Contents

Appendix Table of Comments to Technical Report 2 for Reusable Menstrual Cups [RMC] (OCTOBER 2022)

General remarks

Comments received in AHWG2/written form	JRC Dir. B response
In general, the terms “silicon” and “silicone/s” are mixed up in the whole document; in particular in Criterion 1.1 or Criterion 1.2, but not only.“Silicon” exclusively describes the silicon metal. “Silicone(s)” describes the polymer(s), raw materials for the RMC. “PDMS” stands for “polydimethylsiloxane”: basic linear silicone chain polymer, as basis polymer for silicone elastomers	**COMMENT ACCEPTED** We thank you for the clarification.
We strongly recommend paying special attention to translations. Using the skills of national CBs and/or Professional Federations, for revisions before any publication. Thank you.	**COMMENT ACKNOWLEDGED**

Scope and definitions

Comments received in AHWG2/written form	JRC Dir. B response
[redacted] would like to see a clarification on how selective the listed requirements are. It is important to set the requirement on the most relevant hotspot, but it is equally important to set requirements that are selective in order to ensure that the certified products are products of environmental excellence.	**COMMENTS CLARIFIED** Unfortunately, there are not enough data to evaluate how restrictive EU Ecolabel criteria are on the market. However, proposed criteria ensure low emissions to air and water from the production of the raw materials, as well as a conscious system for optimising the use of water, the generation and management of waste and the consumption of energy, thus saving resources and controlling air and water pollution. Moreover the criteria ensure that hazardous substances cannot be added to the product, in line with the Chemicals Strategy for Sustainability: colourants must be approved for food, fragrances cannot be added, and CMR impurities such as cyclosiloxanes have very low limits. Besides, the packaging of the RMC must be recyclable and contain a certain amount of recycled material. The bag for the menstrual cup shall be made of 100% sustainable certified fibres. As the use phase was found as the most impacting one from an environmental point of view, requirements were developed on the fitness for use of the cup and the information for the user. These two criteria ensure a high quality of the cup (in terms of safety for the user, prevention of leakage and durability of the cup) and a correct use by the user, in line with safety aspects but without wasting resources (mainly energy and water used to clean the cup), thus reducing the risk of an earlier disposal of the cup compared to its expected (long) lifetime. Finally, a social criterion was set to guarantee that the working rights of the workers have been respected.
The ecolabelling criteria should be selective and point out the environmental best products on the market. That means that there are products on the market with different environmental status with potential for improvements and that the ecolabelling criteria can make a difference. However, as regards RMC it seems that there are no big differences between the different cups and in this case ecolabelling becomes only a health or quality label. We can´t see the relevance with ecolabelling RMCs.	

Why is it that RMCs shall not be included in the EU regulation 2017/745 medical devices? Other administrations, such as FDA, class menstrual cups as medical devices already and RMCs have also been found to non-invasively used as a collection method for stem cells, which could also fall into medical device regulation. - Faramarzi et al. (2016) / (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904135/)	**COMMENT CLARIFIED** As mentioned in the scope section, the EU Ecolabel shall not be awarded to products that are registered as medical devices. Therefore, if a menstrual cup is registered as medical device in the EU, it cannot be awarded the EU Ecolabel
For horizontal criteria, all my comments from chapter 5 apply as well	**COMMENT ACKNOWLEDGED**

Assessment and verification (including *Product Description*)

No comments received.

