic materials such as polypropylene (PP), low-density polyethylene (LDPE), or superabsorbent polymer (SAP)[108]. As indicated by Cordella et al. (2015), from 1987 to 2011, the average weight of baby nappies decreased by nearly 45%, mainly due to the reduction of the percentage of fluff pulp and the increment of SAP. The utilisation of SAP in baby nappies has increased from 1% to 37%; however, the percentage of materials sourced from fossil origins comes to a total of 63% (Table 3).

Table 3. Materials for average units of disposable baby nappies sold in Europe in 1987, 1995, 2005 and 2011

Material/ component	1987	1995	2005	2011
Fluff pulp (g)	52.8	37.4	14.1	13.2

[104] Cordella, M., Wolf, O., Schulz, M., Bauer, I., Lehmann, A., Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products"). Preliminary Report – Final. European Commission, Joint Research Centre, 2013. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/contentype/product_group_documents/1581682328/Prelim%20Report%20AHP%20-%20final.pdf

[105] Zhu, Y., Romain, C. & Williams, C. Sustainable polymers from renewable resources. Nature 540, 354–362 (2016). https://doi.org/10.1038/nature21001

[106] Nordic Swan Ecolabelled Sanitary Products, Background to ecolabelling, Version 6.8, 04 May 2021. Available at: https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=023

[107] Stanley A. Mothers and daughters of invention: Notes for a revised history of technology. Rutgers University Press; 1995. ISBN 0813521971, 9780813521978. Available at Google Scholar.

[108] Cordella, M., Wolf, O., Schulz, M., Bauer, I., Lehmann, A., 'Evolution of disposable baby diapers in Europe: life cycle assessment of environmental impacts and identification of key areas of improvement', Journal of Cleaner Production, Vol. 95, Elsevier, 2015, pp. 322-331. https://doi.org/10.1016/j.jclepro.2015.02.040

Material/ component	1987	1995	2005	2011
SAP (g)	0.7	5.1	13.2	11.1
Polypropylene (PP) (g)	4.1	4.5	7.0	5.8
Low density polyethylene (LDPE) (g)	4.2	3.8	2.6	2.2
Elastic (g)	1.3	1.6	1.7	1,0
Adhesives (g)	0.8	0.4	0.6	0.1
Others (e.g. tape, elastic back ear, other synthetic polymers) (g)	1.1	3.2	1.8	2.6
Total (g)	**65.0**	**56.0**	**41.0**	**36.0**

Adapted from Cordella et al., 2015

As defined in the Preliminary Report, SAP is a synthetic material derived from petroleum, manufactured by the polymerisation of acrylic acid with ammonium persulphate as an initiator that can absorb and retain huge quantities of liquids. It was reported that 1 kg of SAP can absorb up to 418 L of water and for this reason it is used to retain high amounts of fluids in baby, incontinence and menstrual products[109]. Polypropylene (PP) can be part of the absorbent core of these products or the main constituent of the microporous barrier that prevents the fluid from leaking. Usually LDPE is used in the packaging in either sales or grouped packaging and the separate component (individual wrapping of the AHP). All in all, the number of synthetic polymers and plastic materials within AHP can be over 60%. Also the LCA screening study included in the PR (and in the updated version published in May 2022) evaluating a baby nappy and a single-use menstrual pad indicated that the highest contributions to the environmental impacts were:

- for baby diapers: PP granulates, and polyester resin (proxy for adhesives), acrylic acid, acetic acid, and electricity used in SAP production, as well as LDPE packaging;
- for sanitary towels: PET and PP granulates, viscose, polyester resin (proxy for adhesives), and LDPE packaging.

It is reported that about 185 L of water are needed to make a kg of plastic[110]. In fact, the production of plastics is related to water consumption and pollution[111] while resultant wastewaters have the potential for high loads of organic compounds[112].

Another key environmental impact of the polymer sector is **energy** demand,[113] as the extraction of raw materials and chemical synthesis of polymers and additives have high energy consumption, being mostly sourced from fossil oil or gas[114]. In addition, large quantities of spent solvents and non-recyclable **waste** are produced by the plastic industry,[115] while leakage and spills from transport of virgin plastic around the world are one of the most common forms of plastic pollution[116].

[109] Bachra., Y., Grouli, A., Damiri, F., Bennamara, A. and Berrada, M. 'A new approach for assessing the absorption of disposable baby diapers and superabsorbent polymers: A comparative study', Results in Materials, Vol. 8, Elsevier, 2020, pp. 100156. https://doi.org/10.1016/j.rinma.2020.100156

[110] Barra et al. 2018. Plastics and the circular economy. Scientific and Technical Advisory Panel to the Global Environment Facility. Washington, DC. Available at: https://www.thegef.org/sites/default/files/publications/PLASTICS%20for%20posting.pdf

[111] 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.

[112] BREF for the production of polymers. Article 16(2) of Council Directive 96/61/EC. https://eippcb.jrc.ec.europa.eu/reference/production-polymers

[113] BREF for the production of polymers. Article 16(2) of Council Directive 96/61/EC. https://eippcb.jrc.ec.europa.eu/reference/production-polymers

[114] Plastic & Climate. The hidden cost of a plastic planet. 2019. Available at: www.ciel.org/plasticandclimate

[115] BREF for the production of polymers. Article 16(2) of Council Directive 96/61/EC. https://eippcb.jrc.ec.europa.eu/reference/production-polymers

[116] Plastic & Climate. The hidden cost of a plastic planet. 2019. Available at: www.ciel.org/plasticandclimate

All in all, synthetic polymers and plastic materials represent a significant share of the weight of AHP and/or packaging, with trends showing the increasing importance of this group of materials but also them being environmental hotspots as the LCA study pointed out.

5.6 CRITERION 5 for Absorbent Hygiene Products: Biobased plastic materials – NEW

Annex I: Final proposal for criterion 5: Biobased plastic materials

This criterion applies only to the final product, separate components, and/or packaging that contain > 1% w/w of biobased plastic material.

The applicant may source, on a voluntary basis, a certain percentage of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final product (including super absorbent polymers (SAP)), the separate components and/or in the packaging, from biobased raw materials. Circular economy principles shall guide the selection of feedstocks (as an example, producers shall prioritise the use of organic waste and by-products as feedstock) [1].

In this case, the following shall apply:

(a) The superior environmental profile of the biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be demonstrated in compliance with the latest applicable methodologies to assess the impacts of biobased plastics compared to fossil-based plastics [2].

(b) Biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be covered by chain of custody certificates issued by an independent third-party certification scheme officially recognised by the European Commission [3].

The final product, separate components, and/or packaging may be voluntarily labelled as containing biobased plastic. In this case, the claim shall be that 'x % of plastic contained in the product [separate components, and/or packaging] is biobased' (where x >1, and x is the exact and measurable share of biobased plastic content in the product [separate components, and/or packaging]). Generic claims such as 'bioplastics', 'biobased', 'plant-based', 'natural-based' and similar shall not be used.

Assessment and verification:

(a) To demonstrate the superior environmental profile of the biobased plastic raw materials used in the product, separate components, and/or packaging, the applicant shall provide an independent third-party certification that refers to the methodology currently available [4].

(b) The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the suppliers of all biobased plastics raw materials used in the product, separate components, and/or packaging. The chain of custody certificates shall be valid for the whole duration of the EU Ecolabel license. Competent bodies shall check the certificates again twelve months after the awarding of the EU Ecolabel license.

Where applicable, the applicant shall provide a high resolution photograph of the sales packaging, where information regarding the biobased plastic claim appears clearly. The standards based on radiocarbon methods such as EN 16640 or EN 16785 or ASTM D 6866-12 shall be used to determine the biobased carbon content of the synthetic polymers and plastic materials present in the product, separate component, and/or packaging. When radiocarbon methods cannot be used, the mass balance method is allowed if a high level of transparency and accountability is ensured and supported by agreed standards.

The use of purchased certificates based on the Book & Claim system is excluded so that the traceability of the biobased plastic raw materials is possible. The proofs of purchase for the biobased plastic raw materials shall be based on processes according to the segregation or mass balance systems.

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.

Notes:

[1] In line with the Communication from the European Commission on EU Policy Framework on biobased, biodegradable and compostable plastics. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0682&qid=1680246180511

[2] Latest methodologies are the framework developed by the Commission's Joint Research Centre, referred to as the 'Plastics LCA method' available at https://publications.jrc.ec.europa.eu/repository/handle/JRC125046

or Commission Recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials available at https://research-and-innovation.ec.europa.eu/system/files/2022-12/Commission%20recommendation%20-%20establishing%20a%20European%20assessment%20framework%20for%20safe%20and%20sustainable%20by%20design.PDF

[3] In line with the sustainability requirements related to the sourcing of biobased raw material as per the review of the Renewable Energy Directive (RED III). The certification schemes officially recognised by the European Commission are available at: https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en

[4] Methodology currently available as explained before.

Rationale for the proposed criterion text

This criterion was added after a comprehensive analysis of current polymer and plastic production trends. The utilisation of available biological resources ready to be acquired which would avoid dependency on fossil resources is an advantage.

As explained in criterion 4, in the previous revision process[117] a criterion promoting the use of synthetic polymers based on renewable materials was considered. Although in the previous revision the promotion of non-biodegradable biobased polymers was not recommended, at this stage it was deemed appropriate to include a criterion on biobased plastic materials where proof of their environmental superiority is to be provided by the applicants. The potential benefits of non-biodegradable biobased polymers such as BioPE and BioPET was explored in the Preliminary Report for AHP (from September 2021)[118].

Some LCA for bio-plastics, biopolymers and especially bioSAP have shown a lower carbon footprint. So if these materials can prove an environmental benefit, they must be fostered through the EU Ecolabel criteria. As the benefit of alternative resources in relation to traditional fossil sources is still very dependent on the origin, type or manufacturing method of the selected biobased plastic, a careful evaluation must be carried out.

During the revision process, the discussion around the criterion on synthetic polymers and plastic materials was very much focused on the inclusion of recycled, biobased and/or biodegradable plastic materials. Most comments and discussions pointed to the possibility of a criterion on biobased plastic materials. As a result, a new criterion shaped through the different exchanges in the EUEB meetings, AHWG meetings and bilateral discussion with relevant stakeholders is proposed.

From the introduction of this criterion on biobased plastic materials, there was a consensus amongst stakeholders on the possibility of making it voluntary. The discussions in relation to the inclusion of this criterion mainly touched upon the actual sustainability, market supply and lack of traceability of these materials.

In all cases, when used, biobased plastic materials shall also comply with criterion 4.

The main topics of discussion addressed during the revision process are summarised below.

Given the discussions and comments received during the revision process, this criterion on biobased plastic materials has been set as **voluntary**. The percentage of biobased plastic materials is left open for each applicant to add the quantity that best relates to their product. However claims can only be made under certain conditions (> 50% w/w). It is worth noting that the criterion is optional although strict requirements are to be fulfilled if it is decided to use biobased plastic material.

[117] Cordella, M., Wolf, O., Schulz, M., Bauer, I., Lehmann, A., Development of EU Ecolabel Criteria for Absorbent Hygiene Products (formerly referred to as "Sanitary Products"). Preliminary Report – Final. European Commission, Joint Research Centre, 2013. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/contentype/product_group_documents/1581682328/Prelim%20Report%20AHP%20-%20final.pdf

[118] More information in the PR. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2021-09/Absorbent%20Hygiene%20Products_Draft%20Preliminary%20report_FINAL.pdf

LCA of biobased plastic materials

The LCA screening study clearly showed that SAP and other polymers represented the main hotspots where focus shall be put to minimise the environmental impact of AHP.

Fostering sustainable biobased plastic materials as an alternative to plastic from fossil resources is proposed as a starting point, as biobased plastic production phases could present lower impacts in certain environmental categories compared to petrochemical plastics. Another advantage would be the lower dependence on non-renewable fossil resources. Also, action 1.6 from the EU Bioeconomy Strategy[119] promotes the development of substitutes to fossil resources, in particular biobased, recyclable and marine-biodegradable substitutes for plastic. It mentions the potential that biobased plastic materials have in relation to job creation, particularly in rural and coastal areas.

Some LCA studies show lower GHG emissions for biobased plastic materials; however, there are large variations depending on the biobased plastic type, feedstock and manufacturing process. It is also necessary to add the huge variation as a result of the different system boundaries conditions chosen[120]. This results in a limited comparability of studies in relation to biobased plastics and also their fossil-based counterparts.

In any case, it should be considered that switching to biobased materials does not equate to greater sustainability as trade-offs, e.g. in terms of land use change, must be taken into account.

The bioplastics' market

According to the latest updated market data compiled by European Bioplastics and the nova-Institute, global bioplastics production capacities are set to increase from around 2.22 million tonnes in 2022 to approximately 6.29 million tonnes in 2027. Hence, the share of bioplastics in global plastic production will overcome the current 1% level. Global production capacities of biobased plastics and forecast are pictured in the following figure.

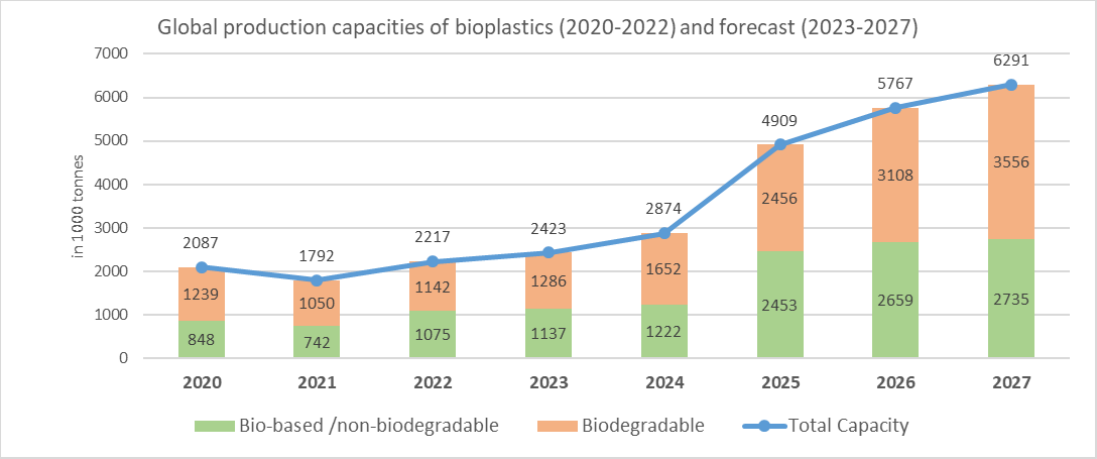

Figure 3. Global production capacities of bioplastics (2020-2022) and forecast (2023- 2027)

Source: Adapted from European Bioplastics, nova-Institute (2022)[121]

Nowadays, the vast majority of biobased plastics are produced from cultivated crops; still they currently account for less than 0.04% of global biomass consumption. Due to higher feedstock prices, biobased plastics are usually more expensive than fossil-based plastics (20% to >100%), thus being the main burden for their application[122].

119 COM (2018)673. https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:52018DC0673

120 Spierling, S., et al. Bio-based plastics - A review of environmental, social and economic impact assessments, Journal of Cleaner Production, Volume 185, 2018, Pages 476-491, ISSN 0959-6526, https://doi.org/10.1016/j.jclepro.2018.03.014 .

121 European Bioplastics and nova-Institute, available at: https://www.european-bioplastics.org/market/ (accessed 03/01/2023)

122 DG ENV, 2022. Confidential study: 'Biobased plastic: sustainable sourcing and content. Final report'. Framework Contract ENV/F1/FRA/2019/0001, Economic Analysis of Environmental Policies and Analytical Support in the Context of Better Regulation.

EC Communication on biobased, biodegradable and compostable plastics

The European Commission recently published a policy framework aiming to contribute to a more sustainable plastic economy. The '**Communication from the EC – EU policy framework on biobased, biodegradable and compostable plastics**'[123] indicates that a possible alternative aligned to reduce GHG emissions, waste generation, littering and derived pollution from fossil-based and non-biodegradable plastics (currently dominant) could be the use of biobased plastics, but considering their whole life cycle. This Communication aims to fill possible gaps and does so by setting orientations to be used by EU policies addressing these plastics in the future.

Biobased plastics (BBP) and biodegradable and compostable plastics (BDCP) have been highlighted as having the potential to have advantages over fossil-based, non-biodegradable plastics. However, the effective sustainability of BBP and BDCP compared to conventional plastics needs to be carefully assessed. In fact, for biobased plastics to provide genuine environmental benefits, they need to comply with sustainability criteria. In this vein, a suitable LCA-based method to compare biobased and fossil-based plastics is needed, based on the Plastics LCA method[124]. The main challenge is the accounting of biogenic carbon uptake and release from products, i.e. the atmospheric carbon incorporated into products during their lifespan. Unfortunately, consensus does not exist across different standards and in the scientific literature on whether and how to account for the biogenic carbon uptake and emissions for products including bio-based plastics. The discussion is ongoing in the context of the UN Life Cycle Initiative[125].

It should be noted that **it is not the intention of this criterion to label the AHP as biobased** (without further specifications) or to call the product "biobased", but to add a certain percentage of biobased plastic materials in order to make a first step in the direction of **including biobased sources**.

The cited 'Communication from the EC on EU policy framework on biobased, biodegradable and compostable plastics' recommends communicating the actual share of biobased content of a product (or packaging); **to avoid misleading consumers, claims should only refer to the exact and measurable share of biobased plastic content in the product**. Therefore, **the EU Ecolabel for AHP has proposed to follow this approach**. Also, the method to measure the biobased content shall be **radiocarbon-based** when possible, as developed by the CEN/TC 411 for bio-based products.

In this Communication document, it is explained that the reference to the share of the end-products that is sourced from biobased materials, known as mass balance method, is not suitable to certify the actual share of biobased content of the product. Nevertheless, if the mass balance method is used in order to reduce administrative burden, a high level of transparency and accountability should be ensured and supported by agreed standards to avoid greenwashing.

It is advised to ban the environmental claims **'bioplastics', 'plant-based', 'natural-based' and similar** for products as they are considered too generic, while the generic environmental claim '**biobased**' **should also be banned if it is not further specified.**

This Communication also advises on how to measure the superior **environmental profile of the biobased raw materials** used for the production of biobased plastic. On the one hand, it is recommended to use the **latest applicable methodologies to assess the impacts of biobased plastics compared to fossil-based plastics**, which are currently considered to be the framework developed by the Commission's Joint Research Centre, referred to as the 'Plastics LCA method'[126] or the Commission Recommendation establishing an European assessment framework for 'Safe and Sustainable by Design' chemicals and materials[127] derived from the Chemical Strategy for Sustainability.

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123 European Commission, 2022. Communication from the EC on EU Policy Framework on biobased, biodegradable and compostable plastics. Available at: https://environment.ec.europa.eu/publications/communication-eu-policy-framework-biobased-biodegradable-and-compostable-plastics_en

124 Nessi, S., Sinkko, T., Bulgheroni, C., Garcia-Gutierrez, P., Giuntoli, J., Konti, A., Sanye Mengual, E., Tonini, D., Pant, R., Marelli, L. and Ardente, F., Life Cycle Assessment (LCA) of alternative feedstocks for plastics production, EUR 30725 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-38144-0, doi:10.2760/693062, JRC125046. Available at: https://publications.jrc.ec.europa.eu/repository/handle/JRC125046

125 UN Environment Life Cycle Initiative https://www.unep.org/explore-topics/resource-efficiency/what-we-do/life-cycle-initiative

126 'Plastics LCA method' available at https://publications.jrc.ec.europa.eu/repository/handle/JRC125046 or

127 Commission Recommendation of 8.12.2022 establishing an European assessment framework for 'safe and sustainable by design' chemicals and materials available at https://research-and-innovation.ec.europa.eu/system/files/2022-

On the other hand, the Communication advises that biobased plastics must meet the **EU sustainability criteria for bioenergy for non-GHG emissions**, meaning that biobased raw materials used for the production of biobased plastic must be sourced in a sustainable form avoiding negative impacts on biodiversity, ecosystems or land and water use. This request is adapted to EU Ecolabel, demanding biobased raw materials to be covered by chain of custody certificates issued by an independent third-party certification scheme. The **certification schemes shall be the ones officially recognised by the European Commission**[128]. In line with the sustainability requirements related to the sourcing of biobased raw material as per the review of the Renewable Energy Directive (RED III), the certification schemes officially recognised by the European Commission for biobased plastics would be: Better Biomass, Bonsucro EC, International Sustainability and Carbon Certification (ISCC EU), REDcert, Round Table on Responsible Soy EU RED (RTRS EU RED) and Sustainable Biomass Program (SBP)[129]. Finally, the Communication indicates that producers should prioritise the use of organic waste and by-products as feedstock for biobased plastic material.

