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Revision of EU Ecolabel criteria for Absorbent Hygiene Products

Technical report v. 3.0

Faraca, G., Pérez Camacho, M. N., Lag Brotons, A. J., Pérez Arribas, Z., Kowalska, M. A., Wolf, O.

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Abstract

This Third Technical Report is intended to provide the background information for the revision of the existing EU Ecolabel criteria for Absorbent Hygiene Products (Commission Decision 2014/763/EU). The work of this Technical Report was carried by the Joint Research Centre, Seville (JRC Dir. B – Growth and Innovation). The work is being developed for the European Commission's Directorate General for the Environment.

The EU Ecolabel criteria for Absorbent Hygiene Products (AHP) set out in Decision 2014/763/EU were established in 2014. Their validity was prolonged until 31 December 2023.

The main purpose of this technical report 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 some of them should be revised, amended or removed; and finally, if any new criteria should be added.

This Technical Report addresses the requirements of the Regulation (EC) No 66/2010 (EC, 2010) for technical evidence to inform about the criteria revision, and sets the scene for the final consultation with stakeholders during the EUEB meeting scheduled for the 16th November 2022, and the following stakeholder consultation. This technical report is supported and complemented by a preliminary report (PR)[1], and the first draft of the technical report (TR1.0)[2], both published in September 2021 and the second draft of the technical report (TR2.0)[3], published in May 2022. In the preliminary report, the results of a life cycle assessment (LCA) for different products under the scope of the EU Ecolabel criteria was presented for the identification of the environmental hotspots. The LCA was performed using the Product Environmental Footprint (PEF) methodology as recommended in the Commission Recommendation 2021/2279[4], for the first time in the revision of EU Ecolabel criteria for a product group and as proposed in the new Circular Economy Action Plan[5]. In accordance with the PEF methodology, the assessment was third-party verified, and the revised version of the assessment, together with the conclusions from the third-party verifier, were published together with the second Technical Report (TR2.0) in May 2022.

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[1] More information can be found in the Preliminary Report, PR, 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%20Preliminary%20report_FINAL.pdf

[2] 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

[3] 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

[4] Commission Recommendation (EU) 2021/2279 of 15 December 2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32021H2279

[5] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM/2020/98 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:98:FIN

1 Introduction

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

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

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

Looking ahead, the EU Ecolabel was 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[6], including: a proposal for the Ecodesign for Sustainable Products Regulation, a 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 Third Technical Report addresses the requirements of the Ecolabel Regulation No 66/2010 for technical evidence to inform about the criteria revision and sets the scene for the final consultation with stakeholders during the EUEB meeting scheduled for the 16th November for the revision of EU Ecolabel criteria for Absorbent Hygienic Products product group.

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

Bringing together the information in the associated Preliminary Report on the assessment of the current scope and criteria validity, on the market analysis and on the life cycle assessment (LCA) studies (performed using the Product Environmental Footprint method), as well as the feedback from stakeholders, a third proposal for a set of revised EU Ecolabel criteria is presented in this Third 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 may define criteria that target environmental impacts from any of these life cycle phases, with the aim being to encompass the areas of greatest impact (life cycle hot spots).

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

This technical report consists of the following key sections:

- Section 2 (Summary of the preliminary report) describes the main findings from the preliminary report and the conclusions obtained regarding the scope definition and the key environmental aspects related to the product group of 'absorbent hygiene products'. After the AHWG1, this section was completed with new information on the environmental profile of reusable menstrual cups;
- Section 3 (Product group scope and definition) presents the proposed changes to the existing name, definitions and scope of the EU Ecolabel criteria;
- Section 4 (Assessment and verification) includes information on the type of documentation required to show compliance with the criteria that shall be provided by applicants and recognised by Competent Bodies;

[6] https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en

- Sections 5 and 6 (Criteria proposal) presents the third proposal for the revised EU Ecolabel criteria for the newly named 'absorbent hygiene products and reusable menstrual cups' product group. The new proposal is written in a blue box and subsequently a rationale is given. The second criteria proposal is included in a grey box for each criterion, to enable the comparison. Under each criterion proposed, the following information is presented:
- A summary of the rationale to the criterion text;
- A summary of the main outcomes received during the AHWG2 and the second stakeholder consultation;
- Further research carried out considering the comments received;
- Section 7 (Impact of changes to criteria) consists of a summary of the main changes proposed for the revised criteria and potential implications on current licence holders and applicants;

Moreover, a table of all comments received at the AHWG2 and during the second stakeholder consultation, together with responses and explanations on how they have been addressed in this TR3.0 report has been published as a separated document at the following webpage: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents

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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)[7] for the revision of EU Ecolabel criteria for absorbent hygiene products (AHP) with a focus on the scope and on the key environmental aspects. Legal and Policy context.

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

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

2.2 Market analysis

Since Absorbent Hygiene Products can be classified in different ways, a revision of the market segmentation according to different sources was undertaken. In the next paragraphs, unless otherwise stated, data are from Euromonitor International[8].

AHP are classified by means of PRODCOM data, Euromonitor data or using the EDANA[9] categorisation. In the PR and in the 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] More information can be found in the Preliminary Report, PR. Available at: https://susproc.jrc.ec.europa.eu/product-bureau//sites/default/files/2021-09/Absorbent%20Hygiene%20Products_Draft%20Preliminary%20report_FINAL.pdf

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

[9] 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/).

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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) whereas for feminine care pads are 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 represents over 34% of the market share, which is below worldwide average due to the higher tampons consumption in Europe (expresses in sales volume). The worldwide values of AHP sales volume are over 55% for baby diapers followed by feminine panty liners and pads (around 40%), whereas tampons' share of the total AHP market was about 5% for 2019 and 2020.

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[10].

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

Among reusable options, the menstrual cup has the highest Compound Annual Growth Rate (CAGR) predicted during 2020–2027. It has been reported that period underwear could experience a superior CAGR through the end of 2030. Consumer perception surveys on willingness to shift from disposable to reusable showed menstrual cups were the most used reusable option due to them being environmentally-friendly, comfortable and a good value for money as they can be used for five to ten years. A survey on reusable baby diapers showed the main attributes for the switch are related to 'value for money' and performance as 'leak protection' or 'soft materials for the baby skin'[11].

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

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

[10] 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).

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

2.3 Technical analysis

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

2.3.1 Literature review of life cycle assessment studies

The AHP within the scope of the EU Ecolabel have been subject to LCA studies for many years (Cordella et al. 2013[12], Mirabella et al. 2013[13], Arena et al. 2016[14], Mendoza et al. 2019[15], Hoffmann et al. 2020[16]). Within the AHP group, baby diapers were the first products to be analysed in LCA studies[12]. In general, diapers are more often studied while feminine care products are only occasionally the subject of the LCA studies. Comparative LCA studies of different types of baby diapers were conducted within several objectives. For instance, scientific articles on LCA of baby diapers have compared single-use and reusable options, single-use diapers with improvement in design or end-of-life scenarios for the disposable options. On the other hand, only one peer-review study has been found on a full LCA of three menstrual products where disposable tampons and sanitary pads, and reusable menstrual cups were compared. Two other academic works on LCA based on a limited range of products were analysed. LCA studies on breast pads are not available at the moment[17].

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[18, 16].

Differences are encountered whether single-use (disposable) products are compared with their correspondent reusable options. However, a limited number of scientific articles analyses the whole life cycle of the AHP that are addressed by the EU Ecolabel scope. The comparative LCA study of disposable and reusable baby diapers showed that for disposable options the production and consumption of raw materials had the highest environmental impacts while reusable baby diapers impacts were driven by consumer behaviour. For reusable diapers, temperature of washing and energy efficiency of the washing machine results in different outcomes whereas a reusable diaper system which optimises energy and water use has lower environmental impacts than single-use options[16].

Innovation seems to be a promising path to decrease the environmental impact of baby diapers. Several studies reported bio-based, glueless or different weights of material compositions as examples of more friendly options[13, 14, 15].

Assessment of the end-of-life scenarios is another option where biodegradation, pyrolysis, and composting might be of high potential for diaper recycling[19]. However, so far there has not been a consensus on what are the best methods for disposal of diapers or absorbent hygiene products. In fact, material recovery and recycling could require significant structural changes to the current waste management system. Thus said, at the moment there is not a well-implemented collection system across EU Member States for AHP[20]. There are

[12] 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

[13] 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

[14] 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

[15] 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

[16] 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

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

[18] 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

[19] 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

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

examples of industrial sites for recycling of baby diapers in Italy (Fater company) and the UK (Knowaste company)[21]. Although 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 the sanitary pads are caused by the manufacturing of low-density polyethylene (LDPE) foil[22]. Tampons are more environmentally favourable due to the different product weights and compositions which include higher content of renewable raw materials such as cotton[23]. 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[24].

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[25].

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

2.3.2 LCA screening study of absorbent hygiene products

A study to assess environmental impacts of average disposable open baby diapers and sanitary towels using PEF methodology[26] was performed. The detail information on the assessment is available in the Preliminary Report. The study aimed to find out the most relevant impacts categories, life cycle stages, processes and flows of selected AHP. The results of the study served as a base to identify the environmental hotspots and define these areas of the product lifecycle that need to be specifically addressed by EU Ecolabel criteria for AHP[27].

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

[21] 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.

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

[23] 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).

[24] 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

[25] 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).

[26] 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

[27] 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

third-party. The final opinion of the third-party verification was the following: "The study is technically 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 contribution between 76% (Climate Change) and 102% (Resource Use - fossils) for baby diapers, and between 91% (Eutrophication, terrestrial) and 100% (Resource Use – fossils and Resource Use - minerals and metals) for sanitary towels. It is worth noting that Resource Use – fossils exceeds 100% due to negative values in the end of life. Distribution has typically contributions around 5%, but in Acidification and Eutrophication, terrestrial it is around 10%. The highest contribution of the transport is in all cases because of the train transport.

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

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

The most relevant processes related to raw material acquisition of the baby diaper include production of superabsorbent polymers (SAP), fluff pulp, and polypropylene (PP), low density polyethylene (LDPE) and polyethylene terephthalate (PET) granulates (the complete list by impact categories and shares can be seen in the Table 12). These raw materials are also the main raw materials in the baby diaper production, especially SAP which was assumed to have 40% share of the all raw materials, and are thus identified to have the highest contributions of the impacts. In addition to raw materials, also 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 US to Europe (in particulate Matter and Photochemical Ozone Formation), and lorry transportation of raw materials and in product distribution phase (in Particulate Matter, Acidification and Eutrophication – terrestrial) are 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 the main contributing life cycle stage also in Cordella et al. (2015) and Mendoza et al. (2019) studies. However, in Hoffman et al. (2020) study, the End of Life is the most contributing life cycle stage with 75% contribution in Climate Change impact category due to emissions from landfilling, which is 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) Climate Change impact is 568 kg CO_2-eq for the 'one toilet trained child' or '4550 used diapers', while Hoffman et al. (2020) obtained an impact of 1236 kg CO_2-eq for same functional unit. In Cordella et al. (2015) the overall CO_2-eq is 592 kg and in the present study Climate Change impact is 410 kg CO_2-eq, if the impact is converted as a use of 4550 diapers.

The most relevant processes related to raw material acquisition of the sanitary towel include production of viscose, fluff pulp, and PET, LDPE and PP granulates (the complete list by impact categories and shares can be seen in the Table 13). 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 case of sanitary towel, LDPE packaging has the higher contribution in the most relevant processes compared to the baby diapers, because of the higher share of the 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, also train transportation of raw materials and packaging and lorry transportation of raw materials and in product distribution phase are identified among the most relevant processes for sanitary towels in some impact categories. In contrary 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 compensates the emissions from the landfilling.

When comparing the results with other studies, Mazgaj at al. (2021), observed that the most contributing process in the sanitary towels is the production of the LDPE foil, while Hait and Powers (2019) and Vilabrille Paz et al. (2020) (as cited in the United Nations Environment Programme report, UNEP (2021)) found that manufacturing of raw materials contributed the most to the overall impact. According to Hait and Powers (2019), the most contributing raw materials 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 has typically 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). 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 small share of impacts in almost all impact categories. Only in Climate Change impact of baby diapers End of Life has 19% of contribution, because of emissions of the landfilling of the product. For sanitary towels this is not the case because the mass of 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) are partly compensating the impacts of landfilling the product. The credits from the end of life of the packaging (assumed to be partly recycled) also explains why the End of Life stage has 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 without significant differences in the results in the majority of the impact categories. Only the Ionising Radiation impact category showed a significant difference because of nuclear energy in the average electricity mix. However, Ionising Radiation is not among the most relevant impact categories, so as a result, the main conclusions are not changed by using a different electricity mix.

Moreover, because SAP production data was based on literature, and resulted to be a hotspot of the system, the most relevant processes inside the SAP production dataset were further investigated. It was noticed that electricity consumption has the highest share of the impacts in many impact categories. Thus the assumption of electricity amount was also explored in the sensitivity analysis. In the absence of knowledge of the range of electricity consumption for SAP production, an arbitrary choice of -20% was decided to be tested. The analysis showed that such a decrease in electricity consumption would have very limited impact on the total results for baby diapers. Only in the case of Ionising Radiation the impact decrease is 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.

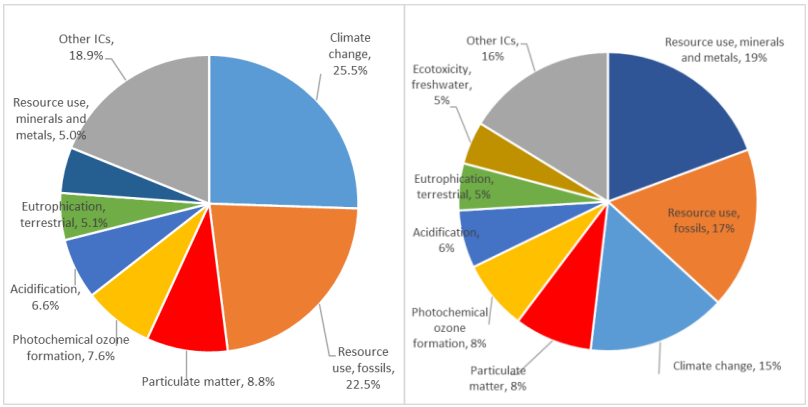

Figure 1. Impact category (IC) contribution to the final weighted score for baby diapers (left figure) and sanitary towels (right figure)

2.3.3 LCA screening study of reusable menstrual cups

A study to assess environmental impacts of average reusable menstrual cups using PEF methodology was performed[28]. The detail information on the assessment is published as a separated 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 impacts categories, life cycle stages, processes and flows of selected RMC. The results of the study served as a base to identify the environmental hotspots and define these areas of the product lifecycle that need to be specifically addressed by EU Ecolabel criteria for RMC.

The functional unit (FU) of the study is *ten 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:

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

— Ten 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 between 98% (Acidification) and 99% (Ecotoxicity – freshwater) in case of silicone cups, and 96% (Acidification) and 99% (Ecotoxicity –freshwater) in case of TPE cups.

[28] 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 have the share around 1-2% in case of silicone cups, and little bit higher, 1-3% in case of TPE cups. Impact of all other life cycle stages are negligible, manufacturing impacts being almost zero for all relevant impact categories.

In 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 environment). In all other impact categories, soap production is the most relevant process, and often also the only relevant process. In case of Climate Change, wastewater treatment after washing hands and RMC was identified as second relevant process, and in case of Resource Use – fossils, electricity used in the households to sterilise the cup before the first use and between cycles.

As use phase was identified as the most relevant life cycle stage with 98-99% share of the impacts, the most relevant impact categories, phases, processes and flows are presented also without use phase in Tables 13 (silicone cup) and 14 (TPE cup). Water Use and Climate Change are still two most important impact categories for both products, with the 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 the shares between 84% and 100% (silicone cup), and 80% and 100% (TPE cup).

In case of silicone cup, cotton bag is the most relevant process in Water Use (92%), Climate Change (36%), Eutrophication – marine (80%), Particulate Matter (33%) and Ecotoxicity – freshwater (80%) impact categories, and second relevant in Resource Use –fossils (32%) impact category. Silicone production is the most relevant process in 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), also corrugated board used for packaging was identified among the most relevant processes with the lower share (14%, 14% and 8%, respectively).

In the case of TPE cup, cotton bag 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 relevant in Resource Use – fossils (32%), Particulate Matter (34%) and Photochemical Ozone Formation (21%). Thermoplastic elastomer production is the most relevant process in Resource Use –fossils impact category (36%), and among the most relevant processes in Climate Change impact category (16%). Also in case of TPE cup, 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, also transport processes are among the most relevant processes in some impact categories, mainly train and lorry transports, which is due to the use of EF transport scenarios, which include also train transport, while in case of silicone cup, 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 impact of this assumption were analysed by sensitivity analysis, considering the case of 5 years lifetime for the silicone RMC, i.e. 2 cups would be needed during the 10 years 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 Resource Use – minerals and metals and Human Toxicity – non-cancer impact categories the impact increase is higher, between 6 and 7%. However, these impact categories are not identified among the most relevant impact categories when use phase is included.

For TPE cup, a 4 years lifetime was assumed in the baseline, i.e. 2.5 cups would be needed during the 10 years period. An alternative case was studied in case the lifetime would be 3 years (3.33 cups) or 5 years (2 cups). Also in case of the TPE cup, the lifetime assumption has only a marginal impact, less than 1% in most of the impact categories. Only in case of Human Toxicity – cancer and Photochemical Ozone Formation, the change is around 2% when 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. change and wash it only 2 times per day. As the use phase was the dominating 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 the TPE cup, the highest decrease can be noticed in Resource Use – minerals and metals, and Ozone Depletion (33%), and the lowest in Resource Use – fossils (15%).

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3 Scope and definition

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

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

Second proposal for product group scope:
1. The product group 'absorbent hygiene products' shall comprise any ~~sanitary~~ 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 to retain and collect menstrual fluid, and made of ~~medical-grade~~ silicone or other elastomers~~, rubber, latex, or elastomer~~. 3. The product groups 'absorbent hygiene products' and 'reusable menstrual cups' shall not include ~~incontinence products and any other type of~~ products falling under the scope of ~~Council Directive 93/42/EEC amended by~~ Regulation (EU) 2017/745.
Third 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 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.

Second proposal for definitions
For the purposes of this Annex, the following definitions shall apply: (1) 'Additional component' means any component (with protective or hygienic function) that is removed before the use of the product, e.g. the individual wrap or film where some absorbent hygiene products are contained within the primary packaging (mainly for tampons and sanitary pads), the release liner or paper in baby diapers and sanitary pads, or the applicator for tampons. The additional component can also be the cloth bag were menstrual cups are usually sold with. (2) '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. (3) 'Impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg). *[to be added to the User Manual: Examples of impurities are residues of the following: residues or reagents including residues of monomers, catalysts, by-products and detergents for production equipment*

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and carry-over from other or previous production lines.]

(4) 'Ingoing substance' means all substances included in the final product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

(5) 'Man-made cellulose fibres' means fibres produced from the raw material cellulose (wood or cotton) which include viscose, modal, lyocell, cupro and triacetate.

~~(6) 'Optical brightener' and 'fluorescent whitening agent' mean any additives used with the only purpose of 'whitening' or 'brightening' the material.~~

(6) 'Plastic materials', also referred to as 'Plastics', means polymeric materials to which additives may have been added. The definition includes polymer-based rubber items and bio-based and biodegradable plastics regardless of whether they are derived from biomass or are intended to biodegrade over time.

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

(8) 'Product unit' means the smallest item that can be used by the consumer and that fulfils the product's function.

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

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

(11) 'Recycling' means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council[29], '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'.

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

(13) 'Substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012([30]) or (EC) No 1107/2009([31]) of the European Parliament and of the Council;

(14) 'Super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass.

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

- A polymerisation process such as poly-addition or poly-condensation or by any other similar process of monomers and other starting substances;

- Chemical modification of natural or synthetic macromolecules;

- Microbial fermentation.

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

[29] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0098-20180705&from=EN

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

[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

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Third proposal for definitions
For the purposes of this Annex, the following definitions shall apply: (1) 'Additional component' means 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 primary packaging (mainly for tampons and sanitary pads), the release liner or paper in baby diapers and sanitary pads, or the applicator for tampons. [to add to 'additional component' definition for RMC only: The additional component can also be the cloth bag were menstrual cups are usually sold with]. (2) 'Additives' means substances added in small quantities to components, materials or the final produc in order to improve or preserve some of its characteristics. (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) 'Compostability' means a property of a material to be biodegraded in a composting process or aerobic process designed to produce compost. Compost is the organic soil conditioner obtained by biodegradation of a mixture principally consisting of various vegetable residues, occasionally with other organic material, and having a limited mineral content. (6) 'Impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg). *[to be added to the User Manual: Examples of impurities are residues of the following: residues or reagents including residues of monomers, catalysts, by-products and detergents for production equipment and carry-over from other or previous production lines.]* (7) 'Ingoing substance' means all substances included in the final product, 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 regarded as ingoing substances. (8) 'Man-made cellulose fibres' means fibres produced from the raw material cellulose (wood or cotton) which include viscose, modal, lyocell, cupro and triacetate. (9) 'Materials' mean the materials constituting different components of an absorbent hygiene product, such as fluff pulp, cotton or polypropylene (PP). (10) 'Plastic materials', also referred to as 'Plastics', means polymeric materials to which additives may have been added. The definition includes polymer-based rubber items and bio-based and biodegradable plastics regardless of whether they are derived from biomass or are intended to biodegrade over time. (11) 'Primary packaging', also known as sales packaging, means packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase. (12) 'Product unit' means the smallest item that can be used by the consumer and that fulfils the product's function. (13) 'Recyclability capacity' means the amount (mass or percentage) of an item available for recycling. (14) '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. (15) 'Recycling' means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council[32], '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

[32] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0098-20180705&from=EN

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backfilling operations'.

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

(17) 'Substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012([33]) or (EC) No 1107/2009([34]) of the European Parliament and of the Council;

(18) 'Super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass.

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

- A polymerisation process such as poly-addition or poly-condensation or by any other similar process of monomers and other starting substances;

- Chemical modification of natural or synthetic macromolecules;

- Microbial fermentation.

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

Rationale for the proposed scope text

The current scope of the EU Ecolabel for absorbent hygiene products (AHP) lists down the disposable single use products that are covered by Commission Decision 2014/763/EU[35]. These are disposable baby diapers, feminine care pads, tampons and nursing pads.

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

In general, stakeholders expressed that feminine care products such as 'pads/panty liners', 'tampons' or 'breast pads' and 'baby diapers' should be maintained in the scope. Moreover, over 80% of respondents would favour the expansion of the scope to incontinence products, while 39% of the respondents to the preliminary questionnaire supported the inclusion in the scope of reusable alternatives for AHP such as: reusable menstrual cups, cloth baby diapers, cloth feminine care pads, reusable breast pads.

For the first proposal included in the TR1.0:

— It was not considered feasible to expand the scope to cover incontinence products. This was due to the fact that incontinence products are usually declared as medical devices, which are excluded from the scope of the EU Ecolabel scheme according to Article 2, point 2 of the EU Ecolabel Regulation[36].

— It was not considered feasible to expand the product group scope to cover reusable textile AHP alternatives (cloth baby diapers, cloth feminine care pads, reusable breast pads). Indeed, reusable

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

[34] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

[35] 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

[36] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010R0066

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alternatives have a material composition which is fundamentally different than disposable AHP, and rather similar to that of textiles, for which a dedicated set of EU Ecolabel criteria exist[37]. Other Ecolabels such as the Austrian Ecolabel also include reusable alternatives under their textile ecolabel scope.

- It was proposed to expand the product group scope to cover also reusable menstrual cups (RMC). Indeed, in addition to the positive opinion of the stakeholders gathered through the preliminary questionnaire, 80% of the EU Ecolabelling Board (EUEB) members were in favour of including reusable menstrual cups in the revised scope (April 2021 meeting). Moreover, the analysis conducted in the preliminary report[38] also suggested the inclusion of reusable menstrual cups in the scope.
- As a result, the revised product group name was proposed to be "Absorbent Hygiene Products and Menstrual Cups". A product scope definition for menstrual cups was proposed, but EU Ecolabel criteria targeting RMC were not proposed at that stage. These are proposed in this TR2.0 for the first time.
- A revised product scope definition of absorbent hygiene products was proposed, based on the feedback from the EUEB members, as follows: *"An Absorbent Hygiene Product is any sanitary article whose function is to absorb and retain human urine, faeces, sweat, blood and milk - excluding textile products."*

For the second proposal in the TR2.0:

- Adult incontinence products not registered as medical devices were proposed to be included in the AHP scope;
- Reusable menstrual cups included in the scope were only those made out of silicone and thermoplastic elastomers;
- The product group scope for reusable menstrual cups now refers simply to 'silicone', and not to 'medical-grade silicone';
- New definitions were included for 'man-made cellulose fibres', 'ingoing substances' and 'impurities'.

Outcomes from and after 2nd AHWG meeting

In total, 17 comments were received from stakeholders. While all comments received can be found in the Table of Comment, the sections below address the main comments received.

Stakeholders were in general in favour of the new wording for the product scope definition for AHP.

Three stakeholders commented that the product group definition is unclear as to what concerns adult incontinence products, and asked for clearly state what products are out of scope and which are in the scope. On the other hand, one stakeholder disagreed with allowing incontinence products in the scope, as these are *'without doubt meeting the definition and falling within the scope of AHP but are excluded by falling under the scope of CD 93/42/EEC amended by Regulation (EU) 2017/745'.*

Two stakeholders were disappointed by the fact that reusable AHP made of textiles were not proposed to be included in the product group scope. Indeed, their environmental benefits range from higher durability, to less chemicals and less waste production. On the other hand, one stakeholder was not in favour to include textile alternatives in the scope, and stated the following: *'the scope is here defined by the similarity of fabrication processes enabling a comparison through LCAs. The general design of the EU Ecolabel is based on environmental impact assessment and need therefore similar/comparable processes and raw materials. If the concern is to offer the possibility for reusable products to access an EU Ecolabel, the criteria for textiles suit perfectly*'.

Four stakeholders expressed their support for including RMC in the scope of this product group. One stakeholder asked clarification as to whether disposable menstrual cups are included in the scope.

One stakeholder referred to the lack of agreed definition for medical-grade silicone, in line with the discussion held during the AHWG1. This stakeholder stated the following: *'No official definition exist of medical grade silicone. Alternative formulation proposal: silicones tested according to relevant biocompatibility criteria and showing no adverse effects in these criteria'.*

[37] 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.

[38] See Section 2.7 of the Preliminary Report. Available at : https://susproc.jrc.ec.europa.eu/product-bureau/product-groups/415/documents

Moreover, three stakeholders, while agreeing on the inclusion of RMC in the product group scope, expressed their concern that an additional Life Cycle Assessment (LCA) targeting RMC should be performed, in order to identify the environmental hotspots of these products. One stakeholder commented the following:

'We support to make criteria for reusable products but does not think these should be included in AHP. The function is the same but since the ingoing materials and the functional unit is different, we think it will be too difficult include both disposable and reusable products in the same criteria. If the inclusion of these products is still considered a more comprehensive LCA study shall be made to identify environmental hotspots and identify areas for improvements. Most products are made of 100% medical silicone – how can we set requirements to differentiate the environmental best products?'

Finally, two stakeholders requested the alignment of the 'Plastics' definition with the one in the EU Single Use Plastic Directive[39]. One stakeholder requested to include the definition of man-made cellulose fibres (MMCF).

During the 2nd AHWG meeting, stakeholders expressed their concern over a possible confusion with respect to the inclusion of incontinence products that are not marketed as medical devices. One stakeholder asked to provide an estimation of what is the market rate of incontinence products in the EU outside the medical device scope.

Further research and main changes in the third proposal

Adult incontinence products

Incontinence products are products intended to be used by adults in order to absorb and keep body fluids when uncontrolled bladder or bowel movements, such as pads, pants/protective underwear, briefs, undergarments and pant/pad systems. Figure 2 below shows the market volume of adult incontinence products in the EU (in million EUR) for the period 2010 and 2020, illustrating an increase in all EU countries except for Croatia, with an average CAGR of 5.1% in the period 2015-2020.

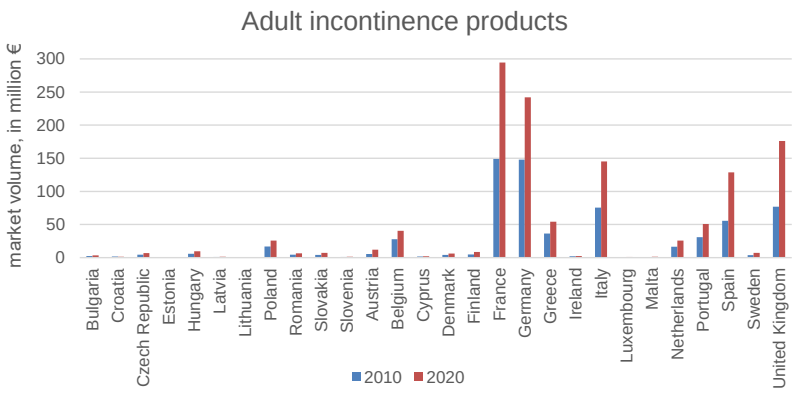

Figure 2. Market volume of adult incontinence products in the EU (in million EUR) for the years 2010 and 2020. Source: Euromonitor International.

Incontinence products might fall under Medical Devices Regulation (MDR) (EU) 2017/745 when the manufacturer demonstrates the intention of covering a medical purpose. In case the product then falls under the MDR, it shall goes 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.

[39] Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0904&qid=1636560280638&from=EN

However, there is no incompatibility between the CE mark and the EU Ecolabel. Indeed, Regulation (EC) No 765/2008[40] 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*'.

According to Article 2 of the EU Ecolabel Regulation, products that are registered as medical devices cannot bear the EU Ecolabel. However, this does not mean that products with a CE mark cannot bear the EU Ecolabel, as not only medical devices are CE marked. For example, growing media products bearing the CE mark can be awarded the EU Ecolabel[41].

Unfortunately, information on the share of incontinence products not registered as medical devices could not be retrieved. Consultation with industry revealed that the incontinence products are usually declared as medical devices i.e. CE marked, but not always. Therefore, the share of incontinence products not registered as 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, 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. Even if only few incontinence products were able to be awarded the EU Ecolabel, this should be seen as a step towards staying within the safe operating zone of the planetary boundaries. 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 the one 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 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 low percentage expected 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 to 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 medical device. This aspect will be taken into account when preparing the User Manual and the application form.

In light of the information above, and considering also that 82% of the stakeholders participating to the preliminary questionnaire were in favour of including incontinence products in the scope of AHP, it is proposed to maintain in the scope of the EU Ecolabel those adult incontinence products that are not registered as medical devices.

No changes are proposed to the text.

[40] 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

[41] Kowalska, M.A., Delre, A. and Wolf, O., EU Ecolabel criteria for growing media and soil improvers, EUR 31125 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-53529-4, doi:10.2760/748007, JRC129683

Definitions

A clarification was introduced in relation to the meaning of 'item' in the definition for 'recycled content': 'Recycled content' means the amount of an item (by area, length, volume or mass) sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or packaging in this case.

The definition for compostability is introduced. According to the standard ISO 16929, compostability is the *'property of a material to be biodegraded in a composting process or aerobic process designed to produce compost. Compost is the organic soil conditioner obtained by biodegradation of a mixture principally consisting of various vegetable residues, occasionally with other organic material, and having a limited mineral content'*[42].

Transport packaging definition was slightly modified. Finally, new definitions were included for the terms 'additives', 'components', and 'materials'. Such definitions were aligned with Nordic Swan as much as possible.

Summary of changes in TR3.0

In summary, the changes proposed in this TR3.0 are the following:

- Clarification of the term, 'item' has been added in the definition of 'recycled content'.
- Definition for 'compostability' is included.
- New wording introduced in the definition for 'transport packaging'.
- New definitions for 'additives', 'components', and 'materials'.

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[42] ISO standard 16929: 2021 - Plastics - Determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test

4 Assessment and verification

Previous proposal for the assessment and verification
For the EU Ecolabel to be awarded to a specific product, applicants must comply with each requirement. Specific assessment and verification requirements are indicated within each criterion. Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate. Competent Bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services. Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence. Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications. Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to Competent Bodies, together with supporting information to enable verification of continued compliance with the criteria. As pre-requisite, the product must meet all respective legal requirements of the Member State 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 to the competent body: - a description of the product, together with the weight of the individual product units and the total weight of the product; - a description of the primary packaging, together with its total weight, if applicable; - a description of the secondary packaging, together with its total weight; - a description of the additional components, together with its total weight; - the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers. A written confirmation from the applicant stating that all the criteria are fulfilled shall also be required for the assessment.
Third proposal for the assessment and verification
For the EU Ecolabel to be awarded to a specific product, applicants shall ~~must~~ 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.

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Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to ~~C~~competent ~~B~~bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product must meet all respective legal requirements of the Member State 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 ~~to the competent body~~:

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

- a description of the primary packaging, together with its total weight, if applicable;

- a description of the secondary packaging, together with its total weight;

- a description of the additional components, together with its total weight;

- the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

~~A written confirmation from the applicant stating that all the criteria are fulfilled shall also be required for the assessment.~~

Rationale behind the General 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.

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.

For the first proposal included in the TR1.0, it was clarified 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.

In the Second Technical Report it was proposed to add a paragraph detailing the information to be provided on the product composition and its packaging (moving it from current criterion 1 in force), being this be prescriptive for the awarding of the EU Ecolabel.

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Outcomes from and after 2nd AHWG meeting

In total, 7 comments were received on the general assessment and verification criteria. The comments made pointed to the need of maintaining current criterion 1 in force ('Product description'), especially in order to facilitate the processing of the applications by competent bodies. One stakeholder mentioned: *"Without this information (the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers) it is very difficult for a CB to assess the product and verification."*

Further research and main changes in the second proposal

As current practice in recent EU Ecolabel criteria, informative criteria have to be removed from the list of criteria in the Annex of Commission Decisions. This is linked to the EU Ecolabel Regulation, which in its Art. 6 stipulates that *"criteria shall be based on the environmental performance of products"*. Information to be provided during the application process cannot constitute individual criteria.

The content of current criterion 1 has thus been moved to the general A&V and it is not proposed to be placed back in a criterion. Nevertheless, please note that this is a prerequisite for awarding the EU Ecolabel, meaning that applications failing to provide this information cannot be awarded the label.

The application form for the EU Ecolabel for absorbent hygiene products and reusable menstrual cups will be developed having this in mind, creating a check list of documentation for the applicant and for the CBs, in order to facilitate the job of the competent bodies.

No changes were made to the assessment and verification.

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5 Criteria proposal for absorbent hygiene products

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

5.1 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, in the TR1.0 few structural changes were proposed, in particular with respect to grouping together the requirements related to the presence of chemicals in AHP. In this TR3.0, further structural changes are proposed, in particular moving the criterion on product description to the general assessment and verification (see Section 4), 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 addition, few new criteria and sub-criteria are proposed. Table 2 below summarises the changes and illustrates the changes proposed.