CRITERION 1: Emissions during production of the raw material

Sub-criterion 1.1 Emissions of dust and chlorides to air

Comments received in AHWG2/written form	JRC Dir. B response

Sub-criterion 1.1(a) Dust

Comments received in AHWG2/written form	JRC Dir. B response
The following wording is suggested: *(i) This requirement applies to **silicones** only. The storage and handling of the elemental silicon raw material containing silicon powder/dust shall* *apply at least one of the following techniques:* *·Storing elemental silicon after grinding in silos;* *·Storing elemental silicon after grinding in covered areas protected from rain and wind;* *·Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon after grinding into storage;* *·Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.* *[Rationale]* Elemental silicon before grinding consists of massive chunks, where dust is not relevant, therefore in these areas, the techniques to minimize emissions of dust are not relevant and not applied. It must be made clear, that the techniques are only applicable for elemental silicon after grinding, containing powder/dust.	**COMMENT PARTIALLY ACCEPTED** The sentence 'containing silicone powder/dust' was not added because unclear. All other suggestions were accepted.
[Criterion 1(a)(ii)] The following changes are proposed: *"(ii) This requirement applies to both **silicones** and **other elastomers.** The ~~yearly average from~~ channelled emissions of dust shall be below 5 mg/Nm3. Where a monitoring is required, the dust emissions should be ~~continuously~~ monitored at least every 3 years."* *[Rationale]* According to the final draft of the WGC BREF, the minimum monitoring frequency for dust is once every 3 years (BAT 8, footnote 7). Continuous monitoring is not applied, thus there is no yearly average from a continuous monitoring. Monitoring may also be replaced by the monitoring of substitute parameters (e.g. pressure drop) in combination with filter specifications in some cases. Monitoring requirements are laid down in the permits.	**COMMENT ACCEPTED** Monitoring of emissions is proposed to be kept at once per year, since no information could be found that emissions of dust during production of silicones and other elastomers is sufficiently stable.

Sub-criterion 1.1(b) Chlorides

Comments received in AHWG2/written form	JRC Dir. B response
The following wordings is suggested:	**COMMENT ACCEPTED**

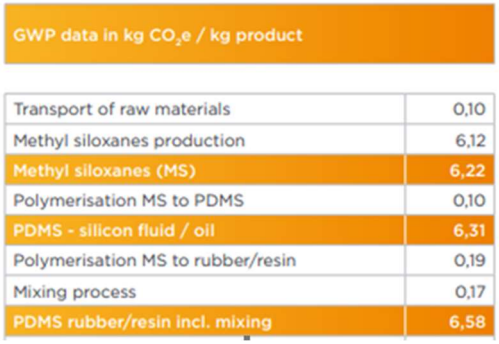
*"(iThis requirement applies to **silicones** only. The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. The thermal oxidation shall be authorised to burn chlorinated compounds. "* [*Clarification*] Not wrong - but not due to the risk of PCDD/F formation, but for the organic compounds in general – this is not correctly assessed on page 30. Although chlorinated and organic compounds are present, the formation of PCDD/F is largely depending on temperature profiles in the process. PCDD/F is not a relevant compound in the waste gas of the processes: methyl chloride synthesis, direct synthesis and distillation in the production of silicones. PCDD/F formation is not relevant in these processes	
The following wording is suggested: *(i)* This requirement applies to ~~both **silicon** and~~ **other elastomers** than silicones**.** PCDD/F emissions shall be below 0.01 ng TEQ/Nm3. Monitoring of the PCDD/F emissions should take place at least once every year ~~six months~~. [*Rationale*] •The processes for the production of silicones are not likely to form PCDD/F due to the temperature profiles. Note: The BAT AEL-range is <0.01 – 0.05 ng TEQ/Nm³, hence the value should be 0.05. Note: According to the final draft of the WGC BREF, the minimum monitoring frequency for PCDD/F is once every year (BAT 8, footnote 9), Note: Waste gas treatment is often organized in a separate unit/installation, especially at integrated production sites, and different monitoring frequencies may apply. •1.1(b) may be not applicable at all – it should therefore be deleted completely	**COMMENT PARTIALLY ACCEPTED** Monitoring of emissions is proposed to be kept at every six months, since no information could be found that emissions of PCDD/F during production of elastomers is sufficiently stable.
No standards or test methods are named [Suggestion] List standards or test methods where possible. [Rationale] Does that mean all kind of measurements are acceptable? For CBs it might be hard to judge whether the report/test is ok. Are measurements of the applicant itself acceptable?	**COMMENT ACCEPTED** Relevant test methods were referenced
The following changes are proposed: ***Assessment and verification:*** *The applicant shall provide a declaration of compliance from the raw material supplier with criterion 1.1. ~~In addition:~~* *~~- To show compliance with criterion 1.1(a).i, the silicon supplier shall indicate which measure is used on site, providing pictures or projects of the measure installed as supplementary data;~~* *~~- To show compliance with criterion 1.1(a).ii, the raw material supplier shall provide the results of the dust measurements taken on site, together with the yearly average of the dust emission. For the production of silicon, the measurement shall cover grinding, storage and handling of elemental silicon containing silicon powder/dust as a minimum;~~* *~~- To show compliance with criterion 1.1(b).i, the silicon supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps;;~~* *~~- To show compliance with criterion 1.1(b).ii, the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases.~~* [Rationale] A declaration of compliance can be delivered in a standardized way. All other additional named documents would mean a huge personal/time effort for the silicone raw material supplier, that would not be covered by a reasonable cost/benefit range.	**COMMENT REJECTED** The listed information is needed in order to verify that the criteria are fulfilled. This information need to be submitted only once.