Standards

Recently, the series EN ISO 22526, prepared by Technical Committee ISO/TC 61, Plastics, Subcommittee SC 14, Environmental aspects, developed standards on the evaluation of the environmental footprint of plastics, i.e. the series is called 'Plastics - Carbon and environmental footprint of bio-based plastics'. It is applicable to plastic products and plastic materials, polymer resins, which are based on bio-based or fossil-based constituents. There are three parts[130]:

- EN ISO 22526-1 'Plastics - Carbon and environmental footprint of bio-based plastics - Part 1: General principles'.
- EN ISO 22526-2 'Plastics - Carbon and environmental footprint of bio-based plastics - Part 2: Material carbon footprint, amount (mass) of CO2 removed from the air and incorporated into polymer molecule'.
- EN ISO 22526-3 'Plastics - Carbon and environmental footprint of bio-based plastics - Part 3: Process carbon footprint, requirements and guidelines for quantification'.

Moreover, the CEN/TC (Technical Committee) 411 developed standards for biobased products covering horizontal aspects based on radiocarbon methods, and in particular:

- EN 16640: Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method;
- EN 16785: Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis.

These standards are listed in the Assessment and Verification section of this criterion as the procedures to follow in order to determine the biobased carbon content of the synthetic polymers and plastic materials present in the product. The standard 'ASTM D 6866-12 - Standard Test Method for Determining the Bio-based Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis' could also be used.

The work of the CEN/TC 411 includes also the development of several standards in relation to several areas of interest such as terminology, biosolvents, biobased content, sustainability criteria and certification.

12/Commission%20recommendation%20-%20establishing%20a%20European%20assessment%20framework%20for%20safe%20and%20sustainable%20by%20design.PDF.

[128] Certification schemes officially recognised by the European Commission are available at: https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en

[129] As listed in European Commission approved voluntary schemes and national certification schemes: https://energy.ec.europa.eu/topics/renewable-energy/bioenergy/voluntary-schemes_en

[130] ISO 22526 - Plastics - Carbon and environmental footprint of bio-based plastics. Available at: https://www.iso.org/standard/73389.html

5.7 CRITERION 5 for Absorbent Hygiene Products: Compostability – REMOVED

~~This criterion applies only to products marketed as compostable (including the packaging). If applied, it shall refer to the whole product and/or packaging.~~

~~If the absorbent hygiene product and/or packaging are compostable, it shall be certified by the supplier.~~

~~A clear statement shall be given on the primary packaging to guide consumers on how to dispose correctly the cited absorbent hygiene product and/or packaging made of compostable material, after use..~~

~~If the product and/or packaging is compostable, theoretical timeframe for composting shall be specified and whether compostability shall be done industrially or at home, shall be specified in the application.~~

~~**Assessment and verification:**~~

~~The applicant shall provide a signed declaration of compliance with this criterion. The declaration shall be supported by a test report performed using one of the test methods mentioned above.~~

~~Compostability must be certified by complying with the EN 14995, ISO 16929, ISO 13432, or ISO 18606.~~

~~Other methods may be accepted as test methods if considered equivalent by a third-party, and must be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation.~~

~~Moreover, the applicant shall submit a high resolution image of the primary packaging (where information on how to dispose the product and/or packaging correctly appears clearly).~~

Note that **this criterion has been withdrawn**. This criterion was proposed during the revision process but removed after several discussions with stakeholders.

During the revision process, the addition of a biodegradable percentage of materials in the final AHP was discussed. It was pointed out by stakeholders that, depending on the final application, biodegradability would make sense but focusing on biobased content only. In line with this, a new criterion on biodegradability was proposed during the revision process. Initially, the proposal did not introduce a mandatory percentage by weight of biodegradable materials as it was left open to manufacturers to add product sections or components able to biodegrade. However, the opinions received from stakeholders pointed to the lack of legislation/regulation and waste management systems across all MS and to the potentially misleading effect on consumer perception of mentioning AHP products being biodegradable, as consumers might perceive that they would naturally degrade in the environment. Since no prior separation of non-biodegradable parts would occur, this would translate into detrimental impacts for the environment.

With this in mind, a new proposal discussed in a stakeholder consultation moved the focus from 'biodegradability' to 'compostability', and the criterion was set as an optional criterion which would apply to the whole absorbent hygiene product and/or packaging. The timeframe and environment where the compostability would happen would have had to be stated on the packaging of the product. The accepted compostability certificates were EN 14995, ISO 16929, and also ISO 13432, or ISO 18606.

Indeed, the "Communication from the EC on EU policy framework on biobased, biodegradable and compostable plastics"[131] highlights the complexity of biodegradation. It should be noted that when a product or packaging is described as biodegradable or compostable, it cannot be assumed that it will biodegrade in the environment and therefore can be freely disposed of . Non-biodegradable plastics released into the environment will persist and accumulate in the form of macro-, micro- or nano-plastic particles. On the other hand, when the plastic is biodegradable, it must do so in a timescale short enough not to be harmful to ecosystems.

[131] European Commission, 2022. Communication from the EC on EU Policy Framework on Biobased, biodegradable and compostable plastics. Available here: https://environment.ec.europa.eu/publications/communication-eu-policy-framework-biobased-biodegradable-and-compostable-plastics_en

In line with the circular economy and waste hierarchy principles, the Communication states that biodegradable and compostable plastics should be limited to applications where reduction, reuse and recycling are not feasible or desirable, or when specific advantages are proven: *(1) the utilisation of compostable plastics brings environmental benefits over alternative materials or options, and (2) the utilisation of compostable plastics does not directly or indirectly result in a reduction of the quality of the resulting compost.*

The recommendation from the EC suggests that the most suitable applications for compostable plastics are a small group of applications such as light plastic carrier bags, tea bags, coffee pods and fruit and vegetable stickers. In all other applications, the benefits of using compostable plastics instead of alternative materials or options are less clear. None of them are AHP; however, it is highlighted that "*among the range of potential non-packaging applications for compostable plastics, AHP merit particular attention*". In fact, to be labelled as compostable, products and packaging applications should display the disposal route directly on the product's primary packaging and provide information possibly through pictograms. Rather than simply raising awareness, accompanying information campaigns should seek to promote effective disposal waste action.

Nevertheless, the opinion of stakeholders on a criterion on compostability was that currently there is no standard that defines the compostability of a full AHP, it can be confusing for consumers, the waste management of AHP is different in each MS and, moreover, composting facilities usually do not accept AHP. Although there are some examples of recycling facilities in Italy and the Netherlands, this solution does not apply to all MS. **All these reasons led to the conclusion that it was appropriate to remove this criterion**.

5.8 CRITERION 6 for Absorbent Hygiene Products: Material efficiency in the manufacturing of the final product

Annex I: Final proposal for criterion 6: Material efficiency in the manufacturing of the final product
Requirements in this criterion shall apply to the final product assembly site. The quantity of waste generated during the manufacturing and packaging of the products which is sent to landfill or incineration without energy recovery, shall not exceed: (a) 8 % by weight of the end products for tampons, (b) 4 % by weight of the end products for all the other products. **Assessment and verification:** The applicant shall confirm compliance with the above requirements. 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. The applicant shall present all of the following: (a) the weight of the product and of the packaging, (b) all the waste streams generated during the manufacturing, (c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration. The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc).

Rationale for the proposed criterion text

The main objective of this criterion is to limit the amount of waste that is sent to landfill or incineration from the final product manufacturing assembly site. The waste recovered for reuse, recycling or energy production is not targeted by this criterion.

Nearly 40 000 disposable diapers are used every minute, producing 1.3 t/min (dry weight) of waste[132]. While the EU Ecolabel can have only a limited impact on the waste production and management of the final used products, a stronger requirement during the product design and manufacturing phases which would minimise the environmental impact in these phases is encouraged. Given the increasing demand for AHP in the EU per year (see details in Section 3 (Market analysis) in the Preliminary Report), even small improvements in resource efficiency during manufacturing can lead to significant environmental savings.

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[133] 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.

[132] Mendoza, J. M. F., Popa, S. A., D'Aponte, F., Gualtieri, D., Azapagic, A., 'Improving resource efficiency and environmental impacts through novel design and manufacturing of disposable baby diapers', Journal of Cleaner Production, Vol. 210, Elsevier, 2019, pp. 916-928. https://doi.org/10.1016/j.jclepro.2018.11.046

[133] 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. https://op.europa.eu/s/w8jD

During the revision process, more ambitious restrictions on the quantity of waste generated during the manufacture and packaging of the products were set (20% increase of the threshold demands).

In line with this, the final threshold for waste generated during the manufacturing and packaging of the products which is sent to landfill or incineration was set at **8 % w/w for tampons and 4 % w/w for all the other products.** This quantity of waste, sent to landfill or incineration, shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.)

As it is acknowledged that incineration with energy recovery is preferable to simple landfilling, it is only incineration **without energy recovery** that is targeted by this criterion.

5.9 CRITERION 7 for Absorbent Hygiene Products: Excluded and restricted substances

5.9.1 Sub-criterion 7.1: Restrictions on substances classified under Regulation (EC) No 1272/2008

Annex I: Final proposal for criterion 7.1: Restrictions on substances classified under Regulation (EC) No 1272/2008

This sub-criterion applies to the final product and any components therein.

Unless derogated in Table 8, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 6, in accordance with Regulation (EC) No 1272/2008.

Table 6. Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	-
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	
Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Endocrine disruptors for human health and the environment	
Category 1	Category 2

EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Persistent, Bioaccumulative and Toxic	
PBT	vPvB
EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Persistent, Mobile and Toxic	
PMT	vPvM
EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resource

Moreover, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) in concentrations greater than 0,010% (weight by weight) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 7, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 8.

Table 7. Restricted hazard classes, categories and associated hazard statement codes

Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	

Table 8. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008

Substance type	Derogated hazard class, category and hazard statement code	Derogation conditions
2-methyl-2H-isothiazol-3-one (MIT)	H400, H314, H301, H311, H318, H410, H330 and H317	Only in water-soluble inks and in a concentration lower than 15 ppm in the ink (before application) and lower than 0.1 ppm in the final product. The ink shall comply with sub-criterion 7.3.4
Dipropylene glycol dibenzoate	H412	Only in hot melt adhesives that are used to indicate wetness
Substances and mixtures with a harmonised classification as H304	H304	Substances with a viscosity under 20.5 cSt at 40°C.
Titanium dioxide (nano form)	H351	Only when used as pigment. It cannot be used in powder or spray

	form.

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

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.

This criterion shall not apply to:

— substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation;

— substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with sub-criterion 7.1, together with relevant declarations from the producers of the components, a list of all chemicals used, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.

For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100% shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0.0100% w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a restricted impurity shall be provided.

For substances exempted from sub-criterion 7.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

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

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

Rationale for the proposed criterion text

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. This sub-criterion is 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'.*

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

In order to correctly match the intention of Articles 6(6) and 6(7) of the EU Ecolabel Regulation, this sub-criterion focuses on the final product and not on hazardous substances and mixtures potentially used during the production process.

During the revision process, a total ban was proposed on ingoing substances with harmonised classifications for CMRs, acute toxicity, STOT and sensitisers in final products, whereas the use of substances with harmonised classifications as hazardous to the aquatic environment and to the ozone layer were restricted to concentrations less than 0.010% w/w in the chemical products. However, impurities within ingoing substances may still be present in the final product, up to a maximum concentration of 0.0100% weight by weight, in line with the proposed definition of '*impurities*'.

In addition, endocrine disruptors, chemicals that do not break down in the environment and that can accumulate in living organisms (Persistent, Bioaccumulative and Toxic – PBT), or that risk entering and spreading across the water cycle, including drinking water, (Persistent, Mobile and Toxic – PMT) are also forbidden from being added in AHP. In fact, in December 2022 the Commission published a proposal for a revised Regulation[134] on classification, labelling and packaging of chemicals (CLP). The revised Regulation introduces a number of changes, such as better and faster processes for all actors, improved communication of chemical hazards, including online, the right for the Commission to develop classification proposals on potentially hazardous substances, in addition to Member States and industry, and first ever specific rules for refillable chemical products. As part of this revision, the Commission also proposed a Delegated Act[135] to introduce new hazard classes under the CLP Regulation for endocrine disruptors, PBT, and PMT substances. The implementation of the exclusion in the EU Ecolabel is however subject to the adoption of the revised CLP Regulation.

During the revision process, the following substances were proposed for derogation:

Dipropylene glycol dibenzoate. Dipropylene glycol dibenzoate (CAS 27138-31-4) is classified as H412 according to the CLP Regulation. This substance is registered under the REACH Regulation and is manufactured in and/or imported to the European Economic Area, at ≥ 1 000 tonnes to < 10 000 tonnes per year[136]. This substance is used in adhesives and sealant, in addition to polymers, coating products, inks and toners, cosmetics and personal care products, biocides (e.g. disinfectants, pest control products) and plant protection products. Dipropylene glycol dibenzoate emerged in the market in 2011, when ECHA listed it as an alternative to phthalates[137]. In AHP, hot-melt adhesives are used as wetness indicators. Hot-melt adhesives, also known as hot glue, are a form of thermoplastic adhesive that is used by industry as an alternative to solvent-based adhesives, thus almost eliminating volatile organic compounds (VOCs) as well as the drying or curing step. A wetness indicator is a common feature in many disposable diapers and toilet training pants. It is a feature that reacts to exposure of liquid as a way to discourage the wearer to urinate in the training pants, or as an indicator for a caregiver that a diaper needs changing. This feature guides parents in the correct use of the diaper and helps to potentially avoid frequent changes of diapers when the product is not yet wet. For this reason, it was proposed to derogate the presence of dipropylene glycol dibenzoate in hot-melt adhesives used for wetness indicators, in line with the Blue Angel.

H304 substances. According to the CLP Regulation, the H304 hazard ("May be fatal if swallowed and enters airways"), induced following an accidental ingestion, is linked to the viscosity parameter (< 20.5 cSt at 40 °C). This risk may arise in the case of ingestion, only if the substance enters the lungs in its liquid form instead of arriving in the stomach, but also in the case of vomiting after ingestion. As a consequence, to pose a risk for human health, the absorbent hygiene product must both have the substance classified H304 in its liquid form and be swallowed. This is considered an unlikely situation, leading to no risk for human health.

Titanium dioxide. TiO_2 is used for many applications, especially as a white pigment. A derogation was needed for this compound, since TiO_2 in inhalable powder form (placed on the market in powder form and consisting of 1% or more of particles with an aerodynamic diameter <= 10 μm) has been reclassified as Carcinogenic 2. However, in November 2022 the Court of Justice of the European Union annulled the harmonised classification and labelling of titanium dioxide as a carcinogenic substance by inhalation in certain powder

134 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7775
135 https://environment.ec.europa.eu/publications/clp-delegated-act_en
136 ECHA, substance infocard. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.043.856. Accessed 26.09.2022
137 https://echa.europa.eu/documents/10162/eec0b364-e29e-48f8-970c-a4cdb78465b8

forms. Nevertheless, as the European Union has appealed the decision of the Court of Justice, the derogation has been kept.

Methylisothiazolinone (MIT). MIT is a preservative that is broadly used in many personal care products thanks to its high effectiveness at low concentrations and in a wide range of pH. MIT is known for its strong sensitising properties[138], and in fact is classified as H317[139]. In AHP, MIT is used as a preservative in water-based inks and, according to industry, it is very difficult to find alternatives. According to stakeholders, if MIT is not allowed solvent-based inks would be used instead, with the environmental problems related to the use of solvent-based inks.

Water-based inks are a later composition of inks compared to traditional solvent-based inks, and they differ from each other in that in water-based inks the organic solvent is replaced by water. From the environmental standpoint, solvent inks contain volatile organic compounds (VOCs), which cause ozone pollution when released into the environment and react with nitrogen oxides. The reaction also leads to health problems like asthma, emphysema and bronchitis, so print workers are regularly exposed to health hazards unless given protection. Finally, solvent-based inks are highly flammable and safety measures must be taken during storage and use of the product.

Given the available evidence, it is suggested here to **derogate MIT when used in water-based inks if its concentration in the ink (before application) is lower than 15 ppm, and nevertheless lower than 0.1 ppm in the final product**. This is in line with the recent Adaptation to Technical and Scientific Progress (ATP) to the CLP Regulation, and to Nordic Swan, which sets a similar exemption. Moreover, given the fact that, according to EU Ecolabel sub-criterion 7.3.d, inks cannot be used in parts in contact with the skin, the sensitising risk is expected to be low.

[138] E.g. Rodrigues Barata A.R. and Conde-Salazar L., 2014, Methylisothiazolinone and methylchloroisothiazolinone: new insights, MJ Dermatol. 2:101-105.

[139] https://echa.europa.eu/es/registration-dossier/-/registered-dossier/23868/2/1

5.9.2 Sub-criterion 7.2: Substances of Very High Concern (SVHCs)

Annex I: Final proposal for criterion 7.2: Substances of Very High Concern (SVHCs)
This sub-criterion applies to the final product and any components therein. The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 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. **Assessment and verification** The applicant shall provide a signed declaration that the final product and any components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein. 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: https://www.echa.europa.eu/candidate-list-table Reference to the list shall be made on the submission date of the EU Ecolabel application. For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100%, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0.0100% w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities. Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a SVHC impurity shall be provided.

Rationale for the proposed criterion text

As with criterion 7.1, sub-criterion 7.2 is directly linked to Articles 6(6) and 6(7) of the EU Ecolabel Regulation (EC) No 66/2010, which effectively states:

'*the EU Ecolabel may not be awarded to goods containing […] Substances of Very High Concern, as referred to in Article 57 of Regulation (EC) No 1907/2006*'

During the revision process, it was proposed to set a full ban on SVHCs, in line with other recently voted EU Ecolabel product groups[140,141], with other national ecolabels (namely Nordic Swan and Blue Angel), and with the objective of the Chemicals Strategy to minimise the presence of hazardous chemicals in products.

It is important to clarify that impurities within ingoing substances may still be present in the final product up to a concentration of 0.0100% weight by weight. However, only unforeseen process impurities are to be considered as such. Indeed, according to the definition of '*ingoing substances*', substances known to be released from ingoing substances (e.g. formaldehyde from preservatives and arylamine from azodyes and azopigments) shall also be regarded as ingoing substances.

[140] Commission Decision (EU) 2021/1870 of 22 October 2021 establishing the EU Ecolabel criteria for cosmetic products and animal care products (OJ L 379, 26.10.2021, p. 8 48).

[141] Commission Decision (EU) 2022/1244 of 13 July 2022 establishing the EU Ecolabel criteria for growing media and soil improvers (OJ L 190, 19.7.2022, p. 141–165).

5.9.3 Sub-criterion 7.3: Other specific restrictions – NEW

Criterion 7.3 was proposed to be added to the revised criteria for absorbent hygiene products in the first Technical Report (TR1.0) to simplify the structure of the criteria set with respect to the current criteria set (Commission Decision 2014/763/EU), where specific chemical restrictions were not sufficiently grouped in the text.

While sub-criteria 7.1 and 7.2 focus on substances in the final product, sub-criterion 7.3 sets down specific restrictions in defined circumstances, targeting the possible use of specific groups of chemicals during the production process, such as biocidal active substances, APEOs, phthalates, PAHs, formaldehyde and organotins.

Criterion 7.3 is subdivided into seven sub-requirements:

- *7.3.1 Excluded substances*
- *7.3.2 Fragrances*
- *7.3.3 Lotions*
- *7.3.4 Inks and dyes*
- *7.3.5 Further restrictions applying to adhesives*
- *7.3.6 Super absorbent polymers*
- *7.3.7 Silicone*
- *7.3.8 Impurities of concern*

5.9.3.1 Sub-criterion 7.3.1 Excluded substances

Annex I: Final proposal for criterion 7.3.1: Specified excluded substances

This sub-criterion applies to the final product and any components therein.

The following substances shall not be added (alone or in mixtures) to the chemical product used in the final product nor in any components therein:

(a) 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);
(b) Acrylamide in superabsorbent polymers;
(c) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]. Sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole are allowed;
(d) Antibacterial agents (e.g. Nanosilver and triclosan);
(e) Formaldehyde and formaldehyde releasers [2];
(f) Nitromusks and Polycyclic musks;
(g) Organotin compounds used as a catalysts in the production of silicone;
(h) Parabens;
(i) Phthalates [3];
(j) Substances identified to have endocrine disrupting properties;
(k) 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.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0.0100% w/w in the chemical product, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

[Notes:

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

[2] The use of formaldehyde and formaldehyde releasers in adhesives is regulated according to sub-criterion 7.3.5

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

This criterion lists the substances and compounds that shall not be present in the product. Some of the substances listed under 7.3(a) are already excluded in current criteria in force, while some other substances were proposed to be banned during the revision process, namely:

- antibacterial agents;
- APEOs and other alkyl phenol derivatives, with the exception of sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole;
- CMIT;
- identified endocrine-disrupting compounds (EDs);
- organotin compounds used as catalysts in the production of silicone polymers;
- phthalates;
- 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.

