STATEMENT

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Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 18: Suitability of taxonomic units notified to EFSA until March 2023

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Abstract

The qualified presumption of safety (QPS) approach was developed to provide a regularly updated generic pre-evaluation of the safety of microorganisms, intended for use in the food or feed chains, to support the work of EFSA's Scientific Panels. The QPS approach is based on an assessment of published data for each agent, with respect to its taxonomic identity, the body of relevant knowledge and safety concerns. Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at the species/strain or product level and reflected by 'qualifications'. In the period covered by this Statement, no new information was found that would change the status of previously recommended QPS TUs. Of 38 microorganisms notified to EFSA between October 2022 and March 2023 (inclusive) (28 as feed additives, 5 as food enzymes, food additives and flavourings, 5 as novel foods), 34 were not evaluated because: 8 were filamentous fungi, 4 were *Enterococcus faecium* and 2 were *Escherichia coli* (taxonomic units that are excluded from the QPS evaluation) and 20 were taxonomic units (TUs) that already have a QPS status. Three of the other four TUs notified within this period were evaluated for the first time for a possible QPS status: *Anaerobutyricum soehngenii*, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*) and *Nannochloropsis oculata*. Microorganism strain DSM 11798 has also been notified in 2015 and as its taxonomic unit is notified as a strain not a species, it is not suitable for the QPS approach. *A. soehngenii* and *N. oculata* are not recommended for the QPS status due to a limited body of knowledge of its use in the food and feed chains. *S. stutzeri* is not recommended for inclusion in the QPS list based on safety concerns and limited information about the exposure of animals and humans through the food and feed chains.

Keywords: *QPS*, *Anaerobutyricum soehngenii*, Microorganism strain *DSM 11798*, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*), *Nannochloropsis oculata*

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Summary

The European Food Safety Authority (EFSA) asked the Scientific Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the QPS list.

The QPS list contains microorganisms, intentionally added to food and feed, which have received QPS status. The request included three specific tasks as mentioned in the Terms of Reference (ToRs). The QPS process was developed to provide a harmonised generic pre-evaluation procedure to support safety risk assessments of microorganisms performed by EFSA Scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms. Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at strain or product level, reflected as 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. A generic qualification for all QPS bacterial TUs applies in relation to the absence of acquired genes conferring resistance to clinically relevant antimicrobials (EFSA, 2008).

The list of microorganisms is maintained and re-evaluated approximately every 6 months in a Panel Statement. The Panel Statement also includes the evaluation of microorganisms newly notified to EFSA in the context of technical dossiers for safety assessment, within the previous 6-month period.

The first ToR requires ongoing updates of the list of microorganisms notified to EFSA, in the context of a technical dossier for safety assessment. The overall list 'Microbiological agents as notified to EFSA' (https://doi.org/10.5281/zenodo.3607183) was updated with the notifications received between October 2022 and March 2023 (inclusive). Within this period, 38 notifications were received by EFSA, of which 28 were proposed for evaluation in feed, 5 for use as food enzymes, food additives and flavourings and 5 as novel foods. The new notifications received between October 2022 and March 2023 are included in the current Statement (see Appendix F).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications. For this revision, articles published from July to December 2022 were assessed. The articles were retrieved and assessed through an extensive literature search (ELS) protocol available in Appendix B (see https://doi.org/10.5281/zenodo.3607188) and the search strategies in Appendix C (see https://doi.org/10.5281/zenodo.3607192). No new information was found that would affect the QPS status or the qualifications for the TUs on the QPS list.

The third ToR requires a (re)assessment of new TUs notified to EFSA, for their suitability for inclusion in the updated QPS list at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566, Appendix E – the link opens at the latest update of the QPS list, and also includes the links to the versions associated to each Panel Statement).

In the current period, 38 notifications were received, 34 of these were not evaluated for the following reasons: 14 notifications were related to microorganisms that are excluded from QPS evaluation (8 were notifications of filamentous fungi, 4 of *Enterococcus faecium*, 2 of *Escherichia coli*) and 20 were related to TUs that already have QPS status and did not require further evaluation.

Three of the remaining four notifications, corresponding to three TUs *Anaerobutyricum soehngenii*, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*) and *Nannochloropsis oculata* were evaluated for the first time for a possible QPS status. The other, Microorganism strain DSM 11798, has also been notified in 2015.

The following conclusions were drawn:

- *A. soehngenii* is not recommended for the QPS status due to a limited body of knowledge of its use in the food and feed chains.
- *S. stutzeri* is not recommended for inclusion in the QPS list based on safety concerns and limited information about the exposure of animals and humans through the food and feed chains.
- *N. oculata* is not recommended for the QPS status due to a limited body of knowledge of its use in the food and feed chains.
- As the taxonomic unit of Microorganism strain DSM 11798 is notified as a strain, not as a species, it is not suitable for the QPS approach.

