2nd Ad-Hoc Working Group (AHWG) meeting for the revision of EU Ecolabel criteria for the product group:

Absorbent Hygiene Products (AHP) & Reusable Menstrual Cups (RMC)

DAY 2
Reusable Menstrual Cups (RMC)
8th June 2022

Online Meeting (Webex)

Presentation about policy and project background, product group scope and definition, and revised criteria proposals

Minutes of the meeting

Contents

Agenda – Day 2 on Reusable Menstrual Cups (RMC)

08/06/2022

Morning session: 08:45-13:00 h CEST

		SCHEDULE
1.	Opening of virtual room and welcome of participants	**08:45 – 09:00**
2.	Introduction and timeline	**09:00 – 09:10**
3.	Scope and definitions LCA screening study on Reusable Menstrual Cups	**09:10 – 09:30**
4.	Criterion 1: Emissions during production of the raw material Criterion 2: Environmental management of production Criterion 3: Material efficiency in the manufacturing	**09:30 – 10:30**
5.	Criterion 4: Excluded and restricted substances	**10:30 – 11:15**
	15 min break	
6.	Criterion 5: Packaging Criterion 6: Guidance on the disposal of the product and of the packaging	**11:30 – 12:00**
7.	Criterion 7: Fitness for use and quality of the product Criterion 8: Information for the user	**12:00 – 12:30**
8.	Criterion 9: Social Responsibility with regard to Labour Aspects Criterion 10: Information appearing on the EU Ecolabel	**12:30 – 12:50**
9.	**Conclusion, next steps and closure of the meeting**	**12:15 - 13:00**

List of participant organizations – Day 2 on Reusable Menstrual Cups (RMC)

Allmatters
CB Austria
CB Belgium
CB Denmark
CB France
CB Germany
CB Finland
CB Norway
CB Portugal
CB Sweden
Claripharm Laboratoire
ELKEM Silicones
Essity
EU Commission DG Environment
EU Commission DG Joint Research Centre
European Environmental Bureau EEB, BEUC
EY
GROUP'HYGIENE
Harp & associés
Johnson & Johnson
Lunette
Merula GmbH
Naturcup
OFI
Wacker Chemie AG

Note to readers:

The meeting was run in a web meeting format using the WEBEX platform. For each agenda point, a short presentation was given by JRC. Participants were asked to comment/ask questions concisely via chat function or orally. These comments were addressed by JRC.

START OF DAY 2 (RMC)

Introduction – RMC

Revised scope and definitions

In relation to product scope and definition, one stakeholder inquired if all elastomers would be covered under the proposed change. Another stakeholder inquired whether latex was under the scope of the EU Ecolabel and suggested excluding it given its allergic properties.

JRC thanked the observation and indicated that probably not all elastomers should be covered under the proposed scope. Given the lack of access to suitable data, JRC is not sure if TPE would be able to comply. On the other hand, JRC confirmed that latex is out of the scope for the moment, so it would not be possible for latex cups to receive an EU Ecolabel. JRC cannot confirm that latex will not be included in the final proposal, as if JRC receives information on latex, then an assessment on latex will be carried on and decision taken.

LCA screening study on Reusable Menstrual Cups

One stakeholder asked about whether a comparison on the environmental improvements (quantified/estimated) had been carried out between products that would be awarded the EU Ecolabel and those that would not. The rationale is that the most impactful phase is usage, which is not directly affected by EU Ecolabel requirements. Hence, the requirements proposed act on life cycle phases which are significantly lower in terms of impacts, which pose the question on whether significant environmental improvements can be achieved through the EU Ecolabel.

JRC acknowledged these limitations highlighted by the LCA and indicated that this was partly expected by design (RMC are reusable and durable, thus longer usage phase) as opposed to other products. In addition, JRC described how the EU Ecolabel could make a difference in terms of environmental/performance gains:

- Better information to users information from companies to the user, which is aligned with the recent proposal for an Ecodesign for Sustainable Products Regulation. Also, the different sensitivity analyses carried out or reviewed by the JRC indicate that correct information can make a difference in terms of environmental impacts.
- Tackling impacts on the production of raw materials this is the second main hotspot, especially if sourced from outside EU. Whilst, silicone producing plants in EU are regulated by BREF, those outside EU are not. The requirement proposed would cover these EU extraterritorial plants.
- Testing fitness for use and performance of the product to ensure quality.
- Ensuring that many chemicals of concern are not added to the RMC.