Sub-criterion 1.2 Emissions of copper and zinc to water

Comments received in AHWG2/written form	JRC Dir. B response
After dewatering of the sludge before disposal, why given the option to either recover the solid metal residues in metal recovery plants or either disposing the sludge via incineration or landfill. The last option would imply that the solid metals are not recovered and that they may end up contaminating the environment, which does not seem very aligned with the circular economy principles and the waste hierarchy.	**COMMENT ACCEPTED**

Sub-criterion 1.3 Emissions of CO_2

Comments received in AHWG2/written form	JRC Dir. B response
[redacted] suggests focusing on the reduction on energy consumption, and not only CO2 emissions. Nuclear power energy is not special and better, and must be treated as every other energy source. Reduction factors for nuclear power is included for the first time, which should be discussed at the EUEB level. Using national CO2emissions factors shall not be possible. In [redacted], this is subject to parliamentary scrutiny.	**COMMENTS PARTIALLY ACCEPTED** The sentence on nuclear power has been removed, as it was anyway not applicable to the criterion. Indeed, for electricity, the reference value in Table 2 is allowed not to be used only when presenting documentation establishing the average value for its suppliers of electricity (contracting suppliers or certified electricity). A new criterion on energy consumption could not be added due to the lack of data.
The [redacted] strongly disagree with rewarding nuclear energy through the EU Ecolabel. Only when electricity from renewable sources is used an incentive should be provided by deducting from the total calculation of CO2 emissions. Otherwise, the average EU energy grid should be used as a reference.	
The following wording is proposed: - *BREF for SIC 1.3-2.8 kg CO2eq/ kg PDMS (page 35)* - *Global Silicon Council 1.14 kg CO2eq/kg PDMS (page 35)* - *CO2 emissions from the production of the silicon shall not exceed 1.3 kg per kg silicon (criterion 1.3)* PDMS and silicon do not have the same meaning, see comment No. 1. Moreover, we do not understand the values given on page 35 and in criterion 1.3. The value of 1,3 kg CO2eq pro kg PDMS (or silicon?) is roughly 5 times below the current technology. These values do not seem to be representative and need further explanation before we can comment on that. In the current version of the Carbon Balance Study, 2012 from GSC Silicon - Chemistry Carbon Balance (siliconescarbonbalance.eu) the following values were developed across companies:	**COMMENT ACCEPTED** A new threshold of 6.58 kg CO2eq/kg PDMS rubber is proposed, in line with the GCS report.

	
Regarding the methodology of Calculating PCFs (pages 36 & 37) we would like to point out that TfS (Together for Sustainability) developed a PCF-guideline which specifically meets the requirements of the chemical industry. The guideline is expected to be published in September 2022. We would like to recommend to refer to this PCF guideline. In general a reference to the standards for the calculation should be provided, e.g. with a statement like that:„*The calculation of PCFs should follow the international standards ISO 14040:2006+A1:2021 and ISO 14044:2006+A2:2020 for Life Cycle Assessment. In addition to these generic guidelines, ISO 14067:2018 for Product Carbon Footprints should be followed, taking also into account other guidelines such as the GHG protocol developed in recent years. The WBCSD guideline Pathfinder 1.5 SOS and of Life Cycle Assessments should be considered as well.*" All of these guidelines mentioned above were the basis for a new PCF guideline from TfS (Together for Sustainability). The 100-year GWP characterization factors (GWP100y) according to the Intergovernmental Panel on Climate Change (IPCC) shall be used in the PCF calculations, based on the IPCC's Sixth Assessment Report (AR6).	**COMMENTS REJECTED** At this stage, a PCF-based calculation is not proposed, as differing very much from the previous approach. Moreover, a PCF-based calculation is expected to increase the costs for companies, due to the analysis to be carried out and to be verified by a third-party verifier. Nevertheless, this aspect has been added to the TR3 as a point for discussion, to gather the other stakeholders points of view.
It is probably not useful to fix data as given in Table 1, as it is state of the art for the industry to update such data continuously, based on new scientific findings. Therefore, TfS prefers to refer to the evaluation method of a PCF calculation, because LCA softwares (such as GaBi for ex.) update such values in the background, for example values of the IPCC AR5 are replaced by the values of the IPCC AR6.	

