EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Directorate B – Fair and Sustainable Economy
**Circular Economy and Sustainable Industry**

*Revision of the EU Ecolabel criteria for detergent and cleaning products*

*Background paper displaying discussions and feedback received during the working sub-group (sub-AHWG) on*

# *Microbial Containing Products (MCP)*

*This background document aims to provide the context and the content on the discussion points addressed during the MCP working sub-group lifetime (1st and 2nd meeting)*

# 1 General introduction

The Joint Research Centre (JRC) can organise Ad Hoc working sub-groups (sub-AHWG) as part of the revision of EU Ecolabel criteria, aimed at feeding, cross-checking and improving draft criteria proposals made on specific aspects.

The scope could be as wide as a criterion *and*/or a number of product groups but also really specific, as examining a particular material/ingredient type within a product sub-group. Whatever the case, it requires the involvement of experts on the chosen topic due to the highly technical nature and/or specificity of the exchanges expected during the sub-AHWGs meeting/s.

The product groups (PGs) under the scope of the EU Ecolabel criteria under revision are:

- "Dishwasher detergents" DD
- "Industrial and institutional automatic dishwasher detergents". IIDD
- "Laundry detergents" LD
- "Industrial and institutional laundry detergents" IILD
- "Hard surface cleaning products" HSC
- "Hand dishwashing detergents". HSC

These PGs are treated horizontally, meaning that there won't be a separated sub-AHWG for each particular product group but rather all discussions on a particular topic for the six PGs will be happening together on the same day.

The sub-AHWGs steps for the revision of the EU Ecolabel criteria for detergent and cleaning products are:

1. Sub-AHWG formation -> JRC released a Call for Expression of Interest (CfI) during May 2025 and then stakeholders confirmed their willingness to participate. After the CfI deadline, the JRC notified relevant parties about their membership in the sub-AHWGs and provided the necessary information for the upcoming meeting/s (i.e. background paper).
2. First (1st) sub-AHWG meeting -> In this 1st sub-AHWG meeting the JRC introduced the topic and clarified any doubt surrounding the background information provided beforehand, inclusive of any questions that may have been shared. The aim was to ensure effective understanding and gathering of relevant/missing data/information. Participants shared their comments and/or replies to these questions prior to the deadline set by JRC (e.g. via *EU survey* platform; using JRC's template). These substantiated/contributed to a new criteria draft proposal which was discussed in the 2nd sub-AHWG meeting. For this initial meeting the duration estimated was 1-2 hours, being modified according to expected participants/topics to be covered.
3. Second (2nd) sub-AHWG meeting -> In this 2nd sub-AHWG meeting the JRC presented a draft criteria proposal informed by/based on the feedback received in the 1st sub-AHWG meeting. This proposal was circulated prior to the 2nd AHWG meeting, highlighting changes made and specific new discussion points/questions. The aim was to gather specific feedback enabling fine-tuning of this draft criteria proposal. Participants shared their feedback during the meeting, then being reflected in a final version of the background document and used to fine-tune the proposal presented. This curated proposal, inclusive of any further work carried out by the JRC, will be brought for discussion during the 2nd AHWG meeting. For this last meeting, the expected duration was 2-4 hours, being modified depending on expected participants/topics to be covered.

# 2 Introduction – *Microbial Containing Products (MCP)* sub-AHWG

The EU Ecolabel Regulation set out general requirements for substances used in EU Ecolabelled products. Generally, these requirements focus on the chemicals used during the life-cycle of a particular product, limiting or excluding toxic and/or harmful substances but also those which could exert detrimental environmental impacts (*Excluded and restricted substances* criterion). However, all ingredients used in a product are considered, some of which could be of biological nature, namely microorganisms. Complementary, other provisions ensure that products perform as expected (*Fitness for Use*). The former plus other requirements ultimately pursue ensuring that ecolabelled products are "best-in-class" not only in terms of safety but also environmentally-wise.

*MCP sub-AHWG* overview

Aim/s: improving provisions in existing detergent and cleaning products EU Ecolabel criteria (HSC products) and/or develop new ones (e.g. scope expansion - LD) having as primary focus safety (hazard/risks identification) but also technical performance at EU level.

Scope: Criteria *Scope*, *Excluded & Restricted substances (microorganisms)*, *Fitness for use*; All PGs but focus on HSC and *LD*.

Transparency: all discussions held in the dedicated sub-AHWG meetings and documents used will be publicly available (i.e. minutes; background paper).

Target audience: Experts with experience in carrying out (microbial) safety assessments and/or experts on this type of products/formulation (e.g. industry – license holders / manufacturers) and/or academics with expertise in this field are especially welcomed here.

Sub-AHWG composition: The total number of sub-AHWG members registered was 22 (as 25/09/24), with industry accounting for the greatest share (15/22), followed by *Other* entities (e.g. testing laboratories; consultancies), Competent / ecolabelling bodies (5/22) and lastly, NGOs (3/22).

The field of products containing microorganisms is relatively new within the detergent and cleaning sector. In it, environmental improvements have been identified (compared to chemical counterparts) yet with potential safety and performance verification concerns associated to their nature and use. Existing EU ecolabel criteria already has provisions in place about microorganisms, but limited to HSC for professional use. Furthermore, there are initial evidences that there are products already in the market containing microorganism belonging to other PGs within the scope of the EU Ecolabel criteria (LD). Whatever the case, there is interest in ensuring that performance, including claims made on the product, can be verified. Hence, the JRC has organised this working sub-group dedicated to hold discussions on MCP-related aspects.

So far, a brief introduction to the topic has been provide but stakeholders willing to have full details about "how we reached up to this point" are invited to read about:

- how existing provisions on microorganisms were set in the final report of the previous EU Ecolabel criteria revision ([1]).
- which is the information available and status in the current revision exercise via the preliminary report ([2]) and the 1st Technical report ([3]).

In order to bring "up-to-speed" with current products' reality (e.g. market & technological development; scientific evidences; etc) the first step carried by JRC was mapping which aspects of the existing criteria required further attention. Then, it inquires about the evidences that could lead

[1] See pages 83 - 88 https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/contentype/product_group_documents/1581681262/Technical%20background%20report.pdf
[2] https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2024-02/Detergents_Draft_Preliminary%20Report.pdf
[3] See the sections *Scope* (pages 24 – 25) and 7.6.9 *Micro-organisms* (pages 113 - 114) https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2024-02/Detergents_Draft_Technical%20Report%201_1.pdf

(fill the gaps) to criteria changes (new/updated proposals), being some aspects very general while others are really specific, thus respectively leading to open or specific questions.

In the 1st meeting, held on the 25/06/24, discussions were articulated in what were perceived as meaningful thematic MCP blocks: 1) existing criteria (HSC); 2) scope expansion (LD) and; 3) performance. Consequently, the first three sections of this background version document follow this same structure. Each of these sections was split into the following sub-sections:

1. Mapping of aspects – A description/listing of the aspects requiring further assessment as identified by JRC and/or stakeholders prior to the 1st MCP sub-AHWG meeting (from focused questionnaire; written comments to TR1).
2. Potential actions – potential outcomes/actions leading to improved/updated of the existing criteria or new additions derived from the mapping exercise.
3. Feedback to 1st MCP sub-AHWG questions – summary of the feedback received on the questions shared during the 1st MCP working sub-group meeting, following the same correlative numbering used then (Q1 –Q24).

Following the 1st MCP sub-AHWG meeting feedback was received from its participants, which either served as direct input or primed JRC's research leading to the 2nd draft proposal of the *microorganisms* sub-criterion legal text. The last section added (*New draft criteria proposal)* was the focus of the discussions in the 2nd meeting of the MCP sub-AHWG, held on 01/10/24. It presented the new draft criteria proposal, the underlying rationales for changes made and proposed some further questions. The feedback received to these 2nd batch of questions (Q25 – 31) was assessed and summarised and it is included as the last sub-section to this chapter. Hence, the structure of the *New draft criteria proposal* section is:

1. Proposal text – the draft criteria text, showing previous proposal (as in Technical report 1, draft criteria version 1)[4] and current proposal with changes made to TR1 version highlighted in blue. Any deletion of text is displayed in strikethrough blue font (~~like this~~).
2. Rationales for proposals – which summarily present and discuss the rationales driving the draft proposal made.
3. New questions/discussion points - which address general and/or specific aspects. Each is numbered correlatively (starting in Q25) across the document. Sub-AHWG members are encouraged and expected to comment/discuss them during the 2nd MCP sub-AHWG.



[4] See the section 7.6.9 *Micro-organisms* (pages 112 - 113) https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2024-02/Detergents_Draft_Technical%20Report%201_1.pdf

# 3 Existing criteria (HSC)

## *3.1 Mapping of aspects*

— The risk-based approach proposed as an alternative and/or complementarily to be in the QPS list [*(ii) Safety* requirement*]* is generally supported, especially to allow microorganisms not in the QPS scope to be eligible for use. However, the following should be consider:

  - Inclusion of further specific details, ideally setting the basis for a standardised approach, considering (not comprehensive list): Scope (e.g. raw material and/or formulated product?); Product formats; Exposure routes (which?); Verification means (via *third parties*? If so, which?).
  - Usefulness and applicability of the European Food Safety Authority (EFSA) instruments (Qualified Presumption of Safety - QPS) and work (e.g guidance) as part of and/or as an alternative to the proposed microbial risk assessment.

— With regards to *(iii) Absence of contaminants* there are no specific concerns or suggestions to complement the pathogens list but rather a general recommendation to consider which additions (if any) are required based on the outcome of the microbial risk assessment and/or via legislative instrument (i.e. revision of the Detergent Regulation.

— In terms of *(vi) performance*:

  - ISO 21149:2017 ([5]) is proposed as an alternative to the existing method ISO 4833-1:2014. ([6])
  - A share of stakeholders support keeping the threshold set ($1 \times 10^5$ CFU/mL) as the minimum threshold proving performance.
  - A share of stakeholders suggested substituting this provision with alternative means: information to the user declaring guaranteed minimum concentration & shelf-life from manufacturing date while proving performance separately via testing.

— In terms of *(vii) shelf life*:

  - the variability in testing results and the wording used in the criteria (no specific scale defined; e.g. logarithmic) difficult compliance with the verification requirement (not exceeding 10% variation yearly).
  - there was consensus and support towards ensuring stability (viability/performance) as declared by the manufacturer rather than via a pre-set minimum mandatory shelf-life threshold (currently 24 months). In practice, this implies considering no upper limit while ensuring minimum threshold compliance all throughout product shelf-life.
  - market pre-validation time is too lengthy. Consideration of the viability for acceptance of shorter periods via alternative means (e.g. accelerated ageing tests) is suggested.

— Comments received about *(x) User information* focused on the exclusions made, particularly:

  - Considering removing the statement "*that the product shall not be used with a spray trigger mechanism*" under the logic that the microbial risk assessment will highlight and minimise any potential risks via aspects as packaging design (droplet size; residence time) and/or information to user via labelling (special instructions / safety remarks).
  - Considering removing the statement "*that the product should not be used on surfaces in contact with food"* following the logic described in the previous point. In addition, consideration of EFSA's work, particularly QPS list, could streamline the process given EFSA scope on food/feed products (amongst others).

— The assessment and verification of existing provisions is complex and can be challenging, thus potentially leading cases to lengthy application procedure times.

[5] ISO 21149:2017 Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria. Available at: https://www.iso.org/standard/72240.html.

[6] ISO 4833-1:2013Microbiology of the food chain — Horizontal method for the enumeration of microorganisms Part 1: Colony count at 30 °C by the pour plate technique. Available at: https://www.iso.org/standard/53728.html

## 3.2 Potential actions

— About *Safety (ii);* Including specific details for the MCP risks assessment (RA), ideally derived from standardised sources. The approaches that can be proposed and discussed, presented in order of preference/importance, are:

1. Selection of suitable/s standardised risk schemes and/or guidance/s relevant to performing MCP RA holistically -> all relevant aspects considered within the scope of the guidance.
2. Selection of suitable/s sections/aspects from (ideally standardised) risk schemes and/or guidance/s relevant to performing MCP RA -> relevant horizontal aspects (e.g. Hazard identification; Exposure assessment) that can be applicable even if the scope of the guidance does not fully match intended for MCP RA.
3. Selection of suitable/s parameters/ specific aspects from standardised risk schemes and/or guidance/s relevant to performing MCP RA -> specific key/core aspects (e.g. Microorganism identification/characterisation) relevant to MCP RA that should/must be included to ensure achieving the aim/s intended in the MCP RA).

Note that developing a complete framework for MCP RA or develop a complete specific guidance is out of the scope of the work that can be performed as part of the revision of the EU Ecolabel.

— About *(iii) Absence of contaminants;* Discussing and agreeing which additional/alternative provisions (if needed) should be considered to ensure additional pathogens are considered in addition to those listed in existing legal text.

— About *(vi) performance:*

- Discussing and agreeing on the substitution of ISO 4833-1:2014 by ISO 21149:2017, inclusive of potential trade-offs
- Discussing whether performance should remain as in existing legal text, thus requiring a minimum number of microorganisms ($1 \times 10^5$ CFU/mL). If not, discussing which could be suitable alternatives.

— About *(vii) shelf-life:*

- Considering removing the requirement on not exceeding a 10% variation in the results of microorganism' enumeration. Alternatively, improve wording to avoid uncertainties (e.g. specify/express the variation allowed in logarithmic scale).
- Exploring feasibility of not requiring a pre-set minimum shelf-life (e.g. via manufacturers declaration) and/or shorten the period to accommodate market product development and EU Ecolabel application reality (e.g. 1 year), considering in both cases implications for verification.

— About *(x) user information:*

- Considering appropriateness of modifying current legal text to introduce specific provisions enabling the safe use of MCP in spray trigger mechanisms.
- Considering appropriateness of modifying current legal text to introduce specific provisions enabling the safe use of MCP in food contact surfaces.

— About *Assessment and verification* (A&V)*;* Map specific A&V factors identified by stakeholders as impeding effective verification and gather suggestions on how to improve them, previously cross-checking impact of other criterion change proposals.

## 3.3 Feedback to 1st MCP sub-AHWG questions

This sub-section provides a summary of the feedback received to each of the questions shared with MCP sub-AHWG participants during the 1st MCP sub-AHWG meeting. The intention is to be informative and transparent with regards to the inputs that JRC received and considered in the formulation of its proposals for update/modification of draft criteria relative to microorganisms containing products, highlighted in the next sub-section.

The main tool set by JRC for feedback collection was an EU survey (active from 25/06/24 to 16/07/24), containing all the question shared during the 1st MCP sub-AHWG meeting to which a total number of 8 participants replied. In the summaries to each question disclosed below the number of blank responses is highlighted to provide context. In addition, any complementary feedback shared during the 1st MCP meeting not included in the EU survey responses is mentioned alongside the summaries of feedback to each question below.

