Council of the
European Union

Brussels, 2 May 2023
(OR. en)

8898/23
ADD 2

ENV 437

COVER NOTE

From:	European Commission
date of receipt:	28 April 2023
To:	General Secretariat of the Council
Subject:	Annex to the COMMISSION DECISION of XXX establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups

Delegations will find attached document D088269/02 - Annex II.

Encl.: D088269/02 - Annex II

EN

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^3. The dust emissions should be continuously monitored.

(b) Emissions of chlorides

(i) This requirement applies to silicones only.

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

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

Polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDF) emissions shall be below 0.01 ng TEQ/Nm^3 (average over the sampling period). Monitoring of the PCDD/F emissions should take place every six months.

Assessment and verification:

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

- 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_2

This criterion applies to silicones only.

CO_2 emissions from the production of the silicone shall not exceed 6.58 kg per kg silicone, including emissions from the production of electricity (whether on-site or off-site). CO_2 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_2 emission from energy sources. If needed, CO_2 emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO_2 emission factors for grid electricity should be in line with Commission Delegated Regulation (EU) 2019/331.

Table 1. Reference values for CO_2 emissions from different energy sources

Fuel	CO_2 emissions	Unit	Reference

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

Assessment and verification:

The applicant shall provide data and detailed calculations for the CO_2 emissions from the production of the silicone.

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

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

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

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

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

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

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[1].

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

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

[1] Please, refer to the footnote 16
[2] Please, refer to the footnote 17
[3] Please, refer to the footnote 18
[4] Please, refer to the footnote 19.

(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*.

4.3.4 Cyclosiloxanes

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

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

Assessment and verification:

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

Criterion 5. Packaging

This criterion sets requirements for sales and grouped packaging.

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

(a) Cardboard and/or paper used for packaging

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

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

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

(b) Plastic used for packaging

- Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20% recycled material.
- From 1 January 2027, sales packaging made of plastic shall contain a minimum 35% recycled material.

(c) Recyclability

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

(d) Additional requirements

— Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.
— Recycled content and recyclability of sales and grouped packaging shall be stated on the sales packaging.

(e) Separate component: bag or pouch

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

Assessment and verification:

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

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

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

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

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

In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation

system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

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

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[5], the UN Global Compact

[5] Please, refer to the footnote 21.

(Pillar 2)[6], the UN Guiding Principles on Business and Human Rights[7] and the OECD Guidelines for Multinational Enterprises[8], the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the aforementioned international texts and the supplementary provisions below have been respected at the final assembly site for the product.

Fundamental conventions of the ILO:

(a) Child Labour:

— Minimum Age Convention, 1973 (No 138)

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

(b) Forced and Compulsory Labour:

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

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

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

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

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

(d) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)

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

Supplementary provisions:

(e) Working Hours:

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

— ILO Weekly Rest (Industry) Convention, 1921 (No 14)

(f) Remuneration:

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

— ILO Holidays with Pay Convention (Revised), 1970 (No 132)

---

6 Please, refer to the footnote 22.
7 Please, refer to the footnote 23.
8 Please, refer to the footnote 24.

— 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[9] 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.

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.

[9] Please, refer to the footnote 25.

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

Assessment and verification:

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

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

[10] Please, refer to the footnote 21.
[11] Please, refer to the footnote 21.

https://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification:

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