Revision of the EU Ecolabel criteria for
DETERGENT AND CLEANING PRODUCTS
01 October 2024

WEBEX SESSION

ETIQUETTE FOR VIRTUAL MEETING PARTICIPANTS

- **Please indicate "NAME OF YOUR ORGANIZATION + YOUR FULL NAME"**
- **MUTE YOUR MIC AND SWITCH OFF you CAMERA (unless you have the floor)**
- **USE THE CHAT only to ask for the FLOOR (write "FLOOR" in the chat), and COMMENT only ORALLY**

Revision of the EU Ecolabel criteria for **DETERGENT AND CLEANING PRODUCTS**

Microbial containing products [MCP] sub-Ad Hoc Working Group (sub-AHWG)

2nd sub-AHWG Meeting; 01st October 2024; Virtual (webex)

Alfonso Jose Lag-Brotons
Maria Grazia La Placa

The Joint Research Centre (JRC)

Directorate B – Fair and Sustainable Economy
Circular Economy and Sustainable Industry

European Commission

Index

1. Introduction – 2nd Sub-AHWG overview.

2. Draft criteria & questions discussion.

3. Next steps + Any other business (AOB).

1. Introduction – 2nd Sub-AHWG overview.

European Commission

1. The EUEL criteria under revision

Commission Decisions establishing the EU Ecolabel criteria for detergents - notified under documents:

- Hand dishwashing detergents (HDD) C(2017) 4227 [OJ L 180, 12.7.2017, p. 1–15]

- Hard surface cleaning products (HSC) C(2017) 4241 [OJ L 180, 12.7.2017, p. 45–62]

- Dishwasher detergents (DD) C(2017) 4240 [OJ L 180, 12.7.2017, p. 31–44]

- Industrial and institutional dishwasher detergents (IIDD) C(2017) 4228 [OJ L 180, 12.7.2017, p. 16–30]

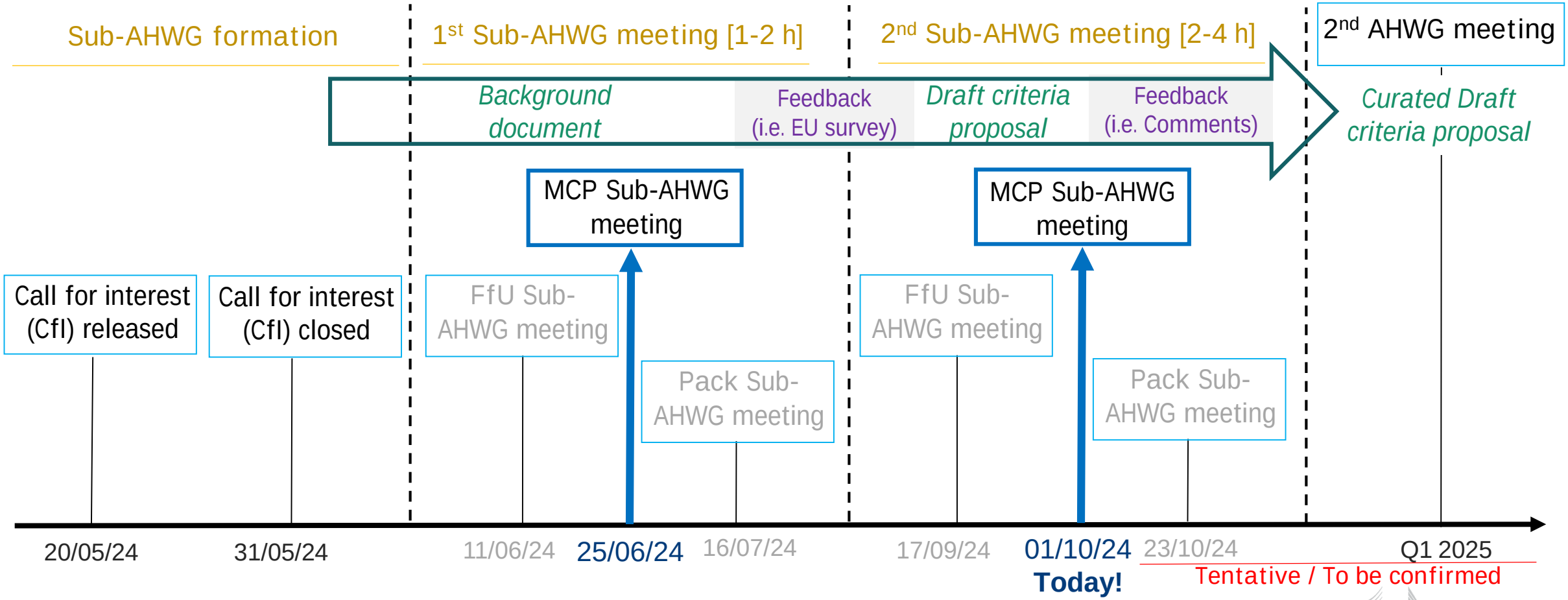
- Laundry detergents (LD) C(2017) 4243 [OJ L 180, 12.7.2017, p. 63–78]