Q1 (ii) – Which should be the scope of a potential MCP RA? What are the core elements you foresee in a MCP RA? *Please, while responding consider that the question refers to all PGs under the EU Ecolabel criteria scope. If you consider that is more appropriate to provide your response applicable to a particular PG (or set of them), please do so and specify why.*

The scope defines the content and structure of any RA. With this question the JRC intend to identify which are the core elements that are essential in any MCP RA. Ideally, these should be applicable to any PG within the EU Ecolabel criteria scope in order to simplify and streamline the process of setting provisions and their verification means. Note that this information is very relevant and linked to which could be the standardised risk schemes/guidance and/or part of these, since it conditions considering them as relevant or not, thus being entitled for consideration and/or uptake as part of EU Ecolabel provision for MCP (See Q2, Q3 & Q4 rationales). Examples of questions that could prime discussion in this regard are: (relative to hypothetical MCP RA) *are environmental impacts included alongside human health*? *Does it cover any "type" of microorganism covered?*

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One respondent indicated that two risk assessments (RA) are required (thus two RA scopes): 1) on the microorganisms used as MCP ingredient; 2) on the MCP as final product. Another two respondents were aligned with this approach. One stated that the core element should be the specific strain safety assessment (thus microorganisms used as ingredient) since it is relevant to all PGs allowing intentional addition of microorganisms, including exposure assessment to mitigate risks (e.g. respiratory sensitization). The other respondent implied that RA for MCP should consider the specific exposure arising from use of a cleaning product, namely dermal and for some product inhalation (e.g. sprays) and oral (e.g. food contact surfaces) but also considering health effects associated with these routes and the use of microorganisms (i.e. dermal and/or respiratory sensitization to microorganisms or its components). In this sense, the elements of the risk assessment are mainly driven (health-wise) by the type of product (cleaning product), being modulated with additional considerations for specific product types (containing microorganisms). Relevant health effect should be considered, that for MCP implies focusing on microorganisms as ingredient, ensuring that those selected belong to "safe/r" strains (non-pathogenic, non-toxigenic, low risk of antimicrobial resistance transmission), demonstrated via evidences from literature, genotypic and phenotypic data.

Another two respondents indicated:

- Hazard identification - Identification of potential sources of risks associated with a microbial ingredient that could result in harm,
- Exposure assessment - Identification and characterization of potential routes and nature of exposure to a microbial ingredient,
- Hazard characterization - Determination of the relationship between exposure to a specified number of microorganisms and the corresponding probability of a specific adverse effect occurring for different subpopulations,
- Risk characterization - Examination of the relationship between the human exposure and the assessment of the likelihood of occurrence and the severity of an adverse effect.
- The MCP RA should cover impact on both human health and the environment for any type of microorganism involved."

Another respondent advocated for compliance with requirements for microorganisms under EFSA scope of work (i.e. food), ensuring purity of microorganisms as ingredients (no contamination), and guaranteed dose delivery (within stipulated variability ranges) and product stability. Specifically for spray products and in addition to comply with these food safety standards, it mentioned testing considering as exposure route inhalation (e.g. acute toxicity test).

One respondent required clear justification on the use of "risk-based" approach versus the "hazard-based", typically applied in EU Ecolabel (e.g. chemicals). Then, if justified pursuing such RA, the scope should include

both human and environmental health and consider properties and usage/exposure for each product group and user category. It also required further precision and clarity in the formulation of requirements (i.e. *The outcome of a microbial risk assessment should be that the risk associated with the use of a products containg microorganisms is deemed acceptable")* ensuring that the elements of such risk assessment are listed and a clear distinction of what an un/acceptable risk is provided.

Finally, one respondent pointed out to a relevant resource: *"Framework for the Risk Analysis of Microorganisms in Microbial Based Cleaning Products",* developed jointly by AISE and ACI, whose expected expansion should cover specific case studies/frameworks related to sprays & food contact surfaces.

Q2 (ii) **–** Could you share any reference to standardised risk schemes and/or guidance/s relevant to performing MCP RA holistically? *Please, note that this implies that all relevant aspects of the pursued MCP RA are considered within the scope of the guidance*.

JRC aims to identify, within the scope/mandate of the EU Ecolabel Regulation, which could be appropriate schemes/guidance to perform MCP RA. In this regard, we would like to identify a set of these to examine and ultimately propose (or discard) for further discussion and/or inclusion in forthcoming criteria proposals. This is especially important given that developing a complete framework for MCP RA or develop a complete specific guidance is out of the scope of the work that can be performed as part of this revision of the EU Ecolabel criteria for detergents. An example that, to our understanding, could meet the description made is Bernatchez et al. 2018 ([7])

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One respondent affirmed that there is a comprehensive body of knowledge and risk assessment (RA) methodologies available at EFSA, suggesting the use of such resources as much as possible due to being standardised, state-of-the-art and providing high level of safety. Contrastingly, another respondent highlighted that such guidance did not exist but that detergent industry was developing one to be published soon.

One respondent quoted performing acute inhalation tests (animal or cell lines) for spray product to assess the risk on lungs. To assess the dermal or ingestion risks in all products it suggested ensuring that all strains are safe to use in food materials, that the microbial product is pure and that the end dose of the product is guaranteed.

Specific resources cited by respondents, presented according to number of mentions (highest to lowest):

- ACI, A.I.S.E. et al. Risk Analysis Framework for Microbial Ingredients in Microbial-based Cleaning Products. 2023. Submitted, currently under scientific review.
- EFSA. Guidance on the characterization of microorganisms used as feed additives or as production organisms. February 2018.[8]
- ECHA. Guidance on the Biocidal Products Regulation: Volume V – Guidance on active micro-organisms and biocidal products. Version 2.1. March 2017:[9]
- FAO. Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL 30-1999 Adopted 1999. Amendments 2012, 2014.[10]
- Government of Canada. Guidelines for the Notification and Testing of New Substances: Organisms. August 2010.[11]



7 Bernatchez, S., V. Anoop, Z. Saikali, and M. Breton, 'A Microbial Identification Framework for Risk Assessment', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 60–65. https://www.sciencedirect.com/science/article/pii/S0278691518301054?via%3Dihub

8 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5206

9 European Chemicals Agency., Guidance on the Biocidal Products Regulation. Volume V, Guidance on Micro-Organisms and Biocidal Products., Publications Office, LU, 2017.DOI: 10.2823/31176; https://data.europa.eu/doi/10.2823/31176

10 Available at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B30-1999%252FCXG_030e_2014.pdf

11 Guidelines for the Notification and Testing of New Substances: Organisms : Pursuant to the New Substances Notification Regulations (Organisms) of the Canadian Environmental Protection Act, 1999, Govt. of Canada, Ottawa, 2010.

- EPA´s Safer Choice Checklist for Formulations Containing Microorganisms
- EFSA Biohaz 2023 "Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes'"[12]

With regards to the previous list of publications, one respondent highlighted that the ECHA/BRP guidance includes requirements for animal testing which might be against ongoing developments advocating for alternatives to animal testing[13], not being necessary for the intended safety assessment. If further stressed such guidance as very conservative on sensitization and not being risk-based, presenting EFSA's guidance on microorganisms in food and feed product as alternative, having a pragmatic risk-based approach easily transferable to consumer product upon accounting for relevant routes of exposure.

Q3 (ii) – Could you share which could be a suitable selection of sections/aspects from (ideally standardised) risk schemes and/or guidance/s relevant to performing MCP RA? *Please, note that this implies all relevant horizontal aspects (e.g. Hazard identification; Exposure assessment) that can be applicable even if the scope of the guidance does not fully match intended for MCP RA.*

JRC understand that there might not be already a holistic guidance fully tailored to the reality and needs of MCP but that there are several RA assessment schemes and/or guidance which could contain certain sections/aspects that indeed could be useful. We would like to identify these sections/aspects in order to assess their applicability to the EU Ecolabel criteria, aiming at providing clarity/certainty but also means for verification. An example is the EFSA QPS ([14]), which follows a framework tailored to EFSA's scope/procedures related to market authorisation of feed/food/plant protection products. The QPS provides a pre-assessment for microorganisms which implies that, by belonging to QPS taxonomic units (TUs) and being included in the QPS list, they are "*unambiguously defined biological agents assessed for the body of knowledge, their safety and their end use*" ([15]). The *Taxonomic aspects* and *Body of knowledge* could be understood as horizontal (useful/applicable despite scope of RA) but *Safety concerns in relation to virulence/pathogenicity* or *Safety for the environment* could be tailored/restricted to particular host, in this example, to human and animals when product is used as food or feed. Therefore, there are useful elements, even directly transferable aspects depending on the MCP submitted to RA. Another example, is the *OECD Guidance to the Environmental Safety Evaluation of Microbial Biocontrol Agents* ([16]). Based purely on scope, this guidance is not directly applicable to MCP (note human risk assessment is excluded, which is necessary for final market authorisation) but certain aspects or elements could inform or be useful for a MCP RA (i.e. framework applicable to crops; this scheme concludes qualifying "*Risk is Acceptable*" or "*Risk is not Acceptable*"). A final example is ECHA's *Guidance on the Biocidal Products Regulation (BPD)*, which "*...substantiate the requirements of Annex II Title 2 (Information Requirements for Active Substances, Micro-organisms) and Annex III Title 2 (Information Requirements for Biocidal Products, Micro-organisms), of the BPR for the preparation and evaluation of dossiers of active micro-organisms at strain level*" ([17]).

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One respondent affirmed:

- *Hazard identification:* Microbial identity, potential for pathogenicity, irritation and sensitization, toxin production, antibiotic resistance, antibiotic production, known virulence factors, mobile genetic elements, lifecycle, impact on microbial communities, contamination.
- *Exposure assessment:* product formulation, delivery system/mechanism, normal product use conditions, foreseeable misuse, use sites, exposure routes (i.e., inhalation, dermal, oral/ingestion,

12 EFSA Panel on Biological Hazards (BIOHAZ), K. Koutsoumanis, A. Allende, A. Alvarez-Ordóñez, D. Bolton, S. Bover-Cid, M. Chemaly, et al., 'Statement on How to Interpret the QPS Qualification on 'Acquired Antimicrobial Resistance Genes'', EFSA Journal, Vol. 21, No. 10, October 2023. DOI: 10.2903/j.efsa.2023.8323; https://data.europa.eu/doi/10.2903/j.efsa.2023.8323

13 The JRC understands that this comment possibly is related to the ongoing revision of the Detergents Regulation.

14 https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps

15 EFSA Panel on Biological Hazards (BIOHAZ), K. Koutsoumanis, A. Allende, A. Alvarez-Ordóñez, D. Bolton, S. Bover-Cid, M. Chemaly, et al., 'Scientific Opinion on the Update of the List of QPS-recommended Biological Agents Intentionally Added to Food or Feed as Notified to EFSA (2017–2019)', EFSA Journal, Vol. 18, No. 2, February 2020. https://data.europa.eu/doi/10.2903/j.efsa.2020.5966

16 OECD, OECD Guidance to the Environmental Safety Evaluation of Microbial Biocontrol Agents, Series on Pesticides and Biocides, OECD, 2014. https://www.oecd-ilibrary.org/environment/oecd-guidance-to-the-environmental-safety-evaluation-of-microbial-biocontrol-agents_9789264221659-en

17 European Chemicals Agency., Guidance on the Biocidal Products Regulation. Volume V, Guidance on Micro-Organisms and Biocidal Products., Publications Office, LU, 2017. https://data.europa.eu/doi/10.2823/31176

ocular), product dilution step, post-application fate, assessment of consumer exposure and professional/institutional exposure.

- *Hazard characterization:* dose/response relationships, use of benchmarks, if possible.
- *Risk characterization:* either qualitatively or quantitatively.
- *Post-market surveillance* as a feedback loop."

One respondent quoted performing acute inhalation tests (animal or cell lines) for spray product to assess the risk on lungs. To assess the dermal or ingestion risks in all products it suggested ensuring that all strains are safe to use in food materials, that the microbial product is pure and that the end dose of the product is guaranteed.

One respondent suggested two references, found in parallel regulations, as starting point for developing criteria for MCP:

- *EFSA guidance*[18] ->These criteria can be applied since the health effects that need to be addressed in the risk assessment are broadly similar between food/feed use and MCPs (Pathogenicity, toxin production, AMR risk) and so are the key lines of evidence required(literature evidence, genotypic, phenotypic data). Hence, such an approach adapted to consider health effects relevant for MCPs and their typical exposure routes could work.
- *BRP Guidance*[19]-> This guidance addresses many of the health effects relevant to MCPs and includes health effects such as sensitisation but has several limitations which might difficult its application for MCP's risk assessment, namely: requirement of animal testing; and hazard-based approach to sensitization (e.g. mandatory labelling and use of PPE to minimise the risk).

One respondent indicated that, as AISE and EPA guidelines specifically refers to MCP (See Q2 response), then all sections/aspect are suitable.

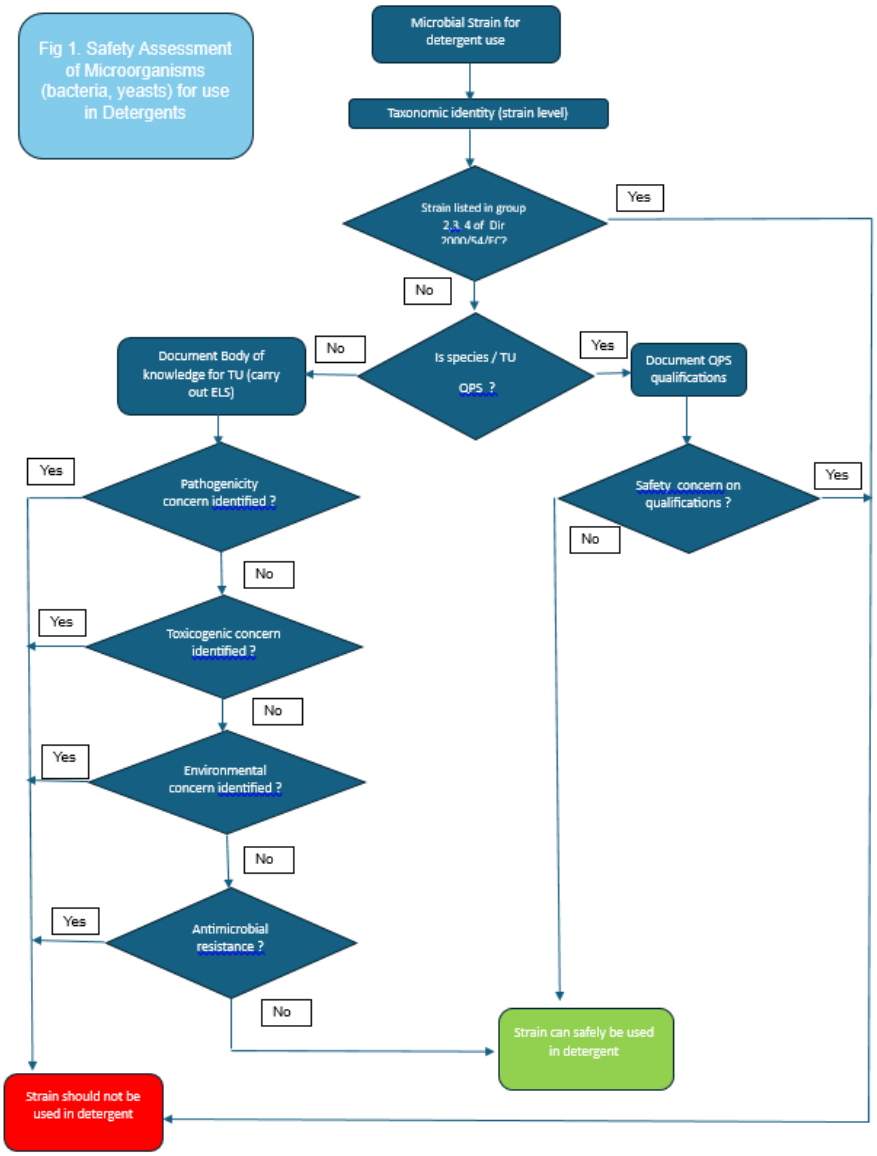
One participant proposed a tailored risk assessment guideline for the safety assessment of microorganisms used in detergents, shown in its summarised form as flow-chart (See Figure 1). It focuses in bacteria and yeast,



[18] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://data.europa.eu/doi/10.2903/j.efsa.2018.5206

[19] European Chemicals Agency., Guidance on the Biocidal Products Regulation. Volume V, Guidance on Micro-Organisms and Biocidal Products., Publications Office, LU, 2017.DOI: 10.2823/31176; https://data.europa.eu/doi/10.2823/31176

as most likely microorganisms' type found in detergents (thus adaptation needed for others) and it requires assessment been made for each microorganism used (i.e. each strain of a given species).




