

Aan de staatssecretaris van Openbaar Vervoer en Milieu
Ministerie van Infrastructuur en Waterstaat
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REFERENCE CGM/250311-0301
SUBJECT Reactie op de EFSA “draft guidance on the characterisation and risk assessment of microorganisms used in the food chain

Geachte heer Jansen,

Op 2 december 2024 heeft de European Food Safety Authority (EFSA) de ‘Draft guidance on the characterisation and risk assessment of microorganisms used in the food chain’ gepubliceerd en opengesteld voor commentaar.¹ De COGEM kan zich in grote lijnen vinden in het conceptrichtsnoer, maar adviseert een aantal verbeterpunten.

1. Introduction

The EFSA has recently launched an open consultation on a draft guidance document concerning the characterisation and risk assessment of microorganisms used in the food chain. It is meant to provide guidance to assist in the preparation of applications for products containing, made from, or produced with microorganisms, whether genetically modified (GM) or not, that require a risk assessment before being placed on the EU market for use in the food chain.

The guidance aims to ensure alignment in the characterisation of microorganisms and harmonisation of the requirements for applications supporting the assessment of microorganisms in the food chain. Furthermore, it seeks to address current gaps in existing guidance documents and establish requirements for certain taxonomic groups of microorganisms/products, as well as for aspects of the risk assessment where guidance is currently lacking or very limited. It sets forth the requirements to: taxonomically identify microorganisms, investigate the production of potentially harmful substances, establish the presence of viable cells in the product, and conduct environmental risk assessments.

1. European Food Safety Authority (EFSA, 21 November 2024). Draft guidance for public consultation: on the characterisation and risk assessment of microorganisms used in the food chain. 4



COGEM welcomes EFSA's initiative and generally supports the guidance. However, COGEM has a few suggestions for improvement concerning the document, starting with two comments on the information in the guidance, followed by a few remarks on the wording of the document. Comments are listed according to their order in the draft guidance text.

In the Netherlands, a food/feed risk assessment is carried out by other organizations, and therefore, COGEM confines its comments to the sections concerning environmental risk assessment (ERA).

2. General comments

The text states in paragraph 3 on line 194 that whole genome sequencing is required for the characterization of many of the microorganisms in question. COGEM agrees with this requirement. However, in the draft guidance this is not required for the taxonomic identification of protists and microalgae, for which the analysis can be done by combining morphological analysis and sequencing of genetic markers (paragraph 3.1, line 233). COGEM suggests requiring whole genome sequencing for all microorganisms under assessment.

In paragraph 5.1, it is mentioned that if microorganisms are already present in the receiving environment and carry no new harmful sequences, their introduction is deemed unlikely to disturb this environment (line 688). For any organisms that fall under the Qualified Presumption of Safety (QPS) criteria, it is also assumed that they pose no danger to the receiving environment (lines 769, 885, 950). In both cases, no mention is made of the effect of the quantity of microorganisms introduced into the environment. There are documented cases that introduction of soil-borne microorganisms introduced into the environment leaves legacy effects, which may have positive or negative effects for the resident community and the ecosystem.^{2,3} With higher density of inoculum this effect may be stronger.⁴ As such it is recommended that the EFSA takes this into consideration.

3. Specific comments

The COGEM advises to change the wording “humans, animals and/or plants” on line 454 in paragraph 3.4.2 to “humans, animals or the environment”. This is the wording that is used on Lines 395 in paragraph 3.4, making the text more consistent, and furthermore it is more encompassing.

On line 725-727 in paragraph 5.3, it is mentioned that when there is no comparator available for the used strain, general information on the taxonomic unit to which the microorganism belongs should be supplied. It is advised to further define the level of taxonomic unit deemed sufficient.

2. Darine T & Ridha M (2013). Microbial inoculants and their impact on soil microbial communities: a review. *BioMed Res. Int.* 863240; 11

3. Liu X *et al.* (2022). The legacy of microbial inoculants in agroecosystems and potential for tackling climate change challenges. *iScience.* 2 25: 103821

4. Han X *et al.* (2022). Soil inoculum identity and rate jointly steer microbiomes and plant communities in the field. *ISME Communications.* 2: 59

4. Conclusions

In conclusion, COGEM values EFSA's efforts to develop a guideline for the characterization and risk assessment of microorganisms in the food chain. Key points of concern include the recommendation to mandate whole genome sequencing for all microorganisms and the need to consider the effects of the quantity of introduced microorganisms on the environment. Additionally, there is a call for clarification and consistency in the terminology within the document.

Yours sincerely,



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c.c.

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