

# DECISIONS

## COMMISSION DECISION (EU) 2023/1809

of 14 September 2023

**establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups**

*(notified under document C(2023) 6024)*

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel <sup>(1)</sup>, and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) Commission Decision 2014/763/EU <sup>(2)</sup> established EU Ecolabel criteria and related assessment and verification requirements for the product group 'absorbent hygiene products'. The period of validity of those criteria and requirements has been extended to 31 December 2023 by Commission Decision (EU) 2018/1590 <sup>(3)</sup>.
- (4) In order to better reflect best practice in the market for the product group and to take account of policy developments, potential future windows of opportunity for increased uptake and the market's demand for sustainable products, it is appropriate to establish a new set of criteria for absorbent hygiene products. As a sustainable alternative with a potential growing market, it is also appropriate to establish a set of criteria for reusable menstrual cups.
- (5) The EU Ecolabel Fitness Check Report <sup>(4)</sup> of 30 June 2017, reviewing the implementation of Regulation (EC) No 66/2010, concluded on the need to develop a more strategic approach for the EU Ecolabel, including the bundling of closely related product groups where appropriate.
- (6) In line with those conclusions and after consulting the EU Ecolabelling Board, it is appropriate to bundle the product group 'absorbent hygiene products' with the product group 'reusable menstrual cups' in the same Decision, as the two product groups fulfil the same function.

<sup>(1)</sup> OJ L 27, 30.1.2010, p. 1.

<sup>(2)</sup> Commission Decision 2014/763/EU 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).

<sup>(3)</sup> Commission Decision (EU) 2018/1590 of 19 October 2018 amending Decisions 2012/481/EU, 2014/391/EU, 2014/763/EU and 2014/893/EU as regards the period of validity of the ecological criteria for the award of the EU Ecolabel for certain products, and of the related assessment and verification requirements (OJ L 264, 23.10.2018, p. 24).

<sup>(4)</sup> Report from the Commission to the European Parliament and the Council on the review of implementation of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and the Regulation (EC) No 66/2010 of the Parliament and of the Council of 25 November 2009 on the EU Ecolabel (COM(2017) 355 final).

- (7) In line with Regulation (EC) No 66/2010, the EU Ecolabel shall not be awarded to any type of medical device, including those defined in Regulation (EU) 2017/745 of the European Parliament and of the Council <sup>(5)</sup>.
- (8) The new Circular Economy Action Plan for a cleaner and more competitive Europe <sup>(6)</sup> adopted on 11 March 2020 stipulates that the durability, recyclability and recycled content requirements are to be more systematically included in the EU Ecolabel criteria.
- (9) The revised EU Ecolabel criteria for absorbent hygiene products and reusable menstrual cups should aim to promote products that have limited environmental impact along their life cycle, and that are produced using material-efficient and energy-efficient processes. In particular, the revised EU Ecolabel criteria promote products that have limited impacts in terms of emissions to water and to air during production, that use raw materials sourced from sustainably managed forests, and that fulfil strict requirements on harmful substances. Moreover, in order to contribute towards the transition to a more circular economy, the criteria promote the use of paper and/or cardboard packaging, when possible, as an alternative to plastic packaging, and promote packaging with recycled content and which can be easily recycled.
- (10) Reusable products made of textiles are appearing on the market as an alternative to single-use products. The revised EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups do not apply to these reusable textile alternatives, whose environmental hotspots and ecological criteria are planned to be specifically investigated for the purposes of the revision of EU Ecolabel criteria for textile products established by Commission Decision 2014/350/EU <sup>(7)</sup>.
- (11) The new criteria and related assessment and verification requirements should remain valid until 31 December 2029, taking into account the innovation cycle for the product groups.
- (12) For reasons of legal certainty, Decision 2014/763/EU should be repealed.
- (13) A transitional period should be available to producers whose products have been awarded the EU Ecolabel for absorbent hygiene products on the basis of the criteria set out in Decision 2014/763/EU, so that they have sufficient time to adapt their products to comply with the new criteria and requirements. For a limited period after adoption of this Decision, producers of absorbent hygiene products should be allowed to submit applications based either on the criteria established by Decision 2014/763/EU or on the new criteria established by this Decision. It should also be allowed to use EU Ecolabels awarded in accordance with the criteria established by Decision 2014/763/EU for a transitional period.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

#### *Article 1*

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. The product group 'absorbent hygiene products' shall include products for both private and professional use.

<sup>(5)</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

<sup>(6)</sup> 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) (OJ C 364, 28.10.2020, p. 94).

<sup>(7)</sup> Commission Decision 2014/350/EU of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (OJ L 174, 13.6.2014, p. 45).

2. The product group 'absorbent hygiene products' shall not include products falling under the scope of Regulation (EU) 2017/745.

#### *Article 2*

1. The product group 'reusable menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body whose function is to retain and collect menstrual fluid, and which are made of silicone or other elastomers.
2. The product group 'reusable menstrual cups' shall not include products falling under the scope of Regulation (EU) 2017/745.

#### *Article 3*

1. In order for a product to be awarded the EU Ecolabel under Regulation (EC) No 66/2010 for the product group 'absorbent hygiene products', it shall fall within the definition of that product group as specified in Article 1 of this Decision, and shall comply with the respective criteria and related assessment and verification requirements set out in Annex I to this Decision.
2. In order for a product to be awarded the EU Ecolabel under Regulation (EC) No 66/2010 for the product group 'reusable menstrual cups', it shall fall within the definition of that product group as specified in Article 2 of this Decision and shall comply with the respective criteria and related assessment and verification requirements set out in Annex II to this Decision.

#### *Article 4*

The EU Ecolabel criteria for the product group 'absorbent hygiene products' and for the product group 'reusable menstrual cups' and the related assessment and verification requirements shall be valid until 31 December 2029.

#### *Article 5*

1. For administrative purposes, the code number assigned to the product group 'absorbent hygiene products' shall be '047'.
2. For administrative purposes, the code number assigned to the product group 'reusable menstrual cups' shall be '055'.

#### *Article 6*

Decision 2014/763/EU is repealed.

#### *Article 7*

1. Applications for the EU Ecolabel for the product group 'absorbent hygiene products', as defined in Decision 2014/763/EU, submitted before the date of application of this Decision shall be evaluated in accordance with the criteria set out in Decision 2014/763/EU.
2. Applications for the EU Ecolabel for products falling within the product group 'absorbent hygiene products' submitted on or within two months from the date of application of this Decision may be based, by the applicant, on, and evaluated in accordance with, either the criteria set out in this Decision, or on the criteria set out in Decision 2014/763/EU.
3. EU Ecolabel licences awarded on the basis of an application evaluated in accordance with the criteria set out in Decision 2014/763/EU may be used for 12 months from the date of application of this Decision.

*Article 8*

This Decision is addressed to the Member States.

It shall apply from 21 September 2023.

Done at Brussels, 14 September 2023.

*For the Commission*  
Virginijus SINKEVIČIUS  
*Member of the Commission*

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## ANNEX I

**EU Ecolabel criteria for awarding the EU Ecolabel to absorbent hygiene products**

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

**Assessment and verification requirements**

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

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate.