5.9.3.2 Sub-criterion 7.3.2: Fragrances

Annex I: Final proposal for criterion 7.3.2: Fragrances
This sub-criterion applies to the final product, any components therein, the separate components and the packaging. Fragrances shall not be added to the final product, to any component thereof, to the separate components nor to the packaging. **Assessment and verification:** The applicant shall provide a signed declaration of compliance with the sub-criterion.

This sub-criterion focuses on the presence of fragrances in the final product.

During the revision process it was proposed to prohibit the use of fragrances in the final product, its components and its packaging. Moreover, a requirement was added on the use of odour control substances in adult incontinence products. However, given the lack of any specific category of ingredients named 'odour control substances' other than fragrances (since the definition of a fragrance ingredient/substance refers to any basic substance (raw material) used for its odour properties or malodour coverage as a component of a fragrance mixture), the requirement on the use of odour control substances has been removed.

5.9.3.3 Sub-criterion 7.3.3: Lotions

Annex I: Final proposal for criterion 7.3.3: Lotions
This sub-criterion applies to the final product and any components therein. Lotions shall not be used in the product, nor in any component thereof.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion.

This sub-criterion focuses on the presence of substances in the final product.

During the revision process it was proposed to set a full exclusion of lotions in EU Ecolabel AHP, with the support of the vast majority of stakeholders.

5.9.3.4 Sub-criterion 7.3.4: Inks and dyes

Annex I: Final proposal for criterion 7.3.4: Inks and dyes

This sub-criterion applies to the final product and any components therein. This requirement does not apply to the separate components, the sales packaging and the information sheets.

(a) The final product and any components therein shall not be dyed or printed on.

(b) The following components are exempted and may be dyed or printed on:

(i) tampon strings;

(ii) closing systems;

(iii) materials that are not directly in contact with the skin, if the dye or ink fulfils specific functions (e.g. reducing visibility of the product through white or light coloured clothes, showing landing zones of tapes, indicating the wetness, indicating the back part of a product) or decorative purposes.

In these cases, the content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dying colorants and inks shall be below the limits given in the Council of Europe's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food[142].

The dying colorants used shall moreover comply with the following:

(a) if used in plastic materials: BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities[143] or Swiss Ordinance 817.023.21 Annex 2[144] and Annex 10[145],

(b) if used in cellulosic materials: BfR's recommendation XXXVI. Paper and board for food contact[146].

The dying colorants and inks used shall also comply with sub-criteria 7.1 and 7.2.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

In case dyes and/or inks are used, their presence shall be justified by indicating the specific function provided, and documentation shall be provided to ensure that impurities in the dying colorant or ink comply with the Council of Europe's Resolution AP (89) 1, and that the used dyes are authorised according to the BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, Swiss Ordinance 817.023.21 Annex 2 and Annex 10, or the BfR's recommendation XXXVI. Paper and board for food contact.

142 Council of Europe, Committee of Ministers, Resolution AP(89)1 on the use of colorants in plastic materials coming into contact with food. Available at: https://rm.coe.int/16804f8648.

143 https://www.bfr.bund.de/cm/349/IX-Colorants-for-Plastics-and-other-Polymers-Used-in-Commodities.pdf.

144 https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht2017/anhang2-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annexe_2.pdf.

145 https://www.blv.admin.ch/dam/blv/en/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht2017/anhang10-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annex-10-ordinance-fdha-materials-and-articles-intended-to-come-into-contact-with-food-stuffs.pdf.

146 https://www.dssmith.com/contentassets/1bbf9877253f458aa0eed26b76f2d705/360-english.pdf.

This sub-criterion focuses on the presence of inks and dyes in the final product.

During the revision process it was proposed to add a requirement specifying that colorants used (for those components where they are allowed) must have been approved for food contact by Regulation 133/2008 on food additives, as well as a requirement on the maximum limit of heavy metals, PAA and PCB as impurities in the colorants used.

However, the requirement on food-contact materials would not be feasible, since the type of dyes/inks used in AHP are normally not used in food-contact materials. Therefore, that part of the criterion has been removed and has been replaced with standards normally used by the AHP industry: the BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, when the dyes/inks are used on plastic materials, and the BfR's recommendation XXXVI. Paper and board for food contact, when the dyes/inks are used on cellulosic materials.

5.9.3.5 Sub-criterion 7.3(e): Further restrictions applying to plastic materials – REMOVED

~~Annex I: Third proposal for criterion 7.3 e: Further restrictions applying to plastic materials~~
~~This sub-criterion applies to ingoing substances in the plastic materials.~~ ~~(i) 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.~~ ~~(ii) 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).~~ ~~**Assessment and verification:**~~ ~~*The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their concentration in the final product.*~~

This sub-criterion focused on the additional requirements for plastic materials in the final product.

During the revision process it was decided to remove this sub-criterion. Indeed, plastic materials are implicitly covered by sub-criteria 7.1 and 7.2, which show the same requirements and also focus on the product's components.

5.9.3.6 Sub-criterion 7.3.5 Further restrictions applying to adhesives

Annex I: Final proposal for criterion 7.3.5: Further restrictions applying to adhesives
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. **Assessment and verification:** The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their

concentration in the adhesive.

The applicant shall also provide test results for the content of formaldehyde, according to the test method ISO 14184-1:2011 or equivalent.

This sub-criterion presents specific requirements for substances that are used in the production of adhesives in AHP.

During the revision process, industry stakeholders from the sector have shared the information that the substance colophony is not used as a blend or mixture component to make adhesives. This means that there is no need to make an exception for rosin. Rosin esters are instead used as tackifiers and blend components in adhesives; however, these substances are not classified as skin sensitisers and thus do not need a derogation. Therefore, the derogation that was in place in the current criteria in force was removed.

5.9.3.7 Sub-criterion 7.3.6 – Superabsorbent polymers (SAPs)

Annex I: Third proposal for criterion 7.3.6 – Superabsorbent polymers (SAPs)

Superabsorbent polymers used in the product shall:

(a) contain a maximum of 1 000 ppm residual monomers [4] that are classified with the H-codes reported in sub-criterion 7.1. For sodium polyacrylate this limit applies to the sum of unreacted acrylic acid and cross linking agents.

(b) as a maximum, contain 10 % (weight/weight) of water-soluble extracts [5] and these shall comply with sub-criteria 7.1, 7.2 and 7.3.1. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.

(c) Acrylamide shall not be included in superabsorbent polymers.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with this sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their concentration in the final product.

In addition, 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 declaration shall be supported by safety data sheets or test results specifying the residual monomers contained in the SAP and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The tested quantities for residual monomers and soluble extracts shall be averages from repeated measures over a certain period of time. The methods used and the measurement frequency for the analyses shall be described, including the information of the laboratories used for the analysis.

[Notes:

[4] Residual monomers are intended as the total of unreacted acrylic acid and crosslinkers

[5] Water-soluble extracts in SAP are intended as monomers and oligomers of acrylic acid with a lower molecular weight than the one of SAP, and salts]

This sub-criterion presents specific requirements for the use of superabsorbent polymers (SAP) in AHP.

No major changes were made to this sub-criterion during the revision process.

5.9.3.8 Sub-criterion 7.3.7 – Silicone

Annex I: Final proposal for criterion 7.3.7: Silicone

This sub-criterion applies to the release liner.

(a) Solvent-based silicone coatings shall not be used.

(b) 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 [6] in concentrations above 800 ppm (0,08 % w/w). The 800 ppm limit is to be applied to each substance separately.

Assessment and verification:

The applicant shall provide a declaration of compliance with this sub-criterion, signed by the manufacturer of the release liner, supported by safety data sheets.

[Note:

[6] Silicone mixture is intended here as the liquid mixture composed of two or more silicone raw materials that is used as a coating on the protective paper or the protective film used for the release liner on some feminine hygiene products (e.g. panty liners and sanitary towels) or on nappy tapes]

Silicone in AHP can be found in the release liners of baby diapers and feminine care products (sanitary towels and panty liners). In these components, silicones (or polysiloxanes) are used in general to protect the adhesive and to achieve a grease- or water-repellent effect as well as a release effect. When they are used in 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.

The first part of this sub-criterion refers to the issues emerging from the use of solvent-based silicones. During the revision process it was proposed to set a ban on solvent-based silicone coatings, with the support of stakeholders and in line with other national ecolabels.

The second part of this sub-criterion refers to the maximum presence of cyclosiloxanes in the silicone treatment used to coat the release liner. During the revision process, important wording modifications were made, as the reference to '*silicone*' in the current EU Ecolabel criteria in force 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 silicone cured onto the release liner. Thus, after holding a thematic workshop on this topic in November 2021, it was proposed to refer to the '*silicone mixture*'. '*Silicone mixture*' is a liquid composition of two or more silicone raw materials, and may also contain other non-silicone cross-linking agents. The release liner manufacturers (customers of the chemical suppliers) usually buy different raw materials from the silicone supplier (silicone formulation) and mix them in-house, obtaining the silicone mixture. The release liner manufacturer is also the one responsible for the curing process of such a mixture when applied on the articles.

During the revision process, silicone suppliers and release liner manufacturers confirmed that it is not common to measure the concentration of siloxanes on the release liner, which is instead done via 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 should be noted that almost all cyclosiloxanes are being removed in a final distillation step carried out by the silicone suppliers. As a matter of fact, a small content of residual cyclosiloxanes 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 of the industry. Therefore, during the revision process it was proposed to increase the concentration limit of the cyclosiloxanes D4, D5 and D6 to 800 ppm (each compound separately).

5.9.3.9 Sub-criterion 7.3.8 - Other chemicals of concern

Annex I: Final proposal for criterion 7.3.8 - Other chemicals of concern

This sub-criterion applies to impurities in the final product.

The following chemicals shall not be present in the final product in a concentration higher than what indicated in Table 9.

Table 9. List of restricted chemicals

Substances	**Restrictions**
Formaldehyde	< 16 ppm
Dibenzo-p-dioxins (PCDDs): 2,3,7,8-TCDD; 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD	sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs < 2ng/kg
Dibenzofurans (PCDFs): 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8- PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; OCDF	
DLPCBs: PCB 77; PCB 81; PCB 126; PCB 169; PCB 105; PCB 114; PCB 118; PCB 123; PCB 156; PCB 157; PCB 167; PCB 189	
PAHs	
Benzo[a]anthracene; Benzo[a]pyrene; Benzo[e]pyrene; Chrysene; Benzo[b]fluoranthene; Benzo[k]fluoranthene; Dibenzo[a,h]anthracene; Benzo[j]fluoranthene; Benzo[g,h,i]perylene; Indeno[1,2,3,cd]pyrene; Phenanthrene; Pyrene; Anthracene; Fluoranthene; Naphthalene	Each PAH < 0,2 mg/kg Sum PAHs < 1 mg/kg
Phenols	
Bisphenol A	< 0,02 %
Nonylphenol-di-ethoxylate	< 10 mg/kg
Nonylphenol	< 10 mg/kg
Phthalates	
DINP, DEHP, DNOP, DIDP, BBP, DBP, DiBP, DIHP, BMEP, DPP/DIPP, DnPP, DnHP, DMP, DHNUP, DCHP, DHxP, DIHxP, DIOP, DPrP, DNP, 1,2-benzenedicarboxylic acid, di-C6-10 alkyl esters, 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	< 0,01% each
Pesticides	
Glyphosate	< 0,5 mg/kg
AMPA	< 0,5 mg/kg
Quintozene	< 0,5 mg/kg
Hexachlorobenzene	< 0,5 mg/kg
Organotins	
Tributyltin	< 2 ppb
Other organotins: Monobutyltin; Dibutyltin; Triphenyltin; Dioctyltin; Monooctylti	Each organotin < 10ppb
Heavy metals	

Antimony	< 30 mg/kg
Cadmium	< 0,1 mg/kg
Chromium	< 1 mg/kg
Lead	< 0,2 mg/kg
Mercury	< 0,02 mg/kg

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

In addition, the applicant shall provide the results of the analyses performed on the final product. The tests shall be carried out on a representative product. In the case of identically produced products (e.g. hygiene products of different sizes), it is sufficient to carry out tests on one of the product sizes. Alternatively, the analyses can be performed separately on each of the material composing the final (representative) product. The methods used and the date of the measurement for the analyses shall be described, including the information of the laboratories used for the analysis. Recommended test methods are NWSP 360.1R0 or equivalent for the sample preparation, NWSP 360.2R0 or equivalent for the analyte extraction, and NWSP 360.3R0 or equivalent for the instrumental analysis. The frequency of the measurement shall be at least once a year.

This sub-criterion was proposed to be added to the current EU Ecolabel criteria in force based on the request of different stakeholders and EUEB members to analyse the situation of trace presence of chemicals of concern (such as dioxins, furans, PAHs and PCBs) in AHP and to set a restriction on such chemicals. These are especially important as PAHs, formaldehyde and some PCDD/Fs and PCBs are carcinogenic and suspected endocrine disruptors.

The possible presence of low amounts of chemicals of concern in feminine care products and baby diapers was revealed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) in two different studies. In the ANSES opinion from 2018 on the safety of feminine hygiene products[147], it was found that some PAHs, dioxins, pesticides and phthalates could be quantified or detected at least once in external and internal feminine hygiene products shredded and analysed by solvent extraction. However, a risk assessment of the substances analysed concluded that there was no health risk effect for the users of the products. In the ANSES opinion from 2019 on the safety of baby diapers[148], it was found that some PAHs, dioxins, pesticides, VOCs, and formaldehyde could be quantified or detected at least once. A risk assessment of the substances analysed concluded that the health threshold was exceeded for six PAHs, recommending regulatory action to be taken. In light of this, a restriction proposal[149] on hazardous chemicals including formaldehyde, dioxins, furans, PCBs as well PAHs and other substances in single-use baby diapers was initiated on the basis of Article 69(1) of the REACH Regulation.

Although the process has not been finalised yet[150], the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) published their opinions on the file: the RAC opinion[151] was that the proposed restriction is not justified because the risk could not be demonstrated for formaldehyde and PCDD/Fs/DL-PCBs, and could not be characterised for PAHs and NDL-PCBs; the SEAC opinion[152] was that there is not a sufficient justification that the REACH restriction would be proportionate, and that it has not been clearly demonstrated that there are feasible measures that the manufacturers could undertake to reduce the contamination. Nevertheless, companies have already started to implement more regular and stricter testing and controls of their raw materials, their finished products and their production lines (additionally to the tests they already performed beforehand). In addition, industries took action with

147 ANSES Opinion on the safety of feminine hygiene products, Request No 2016-SA-0108. Available at: https://www.anses.fr/en/system/files/CONSO2016SA0108EN.pdf

148 ANSES Opinion on the safety of baby diapers, Request No 2017-SA-0019. Available at: https://www.anses.fr/en/system/files/CONSO2017SA0019EN.pdf

149 ANSES, ANNEX XV RESTRICTION REPORT - PROPOSAL FOR A RESTRICTION, 15 December 2020. Available at: https://echa.europa.eu/documents/10162/99f020fd-e8ae-1b66-4fe6-0ec40789db8a

150 All steps and documents can be found at: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840698d5

151 https://echa.europa.eu/documents/10162/c374b7bb-b0e2-e01f-d55d-398dc270343f

152 https://echa.europa.eu/documents/10162/58e146ec-f113-09f3-1d7e-6e03b2061928

voluntary initiatives to provide transparency and reassurance for consumers regarding trace levels of impurities found in AHP, such as the EDANA Stewardship Programme for Absorbent Hygiene Products[153].

In the revised EU Ecolabel criteria, some of these chemicals of concern are already excluded by sub-criterion 7.1, 7.2, or 7.3.a. However, many of the PCBs, PCDDs and PCDFs have only self-classifications, and are not covered by sub-criterion 7.1. While the chemicals of concern found by ANSES are never intentionally added to the product, but rather are the result of trace contamination during the manufacturing of the product, during the revision process it was proposed to add a new requirement limiting the presence of impurities in the final product, in line with the recommendations by EDANA, covering PCDDs, PCDFs, PCBs, PAHs, phenols, pesticides, organotins, and heavy metals.

153 https://www.edana.org/docs/default-source/edana-product-stewardship-for-absorbent-hygiene-products/codex-final.pdf?sfvrsn=ebfc6249_

5.10 CRITERION 8 for Absorbent Hygiene Products: Packaging - NEW

Annex I: Final proposal for criterion 8: Packaging
This criterion sets requirements for sales and grouped packaging. Grouped packaging shall be avoided or made of only cardboard and/or paper. (a) Cardboard and/or paper used for packaging Sales packaging made of cardboard and/or paper shall contain a minimum 40% of recycled material. Grouped packaging made of cardboard and/or paper shall contain a minimum 80% of recycled material. The remaining share (100% minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme. (b) Plastic used for packaging Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20% recycled material. From 1 January 2027, sales packaging made of plastic shall contain a minimum 35% recycled material. (c) Recyclability The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling. (d) Additional requirements Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed. Recycled content and recyclability of sales and grouped packaging shall be indicated on the sales packaging. **Assessment and verification:** The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly. Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027. The applicant shall provide audited accounting documents that demonstrate that the remaining share (100% minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel license. Competent bodies shall check the accounting documents again twelve months after the awarding of the EU Ecolabel license. Recycled content shall be verified by complying with the EN 45557 or ISO 14021 while recyclability shall be verified by complying with the EN 13430 or ISO 18604. Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided. In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by

means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and/or paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

Rationale for the proposed criterion text

This new criterion aims at introducing certain percentages of recycled content and recyclability (availability and compatibility for recycling) in the packaging of AHP in order to support the EU's goal on circular economy.

The packaging of AHP can be made of sales packaging (*also known as primary packaging*) and grouped packaging (*secondary packaging*), as defined in Chapter 3 and in the revised Packaging and Packaging Waste Directive (PPWD). A separate component (known as additional component by other ecolabels) where the product is individually wrapped is sometimes considered (i.e. tampon applicators; release liner or paper in baby diapers).

The LCA screening study based on the PEF methodology for AHP showed that packaging made from LDPE granulates used for sanitary towels or menstrual pads was identified as a hotspot in some impact categories (Resource Use – fossils (17%), Climate Change (11% granulates, 6% extrusion) and Ecotoxicity –freshwater (14%)). With this in mind, a method of reducing the environmental impact of the materials in the product may be to use recycled materials, as specified by the Background Report of the Nordic Swan ecolabel for Sanitary Products. Increasing the share of materials (paperboard, cardboard or plastic) available for recycling as well as using recycled content in the packaging of AHP allows value to be derived 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.

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 in the product[154]. However, the EU Ecolabel aims to promote recyclability and the use of recycled materials in the packaging (sales and grouped) which is removed from the products before use and thus does not come into contact with the user. Furthermore, the revised PPWD sets binding plastic recycled content targets for contact sensitive packaging (e.g. medical applications[155]), which suggest the potentiality to safely use recycled content. Consequently, requirements on recycled content are set on both primary and secondary packaging.

During the revision process the criterion was divided into cardboard/paper and plastic materials. Ambition levels (targets) for recycled content and recyclability were studied according to the best evidence available, including means for verifying and testing them for each of the materials.

With respect to cardboard and/or paper packaging, the initial proposal of 40% recycled content for cardboard/paper was challenged by some stakeholders, who proposed raising the ambition level to 70% or 80% for both sales and grouped packaging. Other stakeholders indicated that requiring 40% and 80% for sales and grouped packaging, respectively, could impose a burden on the paper and/or cardboard demand.

The results of the investigations carried out, either via bilateral consultation meetings or literature research, indicated the following:

[154] 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 08/04/2022).

[155] 'Contact sensitive packaging' means packaging that is intended to be used in any packaging applications in the scope of Regulations: (EC) No 1831/2003 for animal nutrition, (EC) No 1935/2004 for materials and articles intended to come into contact with food, (EC) No 767/2009 for placing on the market and use of feed, (EC) No 2009/1223 on cosmetic products, (EU) 2017/745 on medical devices , (EU) 2017/746 for in vitro diagnosis MD, (EU) 2019/4 for the manufacture, placing on the market and use of medicated feed, (EU) 2019/6 for veterinary medicinal products, Directive 2001/83/EC for medicinal products for human use, or Directive 2008/68/EC for inland transport of dangerous goods.