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1. Introduction

The qualified presumption of safety (QPS) approach was developed by the EFSA Scientific Committee to provide a generic concept for risk assessment within the European Food Safety Authority (EFSA) for microorganisms intentionally introduced into the food and feed chains, in support of the respective Scientific Panels and Units in the context of market authorisations for their use in food and feed and requiring a safety assessment by EFSA (EFSA, 2007; Herman et al., 2019). The list, first established in 2007, has been continuously revised and updated. A Panel Statement is published approximately every 6 months. These Panel Statements include the results of the assessment of relevant new papers related to the taxonomic units (TUs) with QPS status. They also contain the assessment of newly submitted TUs to the EFSA Units on Feed and Contaminants (FEEDCO), Food Ingredients and Packaging (FIP), Nutrition and Food Innovation (NIF), Pesticides Peer Review (PREV). After 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period.

1.1. Background and Terms of Reference as provided by EFSA

A wide variety of microorganisms are intentionally added at different stages of the food and feed chains. In the context of applications for market authorisation, EFSA is requested to assess the safety of microorganisms when used either directly or as sources of food and feed additives, food enzymes and plant protection products.

EFSA's work on QPS activities began in 2004 when the Scientific Committee issued a scientific opinion in continuation of the 2003 working document 'On a generic approach to the safety assessment of microorganisms used in feed/food and feed/food production' prepared by a working group consisting of members of the former Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Committee on Plants of the European Commission.[1] The document, made available for public consultation, proposed the introduction of the concept of Qualified Presumption of Safety (QPS), to be applied to selected groups of microorganisms. Microorganisms not considered suitable for QPS status would remain subject to a full safety assessment. EFSA management asked its Scientific Committee to consider whether the QPS approach could be applied to the safety assessment of microorganisms across the various EFSA Scientific Panels. In doing so, the Committee was required to take into account the response of stakeholders to the QPS approach. In its 2005 opinion (EFSA, 2005), the Scientific Committee concluded that the QPS approach could provide a generic assessment system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed chains. Its introduction was intended to improve transparency and ensure consistency in the approach used across the EFSA Panels. Applications involving a taxonomic unit belonging to a species that falls within a QPS group do not require a full safety assessment.

Several TUs (usually species for bacteria and yeasts; families for viruses) have been included in the QPS list, either following notifications to EFSA, or proposals made initially by stakeholders during a public consultation in 2005, even if they were not yet notified to EFSA (EFSA, 2005). The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and, in 2007, published a list of microorganisms recommended for the QPS list.

In their 2007 opinion (EFSA, 2007), the Scientific Committee recommended that a QPS approach should provide a generic concept to prioritise and to harmonise safety risk assessment of microorganisms intentionally introduced into the food chains, in support of the respective Scientific Panels and EFSA Units in the frame of the market authorisations for their use in the food and feed chains. The same Committee recognised that there would have to be continuing provision for reviewing and modifying the QPS list and, in line with this recommendation, the EFSA Panel on Biological Hazards (BIOHAZ) took the prime responsibility for this and started reviewing annually the existing QPS list. In 2008, the first annual QPS update was published (EFSA, 2008).

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure; the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) was no longer carried out annually but over a 3-year period. From 2017, the search and revision of the possible safety concerns linked to those taxonomic units began instead to be carried out every 6 months through extensive literature searches (ELS). The update of the 2013 QPS list (EFSA BIOHAZ Panel, 2013) was done in 2016 (EFSA BIOHAZ Panel, 2017). From

[1] https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_out178_en.pdf

2016 on, the QPS list (https://doi.org/10.5281/zenodo.1146566) and the list of notifications to EFSA (https://doi.org/10.5281/zenodo.3607183) are constantly updated, independent of the QPS opinion, and are available at the Knowledge Junction in Zenodo. The most recent QPS opinion (EFSA BIOHAZ Panel, 2023) summarises the main results of the 3-year ELS on the QPS TUs, together with an update of the process for granting QPS status. In the meantime, every 6 months a Panel Statement, compiling the assessments for a QPS status of the microorganisms notified to EFSA requested by the Feed and Contaminants (FEEDCO) Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition and Food Innovation (NIF) Unit, the Pesticides Peer Review (PREV) Unit[2], as well as the summary of each 6-month ELS exercise, has been produced and published. Each QPS Panel Statement contains the evaluations of the new notifications for microorganisms submitted for possible QPS status. It also contains the result of a standardised ELS performed every 6 months regarding possible new safety concerns related to the TUs already included in the QPS list. The data identified are used to inform decisions on whether any TU may or may not remain on the QPS list, and whether any qualifications need to be revised.

Establishing a QPS status is based on four pillars: [1] the taxonomic unit (TU) for which QPS is sought ('taxonomic identification'); [2] whether sufficient relevant information is available about the proposed TU to conclude on human/animal exposure via food/ feed ('body of knowledge'); [3] whether the TU proposed contains known 'safety concerns' and, finally, [4] the intended end use ('intended use'). If a hazard related to a TU is identified, which can be tested at the strain or product level, a 'qualification' to exclude that hazard may be established and added. The subject of these qualifications for the microbial strain under investigation is evaluated by the EFSA Unit to which the application dossier has been allocated. The absence of acquired genes coding for resistance to antimicrobials relevant for humans and animals is a generic qualification for all bacterial TUs; the absence of antimycotic resistance should be proven if the pertinent yeasts are to be used as viable organisms in the food or feed chains. The qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied to food and feed products based on microbial biomass (EFSA BIOHAZ Panel, 2020a).