- Industrial and institutional laundry detergents (IILD) C(2017) 4245 [OJ L 180, 12.7.2017, p. 79–96]

Validity expiry date 31/12/26

European Commission

1. Sub-AHWGs “steps” (process) and timeline



European Commission

1. *Excluded and restricted substances* criterion

The aim of this criterion is to exclude or limit toxic or harmful substances, so Ecolabelled product are the least environmental impactful product

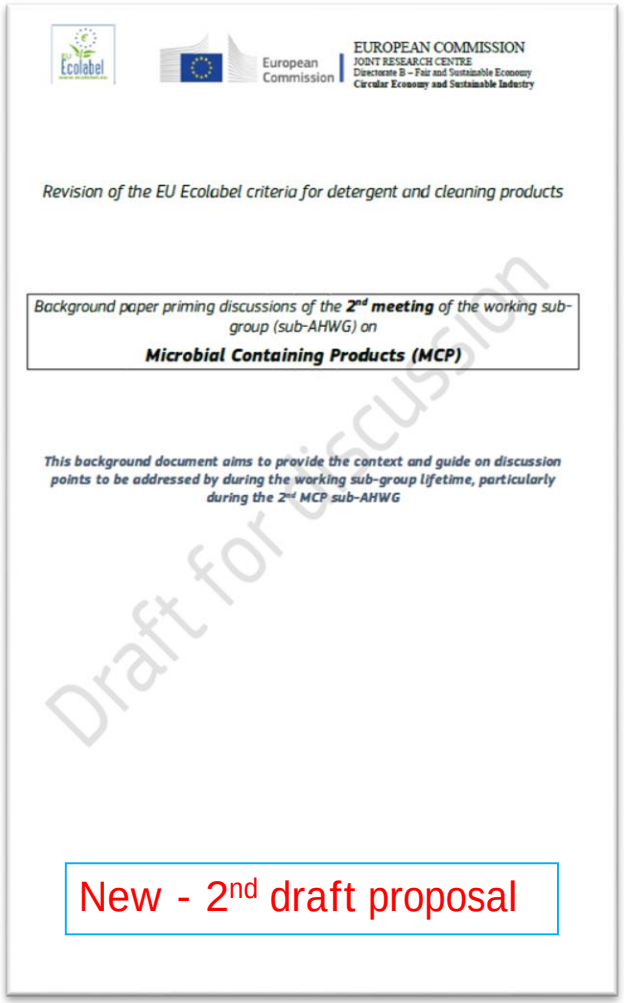
Criterion	Sub-criterion
Excluded and restricted substances	*Specified excluded and restricted substances*
	Hazardous substances
	Substances of very high concern (SVHCs)
	Fragrances
	Preservatives
	Colouring agents
	Enzymes
	Corrosive properties (Only for HDD)
	Micro-organisms (Only for HSC)
Packaging	*Weight/Utility ration (WUR)*

***Aim** – Achieving safe and performing MCP that enable environmental gains via improved/new EU Ecolabel criteria*

[1] Both test for LD in same document -> https://environment.ec.europa.eu/document/download/557d8ab5-4e75-41a4-a901-1548be7f685d_en?filename=fitness%20performance%20LD_V1.7_June%202023.pdf
[2] https://environment.ec.europa.eu/document/download/789ae131-ee3a-4cdd-bfcd-6389aa3d8caa_en?filename=fitness%20performance%20IILD_V1.1_June%202023_0.pdf
[3] https://environment.ec.europa.eu/document/download/ad5b72eb-dab6-4a64-9a37-53d028fec8d7_en?filename=Framework%20Fitness%20Performance%20-%20Dishwasher%20Detergent.pdf
[4] https://www.ikw.org/fileadmin/IKW_Dateien/downloads/Haushaltspflege/2016_EQ_Dishwasher_Detergents_Part_B__Update_2015_aktualisiert.pdf
[5] https://environment.ec.europa.eu/document/download/2a924067-033a-449d-808d-7586475a8cfc_en?filename=fitness_performance_IIDD_20180111.pdf
[6] https://environment.ec.europa.eu/document/download/e0f5e99e-082e-4a70-91ee-70d7d9d00062_en?filename=Framework%20Fitness%20Performance%20-%20HDD.pdf
[7] https://environment.ec.europa.eu/document/download/462d278a-2140-4bd2-bad2-fe0cf4a7b37a_en?filename=Fitness%20Performance%20-%20Hard%20Surface%20Cleaning%20Products_rev1.2.pdf