CRITERION 2: Environmental management of production

Comments received in AHWG2/written form	JRC Dir. B response
The [redacted] support the integration of an EMS, as this requirement will bring savings for the environment and for manufacturers. Why referring only to ISO 14001? EMAS should also be integrated as a reference. Having verified targets would make this criterion more meaningful. In any case, it would be in line with the approach of EMS which are implemented through a continuous improvement approach, by analysis of environmental impacts based on specific indicators, formulation of improvement targets and an action plan to achieve those.	**COMMENT ACCEPTED** Please, refer to the new proposal for criterion 2 as specified in Technical Report 3.

The following wording is suggested: "The applicant shall provide a declaration of compliance with the cited requirement from (1) the producer of raw materials (silicone or other elastomers) and (2) from manufacturer of reusable menstrual cups. Companies have either to provide their ISO 14001 and/or ISO 50001 certificate(s), which is/are then sufficient as proof for compliance with Criterion 2 or the declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirement for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001."	**COMMENT PARTIALLY ACCEPTED** Please, refer to the new proposal for criterion 2 as specified in Technical Report 3. A similar wording is added in the criterion.

CRITERION 3: Material efficiency in the manufacturing

Comments received in AHWG2/written form	JRC Dir. B response
[redacted] *finds the level at 8% high since the production is done with a homogeneous material where waste should be relatively easy to sort and collect to ensure a high degree of reuse.*	**COMMENT ACCEPTED** Please, refer to the new proposal for criterion 3 as specified in Technical Report 3. The % of waste generated requirement has been lowered to 4%.

CRITERION 4 Excluded and restricted substances

Sub-criterion 4.1 Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council

Comments received in AHWG2/written form	JRC Dir. B response
Page 177 –Requirement clarification and implications *"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"* Which requirement: Table 2 or Table 4? this is not clear If Table 2 applies to all the ingredients of the silicone elastomer raw materials before crosslinking to a silicone elastomer, then platinum-catalyzed silicone elastomer raw materials are not useable as raw materials for RMC: - the very commonly used platinum catalyst Karstedt's catalyst, CAS Nr 68478-92-2, is classified as H361d - the very commonly used platinum inhibitor 1-Ethinylcyclohxanol, CAS Nr 78-27-3, is classified as H311 - the very commonly used filler "silanated silica", CAS Nr 68909-20-6, is classified as H373 (18th adaptation to technical progress (ATP))	**COMMENT CLARIFIED** The exemption refer to both Table 2 and Table 4.

Sub-criterion 4.2 Substances of Very High Concern (SVHCs)

Comments received in AHWG2/written form	JRC Dir. B response
With respect to the challenges raised by the dynamic approach of the SVHC candidate list. Manufacturers would need to find alternatives not only from the moment they chemicals are added to the Candidate List. Even before this, they are aware of the problematic properties of the substances which have a CLP classification and the need to substitute them.	**COMMENT ACKNOWLEDGED**

Sub-criterion 4.3 Other specific restrictions

Sub-criterion 4.3(a) Excluded substances

Comments received in AHWG2/written form	JRC Dir. B response

[redacted] would like to recommend to JRC to take into account further sources when determining which hazardous subtsances should be tested in reusable menstrual cups. The following research and references seems relevant: ANSES https://www.anses.fr/fr/system/files/CONSO2016SA0108Ra.pdf ANSES highlights the lack of information regarding material composition also with respect to the use of auxiliaries and intentional additives such as perfumes or colourants (p. 6). In page 7 they describe tests that have been performed with respect to chemicals and VOCs on 9 menstrual cups. Phthalates and plasticisers were not found. As to VOCs they found some problematic levels in 5 menstrual cups. However, the tests were done in conditions that are not representatives of menstrual cycles 60 million consumers (see link below and attached file). https://www.60millions-mag.com/2019/09/13/nous-avons-teste-les-coupes-menstruelles-et-c-est-rassurant-16808 60 million consumers tested the presence of Bisphenol A, SF, phthalates, PAH and azo dyes. All the products were ok. They also point out to different types of silicone quality (medical silicone based on "platine" seems more stable than peroxide, although they did not take this into account in the test).	**COMMENT ACKNOWLEDGED** The JRC would like to thank the stakeholder for providing such information
"x. Substances identified to have endocrine disrupting properties;" According to which regulation or which list? this must be clarified	**COMMENT CLARIFIED** This is clarified in the definition section, where it is reported: "'Substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012( ) or (EC) No 1107/2009( ) of the European Parliament and of the Council