Competent bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes, and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

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

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

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

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

- (a) a description of the product, together with the weight of the individual product units and the total weight of the product;
- (b) a description of the sales packaging, together with its total weight, if applicable;
- (c) a description of the grouped packaging, together with its total weight, if applicable;
- (d) a description of the separate components, together with their individual weight;
- (e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

For the purposes of this Annex, the following definitions shall apply:

- (1) 'additives' means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;
- (2) 'biobased plastic' means a plastic manufactured from biobased raw materials as feedstock for its production. While conventional plastics are made from fossil resources (oil and natural gas), biobased plastics are made from biomass. The biomass currently originates mainly from plants grown specifically to be used as feedstock to substitute fossil resources, such as sugarcane, cereal crops, oil crops or non-food sources like wood. Other sources are organic waste and by-products, such as used cooking oil, bagasse and tall oil. Plastics can be fully or partially made from biobased feedstock. Biobased plastics can be both biodegradable and non-biodegradable;
- (3) 'cellulose pulp' means a fibrous material mainly composed of cellulose and obtained from the treatment of lignocellulosic materials with one or more aqueous solutions of pulping and/or bleaching chemicals;

- (4) 'component' means one or several materials and chemical products that together fulfil a desirable function in the absorbent hygiene product, such as an absorbent core, adhesives, or an outer barrier film;
- (5) 'composite packaging' means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;
- (6) 'grouped packaging', also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;
- (7) 'impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg);
- (8) 'ingoing substance' means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;
- (9) 'man-made cellulose fibres', also known as regenerated fibres, means fibres produced from the raw material cellulose which include viscose, modal, lyocell, cupro and triacetate;
- (10) 'materials' mean the materials constituting different components of an absorbent hygiene product, such as fluff pulp, cotton or polypropylene (PP);
- (11) 'packaging' means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:
  - (a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;
  - (b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;
  - (c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc.;
- (12) 'plastic materials', also referred to as 'plastics', means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(1)</sup>, to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;
- (13) 'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a 'monomer unit' means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC) No 1907/2006;
- (14) 'product unit' means the smallest item that can be used by the consumer and that fulfils the product's function;

<sup>(1)</sup> 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).

- (15) 'recyclability' means the amount (mass or percentage) of an item available for recycling;
- (16) 'recycled content' means the amount of an item (by area, length, volume or mass) that is sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or to the packaging in this case;
- (17) 'recycling' means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council <sup>(2)</sup>, any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;
- (18) 'sales packaging', also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;
- (19) 'separate component', also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of absorbent hygiene products, it is any component with protective or hygienic function that is removed before the use of the product, e.g. the individual wrapping or film where some absorbent hygiene products are contained within the sales packaging (mainly for tampons and sanitary pads), the release liner and paper in baby diapers and sanitary pads, or the applicator for tampons;
- (20) 'substances identified to have endocrine disrupting properties', also referred to as endocrine disruptors, means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 of the European Parliament and of the Council <sup>(3)</sup> or Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(4)</sup>, or Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(5)</sup>;
- (21) 'super absorbent polymers' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass;
- (22) 'synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by:
- a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;
  - chemical modification of natural or synthetic macromolecules;
  - microbial fermentation.

### **Criterion 1. Fluff Pulp**

This criterion applies to fluff pulp that represents  $\geq 1$  % w/w of the final product.

#### **1.1. Sourcing of fluff pulp**

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

<sup>(2)</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

<sup>(3)</sup> Regulation (EU) No 528/2012 of the European Parliament and Council of 22 of May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

<sup>(4)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(5)</sup> 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).

A minimum of 70 % of the wood raw materials used for the production of the fluff pulp shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of the wood raw materials, including any virgin wood material, shall be controlled wood covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing the chain of custody and/or the Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

#### **Assessment and verification:**

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

In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70 % of the wood raw materials used for the production of the fluff pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

If the fluff pulp is used in an air-laid material, then the air-laid material supplier shall allocate credits to the air-laid delivered to the product, providing invoices to support the number of credits allocated.

For the remaining proportion of wood raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30 % and that it is controlled wood covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material. In case the certification scheme does not specifically require that all virgin material is sourced from non-GMO species, additional evidence shall be provided to demonstrate this.

#### **1.2. Bleaching of fluff pulp**

The pulp used in the product shall not be bleached with the use of elemental chlorine (Cl<sub>2</sub>) gas.

In the case of elemental chlorine free (ECF) pulp, the average annual adsorbable organically bound halogens (AOX) emissions, expressed in kg/air dried tonne (ADt), from the production of each pulp used in EU Ecolabel products shall not exceed 0,140 kg/ADt.

#### **Assessment and verification:**

The applicant shall provide a declaration of compliance with this criterion, supported by a test report performed using the ISO 9562:2004 test method, including the AOX emissions relative to the ECF bleached pulp, expressed as kg AOX/ADt pulp. In case different pulp quality grades are used, the applicant shall provide the individual AOX emission corresponding to each pulp. Equivalent methods may be accepted as test methods if considered equivalent by a third-party, and shall be accompanied by detailed calculations showing compliance with this requirement and related supporting documentation.

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

Information on the AOX emissions shall be expressed as the annual average from at least 12 measurements taken at least every month. In case of a new or rebuilt production plant, measurements shall be based on at least 45 subsequent days of stable running of the plant. The supporting documentation shall include an indication of the measurement frequency.

AOX shall only be measured in processes where chlorine compounds are used for bleaching the pulp (ECF bleaching). AOX does not need to be measured in the effluent from pulp production without bleaching or where bleaching is performed with chlorine-free substances.



The applicant shall also provide a declaration from the pulp manufacturer that elemental chlorine (Cl<sub>2</sub>) gas was not used.

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

### 1.3. Emissions from fluff pulp production to water (chemical oxygen demand – COD and phosphorus (P)), and to air (sulphur compounds (S) and NO<sub>x</sub>)

The emissions to water and to air from the pulp production shall be expressed in terms of points (P<sub>COD</sub>, P<sub>P</sub>, P<sub>S</sub>, P<sub>NO<sub>x</sub></sub>). Points are calculated by dividing the actual emission value by the reference values reported in Table 1.

— None of the individual points P<sub>COD</sub>, P<sub>P</sub>, P<sub>S</sub>, and P<sub>NO<sub>x</sub></sub> shall exceed 1,5.

— The sum of the points (P<sub>total</sub> = P<sub>COD</sub> + P<sub>P</sub> + P<sub>S</sub> + P<sub>NO<sub>x</sub></sub>) shall not exceed 4,0.

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

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

Table 1

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

	Reference values (kg/ADt)			
	COD <sub>ref</sub>	P <sub>ref</sub>	S <sub>ref</sub>	NO <sub>x</sub> <sub>ref</sub>
<b>Integrated mills</b>				
Bleached chemical pulp (others than sulphite)	16,0	0,030 <sup>(1)</sup> 0,05 <sup>(2)</sup>	0,6	1,5
Bleached chemical pulp (sulphite)	24,0	0,03	0,6	1,5
Unbleached chemical pulp	6,5	0,02	0,6	1,5
Unbleached chemical pulp (only UKP-E quality)	6,5	0,035	0,6	1,5
CTMP	15,0	0,01	0,2	0,3
NSSC	11	0,02	0,4	1,5
<b>Non-integrated mills <sup>(3)</sup></b>				
Converting process	1	0,001	0,15	0,6

<sup>(1)</sup> 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.

<sup>(2)</sup> The higher value refers to mills using eucalyptus and southern U.S. pine species from regions with higher levels of phosphorus and applies until 31 December 2026. From 1 January 2027, the limit of 0,03 kg P/ADt shall apply also to mills using eucalyptus and southern US pine species from regions with higher levels of phosphorus.