Q4 (ii) – Could you share which could be a suitable selection of key/core aspects from (ideally standardised) risk schemes and/or guidance/s relevant to performing MCP RA? *Please, note that this implies specific key/core*

*aspects (e.g. Microorganism identification/characterisation) relevant to MCP RA that should/must be included to ensure achieving the aim/s intended in the MCP RA)*

Complementary to the rationales of Q2 & Q3, this questions specifically aims at precisely define key aspects that should/must be in a MCP RA, inclusive of the technical means for generating and verifying such data, and where these (or inspiration for them) can be found. An example is *EFSA's guidance on the characterisation of microorganisms used as feed additives or as production organisms* ([20]). Acknowledging that microorganism taxonomic identification could be considered an "horizontal" aspects within RA focused on microorganisms, this is a standardised guidance, widely acknowledged within industry containing highly refined and peer-reviewed indications on the aspects to evaluated and how to do so (inclusive of testing methods). This guidance (acknowledging its scope limitations) could be used as inspiration and/or as direct reference for microorganisms' taxonomic identification within a MCP RA.

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One participant referred to the already quoted risk assessment guideline for the safety assessment of microorganisms used in detergents (See Q3, Figure 1).

One respondent quoted performing acute inhalation tests (animal or cell lines) for spray product to assess the risk on lungs. To assess the dermal or ingestion risks in all products it suggested ensuring that all strains are safe to use in food materials, that the microbial product is pure and that the end dose of the product is guaranteed.

One participant agreed on the high importance of robust identification and characterisation to assess the MCP safety and that having clear guidance would support this. It further referred to the suggested MIFRA framework, as means to identify and characterise microorganisms, and EFSA guidance, as further outlining how to perform hazard assessment.

One respondent affirmed:

- *Hazard identification*: Microbial identity, potential for pathogenicity, irritation and sensitization, toxin production, antibiotic resistance, antibiotic production, known virulence factors, mobile genetic elements, lifecycle, impact on microbial communities, contamination.
- *Exposure assessment*: product formulation, delivery system/mechanism, normal product use conditions, foreseeable misuse, use sites, exposure routes (i.e., inhalation, dermal, oral/ingestion, ocular), product dilution step, post-application fate, assessment of consumer exposure and professional/institutional exposure.
- *Hazard characterization*: dose/response relationships, use of benchmarks, if possible.
- *Risk characterization*: either qualitatively or quantitatively.
- *Post-market surveillance* as a feedback loop."

One respondent indicated that, as AISE and EPA guidelines specifically refers to MCP (See Q2 response), then all sections/aspect are suitable.

One respondent indicated the following sections from EFSA's guidance[21], also highlighting that whole genome sequencing (WGS) would be required:

- 2.1 Identification
- 2.2 Antimicrobial susceptibility
- 2.3 Antimicrobial production
- 2.4 Toxigenecity and pathogenicity

[20] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. https://data.europa.eu/doi/10.2903/j.efsa.2018.5206

[21] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://data.europa.eu/doi/10.2903/j.efsa.2018.5206

Q5 (ii) **–** Under the assumption that a MCP RA is required, should microorganisms presenting EFSA QPS status (namely, be in QPS list) be exempted from performing the whole/certain parts of such MCP RA? *Please, provide a reasoned answer why you consider it should be wholly exempted from a MCP RA. Alternatively, quote which parts could be exempted and which complementary parts would require assessment*

Complementary to the rationales of Q2, Q3 & Q4, this question specifically aims at streamlining the process of proving safety of using a particular microorganism in a MCP via already stablished instruments (thus potentially reducing burden and enhancing efficiency). Current JRC understanding is that EFSA QPS status is not directly transferable (fit-for-purpose) to the EU ecolabel criteria for detergent and cleaning products, being the main difference the exposure assessment, which has knock-on effects on hazard characterization, risk characterization and, ultimately, risk management. The necessary tailoring of the RA to the "reality" of MCP is the ultimate reason for not being directly transferable. However, this does not mean that this instrument can't be used to streamline producing a MCP RA or that, in very specific and well-reasoned circumstances, it could support particular claims/uses of a MCP (i.e. it could be useful for products claiming to be in contact with food contact surfaces). JRC ultimately would like to understand/map "what is missing in QPS / How to complement it" to be equivalent to a full MCP RA, thus ensuring that all necessary elements of a MCP RA are assessed. This could translate into requiring that a MCP should be in the QPS list plus compliance with specific additional provisions requesting information on "missing" and necessary MCP RA aspects.

Blank answers = 2

Several respondents (n=4) were against granting an exemption to microorganisms presenting EFSA QPS status, being the main arguments:

- The QPS listing is not intended for cleaning product applications but rather those under EFSA's scope, thus some safety aspect could remain uncovered.
- The QPS only indicates that an assessment of microorganisms at species level was carried out, when it should be at strain level (e.g. some strains might produce toxins whereas others not).

Complementarily, these respondents acknowledged the usefulness of QPS listing as starting point for conducting a MCP RA

Indeed, other respondents (n=3) considered that microorganisms (MO) belonging to EFSA's QPS could/should exempt from certain MCP RA parts, in particular:

- EFSA's QPS assessment ensures, at taxonomic unit level, that the taxonomic identity, body of knowledge and potential safety concerns are assessed, which supports a simplified assessment. However, aspects not covered include type and level of exposure of users handling the product (e.g. inhalation) and hazards linked to the formulation or other aspects of the processing of MCP products; which should precisely be the focus of the simplified risk assessment.
- The EFSA guidance[22] provides exemptions from some RA sections (e.g. *section 2.3 Antimicrobial production* and *2.4 Toxigenecity and pathogenicity*) for MO fulfilling certain "qualifications" (open aspects in the safety assessment that must be documented at strain level), an approach that is suggested for uptake in this EU Ecolabel revision.

One participant indicated that the use of GRAS[23] organisms should exempt from carrying out additional RA under the logic that, if something is allowed for use under food regulations (much stricter than those applicable to detergent and cleaning products) then it is safe for cleaning. Furthermore, the use of such ingredients is safer/healthier than their purely chemical counterparts, which are not food-safe and have higher risks to humans, animals and the environment (e.g. issue with health maintenance workers[24]). In this sense, it should actually be the purely chemical counter-parts the ones submitted to additional risks analysis on chemical



[22] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://data.europa.eu/doi/10.2903/j.efsa.2018.5206

[23] GRAS = *Generally Recognised as Safe*; The JRC understands it refers to U.S. Food & Drug Agency concept (See https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras), which is also a safety assessment system applicable to microorganisms containing products.

[24] Van Den Borre, L., and P. Deboosere, 'Health Risks in the Cleaning Industry: A Belgian Census-Linked Mortality Study (1991–2011)', International Archives of Occupational and Environmental Health, Vol. 91, No. 1, January 2018, pp. 13–21. DOI: 10.1007/s00420-017-1252-9

agents and chronic exposure tests. It concluded asking for avoidance of inefficient overregulation and support to this type of potentially safer products (containing GRAS organisms).

Q6 (ii) – Should the *independent third-party verification* of the MCP RA be maintained? If so, which should be the criteria defining such *independent third party. Please, provide a reasoned answer*

Requiring cross-checking by a third-party is common practice in many fields to validate particular studies or assessments made. For example, LCA studies are ideally validated by third-parties, which also share remarks/concerns to bear in mind while interpreting the results. Similarly, having a third-party verifying the validity of the outcome of the MCP RA could be a valuable quality check. However, this come at the expenses of further resources required (especially time) which could be a nuance. Further to this, there is a more basic element, related to who would qualify as *independent third party* and under which criteria. Considering upcoming legislative developments, as the revised Detergent Regulation ([25]), there are doubts about the appropriateness to set now such criteria / requirements. Consequently, JRC would like to hear from experts on their view about this.

Blank answers = 0

Most respondents (n=5) aligned with the following argumentation:

> *"The most important aspect is ensuring that the risk assessments are credible, thorough, and of high quality. This suggests that such assessments should be conducted by experienced professionals with relevant training. Companies with access to these resources should be permitted to utilize them without being burdened by the additional time and complexity associated with an external endorsement process. If microbial-based cleaning products (MBCPs) are to be treated as standard cleaning ingredients, there should not be significantly different expectations regarding their marketing."*

Another participant agreed with third-party verification to guarantee that the strains are food-safe and that the microbial end-product is pure. Similarly, a participant agreed given the ongoing revision of the Detergent Regulation, particularly about requirements set in Annex II, point 11[26]:

> *"(a) the laboratories are complying with the principles of good laboratory practice provided for in Directive 2004/10/EC of the European Parliament and of the Council or international standards recognised as being equivalent;*
>
> *(b) the laboratories are accredited in accordance with the standard for laboratories referred to in Regulation (EC) No 765/2008."*

Another respondent mentioned the revised Detergent Regulation, indicating that if its final version third party testing is not maintained, then it should not be mandatory if the company has the in-house resources.

Q7 (iii) – Do you have any suggestion on any microorganism that should be considered for inclusion in the *absence of contaminants* list? Complementary, do you have any suggestion about a legislation and/or scheme



[25] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004 COM/2023/217 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0217

[26] Available at : https://single-market-economy.ec.europa.eu/document/download/d6fb53f3-5afc-42f2-b284-450d846b2d4a_en?filename=COM_2023_217_1_EN_annexe_proposition_part1_v4.pdf

to which EU Ecolabel criteria should consider alignment with? If so, should there be a specific quotation within the legal criteria text? *Please, provide as specific and comprehensive answer as you can, including reasons why.*

Based on the outcome of the stakeholders consultations performed by JRC until now, there has been no concerns or additions to the list suggested. Hence, JRC understands that the list is still fit-for-purpose. Nevertheless, JRC would like to offer as many chances as possible to re-visit this aspect. In addition, JRC also acknowledges that the outcome of MCP RA could suggest setting quality controls in the production process to minimise risks (thus testing for particular microorganisms) and/or that alignment with ongoing legislative developments, as the revised Detergent Regulation ([27]), could inform and complemented this list of undesired microorganisms. In this sense, addition of specific wording in the criteria legal text referring to these aspects could be either seen as necessary or redundant (given the requirement on performing a MCP RA and the mandatory nature of a Regulation). We would like to hear stakeholder view about what would provide higher certainty and clarity whilst not complicating provisions verification.

Blank answers = 0

The three main differentiated blocks in the responses received with regard to the *absence of contaminants* list of microorganisms present in existing EU Ecolabel criteria in force, namely:

4. The existing EU Ecolabel criteria list is sufficient.
5. The existing EU Ecolabel criteria list needs complementation (further microorganisms to be added).
6. No mandatory list is necessary/advisable.

Two respondents supporting block 1 mentioned that the existing list was still fit-for-purpose, being a general good reference to screen for most of the common human pathogens that can be found in food materials. In this regard, they called for alignment with control regimes within food safety.

Two respondents supporting block 2 called for alignment with the revised Detergent Regulation (ongoing process[28]), particularly with the Annex II of the latest version available[29] which adds the following to existing EU ecolabel criteria list:

- *Pseudomonas aeruginosa, test method ISO 22717:2015;*
- *Candida albicans, test method ISO 18416:2015;*
- *...any other micro-organisms listed in Annex 1, Table 4 of Regulation (EU) 2020/741*[30].

One respondent flagged that the ISO testing methodologies are relative to food safety assessment, thus potentially not entirely applicable to detergents (i.e. risk of false positive). The other recommended including expertise and recommendations from EFSA in the drafting of this criterion.

Finally, those respondents supporting block 3 (no list advisable), reasoned that any listing that can be made would soon be outdated/incomplete, difficult to fully justify (in terms of microorganisms addition) and it would imply additional burden (e.g. testing cost). There was agreement amongst respondents that the MCP RA should be the tool flagging any issue associated with the potential presence of pathogens and justifying why the outcome (risk) is acceptable/defensible. A specific suggestion was to align with the Cosmetics Directive[31] concerning the approach to identify microbiologically low-risk products, namely via ISO 29621:2017[32].



27 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004 COM/2023/217 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0217

28 https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-revision-of-the-detergents-regulation

29 P9_TA(2024)0091 – European Parliament legislative resolution of 27 February 2024. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0091_EN.html

30 Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse. OJ L 177, 5.6.2020, p. 32–55. Available at: https://eur-lex.europa.eu/eli/reg/2020/741/oj

31 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast); OJ L 342, 22.12.2009, p. 59–209. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

32 ISO 29621 *Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products.* See https://www.iso.org/standard/68310.html

Q8 (vi) **–** Would you support substituting ISO 4833-1:2014 by ISO 21149:2017? Under your view, which are the potential trade-offs (if any)? *Please, provide as specific and comprehensive answer as you can, including reasons why.*

Blank answers = 2

Irrespective of supporting ISO 4833-1:2014, ISO 21149:2017 or both, a widely repeated comment was to enable the possibility of using the quoted method *or equivalent* via the criteria wording used. In other words, allowing the use of any other equivalent (internationally) scientifically justified/recognised standard to ensure flexibility (e.g. accommodate different growth characteristics of intentionally added microbial species) whilst supporting future developments in the field. In particular, the wording used in requirement 010 of the Nordic Swan cleaning product criteria[33] was proposed (8) as inspiration/for alignment:

> *Shelf-life: show that the microorganisms have a good stability by performing a stability test at room temperature showing that the microorganisms not decrease more than 20% alternatively decrease at < 1log per year according to ISO 4833-1:2014 (Horizontal method for the enumeration of microorganisms) or through other scientifically acknowledged method to count the number of microorganisms.*

A participant did not support the change, reasoning that products are applied to the physical environment and not to the body and also that food safety laws are stricter than cosmetics ones, thus the change could imply a less stringent requirement.

Another participant indicated that ISO 4833-1:2014 is still fit-for-purpose and was supportive of accepting other ISO/CEN methods depending on the species of microorganisms.

A participant provided a comparison of both ISO standards. Both standards focus on enumeration of aerobic mesophilic bacteria (approx.. 30C) and use standard growth media (agar) and approximately 72h incubation, which according to the respondent may not be appropriate for all bacteria potentially used in MCPs. In addition, the respondent stated that ISO 4833 do not provide guidance in case when the standard plate count media (agar) is not compatible with the microorganisms to be counted, which ISO 21149 does, as well as provides provision to neutralize antimicrobial compounds presents.

Finally, two participants indicated that ISO 21149:2017 is designed for the cosmetics industry, which may share some similarities with MCPs in terms of product formulation and microbial quality requirements, which makes it more relevant for MCPs than ISO 4833-1:2014 that is focused on food products.

Q9 (vi) **– Would you support keeping the existing legal text ("***Microbial counts: products in their in-use form shall have a standard plate count equal to or greater than 1 × $10^5$ colony-forming units (CFU) per ml in accordance with ISO 4833-1:2014***")? Alternatively, which change would you suggest?** *Please, if not supporting existing legal text, formulate your response as detailed as possible, ideally reasoning your proposal (why such elements should be included).*

Mixed views were gathered from stakeholders during JRC's consultation, some supporting current wording and having a minimum pre-set, mandatory threshold (1 × $10^5$ CFU/mL). Contrastingly, others suggested considering removing this provision and requiring as part of *information to the user* the minimum guaranteed concentration within the shelf-life of the product since manufacture, with the verification of performance happening within the *Fitness for use criterion*. JRC current understanding is that microorganisms numbers *per se* (with no further complementary information) do not offer enough certainty that the product will be performant. Indeed, as a result of several factors this final number can be very different: the microorganism "type" (and strain within certain species); the type of product and format; the type and conditions of testing, etc. In any case, JRC also acknowledge that MCP frequently contain bacterial species (e.g. *Bacillus sp*) and that the threshold set could be representative for this general case. Consequently, we welcome stakeholder views, especially on which could be alternative requirement formulations, inclusive of wording proposals.