1. MCP sub-AHWG documents

MCP background discussion



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Revision of the EU Ecolabel criteria for detergent and cleaning products

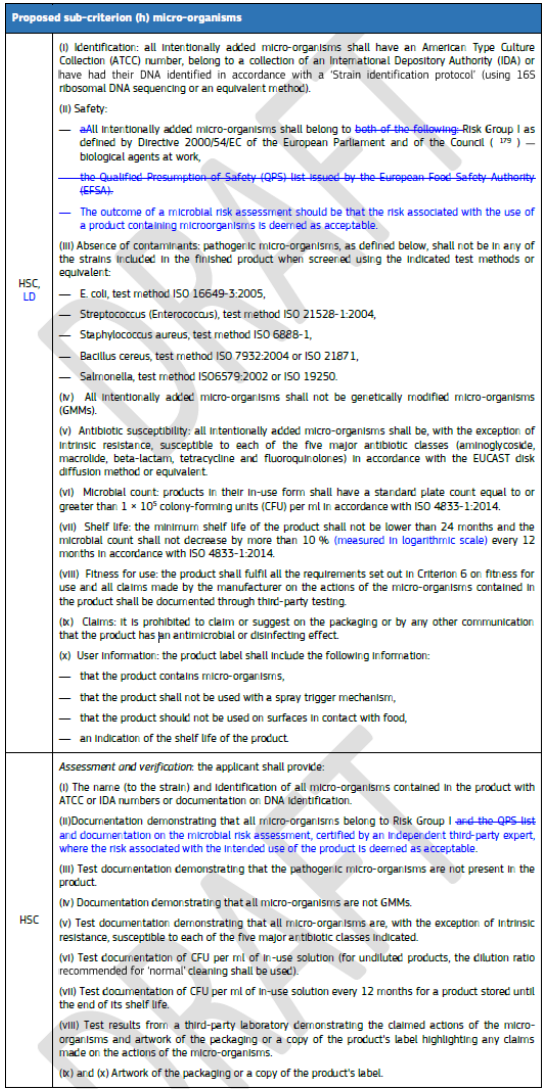
*Background paper priming discussions of the **2nd meeting** of the working sub-group (sub-AHWG) on*

Microbial Containing Products (MCP)

This background document aims to provide the context and guide on discussion points to be addressed by during the working sub-group lifetime, particularly during the 2nd MCP sub-AHWG

Draft for discussion

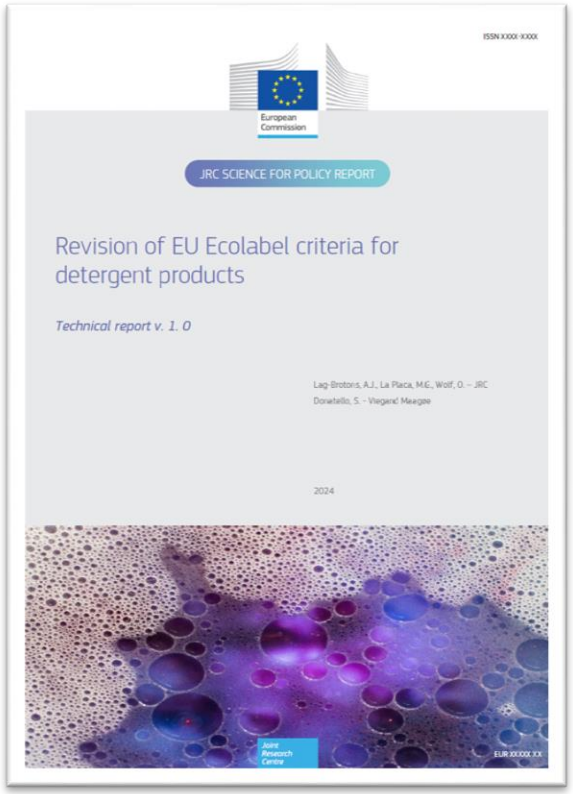
New - 2nd draft proposal



Proposed sub-criterion (h) 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). (ii) Safety: — ~~a~~All intentionally added micro-organisms shall belong to ~~both of the following~~ Risk Group I as defined by Directive 2000/54/EC of the European Parliament and of the Council ([179]) — biological agents at work, — ~~the Qualified Presumption of Safety (QPS) list issued by the European Food Safety Authority (EFSA).~~ — 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. (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: — 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. (iv) All intentionally added micro-organisms shall not be genetically modified micro-organisms (GMMs). (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. (vi) Microbial count: 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. (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. (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. (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. (x) User information: the product label shall include the following information: — that the product contains micro-organisms, — that the product shall not be used with a spray trigger mechanism, — that the product should not be used on surfaces in contact with food, — an indication of the shelf life of the product.
HSC	*Assessment and verification*: the applicant shall provide: (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. (ii)Documentation demonstrating that all micro-organisms belong to Risk Group I ~~and the QPS list~~ 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. (iii) Test documentation demonstrating that the pathogenic micro-organisms are not present in the product. (iv) Documentation demonstrating that all micro-organisms are not GMMs. (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. (vi) Test documentation of CFU per ml of in-use solution (for undiluted products, the dilution ratio recommended for 'normal' cleaning shall be used). (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. (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. (ix) and (x) Artwork of the packaging or a copy of the product's label.