- The European Paper Recycling Council (EPRC)[156] published the 'Monitoring Report 2021'[157], where paper and board recycling rates are summarised. This document reports a recycling rate of 71.4% for paper and board consumed in Europe in 2021 and it explains how consumption of new paper and board and collection of Paper for Recycling (PfR) have both increased[158]. It is to be noted that the recycling rate is defined as the ratio between the recycling of used paper, including net trade of PfR, and paper and board consumption while the term Paper for Recycling (PfR) refers to the different grades of paper and board for recycling used as raw material for recycling in the manufacture of paper and board products in the paper industry as defined by EN 643[159].
- The EPRC report mentioned also highlights that the consumption of paper and board has strongly recovered after the pandemic, reaching a higher level than in 2019 while collection of PfR is recovering more slowly (although it has also increased). As a result, the European recycling rate slightly decreased in 2021 compared to 2020 (73.3%). The use of PfR continued growing as investments were made in new recycling capacities in Europe. In the European paper industry, the use of PfR saw an increment of 5.7% (to 52.4 million tonnes) in 2021. Europe is leading the recycling of paper worldwide while North America accounted for a recycling rate of 68%, Asia 55.3% and Africa 37.6% in 2021, the world average being 59.7% (CEPI and EPRC, 2022). The national recycling rates in the EU-27 for 2021 show that 13 European countries exceeded the 70% recycling rate (15 in 2020) and 10 European countries were below 60% (8 in 2020) (CEPI and EPRC, 2022).
- A position paper[160] from CEPI on the on-going revision of the 'Packaging and Packaging Waste Directive (PPWD)' explains that 'adopting a case by case approach and taking into consideration the current recycling and environmental performance of each material stream, should be preferred over setting horizontal targets [...] This is supported by the fact that, in order to identify the optimal solution for each situation, a life cycle approach must be adopted'. CEPI also adds that, in order 'to align with the overall objective of the revision of the PPWD, the focus should be kept on promoting sustainable packaging solutions over a "one size fits all" approach'.
- Some sources state that packaging made from recycled paper board accounts for just over 41% of the total amount of paper products in use, a figure with the possibility to increase in the near future[161]. Some types of cardboard packaging can contain up to 100% recycled paper (Preston Board & Packaging, 2021) whilst the majority average between 70% and 90% recycled content[162]. However, these high recycled contents mostly apply to corrugated packaging boxes used in transport or transit packaging applications, i.e. packaging examples with high weights.
- Exchanges with industry stakeholders explained that the use of higher percentages of recycled cardboard and/or paper also means thicker walls for the container boxes, which are not always desired and could compromise the whole chain and transport procedures (heavier products). Most market products present packaging for menstrual pads and baby nappies made of plastic materials while panty liners and tampons come in light paper/cardboard boxes where a certain percentage of recycled content (these products are usually individually wrapped) could be applied.

Bilateral exchanges with cardboard and/or paper industry associations provided the following insights:

- The recycled content percentages for sales (primary) packaging is roughly at the level of the European average utilisation rate of paper for recycling in cardboard or other paper and board packaging. This is however often used for secondary packaging as well.
- The recycled content percentage for grouped (secondary) packaging is close the European average utilisation rate of paper for recycling in packaging materials. This is however mostly used in transport packaging.

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156 The European Paper Recycling Council (EPRC) was set up to monitor progress towards meeting higher paper recycling targets, https://www.paperforrecycling.eu/

157 EPRC, 2022. 'MONITORING REPORT 2021, European Declaration on Paper Recycling 2021-2030'. Available at:https://www.cepi.org/wp-content/uploads/2022/09/DRAFT_EPRC-Monitoring-Report-2021_20220909.pdf

158 Data used to calculate recycling rates are collected by Cepi through questionnaires to its national members associations in 18 countries. More information available at: https://www.cepi.org/statistics/

159 Standard EN 643 - Paper and board - European list of standard grades of paper and board for recycling.

160 CEPI, 2022. 'Cepi views on the revision of the Packaging and Packaging Waste Directive'. Available at: https://www.cepi.org/wp-content/uploads/2022/09/PPCG-MG-22-030_Cepi-views-1.pdf

161 Preston Board & Packaging, 2021. Available at: https://www.prestonboard.co.uk/2018/05/16/paperboard-recycling-facts/

162 GWP Group, 2022. Recyclable Packaging. Available at: https://www.gwp.co.uk/advantages/recyclable-packaging/

- In Europe the production of paper is higher than the use, with > 50% being based on paper for recycling. However, it is used in different ways based on the type of packaging. Also, whilst the overall recycling rate could be relatively high, the product-specific rate could be much lower (e.g. very high recycled content in packaging materials while in the product itself it is much lower). Hence, the paper industry's goal is to increase the overall recycling target but not necessarily for specific product applications.
- Generally, collection is closely aligned with recycling and is the main bottleneck. The cardboard and/or paper industry is mature and already has a track record/market for recycling these materials. This implies that different recycling streams have been optimised for particular applications. If mandatory (and higher) recycled content targets are introduced what could happen is that certain streams might be used for applications with less suitability (less efficiency). This would not result in an overall increase of the recycling rates but rather in a transference from one type of application to another.
- Given the above, sustainable sourcing is regarded at the same level as the use of recycled packaging since both will enhance recyclability (availability of paper). In fact, in the EU Ecolabel criteria for Tissue paper and graphic paper[163] (*Criterion 3 Recyclability*), sustainable sourcing (FSC/PFC) fibres are considered at the same level as recycled fibres. This allows a choice between recycled content and virgin fibres originating from certified forests.

The Impact Assessment (IA) accompanying the revised PPWD indicates that cardboard and/or paper packaging generally contains a high proportion of recycled material; for example, the European Corrugated Packaging Association (FEFCO) estimated that the average recycled content used in corrugated cardboard packaging in 2018 was 89%. Besides, the Confederation of European Paper Industries (CEPI) estimates that the average recycled content in carton board packaging at present is 50%.

This PPWD IA also states the following:

- Relatively high levels of recycled content uptake are possible in most other paper/card packaging applications because recycling rates for cardboard and/or paper are high in the EU (84.6% in 2017), meaning there is a good supply of secondary material[164].
- It is technically possible to include a significant proportion of recycled content in cardboard and/or paper packaging, although the recycling process does gradually shorten and weaken the fibres, and so for certain applications virgin fibres must also be used to achieve the performance requirements of the packaging. As a general estimate, fibres can be recycled between 4 and 7 times before they can no longer be used in the paper manufacturing process.[165]

In view of the data available and the stakeholders consulted, in an intermediate proposal, the cardboard and/or paper targets were raised to 100% recycled content for both sales (primary) and grouped (secondary) packaging. Furthermore, as an alternative, all (100%) cardboard and/or paper used for the sales (primary) and grouped (secondary) packaging was allowed to be sustainably sourced (covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent). Evidence suggested a mature technological market, where supply is available and constrained by the availability for recycling. Additionally, depending on the type of application, the use of virgin fibres might be required, which supports ensuring sustainable sourcing as part of the criterion. Together, raising the recycled content or allowing sustainable sourcing should provide producers with the necessary flexibility to ensure compliance while meeting the stringent environmental requirements. However, the final voted criteria were modified in relation to the targets for cardboard and/or paper used for packaging with sales packaging and grouped packaging to contain a minimum of 40% and 80% recycled material respectively. The remaining share (100% minus recycled content percentage) is to be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification schemes.

[163] Kowalska, M., Donatello, S., and Wolf, O., 2019. Final Technical Report, Revision of the EU Ecolabel criteria for Paper products. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/441/documents

[164] EUROSTAT Recycling rates for packaging waste, https://ec.europa.eu/eurostat/databrowser/view/ten00063/default/table?lang=en (accessed 04/01/2023).

[165] Australian Packaging Covenant Design Smart Material Guide: Fibre-Based Packaging, https://www.australianpackagingassessment.com.au/wp-content/uploads/2017/11/2.-Fibre_DSMG.pdf

With regards to plastic packaging, the initial proposal was to set a minimum limit of 10% recycled plastic (to increase up to 25% after 1 January 2028) in AHP packaging.

These targets were the result of investigations previously carried out, either *via* bilateral consultation meetings or literature research, which indicated the following:

- At key stakeholders' meetings, some light was shed on how to approach the recycled plastic content in plastic packaging. The cited study focusing on 'Recycled content in plastic material with focus on PET, HDPE, LDPE, PP' specifies that 90% of LDPE in carrier bags can come from recycled sources; however, plastic bags used in AHP must provide functionality and resistance, with stakeholders explaining that even 20% recycled plastic content in AHP bags was not suitable.
- According to the SUP Directive, by 2025, PET bottles will be required to contain at least 25% recycled plastic. However, as there are still not minimum targets in place and there has not been a requirement for Member States to calculate or monitor the levels of recycled content in materials, there is still a high uncertainty in assessing if it is possible to extend this to other products' packaging. There is evidence, however, of some policies that encourage the uptake of recycled content, for example through Green Public Procurement (GPP).
- According to some sources, Belgium and Spain are the only Member States in which national targets for recycled plastic content are in place. Belgium's Flemish Government has set more ambitious targets for recycled content in plastic bottles than the SUP Directive, mandating a minimum level of 25% recycled content in PET bottles by 2022, and 50% by 2050. In Spain (since 1 January 2020), plastic bags exceeding 50 microns in thickness must contain at least 50% recycled content. There are on-going policy proposals to include a measure to impose fees on takeaway food packaging in Portugal.
- Plastics Europe's position on recycled content targets in plastic packaging was favourable during the review of Directive 94/62/EC on Packaging and Packaging Waste (PPWD)[166]. Plastics Europe explained that the 'harmonised rules on the use of recycled content in plastics packaging would help driving the market towards the uptake of increased quantities and qualities of recycled content, thus helping to avoid incineration and landfilling, and therewith contributing to European climate neutrality and circular economy goals'. It specified that 'final targets should be set collaboratively with the institutions and the value chain, but could be up to 30%, subject to certain necessary enabling conditions'. The most updated position to the new proposal for a PPWD from Plastics Europe[167] is also positive, highlighting that '*the proposal could ensure the recyclability of all plastics packaging*', '*the development of Design for Recycling Guidelines, and regulation that is science-based, fully material and technology neutral is the best way to allow the market to create the required new business models, and recycling, collection and sorting technologies*', 'we also advocate for ambitious and realistic reuse and recycled content targets, supported by the right enabling framework', but '*we continue to call for flexibility in meeting recycled content targets through setting them as averages rather than for every individual item of packaging*' and finally '*we also fear the PPWR proposal is a missed opportunity for the Commission to boost the potential of biobased plastics in contributing to circular feedstock targets while reducing emissions'*.
- Furthermore, the availability of recyclates for plastic packaging shall also take into account closed-loop systems and not only mechanical but chemical recycling[168]. As a definition, 'chemical recycling' means the process of converting polymeric waste by changing its chemical structure and turning it back into substances that can be used as raw materials for the manufacturing of plastics or other products. There are different chemical recycling technologies, e.g. pyrolysis, gasification, hydro-cracking and depolymerisation. On the other hand, closed-loop systems for recycled materials work with mono-materials and no mixed streams from virgin sources, with a high application field mainly in PET bottles.

166 Plastics Europe, 2021. Position on Recycled Content for plastics packaging under the review of the PPWD. Available at: https://plasticseurope.org/knowledge-hub/plastics-europes-position-on-recycled-content-for-plastics-packaging-under-the-review-of-the-directive-94-62-ec-on-packaging-and-packaging-waste-ppwd/

167 Plastics Europe, 2022. EU's ambitious PPWR targets should be matched by equally ambitious investment and innovation support measures. Available at: https://plasticseurope.org/media/eus-ambitious-ppwr-targets-should-be-matched-by-equally-ambitious-investment-and-innovation-support-measures/

168 Plastics Europe, 2022. Chemical recycling. Available at: https://plasticseurope.org/sustainability/circularity/recycling/recycling-technologies/chemical-recycling/

- Nevertheless, recent findings explain that chemical recycling may impose burdens on the actual sustainability of new recyclates[169]. The study is based on estimated future recycling content targets in plastic packaging (30-40%). This range includes the combination of mechanical and chemical recycling technologies. Results show that 'over 75% of the total GHG emissions are attributable to chemical recycling, being the emissions from mechanical recycling lower than those from chemical recycling by a factor of 9'. All in all, this study highlights that mechanical recycling must be prioritised over pyrolysis, wherever possible in combination with a reduction of 20% of packaging. It concludes that the combination of mechanical and chemical recycling used to transform plastic waste into recyclates avoids the GHG emissions associated with the use of primary plastic.
- While the addition of high recycled content targets for plastic packaging to use in AHP can compromise the availability of the recycled plastics in the market, expert consultation with researchers on mass flow analysis of plastic recyclates suggests that for the plastic packaging sector around 30–40% of recycled plastic would be reasonable (in line with above data)[170]. It should be noted that this is an average figure; while plastic carrier bags could contain up to 90% recyclates, other applications would contain a certain lower percentage of recyclates. Altough this study touching upon 'recycled content availability for different applications' is under preparation, expert consultation suggests decreasing the requested percentage of recycled plastic contained in AHP plastic packaging. However, in the near future a higher availability of recycled plastic material is envisaged. In addition, internal discussions suggest a possibility to increase the recycled plastic content of certain packages.

In addition, the study[171] on 'Recycled content in plastic material with focus on PET, HDPE, LDPE, PP' highlights the limiting factors in relation to the use of recycled plastic. Currently, the limitations to the use of plastic recycled content are as follows[172]:

- Product quality and performance: sometimes the quality standards reached with virgin plastic cannot be obtained in relation to the colours and stability of the product or packaging for the desired aim.
- Further recyclability of the materials: only single-use origin polymer streams are easily recyclable but, once recycled, single-origin material is not easy to obtain, which complicates further recycling.
- Availability of materials: manufacturers have a limitation as they may have less confidence in the recycling market and long-term supply.
- Safety of the materials: an example to consider is that of substances that could not be destroyed in the recycling process which remain in the material and subsequently are unintentionally introduced in new products that should not contain such substances for hygienic or sensitive reasons; this is of particular interest for the AHP case.
- Health concerns: during the recycling process there are potential environmental emissions and human exposure to chemicals depending on the behaviour of additives and non-polymer impurities in the recycling process.
- Price of recycled plastics: this is often higher than for their fossil fuel counterparts. It can happen that the use of fossil fuels and derived plastics is favoured by taxation and thus receives a cost advantage over ecological or recycled raw materials. The OECD publication "Improving Markets for Recycled Plastics" (2018) explains that "*although demand for recycled plastic is influential in the short term, it is the price of oil and primary plastic that drives prices for recycled plastics*"[173].

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169 ZWE, 2022. Climate impact of pyrolysis of waste plastic packaging in comparison with reuse and mechanical recycling. Available at: https://zerowasteeurope.eu/library/climate-impact-of-pyrolysis-of-waste-plastic-packaging/?mc_cid=91d03b460a&mc_eid=d535b86cd5

170 Irdanto Saputra Lase, Davide Tonini, Dario Caro, Paola F. Albizzati, Jorge Cristóbal, Martijn Roosen, Marvin Kusenberg, Kim Ragaert, Kevin M. Van Geem, Jo Dewulf, Steven De Meester. *How much can chemical recycling contribute to plastic waste recycling in Europe? An assessment using material flow analysis modelling*. Resources, Conservation & Recycling (*In Press).*

171 GIZ, 2022. 'Recycled content in plastic material with focus on PET, HDPE, LDPE, PP'. Available at: https://www.giz.de/de/downloads/2021-06%20Recycled%20Content%20in%20plastic%20material_barrierefrei.pdf

172 GIZ, 2022. 'Recycled content in plastic material with focus on PET, HDPE, LDPE, PP'. Available at: https://www.giz.de/de/downloads/2021-06%20Recycled%20Content%20in%20plastic%20material_barrierefrei.pdf

173 OECD, 2028. 'Improving Markets for Recycled Plastics'. Available at: https://www.oecd.org/environment/improving-markets-for-recycled-plastics-9789264301016-en.htm

Nevertheless, the proposal for recycled content targets to be set at 10% and 25% by 2028 and 2030 was challenged by several stakeholders, who stated that ambition levels should be set higher than the proposal for the revised PPWD.

The recently released proposal (November 2022) for the revised PPWD sets mandatory targets for recycled content, depending on the type of packaging[174]. For AHP, it is understood that the type of packaging is *other packaging* with targets of 35% by 2030 and 65% by 2040. Besides this, it should be noted that the accompanying IA document of this PPWD proposal for the Regulation[175] indicates the following: "*Firstly, it should be noted that in general, there are significant challenges associated with measuring the amount of recycled content in packaging, and, at present, there is no recognised standard methodology for doing so. It is therefore likely that recycled content measurement methods vary between organisations and across products. When interpreting the (limited) recycled content data that exists, it is important to bear in mind that data points are unlikely to be directly comparable or entirely accurate, but they do still give an indication of current level of recycled content uptake in different packaging materials / formats*."

The Impact Assessment also includes the following data:

- European Plastic Converters (EUPC) estimate that the average recycled content of PET bottles in the EU is 11.7%[176].
- The UK Plastics Pact reported that 10% of Pact members' plastic packaging by weight was comprised of recycled content in 2018, though the data were not broken down further by polymer or pack format[177].
- Analysis by ICIS suggests that the quantity of colourless rPET currently produced is only enough for European packaging and beverage firms to include ~16% rPET content as an average across the industry (and that is if the packaging industry has a 100% market share of the total European rPET market, which it does not)[178].
- A study published by PRE estimated levels of recycled content in PE non-food films for packaging, with 20% averaged recycled content. The findings are summarised in Table 4 below[179].

Table 4. Use of recyclate in key flexible film products, EU28+2 in kt

	Flexible PE Films Demand 2018, kt, est.	Recyclates Used 2018, kt, est.	Recycled Content, 2018
Film and foil (non-food)	3 410 000	400 000	12%
Bags/sacks (refuse)	440 000	300 000	68%
Carrier bags	110 000	100 000	91%
Bags/sacks	1 540 000	200 000	14%
Building film	180 000	100 000	56%
Agricultural film	536 000	118 800	22%
TOTAL NON-FOOD	6 216 000	1 218 800	20%

(Market Expert). Adapted from Eunomia for PRE (2020).

[174] For 2030 (a) contact sensitive packaging made from polyethylene terephthalate (PET) as the major component; (b) contact sensitive packaging made from plastic materials other than PET, except single use plastic beverage bottles; (c) single use plastic beverage bottles; (d) packaging other than those referred to in points (a), (b) and (c). For 2040 (a) contact sensitive plastic packaging, except single use plastic beverage bottles; (b) single use plastic beverage bottles; (c) plastic packaging other than those referred to in points (a) and (b).

[175] Commission Staff Working Document Impact Assessment Report Accompanying the document *Proposal for a Regulation of the European Parliament and Council on packaging and packaging waste, amending Regulation (EU) 2019/1020, and repealing Directive 94/62/EC Part 2/2* https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste_en (Accessed on 20/12/2022)

[176] European Plastics Converters Packaging Statistics, accessed 6 October 2020, https://www.plasticsconverters.eu/project-1

[177] WRAP (2019) UK Plastics Pact Report 2018-19, 2019, https://www.wrap.org.uk/sites/files/wrap/The-UK-Plastics-Pact-report-18-19.pdf

[178] Victory, M. Europe R-PET content targets unrealistic, accessed 20 October 2020, https://www.icis.com/explore/resources/news/2019/01/31/10313630/europe-r-pet-content-targets-unrealistic

[179] Eunomia for PRE (2020), Flexible Films Market In Europe: State Of Play, accessible at https://743c8380-22c6-4457-9895-11872f2a708a.filesusr.com/ugd/dda42a_a45684734c764933a2bc752e54e97212.pdf

The former sources of data derived from the PPWD IA suggest that currently the recycled content that it is (feasible) to use lies in the 10-20% range. However, it should be noted that this range does not allow enough granularity to understand the recycled content used for specific types of plastic and/or applications.

Regarding the (voluntary) ambition of key industrial players, the PPWD IA indicates the following figures:

- Coca-Cola: 50% recycled content in all packaging by 2030 (western European business has pledged to meet this target by 2025)[180].
- Colgate-Palmolive: 50% recycled content across all packaging in 2020 and 25% recycled content in plastic packaging by 2025.
- Danone: average of 25% recycled material for all its plastic packaging by 2025. Average of 50% recycled material for water and beverage bottles.
- Pepsico: 25% of recycled content in global plastic packaging by 2025 and 30% rPET in bottles[181].

