EU Ecolabel criteria for ABSORBENT HYGIENE PRODUCTS
Working Group on Silicone

24th of November 2021

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European Commission

EU Ecolabel criteria for Absorbent Hygiene Products

Silicone Working Group Meeting

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24th November 2021 (Webex)

Joint Research Centre

Agenda

1. Tour de table (all)
2. Update on timeline (JRC)
3. Criterion 6.3 – silicone release manufacture (introduction by JRC + open discussion)
4. Criteria for reusable menstrual cups (introduction by JRC + open discussion)
5. Closure and next steps

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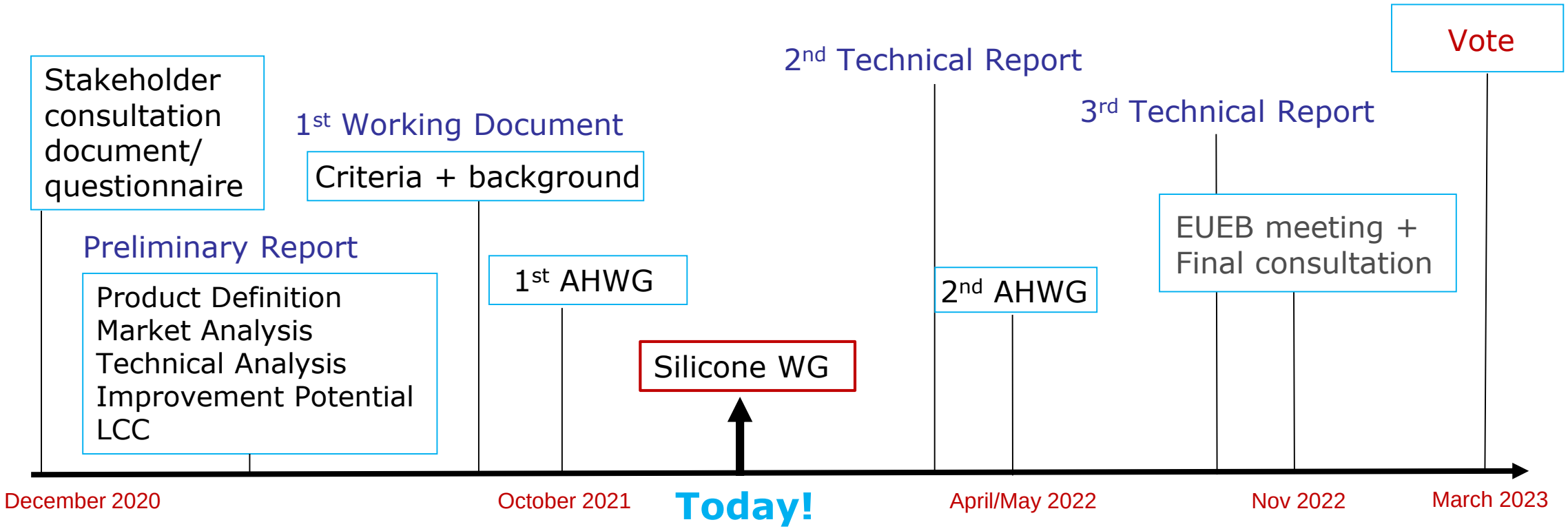
Update on Timeline

Criteria revision process

Current criteria need to be prolonged to end 2023



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Topics of today

Part I: Criterion 6.3.h – Silicone

Part II: Criteria Draft Proposal for Reusable Menstrual Cups

Revised criteria proposal

	Proposed changes to the revised criteria
1	Product Description
2	Fluff Pulp
3	Man-made cellulose fibres
4	Cotton and other natural cellulosic seed fibres
5	Production of polymers
6	Excluded and restricted substances
7	Material efficiency in the manufacturing
8	Packaging
9	Guidance on the packaging and product disposal
10	Fitness for use and quality of the product
11	Corporate Social Responsibility with regard to Labour Aspects
12	Information appearing on the EU Ecolabel

6.1 Restrictions on substances classified under the CLP Regulation
6.2: Restrictions on Substances of Very High Concern (SVHCs)
6.3: Specific restrictions

6.3.h Silicone

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Silicone in AHPs

- Silicone in AHPs can be found in the release liners of baby diapers and feminine care products (sanitary towels and panty liners).
- In release liners, silicones (or polysiloxanes) are used primarily to achieve a grease- or water-repellent effect as a coating on materials or as an additive in materials.

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  - Is silicone used in other parts of AHPs currently in the scope of the EU Ecolabel?
  - Is this the main function for which silicone is used?

Criterion 6.3.h - Silicone

Proposal for criterion 6.3(h) – Silicones
(i) Solvent-based silicone coatings must not be used. (ii) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture in concentrations above 800 ppm (0,08 % by weight).

Point (i): solvent-based silicone

- The use of solvents in silicone coatings may lead to the release of toxins or volatile organic compounds (VOCs) into the air, with possible long-term hazards range from cancer to genetic mutations to developmental and reproductive harm.
- This method is being phased out
- **Nordic Swan and Blue Angel** set a requirement prohibiting their use

Proposal: **to ban the use of solvent-based silicone coatings**.

Point (ii): cyclosiloxanes

Current criteria → Confusion over requirement (ii): *silicone mixture*.