DRAFT

Technical report 1 (TR1)



ISSN XXXX-XXXX

European Commission

JRC SCIENCE FOR POLICY REPORT

Revision of EU Ecolabel criteria for detergent products

Technical report v. 1. 0

Lag-Brotons, A.J., La Placa, M.E., Wolf, O. – JRC
Donatello, S. - Wiegand Meagan

2024

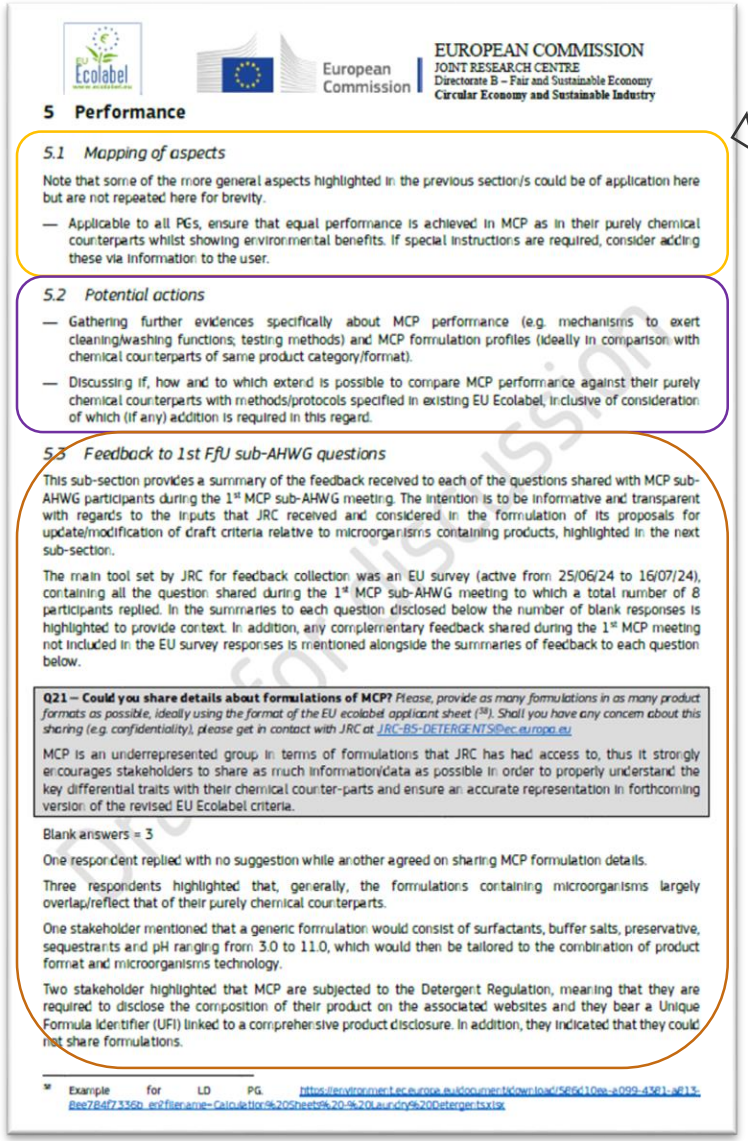
Joint Research Centre

EUR XXXXX XX

1st draft proposal

European Commission

1. MCP background document (1/2)



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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 FfU 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-BS-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/5856110aa-a099-4361-a813-8ee7847f336b_en?filename=Calculation%20Sheets%20-%20Laundry%20Detergents.xlsx

Structure as in MCB background document (v1) in sections:
Criteria – HSC; LD-expansion and Performance

Mapping of aspects

identified by JRC/stakeholders as requiring further assessment (Sources: Focused questionnaire; Written comments to TR1)

Potential actions

which could lead to improved *micro-organisms sub*-criterion versions

Feedback to 1st MCP sub-AHWG meeting

which further informed JRC on general/specific aspects and contributed to shape proposals made.