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

Current criteria		Proposed changes to the revised criteria	
1	Product Description	Product Description	-
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	Synthetic polymers and plastic materials	4
5.1	Production of synthetic polymers and plastic materials	Production of synthetic polymers and plastic materials	4.1
		Bio-based plastic materials - NEW	4.2
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)

	Current criteria	Proposed changes to the revised criteria	
6	Other materials and components	REMOVED (individual sub-criteria moved)	
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)
		Compostability– NEW	5
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)	Restrictions on 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 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: Previous 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.

All (100%) wood raw materials used for the production of the fluff pulp ~~fibres~~ shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

Moreover, 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 used for the production of the fluff pulp ~~fibres~~ shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. The certification bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme.

Assessment and verification:

The applicant shall provide the competent body with a declaration of compliance supported by a valid, independently certified chain of custody certificate ~~from the manufacturer of EU Ecolabel graphic paper and~~ for all ~~virgin pulp fibres~~ wood raw materials used in the product or production line. 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 ~~materials allocated to the product or production line originate from forests or areas managed according to sustainable forestry management principles that meet the requirements set out by the relevant independent chain of custody scheme and/or originate from recycled materials~~. If the fluff pulp is used in air-laid, then the air-laid supplier shall allocate credits to the air-laid delivered to the product, providing invoices to support the number of credits allocated.

If the product or production line includes uncertified virgin material, proof shall be provided that the content of uncertified virgin material does not exceed 30 % and is covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

Annex I: New 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.

All (100%) ~~wood raw materials~~ fluff pulp suppliers ~~used for the production of the fluff pulp fibres shall be covered by~~ shall hold valid chain-of-custody certificate issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

~~Moreover,~~ 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 material, including any virgin wood material, used for the production of the fluff 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 ~~forest and/or~~ the chain of custody or Sustainable Forest Management certificates shall be accredited/recognised by that certification scheme.

Assessment and verification:

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The applicant shall provide ~~the competent body with~~ a declaration of compliance supported by a valid, independently certified chain-of-custody certificate for the suppliers of all fluff pulp ~~wood raw materials~~ used in the product ~~or in the production line~~. 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 at least one year prior to the application date. If the fluff pulp is used in air-laid, then the air-laid supplier shall allocate credits to the air-laid delivered to the product, providing invoices to support the number of credits allocated.

~~If the product or production line includes uncertified virgin material~~ 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.

In the current sub-criterion in force, 100% of the pulp fibres must be covered by a chain of custody certification and be legally sourced. In addition, 25% of the pulp fibres must be covered by valid Sustainable Forestry Management (SFM) certificates.

In the preliminary stakeholder questionnaire (December, 2020), 46% of the respondents indicated the need to change criterion 2.1. The vast majority requested an increase in the ambition level for the minimum SFM-certified fibres content to the same level as the one for the EU Ecolabel for Graphic paper, tissue paper, and tissue paper products[43], which requires a minimum of 70% pulp fibres to be covered by SFM certificates.

On the other hand, one stakeholder commented that *the EU Ecolabel criteria for AHP is comprehensively focused on pulp, which is inconsistent considering the percentage of pulp in a diaper (around 15 g or 23% of a baby diaper is fluff pulp[44])"*.

For the first proposal included in the TR1.0, it was proposed to increase the SFM threshold from 25% to 70%. Moreover, it was proposed to improve the verification of this requirement by harmonising, to the extent possible, the wording with Criterion 3 (Fibres – conserving resources, sustainable forest management) of the EU Ecolabel criteria for graphic paper, tissue paper, and tissue products, (except for the reference to recycled fibres, which was removed).

For the second proposal included in the TR2.0, it was proposed to apply criterion 1 to the fluff pulp present in ≥ 1% w/w of the final product, to refer to the wood raw material used for the production of the fluff pulp and to clarify in the assessment and verification text the case of fluff pulp used in air-laid.

Outcomes from and after the 2nd AHWG meeting

In total, 7 comments were received from stakeholders on this sub-criterion. While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

[43] 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

[44] 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, pp. 302-323.

Three stakeholders supported an ambition of 70% of pulp fibres from SFM, however proposing to increase the threshold even more up to 100% SFM pulp fibres, as the protection of forests is essential to curb climate change and biodiversity loss.

Three stakeholders highlighted the fact that the wording of this criterion is not clear enough, and proposed some alternative suggestions.

Further research and main changes in the third proposal

In this third proposal, only wording clarifications were made, to clarify that it is the fluff pulp supplier who shall hold a Chain-of-Custody certificate, and not the wood raw material.

The ambition of the criterion was maintained as in the previous proposal (70% of pulp fibres from SFM certifications), taking into account that the vast majority of the fluff pulp is produced in the US (75-85% of global fluff pulp market[45,46]), where only 13% of US forestry is covered by a SFM certification scheme[47]. While EU has a higher share of certified forests, only 5% of global fluff pulp is supplied by the EU.

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'[48], 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 to the industries. At the moment 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 removals by natural sinks[49]. Finally, the European Commission recently proposed a Regulation to contrast EU-driven deforestation and forest degradation[50].

In light of this, while it would be 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 requirements to insure that their products are deforestation-free, applying also to EU Ecolabel products.

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 equal 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[51]. 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.

[45] 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

[46] RISI Fastmarkets, 2019

[47] The State of America's Forests, Certified Forests. Available at: https://usforests.maps.arcgis.com/apps/MapJournal/index.html?appid=dfe7da49c651424eb39a14c61c4d5f7

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

[49] 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

[50] 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

[51] 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: Previous proposal for sub-criterion 1.2: Bleaching of fluff pulp

This sub-criterion does not apply to ~~refers to elemental~~ total chlorine free (TCF) pulp.

The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl_2) gas.

The average annual AOX emissions from the production of each pulp used in EU Ecolabel absorbent hygienic product shall not exceed 0,140 kg/ADt.

Assessment and verification: ~~The applicant shall provide a declaration from the pulp manufacturer that elemental chlorine (Cl_2) gas was not used. The declaration shall be supported by a test report using ISO 9562 test methods. Equivalent methods may be accepted as test methods, accompanied by detailed calculations showing compliance with this requirement, together with related supporting documentation.~~

The applicant shall provide a declaration of compliance with this criterion. The declaration shall be supported by a test report performed using the ISO 9562:2004 test method, including ~~supported by a list of the~~ the AOX emissions relative to the ~~different~~ ECF-bleached pulp ~~used in the pulp mix, their respective weightings and their individual amount of AOX emissions~~, expressed as kg AOX/ADt pulp. In case different pulp 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 must 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 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.

~~The supporting documentation shall include an indication of the measurement frequency.~~ 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 ~~non integrated paper production or in the effluents from~~ pulp production without bleaching or where bleaching is performed with chlorine-free substances.

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

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

The applicant shall also provide a declaration from the pulp manufacturer that elemental chlorine (Cl_2) gas was not used.

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

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Annex I: Third proposal for sub-criterion 1.2: Bleaching of fluff pulp

This sub-criterion does not apply to total chlorine free (TCF) pulp.

The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl_2) gas.

The average annual adsorbable organically bound halogens (AOX) emissions from the production of each pulp used in EU Ecolabel ~~absorbent hygienic~~ products shall not exceed 0,140 kg/ADt.

Assessment and verification:

The applicant shall provide a declaration of compliance with this criterion, ~~The declaration shall be~~ supported by a test report performed using the ISO 9562:2004 test method, including the AOX emissions relative to the element chlorine free (ECF) bleached pulp, expressed as kg AOX/ADt pulp. In case different pulp 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 must 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 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 (Cl_2) 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 '90s, causing the discharge of significant amounts of the dioxin and furan chemical families into watercourses.

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

In the TR1.0, it was proposed to lower the AOX limit to 0.15 kg/ADt (there was a typing error in the TR1.0, where the presented value was 0.14 kg AOX/ADt).

In the TR2.0, it was proposed to lower the AOX limit further to 0.14 kg/ADt.

The parameter 'AOX' refers to a 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 provides information about the quantity of chlorinated organic compounds in wastewater, and thus contains a broad mix of

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compounds that have different chemical properties[52]. Minimizing 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[53].

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 bleaching process on the presence of polyhalogenated organic compounds in a final product.

Outcomes from and after 2nd AHWG meeting

In total, 13 comments were received on this sub-criterion. While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

Three stakeholders were in favour of the AOX emission value proposed in TR2.0 (0.14 kg/ADt), even if two of them would have preferred a higher ambition. One stakeholder proposed to relax the limit to 0.15 kg AOX/ADt, while another one argued for a stricter limit of 0.12 kg AOX/ADt. One stakeholders expressed that nowadays AOX levels are not related to the ecotoxicity of the effluent characteristics, and an alternative indicator could be a brightness limit.

Further research and main changes in the third proposal

No changes are proposed in this third proposal. The AOX limit proposed is maintained at 0.14 kg/ADt, as a compromise between a high ambition level and the scientific relevance of the AOX indicator[54,55,56]. Please note that the 0.14 kg/ADt threshold is also in line with the latest Nordic Swan criteria[57].

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[52] 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

[53] 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

[54] Bajpai K., Biermann's Handbook of Pulp and Paper: Raw Material and Pulp Making, Chapter 19: Pulp bleaching, 2018, Elsevier. https://doi.org/10.1016/B978-0-12-814240-0.00019-7

[55] NCASI, Special Report No. 90-07: An Examination of the Relationship between the Adsorbable Organic Halide Content of Paper Industry Wastewaters and Potential Aquatic Biological Effects. Available at: https://www.ncasi.org/resource/special-report-no-90-07-an-examination-of-the-relationship-between-the-adsorbable-organic-halide-content-of-paper-industry-wastewaters-and-potential-aquatic-biological-effects/

[56] Environmental Paper Network, Detoxing Future Pulp Production – Why it's time to revisit the pulp bleaching debate, 2017. Available at: https://environmentalpaper.org/wp-content/uploads/2017/09/170112-Detox-paper-EPN-discussion-document-2-1.pdf

[57] Nordic Swan Ecolabelling, Basic Module for paper products 3.0 - version 5.0. Available at: https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=044

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

Annex I: Previous proposal for sub-criterion 1.3: Emissions of COD and phosphorous (P) to water and of sulphur compounds (S) and NOx to air from the production of fluff pulp

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

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

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

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

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

Table 1

Reference values for emissions from different pulp types. CTMP = chemi-thermomechanical pulp; NSSC = neutral sulphite semi-chemical pulp

	Reference values (kg/ADT)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Bleached chemical pulp (others than sulphite)	16,0	0,030([1]) 0,09 ([2])	0,35	1,5
Bleached chemical pulp (sulphite)	24,0	0,03	0,6	1,5
Unbleached chemical pulp	6,5	0,02	0,35	1,5
CTMP ([3])	15,0	0,01	0,2	0,3
NSSC ([4])	11	0,02	0,4	1,5

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

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

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

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periodical monitoring standard test methods: COD: ISO 15705 or ISO 6060; Total P: EN ISO 6878; NOx: EN 14792 or ISO 11564; S(sulphur oxides): EN 14791 or EPA no 8; S(reduced sulphur): EPA no 15A,16A or 16B; S content in oil: ISO 8754; S content in coal: ISO 19579; S content in biomass: EN 15289. 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. Rapid tests can also be used to monitor emissions as long as they are checked regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents.

In the case of COD emissions, continuous monitoring based on analysis of total organic carbon (TOC) shall be accepted as long as a correlation between TOC and COD results has been established for the site in question.

The minimum measurement frequency, unless specified otherwise in the operating permit, shall be weekly for COD emissions and Total P emissions. Emissions of S and NOx shall be measured at least every six months, in addition to any measurements stipulated in the regulatory requirements.

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 for each emission parameter. The supporting documentation shall include the measurement frequency and 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 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 can be subtracted from the total amount. The following equation shall be used to calculate the proportion of the emissions resulting from heat generation:

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

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

[to be included in the User Manual:

The following diffuse sources should at least be considered:

- *For CNCG: Batch cook blowing, batch cook gassing, continuous cooking, stripper, evaporation plant, methanol processing, black liquor heat treatment, super concentrator;*
- *For DNCG: Vent gases from continuous cooking, vent gases from superbatch cooking (evacuation air, vents from non-pressurised tanks), pulp washing plant vent gases, tall oil cooking plant vent gases, tank vent gases, evaporation plant (atmospheric pressure tanks), causticising plant lime kiln area.*

The following streams should not be considered: ventilation air from buildings, moist water vapour from pulp or paper machines, moist air from cooling towers, water vapour from the surface of effluent treatment ponds, ventilation from drains, and vapour from vacuum pump.]

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Reported emission values for S compounds shall include both oxidised and reduced S emissions (SO_2 and 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 measured, and shall be taken into account.

Annex I: Third proposal for sub-criterion 1.3: Emissions of COD and phosphorous (P) to water and of sulphur compounds (S) and NOx to air from fluff pulp production

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

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

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

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

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

Table 1

Reference values for emissions from different pulp types. CTMP = chemi-thermomechanical pulp; NSSC = neutral sulphite semi-chemical pulp

	Reference values (kg/ADt)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Bleached chemical pulp (others than sulphite)	16,0	0,030([1]) 0,09 ([2])	~~0,35~~0,6	1,5
Bleached chemical pulp (sulphite)	24,0	0,03	0,6	1,5
Unbleached chemical pulp	6,5	0,02	~~0,35~~0,6	1,5
CTMP ([3])	15,0	0,01	0,2	0,3
NSSC ([4])	11	0,02	0,4	1,5

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

([2]) The higher value refers to mills using eucalyptus ~~from regions with higher levels of phosphorous (e.g. Iberian eucalyptus)~~ or loblolly pine species, provided that the amount of supplemental P added during the wastewater treatment is lower than 0.3 kg P/ADt.

([3]) Chemical thermomechanicalpulp

([4]) Neutral sulphite semi-chemical

Assessment and verification:

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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 no 8 or EPA Method 6c; 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 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. Rapid tests can also be used to monitor emissions as long as they are checked regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents.

In the case of COD emissions, continuous monitoring based on analysis of total organic carbon (TOC) shall be accepted as long as a correlation between TOC and COD results has been established for the site in question.

The minimum measurement frequency, unless specified otherwise in the operating permit, shall be weekly for COD emissions and Total P emissions. ~~Emissions of S and NOx shall be measured at least every six months.~~ Unless the regulatory requirements at the site of the fluff pulp production prohibit such measurements, emissions of S and NOx shall be measured at least twice per calendar year (separated by four-six months), in addition to any measurements stipulated in the regulatory requirements. Written verification must be provided if the production site for the fluff pulp is exempt from this requirement for twice per year measurements.

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 for each emission parameter. The supporting documentation shall include the measurement frequency and 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 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 can be subtracted from the total amount. The following equation shall be used to calculate the proportion of the emissions resulting from heat generation:

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

In this calculation, electricity is the electricity produced at the co-generation plant. The heat in this calculation 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.

[to be included in the User Manual:

The following diffuse sources should at least be considered:

- *For CNCG: Batch cook blowing, batch cook gassing, continuous cooking, stripper, evaporation plant, methanol processing, black liquor heat treatment, super concentrator;*
- *For DNCG: Vent gases from continuous cooking, vent gases from superbatch cooking (evacuation*

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air, vents from non-pressurised tanks), pulp washing plant vent gases, tall oil cooking plant vent gases, tank vent gases, evaporation plant (atmospheric pressure tanks), causticising plant lime kiln area.

The following streams should not be considered: ventilation air from buildings, moist water vapour from pulp or paper machines, moist air from cooling towers, water vapour from the surface of effluent treatment ponds, ventilation from drains, and vapour from vacuum pump.]

Reported emission values for S compounds shall include both oxidised and reduced S emissions (SO_2 and 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 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.

In the preliminary stakeholder questionnaire (December, 2020), 36% of respondents did not express any opinion in respect to the possible revision of sub-criterion 1.3, whereas 29% expressed the adequateness of the currently valid requirement. Only 28% of respondents to the questionnaire indicated the need to revise the sub-criterion, half of which expressed that minor changes are needed. The stakeholder comments focused on the need to adjust the limits, preferably harmonising the emission limit with the requirements set in the EU Ecolabel for tissue paper products according to Annex II to Commission Decision (EU) 2019/70.

Outcomes from and after 2nd AHWG meeting

In total, 31 comments were received on this sub-criterion. While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

Many of the comment received addressed the P limits proposed in the TR2.0, and in particular the possible alignment of the P limit for loblolly pine species with the one for eucalyptus species. Stakeholders were in general in favour of a higher limit for loblolly pine. However, two stakeholders argued that *"Introducing exemptions based on different species and/or criteria might impair whole system acceptance and usage"*. Few other comments referred to the sources and measurement requirements for S and NOx emissions in order to make the EU Ecolabel criteria implementable for all actors.

Further research and main changes in the third proposal

Chemical Oxygen Demand (COD) limits

No changes were made to the COD limits in this third proposal.

Phosphorous (P) limits

The P naturally contained in the wood used for the production of fluff pulp plays an important role for the discharge of P to wastewater, and for compliance with emission limits. Phosphorus found in the wood chips partitions between black liquor and pulp fibre in the digester. Approximately 50% of the phosphorus found in wood partitions to pulp fibre, with the partitioning percentage that can range from 35-70%[58,59,60].

[58] 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.

[59] 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. https://imisrise.tappi.org/TAPPI/Products/ICR/ICR98107.aspx

In the second proposal for the revised EU Ecolabel for AHP, a higher P limit (0.09 kg/ADt) was allowed for the Iberian eucalyptus. This limit comes from the BAT-AELs, which set a limit for P discharge in the effluent for eucalyptus-based pulp at 0.12 kg P/ADt, as compared to the 0.03 kg P/ADt for other pulps (a 350% higher limit). Indeed, according to the BREF document[68], wood from Iberian eucalyptus stands contains higher levels of phosphorus compared to other forest species used for pulp production in Europe and elsewhere. This is especially true for eucalyptus pulp mills using wood from regions with higher levels of phosphorus (e.g. the Iberian region). That's why a BAT-AEL at 0.12 kg P/ADt was set: even if no phosphorus is added as a nutrient in a biological treatment plant, the level in discharged effluents is much higher compared to other production sites using non-eucalypt forest species[61]. The BAT-AELs refer to Iberian Eucalyptus because focus on the EU only. However, also eucalyptus from other regions (e.g. from Brazil) has the same high-P characteristics[62,63]. As Brazilian eucalyptus was already allowed in EU Ecolabel graphic paper products, it is here proposed to set that all Eucalyptus species must be compliant with the 0.09 kg P/ADt level.

The case of loblolly pine is similar to the one of eucalyptus species. 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 limits, and more similar to the case of eucalyptus pulp. The conversion[64] was obtained by considering a pulp production yield of 48% (based on the range of 45-55% given by the FAO[65]).

In the TR2.0 it was proposed to set higher P a limit if the mill can show that their supplementary addition of P is negligible. For example, Nordic Swan criteria for sanitary products allow for the total amount of P and COD in intake water to be subtracted from the outgoing phosphorus and COD.

In order to set strict limits on the amount of supplemental P which is added, but not to the wood species used for the fluff pulp production, it is here proposed that mills using loblolly pine must meet the same limit as eucalyptus mills (0.09 kg P/ADt), provided that their supplemental addition of P during the process or wastewater treatment is lower than 0.03 kg P/ADt. The 0.03 kg P/ADt has been chosen as it would be the same limit for kraft pulp. Please note that both mills using eucalyptus and loblolly pine species must demonstrate that the addition of P is lower than 0.03 kg P/ADt.

Sulphur compounds (S) limits

It has been pointed out by stakeholders that an S threshold of 0.35 kg/ADt is not achievable when considering also diffuse sources in the calculation. Indeed, it has been pointed out that the emission sources listed in TR2.0 were not aligned with the BAT conclusions, therefore creating a criterion that could not be achieved. The stakeholders suggested to either bring the S limit back to 0.6 kg S/ADt from all sources, or maintain the TR2.0 limit of 0.35 kg S/ADt but only measured from weak non-condensable gas collection, NCG burners, lime kilns and recovery boilers.

As the Nordic Swan and the Blue Angel criteria set a limit of 0.6 kg S/ADt, and as point sources from the main processes (recovery boiler, lime kiln, dedicated burner for odorous gases), if well managed, may release lower

[60] 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. https://doi.org/10.1016/S0273-1223(99)00703-9

[61] More details on the environmental issues specific to eucalyptus-based kraft pulp-making can be found in Section 3.3.1.1 of the BREF document (https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/PP_revised_BREF_2015.pdf)

[62] 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

[63] 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

[64] (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)

[65] FAO, ITTO and United Nations. 2020. Forest product conversion factors. Rome. https://doi.org/10.4060/ca7952en

sulphuric emissions than diffuse sources, it is proposed to bring the limit back to 0.6 kg S/ADt. Please note that this was modified for bleached and unbleached pulp.

In terms of emissions measurement, it has been pointed out by stakeholders that the wording proposed in the TR2.0 may exclude US actors because of local regulatory requirements that may operate under a continuous emissions monitoring system. Moreover, the wording referring to carry out the measurements every six months may imply difficulties in setting the measurement date exactly every six months, and some flexibility should be given. The following wording is thus proposed:

"*Unless the regulatory requirements at the site of the fluff pulp production prohibit such measurements, emissions of S and NOx shall be measured at least twice per calendar year (separated by four-six months), in addition to any measurements stipulated in the regulatory requirements. Written verification must be provided if the production site for the fluff pulp is exempt from this requirement for twice per year measurements.*"

Please note that similar wording is adopted by the Blue Angel criteria.

Nitrogen compounds (NOx) limits

No changes are proposed at this stage for NOx emissions thresholds.

In terms of emissions measurement, as for the sulphur case, it has been pointed out by stakeholders that the wording proposed in the TR2.0 may exclude US actors because of local regulatory requirements that may operate under a continuous emissions monitoring system. Moreover, the wording referring to carry out the measurements every six months may imply difficulties in setting the measurement date exactly every six months, and some flexibility should be given. The following wording is thus proposed:

"*Unless the regulatory requirements at the site of the fluff pulp production prohibit such measurements, emissions of S and NOx shall be measured at least twice per calendar year (separated by four-six months), in addition to any measurements stipulated in the regulatory requirements. Written verification must be provided if the production site for the fluff pulp is exempt from this requirement for twice per year measurements.*"

Please note that similar wording is adopted by the Blue Angel criteria.

Summary of changes in TR3.0

In summary, in this TR3.0 it is proposed:

- To set a higher limit for P emissions to water for pulp using eucalyptus and loblolly pine raw materials. The limit is set at 0.09 kg P/ADt provided that the company can demonstrate that the amount of additional P used in the process is lower than 0.03 kg P/ADt;
- To set the emissions of S compounds to air back to 0.6 kg S/ADt for bleached kraft pulpand unbleached kraft pulp;

To set the measurement frequency for S compound and NOx emissions at twice yearly, separated by 4-6 months.

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5.2.4 Sub-criterion 1.4- Emissions of CO_2 from production

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

CO_2 emissions from the production of fluff pulp shall not exceed 450 kg per tonne of pulp produced, including emissions from the production of electricity (whether on-site or off-site). For mechanical fluff pulp (CTMP), the limit value for emissions of CO_2 shall be 900 kg CO_2/ADt. Reference emission values according to Table 2 shall be used in the calculation of CO_2 emission from fuels. If needed, CO_2 emission factors for other fuels can be found in Annex VI to Regulation (EU) 2018/2066.

Table 2

Reference values for CO_2 emissions from different energy sources

Fuel	CO_2 fossil emissions	Unit	Reference
Coal	94.6	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Crude oil	73.3	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 1	74.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 2-5	77.4	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
LPG	63.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Natural Gas	56.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Grid Electricity	376~~400~~	g CO_2 fossil/kWh	Regulation (EU) 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 CO_2/ADt. The applicant shall also provide a single CO_2 emission value for the relevant paper machinery(ies) used to produce fluff pulp.

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

~~Emission factors for fuels shall be used in accordance with Annex VI of Regulation (EU) No 601/2012. For grid electricity, an emission calculation factor of 376 (kg CO2/MWh) shall be used in accordance with the Commission Delegated Regulation (EU) 2019/331 ([66]).~~Factors accepted by the authorities in European Union Emissions Trading System (EU ETS) shall also be accepted. The period for the calculations or mass balances shall be based on the production over 12 months. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing that energy from renewable sources is purchased, in which case the

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applicant may use the factor for the purchased electricity (contract for specified electricity or National Inventories), instead of the value quoted in Table 2.~~the average value for its suppliers of electricity (contracting suppliers), in which case the applicant may use this value instead of the value quoted~~. The documentation used as proof of compliance shall include technical specifications that indicate the average value (i.e. copy of a contract).

The amount of energy from renewable sources purchased and used for the production processes counts as zero CO_2 emission when calculating CO_2 emissions. Similarly, energy from nuclear plants counts as zero CO_2 emission. The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased.

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

CO_2 emissions from the production of fluff pulp shall not exceed 450 kg per tonne of pulp produced, including emissions from the production of electricity (whether on-site or off-site). CO_2 emissions shall include all sources of non-renewable energy used during the production of pulp. For chemical thermomechanical pulp (CTMP), the limit value for emissions of CO_2 shall be 900 kg CO_2/ADt. Reference emission values according to Table 2 shall be used in the calculation of CO_2 emission from energy sources ~~fuels~~. If needed, CO_2 emission factors for other energy sources ~~fuels~~ can be found in Annex VI to Regulation (EU) 2018/2066.

Table 2

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 (EU) 2018/2066
Crude oil	73.3	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 1	74.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 2-5	77.4	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
LPG	63.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Natural Gas	56.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Grid Electricity	376~~400~~	g CO_2 fossil/kWh	Regulation (EU) 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 CO_2/ADt. ~~The applicant shall also provide a single CO_2 emission value for the relevant paper machinery(ies) used to produce fluff pulp.~~

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

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. ~~Similarly, energy from nuclear plants counts as zero CO_2 emission.~~ The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased.

Factors accepted by the authorities in European Union Emissions Trading System shall also be accepted. The period for the calculations or mass balances shall be based on the production over 12 months. The

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

Rationale for the proposed criterion text

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

A major part of the respondents (46%) did not express any opinion in respect to the possible revision of the sub-criterion 2.5, whereas 29% confirmed adequateness of the currently valid requirement. Only 21% of respondents indicated the need to revise the sub-criterion.

In the TR1.0, no changes were proposed to the criteria text.

In the TR2.0, the reference value for electricity purchased from the grid was set from 400 to 376 g CO_2 fossil/kWh, and a new limit was added for CTMP pulp at 900 kg CO_2/ADt.

Outcomes from and after the 2nd AHWG meeting

In total, 12 comments were received on this sub-criterion. Most of the comments received referred to the possibility of using national factors for grid electricity. All comments received can be found in the annexed Table of Comment.

Further research and main changes in the third proposal

The main change to the criterion is the removal of the possibility to use national CO_2 factors for grid electricity purchased from a specific country. Indeed, European electricity grid is generally interconnected and discriminations on the ground of country would be inappropriate. The only possibility to use a different CO_2 factor for electricity is provide evidence of purchase either through contracts or through certification of the electricity.

Based on this, the reference to nuclear energy was removed, as the electricity from nuclear energy would be accounted for either via the grid value, or through the contracts and certifications for the purchased electricity.

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

Annex I: First 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:

— $P_{electricity} < 1{,}25$;

— $P_{fuel} < 1{,}25$.

Calculation of electricity consumption:

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

Where:

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

$E_{ref,pulp,i}$ as in Table 3.

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

Calculation of fuel consumption:

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

Where:

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

$F_{ref,pulp,i}$ as in Table 3.

$F_{pulp,i}$ 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.

Table 3

Reference values for electricity and fuel

Pulp grade	Electricity (E_{ref}) kWh/ADt	Fuel (F_{ref}) kWh/ADt
Non-CMTP pulp	900	6000
CMTP pulp	2000	1000

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. The point values include both the manufacture of the pulp and the fluffing process. 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

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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 does not need to be included.

Total fuel consumption F_{pulp} includes all purchased fuels. It also includes heat energy recovered by incinerating liquors and waste from on-site processes (e.g. wood waste, sawdust, liquors, etc.) as well as 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[67]. The energy required for paper production is comparable to that of cement or steel[68], and in 2020 it was estimated to represent 4% of total EU consumption.

At the second Ad-Hoc Working Group meeting, stakeholders commented that the criteria for fluff pulp production should not only focus on CO2 emissions, but include measures oriented to reduce also the energy use. For this reason, in this TR3.0 it is 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[69]. However, the limit values and the reference values were aligned with the Nordic Swan criteria for sanitary products[70]. Indeed, the manufacture and fluffing process for fluff pulp consume more energy than the one for tissue products, as the product needs to be tried to 95% dry matter content; 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.

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

[68] 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)

[69] 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

[70] 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: Second proposal for sub-criterion 2.1: Sourcing of man-made cellulose fibres

This criterion applies to man-made cellulose fibres that represents ≥ 1% w/w of the final product. [to be added to the User Manual: Note that man-made cellulose fibres are obtained from the production of dissolving wood pulp which uses wood raw materials as resources.]

(a) All ~~pulp fibres~~ (100%) wood raw materials used for the production of dissolving wood pulp shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

Moreover, a minimum of ~~70~~ 60 % ~~pulp fibres~~ wood raw materials used for the production of dissolving wood 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 ~~pulp fibres~~ wood raw materials used for the production of dissolving wood pulp shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

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

(b) Dissolving pulp produced from cotton linters shall meet the criterion ~~4.1~~ 3.1 for cotton (sourcing and traceability).

Assessment and verification:

The applicant shall provide the competent body ~~detailed calculations showing compliance with this requirement, together with related supporting documentation.~~ with a declaration of compliance supported by a valid, independently certified chain of custody certificate for all wood raw materials used for the production of dissolving wood pulp in the product or production line. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.

~~(a) The~~ In addition, the applicant shall ~~obtain~~ provide audited accounting documents that demonstrate that at least 60 % of the wood raw materials used for the production of the ~~from the~~ dissolving wood pulp ~~manufacturer(s) valid, independently certified chain of custody certificates demonstrating that~~ ~~wood fibres~~ is defined as certified material according to valid FSC, PEFC or equivalent schemes. ~~have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.~~

If the dissolving wood pulp is used in air-laid or nonwoven, the air-laid or nonwoven supplier shall allocate credits to the air- laid or nonwoven delivered to the product, providing invoices to support the number of credits allocated.

~~(b) Invoices shall be provided which document that 70% of certified fibres have been allocated to the material they supply to the Absorbent Hygiene Product producer.~~

If the product or production line includes uncertified virgin material, proof shall be provided that the content of uncertified virgin material does not exceed 40 % and is covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

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

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

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added to the User Manual: Note that man-made cellulose fibres are obtained from the production of dissolving wood pulp which uses wood raw materials as resources].

~~(a)~~ All (100%) ~~wood raw materials used for the production of~~ dissolving wood pulp suppliers ~~shall be covered~~ shall hold ~~by~~ valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

~~Moreover, a~~ A minimum of ~~60~~ 70% of the wood raw materials used for the production of the dissolving wood 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 wood raw materials, including any virgin wood material, used for the production of dissolving wood 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 ~~forest and/or~~ chain of custody or Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

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

Assessment and verification:

The applicant shall provide ~~the competent body with~~ a declaration of compliance supported by a valid, independently certified chain-of-custody certificate for the suppliers of all ~~wood raw materials used for the production of~~ dissolving wood pulp used in the product or production line. 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 ~~60~~ 70% of the wood raw materials used for the production of the dissolving wood pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for at least one year prior to the application date.

If ~~the dissolving wood pulp is~~ man-made cellulose fibres are used in air-laid or nonwoven, the air-laid or nonwoven supplier shall allocate credits to the air- laid or nonwoven delivered to the product, providing invoices to support the number of credits allocated.

~~If the product or production line includes uncertified virgin material,~~ For the remaining proportion of wood raw materials, proof shall be provided that the content of uncertified virgin material does not exceed ~~40~~ 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 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. In the current sub-criterion in force, 100% of the MMCF must be covered by a chain of custody certification and be legally sourced. Besides, 25% of the MMCF must be covered by valid Sustainable Forestry Management (SFM) certificates.

The outcomes of the preliminary questionnaire showed nearly half of consulted stakeholders indicated the need for the revision of this sub-criterion pointing out that the level of ambition should be increased in line with the sub-criterion 2.1 (now 1.1 for fluff pulp). This questionnaire also mentioned the inclusion of the sustainable sourcing of more bio-based materials, not limited to forest products/wood-derived fibres and to consider certified bio-based polymers. Given this sub-criterion is related to man-made cellulose fibres and for so wood- derived fibres, the inclusion of certified bio-based polymers will be assessed in criterion 4 (synthetic polymers and plastic materials).

The first proposal for sub-criterion 2.1: Sourcing of man-made cellulose fibres was that the threshold of MMCF covered by Sustainable Forestry Management certificates shall increase to 70%. For the assessment and verification it was proposed to require invoices as a proof of evidence for certified fibres.

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Two written comments were received in relation to the clarification of the 'assessment and verification' of this sub-criterion.

In the second Technical Report (TR2.0), the following changes were made:

- To align the wording as much as possible with criterion 1;
- To specify that criterion 2 applied to the MMCF present in **≥ 1% w/w** of the final product;
- To keep a minimum threshold of 60% for the SFM certification;
- To refer in the legal text to the wood raw material used for the production of the dissolving wood pulp;
- To accept both the percentage and credit systems (as it is done currently);
- To clarify in the assessment and verification text the case of dissolving wood pulp used in air-laid or nonwoven.

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting the majority of the stakeholders intervening supported requesting 70% of wood material used for the production of dissolving wood pulp to be covered by Sustainable Forest Management (SFM) certificates, thus aligning with the sourcing criterion for fluff pulp.

After the 2nd AHWG meeting, a total of 13 written comments were received for the sub-criterion 2.1 on sourcing of MMCF. While one comment was in favour of the proposed 60% of wood raw materials used for the production of dissolving wood pulp to be covered by valid Sustainable Forestry Management (SFM) certificates, nine comments proposed to align with sub-criterion 1.1 for fluff-pulp and request a minimum 70% SFM certificates for the wood raw materials used for the production of dissolving wood pulp. One comment requested the addition of the framework of one year for the audited accounting documents to be provided in the assessment and verification step. A clarification on the air-laid or nonwoven if produced from MMCF was also requested. As well as a comment on fluff pulp and MMCF compliance.

Further research and main changes in the third proposal

Sustainable sourcing of MMCF

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 Certification (PEFC).

During the previous revision of the AHP EU Ecolabel criteria in 2014, the percentage of SFM-certified MMCF was aligned with then recently voted EU Ecolabel criteria for Textiles to a value of 25% and in line with the proposal for fluff pulp[71]. While the TR1.0 proposal for fluff pulp increased the level of ambition of SFM-certified fluff pulp to 70%, further research is being considered to substantiate if 70% for SFM-certified MMCF is possible.

Although one comment to the TR1.0 expressed that '*there are no public numbers available on certification % of dissolving wood pulp mills',* 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[72]

Moreover, European producers from MMCF report the utilisation of wood that is certified according to FSC and PEFC standards[73] [74]. For instance, a MMCF manufacturer outside Europe claimed that over 75% of all

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

their wood-based raw material is sourced from FSC or PEFC (incl. SFI) certified forests in 2021[75], while other manufacturers show commitments to sustainable sourcing with certifications already in place (no information on percentages achieved)[76].