The above voluntary industry compromises suggest a feasible target of 25% by 2025.

A comprehensive study based on material flows analysis[182] concluded that: '*the current end-of-life recycling rate (from 2018 data in Europe) based on mechanical recycling is about 24% calculated from the amount of recycled plastic production over the reported plastic waste generation. In future, several scenarios can be deployed to improve this rate. In first instance, stretching the possibilities of current commercially used mechanical recycling technologies can lead to an overall end-of-life recycling rate up to 49% in 2030. Results of this study show that the implementation of chemical and solvent-based recycling technologies bring positive impacts towards the end-of-life-recycling rate as plastic-to-plastic and plastic-to-chemicals recycling (from chemical recycling) will increase the rate up to 80%. In this most positive scenario (and potentially the most realistic one), chemical recycling becomes complementary (and not competitive) to improved mechanical recycling. In this scenario, plastic-to-plastic rate of 61% can be achieved (46% from mechanical recycling and 15% from chemical recycling), with an additional plastic-to-chemical rate of 19%. In all cases, plastic-to-fuel rates range from 3% to 6%, but it will likely be reduced in the future in favor for polymer and chemical production*'.

Hence, this study suggests that there should be enough availability of secondary raw materials to be used for recycled content (based upon availability of recyclates) to indicate a potential recycled content of close to 25% currently and near 49% by 2030.

In light of all the above, **the final proposal for plastic packaging was 20% recycled content**. This represents a compromise between ambition and feasibility in the short-term future. However, for the mid-term (**from the start of 2027**) **the proposed target is 35%**. The proposed recycled content percentages are aligned with the targets proposed by the new proposal for the Packaging and Package Waste Regulation, but requesting the achievement of target plastic recycled content percentages earlier. This would ensure feasibility in the short term, higher environmental ambition in general and the ability to react to the latest industrial/technical innovations and/or policy-landscape developments.

Table 5 summarises the EU Ecolabel proposed targets as well as those from the revised PPWD. Similarly, Table 6 displays the proposed means for Assessment and Verification of recyclability and recycled content.

[180] Ellen MacArthur Foundation (2019) New Plastics Economy Global Commitment: June 2019 Report, 2019, https://www.ellenmacarthurfoundation.org/assets/downloads/GC-Report-June19.pdf

[181] AIM European Brands Association (2020) Brands for a Clean & Circular Economy- Drivers of Sustainability – through Eco-Design https://www.aim.be/wp-content/themes/aim/pdfs/AIM%20Eco%20Design%202020_for%20website_FINAL3.pdf?_t=1588680215

[182] Irdanto Saputra Lase, Davide Tonini, Dario Caro, Paola F. Albizzati, Jorge Cristóbal, Martijn Roosen, Marvin Kusenberg, Kim Ragaert, Kevin M. Van Geem, Jo Dewulf, Steven De Meester. *How much can chemical recycling contribute to plastic waste recycling in Europe? An assessment using material flow analysis modelling*. Resources, Conservation & Recycling (*In Press*).

Table 5. Comparison of Recyclability and Recycled content targets in the two latest versions of the technical report (TR3.0 and final TR) with the revised draft Packaging and Package Waste Directive (PPWD), with distinction between type of packaging and dates of applicability (if relevant)

Type of material	Type of packaging	AHP Criterion 8 TR3.0			AHP Criterion 8 TR FINAL			PPWD[183]			
		Recycled content (% by weight)		Recyclability (% by weight)	Recycled content (% by weight)		Recyclability (% by weight)	Recycled content (% by weight)		Recyclability (% by weight)	
Targets		By 2028	After 2030	NA	Publication until 31/12/2026	From 01/01/2027	From publication	By 2030	2030 – 2040[184]	By 2030	After 2040[185]
Plastic	Sales (primary)	10	25	95% (5% compatible with recycling)	**20**	**35**	**95% (5% compatible with recycling)**	NA	(a) 30% (b) 10% (c) 30% (d) 35%	NA	≥70%
	Grouped (secondary)										
Paper and/or cardboard	Sales (primary)	40			40% and remaining share covered by valid chain of custody certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent			NA	NA	NA	NA
	Grouped (secondary)	80			80% and remaining share covered by valid chain of custody certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent						

[183] *Recycled content in PPWD and AHP EUEL criteria refers to post-consumer recycled content.*

[184] *(a) Contact sensitive packaging made from polyethylene terephthalate (PET) as the major component; (b) contact sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles; (c) single-use plastic beverage bottles; (d) packaging other than those referred to in points (a), (b) and (c). The latter category is assumed to be of application to AHP packaging, thus underlined the relevant recycled content target for AHP.*

[185] Note for 'special cases', Art. 6 will not be applicable until 2034. See *Until 31 December 2034, this Article shall not apply to the following:*
(a) immediate packaging as defined in Article 1, point (23), of Directive 2001/83/EC and in Article 4, point 25, of Regulation (EU) 2019/6;
(b) contact sensitive plastic packaging of medical devices covered by Regulation (EU) 2017/745;
(c) contact sensitive plastic packaging of in vitro diagnostics medical devices covered by Regulation (EU) 2017/746.

Table 6. Assessment and verification test methods for *Recyclability* and *Recycled content* in the two latest versions of the technical report (TR3 and final TR) and in the revised draft Packaging and Package Waste Directive (PPWD)

	AHP Criterion 8 TR3.0			**AHP Criterion 8 TR FINAL**			**PPWD**			
	Recycled content (% by weight)		**Recyclability (% by weight)**	**Recycled content (% by weight)**		**Recyclability (% by weight)**	**Recycled content (% by weight)**		**Recyclability (% by weight)**	
Targets	**By 2028**	**After 2030**	**NA**	**Publication until 31/12/2026**	**From 01/01/2027**	**From publication**	**By 2030**	**2030 – 2040**	**By 2030**	**After 2040**
ASSESSMENT AND VERIFICATION	EN 45557 or ISO 14021 Plastic recycled content in the packaging shall comply with chain of custody standards such ISO 22095		EN 13430 or ISO 18604 & Testing protocol INGEDE for paper and cardboard Testing protocol RecyClass for plastics (equivalent may be accepted)	EN 45557 or ISO 14021 Plastic recycled content in the packaging shall comply with chain of custody standards such ISO 22095 and EN 15343		EN 13430 or ISO 18604 & standard testing protocols: For paper and cardboard (repulpability) supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. For plastics: RecyClass for plastics. (equivalent may be accepted)	NA	To be determined via Implementing Acts adopted with procedure Article 59(3)[186]	To be determined via Implementing Acts adopted with procedure Article 59(3)[186]	

[186] By 31 December 2026, the Commission is empowered to adopt implementing acts establishing the methodology for the calculation and verification of the percentage of recycled content recovered from post-consumer plastic waste, per unit of plastic packaging, and the format for the technical documentation referred to in Annex VII. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59(3).

Recyclability targets

'Recyclability capacity' means the amount (mass or percentage) of an item available for recycling. Thus it means the quantity of an item (in this case a product or the packaging) suitable for mechanical recycling. In mechanical recycling[187], materials are recovered through mechanical processes such as sorting, washing, drying, grinding, re-granulating and compounding. Mechanical recycling does not change the chemical structure of the material as opposed to the chemical recycling previously defined.

While recycling packaging encourages more recycled content into the market, there must also be a 'pull' that draws the material back out into use. In other words, there must be a similar demand for recycled content to balance the market and resource use[188].

First, the packaging should be designed for recyclability. This means that the packaging material can easily flow through the recycling stream at the end-of-life. Recyclable packaging contributes to the supply of recycled content. To achieve recyclability, materials for packaging have to be:

- commonly accepted in municipal recycling collection;
- sorted by a material recovery facility;
- reprocessed into new feedstocks;
- purchased by end markets as new materials.

After three stakeholder consultations, the **recyclability capacity** (mass available for recycling) **for both paper/cardboard and plastic was set at ≥ 95% by weight,** while 5% residuals shall be compatible with recycling.

In relation to the recyclability of cardboard and/or paper, the PTS-Method PTS-RH 021 and the ATICELCA 501 evaluation systems were added to the Assessment and Verification test methods in line with the EU Ecolabel for printed paper[189].

Recyclability is determined by defibration (repulpability) and also by the capacity to form undisturbed paper sheets. Category I product indicates fibre for recycling suitable for the graphic grade, whereas Category II product denotes suitability for use for packaging papers. For Category I, only products with total rejects of less than 5% of the total weight of the product pass the test and are further evaluated for undisturbed sheet formation (deinkability assessment, sheet adhesion and visual adhesion inspection). Total rejects allowed for Category II products make up < 50% of the product weight and a deinkability test is not required.

The PTS-Method PTS-RH 021 and the ATICELCA 501 evaluation systems were developed to assess the recyclability of paper and board packaging. They have some important differences, mainly in the pulping time and methodology to measure screen rejects.

ATICELCA 501 (ATICELCA, 2019)[190] applies to all cellulose-based materials and products and is based on the provisions of the EN 13430 standard and annexes (CR 13688). The test assesses the efficiency of the recycling process as regards the loss of material and costs related to maintenance measures, and the quality of the recycled paper as regards suitability for use in paper products. The method simulates some of the main phases of industrial papermaking from paper for recycling and assesses four levels of recyclability (levels A+, A, B and C) and a 'non-recyclability with paper' level. The parameter with the worst value determines the recyclability level. In the case of non-recyclability, the material or product is not suitable for collection with a paper stream. It can however be used in other industrial processes or sent for energy recovery. The ATICELCA method differentiates between coarse rejects (waste rejects) and fibre flakes while the PTS method measures screen rejects from 0.7 mm screen slots. The PTS method indicates specific parameters and tests for the graphic line and packaging line while the ATICELCA method does not. In particular, the PTS method includes a deinkability test according to INGEDE Method 11.

187 European Bioplastics, 2020. Mechanical Recycling. Available at: https://docs.european-bioplastics.org/publications/bp/EUBP_BP_Mechanical_recycling.pdf

188 Recycled Content in Packaging: What you Need to Know, 2022. Available at : https://www.e2epkg.com/recycled-content/

189 Kowalska, M., Donatello, S., and Wolf, O., 2021. Final Technical Report for the EU Ecolabel for Printed paper. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/410/documents

190 https://www.artigiancarta.net/en/page/what-is-aticelca.html

PTS-Method PTS-RH: 021/97 (PTS, 2019)[191] assesses the recyclability of printed graphic products and paper and board packaging.

Both methods are suitable to verify compliance with criterion 8 in relation to the recyclability of paper and cardboard.

When looking at the recyclability of plastic packaging, standards such as RecyClass appear efficient methods to verify recyclability in a detailed procedure. Note that the standards EN 13430 and ISO 18604 only provide information on the possibility to recycle without information on the recycling stream most suitable to the plastic packaging[192].

When the RecyClass protocol is applied, results must be interpreted, i.e. if the sorting efficiency is higher than 80% and the rest is not sorted (residues) or sorted in the mix stream, then this means that the packaging is fully sortable and no penalties are applied; if more than 10% is sorted in another stream 1 class, a penalty is applied. When a sorting efficiency is lower than 50% the tests are failed, and the packaging is disqualified for recyclability.

Hazardous chemical migration

One of the issues when using **recycled materials** in the packaging of AHP is the risk of hazardous chemical migration or **transfer from the packaging to the product** when they are in close contact. There are no systems to ensure that recycled materials do not contain chemicals that are harmful to health and the environment.

The most known migration tests are those stated for **food contact materials** as in Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food[193], which defines the overall migration limit for the total sum of all migrating substances as well as specific migration limits for more than 1 000 monomers and additives like formaldehyde, bisphenol A, primary aromatic amines (PAA) or phthalates. Furthermore, the so-called non-intentionally added substances (NIAS), chemicals which may occur as impurities of raw materials, degradation or breakdown products of intentionally added chemicals, need to be considered and assessed due to their toxicological risk. These migration tests cover all kinds of substances which are transferred from food packaging to food irrespective of the nature and toxicological profile of the substance. The majority of these tests would be carried out according to the standard series EN 13130 for plastic materials.

Nevertheless, in this revision process it is not required to perform tests to prove that chemical migration does not occur. This aspect should be considered in the next revision of the EU Ecolabel criteria.

[191] https://www.ptspaper.de/en/testing-services/waste-paper-rejects-water/

[192] RecyClass, 2021. SORTING EVALUATION PROTOCOL FOR PLASTIC PACKAGING. Available at: https://recyclass.eu/wp-content/uploads/2021/10/SORTING-EVALUATION-PROTOCOL-FOR-PLASTIC-PACKAGING_FINAL-V1.0.pdf

[193] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN

5.11 CRITERION 9 for Absorbent Hygiene Products: Guidance on the use and on the disposal of the product and of the packaging

Annex I: Final proposal for criterion 9: Guidance on the use and on the disposal of the product and of the packaging
Instructions for the use of the final product shall be made available on the packaging or through a printed and/or digital leaflet. The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging: - that the sales packaging, the grouped packaging (if any), the separate components and the used product shall not be flushed into toilets, and - how to correctly dispose of the sales packaging, the grouped packaging (if any), the separate components and the used product. **Assessment and verification**: The applicant shall provide a high resolution photograph of the instructions for use of the product. The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears 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. In this last proposal, guidance on the use of the product has also been added.

The vast majority of sanitary products (mainly sanitary towels or pads and tampons) are individually packaged (separate component) before being contained in a single pack (sales packaging). Therefore, during the revision process it was proposed that the indications on not flushing them down the toilet and how to dispose of them all correctly would not only refer to the product, but also to the packaging and, if present, any separate component. As current waste management systems vary depending on the Member State, the disposal route of both product and packaging cannot be further specified. Consequently, what 'correctly dispose of' means should be interpreted taking into account this potential heterogeneity. This requirement shall apply to all the products within the scope of this product group and must be fulfilled by means of wording or visual symbols on the sales packaging.

With respect to the different recycling facilities for waste and packaging in different MS, the European Environment Agency (EEA) states that the waste recycling rate (proportion of waste generated that is recycled) has grown in the EU-27 in the last 5 years; however, the rate has slowed down with respect to previous years. In 2020[194], 64% of packaging waste was recycled while only 39% of the electrical and electronic waste stream was. The overall recycling rate across the EU-27 was 46% for all wastes (in 2020 it was slightly lower than in 2019, 48%).

By country[195], 2019 data showed that the overall packaging recycling rate in the EU-27 ranged from over 83% in Belgium to around 33% in Malta. Recycling rates indicate the amounts of packaging waste recycled as a proportion of packaging waste generated. While Belgium, the Netherlands, Luxembourg, the Czech Republic, Finland and Denmark achieved recycling rates of over 70% for packaging, another four countries recycled less than 50% of their packaging. While the new proposal for the Packaging and Packaging Waste Directive defines targets for recycling packaging waste, it is reported that targets may not be reached across

[194] EEA, 2022. Waste Recycling in Europe. Available at: https://www.eea.europa.eu/ims/waste-recycling-in-europe (accessed 04/01/2023)

[195] Recycling rate of packaging waste by type of packaging, Plastic, Paper and cardboard packaging, 2019 https://ec.europa.eu/eurostat/databrowser/view/cei_wm020/default/table?lang=en (accessed 04/01/2023)

all MS in due time. According to EUROSTAT data for 2019, 82% of all paper and cardboard packaging was recycled in the EU-27 while only 40.6% of all plastic packaging was recycled in the same period. Averages data for the EU-27 are shown in the following figure. All in all, data show the differences across the EU-27; however, certain packaging recycling rates are achieved to some extent in all MS.

Figure 4. Recycling rates in the EU-27 in 2019 for plastic, cardboard/paper and total packaging waste

Data sourced from Eurostat.

During the revision process, some stakeholders requested to add *'user health and safety information (duration of wear, toxic shock)'*. However, the duration of wear of AHP cannot be added as there is a high variety depending on the circumstances of use and individual characteristics, as supported by public organisms such as the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)[196] and the US Food & Drug Administration (FDA)[197]. Nevertheless, companies sometimes add this information as best practice. ANSES recommends to follow each product's specific recommendations for use, particularly concerning the length of time that tampons can be worn. Similarly, the FDA in a guidance document to assist industry in preparing premarket notification submissions indicates that, for tampons, information should be provided as part of labelling, more precisely the '*selection of tampon size and absorbency*; *tampon insertion*; *how tampon should be worn and wear-time;*' and '*tampon removal and disposal'*[198]. Specifically for toxic shock syndrome (TSS), it recommends to '*limit wear-time per tampon to no more than 8 hours and to advise against the use of tampons overnight'*. Both these guidance documents indicate the manufacturer as the entity who should ideally provide information on the safety features of their specific AHP.

196 ANSES, 2019, Sécurité des produits de protection intime - Avis rév : https://www.anses.fr/fr/system/files/CONSO2016SA0108Ra.pdf

197 Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff. July 2005 version. Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff | FDA (Accessed 20/12/2022)

198 Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff. July 2005 version. Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff | FDA (Accessed 20/12/2022)

5.12 CRITERION 10 for Absorbent Hygiene Products: Fitness for use and quality of the product

Annex I: Final proposal for criterion 10: Fitness for use and quality of the product

The effectiveness /quality of the final product shall be satisfactory and at least equivalent to that of products already on the market.

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 10. Performance thresholds shall be matched, where these have been identified.

Table 10. 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 ([1])	Consumer panel test (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 ([1])	Absorption rate and absorption before leakage		Syngina method	As for baby diapers and feminine care pads
	T2. Skin dryness ([1])	TEWL, rewet method or corneometric testing		Not applicable	As for baby diapers and feminine care pads

([1]) Panty liners intended to protect the feminine lingerie (light panty liners) are derogated from these requirements.

Assessment and verification:

A test report shall be provided for in-use and technical tests. The test report shall describe, as a minimum, the test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems.

Tests shall be conducted for all the specific type and size of products for which the EU Ecolabel application is made. Nevertheless, if it can be demonstrated that products have the same performance, only one size or a representative mix of sizes per each product design shall be tested.

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 the competent bodies under the respect of confidentiality. 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 in-use 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 (for products specifically designed or not for one gender). 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 shall not participate in the test. In cases where individuals become ill during 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, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively, 80% of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).

— 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 information provided in the application general assessment and verification text.

Rationale for the proposed criterion text

The aim of this criterion is to address the performance tests that AHP must undergo to fulfil all important characteristics and functions of the product. The quality of products awarded with the EU Ecolabel is one of the most important aspects of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendly but poor in terms of performance/inefficient.

During the revision process, the following changes were made:

- Panty liners derogation from requirement with regards to an in-use test, U1- Absorption and leakage protection, and technical tests, T1- Absorption and leakage protection and T2- Skin dryness.
- The threshold for the in-use test 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[199] specified that technical test methods for baby diapers and feminine care pads are also valid for nursery pads[200].
- Slight modification of the initial sentence of this criterion.
- Modification of the wording on the assessment of in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance) to better define the evaluation:
    - 80% of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100).
    - Alternatively, 80% of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).

The possibility to add a vaginal dryness test for tampons was considered. *Vaginal dryness* can be defined as a '*reduction of physiological lubrication of the luminal surface of the female vagina*', occurring at any age (yet with higher prevalence in postmenopausal women and women treated for breast cancer), causing discomfort and being associated with changes in hormone levels (i.e. estradiol)[201]. In the context of AHP use and for the specific case of tampons, it could be related to possible chemical and physical irritation to the mucosa or tissue dryness from absorptive effects[202]. Colposcopy has been used for the safety assessment of intravaginal products (including tampons) but, amongst other reasons, owing to shortcomings for assessing tampon-related effects, alternative methods for assessing potential tissue inflammation and dryness associated with tampons have been proposed. Irrespective of the approach proposed, for correct interpretation of the results, it is important to understand the natural history and clinical significance of minor alterations to the vaginal epithelium, many of which occur in the absence of product use. EDANA has developed guidelines for testing feminine hygiene products[203] and baby diapers[204]. In these guidelines there is no reference to a vaginal dryness test for tampons, nor is there in the last update on the EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021)[205]. Previous evidence suggests that there is no harmonised standard method in place to test vaginal dryness for tampons. Furthermore, the proposed tests within this criterion (*10. Fitness for use and quality of the product*), together with another related to chemical safety (7. *Excluded and restricted substances*) within the AHP set of criteria should be sufficient to ensure safe and fit-for-purpose use of AHP (including tampons). Given the evidence assessed, it was considered that the fitness for use is sufficiently covered with the proposed tests and that a further vaginal dryness test for tampons was not added.