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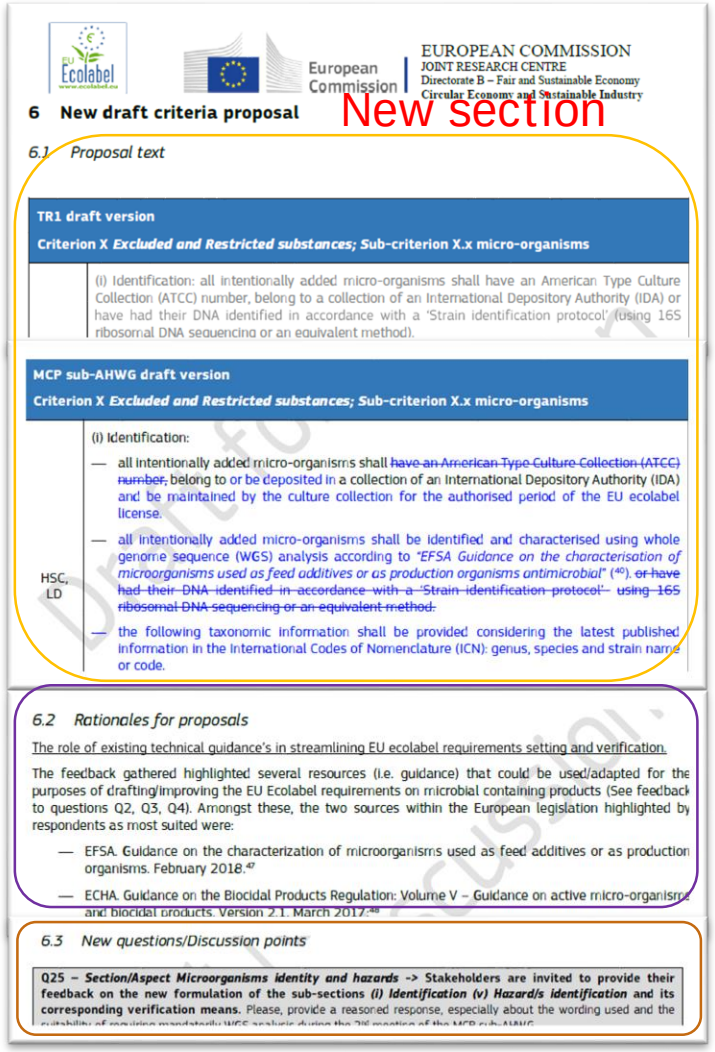
1. MCP background document (2/2)



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6 New draft criteria proposal New section

6.1 Proposal text

TR1 draft version

Criterion X *Excluded and Restricted substances;* Sub-criterion X.x micro-organisms

(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).

MCP sub-AHWG draft version

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 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.

— 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.~~

— 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.

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]

6.3 New questions/Discussion points

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

Proposal text showing the suggested changes.

Rationales for proposals
describing rationales for main changes suggested.

New questions/discussion points
identified that are raised with the aim of contributing to refining further the proposals made.

European Commission

1. MCP sub-AHWG - summary

***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).

2. MCP sub-AHWG – 2nd meeting discussion.

Highlight / Extract of proposals made + Questions to participants

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2. MCP background document denotations

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Microbial Containing Products (MCP)

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6 New draft criteria proposal

6.1 Proposal text

TR1 draft version **Criterion X *Excluded and Restricted substances;* Sub-criterion X.x micro-organisms**	
	(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).

MCP sub-AHWG draft version **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 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. — 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.~~ — 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.

- Contains 1st (in grey font) and new (2nd) draft criteria proposal (MCP sub-AHWG result).

- New draft criteria proposal mark changes from latest version (1st; in TR1). Note that:
  - New text/additions displayed in blue font (Like this)
  - Deletions displayed by strikethrough blue font (~~Like this~~)
  - Even if content remains, might be re-located within the draft criteria text.

2. 1st draft criteria (TR1) - Highlights

Proposed sub-criterion (h) micro-organisms	
	(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).
	(ii) Safety:
	— ~~a~~All intentionally added micro-organisms shall belong to ~~both of the following:~~ Risk Group I as defined by Directive 2000/54/EC of the European Parliament and of the Council ([179]) — biological agents at work,
	— ~~the Qualified Presumption of Safety (QPS) list issued by the European Food Safety Authority (EFSA).~~
2	— 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.
1 HSC, LD	(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:
	— 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.
	(iv) All intentionally added micro-organisms shall not be genetically modified micro-organisms (GMMs).
	(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.
	(vi) Microbial count: 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.
3	(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.
	(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.
	(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.
	(x) User information: the product label shall include the following information:
	— that the product contains micro-organisms,
	— that the product shall not be used with a spray trigger mechanism,
	— that the product should not be used on surfaces in contact with food,
	— an indication of the shelf life of the product.
	Assessment and verification: the applicant shall provide:
	(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.
4	(ii)Documentation demonstrating that all micro-organisms belong to Risk Group I ~~and the QPS list~~ 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.
	(iii) Test documentation demonstrating that the pathogenic micro-organisms are not present in the product.
	(iv) Documentation demonstrating that all micro-organisms are not GMMs.
HSC	(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.
	(vi) Test documentation of CFU per ml of in-use solution (for undiluted products, the dilution ratio recommended for 'normal' cleaning shall be used).
	(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.
	(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.
	(ix) and (x) Artwork of the packaging or a copy of the product's label.