1. cyclosiloxanes are always present in the silicone mixture before curing → current limit of 100ppm technically impossible.
2. adding D4/D5 to the release liner (material or final product) → does not happen in reality
3. 100 ppm of D4/D5 as limit in the silicone present in the release liner (feasible)

→ Supply chain of the use of silicone in the release liners is unclear

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Silicone in the release liner: supply chain

1. Silicone/chemical supplier: supplies the pure silicone or the silicone release coating formulation to the manufacturer of the release paper
2. The manufacturer of the release paper applies the silicone coating to the release liner:

   different coating techniques (metered coating, transfer, size press…) depending on the type of delivery system for the silicone release coating (solventless, solvent-based or emulsion)

3. The manufacturer of the AHP uses the release liner

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   does it make any difference in terms of presence of cyclosiloxanes?

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Blue Angel, Nordic Swan: limit at 800 ppm

Proposal: to add the reference to "silicone mixture"; to increase the limit of D4 and D5 to 800 ppm; to add D6 to the restriction

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Other EU labelling schemes

EU Ecolabel criterion 6.3.h	Nordic Swan requirement O6	Blue Angel criterion 3.7.5
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‘silicone mixture’

- A definition is needed
- Understood to be a liquid composition of two or more silicone raw materials and may also contain other non-silicone crosslinking agents

Proposal: a 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 (adhesive or peel-off strips) on some feminine hygiene products (e.g. panty liners and sanitary towels) or on nappy tapes

Assessment and verification

- Signed declaration of compliance, supported by declarations from suppliers whenever relevant;
    - Information on the method used to manufacture the silicone;
    - Declaration from the silicone supplier that requirement (ii) has been fulfilled

Part II: reusable menstrual cups

- Scope has been extended to cover also **reusable menstrual cups**

First proposal of product group name
Absorbent hygiene products and menstrual cups
First proposal of product group scope and definition:
1. The product group 'absorbent hygiene products' shall comprise any sanitary article whose function is to absorb and retain human urine, faeces, sweat, menstrual fluid and milk - excluding textile products. *2. The product group 'menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body to retain and collect menstrual fluid, and usually made of medical-grade silicone, rubber, latex, or elastomer.* *3. The product groups 'absorbent hygiene products' and 'menstrual cups' shall not include products falling under the scope of Regulation (EU) 2017/745 on medical devices.*

Regulatory framework

1. No global regulatory framework for menstrual products
2. Austria and India (national level)
3. Swedish Institute for Standards (SIS) - ISO standard
4. General Product Safety Directive (2001/95/EC)
5. European Food Contact Materials Regulations 1935/2004/EC (Germany and France- national level)

Materials and manufacturing menstrual cups

- Materials: for silicone, the intention is not to mention food-grade to medical-grade silicone, but probably criteria on biocompatibility test

- Manufacturing: information on the process of injection moulding would be needed in order to set relevant criteria

Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 1: Product description**

This criterion could be as the one for AHP.

- **CRITERION 2: Colouring agents**

What type of colouring agents are used in manufacture of silicone for menstrual cups?

- **CRITERION 3: Silicone**

Is the formulation of criterion 6.3.h of any use here? (*100 ppm threshold)*

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Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 4: Emissions of VOCs**

No data are known to the JRC for setting of a requirement on the emission of VOCs during the production of menstrual cups.

- **CRITERION 5: Emissions of CO2 from production**

This criterion would focus on aspects similar to criterion 2.5 on fluff pulp for AHP.

Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 6: Excluded and restricted substances**
- This criterion could be similar to criterion 6 for AHP.
- CMRs and SVHCs in AHP (and menstrual cups) < 0.01% w/w.
- Substances derogation, according to art 6(7) of the EU Ecolabel Regulation.
- This criterion covers also the exclusion of nanosilver particles. Is it feasible for menstrual cups?

Tests for presence of chemicals in menstrual cups

- Benzophenone (119-61-9)
- Decamethylcyclopentasiloxane (D5) (541-02-6)
- Decamethylcyclononasiloxane(D9) (556-71-8)
- Decamethylcyclohexasiloxane(D6) (540-97-6)
- Hexadecamethylcyclooctasiloxane(D8) (556-68-3)
- Octamethylcyclotetrasiloxane(D4) (556-67-2)
- Tretradecamethylcycloheptasiloxane(D7) (107-50-6)
- Formaldehydes
- Parfums
- VOCs
- Phthalates
- Nitrosamines
- PAHs
- Heavy metals
- Chlorinated paraffins
- Latex proteins or added substances

Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 7: Material efficiency in the manufacturing**
- This criterion could be similar to criterion 7 for AHP.
- Can the quantity of waste generated during the manufacture and packaging of the products be not larger than 5%?

- **CRITERION 8: Packaging**

This criterion could be similar to criterion 8 for AHP. Under discussion: minimum 80% recycled content and 95% recyclable content.

Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 9: Guidance on the packaging and product disposal**

This criterion could require that the producers shall write or indicate through visual symbols on the packaging how to dispose the product correctly.

- **CRITERION 10: Fitness for use and quality of the product**

The content of this criterion will depend on the feedback from stakeholders on the testing methods for menstrual cups, e.g. tests for biocompatibility according to ISO 10993

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Possible criteria areas for Reusable Menstrual Cups

- **CRITERION 11: Corporate Social Responsibility with regard to Labour Aspects**

This criterion could be similar to criterion 11 for AHP.

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Additional work: PEF study of reusable menstrual cups

- Info on the value chain of reusable menstrual cups
- Data of menstrual cups manufacturing process

(all info will be anonymized)

Next steps

- Stakeholders can provide comments before 10th December 2021
- **April/May 2022**: 2nd AHWG meeting
- **Nov 2022**: presentation at EUEB meeting and final open consultation
- **March 2023**: vote on revised criteria

Thanks for your attention!

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Thank you

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