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

#### Assessment and verification:

The applicant shall provide detailed calculations and test data showing compliance with this criterion, together with related supporting documentation that include test reports using the following continuous or periodical monitoring standard test methods: COD: ISO 15705 or ISO 6060; Total P: EN ISO 6878; NO<sub>x</sub>: EN 14792, ISO 11564, or EPA Method 7e; S (sulphur oxides): EN 14791, EPA Method No 6C or 8; S(reduced sulphur): EPA No 15A, 16A, 16B or 16c; S content in oil:

ISO 8754; S content in coal: ISO 19579; S content in biomass: EN 15289. Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an independent third-party shall be accepted. Rapid tests can also be used to monitor emissions as long as they are done regularly (e.g. monthly) against the relevant aforementioned standards or suitable equivalents.

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

The minimum measurement frequency for COD measurements and for total P emissions shall be weekly. Emissions of S and NOx shall be measured at least twice per calendar year (separated by four to six months).

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

- the production campaign is for a limited time period only,
- the production plant is new or has been rebuilt, in which case the measurements shall be based on at least 45 subsequent days of stable running of the plant.

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

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

Emissions to air shall include all emissions of S and NOx that occur during the production of pulp, including steam generated outside the production site, minus any emissions allocated to the production of electricity. In cases where co-generation of heat and electricity occur at the same plant, the emissions of S compounds and NOx resulting from on-site electricity generation shall be subtracted from the total amount. The proportion of the emissions resulting from electricity generation shall be calculated as:

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

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

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

Reported emission values for S compounds shall include both oxidised and reduced S emissions (SO<sub>2</sub> and total reduced sulphur (TRS) – measured as S). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of being measured, and shall be taken into account.

#### 1.4. Emissions of CO<sub>2</sub> from fluff pulp production

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

Reference emission values according to Table 3 shall be used in the calculation of CO<sub>2</sub> emission from energy sources. If needed, CO<sub>2</sub> emission factors for other energy sources can be found in Annex VI to Commission Implementing Regulation (EU) 2018/2066 <sup>(6)</sup>, whereas the CO<sub>2</sub> emission factors for grid electricity should be in line with Commission Delegated Regulation (EU) 2019/331 <sup>(7)</sup>.

<sup>(6)</sup> Commission Implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012, C/2018/8588 (OJ L 334, 31.12.2018, p. 1).

<sup>(7)</sup> Commission Delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council (OJ L 59, 27.2.2019, p. 8).

Table 2

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

<b>Integrated mills</b>	
Chemical and semi-chemical pulp	400 kg CO <sub>2</sub> /ADt
CTMP	900 kg CO <sub>2</sub> /ADt
<b>Non-integrated mills</b>	
Converting process <sup>(1)</sup>	95 kg CO <sub>2</sub> /ADt

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

Table 3

**Reference values for CO<sub>2</sub> emissions from different energy sources**

Fuel	CO <sub>2</sub> emissions	Unit	Reference
Coal	94,6	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Crude oil	73,3	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 1	74,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 2-5	77,4	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
LPG	63,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Natural Gas	56,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Grid Electricity	376	g CO <sub>2</sub> 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<sub>2</sub> emission value in kg CO<sub>2</sub>/ADt.

The CO<sub>2</sub> emission data shall include all sources of energy sources used during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

When calculating CO<sub>2</sub> emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO<sub>2</sub> emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001 of the European Parliament and of the Council <sup>(8)</sup>. The applicant shall provide appropriate documentation that this kind of energy is actually used at the mill or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

<sup>(8)</sup> Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).

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

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

### 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 ( $P_{\text{electricity}}$  and  $P_{\text{fuel}}$ ). The following limits and reference values shall apply:

- $P_{\text{electricity}} < 1,5$ ;
- $P_{\text{fuel}} < 1,5$ ;
- The sum of points ( $P_{\text{total}} = P_{\text{electricity}} + P_{\text{fuel}}$ ) shall not exceed 2,5.

Calculation of electricity consumption points:

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

Where:

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

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

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

Calculation of fuel consumption points:

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

Where:

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

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

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

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

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

Table 4

#### Reference values for electricity and fuel

Pulp grade	$E_{\text{ref}, \text{pulp}}$ kWh/ADt	$F_{\text{ref}, \text{pulp}}$ kWh/ADt
<b>Integrated mills</b>		
Chemical and semi-chemical pulp	800	5 400

CTMP	1 800	900
<b>Non-integrated mills <sup>(1)</sup></b>		
Converting process	250	1 800

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

### Assessment and verification:

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

The applicant shall calculate all energy inputs, divided into heat/fuels and electricity used during the production of the pulp. If a mix of fluff pulps is used, the energy must be proportionally calculated to each fluff pulp. Energy used in the transportation of the raw materials is not included in the energy consumption calculations. The period for the calculations or mass balances shall be based on the production over 12 months. The calculations shall be repeated on a yearly basis. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

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

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

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

### Criterion 2. Man-made cellulose fibres

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

#### 2.1. Sourcing of man-made cellulose fibres

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

A minimum of 70 % of the raw materials used for the production of the dissolving pulp shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The remaining proportion of raw materials used for the production of the dissolving pulp shall be controlled wood covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing the chain of custody and/or Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

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

### Assessment and verification:

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

In addition, the applicant shall provide audited accounting documents that demonstrate that at least 70 % of the raw materials used for the production of the dissolving pulp is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

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

For the remaining proportion of raw materials, proof shall be provided that the content of uncertified virgin material does not exceed 30 % and that it is controlled material covered by a verification system that ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

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

## 2.2. *Bleaching of man-made cellulose fibres*

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

The pulp used to manufacture man-made cellulose fibres shall not be bleached with the use of elemental chlorine (Cl<sub>2</sub>) gas.

The resulting total amount of AOX and organically bound chlorine (OCl) shall not exceed the following:

- 0,140 kg/ADt, measured in the wastewater from pulp manufacturing (AOX), and
- 150 ppm, measured in the finished man-made cellulose fibres (OCl).

### **Assessment and verification:**

The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report (if possible) showing compliance with both the AOX and the OCl requirements, using the appropriate test method:

- For AOX: ISO 9562 or the equivalent EPA 1650C,
- For OCl: ISO 11480.

Frequency of measurement for AOX shall be set in accordance with the criterion 1.2 for fluff pulp.

In case the applicant could not provide the actual value of AOX level measured in the wastewater from pulp manufacturing, a corresponding declaration of compliance signed by the pulp manufacturer, in accordance with the exposed requirement, shall be provided.

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

## 2.3. *Production of man-made cellulose fibres*

- (a) More than 50 % of dissolving pulp used to manufacture man-made cellulose fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by:
  - (i) generating on-site electricity and/or steam; or
  - (ii) manufacturing chemical co-products.

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

Table 5

**Viscose and modal fibres emission values**

Fibre type	Sulphur emissions to air – Limit value (g /kg)	Zinc emissions to water – Limit value (g/kg)	COD measurements in water – Limit value (g/kg)	SO <sub>4</sub> <sup>2-</sup> emissions to water – Limit value (g/kg)
Staple fibre	20	0,05	5	300
Filament fibre				
— Batch washing	40	0,10	5	200
— Integrated washing	170	0,50	6	250

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

**Assessment and verification:**

- (a) The applicant shall provide supporting documentation and evidence that the required proportion of dissolving pulp suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at the related production sites. The list of such dissolving pulp suppliers shall also be provided.
- (b) In relation to test methods:
- (i) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.
  - (ii) Sulphur emissions to air: use method defined in EN 14791, EPA No 8, 15A, 16A or 16B or DIN 38405-D27.
  - (iii) Zinc emissions to water: use method defined in EN ISO 11885.
  - (iv) COD measurements in water: use method defined in ISO 6060, DIN ISO 15705, DIN 38409-01 or DIN 38409-44.
  - (v) SO<sub>4</sub><sup>2-</sup> (sulphates) emissions to water: use method defined in ISO 22743.
  - (vi) Test methods whose scope and requirement standards are considered equivalent to the one of the named national and international standards and whose equivalency has been confirmed by an independent third-party shall be accepted.
  - (vii) The detailed documentation and test reports shall include an indication of the measurement frequency for S, Zn, COD and SO<sub>4</sub><sup>2-</sup>. The minimum measurement frequency, shall be weekly for COD, S, Zn and SO<sub>4</sub><sup>2-</sup>, in addition to any measurements stipulated in the regulatory requirements.