In light of the published information and the comments received to the TR2.0 criteria, it is proposed to request that 70% of wood raw materials used for the production of dissolving wood pulp to be covered by valid Sustainable Forestry Management (SFM) certificates.

Air-laid or nonwoven

According to the ISO 9092[77], an air-laid or nonwoven is a 'sheet of fibres, continuous filaments, or chopped yarns of any nature or origin, that have been formed into a web by any means, and bonded together by any means, with the exception of weaving or knitting'. As one comment from stakeholders requested clarification on the wording, it is understood that the air-laid or nonwovens are made from the fibres of MMCF and not from the dissolving wood pulp, i.e. the dissolving wood pulp is manufactured into fibres which are then made into the air-laid or nonwoven web by means of another processes.

It is worth noting that the ambition level of the other ecolabels was summarised in TR2.0 (section 5.4.1).

Based on the information shown in this section, in this third proposal it is requested to have a minimum threshold of 70% for the SFM certification for man-made cellulose fibres used in AHP. 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.

Assessment and verification

It is proposed to clarify in the text that if 'man-made cellulose fibres are used in air-laid or nonwoven, the air-laid or nonwoven supplier shall allocate credits to the air-laid or nonwoven delivered to the product, providing invoices to support the number of credits allocated'. This proposal is in line with a comment received from one stakeholder.

In line with other stakeholder's comment, in the assessment and verification it is added that 'the audited accounting documents shall be valid for at least one year prior to the application date'.

Summary of changes in TR3.0

The wording of this sub-criterion has been modified in an alignment with comments received from stakeholders during and after the 2nd AHWG meeting. It has also been harmonised with sub-criterion 1.1 wording.

In summary, in this TR3.0 it is proposed:

- To have a minimum threshold of 70% for the SFM certification.
- Some comments have been added to the A&V such the clarification on air-laid or nonwoven production and one year timeframe for the audited accounting documents.

[77] ISO 9092:2019 - Nonwovens — Vocabulary

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

Annex I: Second proposal for sub-criterion 2.2: Bleaching of man-made cellulose fibres
This sub-criterion does not apply to TCF (total chlorine free) 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 adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) shall not exceed ~~either of~~ the following: — 0,140 kg/ADT, ~~if~~ measured in the wastewater from pulp manufacturing (AOX), and — 150 ppm, ~~if~~ measured in the finished fibres (OCl). Assessment and verification: The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with ~~either~~ both the AOX or the OCl requirements, using the appropriate test method: — ISO 9562 or the equivalent EPA 1650C for AOX, — ISO 11480 for OCl. Frequency of measurement for AOX shall be set in accordance with the criterion ~~2.2~~ 1.2 for fluff pulp. In case the applicant does not use any ECF (elemental chlorine free) pulp, a corresponding declaration to the competent body is sufficient.
Annex I: Third proposal for sub-criterion 2.2: Bleaching of man-made cellulose fibres
This sub-criterion does not apply to TCF (total chlorine free) 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 adsorbable organically bound halogens (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 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 ~~either~~ both the AOX and ~~or~~ the OCl requirements, using the appropriate test method: — ISO 9562 or the equivalent EPA 1650C for AOX, — ISO 11480 for OCl. Frequency of measurement for AOX shall be set in accordance with the criterion 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 (elemental chlorine free) pulp, a corresponding declaration ~~to~~

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~~the competent body~~ 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 preliminary questionnaire on criteria validity, less than 20% of stakeholders who responded indicated the need to adjust the limits of the resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) used to manufacture man-made cellulose fibres. However, in order to harmonise with the Nordic Swan, in the TR1.0 it was proposed to make compulsory both requirements of criterion 2.2, i.e. to comply with the AOX emission limit in the wastewater and with the concentration (ppm) of OCl in the finished fibres. Moreover, it was proposed to tighten the AOX limit to 0.150 kg/ADt.

Information on the significance of parameter 'AOX' can be found in Section 5.2 of TR2.0[78]. 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 localized high chlorine concentrations)[79].

A brief overview of the technical aspects of bleaching processes was given in TR1.0, in combination with an analysis of the influence of bleaching process on the presence of polyhalogenated organic compounds in a final product

In the TR2.0, it was proposed to align with the AOX limit of 0.140 kg AOX/ADt for fluff pulp and request also the analysis of OCl (<150 ppm) as Nordic Swan. In the Assessment and verification section, a slight modification of the wording was introduced without major changes.

Outcomes from and after 2nd AHWG meeting

During the 2nd AHWG meeting, JRC highlighted the comment received from industry after the criteria publication (May 2022) in relation to the difficulty to some MMCF manufacturers to obtain both AOX and OCl values to fulfil criterion 2.2 and requested further inputs from key stakeholders in this respect. Pulp producers are not always able to share the AOX value but MMCF producers can measure OCl in the finished fibres.

Another stakeholder posed the question on how it was possible to know whether some producers follow BREF if they cannot measure AOX.

A stakeholder highlighted that the type of information requested must be available, especially to Competent Bodies upon which consumers deposit their trust for environmental performance even if confidential data are provided.

Only one comment was received for this sub-criterion in written form after the 2nd AHWG meeting. In this comment, it was acknowledged that the AOX value was set to 0.14 kg/ADt however 0.10 was requested as feasible as for fluff pulp.

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received both during and after the consultation.

[78] 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

[79] 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

Further research and main changes in the third proposal

Lenzing Group Sustainability Report from 2019[80] indicates that their two dissolving wood pulp mills (sulphite process) from Central Europe are equipped with Totally Chlorine Free (TCF) bleaching process. On the other hand, Lenzing reports that other European mills, as well as South Africa and US mills where the pulping process is either kraft or sulphite, bleaching is performed through the Elemental chlorine free (ECF) process. There are no data on values of AOX/OCl reported.

In addition to data reported in section 5.3.2, the Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board[81], also provides data on the AOX emissions for European dissolving wood pulp plants of 0.0015 kg AOX/ADt (data only for 1 mill shown in tables 4.9, 4.10 and in Figure 4.28 of the referenced document).

The ambition level of the other ecolabels is summarised in TR2.0 (section 5.4.2).

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 lack of public data. Sateri Fibre Co.[82] conducted a EU BAT Assessment in 2021[83] 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 202*1' AOX or OCl data were not made public or reported in their Sustainability Report for 2020[84].

There were not answers received from stakeholders on how to approach the issue raised in bilateral meetings with industry where JRC learnt that some non-European suppliers cannot provide the AOX level as for instance suppliers (1) may not comply with BAT as BREF is a mandatory regulation only applicable in EU or (2) confidentiality issues. It was highlighted by industry that the market for MMCF is supply-driven and not demand-driven and that sometimes for them is only possible to get the OCl value.

The conversations during the 2nd AHWG meeting did not resolve the issue however the level of ambition cannot be lowered if the supply of MMCF is from outside Europe.

Based on the information analysed in this section, in this third proposal it is also proposed to align with the AOX limit of 0.140 kg AOX/ADt for fluff pulp and request also the analysis of OCl (<150 ppm) as Nordic Swan.

Assessment and verification

In this TR3.0, a slight modification of the wording for the 'assessment and verification' has been introduced without major changes.

An extra text has been added for cases when the AOX emission from pulp production cannot be disclosed:

- 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.

Summary of changes in TR3.0

- It is requested to provide (1) AOX limit below 0.140 kg AOX/ADt, from the wastewater from the pulp manufacturing and (2) OCl limit below 150 ppm, measured in the finished fibres.

[80] Lenzing Group, Sustainability Report (2019) https://www.lenzing.com/?type=88245&tx_filedownloads_file%5bfileName%5d=fileadmin/content/PDF/04_Nachhaltigkeit/Nachhaltigkeitsberichte/EN/NHB_2019_EN.pdf

[81] 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

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

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

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

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- A new sentence has been added in the A&V section for the cases when the AOX level cannot be provided, requesting the provision of a declaration of compliance signed by the pulp manufacturer.

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

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

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

— generating on-site electricity and steam, or

— manufacturing chemical co-products.

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

Table 3

~~Viscose and modal fibres sulphur emission values~~

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)	CS_2 emissions to air— Limit value (mg/L)
Staple fibre	20	0,16	20	0,3
Filament fibre		0,3		
— Batch washing	40			
— Integrated washing	170			

Note: Limit values expressed as annual average.

Assessment and verification:

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

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

(c) Sulphur emissions to air: 2-hour composite sample and method EN 14791 or EPA no 8 or EPA no 15A, 16A, 16B or DIN 38405-D27.

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

(e) COD emissions to water: use method defined in ISO 6060 or DIN ISO 15705 or DIN 38409-01 or DIN 38409-44.

(f) CS_2 (sulphide) emissions to water: use method defined in DIN 38405-27 or ISO 10530.

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.

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

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

— generating on-site electricity and steam, or

— manufacturing chemical co-products.

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

Table 4

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)	~~CS_2~~ SO_4^{2-} emissions to water — Limit value (~~mg/L~~g/kg)
Staple fibre	20	~~0,16~~ 0,05	~~20~~ 5	~~0,3~~ 300
Filament fibre		~~0,3~~		
— Batch washing	40	0,10	5	200
— Integrated washing	170	0,50	6	250

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

Assessment and verification:

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

(b.1) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.

(~~c~~b.2) Sulphur emissions to air: 2-hour composite sample and method EN 14791 or EPA no 8 or EPA no 15A, 16A, 16B or DIN 38405-D27.

(~~d~~b.3) Zinc emissions to water: use method defined in EN ISO 11885.

(~~e~~b.4) COD emissions to water: use method defined in ISO 6060 or DIN ISO 15705 or DIN 38409-01 or DIN 38409-44.

(~~f~~b.5) SO_4^{2-} (sulphates) ~~CS_2 (sulphide)~~ emissions to water: use method defined in ~~DIN 38405-27 or ISO 10530~~ ISO 22743.

(b.6) Test methods whose scope and requirement standards ~~is~~ are considered equivalent to the one of the named national and international standards and whose equivalency has~~ve~~ been confirmed by an

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independent third party shall be accepted.

(b.7) The supporting documentation shall include an indication of the measurement frequency for S, Zn, COD and SO_4^{2-}. The minimum measurement frequency, unless specified otherwise in the operating permit, shall be weekly for COD emissions. Emissions of S, Zn and SO_4^{2-} shall be measured at least every six months, 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

During the preliminary questionnaire, 15% of respondents indicated the need to revise the criterion, specifically pointing to adapting the limit threshold to Nordic Swan criteria. The background report to Nordic Swan criteria[85] explains that a tighter limit for sulphur emissions to air was set after discussions with license holders. Nevertheless, the background document also reports a possible slow uptake of the market, since the previous limit of 30 g/kg was already considered not achievable since it requires the use of a combination of different recycling technologies. Nordic Swan criteria set emission thresholds for only staple fibres, since this is the relevant fibre for the product group of absorbent hygiene products.

Given all the above, for the TR1.0 it was proposed to tighten the limit on sulphur emissions to air to 20 g/kg for staple fibres.

The Nordic Swan and Blue Angel criterion on man-made cellulose fibre also includes COD and zinc emission requirements to better address impacts of the production of these fibres. While these should also be considered within the on-going revision, they were not proposed to be added in TR1.0.

Finally, a stakeholder indicated the need to set a requirement for carbon disulphide emission given that acid sulphite process is the preferred manufacturing way to produce viscose[86].

In Technical Report 2, this sub-criterion was modified with the inclusion of requirements for zinc, COD and CS_2 (sulphides) thus raising its level of ambition. The week before the 2nd AHWG meeting, in a bi-lateral meeting with industry stakeholders, these new requirements were proposed to be modified to a more ambitious level while sulphides were replaced by sulphates. These new requirement are detailed in the TR3.0 proposal for this sub-criterion whereas the rationale is explained below.

Outcomes from and after 2nd AHWG meeting

During the discussion at the 2nd AHWG meeting, stakeholders did not provide input on the adequacy of the new set of requirements for sub-criterion 2.3.

After the meeting one comment was received for this sub-criterion in written form. The comment received can be found in the annexed Table of Comment. This comment welcomed the addition of new requirements and requested to explain the modification of sulphide by sulphate. It also added the BAT emissions values for S, Zn and COD for staple fibres and provided two reference documents on viscose and certification.

Further research and main changes in the third proposal

In TR2.0, a detailed explanation of the differences between sulphite mills producing dissolving pulp for MMCF and pulp for papermaking was provided in terms of yield, NaOH dosage, recycling of chemicals and energy.

[85] 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

[86] Strunk, P., ISBN: 978-91-7459-406: "The green loop from wood to cellulose fibre" Digital version available at http://umu.diva-portal.org/ Sweden, 2012.

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 document for the Production of Polymers[87]. 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 the 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 is the BAT associated emission and consumption levels for the production of viscose staple fibres.

In the case of filament fibres, there are not BAT associated emissions. 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.

Sulphur and sulphate emissions

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

Thus the sulphur emissions accounted for in Table 3 of the sub-criterion 2.3 relates 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 document. The sulphate emissions to water are also taken from the referred tables.

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 Nordic Swan and Blue Angel also request.

A copper requirement would be relevant for the production of cupro fibre, however 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 3 in sub-criterion 2.3) are taken from the 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 document.

COD emissions

According to the Best Available Techniques (BAT) Reference Document for the Production of Pulp, Paper and Board[88], 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 3 in sub-criterion 2.3) are from the 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 document.

The ambition level of the other ecolabels was summarised in TR2.0 (section 5.4.3).

[87] 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.

[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

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The indicated values for Zn and COD in other ecolabels type I were not used, while reference limits from the BREF on Polymers were finally used.

Measurement frequency of viscose and modal fibres emissions

The frequency of the measurements specified in Table 3 of the sub-criterion 2.3 shall be established. In line with criterion 1 for fluff pulp, COD emissions should be measured weekly while emissions of S, Zn and SO_4^{2-} should be measured at least twice per year. These frequencies are to be followed unless specified in the operating permit for COD and in addition to any measurements stipulated in the regulatory requirements for all the other pollutants.

Assessment and verification

The wording of the A&V for the requirement (a) has been modified for an easier understanding.

The standardised methods listed for each of the emissions requested from fibre production (requirement b) are as listed below:

For sulphur emissions to air, method EN 14791(Stationary source emissions. Determination of mass concentration of sulphur oxides. Standard reference method) or EPA no. 8 (Method 8-Sulfuric Acid Mist) or EPA no. 15A (Method 15A - Total Reduced Sulfur Emissions From Sulfur Recovery Plants in Petroleum Refineries), 16A (Method 16A - Total Reduced Sulfur – Impinger), 16B (Method 16B - Total Reduced Sulfur - Gas Chromatograph Analysis) or DIN 38405-D27 (German standard methods for water, wastewater and sludge analysis - Anions (Group D) - Part 27: Determination of sulphide by gas extraction (D 27)).

For zinc emissions to water, the method to use is defined in EN ISO 11885 (Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)).

COD emissions to water could be analysed using the method defined in ISO 6060 (Water quality — Determination of the chemical oxygen demand) or DIN ISO 15705 (Water quality — Determination of the chemical oxygen demand index (ST-COD) — Small-scale sealed-tube method) or DIN 38409-01 (German standard methods for the examination of water, waste water and sludge; parameters characterizing effects and substances (group H); determination of total dry residue, filtrate dry residue and residue on ignition (H 1)) or DIN 38409-44 (German standard methods for the examination of water, waste water and sludge; parameters characterizing effects and substances (group H); determination of the chemical oxygen demand (COD), ranging from 5 to 50 mg/l (H 44)).

For SO_4^{2-} (sulphates) emissions to water: the method to use method is defined in the standard ISO 22743 (Water quality — Determination of sulphates — Method by continuous flow analysis (CFA)).

The sentence: '*The supporting documentation shall include an indication of the measurement frequency for S, Zn, COD and SO_4^{2-}. The minimum measurement frequency, unless specified otherwise in the operating permit, shall be weekly for COD emissions. Emissions of S, Zn and SO_4^{2-} shall be measured at least every six months, in addition to any measurements stipulated in the regulatory requirements.*' has been added.

Summary of changes in TR3.0

Requirements for Zn, COD and SO_4^{2-} (sulphates) have been added:

- Water Zn emission requirement has been modified and set as 0.05 g/kg for staple fibre and 0.10 and 0.50 g/kg for batch and integrated washing respectively for filament fibre (both are annual average values of g pollutant per kg of fibre produced).
- Water COD emission requirement has been modified and set as 5 g/kg of fibres for staple fibres and batch washing filament fibres and 6 g/kg for integrated washing filament fibres (as annual average values of g pollutant per kg of fibre produced).
- Water emissions of SO_4^{2-} (sulphates) has replaced the CS_2 (sulphide) emissions requirement for staple fibre (with a value of 300 g/kg) and for filament fibre (200 g/kg for batch washing and 250 g/kg for integrated washing).

- The standard ISO 22743 has been added as of to measure the water emissions of SO_4^{2-} .
- In the A&V, the indication of the measurement frequency for S, Zn, COD and SO_4^{2-} has been requested. The minimum measurement frequency, unless specified otherwise in the operating permit, is indicated to be weekly for COD emissions. Emissions of S, Zn and SO_4^{2-} are to be measured at least every six months, in addition to any measurements stipulated in the regulatory requirements.

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

This criterion applies to cotton that represents ≥ 1% w/w of the final product.

(a) All cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (1), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton grown according to criterion 3.1(a) and used to manufacture absorbent hygiene product shall be traceable ~~from the point of verification of the production standard~~.

Tampon strings are exempted from complying with this requirement.

Assessment and verification:

(a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin.

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

(1) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

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

This criterion applies to cotton that represents ≥ 1% w/w of the final product.

(a) All cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (1) and Regulation (EU) 2018/848 (2), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton grown according to criterion 3.1(a) and used to manufacture absorbent hygiene product shall be traceable ~~from the point of verification of the production standard~~.

Tampon strings are exempted from complying with this requirement.

Assessment and verification:

(a) The organic cotton content shall be certified by an independent control body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007 and Regulation (EU) 2018/848, the US National Organic Programme (NOP) or equivalent legal obligations ~~those~~ set by other trade partners of the Union. Verification shall be provided on an annual basis and for each country of origin.

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

(1) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

(2) 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

Rationale for the proposed criterion text

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

35% of the respondents to the preliminary questionnaire expressed the need to revise the criteria.

In the first proposal in the TR1.0, it was proposed to exempt the tampon string from complying with the criterion on cotton, as stakeholder feedback suggested that the requirement of organic cotton may counteract with the necessary strength requirements of the removal cords. This change is also in line with Nordic Swan requirements.

In the TR2.0, it was clarified that criterion 3 applies to the cotton present in ≥ 1% w/w of the final product.

Outcomes from and after 2nd AHWG meeting

Only two comments were received on this sub-criterion, one welcoming the requirement to rely only on organic cotton and not BCI cotton, and the other one pointing to the need to refer to Regulation (EU) 2018/848 on organic products. The majority of the comments were in favour of organic cotton only, as other schemes such as BCI do not have the same ambition level.

Further research and main changes in the third proposal

The only change proposed in this TR3.0 is to refer to Regulation (EU) 2018/848 on organic products.

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

Previous proposal of sub-criterion 3.2: Bleaching of cotton and other natural cellulosic seed fibres
Cotton shall not be bleached with the use of elemental chlorine gas (Cl2). Assessment and verification: The applicant shall provide a declaration from the supplier that elemental chlorine gas is not used.
Third proposal of sub-criterion 3.2: Bleaching of cotton and other natural cellulosic seed fibres
Cotton shall ~~not~~ be bleached only using ~~with~~ total chlorine free (TCF) technologies ~~the use of elemental chlorine gas (Cl_2)~~. Assessment and verification: The applicant shall provide a declaration from the supplier that ~~elemental chlorine gas is not~~ total chlorine free (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 dioxine formation and other highly carcinogenic pollutants).

Only 14% of the respondents to the preliminary questionnaire reported that the sub-criterion needs revision.

No changes were proposed in the first proposal (TR1.0), while in the TR2.0 it was clarified that it is elemental chlorine gas (Cl_2) which is banned.

Outcomes from and after 2nd AHWG meeting

Only one comment was received on this sub-criterion, proposing to prohibit chlorinated substances for bleacihng, and rely only on total chlorine free (TCF) technologies.

Further research and main changes in the third proposal

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 the 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 than for fluff pulp, and oxygen peroxide (H_2O_2) is widely used as a bleaching agent, thanks to the fact that effects on the environment of effluents are minimal[89] (as it decomposes to O_2 and H_2O), 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[90]. They 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-

[89] 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

[90] 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

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100°C, are needed[91]. While practically all cotton produced is bleached, about 80-90% of all cotton fabrics are bleached with hydrogen peroxide[92,93,88].

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

[92] 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

[93] 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: Synthetic polymers and plastic materials

5.5.1 Sub-criterion 4.1: Production of synthetic polymers and plastic materials

Annex I: Second proposal for sub-criterion 4.1: Production of synthetic polymers and plastic materials
All plants producing synthetic polymers and plastic materials used in the final product shall have systems for the implementation of: — water-saving (e.g. monitoring of water flow in a facility and circulating the water in closed systems), — integrated waste management plan to optimise prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions), — optimisation of energy efficiency and energy management (e.g. reuse of the steam generated during the manufacture of SAPs). Assessment and verification: The applicant shall provide a declaration of compliance with the cited requirement from the suppliers of synthetic polymers and plastic materials. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirement for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001.
Annex I: Third proposal for sub-criterion 4.1: Production of synthetic polymers and plastic materials
All plants producing synthetic polymers and plastic materials used in the final product shall have systems for the implementation of: — water-savings: ~~(e.g.~~ the water management system shall be documented or explained and shall include information on at least the following procedures: monitoring of water flows; ~~in a facility and~~ proof of circulating ~~the~~ water in closed systems; and continuous improvement objectives and targets relating to the reduction of waste water generation and optimisation rates~~)~~, — 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 follow the waste hierarchy in relation to ~~optimise waste~~ prevention, reuse, recycling, recovery and final disposal of waste. ~~(e.g.~~ The waste management plan shall be documented or explained and shall include information on at least the following procedures: 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) ~~the reduction of waste generation and the increase of reuse and recycling rates)~~,~~)~~, — optimisation of energy efficiency and energy management: ~~(e.g. reuse of the steam generated during the manufacture of SAPs~~ 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 procedures: 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 cited requirement from the suppliers of synthetic polymers and plastic materials used in the final product. The declaration shall be supported by a

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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 the 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:

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

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

Rationale for the proposed criterion text

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

Overall, 25% of the respondents to the preliminary questionnaire indicated the need to revise this criterion. One stakeholder expressed the need to remove this criterion. Indeed, apart for the lack of clarity of the sub-criterion, *'the bullet points are not relevant for all polymer or plastic production processes. An AHP may consist of 10 different plastic materials with several polymer granulate suppliers and to get detailed info from the producers is an impossible task'.* Another stakeholder mentioned that *'the use of a % organic or PCR (Post Consumer Recycled) material could be introduced'*. Finally, one stakeholder mentioned that *'it would be relevant to explore the use bioplastics and biopolymers and plastic free solutions'*.

In the previous revision process[94], 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 polymer are referred to as bioderived or bio-based or bio-polymers. In relation to biodegradation, it is worth noting that some polymers derived from petrochemical sources can be biodegradable, while not all bio-based polymers will biodegrade[95]. However, in the previous revision the promotion of non-biodegradable bio-polymers was not recommended. The potential benefits of non-biodegradable bio-based polymers such as BioPE and BioPET was explored in the Preliminary Report for Absorbent Hygiene Products (from September 2021)[96].

As criterion 4.1 (old 5.1) is referred to general environmental practices that could be carried out in the production of bio-based polymers, it was proposed to change the name of criterion 4.1 into ***'production of polymers'***, in order to allow for the inclusion of different types of polymers under one criterion. However, thesecond proposal contained in TR2.0 included the following changes:

- The modification of the title of the criterion 4 as: 'Synthetic polymers and plastic materials' as requested in the first consultation.
- The division of the criterion in two sub-criteria, thus keeping the first sub-criterion to 'Production of synthetic polymers and plastic mater**ials'** and the second sub-criterion as 'Bio-based plastic materials'.
- The assessment and verification of sub-criterion 4.1 was modified to include the possibility of using ISO standards 14001 and 50001 for a more comprehensive and easier verification.

[94] 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

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

[96] 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

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- A new sub-criterion 4.2 on bio-based plastic materials was proposed and discussed in detail during and after the 1st AHWG meeting (and in fact first presented at the May 2022 EUEB meeting).

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

Comments during the 2nd AHWG meeting on regards to criterion 4.1 indicated that manufacturers often explain that water is not used in the production of plastic materials.

Another six comments were received in written form after the 2nd AHWG meeting. While two of these comments also explained that water is not utilised in the process of synthetic polymers and plastic materials' production, the other four comments were related to the 'assessment and verification'. One comment was 'in favour of requiring a comparison with consumptions and emissions from the last 5 years as a more solid proof of compliance to the criterion', however two comments were against the 'inclusion of setting a percentage reduction in relation to water, waste and energy consumption of synthetic polymer and plastic production sites'. It was advised to refer to sub-criterion '5.1 Waste management system of the EU Ecolabel on printed paper products, stationery products and paper bags'. Another comment detailed that often the manufacturer of polymers and plastic materials is not the EU Ecolabel applicant so it is complex to get the detailed information which may not be relevant.

Further research and main changes in the third proposal

Absorbent hygiene products composition has seen an evolution in the last years. While disposable AHP were initially made from cellulose and cotton[97], recent developments evolved to 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)[98]. As indicated by Cordella et al. (2015), from 1987 to 2011 and still applicable nowadays, the average weight of baby nappies decreased in nearly 45% from the late eighties thus mainly 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 origin makes 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 (adapted from Cordella et al., 2015).

Material/ component	1987	1995	2005	2011
Fluff pulp (g)	52,8	37,4	14,1	13,2
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

[97] 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.

[98] 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
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

As defined in the Preliminary Report, SAP is a synthetic material derived from petroleum, manufactured by the polymerisation of acrylic acid with ammonium persulfate as 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 is used to retain high amount of fluids in baby, incontinence and menstrual products[99]. Polypropylene (PP) can be part of the absorbent core of these products or the main constituent of the microporous barrier that prevent the fluid from leaking. Usually LDPE is used in the packaging either primary or secondary and 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 showed 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.

The discussions during the 2nd AHWG meeting and some comments received explained that water is not used in the production of polymers and plastic materials for AHP, however, it is reported that about 185 L of water are needed to make a kg of plastic[100]. In fact, the production of plastics is related to water consumption and pollution[101] while resultant waste waters have a potential for high loads of organic compounds[102].

Another key environmental impact of the polymer sector is energy demand,[103] 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[104]. In addition, large quantities of spent solvents and non-recyclable waste are produced by the plastic industry,[105] while leakage and spills from transport of virgin plastic around the world are one of the most common forms of plastic pollution[106].

Looking at the above evidences, (1) plastics being the hotspots in the LCA of AHP, (2) references on high water and energy consumption for plastic production, and (3) waste generation, it is decided to maintain the

[99] 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

[100] 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

[101] 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.

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

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

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

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

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

requirements in sub-criterion 4.1 applicable to all plants producing synthetic polymers and plastic materials used in the final AHP to have systems for the implementation of water-saving and waste and energy plans.

Since there is not a consensus on whether the establishment of water, waste and energy reduction targets in relation to the last 5 years, it is decided not to proceed with such level of detail. However, as advised, the sub-criterion has been modified in alignment with sub-criterion 5.1 and 6 of the 'EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bag products'[107]. 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 are added to this sub-criterion. In summary, as synthetic polymers and plastic materials represent a significant share of the weight of AHP, with trends showing an increasing importance of this group of materials and environmental hotspots from the LCA study pointed, the production of these materials must be carried out having in place water, waste and energy optimisation management plans.

Assessment and verification

In TR2.0, the inclusion of examples of international standards such as ISO 14001 or ISO 50001 or equivalent were requested while in TR3.0, the EN 16247 has been added.

The international standard ISO 14001 is the Environmental Management Standard[108] that sets out the requirements for implementing an Environmental Management System (EMS). An EMS is used by a business to manage its environmental responsibilities. The way the ISO 14001 standard was designed was meant to measure and improve the environmental impact of a business and to make sure practices have a minimal impact on the environment. Usually the implementing efforts include the limitation of waste sent to landfill and incineration, the source of sustainable materials, the reduction of water and the potential for the pollution of local water and energy reduction.

The international standard ISO 50001 is the Energy Management Standard[109] that sets out the criteria for implementing an Energy Management System (EnMS) with the aim of improving energy performance and reducing its use. This standard helps to tackle climate change by reducing greenhouse gas (CO_2) emissions, improving efficiency and reducing consumption. The main efforts to implement include the monitoring of emissions and energy usage and the sourcing of energy from renewable sources. Thus the ISO 50001 can help to reduce the energy cost of manufacturer site.

The EN 16247 is an international standard for Energy audits - Part 1: General requirements[110], which specifies the requirements, common methodology and deliverables for energy audits. It is applicable to all forms of establishments and organizations, all forms of energy and energy uses. It covers the general requirements common to all energy audits. Specific energy audit requirements complete the general requirements in separate parts dedicated to energy audits for buildings, industrial processes and transport.

This third proposal to sub-criterion 4.1 A&V includes the standards: ISO 14001, ISO 50001, EN 16247 or equivalent to make this requirement more verifiable.

The whole A&V section has been expanded to detailhow the requirement shall be fulfilled.

Summary of changes in TR3.0 for sub-criterion 4.1

- The requirements for water, waste and energy plans for all plants producing synthetic polymers and plastic materials used in the final AHP have been kept.

[107] COMMISSION DECISION (EU) 2020/1803 of 27 November 2020 establishing the EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bag products (notified under document C(2020) 8155) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D1803&from=EN

[108] ISO 14001 Environmental management systems- Requirements with guidance for use. Third edition 2015 - 09 - 15. Reference number ISO 14001: 2015 (E).

[109] ISO 50001 Energy management systems- Requirements with guidance for use. Second edition 2018 - 08. Reference number ISO 50001: 2018 (E).

[110] EN 16247-1:2022 Energy audits - Part 1: General requirements.

- Details are given on how to fulfil the sub-criterion on water, waste and energy plans as these are requested to be documented or explained and information on the procedures to include are listed.
- The A&V section is expanded: the consideration of the cases when the requirements in the sub-criterion are fulfilled is explained.

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5.5.2 Sub-criterion 4.2: Bio-based plastic materials - NEW

Annex I: First proposal for sub-criterion 4.2: Bio-based plastic materials - NEW
This criterion applies to final absorbent hygiene products where synthetic polymers and plastic materials represents ≥ 1% w/w (not counting packaging). A minimum of ≥XX % w/w of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final absorbent hygiene product (including SAP) must be sourced from bio-based raw materials (not counting packaging). All (100%) bio-based raw materials used for the production of bio-based plastic in absorbent hygiene products shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as International Sustainability and Carbon Certification (ISCC), Roundtable on Sustainable Biomaterials (RSB), Roundtable Responsible Soy (RTRS), Roundtable on Sustainable Palm Oil (RSPO), Forest Stewardship Council (FSC), Programme for the Endorsement of Forest Certification Schemes (PEFC), Öko-Landbau-Siegel, Rainforest Alliance (SAN), Bonsucro, REDcert, OCS 100 - Organic Content Standard, TUV Austria, BioPreferred Program or equivalent. Assessment and verification: The applicant shall provide the competent body with a declaration of compliance supported by a valid, independently certified chain of custody certificate from the manufacturer of EU Ecolabel absorbent hygiene product and for all bio-based plastics used in the product or production line to produce. The standard CEN/TS 16137 shall be used to determine the bio-based carbon content of the synthetic polymers and plastic materials present in the product. International Sustainability and Carbon Certification (ISCC), Roundtable on Sustainable Biomaterials (RSB), Roundtable Responsible Soy (RTRS), Roundtable on Sustainable Palm Oil (RSPO), Forest Stewardship Council (FSC), Programme for the Endorsement of Forest Certification Schemes (PEFC), Öko-Landbau-Siegel, Rainforest Alliance (SAN), Bonsucro, REDcert, OCS 100 - Organic Content Standard, TUV Austria, BioPreferred Program or equivalent schemes shall be accepted as independent third-party certification. The use of purchased certificates based on the Book & Claim system is excluded so that the traceability of the raw materials is possible. The proofs of purchase for the raw materials must be based on processes according to the segregation or mass balance systems. In addition, the applicant shall provide audited accounting documents that demonstrate that 100 % of the bio-based raw materials used for the production of the bio-based plastic is defined as certified material according to the valid cited schemes. 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.
Annex I: Second proposal for sub-criterion 4.2: Bio-based plastic materials
~~This criterion applies to final absorbent hygiene products where synthetic polymers and plastic materials represents ≥ 1% w/w (not counting packaging)~~. The applicant may source, on a voluntary basis, a certain percentage ~~A minimum of ≥XX % w/w~~ of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final absorbent hygiene product (including super absorbent polymers (SAP)) ~~must be sourced~~ from bio-based raw materials ~~(not counting packaging)~~. This criterion applies only to absorbent hygiene products that contain > 1% bio-based plastic material. In such case, the percentage of bio-based plastic material added to the product (and/or packaging) shall be stated in the application. The final product (and/or packaging) may be voluntarily labelled as containing "bio-based" plastic materials only if >50% by weight of the total weight of plastics originates from bio-based resources. The

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generic claim "bioplastics" shall not be used.

All (100%) bio-based raw materials used for the production of bio-based plastic in absorbent hygiene products shall be covered by valid chain of custody certificates issued by an independent third party certification scheme officially recognised by the European Commission[1]. ~~such as International Sustainability and Carbon Certification (ISCC), Roundtable on Sustainable Biomaterials (RSB), Roundtable Responsible Soy (RTRS), Roundtable on Sustainable Palm Oil (RSPO), Forest Stewardship Council (FSC), Programme for the Endorsement of Forest Certification Schemes (PEFC), Öko-Landbau Siegel, Rainforest Alliance (SAN), Bonsucro, REDcert, OCS 100 – Organic Content Standard, TUV Austria, BioPreferred Program or equivalent.~~

In addition, bio-based raw materials used for the production of bio-based plastic in absorbent hygiene products (and/or packaging) shall align with the sustainability criteria similar to those applicable to the energy sector[2].

Assessment and verification:

The applicant shall provide ~~the competent body with~~ a declaration of compliance supported by a valid, independently certified chain-of-custody certificate from the suppliers ~~manufacturer of EU Ecolabel absorbent hygiene product and~~ for all bio-based plastics used in the product ~~or production line~~. ~~to produce~~.