Blank answers = 1

[33] Nordic Ecolabelling. 026 Cleaning product. V6.14. 13 August 2024. https://www.nordic-swan-ecolabel.org/criteria/cleaning-products-026/

Two respondents supported the existing legal text formulation; one because such concentration is required for HSC products efficacy in their in-use form and the other in order to ensure with revised Detergent Regulation draft proposal.

Two respondents were not supportive of such microbial counts concentration but rather they would consider setting alternative lower thresholds (i.e. 10.000CFU) or allowing lower CFU count if microbial-driven product performance can be documented.

Three respondents questioned the validity of using, exclusively, microbial counts as deterministic factor driving product performance (i.e. it might vary depending on the included strains). From these, two highlighted that there is not analogous requirement (setting minimum levels) for any other ingredient in cleaning products.

A respondent suggested that rather than setting pre-set concentration thresholds it would be preferable requiring transparency. This could entail providing to users accurate information on: the microbial concentration, product stability; and how the former relates to performance. It suggested the following wording:

> *Microbial count and shelf life: The microorganism count/concentration in the detergent (CFU/ml – Colony Forming Unit for liquids or CFU/g for dry products) shall be guaranteed accordingly and the shelf life and manufacturing date of the detergent indicated on the packaging. This shall be tailored to the claimed effect.*

Q10 (vii) **–** Would you support removing the restriction on not exceeding more than 10% variation yearly? If not, would you support alternative wording (e.g. variation expressed as X LOG).*Please, if supporting keeping this requirement, provide as many details as possible, ideally a wording proposal*

Blank answers = 1

Two respondents did not supported this requirement based on the arguments shared for Q9 (questioned validity of microbial counts as univocal factor determining performance; no precedents on minimum level requirement in cleaning product).

The remaining respondents considered inappropriate the 10% variation allowed in the requirement, with two explicitly requesting removing such requirement and the rest quoting technical difficulties associated with its compliance and proposing alternative formulations. The arguments shared supporting the removal/re-formulation of this provision are:

- A microbial concentration variation of about 0.5 LOG is considered as stable concentration in microbiological practices.
- It is consider more representative that the product meets its expected performance during the expected lifespan in the market (as claimed in the product).
- It is technically very difficult to meet this requirement, even more considering the existing referenced method (i.e. ISO 4833-1), since a 10% variation in logarithm scale variation can be within the range of the associated measurement error.
- Factors a species and/or their life-cycle stage (vegetative cells; spores) affect the natural decay patterns, meaning that some decay rates might be higher than others ire yet still being fit-for-purpose the use of such microorganism. Consequently, ensuring the product remains above a minimum microbial count at the end of shelf-life is proposed as more important parameter than decay rate. In this regard, one stakeholder suggested the following wording:
    - *When placed on the market, detergents containing microorganisms shall have a standard plate count equal to or greater than 1x10^5 colony-forming units (CFUs) per ml in accordance with ISO 4833-1:2014. During the shelf life of at least 24 [or 12] months the CFU count shall remain equal to or greater than 1x10^5.*

Q11 (vii) **–** Would you support reducing the minimum shelf-life (currently 24 month?)? If so, could you state which could be a meaningful and sensible minimum shelf-life? If you do not support having a minimum pre-set value for mandatory shelf-life, could you please propose alternative provisions? *Please, be as specific as*

*possible and reason any reply provided. Also note that, in any case, discussion and agreement on verification means of stability/shelf-life should be in place.*

Blank answers = 1

Two respondents supported keeping a requirement on minimum shelf life, indicating that the revised Detergent Regulation will likely require 24 months as minimum shelf life. In addition, they stated that this period is reasonable to cover the life cycle of the product (production, distribution, storage at retailers, buy and storage at users' premises prior to final use), thus avoiding product wastage in the supply chain.

In contrast, the majority of respondents advocated for removing a requirement on product's minimum shelf-life understanding that it should be tied to the characteristics and the claims made on the product, as per other conventional detergent/cleaning products in the market. In this sense, some respondent indicated that full transparency, meaning accurate information provision to users on declared shelf life period of the product by manufacturers (in any form/at) would be preferable.

*Q12 -* In *(x) User information* is required that the label states **"***that the product should not be used on surfaces in contact with food***". Would you support modifying this provision to allow (in any or specific cases) to use** MCP in food contact surfaces? If so, could you provide references and/or reasoned arguments about why and how?

The inclusion of such provision in the previous revision is assumed to be based on two main aspects: 1) potential presence of unwanted microorganism (especially pathogens) as contaminants; 2) Effects on human health versus lack of scientific/regulatory certainty. The former aspect implies that the contamination of a MCP manufacturing process could result might result in microbial contaminants being present in the product, which could pose threat to human health. On the other hand, the latter implies impossibility to foresee (within a reasonable degree of certainty) the impacts of microorganisms under expected exposure scenarios (e.g. microorganisms and/or their by-products as sensitizing agents). Currently, further evidences are available which could "fill the gaps" on the concerns identified. The type of evidences that could serve for this purpose are data/articles focusing on MCP used, especially about RA (as example, Berg et al. 2018 ([34])) and/or in this particular application context (food contact surfaces); industry reports and knowledge on manufacturing process (inclusive of their quality controls), ecolabelling schemes covering MCP in same/similar PGs (e.g. Bra miljöva ([35])). Furthermore, instruments such as EFSA QPS list could be useful as proof of (or supporting) safety in the particular case of MCP used in food contact surfaces.

Blank answers = 1

The respondents unanimously agreed that MCP should be allowed to us in food-contact surfaces when safety can be guaranteed/be reasonably expect, normally via conducting a RA or having similar tools/processes ensuring safety (e.g. QPS status). They indicated the following remarks either as necessary considerations or as arguments supporting this position:

- The strains in MCP should qualify for the QPS approach (alignment with QPS RA methodology; QPS status) and fulfil related to absence of undesired ingredients and/or microorganisms.
- For the case of MCP used in food-contact surfaces, the RA should specifically address health effects following ingestion.
- It is contrasting that microorganisms authorised for food/feed applications (via EFSA's scope of work) cannot be used in food-contact contexts.
- Conditioned to appropriate use, namely as instructed by manufacturer, the use of safe microbial strains bring benefits in terms of performance, applicability (i.e. acting on surfaces difficult to reach as coolers), environmental sustainability and human health (i.e. altering the microbiome towards less/no presence of pathogenic microorganisms in consumer's environment).

[34] Berg, N.W., M.R. Evans, J. Sedivy, R. Testman, K. Acedo, D. Paone, D. Long, and T.G. Osimitz, 'Safety Assessment of the Use of Bacillus -Based Cleaning Products', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 42–52. https://www.sciencedirect.com/science/article/pii/S0278691517306968?via%3Dihub

[35] Chemical products. Criteria 2018:1. Bra Miljöva (Good Environmental Choice) Swedish Society for Nature Conservation. https://cdn.naturskyddsforeningen.se/uploads/2021/06/22173951/Criteria_Bra_Miljoval_Chemical_Products_2018-1_20181125_0-1.pdf

Q13 (vii) – In *(x) User information* is required that the label states **"***that the product shall not be used with a spray trigger mechanism***". Would you support modifying this provision to allow (in any or spec**ific cases) to use MCP in spray format? If so, could you provide references and/or reasoned arguments about why and how? *Please, be as specific as possible and reason any reply provided. Also note that, in any case, discussion and agreement on verification means of any case/circumstance quoted should also be considered. Finally, provide as many relevant references as feasible.*

The potential sensitization induced by microorganisms and/or their by-products (metabolites) in combination with the concentration of such elements coupled with lack of scientific/regulatory certainty about effects on human effects is (to the best of JRC understanding) the main basis for the origin of this provision (See also Q12 rationale). These concerns are still applicable but the wealth of evidences is expected to have further advanced. By carrying out a potential MCP RA, this potential risks can be minimised and anticipated, in principle, to the extend feasible/reasonable. In this sense and in the light of conversations related to MCP RA, JRC would like to hear experts on their view about this topic, especially on whether such precaution is/should be verifiable via the MCP RA or rather alternative testing is required to derived some of the key parameters (e.g. using a proxy for the allergenic/sensitizing agents; which are relevant units [CFU/m3; ng/m3]; what is the calculated exposure and/or no expectable effects level, etc). Likewise, JRC would like to receive evidences (e.g. scientific references) that stakeholders would deem suitable for the purposes of backing-up the safety of use of such product format. Also, to support stablishing specific technical provisions (if necessary) on the design of the products on the grounds of safety.

Blank answers = 0

One stakeholder advocated for keeping the restriction (not using MCP in spray format) based on the lack of studies showing conclusively effects of MCP via inhalation exposure. It further indicated that a precautionary approach should be followed (keeping the restriction) unless such studies are presented as rationale supporting the use of sprays in MCP.

The rest of respondents were supportive of changing this provision to allow the use of sprays in MCP as long as a RA has been carried out, specifically considering the inhalation exposure route given the sensitisation potential that can't be ruled out, with the outcome being that the use of the product is safe to use. Some further considerations shared are:

- The current draft version of the ongoing revision of the Detergent Regulation foresees the use of MCP in spray format conditioned to having carried out a RA beforehand, thus it would be advisable for the EU Ecolabel criteria under revision to align with this
- The RA must focus on the specific combination of formulation and packaging design (spray-trigger), as main factor determining potential exposure levels, and consider the best evidences available on respiratory (e.g. acute toxicity in lungs) and dermal exposure assessments.
- Microbial derived enzymes in the MCP can be assessed using stablished approaches used by detergents manufacturer controlling risks in enzyme containing products. In addition, the approach followed by Berg et al. 2018[36] for the inhalation exposure to microbial spores can be adapted and extended to other spray-cleaning product.
- Aspects to consider for minimising inhalation exposure and potential derived effects (i.e. sensitisation) are microorganisms (generally bacteria) properties and the use precautionary labelling (i.e. do not breathe sprays).
- Human exposure to microorganisms via respiratory exposure can be considered a natural process that is already happening on daily basis, which contributes to maintain microbial balance (i.e. human microbiome/s). Similarly, the exposure to chemicals, in this case detergents and cleaning products, also happens on daily basis but not being a natural process and with some long-term exposure detrimental effects being reported.
- The use of MCP with a spray-trigger mechanism should be restricted to those companies that have performed an (inhalation) exposure assessment in their products.

[36] Berg, N.W., M.R. Evans, J. Sedivy, R. Testman, K. Acedo, D. Paone, D. Long, and T.G. Osimitz, 'Safety Assessment of the Use of Bacillus -Based Cleaning Products', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 42–52. DOI 10.1016/j.fct.2017.11.028

Q14 (A&V) – If not already addressed in any of the previous questions, which are the factors/aspects impeding an effective *Assessment & verification* with regard to MCP? *Please, be as specific as possible in your response.*

Blank answers = 6

One stakeholder indicated that, for the case of MCP in spray format, the consecution of RA including inhalation exposure studies (microbial cells/spores and their derived enzymatic products) was sufficient to address risks posed by such product.

One stakeholder affirmed that third-party verification was not necessary, since the Competent Body should be able to make this assessment based on the documentation submitted by the applicant.

Q15 – Do you have any further remark applicable/ resource relevant to existing criteria on MCP (not restricted only to HSC)? *Please, be as specific as possible in your response.*

Blank answers = 7

One stakeholder indicated:

- Pursue alignment with the (ongoing) revision of the Detergent Regulation, in particular removing the American Type Culture Collection (ATCC) regarding the identification of the microorganism.
- Providing an extensive list of strains by the applicant could be difficult due to the confidential nature of information.
- Quality assurance parameters in externally accredited laboratories is common and desirable practice for safety reasons (e.g. CFU count, non-desired microorganisms testing) but not so much for functionality or marketing claims.

# 4 Scope expansion (LD)

## *4.1 Mapping of aspects*

Note that some of the more general aspects highlighted in the previous section/s could be of application here but are not repeated here for brevity.

— The expansion to other PGs, in particular LD, is generally supported by stakeholders. Some comments in this regard are:

  - Considering the provisions on microorganisms of other ecolabelling schemes having LD within its scope ([37]).
  - Consider the benefits of alternative cleaning actions (e.g. in LD - prolonged cleaning via microbial action of the organic matter embedded in fabrics).
  - Consider discussing about expanding the scope of MCP to other product groups in addition to LD (i.e. HDD) or to other users additionally to professionals (e.g. household set-ups).

— As mentioned, the assessment and verification is complex, thus a hypothetical scope expansion to other PGs should have equal or lesser complexity.

— Any potential microbial risk assessment should be tailored to their specificities of the particular product group (i.e. exposure scenarios).

## *4.2 Potential actions*

— Considering expanding scope to other PGs than HSC, inclusive of type of end-user (professional; household), gathering for this relevant evidences (e.g. presence of such products in the market, mode of action, presence in other ecolabelling schemes, etc)

— About *(iii) Absence of contaminants;* Discussing and agreeing which additional/alternative provisions (if needed) should be considered to ensure that any additional unwanted microorganism is considered alongside those listed in existing legal text. This should account for the specificities of each PG within the scope of the EU Ecolabel criteria (in this case, LD).

— About *Assessment and verification* (A&V); Map specific A&V factors identified by stakeholders as impeding effective verification and gather suggestions on how to improve them, previously cross-checking impact of other criterion change proposals

## *4.3 Feedback to 1st MCP sub-AHWG questions*

This sub-section provides a summary of the feedback received to each of the questions shared with MCP sub-AHWG participants during the 1st MCP sub-AHWG meeting. The intention is to be informative and transparent with regards to the inputs that JRC received and considered in the formulation of its proposals for update/modification of draft criteria relative to microorganisms containing products, highlighted in the next sub-section.

The main tool set by JRC for feedback collection was an EU survey (active from 25/06/24 to 16/07/24), containing all the question shared during the 1st MCP sub-AHWG meeting to which a total number of 8 participants replied. In the summaries to each question disclosed below the number of blank responses is highlighted to provide context. In addition, any complementary feedback shared during the 1st MCP meeting not included in the EU survey responses is mentioned alongside the summaries of feedback to each question below.



[37] https://cdn.naturskyddsforeningen.se/uploads/2021/06/22173951/Criteria_Bra_Miljoval_Chemical_Products_2018-1_20181125_0-1.pdf

Q16 – Would you support extending the scope of MCP to other PG? Alternatively or complementary, would you allow non-professional end-users to use them? *Please, be as specific and comprehensive in your answer/s as you can, including reasons why.*

Currently, the use of microorganisms is only allowed in HSC aimed at the professional sector (not household/consumer). Also, the use of microorganisms as ingredients in other PGs has been banned on the basis of safety concerns (such is the case of HDD). Some stakeholders inquired whether, as the revision progresses and there is a discussion about microorganism containing products, it could perhaps be discussed whether the restriction to professional products could be removed, thus being extensive to any product irrespective of the end use context (consumer/professional). JRC acknowledge that this is a relevant discussion, potentially affecting the scope, fitting well to the nature of this MCP sub-AHWG. However, JRC would like to highlight that it is very relevant to have this discussion in the light of all trade-offs and within the boundaries of any potential MCP RA, in order to understand which particular provisions are required to minimise risk to users. For example, in the case of undiluted MCP the concentration of microorganisms is considerably higher than the one in RTU. A potential MCP RA could account for this, by not releasing products considered as having high risk to user, but also the legal text can take a precautionary approach and not allowing the use of such products in non-professional end users, for example, above certain microbial numbers thresholds. JRC considers as preferable option to accurately define conditions under which MCP can/not be used by particular users or in particular PGs though also acknowledges the diversity and difficulty in doing so given the potential combinations (multifactorial nature - PG x product format x microorganism types x formulations x exposure etc…). Consequently, it would appreciate the view of experts in the field in this regard.