In summary, JRC agreed that is a complicated aspect to tackle due to the inability to affect directly the main hotspot (the use phase) but still the EU Ecolabel would make a difference, especially given the increasing market volumes in the last years and the certainty regarding safety and quality that it provides.

Criterion 1: Emissions during production of the raw material

1.1. Emissions of dust and chlorides to air

One stakeholder indicated that no standard methods were mentioned. Also, for sub-criterion 1.1a, it was mentioned that there were doubts on how to measure diffuse emissions if the storage is not in a silo but in a covered space. Finally, regarding the threshold limit, one stakeholder asked whether it was related to one or all filters. Another stakeholder asked about how dust emission range was determined. The BAT reference precisely quotes this range, while normally the EU Ecolabel ambition tends to be set in the upper quartile of the BAT quoted range.

JRC answered that would look into available standards, and on how to measure diffuse emissions if the storage is not in a silo. JRC mentioned that the threshold limit for dust is to be intended for the total number of the filters. Finally, on the BAT interval, JRC argued that scarce data were available from European plants, which made difficult the appropriate range/distribution appraisal. Stakeholders' feedback will be very useful on this point.

1.2. Emissions of copper and zinc to water

A stakeholder mentioned that this sub-criterion mandates a specific technology to be used, which is not standard practice as it does not give flexibility to the industry. JRC acknowledged that it is true that, against standard practice, a technology was recommended. Having a requirement on the treatment of Zn and Cu may limit industry's flexibility, although to the JRC's knowledge this is the most used wastewater treatment setting. Nevertheless, JRC is open to understand other methods used by the industry.

Another stakeholder wondered whether priority should be given to more circular treatment options (metals recovery as opposed to incineration). JRC could look into options prioritisation regarding sludge disposal. Actually, there might not be the need for this requirement but JRC believes the recovery could make a difference between EU ecolabelled and non-ecolabelled products.

1.3. Emissions of carbon dioxide (CO_2) from production

One stakeholder reiterated the proposal on linking CO_2 emissions with energy consumption and highlighted the concerns related to how nuclear energy has been included in this criterion, as it could be publicly understood as the EU Ecolabel being supporting electricity production from nuclear plants.

JRC clarified that the aim was not to promote whatsoever power generation from nuclear plants. The intention was just to clarify that this technology has not CO_2 emissions. Additionally, JRC was not able to find quality and available data on energy and how to link it to energy consumption.

Criterion 2: Environmental management of production

Two stakeholders agreed on the difficulty and implications of setting fixed percentages of improvements (starting point, how much, PASS/FAIL nature) on the different manufacturing processes. One of them suggested to consider EMAS as well, given the rationale for continuous improvement, checking on consumption and documenting it. The other suggested to be specific on documentation required, proposing an Action Plan rather than the whole extensive list of procedures associated with ISO14001.

JRC mentioned that this criterion was similar to 4.1 on polymers for AHP. It was decided to add the 14001/15001 since it was requested in the first AHWG and can add clarity on the verification of the criterion. JRC will have a look at the EMAS to check whether to be included or not. The intention with this criterion was not requiring the companies to have ISO certification but to function in a similar way to it. Since this might be confusing, the wording will be revised to clarify this, aiming to facilitate the Assessment and Verification.

Criterion 3: Material efficiency in the manufacturing

A stakeholder mentioned that there should be no problem in setting the requirement close to 0% of the waste generated, given the high quality required for EU ecolabel menstrual cups (high quality materials and processes used). The waste management system should be able to deal with it and be closer to 0%.

JRC clarified that the scope covered is for the final manufacturing site and for the packaging of the cups, not only from the silicone production but from the cup production. The stakeholder insisted that despite this, still the waste management should be able to cope with it and the percentage should be lower. JRC mentioned that industry feedback would be very useful on this point.

Criterion 4: Excluded and restricted substances

4.1. Restrictions based on CLP regulation

One stakeholder asked whether there were any plans to amend the EU Ecolabel with the ongoing revision on the CLP, which aims to integrate hazardous classes related to endocrine disruptive properties. JRC acknowledged the relevance of the question made but mentioned the impossibility to provide a final answer for it. There is time to take a decision, since the new H classes are planned to be introduced in the CLP Regulation not before 2023. JRC also clarified that the EU Ecolabel, once adopted, can be updated with amendments (normally typos or references), but that can't be made to achieve a higher level of ambition.

