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Guidance document for risk assessments of microorganisms used as “other substances” in food supplements and other food

Report of the Panel for Biological Hazards of the Norwegian Scientific Committee for Food Safety

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Assessed and approved

The report has been assessed and approved by the Panel for Biological Hazards of the Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM).

Members of the Panel for Biological Hazards of the Norwegian Scientific Committee for Food Safety are: Yngvild Wasteson (chair), Karl Eckner, Georg Kapperud, Jørgen Lassen, Judith Narvhus, Truls Nesbakken, Lucy Robertson, Jan Thomas Rosnes, Olaug Taran Skjerdal, Eystein Skjerve, Line Vold and Siamak Yazdankhah.

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Competence of VKM experts

Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Glossary

"**Other substances**" are described in the food supplement directive 2002/46/EC as substances other than vitamins or minerals that have a nutritional and/or physiological effect (The European Parliament and the Council of the European Union, 2006).

"**Negative health effect**" and "**adverse health effect**" are broad terms and WHO has established the following definition for "adverse effect": a change in morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences (WHO, 1994).

An **adverse event** is considered serious if it results in death, is life-threatening, requires or prolongs hospitalisation, is a congenital anomaly or birth defect, is a persistent or significant disability/incapacity, or is another serious or important medical event.

Probiotics[1]

In 2001, the Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organisation (WHO) defined probiotics as: Live microorganisms, which when administered in adequate amounts confer a health benefit on the host (FAO 2002).

Currently, there are no approved health claims for probiotics. Applications for health claims on probiotics have been submitted for evaluation to EFSA and no application has received a positive opinion. For this reason, the term 'probiotic', when used on a food label, is

[1] The International Scientific Association for Probiotics and Prebiotics, ISAPP, proposed that when combined with the specifications outlined by the FAO/WHO Working Group for the Evaluation of Probiotics in Food (2002), the key aspects of this definition should be more precise and in addition include the following aspects:

- A probiotic must be alive when administered,

- A probiotic must have undergone controlled evaluation to document health benefits in the

target host,

- A probiotic must be a taxonomically defined microbe or combination of microbes (genus,

species and strain level),

- A probiotic must be safe for its intended use.

considered to be a health claim (http://ec.europa.eu/nuhclaims/) and should not be used but be replaced by “microorganism”.

No claims on probiotics are listed on the EU register as authorised for use. The probiotic claims that have been fully evaluated and rejected are listed as non-authorised on the EU register.

Terms of reference as provided by the Norwegian Food Safety Authority

The Norwegian Food Safety Authority (NFSA) requested the Norwegian Scientific Committee for Food Safety (VKM) to prepare a guidance document outlining the methodology to be used for the safety assessments of microorganisms used as “other substances”.

From the terms of reference for the risk assessments of other substances:

- The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has, at the request of the Norwegian Food Safety Authority (Mattilsynet, NFSA), assessed the risk of "other substances" in food supplements and other food sold in Norway.
- Safety assessments of microorganisms added to food supplements and other foods should be carried out for the general population including vulnerable groups.

Limitations applied to all risk assessments of microorganisms used as other substances:

- Documentation of any potential beneficial effects from these substances is not evaluated.
- The risk assessments regard specific substances/microorganisms, not specific food products.

General principles for the risk assessments

In the present document, the general principles to be used for the safety assessments of “other substances” are presented. The risk assessments have been prepared in accordance with the template shown in Appendix 1.

Literature search

As the recommendation for the Qualified Presumption of Safety (QPS) status (EFSA, 2007) is based on extensive literature search, the literature search for this assessment is limited to the reports and articles published in 2015-2016.

A general literature search was set up in Appendix 2, and appropriate modifications are made for each search. The articles are examined against the relevance to the terms of reference. The reference lists in EFSAs reports and selected citations were scrutinized to

identify additional articles or reports that might have been overlooked by the PubMed searches. Articles are also retrieved by manual search.

Hazard identification and characterisation

Hazard identification is given in ToR. As QPS is based on extensive body of knowledge, their hazard characterisation is accepted at genus level.

Exposure

As this assessment is concerned with general safety of the “other substances” (microorganisms) and is not related to a specific product or dose, the exposure assessment is given in general terms and related to the exposure from food in general.

Risk characterisation

Qualified Presumption of Safety (QPS) (EFSA, 2007) proposes a safety assessment of a defined taxonomic group (e.g. genus or group of related species) based on four pillars (establishing identity, body of knowledge, possible pathogenicity, and end use). If the taxonomic group did not raise safety concerns or, if safety concerns existed but could be defined and excluded (the qualification), the grouping could be granted QPS status. Thereafter, any strain of microorganism the identity of which could be unambiguously established and assigned to a QPS group would not require further safety assessment other than satisfying any qualifications specified. Microorganisms not considered suitable for QPS would remain subject to a full safety assessment (EFSA, 2007).

As the recommendation for the QPS status is based on broad criteria, extensive literature search and transparent expert judgement, VKM has decided to accept the safety status as given by EFSA in the most up-to-date list (EFSA, 2015) including possible qualification criteria. Provided that the data retrieved from the literature search do not identify new information pertinent to safety, the safety status is upheld.

Antibiotic resistance properties of bacteria vary between strains, even among a group of bacteria granted QPS or Generally Recognized as Safe (GRAS) status. As the QPS assessment of antimicrobial resistance is on the genus level, VKM will additionally assess this at strain level and is concerned with transferable resistance properties.

The probability of the adverse effects is given for the general population and vulnerable groups. An occasional association of microorganism with extremely rare individual cases of infections (endocarditis, septicaemia, necrotising pneumonitis, liver abscess etc.) should not be regarded as an indication of human pathogenicity taking into account the extent of exposure to these microorganisms.

Time limitations in the conclusions

Based on the available scientific data, conclusions are given for limited time periods.

Appendix

Appendix 1

The risk assessment template.

- Content
- Summary (in English)
- Summary (in Norwegian)
- Abbreviations and/or glossary
- Background as provided by the Norwegian Food Safety Authority
- Terms of reference as provided by the Norwegian Food Safety Authority
- Introduction
- Literature
- Hazard identification and characterisation
- Exposure assessment
- Probability of adverse effects
- Uncertainties
- Conclusions (with answers to the terms of reference)
- Data gaps
- References

Appendix 2

Literature search

1. Name of the microorganism and strain
2. Limit to years after the last EFSAs QPS list (except for exposure and microorganisms not included in QPS list)
3. Exclude conference abstracts, letters and editorals
4. The language must be English, Norwegian, Swedish or Danish

References

EFSA. (2007) Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal 587: 1-16.

EFSA. (2015) BIOHAZ Panel (EFSA Panel on Biological Hazards). Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 3: Suitability of taxonomic units notified to EFSA until September 2015., EFSA Journal 2015. pp. 25 pp.