**Criterion 3. Cotton and other natural cellulosic seed fibres****3.1. Sourcing and traceability of cotton and other natural cellulosic seed fibres**

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

- (a) All cotton and other natural cellulosic seed fibres shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007<sup>(9)</sup> and Regulation (EU) 2018/848 of the European Parliament and of the Council<sup>(10)</sup>, the US National Organic Programme (NOP<sup>(11)</sup>) or equivalent legal obligations set by trade partners of the European Union. The organic cotton content may include organically grown cotton and transitional organic cotton.
- (b) Cotton and other natural cellulosic seed fibres grown according to criterion 3.1(a) and used to manufacture absorbent hygiene product shall be traceable.

Tampon strings are exempted from complying with this requirement.

#### **Assessment and verification:**

- (a) The organic content of cotton and/or other natural cellulosic seed fibres shall be certified by an independent control body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007 and Regulation (EU) 2018/848, the US NOP or equivalent legal obligations set by other trade partners of the European Union. Verification shall be provided on an annual basis and for each country of origin.
- (b) The applicant shall demonstrate compliance with the material content requirement for the annual volume of cotton and/or other natural cellulosic seed fibres purchased to manufacture the final product(s) and according to each product line, on an annualised basis. Transaction records or invoices documenting the quantity of cotton and/or other natural cellulosic seed fibres purchased on an annual basis from farmers or producer groups, and the total weight of certified bales shall be provided.

#### **3.2. Bleaching of cotton and other natural cellulosic seed fibres**

Cotton and other natural cellulosic seed fibres shall be bleached only using TCF technologies.

This sub-criterion shall not apply to cotton linters used to produce dissolving pulp.

#### **Assessment and verification:**

The applicant shall provide a declaration from the supplier of cotton and/or other natural cellulosic seed fibres that TCF technologies are used.

#### **Criterion 4. Production of synthetic polymers and plastic materials**

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

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

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

<sup>(9)</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

<sup>(10)</sup> Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, PE/62/2017/REV/1 (OJ L 150, 14.6.2018, p. 1).

<sup>(11)</sup> National Organic Program, A Rule by the Agricultural Marketing Service on 12.21.2000, 65 FR 80547.



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

#### **Assessment and verification:**

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

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

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

- (a) the inclusion of water, waste and energy management plans for the production site(s) is documented in the company's EMAS environmental statement; or
- (b) the inclusion of water, waste and energy management plans for the production site(s) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme.

#### **Criterion 5. Biobased plastic materials**

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

The applicant may source, on a voluntary basis, a certain percentage of the total synthetic polymers and plastic materials in relation to the total weight of polymers in the final product (including super absorbent polymers (SAP)), the separate components and/or in the packaging, from biobased raw materials. Circular economy principles shall guide the selection of feedstocks (as an example, producers shall prioritise the use of organic waste and by-products as feedstock) <sup>(12)</sup>.

In this case, the following shall apply:

- (a) The superior environmental profile of the biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be demonstrated in compliance with the latest applicable methodologies to assess the impacts of biobased plastics compared to fossil-based plastics <sup>(13)</sup>.
- (b) Biobased raw materials used to produce biobased plastics in the final product, separate components, and/or packaging shall be covered by chain of custody certificates issued by an independent third-party certification scheme officially recognised by the European Commission <sup>(14)</sup>.

<sup>(12)</sup> In line with the Communication from the European Commission on EU Policy Framework on biobased, biodegradable and compostable plastics. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0682&qid=1680246180511>.

<sup>(13)</sup> Latest methodologies are the framework developed by the Commission's Joint Research Centre, referred to as the 'Plastics LCA method' available at <https://publications.jrc.ec.europa.eu/repository/handle/JRC125046> or Commission Recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials available at <https://research-and-innovation.ec.europa.eu/system/files/2022-12/Commission%20recommendation%20-%20establishing%20a%20European%20assessment%20framework%20for%20safe%20and%20sustainable%20by%20design.PDF>.

<sup>(14)</sup> In line with the sustainability requirements related to the sourcing of biobased raw material as per the review of the Renewable Energy Directive (RED III). The certification schemes officially recognised by the European Commission are available at: [https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes\\_en](https://ec.europa.eu/energy/topics/renewable-energy/biofuels/voluntary-schemes_en).

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

**Assessment and verification:**

- (a) To demonstrate the superior environmental profile of the biobased plastic raw materials used in the product, separate components, and/or packaging, the applicant shall provide an independent third-party certification that refers to the methodology currently available <sup>(15)</sup>.
- (b) The applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the suppliers of all biobased plastics raw materials used in the product, separate components, and/or packaging. The chain of custody certificates shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the certificates again 12 months after the awarding of the EU Ecolabel licence.

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

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

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

**Criterion 6. Material efficiency in the manufacturing of the final product**

Requirements in this criterion shall apply to the final product assembly site.

The quantity of waste generated during the manufacturing and packaging of the products which is sent to landfill or incineration without energy recovery, shall not exceed:

- (a) 8 % by weight of the end products for tampons;
- (b) 4 % by weight of the end products for all the other products.

**Assessment and verification:**

The applicant shall confirm compliance with the above requirements.

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

The applicant shall present all of the following:

- (a) the weight of the product and of the packaging;
- (b) all the waste streams generated during the manufacturing;
- (c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.).

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<sup>(15)</sup> Methodology currently available as explained before.

**Criterion 7. Excluded and restricted substances****7.1. Restrictions on substances classified under Regulation (EC) No 1272/2008**

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

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

Table 6

**Excluded hazard classes, categories and associated hazard statement codes**

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

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Endocrine disruptors for human health and the environment	
Category 1	Category 2
EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Persistent, Bioaccumulative and Toxic	
PBT	vPvB
EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Persistent, Mobile and Toxic	
PMT	vPvM
EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resource

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

Table 7

**Restricted hazard classes, categories and associated hazard statement codes**

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

Table 8

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

Substance type	Derogated hazard class, category and hazard statement code	Derogation conditions
2-methyl-2H-isothiazol-3-one (MIT)	H400, H314, H301, H311, H318, H410, H330 and H317	Only in water-soluble inks and in a concentration lower than 15 ppm in the ink (before application) and lower than 0,1 ppm in the final product. The ink shall comply with sub-criterion 7.3.4
Dipropylene glycol dibenzoate	H412	Only in hot melt adhesives that are used to indicate wetness
Substances and mixtures with a harmonised classification as H304	H304	Substances with a viscosity under 20,5 cSt at 40 °C.
Titanium dioxide (nano-form)	H351	Only when used as pigment. It cannot be used in powder or spray form.