Sub-criterion 4.3(b) Fragances

No comments received.

Sub-criterion 4.3(c) Inks and dyes

Comments received in AHWG2/written form	JRC Dir. B response
[AHWG2 PPT – day 2 Criterion 4.3.c, p. 67] Colour Mixes [redacted] *is made of 100% medical grade silicone. We use FDA and EU approved dye for medical & food use, no heavy metals/phthalates, and colour within the silicone does not leach.* *- EU Regulation 1333/2008* *We propose that the colours used in RMCs should comply with EU regulations for food use, not exceeding specific limits e.g. 2% of total weight.* *- FDA does not approve some Elastosil colour pastels, such as red colours over amounts as low as 1% of total weight (https://www.wacker.com/h/medias/7461E-EN.pdf)*	**COMMENT ACCEPTED**
TR2, Page 182-> Colorants clarification The dying colorants listed in Regulation (EC) No 1333/2008 are not used in silicone elastomers. Pigments are commonly used for coloring the silicone elastomers and they are not listed here.	**COMMENT ACKNOWLEDGED**

Sub-criterion 4.3(d) Further restrictions applying to plastic materials

No comments received.

Sub-criterion 4.3(e) Cyclosiloxanes

Comments received in AHWG2/written form	JRC Dir. B response
The following changes are proposed: 1. *"Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the final product in concentrations above 100 ppm (0,01 % w/w). The 100 ppm limit is to be applied to each substance separately."* 2. ~~To demonstrate compliance with sub-criterion 4.3(e), the applicant shall provide a declaration from the supplier that the requirement has been fulfilled.~~ *[Rationale]* 1. Reliable available analytical methods detect cyclosiloxanes in elastomeric matrixes down to 100 ppm, see https://www.silicones.eu/wp-content/uploads/2019/01/Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf 2. *The cyclosiloxane content in end-articles, made of silicone elastomer raw materials, very much depends on the processing conditions at the manufacturer of the end-article, and only in a limited way on the cyclosiloxane content in the starting raw materials. For ex., following parameters can have a major influence on the content of cyclosiloxanes in the RMC: processing temperatures in the crosslinking process at the end-article manufacturer; post-curing or no post-curing at the end-article manufacturer; and wall thicknesses of the finished end-article, etc…*	**COMMENT PARTIALLY ACCEPTED** The requirement is proposed to apply to the silicone raw material or other elastomers, before the production of the cup. There was a mistake in the previous report and the proposed limit is indeed 100 ppm
Silicones However different levels and definitions are used for the AHP and menstrual cups criteria, which is a bit confusing and to my understanding the criteria for AHP are more strict as it covers the silicon mixture (which after curing probably gives lower values of D4, D5, D6) where the menstrual cups criteria looks at the polymer itself. When comparing the suggested criteria levels for menstrual cups with the ECHA consultation answers for authorization of D4, D5 and D6 it seems as if the levels suggested for the criteria (shall not be present in the final product in concentrations above 10 ppm) are lower than the level industry says exists in medical devices (which I think is quite similar to menstrual cups). Comparing the suggested levels with the KemI tests six out of seven silicon menstrual cups will meet the requirements. One of the tested cups has levels 74-2000 times higher than the proposed levels. The cups made in TPE don't contain any of the tested substances. This is however what could be expected as the substances where chosen with silicone in mind. kemI made a risk assessment for the levels of D4, D5 and D6 in the cups and found that the use could be considered safe also for the highest level detected. I know the Swedish Chemicals Agency made a monitoring project in 2018 on the topic (unfortunately in Swedish, but with an English summary) https://www.kemi.se/download/18.60cca3b41708a8aecdbc26a8/1587038798179/rapport-3-18-kartl%C3%A4ggning-av-farliga-kemiska-%C3%A4mnen-i-intimhygienprodukter.pdf The three substances in the KemI report that where not risk assessed are three cyclosiloxanes: D7, D8 and D9. These are not as common as D4, D5, and D6. Norm from EMA There is n ICH guideline on unwanted impurities in medical devices which could be applied to menstrual cups: ICH Q3D Elemental impurities | European Medicines Agency (europa.eu)	**COMMENT PARTIALLY ACCEPTED** There was a mistake in the previous report and the proposed limit is indeed 100 ppm and not 10 ppm. The requirement is now proposed to apply to the silicone raw material or other elastomers, before the production of the cup.