1 - Scope –> LD proposed for inclusion.

2 - QPS list -> requirement substituted by performing a microbial risk assessment (RA)

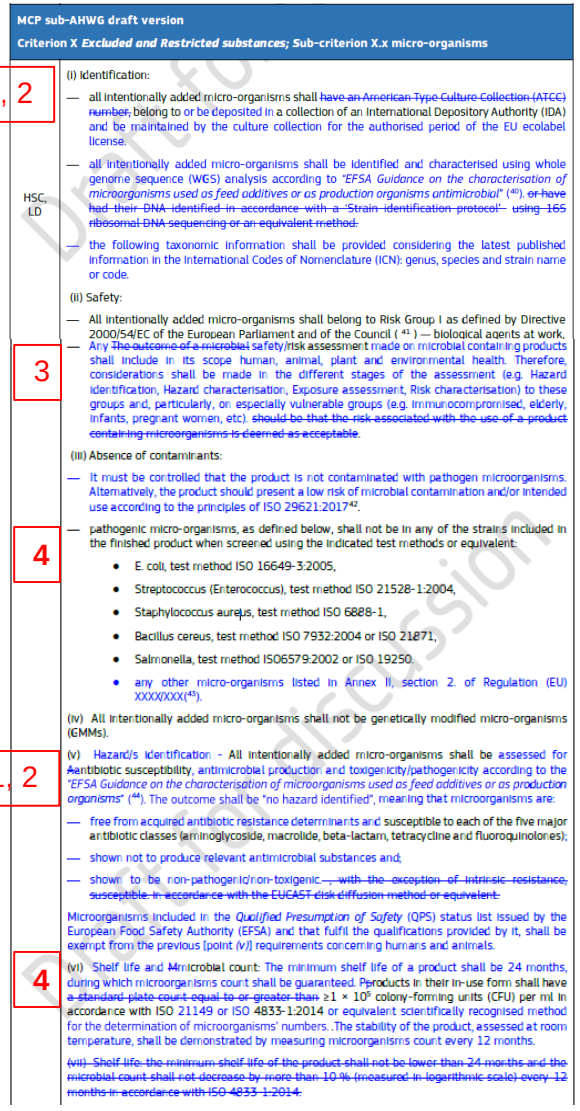
3 - Thresholds -> clarification on units (LOG – scale)

4 - A&V -> Microbial RA documentation + third-party certification

- Question 35 (**Q35**) – do you support requiring a microbial risk assessment as a proof of safety? If not, do you have any proposal to assess microbial containing products safety?
- Question 36 (**Q36**) – do you have any suggestion to complement the microorganisms list in (iii)
- Question 37 (**Q37**) – do you support the threshold set (*equal or greater than* 1×10^5 *CFU*) to prove product performance via microbial counts? If not, could you share reasons?
- Question 38 (**Q38**) – do you support current shelf-life requirements (vi)? Do you consider it represents properly also products falling under LD scope?

4

2. 2nd draft criteria (MCP sub-AHWG) - Highlights



MCP sub-AHWG draft version

Criterion X *Excluded and Restricted substances;* Sub-criterion X.x micro-organisms

1, 2

(i) Identification:

— 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.

HSC, LD

— 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.~~

— 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.

(ii) Safety:

— 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.

3

— 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].

4

— 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).

1, 2

(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;

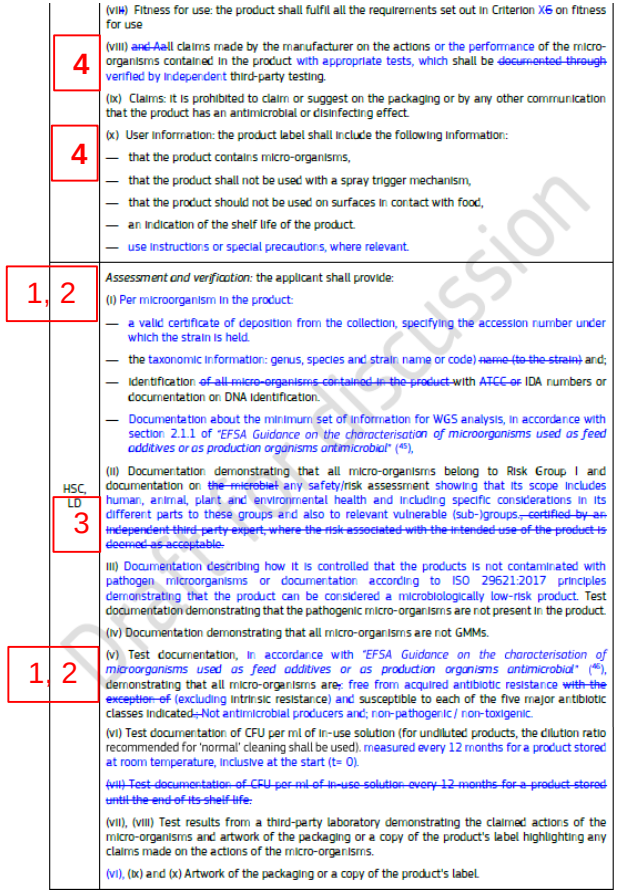
— shown to be non-pathogenic/non-toxigenic ~~, with the exception of intrinsic resistance, susceptible, in accordance with the EUCAST disk diffusion method or equivalent~~.