Another stakeholder asked for a clarification on whether there was any limit in Table 2. In Table 4 there was (0.01%) but it was absent in Table 2. JRC confirmed that there was no limit in Table 2, indicating no presence of listed substances.

4.2. Substances of very high concern

One stakeholder wondered whether it was possible to source raw materials of high quality without impurities of concern. JRC provided a clarification on the sources of impurities along the manufacturing process, highlighting the impossibility to use exclusively materials with no impurities. Precisely for this, JRC mentioned the difficulty in regulating/banning impurities in other EU Ecolabels product groups (examples made were Detergents and Cosmetics) as industry can't comply with it. Nevertheless, the maximum allowance for these impurities is 0.01% in the raw material, which won't anyway be present in a 100% in mass basis.

Another stakeholder asked for a clarification on whether there was a full ban in place unless it was an impurity. JRC clarified that there is no limit – no substances should be added.

COFEE BREAK (15 MIN)

4.3. Other specific restrictions

One stakeholder recommended that the Assessment and Verification section should be listed below each of the criterion for clarity. JRC acknowledged the comments and mention it will consider it.

4.3.a Other specific restrictions – SPECIFIED EXCLUDED SUBSTANCES

One stakeholder inquired about which chemicals were the ones added and for which function, given that menstrual cups are generally announced as 100% silicone. It mentioned that, perhaps, a full ban on all other substances should be considered. The short answer from JRC was that it was unaware of which substances are added as, until recently, there was no access to these data (due to confidentiality reasons). Probably, no substances are added but, to have a safety net, JRC considered appropriate to

have this criterion to avoid addition. Whilst a full ban could be an option, JRC posed the question to industry on whether they would be able to comply with it and invite them to provide feedback.

Another stakeholder mentioned the existence of a report made by ANSES (France) which tested in feminine hygiene products the presence of chemicals of concern, such as PAHs, VOCs, BCPs and phthalates amongst others. A different stakeholder provided access to it (Report 8/18 - Survey of hazardous chemical substances in feminine hygiene products (kemi.se).

4.3.b Other specific restrictions – FRAGRANCES

No comments were made.

4.3.c Other specific restrictions – INK & DYES

One stakeholder proposed to only allow titanium dioxide in RMCs, but not other colorants. JRC considered that by requiring colouring to be aligned with food regulations the compliance with impurities would lead to enough level of safety. Nevertheless, JRC agreed to revise this further.

4.3.d Other specific restrictions – FURTHER RESTRICTIONS APPLYING TO PLASTIC MATERIALS

No comments were made.

4.3.e Other specific restrictions – CYCLOSILOXANES

One stakeholder suggested to mention explicitly that cyclosiloxanes should not be added intentionally but rather and only as impurities with a concentration up to 10 ppm. JRC thanked for the proposal and also clarified that to add intentionally cyclosiloxanes a prior derogation request would be required, which probably would not be granted.

Another stakeholder commented the results from a study from the Swedish Chemical Agency (KEMI) which found that 1/6 of the menstrual cups tested would pass the criteria for cycloxanes as currently formulated (absence). Additionally, it was mentioned that there might be other cyclosiloxanes of potential concern (i.e. D7, D8, D9) which perhaps should be considered. JRC acknowledged the comment on the potential presence of further cycloxanes (i.e. D7, D8, D9) but clarified that it was understood that only D4, D5 and D6 were known to occur as impurities in the silicone. JRC thanked the studies shared and invited stakeholders to provide access to them, so it could consult and consider them.

Criterion 5: Packaging

One stakeholder indicated that it would not be possible to achieve the recycled content. It also suggested reconsidering the recyclability target. JRC thanked the comment and mentioned a potential follow-up after this meeting.

One stakeholder indicated that no other material should be allowed in the packaging of RMCs. JRC acknowledged the comment.

Criterion 6: Guidance on the product disposal

No comments were made.