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

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

This criterion shall not apply to:

- substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation,
- substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

**Assessment and verification:**

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

For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100 % shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

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

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

Since multiple products or potential products using the same process chemicals may be covered by one EU Ecolabel licence, the calculation only needs to be presented for each impurity for the worst-case product or component covered by the licence (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.

## 7.2. **Substances of Very High Concern (SVHCs)**

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

The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation.

### **Assessment and verification**

The applicant shall provide a signed declaration that the final product and any components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein.

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

<https://www.echa.europa.eu/candidate-list-table>.

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

For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

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

## 7.3. **Other specific restrictions**

### 7.3.1. *Specified excluded substances*

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

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

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

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0,0100 % w/w in the chemical product, unless further restricted under criterion 7.3.8. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

[Notes:

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

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

[3] DINP may be allowed if used in adhesive formulations at a maximum concentration of 0,010 % weight by weight of the adhesive formulation]

**7.3.2.       Fragrances**

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

Fragrances shall not be added to the final product, to any component thereof, to the separate components nor to the packaging.

**Assessment and verification:**

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

**7.3.3.       Lotions**

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

Lotions shall not be used in the product, nor in any component thereof.

**Assessment and verification:**

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

**7.3.4.       Inks and dyes**

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

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

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

(i) tampon strings;

(ii) closing systems;

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

In these cases, the content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dyeing colorants and inks shall be below the limits given in the Council of Europe's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food <sup>(16)</sup>.

The dyeing colorants used shall moreover comply with the following:

- (a) if used in plastic materials: BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities <sup>(17)</sup> or Swiss Ordinance 817.023.21 Annex 2 <sup>(18)</sup> and Annex 10 <sup>(19)</sup>;
- (b) if used in cellulosic materials: BfR's recommendation XXXVI. Paper and board for food contact <sup>(20)</sup>.

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

#### Assessment and verification:

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

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

#### 7.3.5. Further restrictions applying to adhesives

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

#### Assessment and verification:

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

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

#### 7.3.6. Super absorbent polymers (SAP)

Superabsorbent polymers used in the product shall:

- (a) contain a maximum of 1 000 ppm residual monomers [4] that are classified with the H-codes reported in sub-criterion 7.1. For sodium polyacrylate this limit applies to the sum of unreacted acrylic acid and cross linking agents;
- (b) as a maximum, contain 10 % (weight/weight) of water-soluble extracts [5] and these shall comply with sub-criteria 7.1, 7.2 and 7.3.1. For sodium polyacrylate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.
- (c) Acrylamide shall not be included in superabsorbent polymers.

<sup>(16)</sup> 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>.

<sup>(17)</sup> <https://www.bfr.bund.de/cm/349/IX-Colorants-for-Plastics-and-other-Polymers-Used-in-Commodities.pdf>.

<sup>(18)</sup> [https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmit-telrecht2017/anhang2-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annexe\\_2.pdf](https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmit-telrecht2017/anhang2-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annexe_2.pdf).

<sup>(19)</sup> <https://www.blv.admin.ch/dam/blv/en/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmit-telrecht2017/anhang10-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annex-10-ordinance-fdha-materials-and-articles-intended-to-come-into-contact-with-food-stuffs.pdf>.

<sup>(20)</sup> <https://www.dssmith.com/contentassets/1bbf9877253f458aa0eed26b76f2d705/360-english.pdf>.



**Assessment and verification:**

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

In addition, the applicant shall also provide a declaration from the supplier documenting the composition of the super absorbent polymer(s) used in the product and the quantity of water-soluble extracts in the superabsorbent polymer(s). The declaration shall be supported by safety data sheets or test results specifying the residual monomers contained in the SAP and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The tested quantities for residual monomers and soluble extracts shall be averages from repeated measures over a certain period of time. The methods used and the measurement frequency for the analyses shall be described, including the information of the laboratories used for the analysis.

[Notes:

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

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

### 7.3.7. Silicone

This sub-criterion applies to the release liner.

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

(b) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture [6] in concentrations above 800 ppm (0,08 % w/w). The 800 ppm limit is to be applied to each substance separately.

**Assessment and verification:**

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

[Note:

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

### 7.3.8. Other chemicals of concern

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

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

Table 9

**List of restricted chemicals**

Substances	Restrictions
Formaldehyde	< 16 ppm
Dibenzo-p-dioxins (PCDDs): 2,3,7,8-TCDD; 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD	sum TEQ of the detected congeners of PCDDs, PCDFs and DLPCBs < 2ng/kg
Dibenzofurans (PCDFs): 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; OCDF	
DLPCBs: PCB 77; PCB 81; PCB 126; PCB 169; PCB 105; PCB 114; PCB 118; PCB 123; PCB 156; PCB 157; PCB 167; PCB 189	

Substances	Restrictions
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; Monooctyltin	Each organotin < 10ppb
Heavy metals	
Antimony	< 30 mg/kg
Cadmium	< 0,1 mg/kg
Chromium	< 1 mg/kg
Lead	< 0,2 mg/kg
Mercury	< 0,02 mg/kg

#### Assessment and verification:

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

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

**Criterion 8. Packaging**

This criterion sets requirements for sales and grouped packaging.

Grouped packaging shall be avoided or made of only cardboard and/or paper.

(a) Cardboard and/or paper used for packaging

Sales packaging made of cardboard and/or paper shall contain a minimum 40 % of recycled material.

Grouped packaging made of cardboard and/or paper shall contain a minimum 80 % of recycled material.

The remaining share (100 % minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

(b) Plastic used for packaging

— Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20 % recycled material.

— From 1 January 2027, sales packaging made of plastic shall contain a minimum 35 % recycled material.

(c) Recyclability

The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95 % by weight, while 5 % residuals shall be compatible with recycling.

(d) Additional requirements

— Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.

— Recycled content and recyclability of sales and grouped packaging shall be indicated on the sales packaging.

**Assessment and verification:**

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging; and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly.

Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.

The applicant shall provide audited accounting documents that demonstrate that the remaining share (100 % minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the EU Ecolabel licence.

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

Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided.

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

### Criterion 9. Guidance on the use and on the disposal of the product and of the packaging

Instructions for the use of the final product shall be made available on the packaging or through a printed and/or digital leaflet.

The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging:

- that the sales packaging, the grouped packaging (if any), the separate components and the used product shall not be flushed into toilets, and
- how to correctly dispose of the sales packaging, the grouped packaging (if any), the separate components and the used product.

#### Assessment and verification:

The applicant shall provide a high resolution photograph of the instructions for use of the product.

The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears clearly.

### Criterion 10. Fitness for use and quality of the product

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

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

Table 10

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

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (1)	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers and feminine care pads
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
Technical tests	T1. Absorption and leakage protection <sup>(1)</sup>	Absorption rate and absorption before leakage		Syngina method	As for baby diapers and feminine care pads
	T2. Skin dryness <sup>(1)</sup>	TEWL, rewet method or corneometric testing		Not applicable	As for baby diapers and feminine care pads

<sup>(1)</sup> Panty liners intended to protect the feminine lingerie (light panty liners) are derogated from these requirements.

### Assessment and verification:

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

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

Special care shall be taken regarding sampling, transport and storage of the products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

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

Additional guidelines for in-use tests:

- Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).
- Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.
- The recommended number of testers shall be at least 30 (for products specifically designed or not for one gender). All the individuals participating to the survey shall be current users of the specific type/size of product tested.
- When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1.
- A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age, countries and genders shall be clearly stated.
- Sick individuals and those with a chronic skin condition shall not participate in the test. In cases where individuals become ill during the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.
- For all in-use tests (absorption and leakage protection, skin dryness, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively, 80 % of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).
- The results shall be statistically evaluated after the user trial has been completed.
- External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

Additional requirements for technical tests:

- Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.
- A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation.
- Technical tests recommended for nursing pads are the same as for baby diapers and for feminine care pads.

Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.

### **Criterion 11. Corporate Social Responsibility with regard to labour aspects**

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

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy <sup>(21)</sup>, the UN Global Compact (Pillar 2) <sup>(22)</sup>, the UN Guiding Principles on Business and Human Rights <sup>(23)</sup> and the OECD Guidelines for Multinational Enterprises <sup>(24)</sup>, the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

Fundamental conventions of the ILO:

(i) Child Labour:

- Minimum Age Convention, 1973 (No 138)
- Worst Forms of Child Labour Convention, 1999 (No 182)

(ii) Forced and Compulsory Labour:

- Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention
- Abolition of Forced Labour Convention, 1957 (No 105)

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

- Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87)
- Right to Organise and Collective Bargaining Convention, 1949 (No 98)

(iv) Discrimination:

- Equal Remuneration Convention, 1951 (No 100)
- Discrimination (Employment and Occupation) Convention, 1958 (No 111)

Supplementary provisions:

(v) Working Hours:

- ILO Hours of Work (Industry) Convention, 1919 (No 1)
- ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(vi) Remuneration:

- ILO Minimum Wage Fixing Convention, 1970 (No 131)
- ILO Holidays with Pay Convention (Revised), 1970 (No 132)

<sup>(21)</sup> ILO NORMLEX (<http://www.ilo.org/dyn/normlex/en>) and supporting guidance.

<sup>(22)</sup> United Nations Global Compact (Pillar 2), <https://www.unglobalcompact.org/what-is-gc/participants/141550>.

<sup>(23)</sup> Guiding Principles for Business and Human Rights, <https://www.unglobalcompact.org/library/2>.

<sup>(24)</sup> OECD Guidelines for Multinational Enterprises, <https://www.oecd.org/daf/inv/mne/48004323.pdf>.

- Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 <sup>(25)</sup> 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 licence, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

### Assessment and verification:

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective <sup>(26)</sup> and where the scope of the inspection systems covers the areas listed above <sup>(27)</sup>, by labour inspector(s) appointed by a public authority.

<sup>(25)</sup> Social Accountability International, Social Accountability 8000 International Standard, <http://www.sa-intl.org>.

<sup>(26)</sup> Please, refer to the footnote 21.

<sup>(27)</sup> Please, refer to the footnote 21.

Valid certifications from third-party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

**Criterion 12. Information appearing on the EU Ecolabel**

The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements:

- ‘Designed to reduce impact on the environment’,
- ‘Fulfils strict requirements on harmful substances’,
- ‘Verified performance’.

The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines:

[http://ec.europa.eu/environment/ecolabel/documents/logo\\_guidelines.pdf](http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf).

**Assessment and verification:**

The applicant shall provide a declaration of compliance with the requirement and a high resolution photograph of the product sales packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

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## ANNEX II

**EU Ecolabel criteria for awarding the EU Ecolabel to reusable menstrual cups**

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

**Assessment and verification requirements**

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

Specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate.

Competent bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

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

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

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

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

- (a) a description of the product, together with the weight of the individual product units and the total weight of the product;
- (b) a description of the sales packaging, together with its total weight, if applicable;
- (c) a description of the grouped packaging, together with its total weight, if applicable;
- (d) a description of the separate components, together with their individual weight;
- (e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

For the purposes of this Annex, the following definitions shall apply:

- (1) 'additives' means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;
- (2) 'composite packaging' means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;
- (3) 'grouped packaging', also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;
- (4) 'impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 %w/w, 100 mg/kg);

- (5) 'ingoing substance' means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;
- (6) 'packaging' means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:
  - (a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;
  - (b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;
  - (c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc.;
- (7) 'plastic materials', also referred to as 'plastics', means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;
- (8) 'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a 'monomer unit' means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC) No 1907/2006;
- (9) 'recyclability' 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. Item can refer to the product or packaging in this case;
- (11) 'recycling' means, in accordance with Article 3 of Directive 2008/98/EC, 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) 'sales packaging', also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;
- (13) 'separate component', also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of reusable menstrual cups, it is any component (with protective or hygienic function) that is removed before the use of the product, e.g. the bag/pouch the menstrual cups are usually sold with;
- (14) 'substances identified to have endocrine disrupting properties', also referred to as endocrine disruptors, means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 or Regulation (EC) No 1107/2009, or Regulation (EC) No 1272/2008;

- (15) 'synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by:
- (a) a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;
  - (b) chemical modification of natural or synthetic macromolecules;
  - (c) microbial fermentation.

### **Criterion 1. Emissions during the production of the raw material**

#### **1.1. Emissions of dust and of chlorides to air**

(a) Emissions of dust

- (i) This requirement applies to silicones only.

The storage and handling of the elemental silicon raw material shall use at least one of the following techniques:

- Storing of elemental silicon in silos (after grinding);
- Storing of elemental silicon in covered areas protected from rain and wind (after grinding);
- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding);
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

- (ii) This requirement applies to both silicones and other elastomers.

The yearly average of channelled emissions of dust shall be below 5 mg/Nm<sup>3</sup>. The dust emissions should be continuously monitored.

(b) Emissions of chlorides

- (i) This requirement applies to silicones only.

The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

- (ii) This requirement applies to elastomers other than silicones.

Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0,01 ng TEQ/Nm<sup>3</sup> (average over the sampling period). Monitoring of the PCDD/F emissions should take place every six months.

#### **Assessment and verification:**

The applicant shall provide a declaration of compliance from the raw material supplier with criterion 1.1. In addition, the declaration shall demonstrate compliance with:

- criterion 1.1(a)(i), the silicone supplier shall indicate which technique is used on site, providing pictures or technical descriptions, as supplementary data;
- criterion 1.1(a)(ii), the raw material supplier shall provide the results of the dust measurements taken on site, together with the yearly average of the dust emission. Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. For the production of silicones, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum;
- criterion 1.1(b)(i), the silicone supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps;
- criterion 1.1(b)(ii), the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases. Methods accepted are EN 1948-1, EN 1948-2 and EN 1948-3.

### 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:

- (a) dewatering of the sludge before disposal; and
- (b) recovering of the solid metal residues in metal recovery plants.

The concentration of copper in the treated effluent shall be below 0,5 mg/l, while the concentration of zinc shall be below 2 mg/l.

#### Assessment and verification:

The applicant shall provide a declaration of compliance from the silicone supplier with criterion 1.2, together with a proof that the plant has in place a wastewater system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicone supplier shall provide the measurement results for copper and zinc in the treated effluent.

### 1.3. Emissions of CO<sub>2</sub>

This criterion applies to silicones only.

CO<sub>2</sub> emissions from the production of the silicone shall not exceed 6,58 kg per kg silicone, including emissions from the production of electricity (whether on-site or off-site). CO<sub>2</sub> emissions shall include all sources of non-renewable energy used during the production of the silicone. Reference emission values according to Table 1 shall be used for the calculation of CO<sub>2</sub> emission from energy sources. If needed, CO<sub>2</sub> emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO<sub>2</sub> emission factors for grid electricity should be in line with Delegated Regulation (EU) 2019/331.