CRITERION 5: Packaging

Comments received in AHWG2/written form	JRC Dir. B response
- Ensuring that packaging materials, particularly primary packaging, are from already 100% recycled sources can be difficult, as there can be questions about the purity of the packaging (e.g. FDA etc. medical device). - We propose that the packaging should be 100% recyclable in further stages, and recycling information and how widely recycled the material is, could also be included in the packaging - Due to differences in materials, such as paper/carton that are very widely recycled, versus some plastics such as PET or plastic films that are not recycled widely and do not result in durable recycled material [redacted] cup packaging is made of carton and paper, including the outer carton shell, inside carton, paper user instructions, and paper stickers. The transparent window is made of cellulose fibre, instead of plastic film and can be normally recycled with carton/paper. These materials are also widely recycled with accessible recycling facilities for most. [redacted] Cup packaging is 100% recyclable, and Lunette secondary packaging includes cardboard boxes, paper stickers, paper sheets to minimise product movement in postage and paper packaging tape, which are also easily recyclable. RMC storage pouch Storage pouch provided with [redacted] are pouches made of recycled polyester materials. Cotton fibre residual on the cup surface could be an issue, and particularly organic cotton is less processed and results in more residual fibres. - [redacted] has decided to opt for this material, since cotton production is very water intensive and often with materials produced from organic cotton it is not certain that the given cotton is organic but only the reflective portion of the production quantity. - Other materials, particularly recycled materials, but also hemp, bamboo and cellulose fibre could also be proposed to be included in storage pouch materials, for more reduction in environmental impacts.	**COMMENT PARTIALLY ACCEPTED** Please, refer to the new proposal for criterion 5 as specified in Technical Report 3. - Cardboard and paper used for the primary and secondary packaging of reusable menstrual cups is requested to be made of 40 and 80 % recycled material respectively. - Plastic used for the primary and secondary packaging of reusable menstrual cups is requested to be made of 10 % recycled material. After 1st January 2028, plastic packaging is requested to contain 25% recycled material. - - The reusable bag or pouch shall be made of 100% sustainable certified fibres and certified as such.

CRITERION 6: Guidance on the disposal of the product and of the packaging

No comments received.