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.

4

(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~~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 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.~~



(vii~~i~~) Fitness for use: the product shall fulfil all the requirements set out in Criterion X~~6~~ on fitness for use

4

(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.

(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.

4

(x) User information: the product label shall include the following information:

— that the product contains micro-organisms,

— that the product shall not be used with a spray trigger mechanism,

— that the product should not be used on surfaces in contact with food,

— an indication of the shelf life of the product.

— use instructions or special precautions, where relevant.

1, 2

Assessment and verification: the applicant shall provide:

(i) Per microorganism in the product:

— a valid certificate of deposition from the collection, specifying the accession number under which the strain is held.

— the taxonomic information: genus, species and strain name or code) ~~name (to the strain)~~ and;

— identification ~~of all micro-organisms contained in the product~~ with ~~ATCC or~~ IDA numbers or documentation on DNA identification.

— 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]),

HSC, LD

3

(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~~.

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.

(iv) Documentation demonstrating that all micro-organisms are not GMMs.

1, 2

(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.

(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).

~~(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.~~

(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.

(vi), (ix) and (x) Artwork of the packaging or a copy of the product's label.

Proposals derived from evidence streams (i.e. ecolabelling schemes, legislation, scientific/technical literature, stakeholders feedback) are grouped according to following points:

1 - Role of existing guidance in EU Ecolabel requirements setting

2 - Boosting safety via unequivocal microorganisms identification.

3 - Boosting safety via scope expansion to environmental aspects.

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

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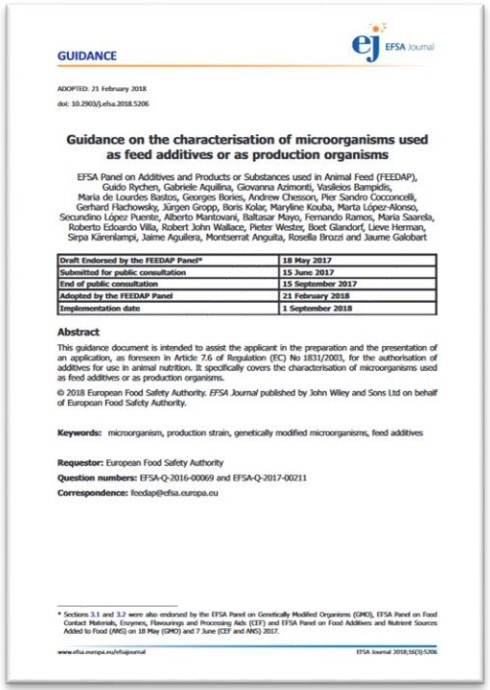
2.1. Proposals & questions

1 Role of existing guidance in EU Ecolabel requirements setting



GUIDANCE

EFSA Journal

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Guidance on the characterisation of microorganisms used as feed additives or as production organisms

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Guido Rychen, Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace, Pieter Wester, Boet Glandorf, Lieve Herman, Sirpa Kärenlampi, Jaime Aguilera, Montserrat Anguita, Rosella Brozzi and Jaume Galobart

Draft Endorsed by the FEEDAP Panel*	18 May 2017
Submitted for public consultation	15 June 2017
End of public consultation	15 September 2017
Adopted by the FEEDAP Panel	21 February 2018
Implementation date	1 September 2018

Abstract

This guidance document is intended to assist the applicant in the preparation and the presentation of an application, as foreseen in Article 7.6 of Regulation (EC) No 1831/2003, for the authorisation of additives for use in animal nutrition. It specifically covers the characterisation of microorganisms used as feed additives or as production organisms.

Keywords: microorganism, production strain, genetically modified microorganisms, feed additives

Requestor: European Food Safety Authority

Question numbers: EFSA-Q-2016-00069 and EFSA-Q-2017-00211

Correspondence: feedap@efsa.europa.eu

* Sections 3.1 and 3.2 were also endorsed by the EFSA Panel on Genetically Modified Organisms (GMO), EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS) on 18 May (GMO) and 7 June (CEF and ANS) 2017.