The standards based on radiocarbon methods such as ~~CEN/TS 16137~~ EN 16640 or EN 16785 or ASTM D 6866-12 shall be used to determine the bio-based carbon content of the synthetic polymers and plastic materials present in the product. 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 sustainability of the bio-based plastics used in the product shall be demonstrated by the provision of independent third party certification schemes officially recognised by the European Commission[1], ~~International Sustainability and Carbon Certification (ISCC), Roundtable on Sustainable Biomaterials (RSB), Roundtable Responsible Soy (RTRS), Roundtable on Sustainable Palm Oil (RSPO), REDcert (EU waste) – exclusively from bio-based waste within the EU, Forest Stewardship Council (FSC), Programme for the Endorsement of Forest Certification Schemes (PEFC), Öko-Landbau Siegel, Rainforest Alliance (SAN), Bonsucro, REDcert, OCS 100 – Organic Content Standard, TUV Austria, BioPreferred Program or equivalent schemes shall be accepted as independent third-party certification.~~

Besides, the applicant shall provide a declaration of compliance for the bio-based raw materials used for the production of bio-based plastic in absorbent hygiene products aligned with the sustainability criteria applicable to the energy sector[2].

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

In addition, the applicant shall provide audited accounting documents that demonstrate that 100 % of the bio-based raw materials used for the production of the bio-based plastic is defined as certified material according to the valid cited schemes.

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.

[1] Approved voluntary schemes and national certification schemes: https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en

[2] As in the Renewable Energy Directive, OJ L 328, 21.12.2018.

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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 the dependency on fossil resources is an advantage.

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 much dependable on the origin, type or manufacture method of the selected bio-based plastic, a careful evaluation should be carried out.

During the 1st AHWG, the discussion around criterion on synthetic polymers and plastic materials was very much focused on the inclusion of recycled, bio-based and/or biodegradable plastic materials. Several comments received in written form requested the possibility of a sub-criterion on bio-based plastics.

In this sense, in the Technical Report 2, a new sub-criterion 4.2 on bioplastics was proposed, requesting ≥XX % w/w of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final absorbent hygiene product (including SAP) to be sourced from bio-based raw materials.

The percentage of bio-based plastic was left open to be discussed during and after the 2nd AHWG. In all cases, bio-based plastic materials shall also comply with sub-criterion 4.1.

Outcomes from and after 2nd AHWG meeting

The feedback received during the 2nd AHWG meeting and after that in written form is aligned with comments received during and after the EUEB meeting in May 2022 where this criterion was introduced.

There has been a consensus amongst stakeholders on the possibility of making this criterion voluntary. Mainly the discussions in relation to this proposed sub-criterion on bio-based plastic materials inclusion touched upon the actual sustainability, market supply and a lack of traceability of these materials.

Another stakeholder clarified that the CEN/TS 16137 had been withdrawn, proposing EN 16640 (for bio-based carbon content) or EN 16785 (for bio-based content and H, N. O) as alternatives.

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting it was emphasised that switching to bio-based materials does not equal to a greater sustainability as trade-off impacts must be considered such as land use change. It was suggested to explore further the schemes for sustainability, certification and reliability. Also the inability of the market to maintain a fixed percentage of bio-based materials to be used in AHP was highlighted

Also, 14 written comments were received in relation to the proposed sub-criterion text. As explained, the main reflections requested the sub-criterion to be made voluntary with no specified percentage of inclusion on bio-based plastics. In relation to the assessment and verification, it was requested to modify the standard initially proposed. A clarification on the use of the mass balance approach was requested.

Other more specific comments were:

- The possibility for the applicant to be allowed the use of a specific claim on the label if criterion is fulfilled.
- As the environmental superiority in terms of lower impacts of bio-based plastics is not fully demonstrated, it is stated that this sub-criterion would be 'contrary to the EU Ecolabel regulation No 66/2010 which in its point (1) states: The aim of Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 *on a revised Community eco-label award scheme was to establish a voluntary ecolabel award scheme intended to promote products with a reduced environmental impact during their entire life cycle and to provide consumers with accurate, non-deceptive, science-based information on the environmental impact of products'.*
- Addition of sustainable sourcing not only for bio-based plastics but also for fossil-based plastics.

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Further research and main changes to the third proposal

Some general comments

In alignment with most of the comments received during and after the 2nd AHWG meeting, the criterion on bio-based plastic materials has been set as voluntary. The percentage of bio-based plastic materials is left open for each applicant to add the quantity that better relates to their product. However claims can only be done under certain conditions. It is worth noting that the criterion is optional however strict requirement are to be fulfilled if it is decided to comply with it.

For the assessment and verification, the CEN/TS 16137 – Plastics – Determination of bio-based carbon content (C14) which is withdrawn, has been substituted by the EN 16640 - Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method, and the EN 16785 – Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis, shall be used. Alternatively, the ASTM D 6866-12, the Standard Test Method for Determining the Bio-based Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis is also accepted[111].

The use of mass balance is also stated under the Assessment and Verification section of the criterion (already in the initial proposal).

CEN/TC 411 Bio-based products

The CEN/TC (Technical Committee) 411 has developed standards for bio-based products covering horizontal aspects. Their work includes the development of several standards in relation to several areas of interest such as terminology, bio-solvents, bio-based content, sustainability criteria and certification.

The standard EN 16640 or EN 16785 are listed in the A&V section of the sub-criterion as the procedures to follow in order to determine the bio-based carbon content of the synthetic polymers and plastic materials present in the product. Both standards detail how to measure the bio-based content using the radiocarbon method.

In the following table[112], other standards developed by the CEN/TC 411 for bio-based products are listed, where selected in bold are the standards to be used for the determination of bio-based content.

Table 4. Standards developed by the CEN/TC 411 for bio-based products.

CEN/TC 411 Bio-based products			
Working Group (WG)	Designation	Standard developed	Title of standard
1	Terminology	EN 16575	Bio-based products. Vocabulary
2	Bio-solvents	EN 16766	Bio-based solvents. Requirements and test methods
3	Bio-based content	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
4	Sustainability criteria, life	EN 16751	Bio-based products – Sustainability criteria

[111] ASTM D6866-04 Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis. www.astm.org .

[112] CEN/TC 411 Bio-based products, https://www.biobasedeconomy.eu/centc-411-bio-based-products/

CEN/TC 411 Bio-based products			
Working Group (WG)	Designation	Standard developed	Title of standard
	cycle analysis and related issue	EN 16760	Bio-based products – Life Cycle Assessment
5	Certification and declaration tools	EN 16848	Bio-based products – Requirements for Business to Business communication of characteristics using a Data Sheet
		EN 16935	Bio-based products – Requirements for Business-to-Consumer communication and claim

Bio-based, biodegradable and compostable plastics in the European Commission

As explained in the TR2.0, currently the European Commission is planning a policy framework aimed to contribute to a more sustainable plastic economy. The draft for the 'Communication from the EC on EU Policy Framework on Bio-based, biodegradable and compostable plastics'[113], 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 bio-based plastics, but considering the whole life-cycle. The Communication aims to fill possible gaps and does so by setting orientations to be used by EU policies addressing these plastics in the future.

Bio-based plastics (BBP) and biodegradable and compostable plastics (BDCP), have been highlighted as having the potential to bring advantages over fossil-based, non-biodegradable plastics. However, the effectively sustainability of BBP and BDCP over conventional plastics needs to be carefully assessed. In fact, for bio-based plastics to provide genuine environmental benefits, they need to comply with sustainability criteria. In this line, a suitable LCA-based method to compare bio-based and fossil-based plastics is needed, based on the Plastics LCA method[114]. 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 emission for products including bio-based plastics. The discussion is ongoing in the context of the UN Life Cycle Initiative[115].

It is to note that it is not the intention of this sub-criterion to label the AHP as bio-based (without further specifications) either to call the product bio-based, but to add a certain percentage of bio-based plastic materials in order to make a first step in the direction of including bio-based sources.

The cited draft for the 'Communication from the EC on EU Policy Framework on Biobased, biodegradable and compostable plastics', recommends to communicate the actual share of bio-based content of a product (or packaging). In addition, to avoid that plastic products made only marginally from biomass are labelled as 'bio-based', there should be a minimum content of biomass to comply with. In principle, in order to label a product (or packaging) as 'bio-based', more than 50% by weight should come from bio-based resources, however the final % is still to be confirmed. Also the method to measure the bio-based 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 referral to the share of the end-products that is sourced from bio-based materials, known as mass balance method, is not suitable to certify the actual share of bio-based 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.

[113] European Commission, 2022. Communication from the EC on EU Policy Framework on Biobased, biodegradable and compostable plastics

[114] 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

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

As remarks, it is advised to ban the environmental claim 'bioplastics' for products as considered too generic, while the environmental claim 'bio-based' should also be banned if it is not further specified, i.e., it must include the minimum bio-based content (over 50%), measured by means of radiocarbon-based methods over the mass balance ones.

LCA of bio-based plastics

It is of relevance to highlight that in the LCA screening study performed to AHP, it was mentioned: '*The raw materials showing highest contributions in case of baby diapers were SAP (which also had the highest share of materials used in the diapers), PP granulates, kraft pulp (cellulose) and polyester resin (proxy for adhesives). In addition to raw materials, also LDPE packaging was identified as a hotspot in some impact categories. For sanitary towels, the most contributing raw materials were PET and PP granulates, viscose, polyester resin (proxy for adhesives) and kraft pulp (cellulose). Also in case of sanitary towels, LDPE packaging was identified as a hotspot in addition to raw materials used in the product.*'

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

Fostering sustainable bio-based plastic materials as an alternative to plastic from fossil resources seems as a starting point, as bio-based plastic production phases could present lower impacts in certain environmental categories compared to petrochemical plastics. Another advantage would be the lower dependence from non-renewable fossil resources. Also the action 1.6 from the EU Bioeconomy Strategy[116] promotes the development of substitutes to fossil resources, in particular bio-based, recyclable and marine-biodegradable substitutes for plastic. It is mentioned the potential that bio-based plastics have in relation to jobs' creation, particularly in rural and coastal areas.

Some LCA studies show lower GHG emissions for bio-based plastics, however there are large variations depending on the bio-based plastic type, feedstock and manufacturing process. Also to add the huge variation as a result of the different system boundaries conditions chosen, as there is not a set of harmonised standards and approaches[117]. This results in a limited comparability of studies in relation to bio-based plastics and also their fossil-based counterparts.

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 from bio-based or fossil-based constituents. There are three parts[118]:

- 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'.

Bioplastics' market

According to the latest market data compiled by European Bioplastics and the nova-Institute, the global bioplastics production capacities are set to increase from around 2.42 million tonnes in 2021 to approximately 7.59 million tonnes in 2026. Hence, the share of bioplastics in the global plastic production will

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

[117] 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 .

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

overcome the current 1%. Global production capacities of bio-based plastics and forecast are pictured in the following figure.

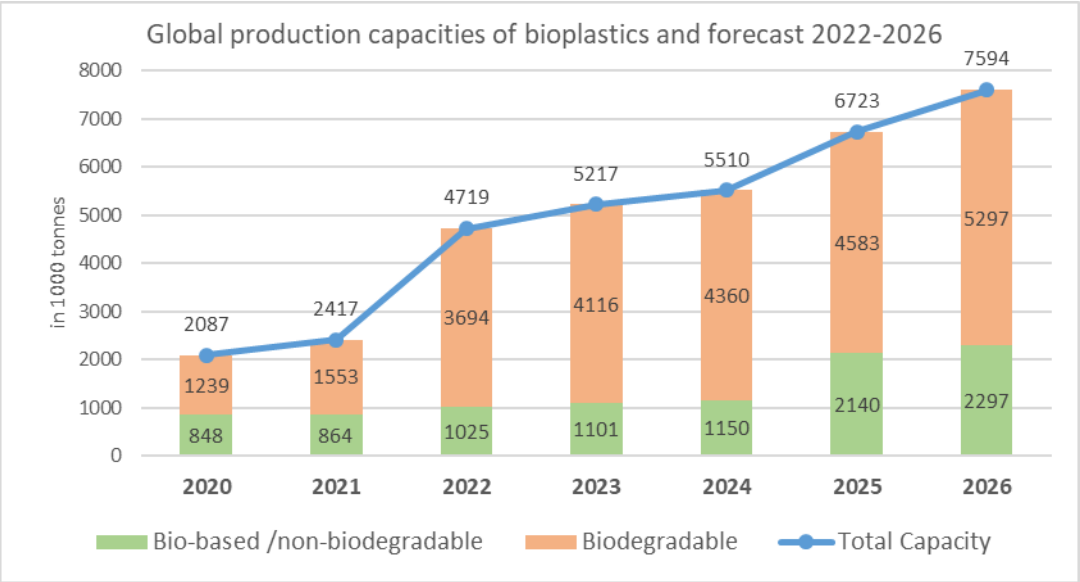

Figure 3. Global production capacities of bioplastics and forecast 2022- 2026. Source: Adapted from European Bioplastics, nova-Institute (2021).

Nowadays, the vast majority of bio-based plastics are produced from cultivated crops; still they currently consume less than 0.04% of global biomass demand. Due to higher feedstock prices, bio-based plastics are usually more expensive than fossil-based plastics (20% to >100%), thus being the main burden for their application[119].

Sourcing of synthetic polymers and plastic materials

In relation to the comment requesting the 'Addition of sustainable sourcing not only for bio-based plastics but also for fossil-based plastics', this shall not be considered as it was something already proposed in the previous revision which was deleted in the end.

Ambition level of the other ecolabels

Other ecolabels type I such as the Nordic Swan and Blue Angel consider the inclusion of bio-based polymers in the packaging, the additional components or the product on a voluntary basis. In Nordic Swan ecolabel (Nordic Swan, 2021) is it explain that one of the following requirements (a, b or c) must be fulfilled:

> *a) Diapers and incontinence products must have ≥50 weight-% of renewable material in the product and additional component. Other products must have ≥60 weight-% of renewable material in the product and additional component.* → In fact during the discussions that took place at the 2nd AHWG meeting, it was mentioned that, in general, this is not a very popular requirement.
>
> *b) The primary packaging contains ≥20 weight-% of renewable and/or recycled material in relation to the total weight of the primary packaging. The amount of renewable/recycled material can be documented on an annual basis.*

[119] 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.

c) ≥7 weight-% of the polymers in relation to the total weight of polymers in the product and additional component (including SAP) must be bio-based and/or recycled.

The Blue Angel Ecolabel considers the inclusion of bio-based plastic for either the packaging or the product. In both cases, the bio-based plastics must be sourced from sustainable cultivation. The list of possible certification schemes to use is set in the main text of this ecolabel (Blue Angel, 2021).

Certification schemes accepted by the EU Ecolabel

A modification introduced in the sub-criterion is in relation to the certification schemes accepted by the AHP EU Ecolabel. Instead of compiling the number of accepted schemes which may change with time, it is decided to include a sentence referring only to officially recognised schemes by the European Commission and summarised in the European Commission webpage currently as https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en.

In the following table, the certification schemes accepted by the EC for biofuels, bioliquids and biomass fuels as being sustainably produced by compliance with the EU sustainability criteria. For so those shall be also accepted in the EU Ecolabel for sub-criterion 4.2 on bio-based plastic materials.

Table 5. Schemes accepted as independent third-party certification in sub-criterion 4.2[120].

PROGRAMME NAMES				
Biomass Biofuels voluntary scheme (2BSvs)	Sustainability and Carbon Certification (ISCC EU)	Red Tractor Farm Assurance Combinable Crops & Sugar Beet Scheme (Red Tractor)	Scottish Quality Farm Assured Combinable Crops (SQC)	Sustainable Resources (SURE) voluntary scheme
Better Biomass	KZR INiG system	Roundtable on Sustainable Biofuels EU RED (RSB EU RED)	Trade Assurance Scheme for Combinable Crops (TASCC)	Austrian Agricultural Certification Scheme (AACS)
Bonsucro EU	REDcert	Roundtable Responsible Soy EU RED (RTRS EU RED)	Universal Feed Assurance Scheme (UFAS)	U.S. Soybean Sustainability Assurance Protocol EU (SSAP EU)
Sustainable Biomass Program (SBP)	Programme for the Endorsement of Forest Certification (PEFC) (pending EC positive technical assessment)		European Renewable Gas Registry (ERGaR) (pending EC positive technical assessment)	

Assessment and verification

The assessment and verification of sub-criterion 4.2 has been formulated in line with the requests set in other ecolabels type I for AHP and harmonised with similar criteria requesting *a 'declaration of compliance supported by a valid, independently certified chain of custody certificate'*.

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

The standard 'CEN/TS 16137:2011 Plastics – Determination of bio-based carbon content' which is currently withdrawn, has been replaced with the standard 'EN 16640 - Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method', the 'EN 16785 – Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis', or the 'ASTM D 6866-12 - Standard Test Method for Determining the Bio-based Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis' shall be used.

It has been added that the certification schemes accepted shall be officially recognised by the European Commission[121]. Also applicants shall provide proofs of alignment with sustainability criteria in a similar way to those applicable to the energy sector[122].

Summary of changes in TR3.0 for sub-criterion 4.2

- The sub-criterion for 'bio-based plastic materials' in AHP is made voluntary.
- The % of bio-based plastic material added to the product (and/or packaging) must be stated.
- The product (and/or packaging) shall voluntarily be labelled as bio-based only if >50% by weight of the total weight of plastics comes from bio-based resources.
- The generic claim **'bioplastics' shall not be used**.
- In line with other ecolabels type I, such as Nordic Swan and Blue Angel and already set in the TR2.0 proposal:
    - The utilisation of certificates based on the book and claim system was excluded. This was to allow the traceability of the raw materials.
    - Allowed raw materials' proofs of purchase shall be based on processes according to the segregation or mass balance systems.
    - Radiocarbon methods are preferred for the determination of the bio-based content of the synthetic polymers and plastic materials present in the product. If a mass balance method is used, a high level of transparency and accountability must be ensured and supported by agreed standards.
- The standard CEN/TS 16137 is withdrawn now and it has been replaced in the text of the sub-criterion with standards such as EN 16640, the EN 16785 or the ASTM D 6866-12 (radiocarbon methods).
- Accepted certification schemes by the AHP EU Ecolabel are currently in line with the officially recognised schemes by the European Commission under the Renewable Energy Directive.

[121] Approved voluntary schemes and national certification schemes: https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en

[122] As in the Renewable Energy Directive, OJ L 328, 21.12.2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.328.01.0082.01.ENG

Draft

5.6 CRITERION 5 for Absorbent Hygiene Products: Compostability – NEW

Annex I: First proposal for criterion 5: Biodegradability
If the absorbent hygiene product (including packaging) contains a certain percentage of biodegradable and/or compostable materials, the biodegradability and/or compostability of that material must be certified by the supplier of that material. A clear statement shall be given on the primary packaging to guide consumers on how to dispose correctly the cited absorbent hygiene product containing biodegradable and/or compostable material, after use. Guidance shall also apply to packaging if it is biodegradable and/or compostable. Assessment and verification: The applicant shall provide a declaration of compliance with this criterion specifying the biodegradable and/or compostable section of the absorbent hygiene product (including packaging). The declaration shall be supported by a test report performed using one of the test methods mentioned below. Biodegradability and/or compostability must be certified by complying with the EN 14995, ISO 14855, ISO 15985 or ISO 16929. Equivalent 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 correctly appear clearly).
Annex I: Second proposal for criterion 5: ~~Biodegradability~~ Compostability
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 ~~contains a certain percentage of~~ compostable, ~~materials, the biodegradability and/or compostability of that material~~ 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 ~~containing~~ compostable material, after use. ~~Guidance shall also apply to packaging if it is biodegradable and/or compostable.~~ 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. ~~specifying the biodegradable and/or compostable section of the absorbent hygiene product (including packaging).~~ The declaration shall be supported by a test report performed using one of the test methods mentioned ~~below~~above. ~~Biodegradability and/or c~~Compostability must be certified by complying with the EN 14995, ~~ISO 14855, ISO 15985,~~ ISO 16929, ISO 13432, or ISO 18606. ~~Equivalent~~ 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).

Draft

Rationale for the proposed criterion text

During and after the 1st AHWG meeting, several comments were received requesting the addition of a biodegradable percentage of materials in the final AHP. One stakeholder pointed out that '*depending on the final application, biodegradability would make sense and suggested to focus on bio-based content only (even if material is biodegradable). There are certification schemes to prove sustainability which could be look at. It would make sense to have a minimum bio-based or recycled share. There are not relevant toxic ingredients in bio-based non-biodegradable plastics and if biodegradable they should provide certification on eco-toxicity testing and heavy metal content*'.

In line with this, in the Technical Report 2, a new criterion on biodegradability and/or compostability was proposed. The proposal did not introduce a requirement on a certain percentage by weight of biodegradable and/or compostable materials to be included in a certain AHP. It was left open to manufacturers to add sections able to biodegrade or compost. In general, in criterion 5 it was requested that:

- Verification had to be conducted.
- Disposal method had to be clearly explained in the primary packaging.

In relation to the 'assessment and verification' section, the proposal included that biodegradability and/or compostability had to be certified by several test methods: EN 14995, ISO 14855, ISO 15985, ISO 16929 or equivalent.

Outcomes from and after 2nd AHWG meeting

The feedback received during the 2nd AHWG meeting and after that in written form is aligned in some aspects with comments received during and after the EUEB meeting in May 2022, where this criterion was introduced.

During the EUEB, three CBs announced their concerns: while it was suggested to change the wording from "biodegradable" to "recyclable", it was also explained that the current wording was unclear in terms of what part of a product was actually biodegradable and also the verification of biodegradability could increase the workload of producers. Other two comments also expressed that the wording, providing that only parts of the product are biodegradable, could give the wrong message to consumer about the correct disposal.

During the 2nd AHWG meeting the majority of the stakeholders intervening were against the introduction of this criterion. The main arguments were:

- Lack of legislation/regulation and waste management systems across all MS:

Two stakeholders affirmed that the most of MS do not count with a legislation allowing AHP in composting or recycling plants or even with the waste management system infrastructure to channel and treat AHP appropriately. In this case, AHP are just landfilled.

- Potential misleading effect on consumer perception:

By mentioning AHP products are biodegradable, consumers might perceive that they would naturally degrade in the environment and/or that they can be composted. Since no prior separation of non-biodegradable parts would occur, this would incur into detrimental impacts.

Finally, one stakeholder indicated that the list of ISO standards methods relate to pass or fail criteria; suggesting referring to the specifications of these criteria: EN 13432/14995 or ISO 17088/18606.

While all comments received after the 2nd AHWG meeting can be found in the annexed Table of Comment, the sections below address the main comments received.

In total 8 comments were received after the 2nd AHWG meeting: half of the comments are in line with comments received during the meeting and are against the introduction of this criterion while the rest of comments request to keep it on a voluntary basis.

It was also requested to clarify it or modify it as the referral to sections of the product able to be biodegradable may lead to bad practices, consumers having to dissemble the product and misleading or even littering of the products in the environment.

Draft

Further research and main changes to the third proposal

Some general comments

As already identified in TR2.0, both terms, biodegradability and compostability need clarification. The definition for compostability has been added to the scope and definition section as this criterion has been only set to refer to compostability only.

In general, biodegradability refers to *'the ability of a material to decompose after interactions with biological elements'*[123]. Biodegradability is also referred to as *'the capacity for biological degradation of organic materials by living organisms down to the base substances such as water, carbon dioxide, methane, basic elements and biomass. Most natural and synthetic materials will biodegrade given an infinite time span[124]'.*

According to the standard ISO 16929, biodegradation is *the 'degradation caused by biological activity especially by enzymatic action leading to a significant change in the chemical structure of a material'*.

On the other hand, compostability is the *'property of a material to be biodegraded in a composting process or aerobic process designed to produce compost. Compost is the organic soil conditioner obtained by biodegradation of a mixture principally consisting of various vegetable residues, occasionally with other organic material, and having a limited mineral content'*[125].

Biodegradability is often referred to either bio-based materials or to plastics or bio-based plastic materials. However it is the intention of the EU Ecolabel to set a requirement applicable not only to the plastic but to other materials present in a given AHP, i.e. to the whole product and packaging. It has been decided to address only compostability in this criterion. The intention is to refer to AHP able to be treated under composting conditions in both controlled industrial conditions or at home (if desired).

The product and/or packaging shall be 100% compostable and clear specification have to be provided, i.e. timeframe and specific environment for degradation thus to avoid misconception on how to dispose the used product and/or packaging.

In bi-lateral meetings with industry stakeholders, it has been discussed that for certain cases, biodegradability of packaging is not desired as the packaging must guarantee enough shelf-life to avoid product discards before consumer acquisition.

It has been also discussed with industry how in some MS it is common to have compost systems at home thus compostable products have a niche market which may not be extended to all MS.

Bio-based, biodegradable and compostable plastics in the European Commission

The draft for the "Communication from the EC on EU Policy Framework on Bio-based, biodegradable and compostable plastics"[126], highlights the complexity of biodegradation. It is to note that when a product or a packaging is described as biodegradable or compostable, it cannot be assumed that it will biodegrade in the environment and for so freely release it. 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.

In line with the circular economy and waste hierarchy principles, 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:

[123] P. Goswami, T. O'Haire, 3 - Developments in the use of green (biodegradable), recycled and biopolymer materials in technical nonwovens, Editor(s): George Kellie, In Woodhead Publishing Series in Textiles, Advances in Technical Nonwovens, Woodhead Publishing, 2016, Pages 97-114, ISBN 9780081005750, https://doi.org/10.1016/B978-0-08-100575-0.00003-6

[124] Kyrikou, I., Briassoulis, D. Biodegradation of Agricultural Plastic Films: A Critical Review. J Polym Environ 15, 125–150 (2007). https://doi.org/10.1007/s10924-007-0053-8

[125] ISO standard 16929: 2021 - Plastics - Determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test

[126] European Commission, 2022. Communication from the EC on EU Policy Framework on Biobased, biodegradable and compostable plastics

(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.

It is worth noting the likely expected increase in the separate collection of organic waste derived from the introduction of mandatory separate organic waste collection by 31st December 2023, as a result the focus on compostable plastics must be directed to applications which may deliver 'added benefits' in terms of plastic contamination of compost and organic waste collection.

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.

In fact, to be labelled as compostable, products and packaging applications should display the disposal route directly on the product primary packaging and provide information possibly through pictograms. Rather than simply raising awareness, accompanying information campaigns should seek to promote effective disposal waste action.

Comparison with other ecolabels

Other ecolabels type I such as the Nordic Swan or the Blue Angel do not specify any criterion on biodegradability and/or compostability.

Rationale behind the proposed 'assessment and verification'

Compostability can be certified by several test methods. The methods listed in the criterion in the TR2.0 were:

- EN 14995 – Plastics - Evaluation of compostability - Test scheme and specifications.
- ISO 16929 – Plastics — Determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test.

As some comments suggested, other standards added are:

- EN 13432 – Packaging – Requirements for packaging recoverable through composting and biodegradation. Test scheme and evaluation criteria for the final acceptance of packaging.
- ISO 18606 – Packaging and the environment — Organic recycling.

Note that the standard ISO 17088 – Specifications for compostable plastics, has not been added as it is now withdrawn.

Summary of changes in TR3.0

- The title of the criterion has been modified from 'biodegradability' to 'compostability' as the late term relates specifically to the aim of this criterion.
- In this proposal the criterion has been set as an optional criterion which would apply to the whole absorbent hygiene product and/or packaging.
- The mention to a certain section of the product to be compostable has been deleted. The whole product and/or packaging shall be compostable.
- The timeframe and environment referred to compostability must be stated. Accepted compostability certificates are EN 14995, ISO 16929, and also ISO 13432, or ISO 18606. However, equivalent methods may be accepted.

Draft

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

Annex I: Second proposal for criterion 6: Material efficiency in the manufacturing
Requirements in this criterion shall apply to the final absorbent hygiene product assembly site. The quantity of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed: — 8~~10~~ % by weight of the end products for tampons, — 4~~5~~ % 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. Calculations shall be shown in accordance with ISO 14025 and the applicant shall present all of the following parameters concerning: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of. The net waste shall be calculated as the difference between the amount of waste produced and the amount of waste recovered.
Annex I: Third proposal for criterion 6: Material efficiency in the manufacturing of the final product
Requirements in this criterion shall apply to the final absorbent hygiene product assembly site. The quantity of waste generated during the manufacture and packaging of the products (and sent to landfill or incineration), , ~~at the net of the fraction that is reused or converted into useful materials and/or energy)~~, shall not exceed: — 8 % by weight of the end products for tampons, — 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. ~~Calculations shall be shown in accordance with ISO 14025 and the~~ The applicant shall present~~all of the following parameters concerning~~: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing ~~(e.g. recycling, incineration) , including~~ of the fraction of recovered waste and that disposed of to landfill or incineration. The quantity of ~~net~~ 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).

Draft

Rationale for the proposed criterion text

In line with the Circular Economy Action Plan 2020, the design and production phases are among the key drivers to achieve circular economy objectives, and ensure that the resources used are kept within the EU economy for as long as possible (EC, 2020). Waste reduction, lower resource consumption and less environmental impacts are general objectives of the Green Deal[127] in relation to sustainable product manufacture. To this end, the reduction of the thresholds of the quantity of waste generated during the manufacture and packaging of AHP is expected in order to meet policy requirements.

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

For the first proposal included in the TR1.0, it was not possible to tighten the waste generation thresholds. Therefore, no changes were proposed.

Any comments to this criterion were received either during the 1st AHWG meeting or later on in written form, however in the second proposal contained in TR2.0 some modifications were included:

- It was clarified within the text that this criterion applied to the final absorbent hygiene product assembly site.
- In line with waste values received in July 2021 from CBs from several LHs, the proposed percentages of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, was set as 8 % w/w for tampons and 4 % w/w for all the other products.

Outcomes from and after 2nd AHWG meeting

During the 2nd AHWG meeting, some comments were made by stakeholders, first the reasons to have incineration in the same target level as recycling and reuse (in reference to the waste management hierarchy) was asked. It was also mentioned that incineration with recovery was a better option than landfill. Finally, it was suggested to revise the reference to the standard ISO 14025 as it was not related to waste production reporting.

In total, three comments were received on this criterion. While all comments received can be found in the Table of Comment, the sections below address the main comments received.

Two of the comments received referred to replacement of the standard ISO 14025 while another comment expressed that the new limits of waste generated during the manufacture and packaging of the products (i.e. 8% w/w for tampons and 4% w/w for all other products) were achievable.

Further research and main changes in the third proposal

Nearly 40,000 disposable diapers are used every minute, producing 1.3 t/min (dry weight) of waste[128]. While little effort can be fostered from the EU Ecolabel on the waste production and management of the final used products, a stronger requirement during the product design and manufacturing phases are encouraged which would minimise the environmental impact in these phases.

In this line, more ambitious restrictions to the quantity of waste generated during the manufacture and packaging of the products, have been set (20 % increment of the exigency of the thresholds) in order to

[127] 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

[128] 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

foster a minimisation of waste during the production of absorbent hygiene products. The responses in summer 2021 provided averaged values of 4% for baby diapers and menstrual pads.

Although the Nordic Swan or Blue Angel ecolabels do not set requirements on the percentages of waste generated during the manufacture and packaging of the final absorbent hygiene products, it is relevant from the circular economy point of view to set limitations on the manufacturing stage in order to recycle and reuse raw materials as much as possible. Given the increasing demand for AHP in the EU per year (see details in section 3- Market analysis from the Preliminary Report), small improvements in resource efficiency can lead to significant environmental savings.

In line with waste values received in July 2021 from CBs from several LHs, the proposed percentages of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, were 8 % w/w for tampons and 4 % w/w for all the other products (this was proposed in the TR2.0).

In this proposal, the changes included aim to shed clarity on how to apply this criterion. Discussion showed it seemed confusing, nevertheless the main objective is to target the percentage of waste that is either sent to landfill or incineration in the final product manufacturing assembly site. This the waste is not recovered for reuse, recycling or energy production.

Rationale behind the proposed 'assessment and verification'

The referral to ISO 14025 has been deleted and clarification on how to fulfil this criterion has been added.

Summary of changes in TR3.0

- Removal of the reference to ISO 14025.
- Slight modification of the explanation on how to calculate the cited % of waste from production for clarity.

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

5.8.1 Sub-criterion 7.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Annex I: Previous proposal for criterion 7.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Unless derogated in Table 5, the final product, and any component articles therein, shall not contain ingoing substances (alone or in mixtures) ~~in concentrations greater than 0,10% (weight by weight)~~ that are assigned any of the ~~following~~ hazard classes, categories and associated hazard statement codes stated in Table 4, in accordance with Regulation (EC) No 1272/2008.

Table 4. 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 on 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

- ~~Group 1 hazards: Category 1A or 1B carcinogenic, mutagenic and/or toxic for reproduction (CMR): H340, H350, H350i, H360, H360F, H360D, H360FD, H360Fd, H360Df.~~
- ~~Group 2 hazards: Category 2 CMR: H341, H351, H361, H361f, H361d, H361fd, H362; Category 1 aquatic toxicity: H400, H410; Category 1 and 2 acute toxicity: H300, H310, H330; Category 1 aspiration toxicity: H304; Category 1 specific target organ toxicity (STOT): H370, H372; Category 1 skin sensitisation H317; Category 1 respiratory Sensitization H334.~~
- ~~Group 3 hazards: Category 2, 3 and 4 aquatic toxicity: H411, H412, H413; Category 3 acute toxicity: H301, H311, H331; Category 2 STOT: H371, H373.~~

Table 5. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard	Derogation conditions

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		statement code	
Titanium dioxide (nano-form)	Pigment	H351: Suspected of causing cancer	It cannot be used in powder or spray form

Moreover the final product, and any component articles 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 6, in accordance with Regulation (EC) No 1272/2008.

Table 6. 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	

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 does not apply to:

— substances not included in the scope of Regulation (EC) No 1907/200618 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.

In order to determine if this exclusion applies, the applicant shall screen any ingoing substances or mixtures present in the product.

Assessment and verification: the applicant shall provide a signed declaration of compliance with sub-criterion 7.1, together with a list of all ~~relevant~~ chemicals used in their production process, ~~together with~~ their ~~relevant~~ safety data sheet or chemical supplier declaration and any relevant declarations ~~from component article suppliers~~ that demonstrate the compliance with the requirement~~. Any chemicals containing substances or mixtures with restricted classifications under Regulation (EC) No 1272/2008 shall be highlighted.~~

For restricted substances and unavoidable impurities with a restricted classification, ~~The approximate dosing rate of the chemical, together with~~ the concentration of the restricted substance or ~~mixture in that chemical~~ impurity ~~(as provided in the Safety Data Sheet or supplier declaration)~~ and an assumed retention factor of 100%, shall be used to estimate the quantity of the restricted substance or ~~mixture~~ impurity remaining in the final product. [to be added in the User Manual: impurities can be present in the final 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 ~~hazardous substance or mixture~~ impurity must be provided ~~in writing to the Competent Body~~.

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

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

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

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

Annex I: Third proposal for criterion 7.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

This sub-criterion applies to ingoing substances in the final product.

Unless derogated in Table 7, the final product, and any components ~~articles~~ 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 5, in accordance with Regulation (EC) No 1272/2008.

Table 5. 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

Moreover, the final product, and any components ~~articles~~ 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 6, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 7.

Table 6. 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 7. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Dipropylene glycol dibenzoate		H412: Harmful to aquatic life with long lasting effects	Only in hot melt adhesives that are used to indicate wetness
Odour control substances		H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects	Only in adult incontinence products if used according to criterion 7.3.b
Substances with a harmonised classification as H304	Absorbent hygiene products for adult use (no baby diapers)	H304: May be fatal if swallowed and enters airways	Substances with a viscosity over 20.5 St at 40°C.
Titanium dioxide (nano-form)	Pigment	H351: Suspected of causing cancer	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 ~~does~~ 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.