Discussions on further explanation of the testing protocols for technical tests to be performed on AHP were held during the revision process. In this way, information was received in relation to the methodology applied for absorption speed before leakage, leakage test and rewet testing conditions for baby diapers as performed

199 KEBS, Kenya Bureau of Standards, 2021: https://www.kebs.org/index.php?option=com_content&view=article&id=938&Itemid=101 (accessed 30/08/2021).

200 Kenya Standard, 2017. Disposable Nursing Pad – Specification, KEBS 2017 First Edition 2017. Available at: https://members.wto.org/crnattachments/2018/TBT/KEN/18_1300_00_e.pdf (accessed 30/08/2021).

201 Myrtle Wilhite, Chapter 59 - Vaginal Dryness, Editor(s): David Rakel, Integrative Medicine (Fourth Edition), Elsevier, 2018, Pages 592-599.e2,ISBN 9780323358682, https://doi.org/10.1016/B978-0-323-35868-2.00059-1.

202 Farage, M.A., Miller, K.W. & Ledger, W.J. Assessing menstrual tampon irritation using the "Behind-The Knee" test. Arch Gynecol Obstet 287, 435–439 (2013). https://doi.org/10.1007/s00404-012-2641-7

203 EDANA, 2018. EDANA Guidelines for Testing Feminine Hygiene Products: https://www.edana.org/docs/default-source/international-standards/femcare-testing-guidelines-final.pdf?sfvrsn=b3f31df6_2 (accessed 12/04/2022).

204 EDANA, 2016. EDANA Guidelines for the Testing of Baby Diapers: https://www.edana.org/docs/default-source/international-standards/edana-diaper-test-protocol-2-0-final.pdf?sfvrsn=213c4e0_2 (accessed 12/04/2022).

205 EDANA, 2021. EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021). Available at: https://www.edana.org/docs/default-source/international-standards/table-of-content-nw-standard-procedures-20210105.pdf?sfvrsn=4ede1add_20 (accessed 12/04/2022).

by International Consumer Research & Testing (ICRT)[206]. This methodology provides different thresholds used as a reference for establishing a rating based on 5 stars. Moreover, EDANA has developed guidelines for testing feminine hygiene products[207] and baby diapers[208].

In the EDANA Guidelines for the Testing of Baby Diapers, there are no test methods for absorption and leakage protection listed. However, in the EDANA Guidelines for Testing Feminine Hygiene Products, the test method for Absorption rate/time of penetration is listed as NWSP 070.7.R0 (15) Repeated Liquid Strike-Through Time (Simulated Urine), the last update of which seems to be NWSP 070.7.R2 (20) according to the last update on the EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021)[209]. There are no test methods for leakage protection listed.

All in all, it was not proposed to provide further information on testing protocols and methodologies in criterion 10; however, it was proposed to add the detailed information of examples already developed in the User Manual of absorbent hygiene products. Here it might also be relevant to follow the developments of the Technical Committee ISO/TC 338 for menstrual products[210].

[206] International Consumer Research & Testing (ICRT), https://www.international-testing.org/

[207] EDANA, 2018. EDANA Guidelines for Testing Feminine Hygiene Products: https://www.edana.org/docs/default-source/international-standards/femcare-testing-guidelines-final.pdf?sfvrsn=b3f31df6_2 (accessed 12/04/2022).

[208] EDANA, 2016. EDANA Guidelines for the Testing of Baby Diapers: https://www.edana.org/docs/default-source/international-standards/edana-diaper-test-protocol-2-0-final.pdf?sfvrsn=213c4e0_2 (accessed 12/04/2022).

[209] EDANA, 2021. EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021). Available at: https://www.edana.org/docs/default-source/international-standards/table-of-content-nw-standard-procedures-20210105.pdf?sfvrsn=4ede1add_20 (accessed 12/04/2022).

[210] Technical Committee ISO/TC 338, Menstrual products https://www.iso.org/committee/8933440.html

5.13 CRITERION 11 for Absorbent Hygiene Products: Corporate Social Responsibility with regard to labour aspects

Annex I: Final proposal for criterion 11: Corporate Social Responsibility with regard to labour aspects

This criterion sets requirements applying to the final absorbent hygiene product assembly site.

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy[211], the UN Global Compact (Pillar 2)[212], the UN Guiding Principles on Business and Human Rights[213] and the OECD Guidelines for Multinational Enterprises[214], the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final 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)

— ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(vi) Remuneration:

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

— ILO Holidays with Pay Convention (Revised), 1970 (No 132)

— Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000[215] guidance on 'Remuneration'.

(vii) Health & Safety:

[211] ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.
[212] United Nations Global Compact (Pillar 2), https://www.unglobalcompact.org/what-is-gc/participants/141550.
[213] Guiding Principles for Business and Human Rights, https://www.unglobalcompact.org/library/2.
[214] OECD Guidelines for Multinational Enterprises, https://www.oecd.org/daf/inv/mne/48004323.pdf.
[215] Social Accountability International, Social Accountability 8000 International Standard, http://www.sa-intl.org.

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

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

— ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148)

(viii) Social protection and inclusion:

— ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)

— ILO Social Security (Minimum Standards) Convention, 1952 (No 102)

— ILO Employment Injury Benefits Convention, 1964 (No 121)

— ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)

— ILO Maternity Protection Convention, 2000 (No 183)

(ix) Fair dismissal:

— ILO Termination of Employment Convention, 1982 (No 158).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

The audit process shall include consultation with external industry-independent organisation stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. Meaningful consultations shall take place with at least two stakeholders from two different subgroups. In locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators.

During the validity period of the EU Ecolabel license, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

Assessment and verification:

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites 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 and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a public authority.

Valid certifications from third-party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

Rationale for the proposed criterion text

The aim of this 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.

The EU Ecolabel Regulation 66/2010, Article 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'.

During the revision process, several modifications were added in order to improve the clarity of the criterion. First, it was clarified that this criterion refers to **first-tier suppliers (final product assembly site).** This is due to the fact that first-tier suppliers (contract manufacturers) increasingly act vertically within the supply chain from purchase to final assembly. This would help the competent bodies to cross-check the availability of independent audit reports as these are also required for verification.

During the revision process, the criterion text was aligned with several other product groups such as the EU Ecolabel for footwear[216] and the EU Ecolabel for Electronic Displays[217], and important ILO conventions, a better definition of a living wage, and the auditing and public reporting of potential violations and remediations.

The International Labour Organization (ILO) is a United Nations agency devoted to promoting social justice and internationally recognised human and labour rights. The ILO helps advance the creation of decent work and economic and working conditions for all[218]. The underlying principles of the ILO fundamental conventions are supplemented by provisions addressing working hours, remuneration and health and safety. It is important to emphasise the references to the underlying principles in the criterion text, because ILO conventions are intended to be ratified at national level, whereas for social auditing they are used as a reference at factory or company level. The ILO conventions/provisions added during the revision process are:

- ILO Holidays with Pay Convention (Revised), 1970 (No 132);
- 2014 Protocol to the Forced Labour Convention;
- ILO Hours of Work (Industry) Convention, 1919 (No 1);
- ILO Weekly Rest (Industry) Convention, 1921 (No 14);
- ILO Minimum Wage Fixing Convention, 1970 (No 131);
- ILO Holidays with Pay Convention (Revised), 1970 (No 132);
- ILO Safety in the use of chemicals at work Convention, 1981 (No 170); ILO Occupational Safety and Health Convention, 1990 (No 155);
- ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148);
- ILO Medical Care and Sickness Benefits Convention, 1969 (No 130);
- ILO Social Security (Minimum Standards) Convention, 1952 (No 102);
- ILO Employment Injury Benefits Convention, 1964 (No 121);
- ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19);
- ILO Maternity Protection Convention, 2000 (No 183);
- ILO Termination of Employment Convention, 1982 (No 158).

Finally, in order to ensure an independent and meaningful audit process, additions were made:

- Reference to 'industry-independent organisation', which is added to make sure that genuine worker engagement is achieved.
- Inclusion of 'in locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators', to ensure that the attribution of the EU Ecolabel measures effectively generates social and labour rights outcomes for stakeholders, even in the case of European extraterritoriality.

[216] 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

[217] Candela Vidal-Abarca, Nicholas Dodd and Oliver Wolf Revision of EU Ecolabel Criteria for Electronic Displays (previously Televisions), 2020. Available at:https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2020-09/Final%20TR%20DISPLAYS.pdf

[218] https://www.ilo.org/global/about-the-ilo/mission-and-objectives/lang--en/index.htm

— Addition of 'meaningful consultations with stakeholders'; as explained by the OECD[219], meaningful stakeholder engagement is characterised by two-way communication and depends on the good faith of the participants on both sides. It includes in many cases engaging with relevant stakeholders before decisions have been made.

Many discussions during EUEB and AHWG meetings were around the need to keep this criterion. Indeed, it was highlighted by stakeholders that most AHP factories are located in the EU and for this reason the suggested additions do not aim to add unnecessary complexity to the criterion but rather to create a safety net for those non-European locations where legislation is less protective of workers. Because it can already ensure compliance with stricter legislation, this should not negatively impact the European industry or create an excessive burden for applications. Therefore, it was agreed with stakeholders that this criterion should be kept.

[219] OECD Due Diligence Guidance for Meaningful Stakeholder Engagement in the Extractive Sector https://www.oecd.org/publications/oecd-due-diligence-guidance-for-meaningful-stakeholder-engagement-in-the-extractive-sector-9789264252462-en.htm

5.14 CRITERION 12 for Absorbent Hygiene Products: Information appearing on the EU Ecolabel

Annex I: Final proposal for criterion 12: Information appearing on the EU Ecolabel
The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements: 'Designed to reduce impact on the environment', 'Fulfils strict requirements on harmful substances', 'Verified performance', The applicant shall follow the instructions on how to use the EU Ecolabel logo as 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 a high resolution photograph of the product sales packaging that clearly shows the label, the registration/license 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 makes an environmentally friendly decision easy. For this reason, this criterion is included in all EU Ecolabels.

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)).

During the revision process, the wording of this criterion was changed to harmonise it with the most recently voted product groups (cosmetic products and animal care products and growing media). It was also proposed to modify the order of the sentences.

6 Criteria proposal for Reusable Menstrual Cups

This chapter analyses the proposals for the development of EU Ecolabel criteria for reusable menstrual cups. Each criterion is analysed within a separate sub-chapter.

6.1 Summary of the proposed structure of the EU Ecolabel criteria for reusable menstrual cups

The proposal for the EU Ecolabel criteria for reusable menstrual cups is illustrated in Table 7. The order of the criteria mirrors the one for the EU Ecolabel criteria for absorbent hygiene products.

Table 7. Proposed EU Ecolabel criteria for reusable menstrual cups

	Proposed criteria
1	Emissions during production of the raw material
2	Environmental management of production
3	Material efficiency in the manufacturing of the final product
4	Excluded and restricted substances
5	Packaging
6	Guidance on the disposal of the product and of the packaging
7	Fitness for use and quality of the product
8	Information for the user
9	Corporate Social Responsibility with regards to Labour Aspects
10	Information appearing on the EU Ecolabel

6.2 CRITERION 1 for Reusable Menstrual Cups: Emissions during production of the raw material

Polyorganosiloxanes (the scientific name for 'silicones') are a special variety of polymers that do not contain carbon, but are a chain of alternating silicon and oxygen atoms, modified with various organic groups attached to the silicon atoms. The most usual repeat unit is the siloxane group (see Figure 5).

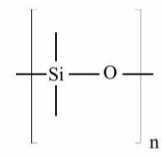

Figure 5. Chemical structure of the siloxane group in silicone polymers

There exist many types of silicones. However, the most important silicone compound is polydimethylsiloxane (PDMS, see Figure 6), covering more than 90 % of the total market amounts of siloxane and silane products. By adjusting the precise chemical structure and chain length of the polysiloxane, it is possible to produce silicone polymers with almost any desired property ranging from rigid solids to low-viscosity liquids[220]. The use of PDMS as elastomer is the use of interest for the scope of the EU Ecolabel. Depending on the processable form of the silicone elastomer, it will be called liquid silicone rubber (LIM or LSR), heat-cured rubber (HCE or HCR) and room-temperature-vulcanised rubber (RTV)[221]. To the JRC's knowledge, it is LSR that is normally used to produce menstrual cups.

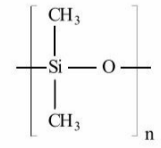

Figure 6. Chemical structure of polydimethylsiloxane (PDMS)

The processes and steps involved in the production of silicone for different uses are depicted in Figure 7. For the purpose of the EU Ecolabel, it is step 9 related to PDMS which is of relevance.

The main raw materials used to produce PDMS are elemental silicon (also called silicon metal), methanol and HCl. Elemental silicon is produced from mined quartz and various reduction agents in submerged electric arc furnaces[222]. Elemental silicon, methanol and HCl form methylchlorosilanes in the so-called Müller-Rochow process (or direct synthesis), which are then transformed to polymeric methyl siloxanes (silicone short linear or low molecular weight cyclic polymers) by hydrolysis. These products are separated into various fractions and further polymerised into PDMS. An increasing number of crosslinks between the polymers leads to rubbers and resins. The Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Production of Speciality Inorganic Chemicals (SIC) provides further details on the production processes[223].

According to the BREF for the Production of Speciality Inorganic Chemicals[223], the main environmental issues associated with the production of silicones are dust and chlorides emissions to air, as well as emission of copper and zinc to water. According to the LCA screening study carried out for the development of the EU Ecolabel criteria, the use phase is the most relevant life cycle phase, accounting for 96-99% of the impacts, depending on the impact category. However, when excluding the use phase and analysing only the other life cycle phases, the production of silicone contributes to 29% of the environmental impacts of silicone menstrual cups in terms of climate change.

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220 Boustead, I., 2002. Eco-profile of Silicones Executive Summary. European Silicones Centre – Centre Européen des Silicones (CES). Brussels, Belgium. Available at : https://www.yumpu.com/en/document/read/8815145/eco-profiles-of-silicones-silicones-science

221 Silicone vs. TPE: How to make the right choice. In: Rubber World, October 2017.

222 Global Silicones Council, Centre Européen des Silicones, Silicones Environmental, Health and Safety Council of North America, and Silicone Industry Association of Japan, Silicon-chemistry carbon balance: An assessment of greenhouse gas emissions and reductions - Covering the Production, Use and End-of-Life of Silicones, Siloxanes and Silane Products in Europe, North America and Japan. 2012. Available at: https://www.silicones.eu/wp-content/uploads/2019/05/SIL_exec-summary_en.pdf

223 JRC, 2007, Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Production of Speciality Inorganic Chemicals. Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/sic_bref_0907.pdf

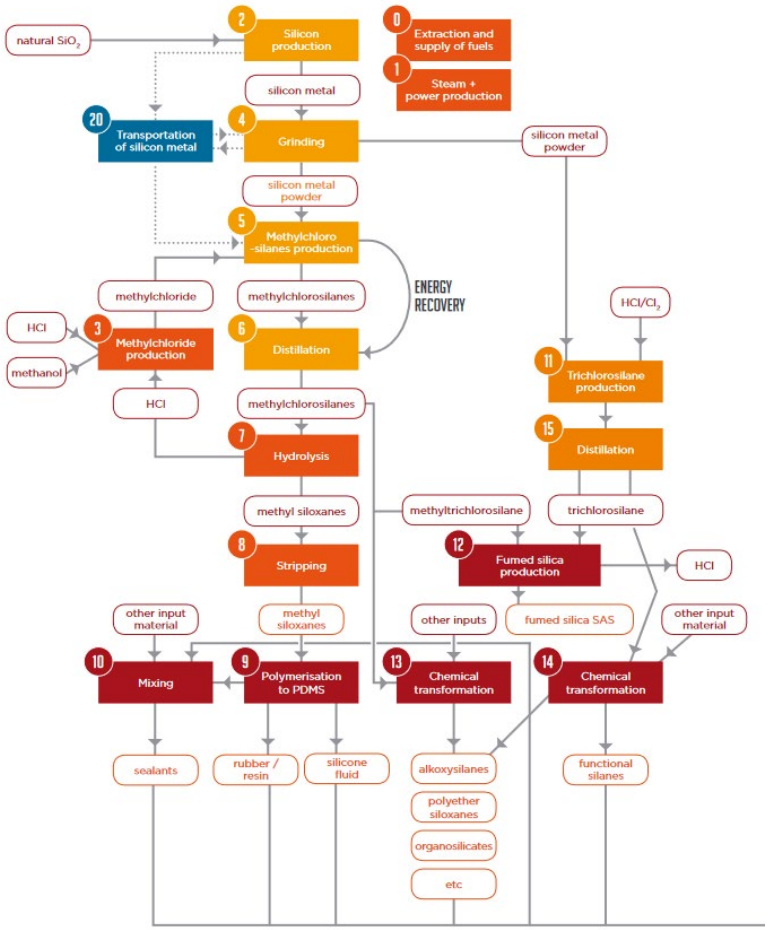

Figure 7. Different steps and processes for the production of different silicone products. For the EU Ecolabel, it is polydimethylsiloxane (PDMS, step 9) which is of relevance

Source: Global Silicones Council[222].

In light of the above, it is proposed to structure criterion 1 for reusable menstrual cups as follows:

- Criterion 1.1: Emissions of dust and chlorides to air;
- Criterion 1.2: Emissions of copper and zinc to water;
- Criterion 1.3: Emissions of CO_2.

During the revision process it was not possible to retrieve detailed information on the production of TPE. Nevertheless, TPE being a type of elastomer, the production process of the raw material can be assumed to be roughly similar. Since some requirements of sub-criteria 1.1-1.3 are also based on the BREF for Common Waste Gas Management and Treatment Systems in the Chemical Sector (WGC)[224], which applies to all chemical plants in Europe, it is proposed to set requirements based on the BREF for WGC.

[224] JRC, Best Available Techniques (BAT) Reference Document for Common Waste Gas Management and Treatment Systems in the Chemical Sector, Industrial Emissions Directive 2010/75/EU (Integrated Pollution Prevention and Control), Final Draft (March 2022). Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2022-03/WGC_Final_Draft_09Mar2022-B-W-Watermark.pdf

6.2.1 Sub-criterion 1.1: Emissions of dust and chlorides to air

Annex II: Final proposal for sub-criterion 1.1: Emissions of dust and of chlorides to air

(a) Emissions of dust

(i) This requirement applies to silicones only.

The storage and handling of the elemental silicon raw material shall use at least one of the following techniques:

Storing of elemental silicon in silos (after grinding);

Storing of elemental silicon in covered areas protected from rain and wind (after grinding);

Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding);

Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

(ii) This requirement applies to both silicones and other elastomers.

The yearly average of channelled emissions of dust shall be below 5 mg/Nm_3. The dust emissions should be continuously monitored.

(b) Emissions of chlorides

(i) This requirement applies to silicones only.

The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

(ii) This requirement applies to elastomers other than silicones.

Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0.01 ng TEQ/Nm3 (average over the sampling period). Monitoring of the PCDD/F emissions should take place every six months.

Assessment and verification:

The applicant shall provide a declaration of compliance from the raw material supplier with criterion 1.1. In addition, the declaration shall demonstrate compliance with:

- criterion 1.1(a)(i), the silicone supplier shall indicate which technique is used on site, providing pictures or technical descriptions, as supplementary data;
- criterion 1.1(a)(ii), the raw material supplier shall provide the results of the dust measurements taken on site, together with the yearly average of the dust emission. Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. For the production of silicones, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum;
- criterion 1.1(b)(i), the silicone supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps;
- criterion 1.1(b)(ii), the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases. Methods accepted are EN 1948-1, EN 1948-2 and EN 1948-3.

Rationale for the proposed criterion text

This criterion aims at minimising the emissions of dust and chlorides to air during production of silicon.

6.2.1.1 Criterion 1.1(a) Dust

During silicone material production, dust is emitted during the first steps, i.e. elemental silicon grinding, storage and handling. One of the measures to reduce diffuse dust emissions is to store elemental silicon, upon its arrival at the site, in silos or in covered areas, protected from wind and rain. Elemental silicon is normally stored in silos after grinding too.

Another way to reduce dust emissions to air from elemental silicon grinding, storage and handling is filtration by use of fabric filters. The dust-loaded off-gas streams from elemental silicon grinding, storage and handling are normally conveyed to off-gas filters before being discharged into the air. According to the BREF for the production of SIC[223], silicone producers in Europe can have between 5 and 20 fabric filters in their filtration system. The dust concentration in the treated off-gas streams generally ranges between 10 - 50 mg/Nm^3. The dust separated in the filters can be collected and recycled back into the process, which also has the advantage of achieving a reduction in raw elemental silicon consumption.