CRITERION 7: Fitness for use and quality of the product

Comments received in AHWG2/written form	JRC Dir. B response
ISO 10993 or USP Class VI guideline for raw material testing, and technical tests on biocompatibility of materials used in manufacturing are supported. We think that some of these tests are not necessary for the final product, like for example biocompatibility for the final menstrual cup. Rather proposing durability tests, design validation or corresponding post-market data analysis from a longer time period would be endorsed to ensure the product durability in the intended use. In-use tests In-use tests such as leakage protection, fit and comfort and overall performance for the final RMC, with an 80% satisfactory rating, or comparable post-market data analysis would be favourable. - For example, we have found that 99% of 1,903 [redacted] users would recommend [redacted] to others ([redacted]). [redacted] has recommended wearing time of up to 12h (except due to market specific regulations in in Germany, Australia, & France - 8h) and within the 17 years of user data, since 2005, [redacted] have not been connected to any TSS (toxic shock syndrome) cases.	**COMMENT PARTIALLY ACCEPTED** Please, refer to the new proposal for criterion 7 as specified in Technical Report 3. For wearing time and TSS specifications, please refer to criterion 8.
Regarding testing for biocompatibility and general leachability tests: The norm for medical devices contains information on how to test for biocompatibility and there are other guidelines for testing silicones or elastomers, but the issue here is that the "environment" in which a menstrual cup is placed is very different from other contact areas in and on the human body. While the cup will be surrounded my mucous tissue this can probably not be compared with dental products also in contact with mucous tissue since the pH in the mouth and the vaginal tract is not the same. So the testing setup has to be carefully considered.	**COMMENT ACKNOWLEDGED**
The text reads: *"Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups applying for the EU Ecolabel. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test only one material. Special care shall be taken regarding sampling, transport and storage of the materials and products to guarantee reproducible results."* It is not clear if only the cross-linked silicone elastomers shall undergo biocompatibility tests or if the RMC shall undergo biocompatibility tests. This must be clarified (See also comment related to the question *Shall biocompatibility tests be performed to the final menstrual cup as well?)*	**COMMENT ACCEPTED** Please, refer to the new proposal for criterion 7 as specified in Technical Report 3. Clarification has been added.
It is suggested the following change: ~~A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation~~. [Rationale] From a toxicological point of view, from an ethical point of view and from an animal-welfare point of view (DIRECTIVE 2010/63/EU), it is not acceptable to repeat unnecessarily tests on animals. The demand for representativeness of the sample is already written in Criterion 7: *"The following elements shall be specified: place and date of the tests; criteria used to select the products tested and their representativeness;"* So a repetition on 5 samples is absolutely redundant, useless and not justifiable.	**COMMENT ACCEPTED** Please, refer to the new proposal for criterion 7 as specified in Technical Report 3. Clarification has been added.

- *Shall both ISO 10993 series and the USP Class VI standard be considered equivalent for biocompatibility compliance?* Yes, as they are intended for the same purpose, they should be handled equivalently. It is to be noted, that USP Class VI tests are exclusively tests on animals (See previous comment on minimum sample number!). - *Shall biocompatibility tests be performed to the final menstrual cup as well?* No. If the raw material supplier can already provide relevant biocompatibility tests certificates on one representative cross-linked silicone elastomer sample, then it is not necessary to perform new tests on the end-article (See previous comment on minimum sample number!). - *Shall hemolysis testing (ISO 10993) be required at all?* No. RMC do not get into contact with circulating blood, therefore this test is not relevant at all for the RMC.	**COMMENTS ACCEPTED** Please, refer to the new proposal for criterion 7 as specified in Technical Report 3. Clarification has been added.

CRITERION 8: Information for the user

Comments received in AHWG2/written form	JRC Dir. B response
[redacted] suggests setting more clear advice on how to use and clean the products. The guidance shall ensure both safety and the environment.	**COMMENT PARTIALLY ACCEPTED** Please see the new proposal for criterion 8 at section 6.9 of the TR3.
EU Ecolabel should precisely prescribe the content of the consumer information. [Rationale] The discussion showed that the specifications could differ greatly depending on the manufacturer. To ensure the highest possible level of safety and environmental compatibility, should the core content be given.	**COMMENT PARTIALLY ACCEPTED** The new proposal adds more details and prescribes the need for validation studies backing up the guidance of the manufacturers. However, very specific indications cannot be given in the context of the EU Ecolabel criteria, as it depends on the specificities of the product and should be the manufacturer's responsibility, especially given the absence of data in the literature.
Due to different materials and designs used for RMCs, we believe all cups should have a product specific cleaning validation test to determine the efficiency of the proposed cleaning practice. General guidelines could potentially be misleading for some materials or different cleaning products might not be sufficient for cleaning the cup during the cycle. As for [redacted], it was found in a lab study that cleaning the cup during the periods with our Cup Cleanser, which is specifically designed for medical grade silicone cups, and boiling it for 5-10 minutes after the period was sufficient to sanitise the RMC.	**COMMENT PARTIALLY ACCEPTED** The new proposal sets the need for validation studies backing up the guidance of the manufacturers. However, very specific indications cannot be given in the context of the EU Ecolabel criteria, as it depends on the specificities of the product and should be the manufacturer's responsibility, especially given the absence of data in the literature.
The 8 to 12 hour wearing time of the internal protection as indicated in the LCA RMC report is not acceptable. After 6 hours the bacteria reach a critical development threshold, at which point the TSST-1 toxin is produced. The toxin leads to Toxic Shock Syndrome (TSS) which can lead to amputations and even death of the user. Because of this risk, there is a lack of information on which hygiene protection to prohibit at night, the recommendations of the French social security system are not to wear internal protection at night in order to reduce the risk of developing TSS (Toxic Shock Syndrome). We recommend a change of cup 4 times a day at least every 6 hours. We therefore warn you that wearing a menstrual cup for 8 hours to 12 hours puts the user at risk. Supporting documents: Study of the ANSES (Safety of intimate protection products December 2019, referral number: 2016-SA-0108) (In collaboration with the expertise of the Claripharm Laboratory) Internal study of wearing time in the face of Toxic Shock Syndrome: with evolution of Staphilococcus aureus	**COMMENTS REJECTED** After researching the relevant literature, clear guidance on the wearing time of the cup could not be concluded. For this reason, and given the absence of an official guidance, it is not proposed to set a maximum wearing time in criterion 8. Rather, it is proposed that the wearing time recommended by manufacturers should be proven by submitting relevant studies supporting the guidance. Relevant studies include biological risk assessment and toxicology studies. Moreover, given the ANSES's findings on the fact that only one woman out of three wash her hands before changing protections, it is proposed to add to the instructions information on the