In order to determine if this exclusion applies, the applicant shall screen any ingoing substances or mixtures present in the product.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with sub-criterion 7.1, together with a list of all chemicals used in their production process, their ~~relevant~~ 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 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. [to be added in the User Manual: impurities

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can be present in the final 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 must 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 license, the calculation only needs to be presented for each impurity for the worst-case product or component article covered by the EU Ecolabel license (e.g. the most heavily printed component article when screening for inks with restricted classifications).

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

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

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 statements 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.

In the first Technical Report it was proposed to:

- have a revised structure of this sub-criterion, following the general recommendations of the 1st and 2nd EU Ecolabel Chemicals Task Forces[129], which translated Article 6(6) into specific CLP hazard categories and resulted in the Group 1, Group 2 and Group 3 hazards as listed in the criterion proposal.
- remove any reference to risk phrases (e.g. R45, R50, etc.) when mentioning the classification of substances and mixtures because these were linked to the Dangerous Substances Directive (67/548/EEC) which was repealed by the CLP Regulation of June 2015.
- closely align the wording of the revised criterion with that of the recently adopted EU Ecolabel criteria for printed paper, stationery paper, and paper carrier bag products (Commission Decision (EU) 2020/1803), AHP being examples of complex articles. This leads to the removal of some parts of the currently valid criterion that were more like a guidance rather than requirements. These parts are proposed to be explicitly described in the User Manual for Absorbent Hygiene Products.

[129] EC, 2018. EU Ecolabel: Chemicals Task Force 2, Final proposals and recommendations. Available at: https://ec.europa.eu/environment/ecolabel/documents/ecolabel_chemical_task_force_2_final_recommendations.pdf (accessed 10/09/2021).

- request industry to submit official derogation requests in case a potential need for derogation is identified.

In the second Technical Report it was proposed to:

- prohibit the use of substances with harmonised classifications as CMRs, acute toxicity, STOT and sensitizers in final products;
- restrict the use of substances with harmonised classifications as hazardous to the aquatic environment and to the ozone layer to concentration less than 0.010% w/w in final products;
- derogate the use of TiO_2 in AHP;
- align the wording of the criterion with the most recently voted product group;
- add to the user manual a clarification on the limit of detection.

Outcomes from and after the 2nd AHWG meeting

In total, 12 comments were received on this sub-criterion. The comments referred mainly to the proposed and potential derogations. All comments received can be found in the Table of Comment.

Further research and main changes in the second proposal

Derogation request - 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 to < 10 000 tonnes per annum[130]. 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. However, only its use in hot melt adhesives is proposed to be derogated in the revised EU Ecolabel for AHP. Hot-melt adhesives, also known as hot glue, is 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. In AHP, hot melt adhesives are used as wetness indicators. 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 a caregiver that a diaper needs changing. This feature guides parents for a correct use of the diaper and helps potentially to avoid frequent changes of diapers when the product is not wet yet. For this reason, it is proposed to derogate the presence of Dipropylene Glycol Dibenzoate in hot-melt adhesives used for wetness indicators, in line with the Blue Angel.

Dipropylene Glycol Dibenzoate has emerged in the market since 2011, when ECHA listed it as an alternative to phthalates[131].

Derogation request - Odour control substances

Odour control substances with a harmonised classification as H400 and H410 are proposed to be excluded in order to allow substances to be eligible for criterion 7.3.b. However, they have to comply with criterion 7.3.b in order to be used in adult incontinence products.

Derogation request – H304 substances

A derogation request for substances with a harmonised classification as H304 was received.

[130] ECHA, substance infocard. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.043.856. Accessed 26.09.2022

[131] https://echa.europa.eu/documents/10162/eec0b364-e29e-48f8-970c-a4cdb78465b8

In the supporting information received, it was specified that 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 case of ingestion, only if the substance enters into the lungs in its liquid form instead of arriving in the stomach, but also in case of vomiting after ingestion.

As a consequence, to get 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.

Nevertheless, as the risk of ingestion for babies cannot be excluded, it is proposed to set a derogation for H304 substances in absorbent hygiene products for adult use only, meaning that the derogation does not apply to baby diapers.

Stakeholders are invited to comment on this proposal.

Other changes to the criterion

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

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

Annex I: Previous proposal for criterion 7.2: ~~Restrictions on~~ Substances of Very High Concern (SVHCs)

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

Assessment and verification

The applicant shall provide a signed declaration that the final product ~~has been produced using supplied chemicals or materials that~~ does not contain any SVHCs ~~in concentrations greater than 0.10% (weight by weight)~~. The declaration shall be supported by safety data sheets of ~~process~~ all supplied chemicals ~~or appropriate declarations from chemical or material suppliers~~ and materials used to produce the final product.

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

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

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

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. [to be added in the User Manual: impurities can be present in the final 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 must be provided.

*[**

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

Annex I: Third proposal for criterion 7.2: ~~Restrictions on~~ Substances of Very High Concern (SVHCs)

This sub-criterion applies to ingoing substances in the final product.

The final product, and any components ~~articles~~ 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 of the European Parliament and of the Council* 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 does 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.

The list of substances identified as SVHCs and included in the candidate list in accordance with Article 59

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of Regulation (EC) No 1907/2006 can be found here:

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

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

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. [to be added in the User Manual: impurities can be present in the final 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 must be provided.

*[**

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

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'

The practical interpretation of this requirement for the majority of EU Ecolabel products that are complex articles has been to set a limit of 0,1 % (weight by weight) in the final product or in any component part therein.

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 the TR1.0, it was proposed to modify the text in order to align with recently voted EU Ecolabel product groups, without changing the content of the criterion.

Only wording modifications were made in the TR2.0.

Outcomes from and after the 2nd AHWG meeting

Only two comments were received to this sub-criterion, one in favour and the other one opposing to the proposed limit for SVHCs.

Further research and main changes in the second proposal

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

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5.8.3 Sub-criterion 7.3: Other specific restrictions - NEW

Rationale of the proposed criterion text

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 along 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 group of chemicals during the production process, such as biocidal active substances, APEOs, phthalates, PAHS, formaldehyde and organotins.

Criterion 7.3 is subdivided into eight sub-requirements:

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

5.8.3.1 Sub-criterion 7.3(a) Excluded substances

Annex I: Previous proposal for criterion 7.3.a: Specified excluded substances
The following substances shall not be ~~present~~ included (alone or in mixtures) in the final product, nor in any component articles therein ~~regardless of the concentration, neither as part of the product, as part of any mixture included in the product, nor as impurities~~: i. 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT); ii. Acrylamide shall not be intentionally added to superabsorbent polymers; iii. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]. Sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole are allowed; iv. Formaldehyde and formaldehyde releasers [2]; v. Methylisothiazolinone (MIT) vi. Nanosilver vii. Nitromusks and Polycyclic musks; viii. Organotin compounds used as a catalysts in the production of silicon; ix. Parabens; x. Phthalates [3]; xi. Substances identified to have endocrine disrupting properties; xii. Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects; xiii. Triclosan.

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Annex I: Third proposal for criterion 7.3.a: Specified excluded substances

This sub-criterion applies to ingoing substances in the final product.

The following substances shall not be ~~included~~ added (alone or in mixtures) to the final product, nor in any components ~~articles~~ therein:

i. 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);

ii. Acrylamide ~~shall not be intentionally added to~~ in superabsorbent polymers;

iii. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]. Sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole are allowed;

iv. Antibacterial agents (e.g. Nanosilver and triclosan) *[to be added to the User Manual: Antibacterial agent are chemicals/products that inhibit or stop growth of microorganisms such as bacteria, fungi or protozoa (single-celled organisms)]*;

v. Formaldehyde and formaldehyde releasers [2];

vi. Methylisothiazolinone (MIT)

~~vii. Nanosilver~~

viii. Nitromusks and Polycyclic musks;

ix. Organotin compounds used as a catalysts in the production of silicon;

x. Parabens;

xi. Phthalates [3];

xii. Substances identified to have endocrine disrupting properties;

xiii. 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;

xiv. ~~Triclosan~~.

Assessment and verification:

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

[Notes:

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

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

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

Rationale of the criterion text

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 in the revised criteria set in the TR1.0.

In particular, in the first Technical Report it was proposed to add the following exclusions:

- APEOs and other alkyl phenol derivatives, with the exception of sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole;
- phthalates;

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- organotin compounds used as catalysts in the production of silicone polymers;
- the preservatives MIT and CMIT;
- identified endocrine disrupting compounds (EDs);
- 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

In the TR2.0, it was proposed to amend the initial sentence of criterion 7.3.a

Outcomes from and after the 2nd AHWG meeting

In total, 7 comments were received on this sub-criterion, mainly addressing the exclusion of phthalates. All comments received can be found in the Table of Comment.

Further research and main changes in the third proposal

Antibacterial agents

One stakeholder suggested to exclude all antibacterial agents in the EU Ecolabel for AHP, and not only nanosilver and triclosan.

Antibacterial agents fight against pathogenic bacteria by inhibiting or reducing the metabolic activity of bacteria, so that their pathogenic effect in the biological environments is minimized[132]. If this agent completely kills the bacteria, it is known as bactericidal. Antibacterial compounds are normally used as therapeutic compounds to stop bacterial diseases[133].

However, if used without the intention of stopping bacterial diseases, extensive use of antibacterial agents may result in eliminating desirable bacteria. This is of concern since AHP are in strict contact with the body, also infant's body, and, if used unnecessarily, antibacterial agents may unintendedly cause resistance in bacteria, so that they will no longer have the desired effect, when needed[134].

It is thus proposed to exclude antibacterial agents from AHP. This is in line with the Nordic Swan. It is also proposed to align the definition of anti-bacterial agents with the one in Nordic Swan:

"An antibacterial agent is a chemical/product that inhibits or stops growth of microorganisms such as bacteria, fungi or protozoa (single-celled organisms)"

This definition will be added in the User Manual.

Other changes to the sub-criterion

Other changes to this sub-criterion include the removal of the exemption for DIBP in adhesives, given its CLP classification as Repr. 1B (H360Df)[135].

Finally, to improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

5.8.3.2 Sub-criterion 7.3(b): Fragrances

Annex I:Previous proposal for criterion 7.3.b: Fragrances

[132] E.R. Kenawy, Biologically active polymers. IV. Synthesis and antimicrobial activity of polymers containing 8-hydroxyquinoline moiety, J. Appl. Polym. Sci. 82 (6) (2001) 1364–1374. https://doi.org/10.1002/app.1973

[133] Santhosh Penta, 2016, Antibacterial agents, In: Advances in Structure and Activity Relationship of Coumarin Derivatives

[134] Reygaert WC., 2018, An overview of the antimicrobial resistance mechanisms of bacteria. AIMS Microbiol. 26:4(3) doi: 10.3934/microbiol.2018.3.482.

[135] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/14308

(i) Fragrances shall not be added to the final product, nor to any component thereof, nor to the packaging. ~~Products marketed as designed and intended for children as well as tampons and nursing pads shall be fragrance-free~~.

(ii) Odour control substances may be permitted only in adult incontinence products. In this case, the odour control substances:

- shall be encapsulated in, or bound/attached to the absorbent core of the adult incontinence product;
- shall not exceed 1.5% w/w of the mass of the absorbent core;
- ~~o~~ shall moreover be indicated on the product packaging.

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

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

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

Annex I: Third proposal for criterion 7.3.b: Fragrances

This sub-criterion applies to ingoing substances in the final product.

(i) Fragrances shall not be added to the final product, nor to any component thereof, nor to the packaging.

(ii) Odour control substances may be permitted only in adult incontinence products. In this case, the odour control substances:

- shall be encapsulated in, or bound/attached to the absorbent core of the adult incontinence product;
- shall not exceed 1.5% w/w of the mass of the absorbent core;
- shall moreover be indicated on the product packaging.

[to be added to the User Manual: "odour-control substances are any substances or mixtures, other than fragrances, that are added to the final product with the specific objective of masking and controlling odours"]

Assessment and verification:

The applicant shall provide a signed declaration of compliance with the sub-criterion. If odour substances are used, the applicant shall provide the list of odour control substances used, together with their H classification if relevant, and visual evidence that information has been added to the packaging.

In the first Technical Report, only minor wording changes were proposed to this sub-criterion.

In the second Technical Report, it was proposed to prohibit the use of fragrances in all products and to add a requirement on the use of odour control substances in adult incontinence products

Outcomes from and after the 2nd AHWG meeting

In total, 13 comments were received on this sub-criterion. The majority of the comments welcomed the exclusion of fragrances, while some comments were received addressing the issue of odour control substances with a harmonised classification. All comments received can be found in the Table of Comment.

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Further research and main changes in the third proposal

It is proposed to add a definition of odour control substance in the user manual.

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

5.8.3.3 Sub-criterion 7.3(c): Lotions

Annex I: Previous proposal for criterion 7.3.b: Lotions
Lotions shall not be used in the product, nor in any component thereof ~~feminine care pads, tampons and nursing pads. The use of lotions in other products shall be indicated on the packaging~~.
Annex I: Third proposal for criterion 7.3.b: Lotions
This sub-criterion applies to ingoing substances in the final product. 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.*

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

In the first Technical Report (TR1.0), no changes were proposed to this sub-criterion.

In the second Technical Report, it was proposed to exclude the use of lotions in all products.

Outcomes from and after the 2nd AHWG meeting

In total, 7 comments were received on this sub-criterion. The majority of comments supported the full exclusion of lotions in all AHP, while one stakeholder reported literature showing that lotions & ointments are known to fight diaper dermatitis. All comments received can be found in the Table of Comment.

Further research and main changes in the third proposal

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

5.8.3.4 Sub-criterion 7.3(d): Inks and dyes

Annex I: Previous proposal for criterion 7.3.d: Inks and dyes
~~Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the pulp used in products.~~ This requirement does not apply to the primary packaging and information sheets. (i) The final product and any component part thereof shall not be dyed. (ii) The following components are exempted and may be dyed ~~Derogations to this requirement shall apply~~

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~~to~~:

— tampon strings, packaging materials and ~~tapes~~ closing system;

— ~~titanium dioxide in polymers and viscose,~~

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

In these cases, the dying colorants and inks used shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

In addition, 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 European Council's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food(*).

~~Inks and dyes~~ The dying colorants and inks used shall also comply with sub-criteria 7.1 and 7.2~~ on excluded or limited substances or mixtures~~.

Annex I: Third proposal for criterion 7.3.d: Inks and dyes

This sub-criterion applies to ingoing substances in the final product. This requirement does not apply to the primary packaging and information sheets.

(i) The final product and any components ~~part thereof~~ therein shall not be dyed.

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

— tampon strings, packaging materials and closing system;

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

In these cases, the dying colorants and inks used shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

In addition, 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 European Council's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food(*).

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 are used, their presence shall be justified by indicating the specific function provided, and documentation shall be provided to ensure that the colouring agent or ink is approved for use in food.

(*) References:

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

In the first Technical Report (TR1.0), no major changes have been included in the sub-criterion text.

In the second Technical Report, a requirement was added 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 presence of heavy metals, PAA and PCB as impurities in the colorants used.

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Outcomes from and after the 2nd AHWG meeting

In total, 2 comments were received on this sub-criterion, which can be found in the Table of Comment.

Further research and main changes in the second proposal

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the final product.

5.8.3.5 Sub-criterion 7.3(e): Further restrictions applying to plastic materials

Annex I: Previous proposal for criterion 7.3. e: Further restrictions applying to 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). e): Further restrictions applying to plastic materials
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.*

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

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No changes were made in the second Technical Report

Outcomes from and after the 2nd AHWG meeting

Only one comment was received on this sub-criterion, pointing to an inconsistency between sub-criterion 7.3.e.ii and sub-criterion 7.1. This aspect was clarified by adding a sentence that this criterion applies to substances added to the plastic materials.

5.8.3.6 Sub-criterion 7.3(f) Further restrictions applying to adhesives

Annex I: Second proposal for criterion 7.3.f: Further restrictions applying to adhesives
The following substances shall not be added to adhesives used in Absorbent Hygiene Products according to the thresholds listed below: — Colophony ~~resins~~: Adhesives shall not contain more than 0.01% (weight by weight) colophony ~~resin~~. Modified colophony derivatives that are not classified as sensitizers, e.g. rosin esters, are allowed; — Formaldehyde: the content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. The threshold for formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Hotmelt adhesives shall be exempted from this requirement.
Annex I: Third proposal for criterion 7.3.f: Further restrictions applying to adhesives
This sub-criterion applies to ingoing substances in adhesives. The following substances ~~shall not be~~ added to adhesives ~~used in Absorbent Hygiene Products according to~~ shall not exceed the thresholds listed below: — Colophony: Adhesives shall not contain more than 0.01% (weight by weight) colophony ~~resin~~. Modified colophony derivatives that are not classified as sensitizers, e.g. rosin esters, are allowed; — Formaldehyde: the content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. The threshold for formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Hotmelt adhesives shall be exempted from this requirement. 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.* *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.

In the first Technical Report it was proposed to clarify that a maximum concentration of 0.1% shall be applied for colophony. Modified colophony derivatives that are not classified as sensitizers, e.g. rosin esters, are allowed.

No changes were made in the second Technical Report.

Outcomes from and after the 2nd AHWG meeting

Only one comment were received on this sub-criterion, which can be found in the Table of Comment.

Further research and main changes in the third proposal

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the chemicals added to adhesives.

Few other wording modifications were made.

5.8.3.7 Sub-criterion 7.3(g) – Superabsorbent polymers (SAPs)

Annex I: Second proposal for criterion 7.3. g – Superabsorbent polymers (SAPs)
Superabsorbent polymers used in the product shall: (i) 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. (ii) 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.a ~~on excluded or limited substances or mixtures~~. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.
Annex I: Third proposal for criterion 7.3.g – Superabsorbent polymers (SAPs)
This sub-criterion applies to ingoing substances in superabsorbent polymers. Superabsorbent polymers used in the product shall: (i) 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. (ii) 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.a. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190. Acrylamide shall not be included in superabsorbent polymers. 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.* *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 SDSs or test results specifying the residual monomers contained in the SAP and the quantities thereof. If tests are used, recommended test methods are ISO 17190 and WSP 210. In these cases, 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 criterion corresponds to current criterion 5.3 in the EU Ecolabel criteria in force.

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Outcomes from and after the 2nd AHWG meeting

No comments were received after the 2nd AHWG meeting.

Further research and main changes in the third proposal

It is proposed to specify that acrylamide is not allowed, as previously mentioned in criterion 7.3.a.

Moreover, to improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the chemicals added to superabsorbent polymers.

5.8.3.8 Sub-criterion 7.3(h) – Silicone

Annex I: Second proposal for criterion 7.3.h: Silicone
(i) Solvent-based silicone coatings shall not be used. (ii) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture [6] in concentrations above 800 ppm (0,08 % w/w). The 800 ppm limit is to be applied to each substance separately.
Annex I: Third proposal for criterion 7.3.h: Silicone
This sub-criterion applies to ingoing substances in the release liner. (i) Solvent-based silicone coatings shall not be used. (ii) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture [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 signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant.* *[Notes:* *[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 Absorbent Hygiene Products (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 release effect as a coating on materials or as an additive in materials. When they are used to produce release liners, silicone coating adheres to the material to be treated in the form of a thin layer, especially to low-porosity and smooth paper substrates. There are release liners which use different types of substrates (papers, films, and combinations), many different types of silicone coatings, and at a wide range of weights/amounts.

During the preliminary questionnaire, one stakeholder expressed that solvent-based silicones shall not be used. In fact, both Nordic Swan and Blue Angel ecolabels set a requirement prohibiting their use. The use of solvents in silicone coatings may lead to the release of toxins or volatile organic compounds (VOCs) into the air. Depending on the type of solvent in use, long-term hazards range from cancer to genetic mutations to

developmental and reproductive harm. For this reason, this method is being phased out, and both Nordic Swan and Blue Angel ecolabels set a requirement prohibiting the use of solvent-based silicone coatings. Therefore, in the first proposal for the revised criterion it was proposed to ban the use of solvent-based silicone coatings.

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

Outcome from the AHWG2 and the stakeholder consultation

Only one comment was received on this sub-criterion.

Further research and main changes in the third proposal

To improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion applies to the chemicals added to superabsorbent polymers.

5.8.3.9 Sub-criterion 7.3(i) - Impurities of concern

Annex I: Previous proposal for criterion 7.3. i - Impurities of concern

The following chemicals shall not be present in the final product in a concentration higher than what indicated in Table 7.

Table 7. 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; Hexachlorobenzene	
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
Pesticides	
Glyphosate	< 0.5 mg/kg
AMPA	< 0.5 mg/kg
Quintozene	< 0.5 mg/kg
Organotins	
Tributyltin	< 2 ppb
Other organotins: Monobutyltin; Dibutyltin; Triphenyltin; Dioctyltin; Monooctylti	Each organotin < 10ppb
Heavy metals	

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Antimony	< 30 mg/kg
Cadmium	< 0.1 mg/kg
Chromium	< 1 mg/kg
Lead	< 0.2 mg/kg
Mercury	< 0.02 mg/kg

Annex I: Third proposal for criterion 7.3.i - Impurities 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 8.

Table 8. 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; Hexachlorobenzene	
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.

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In addition, the applicant shall provide the results of the analyses performed on the final product. Alternatively, the analyses can be performed separately on each of the material composing the final 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. The frequency measurement shall be at least once a year.

This sub-criterion is proposed to be newly added to the EU Ecolabel criteria 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 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.

Outcome from the 2nd AHWG and the stakeholder consultation

Three comments were received on this sub-criterion, which are dealt with in the Table of Comment.

Further research and main changes in the third proposal

Two changes are proposed at this stage:

- to add to the list of impurities to be tested 22 phthalates and one pesticide, in line with the updated EDANA's CODEX list of substances;

- to set the measurement frequency at once per year. This aspect has been specified in the assessment and verification, as it was missing in the TR2.0;

- to improve the clarity and interpretation of the criterion, a clarification is made at the beginning of the sub-criterion to indicate that this criterion refers to impurities in the final product.

Summary of changes in TR3.0

In summary, in this TR3.0 it is proposed to:

- Exclude antibacterial agents from AHP (sub-criterion 7.3.a);
- Remove of the exemption for DIBP in adhesives (now excluded - sub-criterion 7.3.a);
- Replace part ii of sub-criterion 7.3.e with a sentence pointing out that plastic materials shall also fulfil sub-criteria 7.1 and 7.2;
- Add to the list of impurities to be tested 22 phthalates and one pesticide, in line with the updated EDANA's CODEX list of substances (sub-criterion 7.3.i);
- Set the measurement frequency for the impurities at once per year (sub-criterion 7.3.i);
- Split the general assessment and verification into individual sections.

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5.9 CRITERION 8 for Absorbent Hygiene Products: Packaging

Annex I: Second proposal for criterion 8: Packaging
~~The primary packaging must contain information on the packaging and product composition specifying the weight of the packaging and product and of each component as requested in criterion 1.~~ ~~The primary packaging of feminine care products such as sanitary towels or pads and tampons must comply with the marking requirements according to the Article 7 of Directive (EU) 2019/904 of the EU Parliament and the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment136 whose harmonised marking specifications must follow the rules laid down by Annex I of the Commission Implementing Regulation, of 17 December 2020 (Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment)137.~~ ~~The additional packaging must include the marking specifications also in the case of sanitary towels or pads.~~ ~~Primary packaging, secondary, and additional packaging shall include x % of recycled content in their composition, and it must be recyclable.~~ This criterion applies to primary and secondary packaging, as defined in European Parliament and Council Directive 94/62/EC [(1)]. *(a) Cardboard and paper used for packaging* Cardboard and paper used for the primary and secondary packaging of absorbent hygiene products shall be made of 100 % recycled material in the case that additional component (being individual wrapping of the product) is present in the product. If there is not additional component (individual wrapping of the product), only the secondary packaging made of cardboard/paper shall be made of 100% recycled material. Cardboard and paper used for the primary and secondary packaging shall be designed for recycling in at least 95%. *(b) Plastic used for packaging* Plastic used for the primary and secondary packaging of absorbent hygiene products shall be made of at least 80 % recycled material in the case that additional component (being individual wrapping of the product) is present in the product. If there is not additional component (individual wrapping of the product), only the secondary packaging made of plastic shall be made of 80% recycled material. Plastic used for the primary and secondary packaging shall be designed for recycling in at least 95%. Only unmixed plastic without any coating is permitted when using plastic packaging. If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 shall apply. *(c) Additional requirement* Utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not allowed. Assessment and verification: ~~The applicant shall submit a signed declaration of compliance specifying the product composition,~~

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

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

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~~supported by manufacturer documentation, including the composition of the packaging (primary, secondary and additional).~~

~~The applicant shall provide a sample of the primary packaging by submitting either a sample itself or a primary packaging photo (where information requested appears clearly).~~

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content of the primary and secondary packaging; (2) ~~and~~ a declaration of compliance specifying the recyclability capacity ~~in~~ of the primary and secondary packaging ~~where the test methods used must be notified. Invoices demonstrating the purchase of the recycled material must be provided~~ and (3) a high resolution image of the primary packaging (where information regarding recyclable content and recyclability appear clearly).

Recycled content must be verified by complying with the EN 45557 or ISO 14021 while recyclability must be verified by complying with the EN 13430 or ISO 18604.

Equivalent 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. Invoices demonstrating the purchase of the recycled material must be provided.

(1) European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

Annex I: Third proposal for criterion 8: Packaging

This criterion ~~applies to~~ sets requirements for primary and secondary packaging, as defined in European Parliament and Council Directive 94/62/EC (1).

Secondary packaging should be avoided or made of cardboard and paper.

~~*(a) Cardboard and paper used for packaging*~~

~~Cardboard and paper used for the primary and secondary packaging of absorbent hygiene products shall be made of 100 % recycled material in the case that additional component (being individual wrapping of the product) is present in the product. If there is not additional component (individual wrapping of the product), only the secondary packaging made of cardboard/paper shall be made of 100% recycled material.~~

~~Cardboard and paper used for the primary and secondary packaging shall be designed for recycling in at least 95%.~~

~~*(b) Plastic used for packaging*~~

~~Plastic used for the primary and secondary packaging of absorbent hygiene products shall be made of at least 80 % recycled material in the case that additional component (being individual wrapping of the product) is present in the product. If there is not additional component (individual wrapping of the product), only the secondary packaging made of plastic shall be made of 80% recycled material.~~

~~Plastic used for the primary and secondary packaging shall be designed for recycling in at least 95%.~~

~~Only unmixed plastic without any coating is permitted when using plastic packaging.~~

~~If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 shall apply.~~

~~*(c) Additional requirement*~~

~~Utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not allowed.~~

(a) Recycled content

a. 1. Recycled content in cardboard and paper packaging

Primary packaging made of cardboard and paper shall contain a minimum 40% recycled material when individual wrapping of the product is present. If there is not individual wrapping of the product, recycled material shall not be used in primary packaging.

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Secondary packaging made of cardboard and paper shall contain a minimum 80% recycled material.

All (100%) cardboard and paper used for the primary and secondary packaging shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

a. 2. Recycled content in plastic packaging

Primary packaging made of plastic shall contain a minimum 10% recycled material (until 1st January 2028) when individual wrapping of the product is present. After 1st January 2028, primary packaging made of plastic shall contain a minimum 25% recycled material when individual wrapping of the product is present. If there is not individual wrapping of the product, recycled material shall not be used in primary packaging.

Secondary packaging made of plastic shall contain a minimum 10% recycled material (until 1st January 2028). After 1st January 2028, secondary packaging made of plastic shall contain a minimum 25% recycled material.

If primary or secondary packaging are sourced from bio-based plastic, sub-criterion 4.2 shall apply. If primary or secondary packaging are compostable, criterion 5 shall apply.

(b) Recyclability capacity

The content of the primary and secondary packaging (either cardboard and paper or plastic) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.

(c) Additional requirement

Utilisation of composite packaging (primary or secondary), mixed plastics or the coating of the cardboard/paper with plastics or metals are not allowed.

Assessment and verification:

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content of the primary and secondary packaging; (2) a declaration of compliance specifying the recyclability capacity ~~in~~ of the primary and secondary packaging and (3) a high resolution image of the primary packaging (where information regarding recyclable content and recyclability capacity appear clearly).

The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for all cardboard and paper (100%) used for the primary and secondary packaging. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.

Recycled content must be verified by complying with the EN 45557 or ISO 14021 while recyclability must 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 ISO 22095.

Equivalent 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. Invoices demonstrating the purchase of the recycled material must be provided.

In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols such as the ones developed by INGEDE for paper and cardboard or RecyClass for plastics. Equivalent testing methods may be accepted if considered equivalent by a third-party.

(1) European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31994L0062

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Rationale for the proposed criterion text

This criterion aims at the introduction of certain percentages of recycled content and recyclable components in the packaging of AHP (primary and secondary), in order to support the EU's goal of a circular economy. This criterion was proposed in the first Technical Report (September 2021) and revised in TR2.0 (June 2022) and the current TR3.0.

Usually the packaging of AHP can be primary (sales packaging) and secondary packaging as defined in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste[138]. An additional component where the product is individually wrapped is considered sometimes such as in the case of feminine care pads or tampons. The additional component is also the release liner or paper (in baby diapers and sanitary pads) or the applicator for tampons. The additional component can also be the cloth bag were menstrual cups are usually sold with. Note that in the first Technical Report, the now named additional component was called additional packaging. The current criterion on 'Packaging' does not set requirements on the additional component.

Comments during the 1st AHWG meeting acknowledged the inclusion of a packaging criterion, however split views were shared on the inclusion of certain percentages of recycled, recyclable or bio-based content.

In TR2.0 proposal, the packaging criterion text was divided for cardboard/paper and plastic materials in a similar approach that the packaging criterion in the EUEL for footwear[139]. In the same way, when possible for cardboard/paper 100% recycled material was requested for primary and secondary packaging while in the case of plastic packaging, 80% from recyclable sources was set.

Other changes for this criterion were in relation to:

- Both primary and secondary packaging shall be designed for recycling (95%).
- Only unmixed plastic without any coating shall be permitted when using plastic packaging.
- Ban the utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals.
- Application of sub-criterion 4.2 if primary or secondary packaging was sourced from bio-based plastics.
- Recycled content must be verified by complying with the EN 45557 or the ISO 14021 while recyclability must be verified by complying with the EN 13430 or the ISO 18604 (equivalent methods may be accepted).

Outcomes from and after 2nd AHWG meeting

The section below address the main comments received. All comment can be found in the annexed Table of Comment.

During the 2nd AHWG meeting, most of the stakeholders intervening (4) affirmed that the proposed targets were too ambitious and likely not achievable. Main constraints supporting this were availability of raw material, compromise of product technical properties (thus potentially affecting consumer's acceptance) and lack of clarity on meaning of recycled content/recyclability. The INGEDE method was suggested for recyclability. Finally, a stakeholder highlighted that the function of the applicator is aiding in placing the tampon, thus not being considered as packaging.

In total 19 written comments related to AHP criterion 8 were received, generally aligned with the discussion held on the 2nd AHGW meeting. Half of them (9) were related to the recycled content targets for materials used for packaging (100% for cardboard and paper; 80% for plastic). There was a consensus amongst

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

[139] Commission Decision (EU) 2016/1349 of 5 August 2016 establishing the ecological criteria for the award of the EU Ecolabel for footwear https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D1349&from=EN

stakeholders that proposed that ambition levels were not feasible given current recycled materials supply limitations and a potential compromise on packaging quality.

Regarding cardboard and paper, three stakeholders proposed lowering the percentage of recycled content and adding sustainable fibre sourcing. Additionally, one of them suggested a step-wise approach.

Regarding plastics, one stakeholder suggested to keep recycled content target between 30-40% while another propose to increase the share progressively with time (30% at license; >50% after 3 years and >80% after 6 years). Alternatively, one stakeholder proposed using 100% green PE with no recycled content as primary packaging. Similarly, another stakeholder mentioned the case of a manufacturer selling AHP in bulk in sealed PE pouches and suggested considering this option, integrating it within the proposed criteria (sealed pouch + raw materials specifications). Finally, one stakeholder recommended setting recycled content targets above mandatory targets of the Packaging and Packaging Waste Directive. Irrespective of the packaging material, a total of 4 comments required clarifications on the definition 'design for recycling' (making a link with recycling infrastructures, lack of EU harmonization) and on the verification process (such as the need for additional verification processes for instance Recyclass).

Other comments referred to definitions (clarification on the differences and use of primary/secondary packaging), linkage with sub-criterion 4.2, potential incorporation of hazardous chemicals via recycled materials (require testing) and consideration of other type I ecolabels (such as Blue Angel).

Further research and main changes in the third proposal

General comments

The packaging criterion proposes to address the recycled content and recyclability capacity of primary and secondary packaging.

It is worth noting that the performed LCA screening study based on the PEF methodology for AHP showed that packaging made from LDPE granulates used for sanitary towels or menstrual pads were identified as hotspots in some impact categories (Resource Use – fossils (17%), Climate Change (11% granulates, 6% extrusion) and Ecotoxicity –freshwater (14%)). In fact, in case of sanitary towels, LDPE packaging showed the higher contribution in the most relevant processes compared to baby diapers, because of the higher share of the packaging materials compared to the product mass in sanitary towels.

In this line, the impact of plastic packaging must be addressed within the EU Ecolabel criteria for AHP. 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.

In this regard, the use of recycled cardboard/paper or plastic for the primary and secondary packaging is proposed in this TR3.0. In fact, using recycled paperboard, cardboard or plastic in the packaging of AHP allows for extracting value from waste and avoids a significant amount of raw materials and energy use that would otherwise be used in the production of virgin fossil fuel based raw material.

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[140]. However, the EU Ecolabel aims to promote the use of recycled and recyclable materials in the packaging (primary and secondary) which are all removed from the products before use, and thus does not come into contact with the user. It is explained in the criterion, that recycled content is requested in the primary packaging only if the product is not in contact with the mentioned primary packaging, i.e. when the product is individually wrapped.

[140] 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).

Definitions and comparison with the other ecolabels

Definitions for primary, secondary and transport packaging are aligned with Article 3 of the consolidated version of the Directive 94/62/EC on packaging and packaging waste (European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste). Note that this directive is currently being revised. Additional component, recycled content and recyclability capacity were also included in the definitions in Section 3 in the TR1.0. In TR2.0, the definition for additional component (previously additional packaging) was slightly modified and clarification for recyclability capacity was added (Section 3 of TR2.0). In this TR3.0, 'item' was explained in the 'recycled content' definition ('Recycled content' means the amount of an item (by area, length, volume or mass) sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or packaging in this case).

As a matter of comparison with other Ecolabels in the market, the Nordic Swan and the Blue Angel both consider the primary or sales packaging. However, secondary packaging is not mentioned in the Nordic Swan while the Blue Angel called it repackaging. Transport packaging is mentioned in both the Nordic Swan and the Blue Angel. The Blue Angel touches upon the additional component as an individual package item part of the whole packaging criterion which would be revised in the future update of the ecolabel. In relation to the tertiary or transport packaging, ecolabels cannot influence it. Nevertheless, in the Blue Angel, it is mentioned that the applicant shall provide information on the design of the business-to-business transport packaging (with no further implications).