Table 1

#### Reference values for CO<sub>2</sub> emissions from different energy sources

Fuel	CO <sub>2</sub> emissions	Unit	Reference
Coal	94,6	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Crude oil	73,3	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 1	74,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 2-5	77,4	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
LPG	63,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Natural Gas	56,1	g CO <sub>2</sub> fossil/MJ	Regulation (EU) 2018/2066
Grid Electricity	376	g CO <sub>2</sub> fossil/kWh	Regulation (EU) 2019/331

#### Assessment and verification:

The applicant shall provide data and detailed calculations for the CO<sub>2</sub> emissions from the production of the silicone.

The CO<sub>2</sub> emission data shall include all sources of energy used during the production of the raw material, including the emissions from the production of electricity (whether on-site or off-site).

When calculating CO<sub>2</sub> emissions, the amount of energy from renewable sources purchased and used for the production processes shall count as zero CO<sub>2</sub> emission. For biomass combustion, this means that the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in the Directive (EU) 2018/2001. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased (copy of the contract and an invoice indicating the renewable share of the purchased electricity).

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

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

## **Criterion 2. Environmental management of production**

All plants producing either raw materials (silicone or other elastomers) or the final products shall have systems for the implementation of:

- (a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);
- (b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and recovery of waste fractions that cannot be prevented (including energy recovery);
- (c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

### **Assessment and verification:**

The applicant shall provide a declaration of compliance with the criterion from (1) the producer of raw materials (silicone or other elastomers); and (2) from the manufacturer of reusable menstrual cups. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001 for water, waste and energy plans.

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

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

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

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

### Criterion 3. Material efficiency in the manufacturing of the final product

The requirements in this criterion shall apply to the final product manufacturing site.

The quantity of waste generated during the manufacturing and packaging of the end products which is sent to landfill or incineration without energy recovery, shall not exceed 4 % by weight of the end products.

#### Assessment and verification:

The applicant shall confirm compliance with the above requirement.

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

The applicant shall present all of the following:

- (a) the weight of the product and of the packaging,
- (b) all the waste streams generated during the manufacture, and
- (c) the respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc.).

### Criterion 4. Excluded and restricted substances

#### 4.1. **Restrictions on substances classified under Regulation (EC) No 1272/2008**

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

Unless derogated in Table 4, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 2, in accordance with Regulation (EC) No 1272/2008.

Table 2

#### Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	-
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	

Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Endocrine disruptors for human health and the environment	
Category 1	Category 2
EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Persistent, Bioaccumulative and Toxic	
PBT	vPvB
EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Persistent, Mobile and Toxic	
PMT	vPvM
EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resource

Moreover, the final product and any components therein shall not contain ingoing substances (alone or in mixtures) in concentrations greater than 0,010 % (weight by weight) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 3, in accordance with Regulation (EC) No 1272/2008 – unless derogated in Table 4.

Table 3

**Restricted hazard classes, categories and associated hazard statement codes**

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

Table 4

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

Substance type	Derogated hazard class, category and hazard statement code	Derogation conditions
Substances with a harmonised classification as H304	H304	Substances with a viscosity under 20,5 cSt at 40 °C.
Titanium dioxide (nano-form)	H351	Only when used as pigment. It cannot be used in powder or spray form

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

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

This criterion shall not apply to:

- substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation,
- substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with relevant declarations from the producers of the components, a list of all chemicals used, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.



For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.

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

For substances exempted from sub-criterion 4.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

Since multiple products or potential products using the same process chemicals may be covered by one EU Ecolabel licence, the calculation only needs to be presented for each impurity for the worst-case product or component covered by the licence (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.

#### 4.2. **Substances of Very High Concern (SVHCs)**

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

The final product and any components therein shall not contain ingoing substances (alone or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation.

#### **Assessment and verification**

The applicant shall provide a signed declaration that the final product and the components therein do not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product and the components therein.

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

<https://www.echa.europa.eu/candidate-list-table>.

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

For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100 %, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. Impurities can be present in the chemical product up to 0,0100 % w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities

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

#### 4.3. **Other specific restrictions**

##### 4.3.1. *Specified excluded substances*

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

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

- (a) 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);
- (b) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];
- (c) Antibacterial agents (e.g. nanosilver and triclosan);
- (d) Formaldehyde and formaldehyde releasers;
- (e) Methylisothiazolinone (MIT)
- (f) Nitromusks and Polycyclic musks;

- (g) Organotin compounds used as a catalyst in the production of silicone;
- (h) Parabens;
- (i) Phthalates;
- (j) Substances identified to have endocrine disrupting properties;
- (k) Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the sub-criterion, supported by declarations from suppliers, if relevant. The substances listed in this sub-criterion are only allowed as impurities, and nevertheless in concentrations lower than 0,0100 % w/w in the chemical product. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities

[Note:

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

**4.3.2. Fragrances**

This criterion applies to the final product, any components therein, the separate components and the packaging.

Fragrances shall not be added to the final product, nor to any components therein, nor to the separate components, nor to the packaging.

**Assessment and verification:**

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

**4.3.3. Inks and dyes**

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

The dying colorants and inks used in the reusable menstrual cup shall not exceed 2 % of total weight of the cup.

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

The dying colorants used shall moreover comply with BfR's recommendations IX for Colorants for Plastics and other Polymers Used in Commodities <sup>(2)</sup> or Swiss Ordinance 817.023.21 Annex 2 <sup>(3)</sup> and Annex 10 <sup>(4)</sup>.

The dying colorants and inks used shall also comply with sub-criteria 4.1 and 4.2.

**Assessment and verification:**

The applicant shall provide a signed declaration of compliance with the above sub-criterion, supported by declarations from suppliers if relevant, as well as documentation to ensure that impurities in the dying colorant or ink comply with the Council of Europe's Resolution AP (89) 1, and that the used dyes and inks are authorised according to the BfR's recommendations IX. *Colorants for Plastics and other Polymers Used in Commodities*, Swiss Ordinance 817.023.21 Annex 2 and Annex 10, or the BfR's recommendation XXXVI. *Paper and board for food contact*.

<sup>(1)</sup> Please, refer to the footnote 16

<sup>(2)</sup> Please, refer to the footnote 17

<sup>(3)</sup> Please, refer to the footnote 18

<sup>(4)</sup> Please, refer to the footnote 19.

#### 4.3.4. Cyclosiloxanes

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

Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and dodecamethyl-cyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone raw materials in concentrations above 100 ppm (0,0100 % w/w). The 100 ppm limit is to be applied to each substance separately.

#### Assessment and verification:

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

#### Criterion 5. Packaging

This criterion sets requirements for sales and grouped packaging.

Grouped packaging shall be avoided or made only of cardboard and/or paper.

##### (a) Cardboard and/or paper used for packaging

Sales packaging made of cardboard and/or paper shall contain a minimum 40 % of recycled material.

Grouped packaging made of cardboard and/or paper shall contain a minimum 80 % of recycled material.

The remaining share (100 % minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.

##### (b) Plastic used for packaging

— Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20 % recycled material.

— From 1 January 2027, sales packaging made of plastic shall contain a minimum 35 % recycled material.

##### (c) Recyclability

The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95 % by weight, while 5 % residuals shall be compatible with recycling.

##### (d) Additional requirements

— Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.

— Recycled content and recyclability of sales and grouped packaging shall be stated on the sales packaging.

##### (e) Separate component: bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100 % certified sustainable fibres.

#### Assessment and verification:

The applicant shall submit (1) a signed declaration of compliance specifying the percentages of recycled content in the sales and grouped packaging when relevant; (2) a declaration of compliance specifying the recyclability of the sales and grouped packaging; and (3) a high resolution photograph of the sales packaging where information regarding recycled content and recyclability of the sales and grouped packaging appears clearly.

Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.

The applicant shall provide audited accounting documents that demonstrate that the remaining share (100 % minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes. The audited accounting documents shall be valid for the whole duration of the EU Ecolabel licence. Competent bodies shall check the accounting documents again 12 months after the awarding of the licence.

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

Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343. Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided.

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

Moreover, the applicant shall provide a declaration of compliance supported by a valid, independently certified chain of custody certificate for the reusable bag or pouch. FSC, PEFC, OEKO-TEX, GOTS, or equivalent schemes shall be accepted as independent third-party certification.

#### **Criterion 6. Guidance on the disposal of the product and of the packaging**

The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging:

- (a) that the sales packaging, the grouped packaging (if any), the separate components and the cup shall not be flushed into toilets; and
- (b) how to dispose correctly the sales packaging, the grouped packaging (if any), the separate components and the cup at the end of its life.

#### **Assessment and verification:**

The applicant shall provide a high resolution photograph of the sales packaging, where information regarding disposal appears clearly.

#### **Criterion 7. Information on the use of the product**

The product shall be accompanied by instruction for its use. The manufacturer shall make sure that the user receives at least the following information:

- (a) How to choose the right size of cup. Such information shall be placed where it can be accessed by the user before purchase (e.g. on the primary packaging).
- (b) How to correctly wear the cup to avoid leakage and/or discomfort.
- (c) How long to wear the cup before emptying it. Information on the longest wearing time shall be backed up by test studies. This information shall be given in a visible way, e.g. via a logo or in bold characters, and shall be placed both on the packaging and on the instructions for use.
- (d) How to clean the cup before and after use during the same menstrual period, including, as a minimum, information about the importance of washing the hands, the need for boiling (yes/no, and if yes for how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.

- (e) How to clean and store the cup between menstrual periods, including, as a minimum, information about the importance of washing the hands, the importance of boiling (and information on how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. This information should be backed up by test studies.
- (f) How long it is possible to use the cup (the lifetime of the cup). It should moreover be stated that eventual discolouring of the cup has no influence on its lifetime and function.
- (g) Information about the risk of developing toxic shock syndrome shall be provided.

#### Assessment and verification:

The applicant shall provide a sample of the information sheet/leaflet and, if relevant, the packaging sold with the cup displaying the information for the user. The applicant shall also provide relevant tests/studies, e.g. biological risk assessments or toxicology studies, supporting the above requirements.

#### Criterion 8. Fitness for use and quality of the product

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

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Fitness for use shall be tested with respect to the technical tests referred to as for biocompatibility of the materials used for the manufacturing of reusable menstrual cups. Biocompatibility test shall provide the biological evaluation of cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days).

Table 5

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

Characteristic		Testing practice required (performance threshold)
In-use tests	U1. Leakage protection	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)
	U2. Fit and comfort	
	U3. Overall performance	
Technical tests	T1. Biocompatibility	No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993.  Alternatively compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) could be reported.

#### Assessment and verification:

A test report shall be provided describing test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems.

In-use tests shall be conducted for the specific products for which the EU Ecolabel application is made. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups for which the EU Ecolabel application is made. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test that material only once. Reusable menstrual cups are not requested to undergo technical tests, only the materials used in the production of cups (this includes silicones, cross-linked silicone elastomers, other elastomers, colorants used and any other materials).

Special care shall be taken regarding sampling, transport and storage of the materials and products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

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

Additional guidelines for in-use tests:

- Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 or equivalent).
- Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.
- The recommended number of testers shall be at least 30. All the individuals participating to the survey shall be current users of the specific type/size of product tested.
- A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age and countries shall be clearly stated.
- Sick individuals and those with a chronic condition shall not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.
- For all in-use tests (leakage protection, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80 % of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).
- The results shall be statistically evaluated after the user trial has been completed.
- External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

Additional requirements for technical tests:

- Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.
- Technical tests shall be performed in accordance to ISO 10993 series or the USP Class VI standard.
- Test methods whose scope and requirement standards is considered equivalent to the one of the named national and international standards and whose equivalency have been confirmed by an independent third party shall be accepted.

Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.

### **Criterion 9. Corporate Social Responsibility with regard to labour aspects**

This criterion sets requirements applying to the final reusable menstrual cup manufacturing site.

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy <sup>(5)</sup>, the UN Global Compact (Pillar 2) <sup>(6)</sup>, the UN Guiding Principles on Business and Human Rights <sup>(7)</sup> and the OECD Guidelines for Multinational Enterprises <sup>(8)</sup>, the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

<sup>(5)</sup> Please, refer to the footnote 21.

<sup>(6)</sup> Please, refer to the footnote 22.

<sup>(7)</sup> Please, refer to the footnote 23.

<sup>(8)</sup> Please, refer to the footnote 24.

Fundamental conventions of the ILO:

(a) Child Labour:

- Minimum Age Convention, 1973 (No 138)
- Worst Forms of Child Labour Convention, 1999 (No 182)

(b) Forced and Compulsory Labour:

- Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention
- Abolition of Forced Labour Convention, 1957 (No 105)

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

- Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87)
- Right to Organise and Collective Bargaining Convention, 1949 (No 98)

(d) Discrimination:

- Equal Remuneration Convention, 1951 (No 100)
- Discrimination (Employment and Occupation) Convention, 1958 (No 111)

Supplementary provisions:

(e) Working Hours:

- ILO Hours of Work (Industry) Convention, 1919 (No 1)
- ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(f) Remuneration:

- ILO Minimum Wage Fixing Convention, 1970 (No 131)
- ILO Holidays with Pay Convention (Revised), 1970 (No 132)
- Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000<sup>(\*)</sup> guidance on 'Remuneration'.

(g) 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)

(h) Social protection and inclusion:

- ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)
- ILO Social Security (Minimum Standards) Convention, 1952 (No 102)
- ILO Employment Injury Benefits Convention, 1964 (No 121)
- ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)
- ILO Maternity Protection Convention, 2000 (No 183)

(i) Fair dismissal:

- ILO Termination of Employment Convention, 1982 (No 158).

In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

<sup>(\*)</sup> Please, refer to the footnote 25.

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 licence, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

#### **Assessment and verification:**

The applicant shall demonstrate compliance with the requirements by providing copies of the most recent version of their code of conduct which shall be consistent with the provisions specified above and copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled, together with a web link to where online publication of the results and findings can be found.

Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective <sup>(10)</sup> and where the scope of the inspection systems covers the areas listed above <sup>(11)</sup>, by labour inspector(s) appointed by a public authority.

Valid certifications from third party schemes or inspection processes that audit compliance with the applicable principles of the listed fundamental ILO Conventions and the supplementary provisions on working hours, remuneration and health & safety and consultation with external stakeholders, shall be accepted. These certifications shall be not more than 12 months old, on the date of application.

#### **Criterion 10. Information appearing on the EU Ecolabel**

The EU Ecolabel logo may be displayed on the sales packaging of the product. If the optional label with text box is used, it shall contain the following three statements:

- ‘Designed to reduce impact on the environment’,
- ‘Fulfils strict requirements on harmful substances’,
- ‘Verified performance’.

The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines:

[https://ec.europa.eu/environment/ecolabel/documents/logo\\_guidelines.pdf](https://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf)

#### **Assessment and verification:**

The applicant shall provide a declaration of compliance with the requirement and a high resolution photograph of the product sales packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

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<sup>(10)</sup> Please, refer to the footnote 21.

<sup>(11)</sup> Please, refer to the footnote 21.