Blank answers = 8

Respondents unanimously supported or were open to expand the use of microorganisms as ingredients to all users (i.e. consumers, professionals) and to all product groups under the EU Ecolabel criteria scope. Remarks shared in this regards were:

- The use of microbial containing products by non-professional should be conditioned to a previous RA where risks had been deemed as negligible/acceptable, with safety measures being taken and tailored according to intended users and product group.
- Microbial containing products is a very dynamic area, particularly in the sustainability context, currently used across scales (household, professional, I&I) and for variety of product types/applications (i.e. LD, stain removers, HSC, wastewater treatment, drain cleaning, air care, vehicle care, odour controller, bathroom cleaning, DD). Furthermore, its use increased in the I&I by 50% in the last 5 years and It is foreseen to further double its size in the next 5 years, while in the household segment is growing globally.
- Expanding the scope to allow the use of microbial containing products to all PGs and users appears the only compatible way with the quoted market trends (see previous) and the ongoing legislative developments (revision of the Detergents Regulation).
- Product containing microorganism are efficient and more environmentally friendly than their purely chemical counter-parts, offering an excellent opportunity to reduce environmental impacts particularly in HDD and HSC product groups.

Q17 (iii) – Complementary to Q7, Do you have any suggestion on any microorganism that should be considered for inclusion in the *absence of contaminants* list specific to the nature/usage of other PGs than HSC? *Please, consider Q7 rational and be as specific and comprehensive in you answer/s as you can, including reasons why.*

Blank answers = 5

One respondent replied with no suggestion while another two indicated that a pre-set list was not necessary, with relevant RA addressing this aspect by not allowing microorganism with associated safety concerns.

Q18 (A&V) – If not already addressed in any of the previous questions, which are the factors/aspects impeding an effective *Assessment & verification* with regard to MCP? Complementary, which are the A&V elements you missing for alternative products groups to HSC (e.g. LD, HDD)? *Please, be as specific as possible in your response.*

Blank answers = 4

One respondent replied with no suggestion while another three indicated that a RA would be able to include all relevant safety aspects required, accounting and being tailored to each product group nature and users behaviour/practices.

Q19– Do you consider that existing EU Ecolabel *Fitness for use* protocols/frameworks should be modified/complemented during this revision for better testing of the performance of laundry detergents products containing microorganisms (these being the origin of the washing function)? If so, please provide a reasoned answer on why and how the performance of such products could be tested.

JRC has identified that there are already laundry detergent products in the market containing microorganisms, as reflected in TR1 (See TR1 lines 524 – 569, pages 24-25). However, this trend still seems not widespread (niche product) and evidences in the public domain (that JRC accessed) do not currently lead to an accurate and full picture of this market. In addition, fitness for use protocols/frameworks do not account for this type of product and their mode of washing/cleaning action. Considering the former, JRC is considering whether a tailored method / complementing existing is necessary at this stage.

Blank answers = 2

One respondent replied with no suggestion and another affirmed that additional performance benefits are associated to the use of LD containing microorganisms owing to the production of enzymes and presence of benign microorganisms.

Three respondents affirmed that the mode of action of LD containing microorganism is different from its purely chemical counter-part, thus being necessary additional considerations lacking in existing EU Ecolabel Fitness for use protocols/frameworks. In particular, they indicated:

- Microorganisms in LD containing microorganisms break down stains and soils through biological (enzymatic) activity, which may continue over longer periods even after the washing cycle has ended.
- LD containing microorganisms differ from HSC in: consumers' usage; the dilutions used; the performance effects (i.e. Malodour and stain removal). In addition, there is need for development of new performance standard methods.

One respondent affirmed that the testing protocol could be the same irrespective if the LD contains or not microorganisms. In addition it suggested that, for cases not specifically covered in the EU Ecolabel performance frameworks/protocols, a generic requirement could be added drawing inspiration from the European Parliament's position on the Detergents Regulation: "*The manufacturer shall substantiate all claims made regarding the actions or performance of the micro-organisms contained in the product with appropriate tests. Those tests shall be verified by an independent third party*."

Q20– Do you have any further remark applicable/ resource relevant to MCP supporting scope expansion to other PGS / context of use? *Please, be as specific as possible in your response.*

Blank answers = 5

One respondent replied with no suggestion while another claimed that microorganism containing products had several benefits for the various cleaning application, thus being advisable to expand the scope.

Contrastingly, another respondent indicated that the outlined potential environmental benefits of MCPs had not been backed up by suitable studies in JRC's related draft reports, thus being very valuable to have such evidences in upcoming new draft reports.

# 5 Performance

## *5.1 Mapping of aspects*

Note that some of the more general aspects highlighted in the previous section/s could be of application here but are not repeated here for brevity.

— Applicable to all PGs, ensure that equal performance is achieved in MCP as in their purely chemical counterparts whilst showing environmental benefits. If special instructions are required, consider adding these via information to the user.

## *5.2 Potential actions*

— Gathering further evidences specifically about MCP performance (e.g. mechanisms to exert cleaning/washing functions; testing methods) and MCP formulation profiles (ideally in comparison with chemical counterparts of same product category/format).

— Discussing if, how and to which extend is possible to compare MCP performance against their purely chemical counterparts with methods/protocols specified in existing EU Ecolabel, inclusive of consideration of which (if any) addition is required in this regard.

## *5.3 Feedback to 1st MCP sub-AHWG questions*

This sub-section provides a summary of the feedback received to each of the questions shared with MCP sub-AHWG participants during the 1st MCP sub-AHWG meeting. The intention is to be informative and transparent with regards to the inputs that JRC received and considered in the formulation of its proposals for update/modification of draft criteria relative to microorganisms containing products, highlighted in the next sub-section.

The main tool set by JRC for feedback collection was an EU survey (active from 25/06/24 to 16/07/24), containing all the question shared during the 1st MCP sub-AHWG meeting to which a total number of 8 participants replied. In the summaries to each question disclosed below the number of blank responses is highlighted to provide context. In addition, any complementary feedback shared during the 1st MCP meeting not included in the EU survey responses is mentioned alongside the summaries of feedback to each question below.

Q21 – Could you share details about formulations of MCP? *Please, provide as many formulations in as many product formats as possible, ideally using the format of the EU ecolabel applicant sheet ([38]). Shall you have any concern about this sharing (e.g. confidentiality), please get in contact with JRC at JRC-B5-DETERGENTS@ec.europa.eu*

MCP is an underrepresented group in terms of formulations that JRC has had access to, thus it strongly encourages stakeholders to share as much information/data as possible in order to properly understand the key differential traits with their chemical counter-parts and ensure an accurate representation in forthcoming version of the revised EU Ecolabel criteria.

Blank answers = 3

One respondent replied with no suggestion while another agreed on sharing MCP formulation details.

Three respondents highlighted that, generally, the formulations containing microorganisms largely overlap/reflect that of their purely chemical counterparts.

One stakeholder mentioned that a generic formulation would consist of surfactants, buffer salts, preservative, sequestrants and pH ranging from 3.0 to 11.0, which would then be tailored to the combination of product format and microorganisms technology.

Two stakeholder highlighted that MCP are subjected to the Detergent Regulation, meaning that they are required to disclose the composition of their product on the associated websites and they bear a Unique Formula Identifier (UFI) linked to a comprehensive product disclosure. In addition, they indicated that they could not share formulations.

[38] Example for LD PG. https://environment.ec.europa.eu/document/download/586d10ea-a099-4381-a813-8ee784f7336b_en?filename=Calculation%20Sheets%20-%20Laundry%20Detergents.xlsx

Q22 – Could you share details about the specific mechanisms of washing/cleaning of MCP? *Please, provide as many specific references as possible (i.e. scientific articles; industry reports), especially in products groups that you consider should be considered for scope inclusion (e.g. LD, HDD).*

Currently, there is information available for HSC but references to other PG are scarce and, up to some point, not fully conclusive. For example, there is information about patents for MCP within the LD PG, plus there is general information on the mode of action, but not conclusive information about how a LD MCP would act (in technical level) is available. Consequently, JRC aims with this question to fill particular gaps on key knowledge necessary to understand technical aspects related to performance, but also to (secondarily) scope expansion.

Blank answers = 2

Two respondent indicated that answering to this question was out of the scope of their commercial activity and another agreed to share information at a later stage and not via the EU survey.

Three respondents provided a description of the fundamental principles of microorganisms action, which relied on biologic principles, namely growth via substrate consumption and then senescence upon resources restriction (thus cleaning action concluded). Different bacterial strains would have different substrate (dirt/soil) affinities, thus specifically targeting particular types (e.g. fat/oil/grease; proteins and starches; ammonia-based molecules). The cleaning effect allows for long-term effects (as long as growing conditions are favourable; i.e. substrate) and deep cleaning (given the scales at which enzymatic fragmentation and consumption of substrates occur).

Q23 – Could you share details about the performance test/indicators that you use or that would recommend? *Please, provide as many specific references as possible, especially in products groups that you consider should be considered for scope inclusion (e.g. LD, HDD).*

As indicated, performance is an essential requirement to any EU Ecolabel criteria set. Not having the means to proof compliance with it, inclusive of proper testing methods, could impede *de facto* either including new product groups/formats within the EU Ecolabel criteria or lead to compliance but under sub-optimal level, which could raise doubts about proper performance (in this case) of MCP. Consequently, JRC aims to ensure the compatibility of existing testing methods with the nature of MCP (i.e. mode of cleaning/washing action), inclusive of any of the claims that can be made on such products (i.e. "legacy" or "long-lasting" effect). This include indicators or proxies used/well acknowledged in terms of cleaning/washing performance (if any). If a gap on performance testing is found, then the aim is to discuss the feasibility to refer or to incorporate already existing testing methods (or parts of them) into the current set of criteria. Note, that it is out of scope of work of the current revision of the EU Ecolabel criteria to develop *de novo* testing methods fully tailored to MCP.

Blank answers = 2

One respondent replied with no suggestion, another indicated that it was out of the scope of its remit and a third one agreed on sharing further information a later stage.

One respondent suggested enzyme production as relevant performance indicator, since microorganisms are selected based on their ability to produce enzymes to digest target substrates (e.g. organic pollutants). It highlighted that it is not yet a fully consolidated but that could be measured via standard enzyme activity tests.

Two respondent highlighted that a performance test tailored to MCP is needed, as existing protocol would not be suitable for such products. One of these provided the following specific consideration for developing such methodology:

- (1) MCP differ from convention cleaners in the presence of biological agents exerting the function (microorganisms) in the product/formulation.
- (2) "Deep cleaning" efficacy should be evaluated over a period of time (i.e. 24 hours) to allow bacteria to adhere, germinate and grow, thus releasing enzymes to degrade its substrate (the dirt).
- (3) Differential effects of microbial cleaners from regular cleaners can be demonstrated via dedicated experiments (e.g. a kitchen sponge cleaned with MCP and conventional products; MCP cleaning expected to last longer, even after application of the products, with appreciable visual results)

- (4) Several approaches can be followed with regard to measuring and interpreting the results from MCP performance testing versus conventional cleaners:
  - (1) "long lasting" cleaning on surfaces can be evaluated using visual, microscopic or laboratory readings.
  - (2) Cleaned items (e.g. sponge) can be measured using Baroscope and/or SEM imaging.
  - (3) MCP cleaning efficiency can be quantified via laboratory measurement of target surfaces.
  - (4) MCP can counteract malodour, which can be measured using sensors.

Q24 – Do you have any further remark applicable/ resource relevant to the performance of MCP? *Please, be as specific as possible in your response.*

Blank answers = 4

Two respondents indicated their participation in the development of a framework for risk assessment of micro-organisms in cleaning products lead by detergent industry in US (ACI) and Europe (AISE), whose draft was shared with the JRC.

One stakeholder agreed on sharing further information a later stage.

# 6 New draft criteria proposal

## *6.1 Proposal text*

| TR1 draft version<br>Criterion X *Excluded and Restricted substances;* Sub-criterion X.x micro-organisms | |
|---|---|
| HSC, LD | (i) Identification: all intentionally added micro-organisms shall have an American Type Culture Collection (ATCC) number, belong to a collection of an International Depository Authority (IDA) or have had their DNA identified in accordance with a 'Strain identification protocol' (using 16S ribosomal DNA sequencing or an equivalent method).<br>(ii) Safety:<br>— All intentionally added micro-organisms shall belong to Risk Group I as defined by Directive 2000/54/EC of the European Parliament and of the Council ( [39] ) — biological agents at work,<br>— The outcome of a microbial risk assessment should be that the risk associated with the use of a product containing microorganisms is deemed as acceptable.<br>(iii) Absence of contaminants: pathogenic micro-organisms, as defined below, shall not be in any of the strains included in the finished product when screened using the indicated test methods or equivalent:<br>— E. coli, test method ISO 16649-3:2005,<br>— Streptococcus (Enterococcus), test method ISO 21528-1:2004,<br>— Staphylococcus aureus, test method ISO 6888-1,<br>— Bacillus cereus, test method ISO 7932:2004 or ISO 21871,<br>— Salmonella, test method ISO6579:2002 or ISO 19250.<br>(iv) All intentionally added micro-organisms shall not be genetically modified micro-organisms (GMMs).<br>(v) Antibiotic susceptibility: all intentionally added micro-organisms shall be, with the exception of intrinsic resistance, susceptible to each of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones) in accordance with the EUCAST disk diffusion method or equivalent.<br>(vi) Microbial count: products in their in-use form shall have a standard plate count equal to or greater than $1 \times 10^5$ colony-forming units (CFU) per ml in accordance with ISO 4833-1:2014.<br>(vii) Shelf life: the minimum shelf life of the product shall not be lower than 24 months and the microbial count shall not decrease by more than 10 % (measured in logarithmic scale) every 12 months in accordance with ISO 4833-1:2014.<br>(viii) Fitness for use: the product shall fulfil all the requirements set out in Criterion 6 on fitness for use and all claims made by the manufacturer on the actions of the micro-organisms contained in the product shall be documented through third-party testing.<br>(ix) Claims: it is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.<br>(x) User information: the product label shall include the following information:<br>— that the product contains micro-organisms, |

[39] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 262, 17.10.2000, p. 21). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32000L0054

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| | — that the product shall not be used with a spray trigger mechanism,<br>— that the product should not be used on surfaces in contact with food,<br>— an indication of the shelf life of the product. |
| HSC, LD | *Assessment and verification:* the applicant shall provide:<br>(i) The name (to the strain) and identification of all micro-organisms contained in the product with ATCC or IDA numbers or documentation on DNA identification.<br>(ii)Documentation demonstrating that all micro-organisms belong to Risk Group I and documentation on the microbial risk assessment, certified by an independent third-party expert, where the risk associated with the intended use of the product is deemed as acceptable.<br>(iii) Test documentation demonstrating that the pathogenic micro-organisms are not present in the product.<br>(iv) Documentation demonstrating that all micro-organisms are not GMMs.<br>(v) Test documentation demonstrating that all micro-organisms are, with the exception of intrinsic resistance, susceptible to each of the five major antibiotic classes indicated.<br>(vi) Test documentation of CFU per ml of in-use solution (for undiluted products, the dilution ratio recommended for 'normal' cleaning shall be used).<br>(vii) Test documentation of CFU per ml of in-use solution every 12 months for a product stored until the end of its shelf life.<br>(viii) Test results from a third-party laboratory demonstrating the claimed actions of the micro-organisms and artwork of the packaging or a copy of the product's label highlighting any claims made on the actions of the micro-organisms.<br>(ix) and (x) Artwork of the packaging or a copy of the product's label. |
| MCP sub-AHWG draft version<br>Criterion X *Excluded and Restricted substances;* Sub-criterion X.x micro-organisms | |
| HSC, LD | (i) Identification:<br>— all intentionally added micro-organisms shall ~~have an American Type Culture Collection (ATCC) number,~~ belong to or be deposited in a collection of an International Depository Authority (IDA) and be maintained by the culture collection for the authorised period of the EU ecolabel license.<br>— all intentionally added micro-organisms shall be identified and characterised using whole genome sequence (WGS) analysis according to *"EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms antimicrobial"* ([40]). ~~or have had their DNA identified in accordance with a 'Strain identification protocol'~~ ~~using 16S ribosomal DNA sequencing or an equivalent method.~~<br>— the following taxonomic information shall be provided considering the latest published information in the International Codes of Nomenclature (ICN): genus, species and strain name or code.<br>(ii) Safety:<br>— All intentionally added micro-organisms shall belong to Risk Group I as defined by Directive 2000/54/EC of the European Parliament and of the Council ( [41] ) — biological agents at work, |

[40] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206

[41] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 262, 17.10.2000, p. 21). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32000L0054

— Any ~~The outcome of a microbial~~ safety/risk assessment made on microbial containing products shall include in its scope human, animal, plant and environmental health. Therefore, considerations shall be made in the different stages of the assessment (e.g. Hazard identification, Hazard characterisation, Exposure assessment, Risk characterisation) to these groups and, particularly, on especially vulnerable groups (e.g. immunocompromised, elderly, infants, pregnant women, etc). ~~should be that the risk associated with the use of a product containing microorganisms is deemed as acceptable~~.