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

The Blue Angel considers recyclability aspects (content available for recycling > 95%) in the primary or sales packaging and in the repackaging (or secondary packaging) while only allows recycled content in the secondary packaging. Although Blue Angel considers that secondary packaging should be avoided or be made of paper and cardboard, it requires that recycled fibres must account for at least 80% by mass with the approved proportion of virgin fibres not sourced from forests that are particularly worthy of protection. If plastic secondary packaging is used, Blue Angel requests to contain > 80% recycled plastic (Blue Angel, DE-UZ 208, 2021).

The Nordic Swan does not allow recycled material in the sanitary product (e.g. in cotton, paper and fluff) with the exception of recycled plastic. However recycled material is allowed in additional components, e.g. in tape or release paper that shall be removed before use and in primary packaging. In the primary packaging, ≥20% recycled or renewable materials are requested (actually this is one of three requirements to choose from). Recyclability percentages are not mentioned (Nordic Swan, Version 6.8, 2021).

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 not 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 the Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food[141] 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 break down products of intentionally added chemicals, need to be considered and assessed due to their toxicological risk. These migration tests covers 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.

[141] 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

Limitations of recycled materials

Some of the limitations when using recycled plastic materials are listed below. In fact, many of these also apply to cardboard and papers and in general to the products and packaging. The study[142] focusing 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, which may impact:

- the product quality and performance: sometimes the standard reached with virgin plastic cannot be obtained in relation to colours and stability of the product or packaging for the desired aim. The 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.
- the availability of materials: manufacturers have a limitation as they may have less confidence in the recycling market and long-term supply.
- the 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 exposition of chemicals depending on the behaviour of additives and non-polymer impurities in the recycling process.
- the price of recycled plastics 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"*[143].

Recycled content targets for paper and cardboard

Several comments received after the 2nd AHWG meeting highlighted the impossibility to supply 100% of recycled cardboard and paper materials for cardboard and paper packaging for AHP. However, the possible percentage that could be requested according to the supply and functionality of the packaging was not provided.

The European Paper Recycling Council (EPRC)[144], recently published the 'Monitoring Report 2021'[145] 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[146].

Note 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 Paper for Recycling (PfR) term 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 the EN 643[147].

The mentioned EPRC report 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 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 in new recycling capacities in Europe. In the

[142] 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

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

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

[145] 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

[146] 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/

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

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, being the world average of 59.7% (CEPI and EPRC, 2022). The national recycling rates in EU-27 for 2021 show that thirteen European countries exceeded the 70% recycling rate (15 in 2020) and for ten European countries were below 60% (8 in 2020) (CEPI and EPRC, 2022).

Views[148] from CEPI on the on-going revision of the 'Packaging and Packaging Waste Directive (PPWD)' explain 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'. Besides, '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'.

The actual figure (or percentage) on availability of recycled paper and cardboard for its use in packaging are not found, however, some sources cite 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[149]. Some types of cardboard packaging can contain up to 100% of recycled paper (Preston Board & Packaging, 2021) whilst the majority average between 70% and 90% recycled content[150]. However, these recycled high contents mostly apply to corrugated packaging boxes used in transport or transit packaging applications, i.e. packaging examples with high weight.

Exchanges with industry stakeholders explained that the use of higher percentages of recycled cardboard and 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 nappies made of plastic materials while panty liners and tampons come in light paper/cardboard boxes where a certain percentages of recycled (these products are usually individually wrapped) could be applied.

Looking at the evidence, in this TR3.0, the proposal is that paper and cardboard packaging used for AHP must be 40% sourced from recycled fibres in the case of primary packaging (applicable if there is individual wrapping of the products). While secondary packaging must be composed from a minimum 80% recycled fibres. In case the AHP are sold in bulk packaging (primary or sales packaging) where products (i.e. nappies, menstrual pads, etc) are not individually wrapped, EU Ecolabel is not imposing any requirement on recycled content in the primary packaging (either if packaging is made of paper and cardboard or plastic). However, often AHP are individually wrapped (in the so-called additional component), cases, when primary packaging shall contain recycled fibres.

It is also requested that all (100%) cardboard and paper used for the primary and secondary packaging shall be covered by valid chain of custody certificates.

Recycled content targets for plastics and polymers

Most of comments received after the 2nd AHWG meeting highlighted the impossibility to supply 80% of recycled plastic and polymer materials in the plastic packaging for AHP. The content available to be requested without compromising the supply and functionality of the packaging was not provided.

Further investigation and bilateral meetings with key stakeholders shed some light on how to approach the recycled plastic content in plastic packaging. The cited study[151] 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% of recycled plastic in AHP bag content was not suitable.

According to the SUP Directive, by 2025, PET bottles will be required to contain at least 25% of recycled plastic. However, as there are still not minimum targets in place and there has not been a requirement to

[148] 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

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

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

[151] 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

Member States to calculate or monitor the levels of recycled content in materials[152], there is still a high uncertainty in assessing if this is possible to be extended 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[153]. In Spain (since 1st January 2020) plastic bags exceeding 50 microns in thickness must contain at least 50% recycled content[154]. 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 targets in plastic packaging is favourable to the current recycled content for plastics packaging under the review and included in the Directive 94/62/EC on Packaging and Packaging Waste (PPWD)[155]. Plastics Europe explains 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 is 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'.

Besides, the availability of recyclates for plastic packaging shall also take into account closed-loop systems and not only mechanical but chemical recycling[156]. 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.

Nevertheless recent findings explain that chemical recycling may set burdens to the actual sustainability of new recyclates[157]. 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 prioritized 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)[158]. It is to note that this is an average figure, while carrier plastic bags could contain up to 90% recyclates, other applications would contain a certain lower percentage of recyclates. Whereas this study touching upon 'recycled content availability for different applications' is under preparation, expert consultation suggests to decrease the requested percentage of recycled plastic contained in AHP plastic packaging. However, in the near future a higher availability of

[152] Eunomia confidential report.
[153] Member State Questionnaire response from Belgium, September 2020.
[154] Member State Questionnaire response from Spain, September 2020.
[155] 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/
[156] Plastics Europe, 2022. Chemical recycling. Available at: https://plasticseurope.org/sustainability/circularity/recycling/recycling-technologies/chemical-recycling/
[157] 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
[158] Study under preparation with expected publication in early 2023.

recycled plastic material is envisaged. In addition, internal discussions suggest a possibility to increase the recycled plastic content of certain packages.

Looking at the evidence, in this TR3.0, it is proposed that plastic packaging (both primary and secondary) used for AHP must contain a 10% sourced from recycled plastic (applicable if there is individual wrapping of the products) up to 1st January 2028.

After 1st January 2028, primary and secondary packaging made of plastic shall contain a minimum 25% recycled material when individual wrapping of the products is present.

In case the AHP are sold in bulk packaging, i.e. without individual wrapping, EU Ecolabel is not imposing any requirement on recycled content in the primary plastic packaging. It is also consider to look at sub-criterion 4.2 if primary or secondary packaging are sourced from bio-based plastic and to criterion 5 if is compostable.

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[159], 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 opposite to 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[160].

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.

In relation to recyclability of paper and cardboard, EPRC (European Paper Recycling Council) explains that the International Association of the Deinking Industry (INGEDE)[161], launched a project on the quality of Paper for Recycling (PfR) coming from sorting plants. The scope of the work also includes the assessment of technical measurements and the exchange of quality data. In addition, CEPI and INGEDE have contributed to a CEN technical specification on the application of the term 'prohibited materials' in the EN 643 – European list of grades of paper and board for recycling. Methods 11 and 12 from INGEDE are examples that can be used for the assessment of the recyclability of paper and cardboard products[162].

The general recommendations on how to design better recyclable fibre-based packaging elaborated by CEPI in the context of the '4evergreen' packaging alliance[163] set components to avoid in fibre-based packaging to be recycled and gives general design guidelines[164]. The test method emulates the most common phases of the industrial processes, to measure the main parameters of recyclability of paper and board-based materials and other cellulose fibre-based products based on current knowledge and technology. The

[159] European Bioplastics, 2020. Mechanical Recycling. Available at: https://docs.european-bioplastics.org/publications/bp/EUBP_BP_Mechanical_recycling.pdf
[160] Recycled Content in Packaging: What you Need to Know, 2022. Available at : https://www.e2epkg.com/recycled-content/
[161] International Association of the Deinking Industry (INGEDE) https://www.ingede.com/
[162] INGEDE methods, 2018. Available at: http://pub.ingede.com/en/methods/
[163] Industry alliance, 4evergreen, 2021. More information: https://4evergreenforum.eu/
[164] 4evergreen, 2021. 'CIRCULARITY BY DESIGN GUIDELINE FOR FIBRE-BASED PACKAGING'. Available at: https://4evergreenforum.eu/wp-content/uploads/4evergreen-Circularity-by-Design-2.pdf

revised Cepi recyclability laboratory test method is used by 4evergreen as a basis to develop a standardised, publicly available, Recyclability Evaluation Protocol for fibre-based packaging.

When looking at the recyclability of plastic packaging, standards such as RecyClass appear as efficient methods to verified recyclability in a detailed procedure. Note that the standards (EN 13430 or ISO 18604) only provided information on the possibility to recycle without information on the recycling stream more suitable to the plastic packaging[165].

When the RecyClass protocol is applied, the following information must be reported:

- Reference to the Sorting Protocol.
- Description of the sorting facility: equipment and settings applied.
- A full and complete identification of the material tested with photographs.
- Description of the samples during each step.
- The photographs are welcome whenever useful for documenting specific situations.
- Details of any deviation from the test method, as well as any incident which may have influenced the results.
- Results & Discussion
- Conclusions, percentage of each fraction and recommendations (if any)
- Test figures. Use the tables below as reference.

Results must be interpreted i.e., if 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.

In this TR3.0, it is proposed that primary and secondary packaging (either cardboard and paper or plastic) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.

Rationale behind the proposed 'assessment and verification'

As per the questionnaires sent to stakeholders in December 2020, many comments expressed that a sample of packaging would not be needed as far as a clear photograph was provided. So in the TR1.0, it was requested to provide a clear image instead of a sample of the product.

In TR1.0, the methods for verification the recyclability and recycled content of the packaging was left open for discussion.

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

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

The recycled content must be verified by complying with the EN 45557 (General method for assessing the proportion of recycled material content in energy-related products) or the ISO 14021 (Environmental labels and declarations — Self-declared environmental claims) or equivalent methods.

The standard EN 45557 was proposed as the standardisation request for the ecodesign requirements on material efficiency aspects for energy-related products in support of the implementation of Directive

[165] 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

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2009/125/EC of the European Parliament and of the Council. The ISO 14021 specifies the requirements for self-declared environmental claims regarding products. It also describes a general evaluation and verification methodology for self-declared environmental claims and specific evaluation and verification methods for the selected claims.

It is also added that plastic recycled content in packaging shall comply with chain of custody standards such ISO 22095- Chain of custody — General terminology and models. This standard is applicable to all materials and products (apart from services or final outputs). It can be used by any organization operating at any step in a supply chain, as well as by standard setting organizations as a reference point for specific chain of custody standards. It enhances the transparency of specific claims regarding materials or products and thereby support the reliability of these claims.

The recyclability capacity must be verified by complying with the EN 13430 (Packaging - Requirements for packaging recoverable by material recycling) or the ISO 18604 (Packaging and the environment — Material recycling) or equivalent methods.

The standard EN 13430 specifies the requirements for packaging to be classified as recoverable in the form of material recycling whilst accommodating the continuing development of both packaging and recovery technologies and sets out procedures for assessment of conformity with those requirements, it is the second standardization mandate to CEN related to the packaging and packaging waste directive 94/62/EC. The ISO 18604 specifies the requirements for packaging to be classified as recoverable in the form of material recycling while accommodating the continuing development of both packaging and recovery technologies and sets out procedures for assessment of meeting its requirements.

Besides, recyclability (availability and compatibility for recycling) shall be tested by means of standard testing protocols such as the ones developed by INGEDE for paper and cardboard or RecyClass for plastics. Equivalent testing methods may be accepted if considered equivalent by a third-party.

Plastic packaging is requested to be ≥95%wt recyclable while the 5%wt residuals has to be compatible with recycling (in both cases, checks can be done by means of fact-based guidelines with pan-European approach such as RecyClass).

However, it is to note that both Design for Recycling guidelines and testing protocols are subjected to the European standardization to CEN CENELEC.

A negative list of chemicals making the packaging non-recyclable per definition has not been introduced as per the difficulties to find relevant literature and unified criteria however this is something to be further followed.

In the case of recyclability, self-declaration has not been allowed but third- party certification.

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Summary of changes in TR3.0

- The structure of the criterion has been modified to include 'Recycled content', 'Recyclability capacity', 'Additional requirements' and 'A&V' sections.
- Requirements for recycled content for primary packaging shall only apply when individual wrapping of the AHP is used (40% if cardboard/paper and 10% if plastic packaging). The requirement will increase after 1st January 2028 for plastic primary packaging up to 25% when products are individually wrapped.
- Secondary packaging shall contain recycled materials (80% if cardboard/paper and 10% if plastic packaging). The requirement will increase after 1st January 2028 for plastic packaging up to 25% for secondary packaging.
- If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 shall apply. If packaging is compostable, criterion 5 shall apply.
- The content of the primary and secondary packaging (either cardboard and paper or plastic) that is available for recycling shall be at least 95% by weight, while 5% residuals shall be compatible with recycling.
- Primary and secondary packaging recycled content verification: EN 45557 or ISO 14021.

- Primary and secondary packaging recyclability verification: EN 13430 or ISO 18604.
- Declaration of compliance supported by a valid, independently certified chain of custody certificate for all cardboard and paper (100%) used for the primary and secondary packaging is requested.
- Plastic recycled content in the packaging shall comply with chain of custody standards such ISO 22095.
- Primary and secondary packaging also to be tested by standard testing protocols for recyclability. Examples: INGEDE for paper and cardboard or RecyClass for plastics. Equivalent testing methods shall be accepted.

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

Annex I: Second proposal for criterion 9: Guidance on the disposal of the product and of the packaging ~~on the packaging and product disposal~~
The primary packaging must contain ~~information on the~~ guidance regarding disposal of the primary packaging, the secondary packaging (if any), the additional ~~packaging~~ components and the product ~~disposal~~. The following information shall be written or indicated through visual symbols on the primary packaging: — that the primary packaging, the secondary packaging (if any), the additional ~~packaging~~ components and the hygiene used product must not be flushed into toilets, and — how to dispose the primary packaging, the secondary packaging (if any), the additional components and the hygiene used product correctly. — ~~that the hygiene used products should be disposed of within the household waste.~~ — ~~that the primary packaging and additional packaging should be disposed of within the recyclable waste if such solution is offered.~~ Assessment and verification: The applicant shall provide a high resolution image of the primary packaging (where information regarding disposal appear clearly).
Annex I: Third proposal for criterion 9: Guidance on the disposal of the product and of the packaging
The primary packaging ~~must~~ shall contain guidance regarding disposal of the primary packaging, the secondary packaging (if any), the additional components and for the disposal of the product. The following information shall be written or indicated through visual symbols on the primary packaging: — that the primary packaging, the secondary packaging (if any), the additional components and the ~~hygiene~~ used product must not be flushed into toilets, and — how to dispose correctly the primary packaging, the secondary packaging (if any), the additional components and the ~~hygiene~~ used product. ~~correctly~~. Assessment and verification: The applicant shall provide a high resolution image of the primary 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.

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

The vast majority of sanitary products (mainly sanitary towels or pads and tampons) are individually packaged (additional component) before being contained in a single pack (primary packaging). Therefore, in the TR1.0 it was proposed that the indication of not flushing into the toilet would not only refer to the product, but to the packaging as well. As current waste management systems in the majority of Member States do not consider the recycling or any other type of valorisation of used absorbent hygiene products, it was proposed to include the indication that these products should be disposed of within the household waste.

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Finally, a third sentence was proposed in TR1.0 to indicate that the primary packaging (which is normally made out of cardboard or plastic) should be disposed of within the recyclable waste. More precise indications are not possible at this stage given the variation in product used as well as in waste management systems across MSs.

In TR2.0 it was proposed to request applicants to write or indicate through visual symbols on the primary packaging that the primary packaging, the secondary packaging (if any), the additional component and the used hygiene product must not be flushed into toilets, and how to dispose them all correctly. The title was slightly modified and now it is 'Guidance on the disposal of the product and of the packaging'.

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting there were not any comments on regards to criterion 9, while six comments were received after the meeting mainly related to the possibility to indicate how to dispose the used and packaging through icons. A comment suggested a modification of the wording and another comment highlighted it was not need to add the disposal information on the individual wrapping of each product.

Main changes in the third proposal

Mostly comments after the 2nd AHWG meeting requested the possibility to fulfil this criterion by means of icons and/or pictograms and this was already the case. The criterion reads: 'The following information shall be written or indicated through visual symbols on the primary packaging'.

A slight modification of the information requested in this criterion has been introduced.

Rationale behind the proposed 'assessment and verification'

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

As a result of the preliminary questionnaire sent to stakeholders in December 2020, some stakeholders expressed that a sample of packaging would not be needed as far as a clear photograph is provided. Therefore, in TR1.0, TR2.0 and TR3.0 it is proposed to require a photograph of the primary packaging as a proof of compliance. The photograph should clearly show the indications displayed on the primary packaging.

No further changes are proposed for criterion 9 in TR3.0.

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

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

The efficiency/quality of the product shall be at least as satisfactory ~~and at~~ as the ~~least~~ equivalent ~~of~~ products already on the market. Fitness-for-use shall be tested with respect to the characteristics and parameters reported in Table ~~5~~8. Performance thresh- olds shall be matched, where these have been identified.

Table ~~5~~8

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

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (*)	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers and feminine care pads
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1. Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	As for baby diapers and feminine care pads
	T2. Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	As for baby diapers and feminine care pads

(*) Panty liners intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

Assessment and verification:

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

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

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

Additional guidelines for user tests.

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

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

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

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

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

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

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

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

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

Additional requirements for technical tests.

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

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

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

Weight, dimensions and design features of the product shall be described and provided in accordance with ~~criterion 1~~ information provided in the application general assessment and verification text.

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

The efficiency/quality of the product shall be ~~at least as~~ satisfactory and the least equivalent to that of ~~as the equivalent~~ products already on the market. Fitness-for-use shall be tested with respect to the characteristics and parameters reported in Table 8. Performance thresh- olds shall be matched, where these have been identified.

Table 8

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

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (*)	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers and feminine care pads
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1. Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	As for baby diapers and feminine care pads
	T2. Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	As for baby diapers and feminine care pads

(*) Panty liners intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

Assessment and verification:

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

Tests shall be conducted for all the specific type and size of products applying for the EU Ecolabel.

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

Additional guidelines for user tests~~:~~.

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

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

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

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

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

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

— For all in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance), 80% of the consumers testing the product shall rate the performance as satisfactory, ~~which could for instance mean that~~ with a rate above 60 ~~is~~ assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80% of the consumers testing ~~or that~~ the product shall rate it ~~has been assessed~~ 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

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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 performance/inefficient.

At the preliminary questionnaire (December 2020), 25% of the respondents indicated the need for revision of the current criterion on 'fitness for use and quality of the product'.

In TR1.0 and TR2.0, the following changes were proposed:

- Panty liners derogation from requirement regards in-use test, U1- absorption and leakage protection. This was kept in TR2.0.
- Threshold for 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[166] specified technical test methods for baby diapers and feminine care pads are also valid for nursery pads[167]. Therefore, the technical tests recommended were the same for these three product categories in TR1.0 and TR2.0.

In addition, in TR2.0, a slight modification of the initial sentence of this criterion was added: **'**The efficiency/quality of the product shall be at least as satisfactory as the equivalent products already on the market'.

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting, a stakeholder highlighted the absence of harmonised tests for in user tests such as absorption and leakage protection. It was also mentioned that, since results are dependent on the test method used, standardisation is required to have accurate understanding on whether a product meets the requirement.

In total three written comments were received after the 2nd AHWG meeting on regards to this criterion. One comment claimed that 100 test subjects shall be required in opposition to the 30 proposal, while two other comments pointed to the possibility to request a detailed explanation of the technical tests for baby diapers in line with the meeting discussion.

Further research and main changes in the third proposal

Comments received to this criterion requested a clarification and further explanation on the testing protocols for in user tests to be performed to AHP.

In this line, 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 by International Consumer Research & Testing (ICRT)[168]. This methodology provides different thresholds used as reference for establishing a rating based on 5 stars.

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

[166] 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).

[167] 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).

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

- Guidelines for testing baby diapers[169]
- Guidelines for testing feminine hygiene products[170] (EDANA, 2018)

In the EDANA Guidelines for the Testing of Baby Diapers, there is no listed test methods for absorption and leakage protection. 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) which last update seems to be NWSP 070.7.R2 (20) according to the last update on the EDANA Harmonized Nonwovens Standard Procedures (updated in January 2021)[171]. There are not listed test methods for leakage protection.

In this TR3.0, it is not proposed to provide further information on testing protocols and methodologies in criterion 10, however it is proposed to add the detailed information of examples already developed in the User Manual of Absorbent Hygiene Products.

Rationale behind the proposed 'assessment and verification'

In TR1.0, it was proposed that the minimum amount of consumers tested shall increase to 100 subjects for products not specifically designed for one gender however in TR2.0 it was decrease again to 30 as comments during the 1st AHWG meetings requested not to increase the burden on test subjects.

In TR2.0, it was introduced that the applicant shall document the test protocol (laboratory test(s) or consumer test) that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the functions claimed on the product label or packaging.

After the 2nd AHWG meeting, one comment, requested the increment of consumers tested to 100 instead of 30. However there was no further explanation or reasoning. To avoid an increment to the limitations given to applicants a number of 30 test subjects (for products specifically designed or not for one gender) is requested.

The recommendations published by EDANA for tests[172] (EDANA 2016, 2018) indicate that at least 100 test subjects should be used for products that are not specifically designed for one gender while for products that are specifically designed for one gender at least 30 test subjects should be included.

In this TR3.0, the wording on the assessment of in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance) has been modified 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).

[169] 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).

[170] 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).

[171] 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).

[172] EDANA, 2020. The relevant test methods. Available at: https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products/the-edana-absorbent-hygiene-product-stewardship-programme-codex/test-methods and https://www.edana.org/about-us/news/edana-ahp-stewardship-programme-to-give-consumers-further-assurances-about-the-safety-of-the-products (accessed 12/04/2022).

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

Annex I: Second proposal for criterion 11: Corporate Social Responsibility with regard to Labour Aspects
Requirements in this criterion shall apply 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 ([1]), the UN Global Compact (Pillar 2) ([2]), the UN Guiding Principles on Business and Human Rights ([3]) and the OECD Guidelines for Multinational Enterprises ([4]), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the ILO's fundamental conventions and the supplementary provisions below have been respected at the final AHP assembly site for the product. Fundamental conventions of the ILO: (i) Child Labour: — Minimum Age Convention, 1973 (No 138); — Worst Forms of Child Labour Convention, 1999 (No 182). (ii) Forced and Compulsory Labour: — Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention; — Abolition of Forced Labour Convention, 1957 (No 105). (iii) Freedom of Association and Right to Collective Bargaining: — Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87); — Right to Organise and Collective Bargaining Convention, 1949 (No 98). (iv) Discrimination: — Equal Remuneration Convention, 1951 (No 100); — Discrimination (Employment and Occupation) Convention, 1958 (No 111). Supplementary provisions: (v) Working Hours: — ILO Hours of Work (Industry) Convention, 1919 (No 1). (vi) Remuneration: — ILO Minimum Wage Fixing Convention, 1970 (No 131); — Living wage: The applicant shall ensure that wages paid for a normal working week shall always meet at least legal or industry minimum standards, are sufficient to meet the basic needs of personnel and provide some discretionary income. Implementation shall be audited with reference to the SA8000 guidance on 'Remuneration'. (vii) Health & Safety: — ILO Safety in the use of chemicals at work Convention, 1981 (No 170); — ILO Occupational Safety and Health Convention, 1990 (No 155). In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues. The audit process shall include consultation with external stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. The applicant shall publish the aggregated results and key findings from the audit online in order to provide evidence of their supplier's

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performance to interested consumers.

These standards shall be communicated to production sites along the supply chain used to manufacture the final product.

Assessment and verification:

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

The third-party site audit shall be carried out by private auditors qualified to assess the compliance of the AHP industry supply chain with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective ([1]) and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a national authority.

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

([1]) ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.

([2]) United Nations Global Compact (Pillar 2) https://www.unglobalcompact.org/what-is-gc/participants/141550

([3]) Guiding Principles for Business and Human Rights https://www.unglobalcompact.org/library/2

([4]) OECD Guidelines for Multinational Enterprises https://www.oecd.org/daf/inv/mne/48004323.pdf

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

This criterion sets ~~R~~requirements ~~in this criterion shall apply~~ 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 ([1]), the UN Global Compact (Pillar 2) ([2]), the UN Guiding Principles on Business and Human Rights ([3]) and the OECD Guidelines for Multinational Enterprises ([4]), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts ~~ILO's fundamental conventions~~ and the supplementary provisions below have been respected at the final ~~AHP~~ assembly site for the product.

Fundamental conventions of the ILO:

(i) Child Labour:

— Minimum Age Convention, 1973 (No 138)~~;~~

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

(ii) Forced and Compulsory Labour:

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

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

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

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

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

(iv) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)~~;~~

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

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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 working week (not exceeding 48 hours) shall be always meet at least legal or industry minimum standards, are sufficient to afford meet the basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, personnel and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 [5] guidance on 'Remuneration'.

(vii) Health & Safety:

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

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

— 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, the 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 supplier's performance to interested consumers.

These standards shall be communicated to production sites along the supply chain used to manufacture the final product.

Assessment and verification:

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

~~The T~~third-party site audits shall be carried out by ~~private~~ auditors qualified to assess the compliance of the ~~AHP~~ industry manufacturing sites ~~supply chain~~ with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective ([1]) and where the scope of the inspection systems covers the areas listed above ([1]), by labour inspector(s) appointed by a public ~~national~~ authority.

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

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.

([1]) ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.

([2]) United Nations Global Compact (Pillar 2), https://www.unglobalcompact.org/what-is-gc/participants/141550

([3]) Guiding Principles for Business and Human Rights, https://www.unglobalcompact.org/library/2

([4]) OECD Guidelines for Multinational Enterprises, https://www.oecd.org/daf/inv/mne/48004323.pdf

([5]) Social Accountability International, Social Accountability 8000 International Standard, http://www.sa-intl.org

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, Art 6(3) specifies that: '*EU Ecolabel criteria shall be determined on a scientific basis considering the whole life cycle of products. In determining such criteria, the following shall be considered: (...) (e) where appropriate, social and ethical aspects, e.g. by making reference to related international conventions and agreements such as relevant ILO standards and codes of conduct*'.

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

In order to improve the clarity of the criterion, in the first TR published before the AHWG meeting 1, this criterion text was proposed to be harmonised with the EU Ecolabel for footwear[173].

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

In the first proposal for this criterion (TR1.0), the first sentence was set to clarify that this criterion verification refers to the final Absorbent Hygiene Product assembly site (final production site). This criterion text was harmonised with the EU Ecolabel for footwear.

This criterion was presented during the EUEB meeting in November 2021, from where several comments were received on whether to keep Corporate Social Responsibility (CSR) with regards to Labour Aspects in

[173] 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

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criterion 11. Several stakeholders commented explaining the need to keep this criterion. At the same time, the desire for a discussion on how compliance had be documented and its update up to the latest standards were requested.

In TR2.0, a comprehensive analysis of all comments received was developed in the discussion section. It resulted that many comments either requested information to be added that was already in the criterion or requested the use of assessment and verification protocols which were not aligned with the purpose of the criterion. As a result, no changes were introduced with respect to TR1.0.

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting comments on regards to criterion 11 focused on the expansion of the scope to include further tiers than only the final assembly site or to update it as other product groups did.

One stakeholder pointed towards the social criterion from the EU Ecolabel for Electronic Displays which was more recent.

Another stakeholder agreed and provided detailed and specific proposals:

- Enriching the list of supplementary provisions with additional ILO conventions (as the criterion is restricted to social and labour rights).

- Expanding the application of the criterion to go beyond to the assembly site, up to tier 2 & 3 in the manufacturing plants (lower tiers of the value chain).

- Inclusion of in locations where the application of ILO conventions cannot be meet by national laws.

Another stakeholder supported previous consideration and further clarified:

- The criterion should be defined in such a way that is also applying a risk-based approach eventually for due diligence. Based on the legislative development regarding the due diligence and taxonomy, these criteria relate to the integration of social aspects as a minimum social safety net for activities to qualify as taxonomy eligible. It is important to use a proper wording, expanding the proposed scope to address social organizations criticisms (i.e. limiting the scope to assembly plants).

- The EU Ecolabel for electronic displays delve further into social aspects, such as minimum living wage, because more in-depth discussion and focus were carried out when the label was being developed.

A total of 11 comments were received to this criterion in written form after the 2nd AHWG meeting. Comments were in line with discussion during the meeting.

Mixed views were received in relation to expansion to tiers 2 & 3 in the manufacturing plants. Several comments provided suggestion in relation to additions to be made to this criterion for a better assurance of social rights.

Further research and main changes in the third proposal

Other products groups with a specific EU Ecolabel such as textiles and footwear indicated this type of criterion. Other ecolabels for textiles (Blue Angel or Nordic Swan) present similar requirements to what listed in the proposal from TR1.0. However, other type I ecolabels for AHP do not include a social criterion.

Further research has been conducted in order to understand and present the last developments of application for this criterion. The criteria has been harmonised as much as possible with the EU Ecolabel Criteria for Electronic Displays[174]. This is the most recently revised EU Ecolabel product including a social criterion.

The main elements and rationale behind this proposal are summarised as it follows.

[174] 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

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ILO fundamental conventions

Currently the proposal is mainly based on the International Labour Organisation's (ILO) Tripartite Declaration of Principles, setting requirements for the fundamental rights principles at work. Nevertheless it includes also references to the UN Global Compact (Pillar 2), the UN Guiding Principles on Business and Human Rights and the OECD Guidelines for Multinational Enterprises.

The International Labour Organization (ILO) is a United Nations agency devoted to promoting social justice and internationally recognized human and labour rights. The ILO helps advance the creation of decent work and economic and working conditions for all[175]. The underlying principles of the ILO fundamental conventions are supplemented by provisions addressing working hours, remuneration and health and safety. Reference to the underlying principles is important to emphasise 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.

In terms of remuneration, in TR3.0 it has been added that ILO's Minimum Wage Fixing Convention 131 (1970) specifies in Article 3 (a) and (b) that the following two elements are taken into consideration in determining the minimum wage:

- the needs of workers and their families taking into account the general level of wages in the country, the cost of living, social security benefits, and the relative living standards of other social groups;
- economic factors, including the requirements of economic development, levels of productivity, and the desirability of attaining and maintaining a high level of employment.

It has also been added: ILO Holidays with Pay Convention (Revised), 1970 (No 132).

According to SA8000[176], in most countries these two considerations are at odds and may not be weighted equally in the determination of the minimum wage. These wages also frequently do not reflect inflation and other factors that affect actual standards of living. Lack of enforcement of even these minimal rates of pay is common, forcing workers to work excessive overtime just to earn the legal minimum wage. For this reason, the proposed EU Ecolabel criteria include an additional requirement on the '**living wage' being sufficient** to meet the basic needs of personnel and to provide some discretionary income. For a definition of 'living wages', interpretations, implementation, auditing and evidence of compliance, reference is made to the SA8000 Consolidated Guidance on Remuneration.

As some comments after the 2nd AHWG meetings new inclusions in this criterion are:

In (vii) Health & Safety, ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148), has been added.

Besides, social protection and inclusion and fair dismissal were added:

(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 order to ensure an independent and meaningful audit process, additions were made:

- referral to 'industry independent organisation', this is added to make sure that genuine worker engagement is achieved;

[175] https://www.ilo.org/global/about-the-ilo/mission-and-objectives/lang--en/index.htm
[176] SA8000 standard: https://sa-intl.org/resources/sa8000-standard/

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- 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 generate social and labour rights outcomes for stakeholders, even in case of European extraterritoriality.
- Addition of 'meaningful consultations with stakeholders', as explained by OECD[177], 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.

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 nor create excessive burden to applications.

Scope of the criteria proposal

This criterion proposed only to address 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 with the availability of independent audit reports as also being required for verification.

Rationale behind the proposed 'assessment and verification'

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

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

- Two ways of verification were explained (1) knowledge of national law in order to verify that the listed ILO standards are fulfilled or (2) third-party certification enabled to show compliance with the ILO standards.
- Confirmation by each supplier providing BSCI Certificate, SA8000 Certificate, or SMETA - Sedex (public declaration).

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

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

In TR3.0 proposal, this section has been modified for a better understanding.

[177] 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

All in all, in TR3.0 several modifications are included in harmonisation with the EU Ecolabel Criteria for Electronic Displays and by means of new additions from comments made by stakeholders during and after the 2nd AHWG in written form.

Summary of changes in TR3.0

- Inclusion of considerations in determining the minimum wage.
- In (vii) Health & Safety, ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148), was added.
- Addition of (viii) Social protection and inclusion and (ix) Fair dismissal considerations.
- Inclusion of alternative mechanisms to express their grievances (in relation to free association).
- In relation to audits: wording has been modified including a referral to industry independent organisation, unannounced spot inspections by industry-independent or meaningful consultations.
- Request for supporting details for audits: (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.
- In the 'Assessment and verification' section, wording has been modified for an easier understanding.

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5.13 CRITERION 12 for Absorbent Hygiene Products: Information appearing on the EU Ecolabel

Annex I: Second proposal for criterion 12: Information appearing on the EU Ecolabel
The ~~optional~~ EU Ecolabel logo may ~~shall~~ be applied on the primary packaging of the product. The optional label with box shall contain the following text: — 'Product designed to reduce impact on the environment', — Restricted use of hazardous substances', — ~~'Product designed to reduce environmental impact',~~ — 'Verified performance'. The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The photograph provided must be a high resolution image of the product primary packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.
Annex I: Third proposal for criterion 12: Information appearing on the EU Ecolabel
The EU Ecolabel logo may be ~~applied~~ displayed on the primary packaging of the product. If t~~T~~he optional label with text box is used, it shall contain the following three statements ~~the following text~~: — (a) '~~Product~~ Ddesigned to reduce impact on the environment', — ~~'Restricted use of hazardous substances',~~ — (b) 'Fulfils strict requirements on harmful substances', — (c) 'Verified performance', The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The provided photograph ~~provided must~~ shall be a high resolution image of the product primary packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

Rationale for the proposed criterion text

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

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

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

Finally, for the first proposal included in TR1.0, the wording of the criterion was changed to harmonise with the most recently voted product group (Cosmetic products and animal care products). Clarification about the visual evidence was also added in the proposal in TR1.0, thus allowing applicants to send a high resolution image of the primary packaging instead of the product itself. Besides the statement to appear was redefined.