Nevertheless, the BREF for Common Waste Gas Management and Treatment Systems in the Chemical Sector (WGC) indicates a Best Available Technique-Associated Emission Levels (BAT-AEL) for channelled emissions to air of dust of 1-5 mg/Nm^3. This BAT-AEL applies to all chemical plants, including those for silicon and for other elastomers. Therefore, a 5 mg/Nm^3 dust emission level was proposed as a threshold (yearly average).

6.2.1.2 Criterion 1.1(b) Chlorides

During silicone material production, chlorides emissions occur during the methyl chloride synthesis, the direct synthesis and the distillation process steps. The off-gases from the methyl chloride synthesis mainly consist of nitrogen (87-89%), dimethylether (10%), methyl chloride (1-3%), methanol and traces of hydrocarbons. The off-gases from the direct synthesis step mainly consist of nitrogen (70-80%), methane (10-20%), hydrogen (5%), hydrocarbon (1-2%) and methyl chloride (1%). Finally, the off-gases from the distillation step contain nitrogen, methyl chloride and methylchlorosilane[223].

Given the presence of light hydrocarbons and chlorinated compounds, the off-gases from these steps must undergo a thermal oxidation step to minimise the risk of polychlorinated dibenzodioxins/furans (PCDD/Fs) formation. In addition, some plants apply a 'fast-quench' of post-combustion gases by cooling them very quickly from high temperatures to below the temperature window of dioxins/furans reformation. Finally, in the case of the combustion of halogenated VOC substances, an HCl scrubber is necessary.

During the revision process it was proposed to require, for the production of silicon, the thermal oxidation followed by scrubbing of the off-gases from the methyl chloride, direct synthesis and distillation process, and, for both silicon and TPE, PCDD/F emission levels below 0.01 ng TEQ/Nm^3, which is at the lower end of range given in the BREF.

6.2.2 Sub-criterion 1.2: Emissions of copper and zinc to water

Annex II: Final proposal for sub-criterion 1.2: Emissions of copper and of zinc to water
This criterion applies to silicones only. The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This shall include: - dewatering of the sludge before disposal; and - recovering of the solid metal residues in metal recovery plants. The concentration of copper in the treated effluent shall be below 0.5 mg/l, while the concentration of zinc shall be below 2 mg/l. **Assessment and verification**: The applicant shall provide a declaration of compliance from the silicone supplier with criterion 1.2, together with a proof that the plant has in place a wastewater system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicone supplier shall provide the measurement results for copper and zinc in the treated effluent.

Rationale for the proposed criterion text

This criterion aims at minimising the emissions of copper and zinc to water during production of silicon. As it was not possible to retrieve detailed information on the production of TPE, criterion 1 applies to silicon menstrual cups only.

Inorganic impurities in wastewater arise from the use of different catalysts and other additives during silicon production (the composition of the catalysts and additives is usually confidential). The main inorganic compounds present in the wastewater are copper and zinc.

To minimise the concentration of copper and zinc in the effluent, the wastewater from PDMS production can be treated in two steps: a pre-treatment by precipitation/flocculation, and a sedimentation step to remove heavy metals.

In this last stage of the revision process, the only change made was to delete the third bullet point, specifying only that the water treatment of the PDMS shall include dewatering of the sludge before disposal and the recovery of the solid metal residues.

6.2.3 Sub-criterion 1.3: Emissions of CO_2

Annex II: Final proposal for sub-criterion 1.3: Emissions of CO_2

This criterion applies to silicones only.

CO_2 emissions from the production of the silicone shall not exceed 6.58 kg per kg silicone, including emissions from the production of electricity (whether on-site or off-site). CO2 emissions shall include all sources of non-renewable energy used during the production of the silicone. Reference emission values according to Table 1 shall be used for the calculation of CO2 emission from energy sources. If needed, CO_2 emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO_2 emission factors for grid electricity should be in line with Commission Delegated Regulation (EU) 2019/331.

Table 1. Reference values for CO_2 emissions from different energy sources

Fuel	CO_2 emissions	Unit	Reference
Coal	94.6	g CO_2 fossil/MJ	Regulation 2018/2066
Crude oil	73.3	g CO_2 fossil/MJ	Regulation 2018/2066
Fuel oil 1	74.1	g CO_2 fossil/MJ	Regulation 2018/2066
Fuel oil 2-5	77.4	g CO_2 fossil/MJ	Regulation 2018/2066
LPG	63.1	g CO_2 fossil/MJ	Regulation 2018/2066
Natural Gas	56.1	g CO_2 fossil/MJ	Regulation 2018/2066
Grid Electricity	376	g CO_2 fossil/kWh	Regulation 2019/331

Assessment and verification:

The applicant shall provide data and detailed calculations for the CO_2 emissions from the production of the silicone.

The CO_2 emission data shall include all sources of energy used during the production of the raw material, including the emissions from the production of electricity (whether on-site or off-site).

When calculating CO_2 emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO_2 emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

The period for the calculations and/or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. 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 the grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing the specific value for its suppliers of electricity (contract for specified electricity or certified electricity). In this 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 (e.g. copy of a contract).

Rationale for the proposed criterion text

The production of silicones is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. This criterion thus aims at reducing the emissions of CO_2 occurring during the production of the raw material (silicone or other elastomers).

Energy sources used for the production of silicones are electricity, steam and natural gas. Electricity is used to run pumps, compressors, agitators and other electric motors. The direct synthesis step is a net producer of energy, which is normally recovered and converted into steam, which is used particularly for the distillation step. Natural gas is mainly used to operate the vent incineration units.

During the revision process, a threshold of 6.58 kg CO_2 per kg silicon was proposed for silicon-producing installations, according to the (few) relevant data points that could be found in the literature[177]. The structure of this sub-criterion was aligned with criterion 1.4 for AHP.

However, it was also discussed whether this sub-criterion should be maintained, since given the limited data availability it is difficult to estimate the impact of the proposed threshold for CO_2 emissions during silicone production. Nevertheless, it was finally decided to maintain the criterion, as it will allow the possibility to give an indication of a better CO_2 threshold in the next revision process.

6.3 CRITERION 2 for Reusable Menstrual Cups: Environmental management of production

Annex II: Final proposal for criterion 2: Environmental management of production

All plants producing either raw materials (silicone or other elastomers) or the final products shall have systems for the implementation of:

(a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);

(b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and, recovery of waste fractions that cannot be prevented (including energy recovery);

(c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

Assessment and verification:

The applicant shall provide a declaration of compliance with the criterion from (1) the producer of raw materials (silicone or other elastomers) and (2) from the manufacturer of reusable menstrual cups. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001 for water, waste and energy plans.

If waste management is outsourced, the sub-contractor shall provide a declaration of compliance with this criterion as well.

Applicants registered with EU Eco-Management and Audit Scheme (EMAS) and/or certified according to ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme shall be considered as having fulfilled these requirements if:

(a) the inclusion of water, waste and energy management plans for the production site(s) is documented in the company's EMAS environmental statement; or

(b) the inclusion of water, waste and energy management plans for the production site(s) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme.

Rationale for the proposed criterion text

The aim of this criterion is to set a series of additional measures in line with the reduction of the environmental impact of the manufacturing of raw materials (silicone or other elastomers) and the cups themselves. It should be noted that this criterion would apply to the main raw material manufacture (silicone or other elastomers) and to all production sites of RMC, i.e. without differentiation of material or technology used in these two manufacturing stages.

The LCA screening study performed on reusable menstrual cups (RMC) identified that, when the use phase is excluded from the assessment, raw material acquisition is the most relevant life cycle stage for all impact categories for both cup types, with the shares between 84% and 100% (silicone cup), and 80% and 100% (TPE cup). The study concluded that silicone production was the most relevant process in the Resource Use – minerals and metals (95%) and Human Toxicity – non-cancer (95%) impact categories, which were not identified among the most relevant life cycle stages when analysing results with the use phase. Similarly, for the thermoplastic elastomer production the most relevant process was also the Resource Use – fossils impact category (36%).

During the production of RMC, the majority of environmental burdens are associated with a demand for energy, usually electricity used for the moulding of the cups. However, the potential for setting criteria on this issue is considered limited due to the lack of statistical information on the consumption of energy per unit of product.

In light of the above, in this criterion it is required that manufacturers of silicone or other elastomers and RMC manufacturing sites implement systems for:

— water-saving,

— an integrated waste management plan,

— optimisation of energy efficiency and energy management.

These measures have the potential to reduce negative effects on the environment due to energy and water use and release of residues. Moreover, the text of the criterion is in line with criterion 4 for absorbent hygiene products. The application of the proposed measures can furthermore lead to cost savings (e.g. reduced water use and reduction of chemicals and other auxiliaries). It is worth noting that the implementation of energy and waste management strategies can save resources and produce monetary benefits in the long term.

6.4 CRITERION 3 for Reusable Menstrual Cups: Material efficiency in the manufacturing of the final product

Annex II: Final proposal for criterion 3: Material efficiency in the manufacturing of the final product
The requirements in this criterion shall apply to the final product manufacturing site. The quantity of waste generated during the manufacturing and packaging of the end products which is sent to landfill or incineration without energy recovery, shall not exceed 4% by weight of the end products. **Assessment and verification:** The applicant shall confirm compliance with the above requirement. 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. The applicant shall present all of the following: (a) the weight of the product and of the packaging, (b) all the waste streams generated during the manufacture, and (c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration. The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc).

Rationale for the proposed criterion text

The development of a criterion on the production and disposal of waste from the production of RMC is feasible, even if this issue plays a less significant role in the whole environmental assessment as highlighted by the LCA screening study of reusable menstrual cups. Economic and environmental benefits are associated with the reduction of production waste that cannot be reused in the manufacturing process or that is not converted to useful materials and energy.

During the revision process, it was requested that the net amount of waste generated during the manufacture and packaging of reusable menstrual cups shall be below 4% by weight of the produced cups, in line with criterion 6 for absorbent hygiene products.

6.5 CRITERION 4 for Reusable Menstrual Cups: Excluded and restricted substances

It is proposed that this criterion is structured in the same way as criterion 7 for absorbent hygiene products, therefore having three sub-criteria:

- Sub-criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council;
- Sub-criterion 4.2: Substances of very high concern (SVHCs);
- Sub-criterion 4.3: other specific restrictions.

6.5.1 Sub-criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Annex II: Final proposal for sub-criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

This criterion applies to the final product and any components therein.

Unless derogated in Table 4, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 2, in accordance with Regulation (EC) No 1272/2008.

Table 2. Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	-
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	
Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2

H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Endocrine disruptors for human health and the environment	
Category 1	Category 2
EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Persistent, Bioaccumulative and Toxic	
PBT	vPvB
EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Persistent, Mobile and Toxic	
PMT	vPvM
EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resource

Moreover, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) in concentrations greater than 0,010% (weight by weight) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 3, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 4.

Table 3. Restricted hazard classes, categories and associated hazard statement codes

Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	

Table 4. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008

Substance type	Derogated hazard class, category and hazard	Derogation conditions

	statement code	
Substances and mixtures with a harmonised classification as H304	H304	Substances with a viscosity under 20.5 cSt at 40°C.
Titanium dioxide (nano-form)	H351	Only when used as pigment. It cannot be used in powder or spray form

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

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.

This criterion shall not apply to:

— substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation;

— substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with relevant declarations from the producers of the components, a list of all chemicals used, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.

For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100%, shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0.0100% w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a restricted impurity shall be provided.

For substances exempted from sub-criterion 4.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

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

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

Rationale for the proposed criterion text

This criterion aims at minimising the use during the production process and presence in a final RMC of substances and mixtures that have hazardous properties. This sub-criterion is 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.*'

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

In order to correctly match the intention of Articles 6(6) and 6(7) of the EU Ecolabel Regulation, this sub-criterion focuses on the final product and not on hazardous substances and mixtures potentially used during the production process.

During the revision process, stakeholders commented that, if kept this way, this sub-criterion has the potential to be very restrictive. Indeed, some of the raw materials used for the production of RMC, such as catalysts, inhibitors and fillers, have a harmonised classification according to the CLP Regulation. While it is expected that these substances will not remain in the final product in a way that could be transferred to humans (for example, fillers are bound and fixed in the solid matrix of the silicone so that would not constitute a risk), the absence of analytical methods for silicone rubbers makes it impossible to ensure that such substances are not present in the final product. Moreover, because the criterion targets the substances that are added to the product formulation, the above-mentioned substances would not be allowed to be used.

Stakeholders suggested modifying the criterion and bringing it from a negative list (substances that cannot be used) to a positive list (substances that can be used), and informed that the silicone sector normally follows European Member States' lists for food contact, the main ones being the *BfR Recommendation XV for silicones*[225] (from Germany), and the *Arrêté du 25 novembre 1992*[226] (from France).

However, the EU Ecolabel criteria must comply with the EU Ecolabel Regulation, and in particular with its Article 6(6) which explicitly refers to the hazard classification according to the CLP Regulation, meaning that substances with a certain hazard classification according to the CLP Regulation *must* be restricted in EU Ecolabel products.

[225] https://www.bfr.bund.de/cm/349/XV-Silicones.pdf
[226] https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000178085/

6.5.2 Sub-criterion 4.2: Substances of Very High Concern (SVHCs)

Annex II: New proposal for sub-criterion 4.2: Substances of Very High Concern (SVHCs)
This criterion applies to the final product and any components therein. The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 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. **Assessment and verification** The applicant shall provide a signed declaration that the final product and the components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein. 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: https://www.echa.europa.eu/candidate-list-table Reference to the list shall be made on the submission date of the EU Ecolabel application. For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100%, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0.0100% w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a SVHC impurity shall be provided.

Rationale for the proposed criterion text

As with criterion 4.1, sub-criterion 4.2 is directly linked to Articles 6(6) and 6(7) of the EU Ecolabel Regulation (EC) No 66/2010, which effectively states:

'*the EU Ecolabel may not be awarded to goods containing […] Substances of Very High Concern, as referred to in Article 57 of Regulation (EC) No 1907/2006*'

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.

In line with the proposal for revised criterion 7.2 for AHP, and in light of the fact that RMC are products in direct and prolonged contact with the skin, this sub-criterion proposes a full ban on SVHCs.

6.5.3 Sub-criterion 4.3: Other specific restrictions

Rationale of the proposed criterion text

As for the case of sub-criterion 7.3 for AHP, sub-criterion 4.3 for RMC sets down specific restrictions.

Criterion 4.3 is subdivided into four sub-requirements:

- *4.3.1 Excluded substances*
- *4.3.2 Fragrances*
- *4.3.3 Ink and dyes*
- *4.3.4 Cyclosiloxanes*

6.5.3.1 Sub-criterion 4.3.1 Excluded substances

Annex II: Final proposal for sub-criterion 4.3.1 Specified excluded substances

This criterion applies to the final product and any components therein.

The following substances shall not be added (alone or in mixtures) to the chemical product used in the final product nor in any components therein:

(a) 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);
(b) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];
(c) Antibacterial agents (e.g. nanosilver and triclosan);
(d) Formaldehyde and formaldehyde releasers;
(e) Methylisothiazolinone (MIT)
(f) Nitromusks and Polycyclic musks;
(g) Organotin compounds used as a catalyst in the production of silicone;
(h) Parabens;
(i) Phthalates;
(j) Substances identified to have endocrine disrupting properties;
(k) 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.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0.0100% w/w in the chemical product. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

[Note:

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

This criterion lists the substances and compounds that shall not be present in the product.

No major comments were received on this criterion after its proposal, and no changes were made in this last stage of the revision process.

6.5.3.2 Sub-criterion 4.3.2: Fragrances

Annex II: Final proposal for sub-criterion 4.3.2 Fragrances

This criterion applies to the final product, any components therein, the separate components and the packaging.

Fragrances shall not be added to the final product, nor to any components therein, nor to the separate components, nor to the packaging.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion

During the revision process, it was proposed to exclude the use of fragrances from RMC, in line with the sub-criterion 7.3(b) for AHP.

No comments were received on this sub-criterion and no changes were made to this sub-criterion in the last stage of the revision process.

6.5.3.3 Sub-criterion 4.3.3: Inks and dyes

Annex II: Final proposal for sub-criterion 4.3..3 Inks and dyes

This sub-criterion applies to the final product and any components therein. This requirement does not apply to the separate components, the sales packaging and the information sheets.

The dying colorants and inks used in the reusable menstrual cup shall not exceed 2% of total weight of the cup.

The content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dying colorants and inks shall be below the limits given in the Council of Europe's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food .

The dying colorants used shall moreover comply with BfR's recommendations IX for Colorants for Plastics and other Polymers Used in Commodities or Swiss Ordinance 817.023.21 Annex 2 and Annex 10 .

The dying colorants and inks used shall also comply with sub-criteria 4.1 and 4.2.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, as well as documentation to ensure that impurities in the dying colorant or ink comply with the Council of Europe's Resolution AP (89) 1, and that the used dyes and inks are authorised according to the BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, Swiss Ordinance 817.023.21 Annex 2 and Annex 10, or the BfR's recommendation XXXVI. Paper and board for food contact.

This sub-criterion did not propose a full ban on colouring agents, since their use could prevent or mask the natural discolouring of the cup which can occur over the years, thus reducing the risk that consumers unnecessarily replace their cup with a new one.

During the revision process it was proposed that colouring agents must be approved for use as food additives in accordance with Regulation 133/2008[227]. However, since the dying colorants listed in that Regulation are not used in silicone elastomers, that part of the criterion was removed and replaced with standards normally used by the silicone industry, such as the BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities.

[227] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16–33. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32008R1333

In addition, there are certain levels of heavy metals present as impurities that should be respected, in accordance with the European Council's Resolution AP(89)1 on the use of colorants in plastic materials coming into contact with food.

6.5.3.4 Sub-criterion 4.3(d): Further restrictions applying to plastic materials – REMOVED

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

~~(ii) Additives used in plastics shall comply with sub-criterion 4.1 and 4.2.~~

~~**Assessment and verification:**~~

~~*The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, and safety data sheets (SDS) of any substance/mixture and their concentration in the final product.*~~

This sub-criterion was initially proposed in alignment with criterion 7.3(f) for AHP, which has now also been removed.

6.5.3.5 4.3.4 – Cyclosiloxanes

Annex II: Final proposal for sub-criterion 4.3.4 Cyclosiloxanes

This sub-criterion applies to the final product and any components therein.

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 raw materials in concentrations above 100 ppm (0,0100 % w/w). The 100 ppm limit is to be applied to each substance separately.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.

This criterion is in line with criterion 7.3(h) for AHP, and refers to the presence of the cyclosiloxanes D4, D5 and D6 in the final product.

D4, D5 and D6 are substances of very high concern according to the latest candidate list for authorisation: D4 has PBT (persistent, bioaccumulative and toxic) properties, is suspected to be toxic to reproduction, and is under assessment as a persistent organic pollutant[228]; while D5 and D6 have PBT properties[229]. However, these cyclosiloxanes are not intentionally added to the polymer, but are unavoidable impurities formed during the production of the polymer. Indeed, almost all cyclosiloxanes are removed in a final distillation step. However, a small content of residual cyclics remain in the silicone raw materials for technical/chemical reasons. Therefore, a full exclusion of these compounds is not possible.

[228] https://echa.europa.eu/substance-information/-/substanceinfo/100.008.307

[229] https://echa.europa.eu/substance-information/-/substanceinfo/100.007.969; https://echa.europa.eu/substance-information/-/substanceinfo/100.007.967

6.6 CRITERION 5 for Reusable Menstrual Cups: Packaging

Annex II: Final proposal for criterion 5: Packaging

This criterion sets requirements for sales and grouped packaging.

Grouped packaging shall be avoided or made only of cardboard and/or paper.

(a) Cardboard and/or paper used for packaging

Sales packaging made of cardboard and/or paper shall contain a minimum 40% of recycled material.

Grouped packaging made of cardboard and/or paper shall contain a minimum 80% of recycled material.

The remaining share (100% minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

(b) Plastic used for packaging

Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20% recycled material.

From 1 January 2027, sales packaging made of plastic shall contain a minimum 35% recycled material.

(c) Recyclability

The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.

(d) Additional requirements

Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.

Recycled content and recyclability of sales and grouped packaging shall be stated on the sales packaging.

(e) Separate component: bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100% certified sustainable fibres.

Assessment and verification:

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly.

Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.

The applicant shall provide audited accounting documents that demonstrate that the remaining share (100% minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel license. Competent bodies shall check the accounting documents again twelve months after the awarding of the license.

Recycled content shall be verified by complying with the EN 45557 or ISO 14021 while recyclability shall be verified by complying with the EN 13430 or ISO 18604.

Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting

documentation. Invoices demonstrating the purchase of the recycled material shall be provided.

In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

Moreover, the applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the reusable bag or pouch. FSC, PEFC, OEKO-TEX, GOTS, or equivalent schemes shall be accepted as independent third-party certification.