(iii) Absence of contaminants:

— It must be controlled that the product is not contaminated with pathogen microorganisms. Alternatively, the product should present a low risk of microbial contamination and/or intended use according to the principles of ISO 29621:2017[42].

— pathogenic micro-organisms, as defined below, shall not be in any of the strains included in the finished product when screened using the indicated test methods or equivalent:

- E. coli, test method ISO 16649-3:2005,
- Streptococcus (Enterococcus), test method ISO 21528-1:2004,
- Staphylococcus aureus, test method ISO 6888-1,
- Bacillus cereus, test method ISO 7932:2004 or ISO 21871,
- Salmonella, test method ISO6579:2002 or ISO 19250.
- any other micro-organisms listed in Annex II, section 2. of Regulation (EU) XXXX/XXX([43]).

(iv) All intentionally added micro-organisms shall not be genetically modified micro-organisms (GMMs).

(v) Hazard/s identification - All intentionally added micro-organisms shall be assessed for ~~A~~antibiotic susceptibility, antimicrobial production and toxigenicity/pathogenicity according to the *"EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms"* ([44]). The outcome shall be "no hazard identified", meaning that microorganisms are:

— free from acquired antibiotic resistance determinants and susceptible to each of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones);

— shown not to produce relevant antimicrobial substances and;

— shown to be non-pathogenic/non-toxigenic.~~, with the exception of intrinsic resistance, susceptible. in accordance with the EUCAST disk diffusion method or equivalent.~~

Microorganisms included in the *Qualified Presumption of Safety* (QPS) status list issued by the European Food Safety Authority (EFSA) and that fulfil the qualifications provided by it, shall be exempt from the previous [point *(v)*] requirements concerning humans and animals.

(vi) Shelf life and ~~M~~microbial count: The minimum shelf life of a product shall be 24 months, during which microorganisms count shall be guaranteed. P~~p~~roducts in their in-use form shall have ~~a standard plate count equal to or greater than~~ ≥1 × $10^5$ colony-forming units (CFU) per ml in accordance with ISO 21149 or ISO 4833-1:2014 or equivalent scientifically recognised method for the determination of microorganisms' numbers. .The stability of the product, assessed at room temperature, shall be demonstrated by measuring microorganisms count every 12 months.

~~(vii) Shelf life: the minimum shelf life of the product shall not be lower than 24 months and the microbial count shall not decrease by more than 10 % (measured in logarithmic scale) every 12 months in accordance with ISO 4833-1:2014.~~

[42] ISO 29621 *Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products.* See https://www.iso.org/standard/68310.html

[43] Regulation (EU) XXXX/ XXX refers to the final adopted version of the revised Detergent Regulation

[44] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206

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| | (vii~~i~~) Fitness for use: the product shall fulfil all the requirements set out in Criterion X~~6~~ on fitness for use<br><br>(viii) ~~and A~~all claims made by the manufacturer on the actions or the performance of the micro-organisms contained in the product with appropriate tests, which shall be ~~documented through~~ verified by independent third-party testing.<br><br>(ix) Claims: it is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.<br><br>(x) User information: the product label shall include the following information:<br><br>— that the product contains micro-organisms,<br><br>— that the product shall not be used with a spray trigger mechanism,<br><br>— that the product should not be used on surfaces in contact with food,<br><br>— an indication of the shelf life of the product.<br><br>— use instructions or special precautions, where relevant. |
| HSC, LD | *Assessment and verification:* the applicant shall provide:<br><br>(i) Per microorganism in the product:<br><br>— a valid certificate of deposition from the collection, specifying the accession number under which the strain is held.<br><br>— the taxonomic information: genus, species and strain name or code) ~~name (to the strain)~~ and;<br><br>— identification ~~of all micro-organisms contained in the product~~ with ~~ATCC or~~ IDA numbers or documentation on DNA identification.<br><br>— Documentation about the minimum set of information for WGS analysis, in accordance with section 2.1.1 of *"EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms antimicrobial"* ([45]),<br><br>(ii) Documentation demonstrating that all micro-organisms belong to Risk Group I and documentation on ~~the microbial~~ any safety/risk assessment showing that its scope includes human, animal, plant and environmental health and including specific considerations in its different parts to these groups and also to relevant vulnerable (sub-)groups.~~, certified by an independent third-party expert, where the risk associated with the intended use of the product is deemed as acceptable.~~<br><br>iii) Documentation describing how it is controlled that the products is not contaminated with pathogen microorganisms or documentation according to ISO 29621:2017 principles demonstrating that the product can be considered a microbiologically low-risk product. Test documentation demonstrating that the pathogenic micro-organisms are not present in the product.<br><br>(iv) Documentation demonstrating that all micro-organisms are not GMMs.<br><br>(v) Test documentation, in accordance with *"EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms antimicrobial"* ([46]), demonstrating that all micro-organisms are~~,~~: free from acquired antibiotic resistance ~~with the exception of~~ (excluding intrinsic resistance) and susceptible to each of the five major antibiotic classes indicated~~,~~ Not antimicrobial producers and; non-pathogenic / non-toxigenic. |



[45] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206

[46] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206

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| | (vi) Test documentation of CFU per ml of in-use solution (for undiluted products, the dilution ratio recommended for 'normal' cleaning shall be used). measured every 12 months for a product stored at room temperature, inclusive at the start (t= 0).<br><br>~~(vii) Test documentation of CFU per ml of in-use solution every 12 months for a product stored until the end of its shelf life.~~<br><br>(vii), (viii) Test results from a third-party laboratory demonstrating the claimed actions of the micro-organisms and artwork of the packaging or a copy of the product's label highlighting any claims made on the actions of the micro-organisms.<br><br>(vi), (ix) and (x) Artwork of the packaging or a copy of the product's label. |

## *6.2 Rationales for proposals*

The role of existing technical guidance's in streamlining EU ecolabel requirements setting and verification.

The feedback gathered highlighted several resources (i.e. guidance) that could be used/adapted for the purposes of drafting/improving the EU Ecolabel requirements on microbial containing products (See feedback to questions Q2, Q3, Q4). Amongst these, the two sources within the European legislation highlighted by respondents as most suited were:

- EFSA. Guidance on the characterization of microorganisms used as feed additives or as production organisms. February 2018.[47]
- ECHA. Guidance on the Biocidal Products Regulation: Volume V – Guidance on active micro-organisms and biocidal products. Version 2.1. March 2017:[48]

Feedback also outlined that the ECHA/BRP guidance includes requirements for animal testing which might be against ongoing developments advocating for alternatives to animal testing[49], not being necessary for the intended safety assessment. This is reflected in the latest amendments to the proposed for a revised Detergent Regulation[50], particularly amendment 130:

> *7. Detergents containing micro-organisms shall be allowed to be placed on the market in a spray format after appropriate non-animal approaches to testing the respiratory sensitisation properties of micro-organisms have been established in accordance with Article 26(6a)*

The feedback further stressed ECH/BPR being very conservative on sensitization and not being risk-based, presenting EFSA's guidance on microorganisms in food and feed product as alternative, having a pragmatic risk-based approach easily transferable to consumer product upon accounting for relevant routes of exposure. Given the former, the JRC approached and examined firstly EFSA's guidance for inspiration/uptake of relevant elements.

It is important to understand the context and scope of work of EFSA and its associated instruments in order to discriminate elements directly transferable and aspects that are missing but that it would be desirable to consider within the EU Ecolabel criteria revision. All work under EFSA's scope is tailored to suit the needs for market authorisation of feed additives, food additives, food enzymes, food flavourings, novel foods, and plant protection products ("regulated products")[51]. In this sense, it considers those organisms included in products for which such market authorisation are submitted. The same applies to the Qualified Presumption of Safety (QPS) status, which is a simplified safety assessment used by EFSA to streamline the application process. The QPS assessment is only triggered by market authorisation products and examines microorganism at taxonomic unit (TU) level for: taxonomic identify, body of knowledge and potential safety concerns (including knowledge of



47 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5206

48 European Chemicals Agency., Guidance on the Biocidal Products Regulation. Volume V, Guidance on Micro-Organisms and Biocidal Products., Publications Office, LU, 2017.DOI: 10.2823/31176; https://data.europa.eu/doi/10.2823/31176

49 The JRC understands that this comment possibly is related to the ongoing revision of the Detergents Regulation.

50 https://www.europarl.europa.eu/doceo/document/TA-9-2024-0091_EN.html

51 https://www.efsa.europa.eu/en/applications/qps-assessment

relevant acquired antimicrobial resistance for bacteria). If a hazard is identified to a TU that can be tested at the strain or product level a "qualification" to exclude that hazard may stablished during the QPS assessment which is then assessed by a separately by EFSA safety assessment unit (thus separate from QPS assessment). Examples of qualifications (summarily) are absence of antimicrobial or antimycotic resistance or restriction of use for production purposes (no viable cells). Also, the QPS concept does not cover the following safety aspects, which are covered separately in EFSA safety assessments:

- type and level of exposure of users handling the product (e.g., dermal contact, ingestion, inhalation);
- potential allergenicity to microbial residual components;
- hazards linked to the formulation or other aspects of the processing of those products.

Hence, the QPS list is a "positive list" containing only the taxonomic units (TUs) notified to EFSA for which QPS status has been granted. Either due to being relevant and/or in the absence of a better legislative framework for MCP, industry has adopted the QPS approach as "state-of-art" with regard the safety of microorganisms used in products. Another broadly analogous figure commonly used in US is the *Generally Recognised as Safe* (GRAS)[52].

Relevant implications of the former with regards to EU Ecolabel revision is that the QPS concept and, especially, the guidance derived from EFSA's work contains several technical elements that can be used/transferred into the EU Ecolabel criteria. However, limitations of such concept and other considerations are necessary in order to complement (if necessary) aspect that are missing or that are not tailored to the scope of the EU Ecolabel criteria for detergents. An example of such is that microorganisms that are/can be used in MCP might not be in the QPS list, as only microorganisms included in products submitting a market authorisation application to EFSA can potentially be in the QPS list. Consequently, referring exclusively to QPS status as sole way to meet EU ecolabel criteria requirements is not an option and requirements should be stated for any MCP applying for the EU Ecolabel. Another relevant aspects is the scope of work, which for the cited guidance focus on human and animal's health, but not in other environmental compartments (e.g plants). Consequently, the intention of JRC is aligning EU ecolabel criteria requirement to the extent technically feasible/sensible with EFSA's work.

## Improving safety via unequivocal microorganisms identification

Several elements of the new proposals and/or questions made in this 2nd sub-AHWG derive from EFSA's guidance[53], which was frequently cited by MCP sub-AHWG participants as industry standard for MCP. As highlighted earlier, the guidance covers EFSA's scope of work, thus feed additives containing microorganisms or produced with microorganism by fermentation (GMO or not) pursuing mandatory market authorisation. In particular, it covers bacteria, yeasts and fungi, being also broadly valid for other taxonomical groups. Despite the scope of this guidance is not fully tailored to MCP, it focuses on the microorganisms mostly used in MCP, which predominantly belong to bacterial species, with few yeast and fungal species[54], describing which aspects and via which methods should be considered for the unequivocal identification of a microorganisms at taxonomic level. In this sense, the technical guidance provided (at least some elements of it) could be reasonably assumed to be horizontal and transferable to microbial containing products, being this the main rationale for aligning the draft criteria proposal with it (where relevant).

The feedback received before and during the MCP sub-AHWG life-time also served as driver of the changes proposed. For example, the feedback received indicated that Whole Genome Sequencing (WGS) is a state-of-the-art technique, whose cost is bearable and dimensioned to the information and accuracy it offers. The benefit of WGS is that it not only provides unequivocal taxonomic identification as well as it enables to characterise strains regarding their potential functional traits of concern (e.g. virulence factors, production of or resistance to antimicrobials of clinical relevance, production of know toxic metabolites). This fact is acknowledged in upcoming industry guidance for the risk analysis of MCP[55]., indicating that information from



52 https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

53 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5206

54 Spök, A., G. Arvanitakis, and G. McClung, 'Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 10–19. DOI: 10.1016/j.fct.2017.12.057

55 Framework for the Risk Analysis of Microorganisms in Microbial Cleaning Products. American Cleaning Institute (ACI) and The International Association for Soaps, Detergents and Maintenance Products (AISE). Currently under peer review process for publication

multiple genetic elements (e.g. 16S ribosomal gene sequencing, housekeeping genes, etc), or other analysis, may help to make important distinctions between microorganism which can inform and improve the overall hazard identification process, which is especially relevant for certain groups of microorganisms (e.g. *Bacillus* genera). Moreover, an additional benefit is that WGS allows for re-interrogation of existing data once new evidences become available (e.g. new databases), thus allowing for a dynamic assessment via a single initial test/analysis. This would contribute to solve issues identified associated with the quality of the products, boosting it via precise knowledge and control of production processes[56].

The Directive 2000/54/EC[57] states minimum provision to ensure safety of workers related to biological agents. Therefore, its scope includes MCP but only in professional use contexts (e.g. manufacturers, blenders, professional cleaning service providers, etc) and mainly concerning human impacts. This legislation classifies microorganisms according to its pathogenic potential into four risk groups, with risk group 1 being the less "risky" (not pathogenic to healthy adults). According to Spok et al. 2018[58], the microorganisms commonly found in MCP predominantly belong to risk group 1, which is also a common requirement across ecolabelling schemes with MCP under their scope. Note that the potential allergenic or toxigenic effects of microorganisms belonging to group risk 1 is not reflected by this risk grouping, yet it is still desirable to be considered[59].

Lastly, microorganism used in MCP may hold other qualifications in terms of safety, generally associated with food context, such as *Generally Recognised as Safe* (GRAS) or the *Qualified Pressumption of Safety* (QPS), which could aid in streamlining the assessment for compliance with MCP requirements.

Considering all the former aspects, especially EFSA's guidance, the proposed draft criteria required a series of changes, importantly requiring mandatorily performing WGS analysis, aimed at making the requirement more relevant and ambitious.

The changes/proposals made are:

— Point *(i) Identification*

- Use of Whole Genome Sequence (WGS) analysis as mandatory technique for microorganisms' characterisation.
- The minimum taxonomic information required per microorganism: genus, species and strain name or code
- The organisms have to be deposited in internationally recognised culture collection with the status "Internationally Depository Authority" (IDA).
- The organisms should be maintained by the culture collection for the authorised period of the additive (in EU Ecolabel case, proposed duration of the EU Ecolabel license)

— Point *(v) Hazard/s identification*

- Making the *Antibiotic susceptibility* requirement more ambitious, by not only performing the phenotypic testing (e.g. EUCAST disk diffusion method) but also perform a search for antimicrobial resistance genes, being the qualification "*free from acquired antibiotic resistance determinants*" imply no hazard identified in neither of these aspects.
- Add two explicit requirements to screen for *Antimicrobial production* and *Toxigenicity and pathogenicity* of the microorganisms under evaluation, in accordance with EFSA's guidance section 2.3 and 2.4.