EFSA guidance preferred against ECHA/BPR' due to "industry standard" & alternative approach to animal testing

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]
- 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]

EFSA scope/"needs" are not EU Ecolabel's BUT some technical elements are transferable/adaptable.

- Market authorization of "regulated products" (under EFSA's scope of work) -> feed additives, food additives, food enzymes, food flavourings, novel foods, and plant protection products
- Qualified presumption of safety (QPS) streamlines safety assessment of "regulated products"
- In QPS list only microorganisms of "regulated products", thus not all possible; neither all relevant for MCP.
- Aspects not covered in QPS but covered in other pieces of EFSA's work:
  - 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.

- 2.1 IDENTIFICATION
- 2.2 ANTIMICROBIAL SUSCEPTIBILITY
- 2.3 ANTIMICROBIAL PRODUCTION
- 2.4 TOXICOGENECITY AND PATHOGENECITY

European Commission

2.2. Proposals & questions

2 Boosting safety via unequivocal microorganisms identification.

MCP sub-AHWG draft version 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 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. — 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.~~ — 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.
	(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.
	Assessment and verification: the applicant shall provide: (i) Per microorganism in the product: — a valid certificate of deposition from the collection, specifying the accession number under which the strain is held. — the taxonomic information: genus, species and strain name or code) ~~name (to the strain)~~ and; — identification ~~of all micro-organisms contained in the product~~ with ~~ATCC or~~ IDA numbers or documentation on DNA identification. — 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]), (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.

Further requirements to culture collection

as being maintained for the life-cycle of the EU Ecolabelled product

Whole Genome Sequencing

boosting micro-organisms characterization as cornerstone of down-stream risk-assessment related aspects

Definition of taxonomic information

Further aspects considered additionally to antibiotic susceptibility (*Antimicrobial production ; Toxigenecity/Pathogenecity)*

which should be proven as no hazards.

Streamlining QPS concept

by allowing certain exemptions if in QPS list/holding QPS qualifications when relevant/applicable.

The minimum set of information includes:

- the DNA extraction method;
- the sequencing strategy and instrumentation used;
- the assembly method applied (e.g. the bioinformatic approach, *de novo* or re-seq strategy);
- the statistical measure of sequence quality (e.g. average Phred score, number of reads, coverage, N50 and K-mer);
- the FASTA file(s) of the WGS;
- the total length of contigs relative to the expected genome size;
- the annotation protocol used;
- for fungi: information on the quality of the annotations obtained from relevant databases (e.g. BUSCO[8]).

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

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**

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

2.3. Proposals & questions

3 Boosting safety via scope expansion to environmental aspects.

(ii) Safety:

— 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,

— 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~~.

HSC, LD	*Assessment and verification:* the applicant shall provide: (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.~~

EU Ecolabel criteria not the right tool to set "risk-based" requirements…

as it exceeds EU Ecolabel revision process competences and resources

… but it can ensure alignment/broadening of any safety assessment made on the product

by ensuring the all environmental compartments and underrepresented groups are considered in such assessments.

2.4. Proposals & questions

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

(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]).

(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~~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 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.~~

(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.

(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.

(x) User information: the product label shall include the following information:

— that the product contains micro-organisms,

— that the product shall not be used with a spray trigger mechanism,

— that the product should not be used on surfaces in contact with food,

— an indication of the shelf life of the product.

— use instructions or special precautions, where relevant.

Ensure process control or low risk
to avoid potential contamination

General alignment with revised Detergent Regulation

Ensure minimum shelf-life via guaranteed microbial numbers & period

These could be modified
but no changes effected at this stage

Assessment and verification: the applicant shall provide:

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.

(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).

~~(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.~~

(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.

(vi), (ix) and (x) Artwork of the packaging or a copy of the product's label.

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

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 requirement? If so, do you consider suitable the alternative stated (compliance with ISO 2961:2017)?** Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

2.5. List of questions

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

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

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

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 requirement? If so, do you consider suitable the alternative stated (compliance with ISO 2961:2017)?** Please, provide a reasoned response during the 2nd meeting of the MCP sub-AHWG

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

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

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

3. Next steps +
Any other business (AOB).

3. Next steps – Feedback & 2nd AHWG meeting

- Feedback to questions (Q25 –Q31), if needed, via email (deadline 15/10/24).

- The 2nd AHWG is scheduled during Q1 2025 (details to be confirmed via email).
-

- The draft criteria proposal for 2nd AHWG will be a curated version of the draft proposal made in this 2nd MCP sub-AHWG meeting.

3. Any other business (AOB)

- Please, share any pending feedback, for example, about:
  - aspects covered (or not covered!) in the draft proposal presented during this meeting.
  - the MCP sub-AHWG and/or the revision process

Thank you for your attention!

Questions?

European Commission