In TR2.0, the verb 'shall' was modified by 'may' to indicate optional indication of the EU Ecolabel logo while also the order of the sentences are proposed to be modified at this stage of the revision process. In the 'assessment and verification' section, a slight modification, i.e. the addition of 'primary' to packaging was added.

Outcomes from and after 2nd AHWG meeting

Any comments to this criterion were received during the 2nd AHWG meeting while one comment in written form was received afterwards. The comment received asked '*why this criterion become not optional*'.

Further research and main changes in the third proposal

The criterion is still optional. Applicants may or not add the EU Ecolabel logo, registration/licence number and, where relevant, the statements that can be displayed together with the label or just the label can be displayed.

In this TR3.0, the sentence on 'Restricted use of hazardous substances', has been replaced by 'Fulfils strict requirements on harmful substances', to align with one the latest products revised (Cosmetics[178]). Besides, a fourth optional sentence has been added in terms of the voluntary sub-criterion 4.2 relating to 'bio-based plastic ingredients used'.

This new sentence serves to specify the certain percentage of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final absorbent hygiene product sourced from bio-based raw materials.

The sentences is:

- 'X % by weight (of the total plastics) of certified bio-based plastic ingredients used' (when relevant)(1),

It has to be noted that AHP can be composed of other bio-based materials such as fluff pulp and man-made cellulose fibres not accounted for in the criterion 4. The fourth sentence can only be shown when bio-based plastic ingredients are used. However it is worth noting that it is also optional as the other three sentences. It is added also that only 3 out of the 4 statements may be used.

Rationale behind the proposed 'assessment and verification'

Wording has been slightly modified in relation to the provided photograph while the verb 'must' has been replaced by 'shall'.

It has been added that 'If statement d) is used, the applicant shall provide the relevant certificate(s) related to the percentage of certified bio-based plastic ingredient(s) used'.

No further changes are proposed in TR3.0.

[178] OJ L 379, 26.10.2021, p. 8–48 https://eur-lex.europa.eu/eli/dec/2021/1870/oj

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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 separated 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 6. The order of the criteria mirrors the one for the EU Ecolabel criteria for Absorbent Hygiene Products.

Table 6 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

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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 next figure).

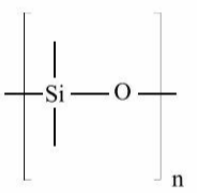

Figure 4. Chemical structure of the siloxane group in silicone polymers.

There exist many types of silicones, however the most important silicone compound is polydimethylsiloxane (PDMS, see Figure 5), 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[179]. 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 vulcanized rubber (RTV)[180]. To the JRC's knowledge, it is LSR that is normally used to produce menstrual cups.

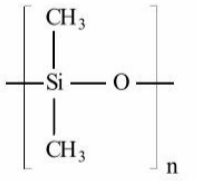

Figure 5. Chemical structure of polydimethylsiloxane (PDMS).

The processes and steps involved in the production of silicone for different uses are depicted in Figure 6. 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[181]. 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

[179] 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

[180] Silicone vs. TPE: How to make the right choice. In: Rubber World, October 2017.

[181] 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

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Techniques for the Production of Speciality Inorganic Chemicals (SIC) provides further details on the production processes[182].

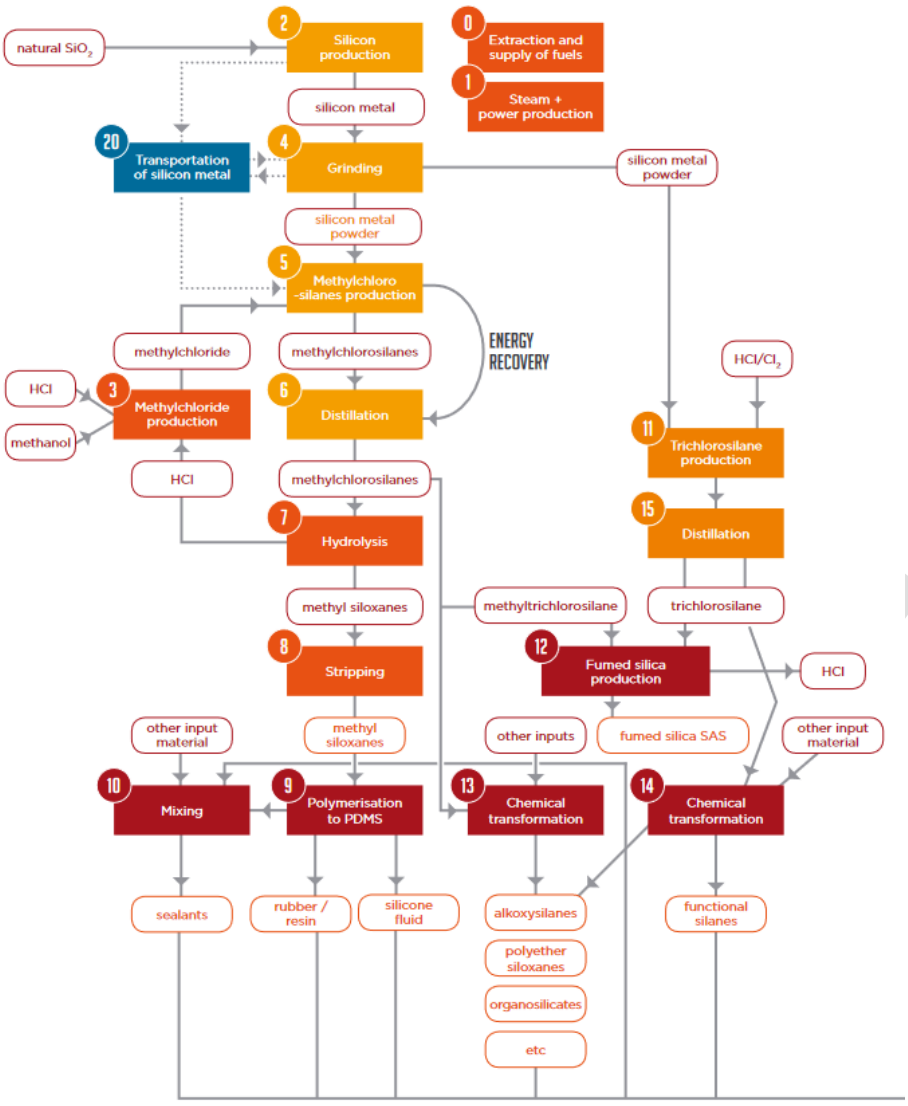

Figure 6. Different steps and processes for the production of different silicone products. For the EU Ecolabel, it is polydimethylsiloxane (PDMS, step 9) which is of relevance. Source: Global Silicones Council[181]

According to the BREF for the Production of Speciality Inorganic Chemicals[182], 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 results, 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.

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;

[182] 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

- Criterion 1.3: Emissions of CO_2

At this stage of the revision process it was not possible to retrieve detailed information on the production of TPE. Therefore, the current proposal for criterion 1 mainly refer to silicon menstrual cups.

Nevertheless, being TPE a type of elastomer, the production process of the raw material can be assumed roughly similar. Since some requirements of sub criteria 1.1-1.3 are based also on the BREF document for Common Waste Gas Management and Treatment Systems in the Chemical Sector (WGC)[183], whose work is still under finalisation, but once finalised it will apply to all chemical plants in Europe, it is proposed to apply that those requirements based on the BREF for WGC apply to both silicon and TPE. In the criteria text, it was clearly stated what requirements apply to only silicon cups or to both silicon and TPE cups.

Stakeholders are kindly requested to confirm or reject the validity of this proposal for TPE.

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[183] 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: Previous proposal for sub-criterion 1.1: Emissions of dust and of chlorides to air

1.1(a) Dust

(i) This requirement applies to silicones only. The storage and handling of the elemental silicon raw material shall apply at least one of the following techniques:

- Storing elemental silicon in silos;
- Storing elemental silicon in covered areas protected from rain and wind;
- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage;
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

(ii) This requirement applies to both silicon and other elastomers. The yearly average from channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored.

1.1(b) Chlorides

(i) This requirement applies to silicon only. The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. The thermal oxidation shall be authorised to burn chlorinated compounds.

(ii) This requirement applies to both silicon and other elastomers. PCDD/F emissions shall be below 0.01 ng TEQ/Nm^3. 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:

- To show compliance with criterion 1.1(a).i, the silicon supplier shall indicate which measure is used on site, providing pictures or projects of the measure installed as supplementary data;
- To show compliance with 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. For the production of silicon, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum;
- To show compliance with criterion 1.1(b).i, the silicon supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps,;
- To show compliance with criterion 1.1(b).ii, the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases.

Annex II: New proposal for sub-criterion 1.1: Emissions of dust and of chlorides to air

1.1(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 elemental silicon in silos (after grinding);
- Storing 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);

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- 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 from channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored.

1.1(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. The thermal oxidation shall be authorised to burn chlorinated compounds.

(ii) This requirement applies to elastomers other than silicones. Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0.01 ng TEQ/Nm^3 (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:

- ~~To show compliance with~~ criterion 1.1(a).i, the silicon supplier shall indicate which technique ~~measure~~ is used on site, providing pictures or projects of the technique ~~measure~~ installed as supplementary data;
- ~~To show compliance with~~ 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 1, EN 15267-1, EN 15267-2, EN 1526, 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;
- ~~To show compliance with~~ criterion 1.1(b).i, the silicon supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps;
- ~~To show compliance with~~ 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 minimizing 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 also after grinding.

Another way to reduce dust emissions to air from elemental silicon grinding, storage and handling are filtration systems 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 document for the production of SIC[182], silicone producers in Europe can have between 5 to 20 fabric filters in its 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 has also the advantage of achieving a reduction in raw elemental silicon consumption.

Nevertheless, the working document for the BREF document for Common Waste Gas Management and Treatment Systems in the Chemical Sector (WGC, which is still under development) indicates a Best Available Technique-Associated Emission Levels (BAT-AEL) for channelled emissions to air of dust of 1-5 mg/Nm^3. If

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confirmed (as it is most likely given the advanced status of the revision), this BAT-AEL would apply to all chemical plants, including those for silicon and for other elastomers.

In the second Technical Report, it was proposed to require (1) to have in place measures to minimise dust emissions, and (2) to achieve dust emission levels below 5 mg/Nm^3 (yearly average). Please note that the 5 mg/Nm^3 limit is at the lower end of the BAT for the production of SIC, and at the higher end of the BAT for WGC. For the assessment and verification, it is proposed to require the silicon supplier to indicate which measure is used on site for the reduction of diffuse dust emissions, providing moreover pictures or projects of the measure installed on site. The silicon and the TPE supplier should moreover provide the results of the dust measurements taken on site.

Outcomes from and after 2nd AHWG meeting

Only two comments were received, providing wording suggestions and pointing to the measurement frequency of dust emissions.

Further research and changes to the previous proposal

No main changes are proposed in this TR3.0. Testing methods were provided for measurements of dust.

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 consists of nitrogen (87 – 89 %), dimethylether (10 %), methyl chloride (1 – 3 %), methanol and traces of hydrocarbons. The off-gases from the direct synthesis step mainly consists of nitrogen (70 – 80 %), methane (10 – 20 %), hydrogen (5 %), hydrocarbon (1 – 2 %) and methyl chloride (1 %). Finally, the off-gases from the distillation step contains nitrogen, methyl chloride and methylchlorosilane[182].

Given the presence of light hydrocarbons and chlorinated compounds, the off gases from these steps must undergo a thermal oxidation step to minimize the risk of polychlorinated dibenzodioxins/furans (PCDD/F) formation.

As indicated in several EU regulations on incineration (e.g. Directive 2010/75/EU[184]), to avoid the formation of PCDD/F when incinerating chlorinated compounds with a content of more than 1 % of halogenated organic substances, the following special operating conditions should be applied:

- temperature >1100 °C (850 °C when incinerating waste with less than 1 % of halogenated organic substances)
- residence time >2 s
- oxygen content >3 %.

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.

In any case, the final draft of the BREF document for WGC indicate a BAT-AEL for PCDD/F emissions < 0.01-0.05 ng TEQ/Nm^3.

Finally, in the case of the combustion of halogenated VOC substances, an HCl scrubber is necessary.

In the second Technical Report, it was proposed to require, for silicone RMC, 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.

[184] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), OJ L 334, 17.12.2010, p. 17–119. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010L0075

Outcome from and after the 2nd AHWG and stakeholder consultation

Four comments were received, providing wording suggestions and pointing to the measurement frequency of PCDD/F emissions.

Further research and changes to the previous proposal

No main changes are proposed in this TR3.0. Testing methods were provided for measurements of dust.

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6.2.2 Sub-criterion 1.2: Emissions of copper and zinc to water

Annex II: Previous proposal for sub-criterion 1.2: Emissions of copper and zinc to water
This criterion applies to silicon only. The water effluents from the PDMS production step shall be pre-treated by precipitation/flocculation under alkaline conditions followed by sedimentation and filtration. This shall include: - dewatering the sludge before disposal; and - recovering the solid metal residues in metal recovery plants; or - disposing of the sludge via incineration or landfill. 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 silicon supplier with criterion 1.2, together with a proof that the plant has in place a waste water system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicon supplier shall provide the measurement results for copper and zinc in the treated effluent.
Annex II: New 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; or - disposing of the sludge via incineration ~~or landfill~~. 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 silicon supplier with criterion 1.2, together with a proof that the plant has in place a waste water system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicon supplier shall provide the measurement results for copper and zinc in the treated effluent.

Rationale for the proposed criterion text

This criterion aims at minimizing 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 waste water 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 waste water are copper and zinc.

To minimise the concentration of copper and zinc in the effluent, the waste water from PDMS production can be treated in two steps: a pre-treatment by precipitation/flocculation, and a sedimentation step to remove heavy metals.

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Only one comment was received to the proposal, requesting not to allow landfill as a treatment method for the sludge. The proposal was accepted, in line with the circular economy principles.

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6.2.3 Sub-criterion 1.3: Emissions of CO_2

Annex II: Previous proposal for sub-criterion 1.3: Emissions of CO_2

This criterion applies to silicon only.

CO_2 emissions from the production of the silicon shall not exceed 1.3 kg per kg silicon, including emissions from the production of electricity (whether on-site or off-site). Reference emission values according to Table 1 shall be used in the calculation of CO_2 emission from fuels. If needed, CO_2 emission factors for other fuels can be found in Annex VI to Regulation (EU) 2018/2066.

Table 1

Reference values for CO_2 emissions from different energy sources

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

Assessment and verification:

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

The CO_2 emission data shall include all sources of non-renewable fuels used during the production of the raw material, including the emissions from the production of electricity (whether on-site or off-site).

Factors accepted by the authorities in European Union Emissions Trading System (EU ETS) shall also be accepted. The period for the calculations or mass balances shall be based on the production over 12 months. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing that energy from renewable sources is purchased, in which case the applicant may use the factor for the purchased electricity (contract for specified electricity or National Inventories), instead of the value quoted in Table 1. The documentation used as proof of compliance shall include technical specifications that indicate the average value (i.e. copy of a contract).

The amount of energy from renewable sources purchased and used for the production processes counts as zero CO_2 emission when calculating CO_2 emissions. Similarly, energy from nuclear plants counts as zero CO_2 emission. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased.

Annex II: New proposal for sub-criterion 1.3: Emissions of CO_2

This criterion applies to silicones only.

CO_2 emissions from the production of the silicon shall not exceed 6.58 kg per kg polydimethylsiloxane rubber (PDMS rubber) ~~1.3 kg per kg silicon~~, including emissions from the production of electricity (whether on-site or off-site). CO_2 emissions shall include all sources of non-renewable ~~fuels~~ energy used during the production of pulp. Reference emission values according to Table 1 shall be used for the calculation of CO_2 emission from energy sources ~~fuels~~. If needed, CO_2 emission factors for other energy sources ~~fuels~~ can be found in Annex VI of Regulation (EU) 2018/2066.

Table 1

Reference values for CO_2 emissions from different energy sources

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

Assessment and verification:

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

The CO_2 emission data shall include all sources of non-renewable energy sources ~~fuels~~ 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. ~~Similarly, energy from nuclear plants counts as zero CO2 emission.~~ The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased.

Factors accepted by the authorities in European Union Emissions Trading System (EU ETS) shall also be accepted. 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.

For grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing that energy from renewable sources is purchased, in which case the applicant may use the factor for the purchased electricity (contract for specified electricity or certified electricity ~~National Inventories~~), instead of the value quoted in Table 1. The documentation used as proof of compliance shall include technical specifications that indicate the average value (i.e. copy of a contract).

The amount of energy from renewable sources purchased and used for the production processes counts as zero CO_2 emission when calculating CO_2 emissions. Similarly, energy from nuclear plants counts as zero CO_2 emission. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased.

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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 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 recuperated and converted into steam, which is used particularly for the distillation step. Natural gas is mainly used to operate the vent incineration units.

In the second Technical Report (TR2.0), a threshold of 1.3 kg CO2 per kg silicon was proposed for silicon-producing installations, according to the (few) relevant data points that could be found in literature. The structure of this sub-criterion was aligned with criterion 1.4 for AHP.

Outcomes from and after 2nd AHWG meeting

Five comments were received on this sub-criterion. One comment pointed to the unfeasibility of the threshold proposed, which is 5 times below the current technology. In addition, comments pointed to an alternative approach to the criterion, relying on product carbon footprint instead of the CO2 emissions reference values proposed in Table 1 of the criterion proposal.

Further research and changes to the previous proposal

The most relevant report available in the literature with respect to the GWP of the silicon production is the one published in 2012 by the Global Silicon Council (GSC) together with the Centre Européen des Silicones, the Silicones Environmental, Health and Safety Council of North America, and the Silicone Industry Association of Japan[177]. This study is the only one of its kind for silicones, and while an update of the result is under development, it was not available at the moment of writing this report.

In the GCS report, the GWP data reported for the production of PDMS rubber indicate a value of 6.58 kg CO2eq/kg of PDMS rubber. This value is higher than the one proposed in the TR2.0, and is in line with the comment from stakeholders that the previous proposal was unfeasible for the current technology.

For these reasons, in this Third Technical Report it is proposed to set a maximum CO_2 emissions value of 6.58 kg CO_2/kg PDMS rubber.

Stakeholders also commented that a Product Carbon Footprint (PCF) method for calculating the GWP of PDMS production would be preferable to the current proposed approach of using reference CO2 values for different energy sources. However, a PCF-based approach would require increased costs for companies, who would have to carry-out a PCF analysis and have it third-party verified.

This is not proposed at this stage of the revision process, however stakeholders' opinion is welcome on this point.

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6.3 CRITERION 2 for Reusable Menstrual Cups: Environmental management of production

Annex II: First proposal for criterion 2: Environmental management of production
All plants producing either raw materials (silicone or other elastomers) or the reusable menstrual cups shall have systems for the implementation of: — water-saving (e.g. monitoring of water flow in a facility and circulating the water in closed systems), — integrated waste management plan to optimise prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions), — optimisation of energy efficiency and energy management (e.g. reuse /recovery of surplus energy generated during the manufacture of the cups). Assessment and verification: The applicant shall provide a declaration of compliance with the cited requirement from (1) the producer of raw materials (silicone or other elastomers) and (2) from 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 requirement for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001.
Annex II: Second proposal for criterion 2: Environmental management of production
All plants producing either raw materials (silicone or other elastomers) or the reusable menstrual cups shall have systems for the implementation of: — water-savings (~~e.g.~~ the water management system shall be documented or explained and shall include information on at least the following procedures: monitoring of water flows; ~~in a facility and~~ proof of circulating ~~the~~ water in closed systems; and continuous improvement objectives and targets relating to the reduction of waste water generation and optimisation rates), — 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 follow the waste hierarchy in relation to ~~optimise waste~~ prevention, reuse, recycling, recovery and final disposal of waste. ~~(e.g.~~ The waste management plan shall be documented or explained and shall include information on at least the following procedures: 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) ~~the reduction of waste generation and the increase of reuse and recycling rates)~~,, — optimisation of energy efficiency and energy management (~~e.g. reuse of the steam generated during the manufacture of SAPs~~ 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 procedures: 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 cited requirement from (1) the producer of raw materials (silicone or other elastomers) and (2) from 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

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ISO 14001 and/or ISO 50001 for water, waste and energy plans.

If the 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:

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

([2]) the inclusion of water, waste and energy management plans for the production site(s) are 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 is to note 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 text for criterion was proposed in line with criterion 4.1 for Absorbent Hygiene Products.

The measures have been identified in order to reduce negative effects on the environment due to energy and water use and release of residues. Emissions of pollutants to water and air have been considered in criterion 1 for RMC (previous section).

The application of the proposed measures can 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.

In the first proposal, it was required that manufacturers of silicone or other elastomers and RMC manufacturing sites implement systems for:

— water-saving,

— integrated waste management plan,

— optimisation of energy efficiency and energy management.

Outcomes from and after 2nd AHWG meeting

In the previous meeting, two stakeholders agreed on the difficulty and implications of setting fixed percentages of improvements (starting point, how much, PASS/FAIL nature) on the different manufacturing processes. One of them suggested to consider EMAS as well, given the rationale for continuous improvement, checking on consumption and documenting it. The other suggested to be specific on documentation required, proposing an Action Plan rather than the whole extensive list of procedures associated with ISO 14001.

These comments are in line with the two comments (in written form) received after the meeting (all comments received can be found in the annexed Table of Comment). One comment also specified the possibility for companies to provide their ISO 14001 and/or ISO 50001 certificate(s) in order to be sufficient as proof for compliance with the criterion.

Further research and changes to the previous proposal

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 Resource Use – minerals and metals (95%) and Human Toxicity – non-cancer (95%) impact categories, which

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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 Resource Use –fossils impact category (36%).

During the production of RMC, the dominant proportion of environmental burdens are associated with a demand of energy, usually electricity used for the moulding of the cups. However, 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 line with comments received during the 2nd AHWG meeting, this criterion has been modified with more detailed explanation of what it is needed to be fulfilled and when it shall be considered as being fulfilled.

Rationale behind the proposed 'assessment and verification'

Compliance with this criterion shall be carried out by a declaration of compliance from the producers of silicones or other elastomers and RMC manufacturers. The declaration must be supported by a report where environmental saving procedures are described or when 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 fulfil the requirements as cited in the criterion.

Summary of changes in TR3.0

- Details are given on how to fulfil this criterion on environmental management of production in relation to water, waste and energy plans: information on the procedures to include are listed.
- The A&V section is expanded: the consideration of the cases when the requirements in the sub-criterion are fulfilled is explained.

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6.4 CRITERION 3 for Reusable Menstrual Cups: Material efficiency in the manufacturing of the final product

Annex II: First proposal for criterion 3: Material efficiency in the manufacturing
The quantity of waste generated during the manufacture and packaging of reusable menstrual cups, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed: — 8 % by weight of the end products Assessment and verification: The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy. Calculations shall be shown in accordance with ISO 14025 and the applicant shall present all of the following parameters concerning: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of. The net waste shall be calculated as the difference between the amount of waste produced and the amount of waste recovered.
Annex II: Second proposal for criterion 3: Material efficiency in the manufacturing of the final product
The quantity of waste generated during the manufacture and packaging of reusable menstrual cups, and sent to landfill or incineration, ~~at the net of excluding the fraction that is reused or converted into useful materials and/or energy~~, shall not exceed 4 ~~8~~ % by weight of the end ~~products~~ reusable menstrual cups. 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. ~~Calculations shall be shown in accordance with ISO 14025 and the~~ The applicant shall present~~all of the following parameters concerning~~: — the weight of product and packaging, — all the waste streams generated during the manufacture, and — the respective treatment processing ~~(e.g. recycling, incineration), including~~ of the fraction of recovered waste and that disposed of to landfill or incineration. The quantity of ~~net~~ 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).

Rationale for the proposed criterion text

In line with criterion 2, 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 impact assessment as highlighted by the LCA screening study of these products. Economic and environmental benefits are associated with the reduction of production waste that cannot be reused in the manufacturing process or that are not converted to useful materials and energy.

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In the first proposal, it was requested that the net amount of waste generated during the manufacture and packaging of reusable menstrual cups shall be below 8% by weight of the produced cups.

Outcomes from and after 2nd AHWG meeting

In the 2nd AHWG meeting, a stakeholder mentioned that the requirement shall be close to 0% of the waste generated.

Only comment was received in written form after the meeting (as summarised in the annexed Table of Comment for RMC). This comment suggested that the level of 8% of waste generated from the manufacturing of the cups seemed high as the 'production is done with a homogeneous material where waste should be relatively easy to sort and collect to ensure a high degree of reuse'.

Further research and changes to the previous proposal

The criterion text is harmonised with criterion 6 for Absorbent Hygiene Products. After careful consideration and in line with comments received, it has been decided to propose a threshold for the amount of waste generated during the manufacture and packaging of reusable menstrual cups below 4% by weight of the produced cups (also aligned with tampons).

Rationale behind the proposed 'assessment and verification'

The assessment and verification for this criterion is proposed to be the same as the one of criterion 6 for AHP. In order to harmonise both criteria, modifications have been introduced.

Summary of changes in TR3.0

- The quantity of waste generated during the manufacture and packaging of reusable menstrual cups, has been decreased to 4% (as for tampons).
- Slight modification of the explanation on how to calculate the cited % of waste from production has been added for clarity.
- Removal of the reference to ISO 14025.

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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 5 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: Previous proposal for sub-criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Unless derogated in Table 3, the final product, and any component articles 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 on 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

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H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

Table 3. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Titanium dioxide (nano-form)	Pigment	H351: Suspected of causing cancer	It cannot be used in powder or spray form

Moreover the final product, and any component articles 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 4, in accordance with Regulation (EC) No 1272/2008.

Table 4. 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	

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 does not apply to:

— substances not included in the scope of Regulation (EC) No 1907/200618 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.

In order to determine if this exclusion applies, the applicant shall screen any ingoing substances or mixtures present in the product.

Assessment and verification: the applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with a list of all chemicals used in their production process, 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. [to be added in the User Manual: impurities can be present in the final product up to 0.0100% w/w. Substances known to be released

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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 must be provided.

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

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

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

Annex II: New proposal for sub-criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Unless derogated in Table 4, the final product~~, and any component articles 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 of 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

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Moreover the final product, ~~and any component articles 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 and applicable conditions

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Substances with a harmonised classification as H304		H304: May be fatal if swallowed and enters airways	Substances with a viscosity over 20.5 St at 40°C.
Titanium dioxide (nano-form)	Pigment	H351: Suspected of causing cancer	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 1907/200618 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.

In order to determine if this exclusion applies, the applicant shall screen any ingoing substances or mixtures present in the product.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with a list of all chemicals used in their production process, 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

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quantity of the restricted substance or impurity remaining in the final product. [*to be added in the User Manual: impurities can be present in the final 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 license, the calculation only needs to be presented for each impurity for the worst-case product or component article covered by the EU Ecolabel license (e.g. the most heavily printed component article when screening for inks with restricted classifications).

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

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

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 hazard is based on a list of hazard classes, categories and hazard statements codes that are grouped based on the CLP classification and labelling rules and harmonised across different EU Ecolabel product groups. 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.

Outcomes from and after 2nd AHWG meeting

Only one clarification comment was received.

Changes proposed in this TR3.0 are in line with the ones proposed for Annex I on AHP. The reader is kindly redirected to Section 5.8.1 of this Report for the justification of the changes.

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6.5.2 Sub-criterion 4.2: Substances of Very High Concern (SVHCs)

Annex II: Previous proposal for sub-criterion 4.2: Substances of Very High Concern (SVHCs)

The final product, and any component articles 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 of the European Parliament and of the Council* 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 does 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.

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

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

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

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. [to be added in the User Manual: impurities can be present in the final 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 must be provided.

*[**

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

Annex II: New proposal for sub-criterion 4.2: Substances of Very High Concern (SVHCs)

The final product, ~~and any components articles 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 of the European Parliament and of the Council* 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 does 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.

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

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

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

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. [to be added in the User Manual: impurities can be present in the final 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]

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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.

*[**

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

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, in the TR2.0 it was proposed place a full ban on SVHCs.

Outcomes from and after 2nd AHWG meeting

Only one comment was received on this criterion.

Wording changes proposed in this TR3.0 are in line with the ones proposed for Annex I on AHP.

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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 five sub-requirements:

- *4.3(a) Excluded substances*
- *4.3(b) Fragrances*
- *4.3(c) Ink and dyes*
- *4.3(d) Further restrictions applying to plastic materials*
- *4.3(e) Cyclosiloxanes*

6.5.3.1 Sub-criterion 4.3(a) Excluded substances

Annex II: Previous proposal for sub-criterion 4.3: Other specific restrictions
4.3(a) Specified excluded substances The following substances shall not be included (alone or in mixtures) in the final product, nor in any component articles therein: - 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT); - Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]; - Formaldehyde and formaldehyde releasers; - Methylisothiazolinone (MIT) - Nanosilver - Nitromusks and Polycyclic musks; - Organotin compounds used as a catalyst in the production of silicon; - Parabens; - Phthalates; - Substances identified to have endocrine disrupting properties; - 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; - Triclosan. *[Notes:* *[1] Substance name = "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals]*
Annex II: New proposal for sub-criterion 4.3.a Specified excluded substances
The following substances shall not be added ~~included~~ (alone or in mixtures) to ~~in~~ the final product~~, nor in any components articles therein~~: i. 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT); ii. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1]; iii. Antibacterial agents (e.g. nanosilver and triclosan) [to be added to the User Manual: Antibacterial agent are chemicals/products that inhibit or stop growth of microorganisms

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such as bacteria, fungi or protozoa (single-celled organisms)];

iv. Formaldehyde and formaldehyde releasers;
v. Methylisothiazolinone (MIT)
vi. Nanosilver
vii. Nitromusks and Polycyclic musks;
viii. Organotin compounds used as a catalyst in the production of silicon;
ix. Parabens;
x. Phthalates;
xi. Substances identified to have endocrine disrupting properties;
xii. Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects;
xiii. Triclosan.

Assessment and verification:

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

[Notes:

[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.

Outcomes from and after 2nd AHWG meeting

Only one comment was received to this sub-criterion.

Further research and changes to the previous proposal

The main change with respect to this criterion is to prohibit the presence of antibacterial agents, and not only nanosilver and triclosan, as explained in the case of AHP (See section 5.9.3.1).

6.5.3.2 Sub-criterion 4.3(b): Fragrances

Annex II: Previous proposal for sub-criterion 4.3.b Fragrances
Fragrances shall not be added to the final product, nor to any component thereof, nor to the packaging.
Annex II: New proposal for sub-criterion 4.3.b Fragrances
Fragrances shall not be added to the final product, nor to any component thereof, nor to the packaging. Assessment and verification: *The applicant shall provide a signed declaration of compliance with the sub-criterion*

In the second Technical Report, it was proposed to exclude the use of fragrances from RMC, in line with the sub-criterion 7.3(b) for AHP.

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Outcomes from and after 2nd AHWG meeting

No comments were received to this sub-criterion.

No changes were made to this sub-criterion.

6.5.3.3 Sub-criterion 4.3(c): Inks and dyes

Annex II: Previous proposal for sub-criterion 4.3.c Inks and dyes
The dying colorants and inks used in the reusable menstrual cup shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008. In addition, 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 European Council's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food(*). The dying colorants and inks used shall also comply with sub-criteria 4.1 and 4.2.
Annex II: New proposal for sub-criterion 4.3.c Inks and dyes
The dying colorants and inks used in the reusable menstrual cup shall not exceed 2% of total weight of the cup, and shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008. In addition, 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 European Council's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food(*). 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 the colouring agent or ink is approved for use in food.* *(*) References:* *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*

In the second Technical Report, the use of colouring agents is not prohibited, however these must be approved for use as food additives in accordance with Regulation 133/2008[185]. 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. These requirements are in line with the proposal for AHP and with the recently voted EU Ecolabel criteria for cosmetic products.

[185] 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

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Outcomes from and after 2nd AHWG meeting

Only two comments were received to this sub-criterion.

Further research and changes to the previous proposal

Based on data received from stakeholders, it is proposed to limit the amount of colorants and dyes in menstrual cups to a maximum of 2% of the weight of the cup.

6.5.3.4 Sub-criterion 4.3(d): Further restrictions applying to plastic materials

Annex II: Previous proposal for sub-criterion 4.3.d Further restrictions applying to synthetic polymers and 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 the 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).
Annex II: New proposal for sub-criterion 4.3.d Further restrictions applying to synthetic polymers and 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 the synthetic polymer used in the product. (ii) Additives used in plastics shall comply with sub-criterion 4.1 and 4.2 ~~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 ensures that heavy metals and classified substances are not present in the final product. This criterion adds a level of safety to sub-criterion 4.1, which also applies to plastic materials.

Outcomes from and after 2nd AHWG meeting

No comments were received to this sub-criterion.

Further research and changes to the previous proposal

The only change proposed is to specify that the restrictions in sub-criteria 4.1 and 4.2 apply also to plastic materials, in line with the proposal for AHP (see Section 5.9.3)

6.5.3.5 4.3(e) – Cyclosiloxanes

Annex II: Previous proposal for sub-criterion 4.3.e Cyclosiloxanes
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 final product in concentrations above 10 ppm (0,001 % w/w). The 10 ppm limit is to be applied to each substance separately.
Annex II: New proposal for sub-criterion 4.3.e Cyclosiloxanes
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 ~~final product~~ silicone raw material 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 persistent organic pollutant[186]; while D5 and D6 have PBT properties[187]. However, these cyclosiloxanes are not intentionally added to the polymer, but are rather unavoidable impurities formed during the production of the polymer. Indeed, almost all cyclicsiloxanes 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.

Outcomes from and after 2nd AHWG meeting

Two comments were received to this sub-criterion.

[186] https://echa.europa.eu/substance-information/-/substanceinfo/100.008.307

[187] https://echa.europa.eu/substance-information/-/substanceinfo/100.007.969; https://echa.europa.eu/substance-information/-/substanceinfo/100.007.967

Further research and changes to the previous proposal

There was a mistake in the previous report and the proposed limit for the cyclosiloxanes is indeed 100 ppm. The only change proposed is to specify that the limit applies to the silicone raw material before the production of the cup.

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6.6 CRITERION 5 for Reusable Menstrual Cups: Packaging

Annex II: First proposal for criterion 5: Packaging

This criterion applies to primary and secondary packaging, as defined in European Parliament and Council Directive 94/62/EC ([1]). It also applies to the additional component, i.e. the bag where reusable menstrual cups are sold with.

5.1. Primary and secondary packaging

— Cardboard and paper used for the primary and secondary packaging of reusable menstrual cups shall be made of 100 % recycled material.

— Plastic used for the primary and secondary packaging of reusable menstrual cups shall be made of at least 80 % recycled material.

— Only unmixed plastic without any coating is permitted when using plastic packaging.

— Utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not allowed.

— If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 of absorbent hygiene products (annex I) shall apply.

— Cardboard and paper or plastic used for the primary and secondary packaging shall be designed for recycling in at least 95%.

5.2. Additional component: cotton bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100% organic cotton.

(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 ([2]), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton shall not be bleached with the use of elemental chlorine gas (Cl_2).