In addition, to streamline the application process, an exemption for compliance with point *(v)* has been explicitly stated for those microorganisms holding QPS status, thus being in the QPS list. Note that this exemption only



[56] Teasdale, S.M., and A. Kademi, 'Quality Challenges Associated with Microbial-Based Cleaning Products from the Industry Perspective', Food and Chemical Toxicology, Vol. 116, June 2018, pp. DOI 20–24. 10.1016/j.fct.2017.10.029

[57] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) OJ L 262, 17.10.2000, p. 21–45. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32000L0054

[58] Spök, A., G. Arvanitakis, and G. McClung, 'Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 10–19. DOI: 10.1016/j.fct.2017.12.057

[59] Spök, A., G. Arvanitakis, and G. McClung, 'Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 10–19. DOI: 10.1016/j.fct.2017.12.057

applied to the scope of EFSA's guidance with regards to organism considered, namely humans and animals. Others not included within the scope of EFSA's guidance (e.g. plants) still should be considered if relevant.

Improving safety via scope expansion to environmental impacts

In the first proposal, the JRC included a requirement to perform a risk assessment (RA) whose outcome should be that the risk is acceptable. Stakeholders inquired for further definition of the criteria to define a *risk being acceptable*. After carefully considering the scope of work of the EU ecolabel revision and considering ongoing legislative developments (i.e. revision of the Detergents Regulation), the JRC has concluded that the EU ecolabel is not the right instrument to set a definition of which risk is acceptable or not. Instead, market surveillance and other specific legislative instruments (e.g. Revised Detergent Regulation) should serve to set such minimum requirements for any particular safety/risk assessment. Furthermore, even in the absence of specific instruments, it would be down to agents placing in the market and Market surveillance authorities ensuring the safety of any product placed in the EU market, in accordance with the General Product Safety Regulation (EU) 2023/88[60]. Consequently, the JRC revised this requirement about setting a mandatory RA and concluded that it exceeded the competences and resources within the EU Ecolabel revision process. Furthermore, feedback received highlighted that the approach followed in the EU Ecolabel regulation was Hazard-based and not risk-based (at least for the case of chemicals), thus careful justification should be provided while adopting the later approach.

The focus of JRC's proposal is now ensuring that any safety/risk assessment work carried out by EU ecolabel applicants/for EU ecolabelled products has its scope aligned with the principles and scope of the EU Ecolabel. As mentioned, the main EU legislation of clear application to MCP, namely Directive 2000/54/EC[61], focus on workers (professionals), thus its scope is mostly related to human health. Complementary, the scope of EU Ecolabel, as per other ecolabel schemes, additionally includes environmental impacts/health. In this sense, Spok et al. 2018[62] highlighted the lack of specific MCP criteria considering environmental properties and mentioned that risk group 1 microorganisms could still be pathogenic to plants and animals. Similarly, the Norwegian Scientific Committee for Food Safety (VKM), amongst other considerations, highlighted the lack of/need for environmental impacts emphasis and information about vulnerable groups (e.g. immunocompromised, elderly, infants, pregnant women, etc) when assessing MCP health and environmental risks[63]. In a follow-up work focusing on the state-of-art about this topic, the VKM concluded still there were considerable knowledge gaps, uncertainties regarding effect/safety, meachisms of action, and insufficient transparency on the content of microbial-based cleaning products to the strain level, thus limiting its ability to conduct data-driven environmental and health risk assessments[64].

Considering the former, the potential realisation of environmental benefits and avoidance of environmental impacts by MCP lies, firstly, in the proper framing of the evidences available. In this sense, the JRC is proposing a modification of the new *(ii) Safety* clause, which does no request to perform a risk assessment, neither states which should be the acceptable outcome of it, but that requires that safety/risk assessment made must also consider other underrepresented environmental compartments and vulnerable (sub-)groups. This ensures that any ecolabelled product can affirm that any safety assessment made is aligned with EU Ecolabel scope, thus addressing environmental properties and contributing to build-up the necessary evidences to fully appraise MCP use implications. In practical terms, implies broadening the scope of safety assessments required by specific or general EU regulations applicable to MCP.

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60 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) OJ L 135, 23.5.2023, p. 1–51 Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.135.01.0001.01.ENG&toc=OJ%3AL%3A2023%3A135%3ATOC

61 Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) OJ L 262, 17.10.2000, p. 21–45. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32000L0054

62 Spök, A., G. Arvanitakis, and G. McClung, 'Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 10–19. DOI: 10.1016/j.fct.2017.12.057

63 VKM. (2016) Health and environmental risk assessment of microbial cleaning products. Scientific Opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-231-4, Oslo, Norway.

64 VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978-82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

Note about ongoing work streams - Studies reporting environmental benefits and effects of MCP

The JRC would like to inform that it is still looking for evidences on more precisely define the environmental benefits and the environmental effects of MCP, via different means (i.e. primary data; literature search; personal communications). However, so far, further work is envisaged in this regard, especially related to absence of concrete evidences in the public domain. A VKM report[65] reported stressed the limitations observed with regards to evidences access, leading to reasonable doubts on well-stablished microorganisms with long-history of safe use, owing to lack of transparency and third-party assessment on the detailed chemical and microbial formulation of the products, the potential for misclassification and contamination with pathogens.

What has been observed is that in some setting (health care) MCP may have neutral or positive effects. Spok et al. 2018[66] did not found any report available reporting health incidents resulting from professional or consumer use of MCP and indicated that some evidences suggest that MCP use in health-care setting do not contribute to hospital-acquired infections[67],[68]. Similarly, the cited VKM report[69] reported certain MBCPs may have long-term effects on surfaces, preventing the recontamination, persistence and spread of pathogenic microorganisms and opportunists.

Aspects un/changed considering ongoing legislative developments (i.e. revision of the Detergent Regulation)

Performance is understood in the context of MCP as the effect of general instant cleaning + some additional effects associated to the biological action of microorganisms' post-application. These can contribute to break-down organic matter and other soil/dirt present in surfaces becoming in contact with microorganisms. For the purposes of the EU Ecolabel criteria, many of this performance effects can be considered secondary, since contribute to one particular aspect of the main function attributed the particular product group (i.e. cleaning surfaces for HSC, washing fibres for LD). In this sense, they can be acknowledged as being secondary claims (e.g. odour removal) which could be proven as per any claim made on the product not explicitly specified within the EU ecolabel *Fitness for Use* performance frameworks/protocols. Consequently, meeting *Fitness for Use criterion* would imply passing the performance test (as per any conventional product) plus proving the secondary effects exclusively attributed to MCP due to the biological action of microorganisms (e.g. odour removal).

Another aspect is about who would be able to perform such test. Generally, the recommendation is that whenever available, accredited laboratories should carried out such test as these are understood as independent third-party. This option, unbiased third-party certification, is advocated by some authors[70],[71] as an effective and necessary way to enhance transparency regarding MCP quality. However, this comes at a cost



65 VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978-82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

66 Spök, A., G. Arvanitakis, and G. McClung, 'Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada', Food and Chemical Toxicology, Vol. 116, June 2018, pp. 10–19. DOI: 10.1016/j.fct.2017.12.057

67 Caselli, E., M. D'Accolti, A. Vandini, L. Lanzoni, M.T. Camerada, M. Coccagna, A. Branchini, et al., 'Impact of a Probiotic-Based Cleaning Intervention on the Microbiota Ecosystem of the Hospital Surfaces: Focus on the Resistome Remodulation', Edited by Y.-F. Chang, PLOS ONE, Vol. 11, No. 2, February 17, 2016, p. e0148857. DOI: https://dx.plos.org/10.1371/journal.pone.0148857

68 Caselli, E., P. Antonioli, and S. Mazzacane, 'Safety of Probiotics Used for Hospital Environmental Sanitation', Journal of Hospital Infection, Vol. 94, No. 2, October 2016, pp. 193–194. DOi 10.1016/j.jhin.2016.06.021

69 VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978-82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

70 Jackson, S.A., J.L. Schoeni, C. Vegge, M. Pane, B. Stahl, M. Bradley, V.S. Goldman, P. Burguière, J.B. Atwater, and M.E. Sanders, 'Improving End-User Trust in the Quality of Commercial Probiotic Products', Frontiers in Microbiology, Vol. 10, April 17, 2019, p. 739. DOI 10.3389/fmicb.2019.00739

71 VKM, Elisabeth Henie Madslien, Nana Asare, Øivind Bergh, Erik Joner, Pål Trosvik, Siamak Yazdankhah, Ole Martin Eklo, Kaare Magne Nielsen, Bjørnar Ytrehus, Yngvild Wasteson (2019). Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. VKM report 2019:09, ISBN: 978-82-8259-325-0, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

which could imply a burden, especially to small and medium enterprise which are common across the MCP market. Current JRC position remain as it was (shown by *(viii))*, which is in alignment with the current version of the revised Detergent Regulation, where third-party testing is required.

There are further aspects where the revised Detergent Regulation will have resonating effects in the EU Ecolabel criteria for detergent and cleaning products, plainly because it will state the minimum requirements to be abide by any detergent and cleaning product in the market. For these particular aspects, the JRC has introduced minor or no modifications, waiting to appraise final version for further changes consideration. These aspect are:

- Point *(iii) Absence of* contaminants - Pathogenic organisms. The feedback received by the JRC was contrasting, some supporting the current list or its expansion aligning with the revised Detergent Regulation and other advocating for removing such list.
- Point *(vi) Shelf life and microbial count* – Previous points *(vi)* and *(vii)* have been merged into a single clause, with the requirement on not exceeding a yearly variation of 10% being removed. The logic of this change is to ensure that the product always exceeds the microbial counts set by the manufacturer as minimum required for product's performance (as declared in it). Feedback received by the JRC pointed to the number not necessarily being an unequivocal indicator of performance as it depends on the microbial strain and being above a critical threshold to ensure induction of the desired effect. Feedback also pointed towards $\geq 1 \times 10^5$ colony-forming units (CFU) as being a representative minimum level, as per existing criteria which is aligned to proposal of the revised Detergent Regulation. Considering the key role of ensuring product stability, it is requested to measure microbial numbers every year under representative storage conditions (room temperature) understand decay dynamics and also ensure numbers are above the minimum pre-set threshold. Related to this, flexibility is given on the microbial counts method, either using the suggested or equivalent. Given this and also the developments on the revision of the Detergent Regulation, the JRC is holding on making any further suggestion at this stage.
- Point *(X) User information* – Food contact surfaces -> The current understanding of JRC is that this restriction could be modified but not changes are effected at this stage given ongoing legislative developments.
- Point *(X) User information* – spray trigger mechanism -> The current understanding of JRC is that this restriction could be modified but not changes are effected at this stage given ongoing legislative developments.

## 6.3 Feedback to 2nd MCP sub-AHWG meeting

This sub-section provides a summary of the feedback received during & after the 2nd MCP sub-AHWG meeting. The intention is to be informative and transparent with regards to the inputs that JRC received and considered in the formulation of its proposals for update/modification of draft criteria relative to microorganisms containing products, highlighted in the next sub-sections.

The main tool set by JRC for feedback collection was the recording and notes of the 2nd MCP sub-AHWG meeting and feedback shared post-meeting via email (deadline 15/10/24). Feedback was received from 8 of the 15 participants in the meeting), irrespective if orally during it or in written after it. On what follows, such feedback is arranged in two blocks: 1) directly addressing the questions shared by JRC (A25 –Q31); 2) addressing other aspects.

Q25 – *Section/Aspect Microorganisms identity and hazards* -> Stakeholders are invited to provide their feedback on the new formulation of the sub-sections *(i) Identification (v) Hazard/s identification* and its

corresponding verification means. Please, provide a reasoned response, especially about the wording used and the suitability of requiring mandatorily WGS analysis during the 2nd meeting of the MCP sub-AHWG

As described in section 6.3 (See *Improving safety via unequivocal microorganisms identification*) the changes exerted in the criteria aim to cover fundamental aspects of microorganisms characterisation, namely identify and hazards identification. The changes aim to be precise, proportionate and leading to much robust and trustful identification, as cornerstone of performing relevant and appropriate safety/risk assessments. Given its importance, we invite participants to comment in detail about the suitability of the proposals made from different angels (e.g. clarity of legal text; technical validity; potential resources required; verification)

One participant asked about what was the foreseeable effect of introducing the Whole Genome Sequence (WGS) analysis, especially considering the proposal of removing the requirements on performing a risk assessment. It also mentioned that, if some of the EU ecolabel requirements proposed at this stage are applicable to microorganisms not holding QPS status, then this might not be of application since in the draft proposal of the revised Detergent Regulation requires microorganisms to be in the QPS list. Furthermore, some aspects are not covered by the QPS status (e.g. sensitization) which should be considered within the EU Ecolabel draft criteria text. The JRC indicated that WGS provides additional information/accuracy for a proportionate cost, enabling dynamic assessment throughout time and that it was recommended in scientific literature and technical guidance consulted. The JRC also clarified that current proposal is aligned with the Detergent Regulation but using a wording potentially more precise, understanding that a microorganisms that holds QPS status would meet the additional requirements included in this MCP sub-AHWG draft criteria proposal and acknowledging potential redundancy risk depending on final version of the revised Detergent Regulation.

One participant shared one concern about antibiotic resistance and susceptibility to each of the five major antibiotic classes, indicating that it was very stringent in its current formulation, since not all microorganisms have susceptibility to all classes of antibiotics. It highlighted that intrinsic resistance should not be considered a concern as long as there is susceptibility to other clinically relevant antibiotics and it affirmed that the breakpoints for assessing susceptibility (e.g. EUCAST) were not available for all organisms of all five classes of antibiotics. Given the former, it called for revising this requirement to reflect the nuances around assessment of antimicrobial resistance and susceptibility to to relevant or therapeutic antibiotic classes taking into account intrinsic resistance. It also asked for further clarity on what (antimicrobial) substances are in and out of the scope and how the assessment should be carried out, as current formulation is vague and some antimicrobials might be produced normally during the life-cycle of certain microorganisms. Finally, it asked about confidentiality and governance of the verification of compliance with EU Ecolabel requirements, because strain information and accession numbers may be considered proprietary information by the suppliers. The JRC acknowledged that intrinsic resistance is not presented as an aspect of concern within the references consulted (e.g. EFSA's guidance) and, whilst acknowledged the comments shared, the requirement on being susceptible to the five major antibiotic classes is already in existing criteria in force, thus indicating that it should be possible to comply with it in some cases given the number of EU Ecolabel licenses of MCP. The JRC also noted the suggestion for further precision on the antimicrobial substances formulation and finally described that verification by Competent Bodies includes mechanisms for confidential/proprietary data to be protected (.e.g ingredients producers can send to the CB directly the information required for the verification of the EU Ecolabel application of a producer using the ingredients supplied).

One participant described as current industrial practice (for microorganisms producers) to have a known antibiotic resistance profile in the starter culture and suggested as easily implementable a periodic verification that this is maintained throughout time (i.e. confirming that no antibiotic resistance has been acquired), performed by the ingredient (e.g. microorganisms) supplier.

One participant found timely and scientifically justified to require the WGS approach with reference to EFSA.