Criterion 7: Fitness for use and quality of the product

Split views were shared by stakeholders in relation to the biocompatibility testing. One stakeholder indicated that it did not see the need to repeat the test on the final product. At least not for liquid silicone. Also, this would be in line with reducing animal testing (used in biocompatibility test). Perhaps only additional test should be considered with test not using animals (e.g. cytotoxicity).

Another stakeholder supported testing in the final product rather than in the raw materials only, as in this way the imprint associated with the manufacturing process would also be measured. Testing in the raw material would not inform about potential changes or contaminations that might occur.

A different stakeholder made a comment on the validity of the method when a comparison is made between the user and testing conditions (i.e. pH choice, like vaginal tract). It is not sure whether this would make a difference. Another stakeholder affirmed that there is a flexibility in the method to specific particular aspects. JRC acknowledged that this would be taken into consideration for Technical Report 3.

JRC made a comment related to laboratory testing on tensile strength for which shape/dimensions were essential in relation to the pressure points, so the issue may be related to how to test the final products if dimensions are modified. A stakeholder mentioned that in their institution, tensile strength was tested for menstrual cups so further comments from colleagues could be sent. JRC thanked this offer and indicated that a follow-up would be requested.

It was discussed that hemolysis testing might not be needed in order to decrease the number of testing and also avoid the performance of unnecessary testing on animals. However it was also mentioned by JRC that alternatives methods with the absence of animal testing were recently added to the ISO 10993 series.

Given that the message did not matched with the aim pursued, one stakeholder suggested to remove the following sentence from the text formulated for criterion 7: "*The efficiency/quality of the product shall be at least as satisfactory as the equivalent products already on the market*". JRC acknowledged the comment and committed to check this.

Criterion 8: Information for the user

The majority of stakeholders focused on the implications of the wearing time, with particular focus on human safety. One stakeholder raised the question on which was the optimal wearing time of cup, specifically, by which technical means is this period determined. Another stakeholder indicated that based on different studies (with focus on tampons) and for safety reasons, the maximum wearing time allowed was 6 hours. Also, one stakeholder discouraged extended wearing periods (such as overnight). Other clarifications made were related to risk assessments of the separate processes of disinfection and cleaning of the cup. Along these lines, a different stakeholder highlighted the variability in literature regarding recommended wearing times (normally 4-8 hours but also found as high as 12 hours). The existence of trade-off between environmental benefits (based on LCA of extended usage) and safety issues regarding excessive wearing time/exposure was acknowledged. The importance of hygienic practices on the handling was also pointed out. After the discussion held, one stakeholder highlighted the importance of being clearer in the information provided to consumers, including whether these are to be understood as suggestions or obligations.

JRC acknowledged the relevance of the wearing time. JRC pointed out that the differences in wearing time are based on companies' recommendations and that a way forward could be making this information available. Additionally, JRC considered the possibility of asking the companies to provide a risk assessment justifying this wearing time. Failing this, the most conservative period (6 hours) could be recommended. The information has to be made available in order to allow consumers to make an informed choice. Nevertheless, JRC highlighted that the safety of the product is in any case first over environmental gains.

Concerning disinfection practice, JRC explained it is normally required in between menstrual cycles. Available studies indicated that there was no difference in terms of safety on emptying the cup and cleaning it with water during the same menstrual cycle as opposed to boiling it every single time. JRC clarified that the intention of the criterion is not to decrease the level of hygiene related to wearing

menstrual cups in order to achieve environmental gains, but rather avoiding consumers adopting excess hygiene practices due to misconceptions, as these are linked with higher environmental impacts, such as boiling the cup for half an hour in between menstrual cycles.

Criterion 9: Social aspects

No comments were made to this criterion.

Criterion 10: Information appearing on the EU Ecolabel

No comments were made to this criterion.

Next steps

The JRC thanked the participants for their time and contributions and explained next steps:

- *Stakeholders can provide comments on technical report and criteria proposals not later than 20th June 2022.*
- *Comments need to be submitted to the JRC either using the Word template provided or by using the BATIS system. JRC to publish the presentation used during the day as soon as possible.*
- *October 2022: TR3.0 publication and launch of third (and last) stakeholder consultation.*

Note to readers

An email was sent to stakeholders the following day of the meeting where:

- Presentation was made available via BATIS or website https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents.
- Information on deadline for comments (20th June 2022) was reminded.

END OF DAY 2 (RMC)