Rationale for the proposed criterion text

This criterion has been proposed in line with criterion 8 for absorbent hygiene products. In this criterion, guidelines on the composition of the sales and grouped (also referred to as primary and secondary) packaging are specified.

Usually RMC are packed in a bag/pouch, placed in a box made of cardboard/paper or plastic, which constitutes the sales packaging. Often cups are sold in pairs, allowing the possibility for them to be provided with grouped packaging. Most RMC are sold within a cloth bag or pouch made of textile which is considered a separate (also known as additional) component and is used to store the cup when not in use.

Excluding the use phase, the LCA screening study identified the production of cotton for the bag/pouch as a hotspot in almost all relevant impact categories, and to a lesser extent also the cardboard packaging in some impact categories. The LCA screening study showed that the production of a cotton bag is the most relevant process in Water Use (92% and 97% for silicone and TPE cups respectively), Ecotoxicity – freshwater (80% for both types), Eutrophication – marine (80% and 77%), and Climate Change (36% and 38%). In the impact categories Climate Change, Resource Use – fossils and Particulate Matter, the corrugated board used for packaging was identified among the most relevant processes with a lower share (14%, 14% and 8%, respectively for silicone cups). Also, in the case of TPE cups, corrugated board packaging was identified among the most relevant processes in Climate Change (17%), Resource Use – fossils (16%), Particulate Matter (10%) and Photochemical Ozone Formation (11%).

The criterion is aligned with new requests in criterion 8 for AHP where an extended discussion on the availability of recycled cardboard and/or paper and plastic materials is developed.

6.7 CRITERION 6 for Reusable Menstrual Cups: Guidance on the disposal of the product and of the packaging

Annex II: Final proposal for criterion 6: Guidance on the disposal of the product and of the packaging
The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging: (a) that the sales packaging, the grouped packaging (if any), the separate components and the cup shall not be flushed into toilets, and (b) how to dispose correctly the sales packaging, the grouped packaging (if any), the separate components and the cup at the end of its life. **Assessment and verification**: The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears clearly.

Rationale for the proposed criterion text

This criterion has been proposed in line with criterion 9 for absorbent hygiene products.

6.8 CRITERION 7 for Reusable Menstrual Cups: Information for the user

Annex II: Final proposal for criterion 7: Information for the user

The product shall be accompanied by instruction for its use. The manufacturer shall make sure that the user receives at least the following information:

(a) How to choose the right size of cup. Such information shall be placed where it can be accessed by the user before purchase (e.g. on the primary packaging).
(b) How to correctly wear the cup to avoid leakage and/or discomfort.
(c) How long to wear the cup before emptying it. Information on the longest wearing time shall be backed up by test studies. This information shall be given in a visible way, e.g. via a logo or in bold characters, and shall be placed both on the packaging and on the instructions for use.
(d) How to clean the cup before and after use during the same menstrual period, including, as a minimum, information about the importance of washing the hands, the need for boiling (yes/no, and if yes for how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
(e) How to clean and store the cup between menstrual periods, including, as a minimum, information about the importance of washing the hands, the importance of boiling (and information on how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
(f) How long it is possible to use the cup (the lifetime of the cup). It should moreover be stated that eventual discolouring of the cup has no influence on its lifetime and function.
(g) Information about the risk of developing toxic shock syndrome shall be provided.

Assessment and verification:

The applicant shall provide a sample of the information sheet/leaflet and, if relevant, the packaging sold with the cup displaying the information for the user. The applicant shall also provide relevant tests/studies, e.g. biological risk assessments or toxicology studies, supporting the above requirements.

Rationale of the criterion text

According to the LCA screening study performed on reusable menstrual cups (see Section 2.3.3), the use phase is the most relevant life cycle phase, accounting for 96-99% of the impacts, depending on the impact category. While the EU Ecolabel cannot set criteria to limit the impacts during the use phase, as the behaviour of the user is out of control, it is possible to make sure that the users receive the relevant information needed to correctly use the menstrual cups. The intention of criterion 8 is not to decrease the level of hygiene related to the use of the cup, but rather to prevent consumers adopting excessive hygiene practices due to misconceptions, as these are linked with higher environmental impacts.

The proposed criterion above requires that the user receives information on the following aspects:

- How to choose the right size of cup
- How to correctly wear the cup
- How long to wear the cup before emptying it
- How to clean the cup (during the same menstrual cycle)
- How to clean the cup (between menstrual cycles)
- The lifetime of the cup
- Toxic shock syndrome

During the revision process the discussion especially focused on whether this criterion should mandate the maximum wearing time that women should follow to avoid the development of toxic shock syndrome.

Literature, studies and guidance on different brands of reusable menstrual cups point to a recommended wearing time of 4-12 hours[230,231,232,233,234]. While there is no official medical advice on the recommended wearing time of the menstrual cups, ANSES (the French Agency for Food, Environmental and Occupational Health and Safety) has published an opinion on the safety of feminine hygiene products[(186)]. In its study, ANSES investigated the use of feminine hygiene products and the perception of the risks in a sample of 1 065 French women from 13 to 50 years of age. As reported by ANSES, the risk of developing menstrual TSS is associated with wearing feminine hygiene products (so tampons and menstrual cups), and the risk of developing TSS increases with the time that internal feminine hygiene products are worn. While the assumption of a link between the risk of menstrual TSS and the composition of internal feminine hygiene products or the presence of residual chemicals was put forward by the experts, no evidence in the scientific literature or in the results of the ANSES study can currently confirm or refute this assumption[186]

It is important to take into account that the majority of the information available on menstrual TSS relates to the use of tampons, as this product has been in the market for longer. Moreover, the results of the survey indicate that nearly 30% of surveyed women do not change their menstrual cup for a whole day.

The conclusions of the ANSES study point to clear guidance on the wearing time of the reusable menstrual cup. However, even the ANSES study does not conclude on a recommended wearing time; rather, it recommends that manufacturers provide clear guidance in the instructions for use.

[230] ANSES, 2019, Sécurité des produits de protection intime - Avis révisé de l'Anses. Rapport révisé d'expertise collective. Available at : https://www.anses.fr/fr/system/files/CONS02016SA0108Ra.pdf

[231] 60 millions de consommateurs, 2019, Essai comparative: Nous avons testé les coupes menstruelles, et c'est rassurant. Available at : https://www.60millions-mag.com/2019/09/13/nous-avons-teste-les-coupes-menstruelles-et-c-est-rassurant-16808

[232] Lunacopine, available at: https://www.bivea.fr/marque/8-lunacopine?gclid=EAIaIQobChMItdrBup28-gIVx-J3Ch1SNAMNEAAYASAAEgJZYvD_BwE (accessed 30.09.2022)

[233] Healthline, 2019, Everything You Need to Know About Using Menstrual Cups. Available at: https://www.healthline.com/health/womens-health/menstrual-cup#how-to-choose (accessed 30.09.2022)

[234] UNFA, UNICEF and UNHCR, Menstrual Cup Specifications. General description. Available at: https://www.unfpa.org/sites/default/files/resource-pdf/Specifications%20Reusable%20Menstrual%20Cup%20%20-%20UNFPA%2C%20UNHCR%2C%20UNICEF.pdf

6.9 CRITERION 8 for Reusable Menstrual Cups: Fitness for use and quality of the product

Annex II: Final proposal for criterion 8: Fitness for use and quality of the product

The effectiveness /quality of the final product shall be satisfactory and at least equivalent to that of products already on the market.

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Fitness for use shall be tested with respect to the technical tests referred to as for biocompatibility of the materials used for the manufacturing of reusable menstrual cups. Biocompatibility test shall provide the biological evaluation of cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days).

Table 5. Characteristics and parameters describing the fitness for use of the product to be tested

Characteristic		Testing practice required (performance threshold)
In-use tests	U1. Leakage protection	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)
	U2. Fit and comfort	
	U3. Overall performance	
Technical tests	T1. Biocompatibility	No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993. Alternatively compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) could be reported.

Assessment and verification:

A test report shall be provided describing test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems.

In-use tests shall be conducted for the specific products for which the EU Ecolabel application is made. 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.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups for which the EU Ecolabel application is made. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test that material only once. Reusable menstrual cups are not requested to undergo technical tests, only the materials used in the production of cups (this includes silicones, cross-linked silicone elastomers, other elastomers, colorants used and any other materials).

Special care shall be taken regarding sampling, transport and storage of the materials and 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 the 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 materials 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 in-use 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.

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

— Sick individuals and those with a chronic condition shall 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 (leakage protection, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80% of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).

— 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.

— Technical tests shall be performed in accordance to ISO 10993 series or the USP Class VI standard.

— Test methods whose scope and requirement standards is considered equivalent to the one of the named national and international standards and whose equivalency have been confirmed by an independent third party shall be accepted.

Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.

Rationale for the proposed criterion text

This criterion has been proposed in line with criterion 10 for absorbent hygiene products and as such it was aligned with it as much as possible.

The aim of this criterion is to address the performance tests that RMC must undergo to fulfil all the important characteristics and functions of the product. The quality of products awarded the EU Ecolabel is one of the most important aspects of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendlier but poor in terms of performance/inefficient.

During the revision process, it was requested that RMC shall be tested with (1) 'in-use tests' such as leakage protection, fit and comfort and overall performance (the three to be assessed though a consumer panel test) and (2) 'technical tests' such as biocompatibility (cytotoxicity, hemolysis, pyrogenicity, sensitisation, dermal irritation and implantation (90 days) as indicated by ISO 10993) or compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test). A description of the 'in-use tests' (leakage protection, fit and comfort and overall performance) and 'technical tests' (biocompatibility according to ISO 10993 or USP Class VI) can be found in TR2.0[235].

During the revision process, the main discussions addressed aspects related to the *Assessment and verification* section, which led to the clarification that only materials used in the manufacturing of cups have to undergo technical testing, not the final products.

[235] https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2022-06/Technical%20Report%202__0.pdf

6.10 CRITERION 9 for Reusable Menstrual Cups: Corporate Social Responsibility with regards to Labour Aspects

Annex II: Final proposal for criterion 9: Corporate Social Responsibility with regard to Labour Aspects

This criterion sets requirements applying to the final reusable menstrual cup manufacturing site.

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy[236], the UN Global Compact (Pillar 2)[237], the UN Guiding Principles on Business and Human Rights[238] and the OECD Guidelines for Multinational Enterprises[239], the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

Fundamental conventions of the ILO:

(a) Child Labour:

— Minimum Age Convention, 1973 (No 138)

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

(b) 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)

(c) 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)

(d) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)

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

Supplementary provisions:

(e) Working Hours:

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

— ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(f) Remuneration:

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

— ILO Holidays with Pay Convention (Revised), 1970 (No 132)

— Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000[240] guidance on 'Remuneration'.

(g) Health & Safety:

[236] ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.
[237] United Nations Global Compact (Pillar 2), https://www.unglobalcompact.org/what-is-gc/participants/141550.
[238] Guiding Principles for Business and Human Rights, https://www.unglobalcompact.org/library/2.
[239] OECD Guidelines for Multinational Enterprises, https://www.oecd.org/daf/inv/mne/48004323.pdf.
[240] Social Accountability International, Social Accountability 8000 International Standard, http://www.sa-intl.org.

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

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

— ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148)

(h) Social protection and inclusion:

— ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)

— ILO Social Security (Minimum Standards) Convention, 1952 (No 102)

— ILO Employment Injury Benefits Convention, 1964 (No 121)

— ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)

— ILO Maternity Protection Convention, 2000 (No 183)

(i) Fair dismissal:

— ILO Termination of Employment Convention, 1982 (No 158).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

The audit process shall include consultation with external industry-independent organisation stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. Meaningful consultations shall take place with at least two stakeholders from two different subgroups. In locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators.

During the validity period of the EU Ecolabel license, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

Assessment and verification:

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites 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 and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a public authority.

Valid certifications from third party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

Rationale for the proposed criterion text

This criterion has been proposed in line with criterion 11 for absorbent hygiene products. For more details for this requirement, please refer to Section 5.13 of this report.

6.11 CRITERION 10 for Reusable Menstrual Cups: Information appearing on the EU Ecolabel

Annex II: Final proposal for criterion 10: Information appearing on the EU Ecolabel
The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements: — 'Designed to reduce impact on the environment', — 'Fulfils strict requirements on harmful substances', — 'Verified performance'. The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines: https://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf **Assessment and verification:** The applicant shall provide a declaration of compliance with the requirement and a high resolution photograph of the product sales packaging that clearly shows the label, the registration/license 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 makes an environmentally friendly decision easy. For this reason, this criterion is included in all the criteria set for all EU Ecolabel product groups.

Although, according to the LCA screening study performed on reusable menstrual cups (RMC), the environmental hotspots identified are mainly from the use phase, having contributions between 98% (Acidification) and 99% (Ecotoxicity – freshwater) in the case of silicone cups, and 96% (Acidification) and 99% (Ecotoxicity – freshwater) in the case of TPE cups, when the use phase is excluded from the assessment, raw material acquisition is the most relevant life cycle stage for all impact categories for both cup types, with the shares between 84% and 100% (silicone cup), and 80% and 100% (TPE cup); this is addressed by criterion 1 (emissions during production of raw materials).

In addition, the study concluded that silicone production was the most relevant process in the Resource Use – minerals and metals (95%) and Human Toxicity – non-cancer (95%) impact categories, which were not identified among the most relevant life cycle stages when analysing results with the use phase. In the same way, for the thermoplastic elastomer production the most relevant process was also the Resource Use – fossils impact category (36%). These impacts are minimised by means of criteria 2, 3, 5 and 6 (environmental management of production, material efficiency in the manufacturing of the final products, packaging and guidance on the disposal).

This justifies the choice of the three statements proposed for this criterion.

7 IMPACTS OF THE CHANGES TO THE CRITERIA

This section consists of a summary of the main general changes proposed for the revised criteria and potential implications for current licence holders and possible applicants.

The scope has been enlarged to also add reusable menstrual cups. In addition, adult incontinence products are not excluded *a priori* if the product is not registered as a medical device.

Absorbent hygiene products

The revised criteria see a general increase in the level of ambition proposed, and the addition of new criteria, in particular to reinforce aspects related to the product's circularity:

- In relation to criteria 1 and 2 on fluff pulp and man-made cellulose fibres (MMCF), it is proposed to raise the minimum share of sustainable fibres from 25% in the criteria in force to 70% for fluff pulp and MMCF, an important contribution towards fighting the decrease in biodiversity. Moreover, the level of ambition for emissions to air and water for both fluff pulp and MMCF has also been raised, requiring much stricter emission limits compared to the current criteria in force. A new criterion on the energy use during the production of fluff pulp has also been added, setting a maximum threshold that companies should comply with. Since the pulp and paper industry is the fourth largest industrial user of energy and the second industrial electricity consumer in Europe, estimated to represent 4% of total EU consumption, this criterion is an important step towards the objectives of the Green Deal.
- Criterion 3 on cotton has been modified to accept only organic cotton bleached with total chlorine free techniques.
- Criterion 4 on plastics has been modified, requiring plastic manufacturing facilities to have in place water-saving, integrated waste management, and optimisation of energy efficiency and energy management systems.
- A new criterion 5 for biobased plastic is proposed. According to this criterion, if biobased plastic materials are used in the product, their superior environmental profile compared to that of fossil-based plastics shall be demonstrated, in compliance with the latest applicable methodologies. It is not mandatory to use biobased plastic materials in the final product.
- In criterion 6 on material efficiency in the manufacturing, based on the information received from stakeholders, the proposed percentages of waste generated during the manufacture and packaging of the products are proposed to be restricted to 8% w/w for tampons and 4% w/w for all the other products.
- With respect to criterion 7 on chemical substances, its ambition level has been significantly increased, with much lower concentration levels allowed and additional requirements proposed, for example on phthalates, substances identified or suspected of having endocrine-disrupting properties and hazardous impurities such as PCDDs, PCDFs, PCBs, PAHs, phthalates and heavy metals. The use of lotions and fragrances is now excluded in all products. The changes applied in this criterion ensure that the inclusion of substances with hazard properties is drastically reduced, in line with the recent Chemicals Strategy for Sustainability.
- A new criterion on packaging (criterion 8) has been proposed, requiring sales and grouped (or primary and secondary) packaging to be sourced from recycled materials (100% if sales and grouped packaging are made of cardboard/paper and 20% if sales packaging is made of plastic) and both to be designed for recycling (95%). The minimum plastic recycled content will increase to 35% from 1 January 2027 (sales packaging). This is an important step towards a circular economy, especially given the single-use nature of this product group.
- Finally, criterion 11 on Corporate Social Responsibility with regard to labour aspects ensures that the International Labour Organisation's Principles, the UN Global Compact, the UN Guiding Principles on Business and Human Rights, and the OECD Guidelines for Multinational Enterprises are fulfilled. The criterion has been strengthened, adding aspects such as the inclusion of considerations in determining the minimum wage, alternative mechanisms to express grievances (in relation to free association), reference to Health & Safety, ILO Working Environment (Air Pollution, Noise and

Vibration), and the addition of (viii) Social protection and inclusion and (ix) Fair dismissal considerations.

In conclusion, the revised criteria for absorbent hygiene product set a higher ambition level, reflecting front runners' performance, and potentially allow new products to be awarded the EU Ecolabel as a result of the changes in the scope. Special attention was paid to the circularity of the products and their packaging, which has been particularly increased with new requirements on biobased plastic and the packaging characteristics, which shall be recyclable and with a minimum content of recycled materials (varying depending on the material). These changes are in line with the new proposal for an 'Ecodesign for Sustainable Products Regulation' (ESPR), as the revised EU Ecolabel criteria reinforce measures to reduce AHP's carbon and environmental footprints, especially ensuring that EU Ecolabel AHP are fit for a climate-neutral and circular economy, preventing waste and boosting material recovery, and a minimum uptake of recycled material. Despite the single-use nature of absorbent hygiene products and their safety characteristics which do not allow the inclusion of recycled material within the product, this proposal for revised EU Ecolabel criteria allows the singling out of those absorbent hygiene products with a better environmental profile.

Reusable menstrual cups

The proposed criteria for reusable menstrual cups are the first of their kind, since so far no other environmental schemes have developed environmental criteria for their performance, and allow the EU Ecolabel to be awarded to a product that represents an alternative to (single-use) absorbent hygiene products, and whose market share is growing fast.

The proposed criteria ensure low emissions to air and water from the production of the raw materials, as well as a conscious system for optimising the use of water, the generation and management of waste and the consumption of energy, thus saving resources and controlling air and water pollution.

Moreover, the criteria ensure, as in the case of AHP, that hazardous substances cannot be added to the product and impurities are kept at a low level, in line with the Chemicals Strategy for Sustainability, and that the packaging is recyclable and contains a certain amount of recycled material (100% if made of cardboard/paper and 15% if made of plastic). The minimum plastic recycled content will increase to 35% from 1 January 2027, and to 65% from 2035. The pouch or bag the cups are sold with shall be made from 100% SFM fibres.

As the use phase was found to be the most impactful one from an environmental point of view, requirements were developed on the fitness for use of the cup and the mandatory information that manufacturers shall make available to the users. These two criteria ensure the high quality of the cup (in terms of safety for the user, prevention of leakage and durability of the cup) and a correct use by the user, thus reducing the risk of an earlier disposal of the cup compared to its expected (long) lifetime.

Finally, a social criterion was set to guarantee that the rights of the workers are respected.

8 TABLE OF COMMENTS

A table summarising all comments received during the three stakeholder consultations together with JRC responses is available at the following website:

https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents

List of abbreviations and definitions

AHP	Absorbent Hygiene Product
AHWG	Ad-Hoc Working Group Meeting
AOX	Adsorbable Organic Halogen
BAT	Best Available Technology
BAT-AELs	BAT-associated emission levels
BREF	Best Available Techniques Reference Document
CLP	Classification, Labelling and Packaging
CO_2	Carbon dioxide
COD	Chemical Oxygen Demand
DIBP	Diisobutyl phthalate
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
ISO	International Standardisation Organisation
LCA	Life Cycle Assessment
NGO	Non-governmental organisation
NOx	Nitrogen oxide(s)
MDR	Medical Device Regulation
PEFC	Programme for the Endorsement of Forest Certification
PAH	Polycyclic aromatic hydrocarbons
PBT	Persistent Bioaccumulative Toxic
PP	Printed paper products
PUR	Polyurethane
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMC	Reusable Menstrual Cup

SO_2	Sulphur dioxide
TOC	Total organic carbon, expressed as C (in water or in gases)
VOCs	Volatile organic compounds
vPvB	Very persistent, very bioaccumulative

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