Q26 – *Section/Aspect (i) Identification* -> With regard to this new criteria text: "...belong to or be deposited in a collection of an International Depository Authority (IDA) *and be maintained by the culture collection for the authorised period of the EU ecolabel license.* Should the period be extended before the award and/or after the expiry of the

EU Ecolabel license? Do you have other comment/suggestion to improve this clause? Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

This rationale is aligned with EFSA's guidance, which requires the microbiological material being maintained for the period of the market authorisation. In the case of the EU Ecolabel, the analogous administrative figure would be the license during which the EU Ecolabel award is valid, thus the formulation referring to EU Ecolabel licence. The rationale of this requirement is ensuring that microorganisms used within a product remain available for access during its life-time in case access to such material is required. However, the JRC would like to ensure that the phrasing is accurate enough to cover all the necessary periods, even pre-/post-award. Therefore, this questions aims at getting feedback from license holders and competent bodies (primarily) to understand whether the requirements needs to request any period before or after in order to adjust the wording of the legal text accordingly.

No explicit/specific feedback was received to this question.

Q27 – *Section/Aspect (iii) absence of contaminants* -> With regard to this new criteria text: "any other micro-organisms listed in Annex II, section 2. of Regulation (EU) XXXX/XXX([72]).. Do you support its current formulation referring to Annex II of the revised Detergent Regulation (denoted as (EC) XXXX/XX? If not, could you propose an alternative formulation? Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

The feedback received by JRC did not specifically suggested any particular microorganism for inclusion into existing criteria *(iii) absence of contaminants*. However, it pointed towards the ongoing revision of the Detergents Regulation[73], which in its latest stage[74] added two specific species and an additional clause referring to Regulation Annex I, Table 4 of Regulation (EU) 2020/741([75]). The final form of the revised Detergent Regulation, once into force, will introduce compulsory requirements, with which EU Ecolabelled products would also need to comply with. Considering the former and also the contrasting feedback received after the 1st MCP sub-AHWG meeting (almost equal division of those supporting existing list versus those advocating for removing it) the JRC has opted for not removing the list and restrict its expansion to aligning with ongoing developments in the revision process of the EU Detergents Regulation.

One participant supported the clause included, making reference to Annex II of the (still to be adopted) revised Detergent Regulation. However, it called for ensuring that the three specific pathogens previously suggested are considered for inclusion in the EU Ecolabel draft criteria proposal irrespective of the outcome of the revised Detergent Regulation.

One participant supported the reference to the revised Detergent Regulation in the EU Commission proposal but not those microorganism proposed by the Parliament and the Council. In addition, it suggested the allowance of technically unavoidable traces provided that the product has been demonstrated to be safe. The JRC highlighted that EU Ecolabel would be aligned with the revised Detergent Regulation, which might imply also alignment with the microorganisms species included in Annex II list.

One participant supported this proposal, acknowledging the importance of consistency between specific requirements of the upcoming revised Detergent Regulation and the EU Ecolabel.

Q28 – *Section/Aspect (iii) absence of contaminants* -> With regard to this new criteria text: *"It must be controlled that the product is not contaminated with pathogen microorganisms. Alternatively, the product should present a low risk of microbial contamination and/or intended use according to the principles of ISO 29621:2017*[76]*"* Do you support this new



[72] Regulation (EU) XXXX/ XXX refers to the final adopted version of the revised Detergent Regulation
[73] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52023PC0217
[74] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0091_EN.html
[75] Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse (Text with EEA relevance) OJ L 177, 5.6.2020, p. 32–55. Available at: https://eur-lex.europa.eu/eli/reg/2020/741/oj
[76] ISO 29621 *Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products.* See https://www.iso.org/standard/68310.html

requirement? If so, do you consider suitable the alternative stated (compliance with ISO 29621:2017)? Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

The sources consulted in preparation for this meeting, mainly state-of-the-art literature, highlighted lack of transparency and potential biological contamination at the manufacturing stage, being this information necessary for understanding of potential risk associated with the product. The already existing provisions within the EU Ecolabel criteria for detergents requires testing for pathogenic microorganisms (see *(iii) Absence of contaminants*) of the end-product but does not focus on its manufacturing process. In alignment with Nordic Swan cleaning products 026, a requirement has now being introduced providing information about the process and controls stated, valuable information for context interpretation of other aspects relative to the product and also with regards to compliance with ecolabelling schemes criteria. Alternative to this, the JRC is proposing proving that the likelihood of contamination of the end-product is low according to ISO 29621:2017[77]". However, this ISO standard refers specifically to Cosmetic products, thus not being totally aligned with Detergent and cleaning products. There are reasonable grounds to consider that the aspect quoted in the standards as leading to low contamination risk (e.g. pH, water activity, other ingredients) could also be applicable to products under the scope of the EU Ecolabel criteria for detergents. If so, then this could also serve to prove, in an standardised way, that the properties of the end-product are the primary determinant of low contamination likelihood, thus not being so influenced by the manufacturing process and its potential contamination. The JRC would like to hear from participants in this regard, not only about the suitability of the requirements proposed but also on the validity, from their perspective, on the alternative proposed with compliance with ISO 29621:2017.

One participant supported the proposed text.

One participant did not believe that the EU Ecolabel needs to wait for the final text of the revised detergents regulation and then simply align the list of excluded pathogens. Instead, it can and should go further, thus being justified banning additional pathogens (i.e. in line Parliament's position on the proposal for a revised Detergents Regulation).

One participant did not believe that it is valuable to add additional criteria at product level, since there will already be evidence at microorganism level. This might be burdensome for industry. In addition, it considered the alternative ISO method to be suitable and are open to new methods for detection of pathogenic organisms (not restricted to ISO methods) if this provision is in the final text.

Q29 – *Section/Aspect (iv)* -> Should the legal text in point *(iv)* specify the definition of Genetically Modified Microorganisms *(GMMs)*? If so, which could/should be the source of such definition? Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

The feedback received by the JRC highlighted that providing a definition for GMMs would provide legal certainty and should be considered. In this regard, the definition included in Directive 2001/18/EC[78] was proposed. The JRC would like to hear from participants about their view on: a) necessity/advisability of including such definition; b) if so, which could be suitable candidates, inclusive appraising suitability of Directive 2001/18/EC

No explicit/specific feedback was received to this question.

Q30 – *Section/Aspect (v) Hazard identification* -> Do you support the current formulation of the draft criteria text? In addition, would you explicit request consideration of further aspects (e.g. Known virulence factors;

[77] ISO 29621 *Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products.* See https://www.iso.org/standard/68310.html

[78] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration OJ L 106, 17.4.2001, p. 1–39. Available at: https://eur-lex.europa.eu/eli/dir/2001/18/oj

Mobile genetic elements; lifecycle information, Impacts on microbial communities, etc? Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

Based on the feedback received and the research carried out by the JRC, it become evident that accurate information, especially concerning microbial identity and hazards associated to it, was a necessary enabler of fit-for-purpose risk analysis (thus risk management). The guidance quoted from EFSA[79] is comprehensive and state-of-the-art with regards to microorganisms' characterisation. However, further elements could be considered that can contribute to a most accurate identification of the hazards associated with microorganism used as ingredients in detergent and cleaning products. In this sense, the framework for the Risk Analysis of Microorganisms in MCP[80], developed by the main US and Europe industry associations (ACI and AISE, respectively), indicates a series of factors additional factors not specifically quoted in the current formulation of the criteria text, namely (as intrinsic) Know virulence factors, Mobile genetic elements, lifecycle information and (as extrinsic) Impacts on microbial communities. Consequently, the JRC would like to hear from experts on which could/should be the additional elements that would require consideration, inclusive of the implications of determining such (e.g. resources) for the benefit achieved.

Beyond those answers received to Q25 applicable to *(v) hazard/s identification*:

- One participant found referring to the EFSA 2018 guidance document for hazard identification to be appropriate. Regarding the specific sentence: "*free from acquired antibiotic resistance determinants and susceptible to each of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones*" it find the wording a bit confusing. If it is meant that microbes must be susceptible to all the five mentioned antibiotic classes, then this may be impossible to achieve for some relevant bacterial species due to their intrinsic resistance phenotype.

  According to its view, to fulfil the purpose of this requirement (ensure treatment options following un-expected infection) and at the same time to ensure consistency with other EU guidance documents, it suggested to adopt the following text from SANTE/2020/12260 (Guidance on the approval and low-risk criteria linked to antimicrobial resistance, applicable to microorganisms used for plant protection in accordance with Regulation (EC) No 1107/2009): "*Susceptibility shall be demonstrated for compounds of at least two classes of antimicrobials selected among medically important antimicrobials*".

  It suggested making a precision to the sentence: "*shown not to produce relevant antimicrobial substances*" to clarify what is meant by "relevant". Reference to the "WHO List of Medically Important Antimicrobials" may be useful here.

Q31 – *Section/Aspect All -> Do you have any other remarks on any aspect about the draft criteria proposal not already included within previous questions? Stakeholder are invited to critically assess the whole draft criteria proposal* and provide a reasoned comments during the 2nd meeting of the MCP sub-AHWG

On what follows, the comments received are presented according to the draft criteria aspect they refer to:

*(ii) Safety*

One participant wondered about the effectivity of the substitution of the clause on performing a risk assessment by one enlarging the scope of any safety/risk assessment (RA) already required by other legal instruments, as it perceived that risks assessment might not be carried out if not mandatorily required by the revised Detergent Regulation, neither by the EU Ecolabel criteria. The JRC mentioned that the General Product Safety Directive (GPSR) should, in the absence of more specific legislation, ensure that products placed on the market are safe to use, being this shared responsibility (in different aspects) of producers and market surveillance authorities. The same stakeholder acknowledged this fact but indicated that EU Ecolabel could require stricter/more specific requirements than those stated by the GPSR. Along this line, it expressed that expanding the dimensions of any RA was a weak requirement and it believed that the EU Ecolabel should require a risk assessment to be performed

[79] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), G. Rychen, G. Aquilina, G. Azimonti, V. Bampidis, M. de L. Bastos, G. Bories, et al., 'Guidance on the Characterisation of Microorganisms Used as Feed Additives or as Production Organisms', EFSA Journal, Vol. 16, No. 3, March 2018. DOI: 10.2903/j.efsa.2018.5206; https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5206

[80] Framework for the Risk Analysis of Microorganisms in Microbial Cleaning Products. American Cleaning Institute (ACI) and The International Association for Soaps, Detergents and Maintenance Products (AISE). Currently under peer review process for publication

with the specifications suggested, even in the absence of a qualification criteria for the RA outcome to be acceptable or not.

One participant supported requiring a risk assessment, understanding it was reasonable request and inquired which had been the basis for concluding that it was not a suitable possibility (thus as per current proposal removed). It also mentioned that allergenicity was not a part of the QPS assessment and that there was not requirement in such direction within current EU Ecolabel proposal. Another participant indicated that allergenecity criteria should apply to all microorganisms (not solely those holding QPS status) and proposed the EU Ecolabel to require a risk assessment and hazard identification to be conducted, especially for parts that are not part of the QPS assessment as allergenicity. The JRC reasoned that requiring a risk assessment would possibly also imply defining the content of such and criteria for pass/fail, which would potentially exceed resources allocated to the revision process. In terms of allergenicity, the JRC acknowledged this aspects as one to follow-up

One participant wondered what would include a safety assessment with its scope expanded according to draft criteria formulation other than humans and plants. It anticipated that data might be lacking for this very broad scope (whole animal and plant kingdoms), this potentially resulting in considerable uncertainty. It further inquired about the form in which the assessment would need to be provided and if it would be kept confidential. The JRC indicated that the requirement was proposed to align EU Ecolabel principles (environmental focus) to ensure that such compartments, normally underrepresented and subjected to scope decisions of the producer in absence of explicit requirement by legislation, would be considered, even if ultimately not covered in comprehensive detail, for example, due to uncertainty (lack of information).

*(ii) User information* – Spray products

One participant wondered whether MCP products in spray products should be explicitly banned rather than (as per existing criteria) require to inform the user about not using it. The JRC indicated that this provision on spray format products in practical terms impeded the use of products in spray formats. Furthermore, it mentioned that, based on latest publicly available information on the revised Detergent Regulation file, the use of MCP in spray format could be allowed conditioned to testing its respiratory sensitization properties, with JRC willing to consider further actions related to this requirement.

One participant asked for clarification on the rationale behind forbidding MCP in spray format (very relevant application-wise) and stressed that microorganisms have been used for long time (e.g. >30 years probiotics for animal nutrition) , that proper safety checks are in place prior to commercialisation of microorganisms and that EU ecolabel requirements (comparatively with other products) should be proportionate. The JRC acknowledged that ways to account and control for potential risks had been consulted but that it was JRC's intention to allocate the resources and the efforts at the right timing and in alignment with the forthcoming revised Detergent Regulation. It also reasoned that the application of a precautionary principle, possibly grounded on uncertainty (e.g. lack of systematic/harmonised assessment and gathering of information; clear legislative framework), might have led to the current situation. In this regard, another participant argued that it was more related with environmental performance rather than with health aspect the fact of setting strict requirements, as done for purely chemical counterparts.

One participant asked the JRC if any further evidence would be requested at this stage with regards to the use of MCP in spray format and on food-contact surfaces. It also acknowledged the importance of the revision of the Detergent Regulation with regard to the EU Ecolabel revision process and asked about the timings of these processes when further clarity with regard to their alignment will be reached. The JRC confirmed that no further evidences are actively looked for and that internal check for alignment were being performed but no confirmation could be provided on the alignment matter.

One participant informed about studies being carried in MCP in spray format using cell lines and express its willingness to share them with the right parties in order to fulfil its aim: prove that the use of MCP in spray format is safe. It further inquired whether an exemption could be granted within the EU Ecolabel revision. The JRC indicated that evidences are welcomed in the EU commission policy-making process, conditioned to use the right channels and timings.

*(viii) Claims* – Third party verification

One stakeholder flagged that the third-party testing, said by JRC to be in alignment with the revised Detergent Regulation proposal, was removed in the Council position.

*(vi) Shelf life and Microbial count*

One participant asked how the stability of a solid MCP would be tested – in its in-use form (liquid after dissolution) or rather directly as solid (dry product). The JRC replied to this hypothetical case indicating that it would be test the in-use form but stressed that this proposal still was not definitive and would need to be cross-checked with other stakeholders (e.g. Competent Bodies)

Others

One participant found very concerning that the revised Detergent Regulation proposal has as absolute requirement that microorganisms intentionally added to detergents shall belong to the QPS list issued by EFSA, requirement with which the EU Ecolabel would need to comply. It indicated that, apparently, this position is shared by the European Commission, the Parliament and the Council. Contrastingly, according to its understanding, the JRC presented a risk-based approach, which would allow for the use of relevant non-QPS species provided sufficient assessment is performed. It acknowledged the rationales presented in the background document (section 6.2) by the JRC as scientifically well justified and supported what it understood as the conclusion: *"referring exclusively to QPS status as sole way to meet EU ecolabel criteria requirements is not an option and requirements should be stated for any MCP applying for the EU Ecolabel."*. In the opinion of this participant, restricting the use of microbes in detergents to those listed as QPS is not appropriate and may severely impact development within this sector and in some instances ban currently used microbial ingredients from detergent products. It found very important to ensure consistency across the EU Ecolabel and the revised Detergent Regulation (when possible) as articulated in the original proposal for a revised Detergent Regulation where it stated: *"The proposed new rules on microbial cleaning products will be consistent with the voluntary scheme provided by the EU Ecolabel Regulation"*. Finally, it also hoped that the JRC would raise concern on this issue to relevant parties involved in the revision of the Detergent Regulation

One participant disagreed with the view expressed by another participant implying that microorganism must be good because they are part of nature. It stressed that there are many substances occurring natural which still are very hazardous. It also highlighted that the EU Ecolabel ambition is to go beyond legal requirements and identify the most environmentally preferable products, being this of application to any area. Consequently, it considered justified to apply as strict requirements to MCP as per conventional chemicals, which are already subjected to such.

## List questions