Assessment and verification:

5.1. Primary and secondary packaging

The applicant shall submit (i) a signed declaration of compliance specifying the percentages of recycled content of the primary and secondary packaging; (ii) a declaration of compliance specifying the recyclability capacity of the primary and secondary packaging; and (iii) a high resolution image of the primary packaging (where information regarding recyclable content and recyclability appear clearly).

Recycled content must be verified by complying with the EN 45557 or ISO 14021 while recyclability must be verified by complying with the EN 13430 or ISO 18604.

Equivalent 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. Invoices demonstrating the purchase of the recycled material must be provided.

5.2. Additional component: cotton bag or pouch

(a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin.

(b) The applicant shall provide a declaration from the supplier that elemental chlorine gas is not used.

([1]) *European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).*

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(2) *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*

Annex II: Second proposal for criterion 5: Packaging

This criterion ~~applies to~~ sets requirements for primary and secondary packaging, as defined in European Parliament and Council Directive 94/62/EC (1). ~~It also applies to the additional component, i.e. the bag where reusable menstrual cups are sold with.~~

Secondary packaging should be avoided or made of cardboard and paper.

(a) Primary and secondary packaging

— Cardboard and paper used for the primary and secondary packaging of reusable menstrual cups shall be made of ~~100~~ 40 and 80 % recycled material respectively.

— All (100%) cardboard and paper used for the primary and secondary packaging shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

— Plastic used for the primary and secondary packaging of reusable menstrual cups shall be made of ~~at least 80~~ a minimum 10 % recycled material (until 1st January 2028). After 1st January 2028, primary and secondary packaging made of plastic shall contain a minimum 25% recycled material.

— Only unmixed plastic without any coating is permitted when using plastic packaging.

— Utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not allowed.

— If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 of absorbent hygiene products (annex I) shall apply. If primary or secondary packaging are compostable, criterion 5 of absorbent hygiene products (annex I) shall apply.

— The content of the primary and secondary packaging (either cardboard and paper or plastic) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.

~~— Cardboard and paper or plastic used for the primary and secondary packaging shall be designed for recycling in at least 95%.~~

(b) Additional component: ~~cotton~~ bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100% sustainable certified fibres ~~organic cotton~~.

~~(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 (2), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton.~~

~~(b) Cotton shall not be bleached with the use of elemental chlorine gas (Cl_2).~~

Assessment and verification:

For (a) primary and secondary packaging:

The applicant shall submit (i) a signed declaration of compliance specifying the percentages of recycled content of the primary and secondary packaging; (ii) a declaration of compliance specifying the recyclability capacity of the primary and secondary packaging; and (iii) a high resolution image of the primary packaging (where information regarding recyclable content and recyclability appear clearly).

The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for all cardboard and paper (100%) used for the primary and secondary packaging. FSC, PEFC or equivalent schemes shall be accepted as independent third-party certification.

Recycled content shall ~~must~~ be verified by complying with the EN 45557 or ISO 14021 while recyclability shall ~~must~~ be verified by complying with the EN 13430 or ISO 18604.

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Plastic recycled content in the packaging shall comply with chain of custody standards such ISO 22095.

Equivalent methods shall ~~must~~ be accepted ~~as test methods~~ if considered equivalent by a third-party, and shall ~~must~~ be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall ~~must~~ be provided.

In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols such as the ones developed by INGEDE for paper and cardboard or RecyClass for plastics. Equivalent testing methods may be accepted if considered equivalent by a third-party.

For (b) additional component: ~~cotton~~ bag or pouch

The applicant shall provide a declaration of compliance to show that the reusable bag or pouch is made of 100% sustainable certified fibres.

~~(a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin.~~

~~(b) The applicant shall provide a declaration from the supplier that elemental chlorine gas is not used.~~

([1]) *European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).*

([2]) *Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91*

Rationale for the proposed criterion text

This criterion has been proposed in line with criterion 8 for Absorbent Hygiene Products. In this criterion guidelines on the composition of the primary and secondary packaging are specified.

Usually RMC are packed in a box made of cardboard/paper or plastic which constitutes the primary packaging. Often cups are sold in pairs having the possibility to be provided with secondary packaging. Most RMC are sold within a cloth bag or pouch made of textile which is considered additional component and it used to store the cup when not in use.

The first proposal for this criterion proposal requested:

- Primary and secondary packaging made of cardboard/paper to be 100% from recycled sources while if packaging is made from plastic, it shall be 80% recycled.
- Unmixed plastic, composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not permitted.
- Sub-criterion 4.2 for AHP applies if primary or secondary packaging is sourced from bio-based plastic.
- Primary and secondary packaging to be designed for recycling in a 95%.
- The bag provided by RMC producers shall be 100% organic cotton (criterion 3 for AHP applies).

Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

During the 2nd AHWG meeting comments on regards to criterion 5 indicated the impossibility to achieve the recycled content and recyclability targets requested for primary and secondary packaging. One comment was received in written-form addressing the same concern and touching upon the sustainability concerns over

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organic cotton used for the pouch or storage bag for the cups (considered additional component): 'the storage pouch provided with our brand are pouches made of recycled polyester materials. Cotton fibre residual on the cup surface could be an issue, and particularly organic cotton is less processed and results in more residual fibres. We have decided to opt for this material, since cotton production is very water intensive and often with materials produced from organic cotton it is not certain that the given cotton is organic but only the reflective portion of the production quantity. Other materials, particularly recycled materials, but also hemp, bamboo and cellulose fibre could also be proposed to be included in storage pouch materials, for more reduction in environmental impacts'.

Further research and changes to the previous proposal

In the absence of the use phase, the LCA screening study identified the production of cotton packaging as a hotspot in almost all relevant impact categories, and in the lower extent also cardboard packaging in some impact categories. The LCA screening study showed that the 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 case of TPE cup, 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%).

This criterion requirements have been decreased in line with comments received during and after the 2nd AHWG meeting.

The new proposal is aligned with new requests in criterion 8 for AHP where extended discussion on availability of recycled cardboard and paper and plastic materials is developed.

The requirement on organic cotton for the pouch or bag the cups are sold with, has been removed. A requirement for 100% sustainable certified fibres has been proposed.

Rationale behind the proposed 'assessment and verification'

The assessment and verification for the requirements for primary and secondary packaging are harmonised to those of criterion 8 for AHP.

In relation to the reusable bag or pouch the cups are sold with, since comments received highlighted that organic cotton is not the most suitable material for it, it is decided to request the bag to be made with 100% sustainable certified fibres for which a declaration of compliance must be provided.

Summary of changes in TR3.0

- The level of ambition of the requirements for recycled content for primary and secondary packaging have been lowered.
- Cardboard and paper used for the primary and secondary packaging of reusable menstrual cups is requested to be made of 40 and 80 % recycled material respectively.
- Plastic used for the primary and secondary packaging of reusable menstrual cups is requested to be made of 10 % recycled material. After 1st January 2028, it shall contain 25% recycled plastic.
- If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 of AHP shall apply. While if packaging is compostable, criterion 5 of AHP shall apply.
- The content of the primary and secondary packaging (either cardboard and paper or plastic) that is available for recycling shall be at least 95% by weight, while 5% residuals shall be compatible with recycling.
- A declaration of compliance supported by a valid, independently certified chain of custody certificate for all cardboard and paper (100%) used for the primary and secondary packaging is requested.

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- Plastic recycled content in the packaging shall comply with chain of custody standards such ISO 22095.
- Primary and secondary packaging is also to be tested by standard testing protocols for recyclability.
- The reusable bag or pouch shall be made of 100% sustainable certified fibres and certified as such.

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6.7 CRITERION 6 for Reusable Menstrual Cups: Guidance on the disposal of the product and of the packaging

Annex II: First proposal for criterion 6: Guidance on the disposal of the product and of the packaging
The primary packaging must contain information on the guidance of the primary packaging, the secondary packaging (if any), the additional components and the product disposal. The following information shall be written or indicated through visual symbols on the primary packaging: — that the primary packaging, the secondary packaging (if any), the additional components and the cup must not be flushed into toilets, and — how to dispose the primary packaging, the secondary packaging (if any), the additional components and the cup (at the end of its life) correctly. Assessment and verification: The applicant shall provide a high resolution image of the primary packaging (where information regarding disposal appear clearly).
Annex II: Second proposal for criterion 6: Guidance on the disposal of the product and of the packaging
The primary packaging shall ~~must~~ contain information on the guidance for the disposal of the primary packaging, the secondary packaging (if any), the additional components and for the disposal of the product ~~disposal~~. The following information shall be written or indicated through visual symbols on the primary packaging: — that the primary packaging, the secondary packaging (if any), the additional components and the cup shall ~~must~~ not be flushed into toilets, and — how to dispose correctly the primary packaging, the secondary packaging (if any), the additional components and the cup ~~(~~at the end of its life~~) correctly~~. Assessment and verification: The applicant shall provide a high resolution image of the primary 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.

Outcomes from and after 2nd AHWG meeting

No comments were received to this criterion either during or after the 2nd ADHWG meeting.

Rationale behind the proposed 'assessment and verification'

The assessment and verification for this criterion is proposed to be the same as the one of criterion 9 for AHP.

Slight modifications are proposed at this stage of the revision process to criterion 6 for RMC.

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6.8 CRITERION 7 for Reusable Menstrual Cups: Fitness for use and quality of the product

Annex II: First proposal for criterion 7: Fitness for use and quality of the product

The efficiency/quality of the product shall be at least as satisfactory as the equivalent products already on the market.

Fitness-for-use shall be tested with respect to the characteristics and parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Reusable menstrual cups shall undergo the following in-use tests: leakage protection, fit and comfort and overall performance.

Moreover, 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 must provide the biological evaluation of cytotoxicity, hemolysis, 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, hemolysis, 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 laboratories certified to implement quality management systems, no matter if internal or external.

In-use tests shall be conducted for the specific products applying for the EU Ecolabel. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups applying for the EU Ecolabel. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test only one material.

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 Competent Bodies under the respect of confidentiality

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

Additional guidelines for user tests:

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

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

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

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

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

— 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 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.

Annex II: Second proposal for criterion 7: Fitness for use and quality of the product

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

Fitness for use shall be tested with respect to the characteristics and parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

~~Reusable menstrual cups shall undergo the following in-use tests: leakage protection, fit and comfort and overall performance.~~

~~Moreover,~~ ~~f~~Fitness for use shall be tested with respect to the technical tests referred to as for

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biocompatibility of the materials used for the manufacturing of reusable menstrual cups. Biocompatibility test ~~must~~ shall provide the biological evaluation of cytotoxicity, ~~hemolysis,~~ 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, ~~hemolysis,~~ 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 laboratories certified to implement quality management systems~~, no matter if internal or external~~.

In-use tests shall be conducted for the specific products applying for the EU Ecolabel. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups applying for the EU Ecolabel. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test only one material. 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 ~~C~~competent ~~B~~bodies under the respect of confidentiality issues. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the ~~products~~ 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 user tests:

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

— Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a

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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 ~~should~~ not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.

— For all in-use tests (leakage protection, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, ~~which could for instance mean that~~ with a rate above 60 ~~is~~ assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80% of the consumers testing ~~or that~~ the product shall rate it ~~has been assessed~~ 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 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 for such it is harmonised when possible with it.

The aim of this criterion is to address the performance tests that RMC 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 friendlier but poor in performance/inefficient.

In the first proposal, it was requested that RMC shall be tested for (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, sensitization, 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 acc**ording to ISO 10993 or USP Class VI) was provided in the previous TR2.0.

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Outcomes from and after 2nd AHWG meeting

While all comments received can be found in the annexed Table of Comment, the sections below address the main comments received.

In the 2nd AHWG meeting, split views were shared by stakeholders in relation to the biocompatibility testing. One stakeholder indicated that it did not see the need to repeat the test on the final product. At least not for liquid silicone. Also, this would be in line with reducing animal testing (used in biocompatibility test). Perhaps only additional test should be considered with test not using animals (e.g. cytotoxicity).

Another stakeholder supported testing in the final product rather than in the raw materials only, as in this way the imprint associated with the manufacturing process would also be measured. Testing in the raw material would not inform about potential changes or contaminations that might occur.

A different stakeholder made a comment on the validity of the method when a comparison is made between the user and testing conditions (i.e. pH choice, like vaginal tract). It is not sure whether this would make a difference. Another stakeholder affirmed that there is a flexibility in the method to specific particular aspects.

A stakeholder mentioned that in their institution, tensile strength was tested for menstrual cups.

It was discussed that hemolysis testing might not be needed in order to decrease the number of testing and also avoid the performance of unnecessary testing on animals.

Another stakeholder suggested to remove the following sentence from the text formulated for criterion 7: "*The efficiency/quality of the product shall be at least as satisfactory as the equivalent products already on the market*".

Comments received after the 2nd AHWG meeting addressed some of the discussions during the meeting (5 comments):

- Mostly explained there is no need to perform biocompatibility tests to final RMC.
- Removal of hemolysis testing.
- Clarification of materials to be subject to technical testing.
- Removal of the need to repeat technical testing on 5 samples ('from a toxicological, an ethical and from an animal-welfare points of view according to Directive 2010/63/EU[188]).
- Biocompatibility can be assessed by both ISO 10993 and USP Class VI.

Further research and changes to the previous proposal

Given the absence of harmonised standards or widely accepted industry methods, most of manufacturers test the materials used for the production of reusable menstrual cups according to the biocompatibility test methods described in the ISO 10993 series. This has been identified as the most common testing procedure for silicone and other elastomer cups.

ISO 10993 standard series

The ISO 10993 standardised method series is applied by all RMC suppliers contacted. This ISO 10993 has been developed by the International Organization for Standardization for the biological evaluation of medical devices. It is a multi-part standard aimed to evaluate the effects of medical device materials on the body. Most of the parts of the ISO 10993 standard series discuss appropriate methods to conduct biological tests that may be identified when following Part 1 of the standard[189].

Another standard identified by stakeholders is the USP Class VI. The USP Class VI standard is a designation from the U.S. Pharmacopeia, which refers to a panel of tests that are used to determine the biological reactivity of the silicone in vivo. There are other USP classes as well, but USP Class VI is the strictest. There is

[188] OJ L 276, 20.10.2010, p. 33–79, Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

[189] As stated in the AHP Preliminary Report, 2021. https://susproc.jrc.ec.europa.eu/product-bureau/product-groups/415/documents

not a designation for Europe. However, some of the tests included in the ISO 10993 series seem to be very similar.

Biocompatibility certification in accordance to the ISO 10993 can be referred as:

- cytotoxicity,
- hemolysis,
- pyrogenicity,
- sensitization,
- dermal irritation and,
- implantation (90 days).

According to comments received from stakeholders, hemolysis testing is not relevant since RMC do not get into contact with circulating blood, and for such this requisite on hemolysis has been deleted.

On the other hand, when compliance to the USP Class VI was certified, acute systemic toxicity, intracutaneous toxicity and implantation test were listed.

Rationale behind the proposed 'assessment and verification'

The assessment and verification for this criterion addresses some practical issues related to the flexibility of the test, the representativeness of the sample of consumers and on the reliability of the results through independent assessment.

For the in-use tests, consumer panel testing is proposed as the most reliable method while for the technical biocompatibility tests, ISO 10993 series or the USP Class VI standard must be followed.

In-use tests

The assessment of the overall performance through consumer tests is considered to be fulfilled if the score received is at least 60 from 80% or more of the consumers tested. In order to clarify this, the text has been modified: *'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)'.* This clarification has been added in line with criterion 10 for AHP.

Technical tests

A clarification has been introduced as only materials used in the manufacturing of cups shall undergo technical testing, not the final products. Text included reads as: *'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)'.*

The referral to the need to test a minimum of five samples have been deleted as there is another specification in relation to *'materials tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included'.* In this line the word '*products'* has been replaced by '*materials'* as it is been clarified that only the materials conforming the final RMC shall under-go technical testing (biocompatibility) and not the final RMC.

Summary of changes in TR3.0

- Hemolysis has been removed from the biocompatibility testing according to ISO 10993 series.
- **Clarification in 'A&V' wording** for all in-use tests and 'technical tests'.

6.9 CRITERION 8 for Reusable Menstrual Cups: Information for the user

Annex II: Previous proposal for criterion 8: Information for the user
The manufacturer shall make sure that the user receives at least the following information: i. How to choose the right size of cup. Such information must be placed where it can be accessed by the user before purchase (e.g. on the packaging). ii. How to correctly wear the cup to avoid leakage and/or discomfort. iii. How long to wear the cup before emptying it. iv. How to clean the cup before and after use during the same menstrual cycle, including, as a minimum, information about the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. It should also be mentioned that boiling is not needed when cleaning the cup during the same menstrual cycle. v. How to clean and store the cup between menstrual cycles, including, as a minimum, information about 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. vi. 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. If the user is recommended to use soap, the following sentence should be included: "*use the soap sparingly in order to minimise the impact on the environment*". Moreover, information about the risk of developing toxic shock syndrome must be provided, including how to recognise it (what are the symptoms) and how to react in case of developing it. Assessment and verification: The applicant shall provide the competent body with a sample of the information sheet and, if relevant, the packaging sold with the cup displaying the information for the user.
Annex II: New proposal for criterion 8: Information for the user
The product shall be accompanied by a leaflet containing the instruction for use. The manufacturer shall make sure that the user receives at least the following information: i. 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). ii. How to correctly wear the cup to avoid leakage and/or discomfort. iii. 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 ~~should~~ shall be placed both on the packaging and on the instructions for use. iv. How to clean the cup before and after use during the same menstrual cycle, 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. ~~It should also be mentioned that boiling is not needed when cleaning the cup during the same menstrual cycle.~~ This information should be backed up by test studies. v. How to clean and store the cup between menstrual cycles, including, as a minimum, information about the importance of washing the hands, the importance of boiling (~~yes/no, and if yes~~ 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. vi. 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.

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If the user is recommended to use soap, the following sentence should be included: "use the soap sparingly in order to minimise the impact on the environment".

Moreover, information about the risk of irritation, discomfort, injury, and developing toxic shock syndrome shall be provided. [to be added to the User Manual: For the toxic shock syndrome, the importance of washing the hands and the longest wearing time of the cup shall be stated. Information shall also be given on how to recognise it what are the related symptoms, and how to react in case of developing the symptoms].

Information shall also be given on not using the cup during non-flow days of the cycle and on the precautions to be taken by women using intra-uterine devices for contraception.

Assessment and verification:

The applicant shall provide ~~the competent body with~~ a sample of the information sheet and, if relevant, the packaging sold with the cup displaying the information for the user. The applicant shall also provide relevant studies, e.g. biological risk assessments or toxicology studies, supporting the guidance about the wearing time of the cup. Validation tests for the cleaning of the cup shall also be submitted.

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 results, 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 avoiding 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

Outcomes from and after 2nd AHWG meeting

Eight comments were received to this sub-criterion, especially pointing to the importance of recommending the right wearing time. All comments can be found in the Table of Comment.

Further research and changes to the previous proposal

The wearing time of the reusable menstrual cup was the most commented aspect of criterion 8, especially since it is linked to the risk of developing the toxic shock syndrome (TSS).

Literature, studies and guidance of different brands of reusable menstrual cups point to a recommended wearing time of 4-12 hours[190,191,192,193,194]. While there is no official medical advice on the recommended

[190] 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/CONSO2016SA0108Ra.pdf

[191] 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

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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 perception of the risks on a sample of 1065 French women from 13 to 50 years of age. As reported 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].

The conclusion of the ANSES study on the use of feminine hygiene products (all, external and internal) and on the microbiological risk of developing TSS (tampons and menstrual cups) are as follows:

- on the use of feminine hygiene products, it is recommended:
    - To improve information for women on good hygiene practices to reduce the risk of infection, by means of institutional communication;
    - To increase awareness among information relays such as health professionals, particularly general practitioners and gynaecologists, of the need to inform women about hygiene practices;
    - That each internal feminine hygiene product sold (tampon, menstrual cup) should be systematically accompanied by a package leaflet with instructions for use and hygiene recommendations (on wearing time, washing menstrual cups between each use, etc.);
    - Due to misuses of internal feminine hygiene products, particularly tampons (wearing them during episodes of abnormal vaginal discharge, simultaneous wearing of two tampons, etc.), to use them in accordance with the manufacturers' recommendations;
- on the microbiological risk (menstrual TSS), it is recommended:
    - To improve information for women on menstrual TSS by promoting the dissemination of information on this risk via health professionals (general practitioners, gynaecologists, nurses, school doctors and nurses, midwives, etc.) or more generally through information campaigns or dedicated internet pages;
    - That all manufacturers improve user information on the existence of menstrual TSS by clearly indicating this risk on the packaging and instructions for use of internal feminine hygiene products (tampons and menstrual cups);
    - That users comply with the manufacturers' recommendations, particularly those regarding how long tampons and cups can be worn, wearing a tampon only during menstruation and using tampons with the lowest absorbency needed for their menstrual flow, in order to avoid wearing these products longer than the recommended time;
    - To improve how key information (symptoms of menstrual TSS, wearing time, etc.) is displayed on the packaging – for example by creating a logo – and in the instructions for use;
    - That women who have already had menstrual TSS refrain from using internal feminine hygiene products (tampons and menstrual cups);
    - That external feminine hygiene products should be used at night to reduce the risk of developing menstrual TSS, given the length of time they are worn.

It is important to take into account that the majority of 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.

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[192] Lunacopine, available at: https://www.bivea.fr/marque/8-lunacopine?gclid=EAIaIQobChMItdrBup28-gIVx-J3Ch1SNAMNEAAYASAAEgJZYvD_BwE (accessed 30.09.2022)

[193] 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)

[194] 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

As it can be understood from the conclusions of the ANSES opinion, clear guidance on the wearing time of the reusable menstrual cup is important. However, the ANSES study does not conclude on a recommended wearing time; rather, it recommends that manufacturers should provide clear guidance in the instructions for use. During the AHWG2, it was mentioned that France is preparing a law on the use of menstrual cups; however, evidence could not be found.

For this reason, and given the absence of an official guidance, it is not proposed to set a maximum wearing time in criterion 8. Rather, it is proposed that the wearing time recommended by manufacturers should be proven by submitting relevant studies supporting the guidance. Relevant studies include biological risk assessment and toxicology studies.

Moreover, given the ANSES's findings on the fact that only one woman out of three wash her hands before changing protections, it is proposed to add to the instructions information on the importance of washing the hands to avoid the transmission of bacteria.

Finally, given available evidence on the possible risk of menstrual cups to dislodge intra-uterine devices for contraception[190,195], such information shall also be made available.

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[195] Long J., Schreiber C., Creinin M.D., Kaneshiro B., Nanda K., Blithe D., 2020, Menstrual Cup Use and Intrauterine Device Expulsion in a Copper Intrauterine Device Contraceptive Efficacy Trial [OP01-1B]. Obstetrics & Gynecology 135, doi: 10.1097/01.AOG.0000662872.89062.83

6.10 CRITERION 9 for Reusable Menstrual Cups: Corporate Social Responsibility with regards to Labour Aspects

Annex II: First proposal for criterion 9: Corporate Social Responsibility with regard to Labour Aspects
Requirements in this criterion shall apply to the final reusable menstrual cup manufacturing site. These standards shall be communicated to production sites along the supply chain used to manufacture the final product. Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy ([1]), the UN Global Compact (Pillar 2) ([2]), the UN Guiding Principles on Business and Human Rights ([3]) and the OECD Guidelines for Multinational Enterprises ([4]), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the ILO's fundamental conventions and the supplementary provisions below have been respected at the final reusable menstrual cup manufacturing site. Fundamental conventions of the ILO: (i) Child Labour: — Minimum Age Convention, 1973 (No 138); — Worst Forms of Child Labour Convention, 1999 (No 182). (ii) Forced and Compulsory Labour: — Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention; — Abolition of Forced Labour Convention, 1957 (No 105). (iii) Freedom of Association and Right to Collective Bargaining: — Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87); — Right to Organise and Collective Bargaining Convention, 1949 (No 98). (iv) Discrimination: — Equal Remuneration Convention, 1951 (No 100); — Discrimination (Employment and Occupation) Convention, 1958 (No 111). Supplementary provisions: (v) Working Hours: — ILO Hours of Work (Industry) Convention, 1919 (No 1). (vi) Remuneration: — ILO Minimum Wage Fixing Convention, 1970 (No 131); — Living wage: The applicant shall ensure that wages paid for a normal working week shall always meet at least legal or industry minimum standards, are sufficient to meet the basic needs of personnel and provide some discretionary income. Implementation shall be audited with reference to the SA8000 guidance on 'Remuneration'. (vii) Health & Safety: — ILO Safety in the use of chemicals at work Convention, 1981 (No 170); — ILO Occupational Safety and Health Convention, 1990 (No 155). In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues. The audit process shall include consultation with external stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. The applicant shall publish the

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aggregated results and key findings from the audit online in order to provide evidence of their supplier's performance to interested consumers.

Assessment and verification:

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

The third-party site audit shall be carried out by private auditors qualified to assess the compliance of the AHP industry supply chain with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective ([1]) and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a national authority.

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

([1]) ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.

([2]) United Nations Global Compact (Pillar 2) https://www.unglobalcompact.org/what-is-gc/participants/141550

([3]) Guiding Principles for Business and Human Rights https://www.unglobalcompact.org/library/2

([4]) OECD Guidelines for Multinational Enterprises https://www.oecd.org/daf/inv/mne/48004323.pdf

Annex II: Second proposal for criterion 9: Corporate Social Responsibility with regard to Labour Aspects

This criterion sets ~~R~~requirements ~~in this criterion shall apply~~ applying to the final reusable menstrual cup manufacturing site.

~~These standards shall be communicated to production sites along the supply chain used to manufacture the final product~~.

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy ([1]), the UN Global Compact (Pillar 2) ([2]), the UN Guiding Principles on Business and Human Rights ([3]) and the OECD Guidelines for Multinational Enterprises ([4]), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts ~~ILO's fundamental conventions~~ and the supplementary provisions below have been respected at the final ~~AHP~~ assembly site for the product.

Fundamental conventions of the ILO:

(i) Child Labour:

— Minimum Age Convention, 1973 (No 138)~~;~~

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

(ii) Forced and Compulsory Labour:

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

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

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

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

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

(iv) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)~~;~~

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— 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~~ing~~ week (not exceeding 48 hours) shall be ~~always meet at least legal or industry minimum standards, are~~ sufficient to afford ~~meet the~~ basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, ~~personnel~~ and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 [(5)] guidance on 'Remuneration'.

(vii) Health & Safety:

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

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

— 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, the ~~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 ~~supplier's~~ performance to interested consumers.

~~These standards shall be communicated to production sites along the supply chain used to manufacture the final product.~~

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

~~The T~~third-party site audits shall be carried out by ~~private~~ auditors qualified to assess the compliance of the ~~AHP~~ industry manufacturing sites ~~supply chain~~ with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective ([1]) and where the scope of the inspection systems covers the areas listed above ([1]), by labour inspector(s) appointed by a public ~~national~~ authority.

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

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.

([1]) ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.

([2]) United Nations Global Compact (Pillar 2), https://www.unglobalcompact.org/what-is-gc/participants/141550

([3]) Guiding Principles for Business and Human Rights, https://www.unglobalcompact.org/library/2

([4]) OECD Guidelines for Multinational Enterprises, https://www.oecd.org/daf/inv/mne/48004323.pdf

([5]) Social Accountability International, Social Accountability 8000 International Standard, http://www.sa-intl.org

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 5.12 of this report.

Outcomes from and after 2nd AHWG meeting

No specific comments were received for this criterion during or after the 2nd AHWG meeting, however some stakeholders remarked their comments to criterion 11 for AHP were also valid for criterion 9 for RMC.

In line with the comments, this criterion has modified in harmonisation with requests for AHP.

Rationale behind the proposed 'assessment and verification'

The assessment and verification for this criterion is proposed to be the same as the one of criterion 11 for AHP.

Summary of changes in TR3.0

- Several modifications are included in harmonisation with the EU Ecolabel Criteria for Electronic Displays and by means of new additions from comments made by stakeholders during and after the 2nd AHWG in written form.
- Inclusion of considerations in determining the minimum wage.

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- In (vii) Health & Safety, ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148), was added.
- Addition of (viii) Social protection and inclusion and (ix) Fair dismissal considerations.
- Inclusion of alternative mechanisms to express their grievances (in relation to free association).
- In relation to audits: wording has been modified including a referral to industry independent organisation, unannounced spot inspections by industry-independent or meaningful consultations.
- Request for supporting details for audits: (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.
- In the 'Assessment and verification' section, wording has been modified for an easier understanding

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6.11 CRITERION 10 for Reusable Menstrual Cups: Information appearing on the EU Ecolabel

Annex II: First proposal for criterion 10: Information appearing on the EU Ecolabel
The EU Ecolabel logo may be applied on the primary packaging of the product. The optional label with box shall contain the following text: — 'Product designed to reduce impact on the environment', — 'Restricted use of hazardous substances', — 'Verified performance'. The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The photograph provided must be a high resolution image of the product primary packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.
Annex II: First proposal for criterion 10: Information appearing on the EU Ecolabel
The EU Ecolabel logo may be ~~applied~~ displayed on the primary packaging of the product. If the optional label with text box is used, it shall contain the following three statements ~~The optional label with box shall contain the following text~~: — '~~Product~~ Ddesigned to reduce impact on the environment', — ~~'Restricted use of hazardous substances',~~ — 'Fulfils strict requirements on harmful substances', — 'Verified performance'. The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The provided photograph ~~provided must~~ shall be a high resolution image of the product primary packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

Rationale for the proposed criterion text

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

This criterion has been proposed in line with criterion 12 for Absorbent Hygiene Products.

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Outcomes from and after 2nd AHWG meeting

No specific comments were received in relation to this criterion during the 2nd AHWG meeting. One comment received in written form after the meeting mentioned that the claim 'Product designed to reduce impact on the environment' can be misleading if the user phase accounts for over 98% of environmental impacts.

Further research and changes to the previous proposal

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 case of silicone cups, and 96% (Acidification) and 99% (Ecotoxicity –freshwater) in 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 looked up by means of criterion 1 (emissions during production of raw materials).

In addition, the study concluded that silicone production was the most relevant process in 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 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).

It is worth noting the contribution of criteria 4 (excluded and restricted substances) and 7 (fitness for use and quality of the product) on the safety and performance of the ecolabelled products.

All in all, it is sufficiently proven that EU ecolabelled RMC would:

- be designed to reduce impact on the environment,
- fulfil strict requirements on harmful substances,
- have verified performance.

Rationale behind the proposed 'assessment and verification'

The assessment and verification for this criterion is proposed to be the same as the one of criterion 12 for AHP.

Summary of changes in TR3.0

This criterion has slightly been modified in harmonisation with requests for AHP, highlighting the optional aspect of the criterion.

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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 license holders and possible applicants.

The scope of this product has been enlarged to add also 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 requirements, in particular as to reinforce to product's circularity requirements:

- 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 levels. A new criterion on the energy use during the production of fluff pulp has also been added. 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, with the addition of a requirement on bio-based plastic content.
- In criterion 6 on material efficiency in the manufacturing, in a closer line to 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.
- A new criterion on compostability is proposed (criterion 5), as well as a new criterion (criterion 8) for the packaging, requiring primary and secondary packaging to be sourced from recycled materials (40% if made of cardboard/paper and 10% if made of plastic) and both to be designed for recycling (95%). The plastic recycled content would increase up to 25% after the 1st January 2028. These requirements for recycled content for primary packaging shall only apply when individual wrapping of the product is used.
- Finally, with respect to criterion 7 on chemical substances, its ambition level has been significantly increased, with much lower concentration levels allowed and additional requirements, for example on isothiazolinones, 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 a hazard profile is drastically reduced, in line with the recent Chemicals Strategy for Sustainability.

In conclusion, the revised criteria for absorbent hygiene products 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 its packaging, which has been particularly increased with new requirements on bio-based plastic, biodegradable content and special features of the secondary packaging, which shall be recyclable and with a certain recycled content (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' carbon and environmental footprints, especially ensuring EU Ecolabel AHP are fit for a climate neutral and a 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 its safety characteristics that do not allow the inclusion of recycled material in the product, this proposal for revised EU Ecolabel criteria allows to single out those absorbent hygiene products with a better environmental profile.

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Reusable menstrual cups

The proposed criteria for reusable menstrual cups are the first of its kind, since so far no other schemes have developed environmental criteria for its performance, and allow to award the EU Ecolabel to a product that represents a circular alternative to 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. The pouch or bag the cups are sold with shall be made from 100% SFM fibres.

As the use phase was found as the most impacting one from an environmental point of view, requirements were developed on the fitness for use of the cup and the information for the user. These two criteria ensure a 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 working rights of the workers have been respected.

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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
BPA	Bisphenol-A
BREF	Best Available Techniques Reference Document
CLP	Classification, Labelling and Packaging
CO_2	Carbon dioxide
COD	Chemical Oxygen Demand
CTP	Computer to Plate
DIBP	Diisobutyl phthalate.
DIPN	Diisopropylnaphthalene.
EMAS	Eco Management and Audit Scheme
EN	European Norm
EU	The European Union
EUEB	The European Union Eco-labelling board
FSC	Forest Stewardship Council
GMO	Genetically modified organism
IPPC	Integrated Pollution Prevention and Control
ISO	International Standardisation Organisation
LCA	Life Cycle Assessment
NGO	Non-governmental organizations
NOx	Nitrogen Oxides
MD	Medical Device
PEFC	Programme for the Endorsement of Forest Certification
PAH	Polycyclic aromatic hydrocarbons.
PBT	Persistent Bioaccumulative Toxic

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PP	Printed paper products
PVC	Polyvinyl chloride
PUR	Polyurethane
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMC	Reusable Menstrual Cup
RSB	Roundtable on Sustainable Biomaterials
SETAC	Society of Environmental Toxicology and Chemistry
SO_2	Sulphur Dioxide
TOC	Total organic carbon, expressed as C (in water or in gases)
TVOC	Total volatile organic carbon, expressed as C (in air).
VOCs	Volatile Organic Compounds
vPvB	Very persistent, very bioaccumulative

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List of figures

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List of tables

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ANNEX I. Substitution information and Derogation request form

Stakeholders should fulfil to communicate the derogation from of substances that cannot be replaced and are not able to comply with article 6 (6) of the EU Ecolabel Regulation.

1. Common information requirements

To be treated as confidential?	☐Yes ☐No

Contact name	
Organisation	
Email	
Telephone No.	
Supplementary documents attached	

1a. Chemical substance name(s)	
1b. CAS, EC or Annex VI numbers	
1c. Current EU regulatory status	
1d. CLP Classifications from the EU Ecolabel hazard listing	
1e. Proportional contribution to final product classification (for mixture ingredients)	
1f. Existing scientific evidence and risk assessments relating to the substance	
1g. Functional need and significance to the final product	

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1h. Typical concentration in the final product and specific components or articles	

2. Additional information required for derogation requests

2a. The relevance of the hazard classification(s) along the life cycle of the product (e.g. manufacturing, use, disposal)	
2b. Market availability of alternatives and the potential for substitution	

3. Additional information required about substitutes

3a. Comparative evaluation of environmental performance	
3b. The relevance of the hazard substitution along the life cycle of the product (e.g. manufacturing, use, disposal)	
3c. Compliance with product performance and functional requirements	
3d. Market diffusion and technical maturity	

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