Clarifharm can make available the study performed on the development of the bacteria.	importance of washing the hands to avoid the transmission of bacteria. Please refer to section 6.9 of the TR3 for more details.
based on different studies (with focus on tampons) and for safety reasons, the maximum wearingtime allowed is 6 hours.	
We would like to highlight the variability in literature regarding recommended wearing times (normally 4-8 hours but also found as high as 12 hours)	
With respect to information for use it is important to consider the following: - Washing hands before use. According to ANSES less than one women in three was hands before changing protections, while hands are the main vector for transmission of staphylococcus. - Avoid wearing the menstrual cup more than 6 hours. There is not yet official recommendations developed, although in the 2nd AHWG we learned that in France a law is in preparation with regards to this. Some manufacturers recommend 12 hours, but this is far too long compared to the maximum duration recommended by "Centre National de Reference des staphylococcus" in France which is 6 hours. The main reason for this is the risk Toxic Shock Syndrome. This center also advices not to wear tampons or menstrual cups overnight. We understand that there is a trade-off with environmental impact that would be lower if wearing the cup for more hours. However, safety should come first. We recommend to the JRC to take into account the recommendations from ANSES, the CNR and the decree under preparation in France. See more details in this article: https://www.60millions-mag.com/2019/09/13/nous-avons-teste-les-coupes-menstruelles-et-c-est-rassurant-16808	
In the LCA RMC report it is stated that the lifetime of the cup is 10 years, however each supplier must be able to justify the lifetime of the silicone. Addition: A justification for the lifetime of the cup is necessary and is to be proven by the "Biological Risk Assessment" for example.	**COMMENT ACCEPTED**

CRITERION 9: Corporate Social Responsibility with regards to Labour Aspects

No comments received.

CRITERION 10: Information appearing on the EU Ecolabel

Comments received in AHWG2/written form	JRC Dir. B response
As mentioned repeatedly in the TR, "according to the LCA screening study performed on RMC, the use phase is the most relevant life cycle phase, accounting for 96-99% of the results, depending on the impact category". As vehemently reminded during the AHWG, any modification of the use phase to reduce this impact (namely, increasing the duration of use) is strictly not recommended for obvious (and documented) sanitary reasons. If we take this in account, the EE claim "Product designed to reduce environmental impact" is not only inappropriate but also misleading. It could be useful to make a double check – with legal advisors - before going ahead.	**COMMENT ACKNOWLEDGED** The LCA screening study performed on Reusable Menstrual Cups (RMC) identified that when the use phase is excluded from the assessment, raw material acquisition is the most relevant life cycle stage for all impact categories for both cup types, with the shares between 84% and 100% (silicone cup), and 80% and 100% (TPE cup). The study concluded that silicone production was the most relevant process in Resource Use – minerals and metals (95%) and Human Toxicity – non-cancer (95%) impact categories, which were not identified among the most relevant life cycle stages when analysing results with the use phase. In the same way, for the thermoplastic elastomer production the most relevant process was also Resource Use –fossils impact category (36%).

	Criteria are designed in line with these requirements. All in all, it is sufficiently proven that EU ecolabelled RMCs would: - be designed to reduce impact on the environment, - fulfil strict requirements on harmful substances, - have verified performance.