Because the QPS evaluation is, after its initial creation, only triggered through an application dossier notified to EFSA, the QPS list is not exhaustive.

In summary, the QPS evaluation provides a generic safety pre-assessment approach for use within EFSA that covers safety concerns for humans, animals and the environment. In the QPS concept, a safety assessment of a defined TU is performed independently of the legal framework under which the application is made in the course of an authorisation process. Although general human safety is part of the evaluation, specific issues relating to type and level of exposure of users handling the product (e.g. dermal contact, inhalation, ingestion) are not addressed. In the case of Genetically Modified Microorganisms (GMMs) for which the species of the recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to genetically modified production strains (EFSA BIOHAZ Panel, 2018). The assessment of potential allergenic microbial residual components is beyond the QPS remit; however, it is reported if science-based evidence is available for a microbial species. These aspects are separately assessed, where applicable, by the EFSA Panel responsible for assessing the application.

The lowest TU for which the QPS status is granted is the species level for bacteria, yeasts and protists/algae, and family for viruses.

Filamentous fungi, bacteriophages, Streptomycetes, Oomycetes, *Enterococcus faecium*, *Escherichia coli* and recently *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020a,b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits by some strains of the taxonomic unit, therefore requiring a specific assessment for each strain for which an application is made.

The **Terms of Reference** are as follows:

ToR 1: Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units such as Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF),[2] for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products (PPPs) and Genetically Modified Microorganisms (GMO) for safety assessment.

ToR 2: Review taxonomic units previously recommended for the QPS list and their qualifications when new information has become available. The latter is based on an update of the ELS aiming to

[2] Units as in December 2022.

verify whether any new safety concern has arisen that could require the removal of a taxonomic unit from the list, and to verify if the qualifications still effectively exclude safety concerns.

ToR 3: (Re) assess the suitability of new taxonomic units notified to EFSA for their inclusion in the QPS list. These microorganisms are notified to EFSA in the context of technical dossiers for safety assessment and trigger a QPS assessment.[3]

2. Data and methodologies

2.1. Data

In reply to ToR 3, (re)assessment of the suitability of TUs notified within the time period covered by this Statement (between October 2022 and March 2023 (inclusive)) was carried out. The literature review considered the information on taxonomy, the body of knowledge, the potential safety concerns related to human and animal health and to the environment (EFSA BIOHAZ Panel, 2023) for each TU. The environmental risk assessment of PPPs is not included in the QPS assessment but is carried out by the Pesticide Peer Review (PPR) Unit, based on the risk assessment in the application.

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. In the case of *Nannochloropsis oculata*, an ELS-based approach was applied to ensure the completeness of the information retrieved from the literature in terms of body of knowledge and possible safety concerns. The ELS followed the same methodology as used for monitoring new safety concerns related to species with QPS status but also included information on the body of knowledge. More details on the search strategy, search keys and approach for each of the assessments are described in Appendix A. Only the literature that is considered, based on expert judgement, to be relevant for the QPS assessment is reflected in the Statement.

Only valid TUs covered by the relevant international committees on the nomenclature for microorganisms are considered for the QPS assessment (EFSA BIOHAZ Panel, 2023).

2.2. Methodologies

2.2.1. Evaluation of a QPS recommendation for taxonomic units notified to EFSA

In response to ToR 1, the EFSA Units were asked to update the list of microorganisms being notified to EFSA. A total of 38 notifications were received between October 2022 and March 2023 (inclusive), of which 28 were for evaluation for use in feed, 5 for use as food enzymes, food additives and flavourings, 5 as novel foods and none as plant protection products (Table 1).

In response to ToR 3, 4 of the 38 notifications, corresponding to four TU, were evaluated for a possible QPS status: *Anaerobutyricum soehngenii*, Microorganism strain DSM 11798, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*) and *Nannochloropsis oculata*. Three of these four were evaluated for the first time and Microorganism strain DSM 11798 has also been notified in 2015. Microorganism strain DSM 11798 could not be further assessed because it was not identified to the species level. The remaining 34 notifications were excluded from QPS evaluation for the following reasons: 14 notifications were related to microorganisms that are generally excluded from QPS evaluation (eight were notifications of filamentous fungi, four of *Enterococcus faecium*, two of *Escherichia coli*) and 20 were related to TUs that already had QPS status and did not require further evaluation in this mandate.

[3] Previous text 'These microorganisms are notified to EFSA and requested by the Feed Unit, the FIP Unit, the Nutrition Unit or by the Pesticides Unit'.

Table 1: Notifications received by EFSA, per risk assessment area and by micro biological group, from October 2022 to March 2023

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[(b)]	Total
Microbiological group	Already QPS	Excluded in QPS[(a)]		
Feed additives	**17**	**10**	**1**	**28**
Bacteria	14	6	1	21
Filamentous fungi		4		4
Yeasts	3			3
Novel foods	**1**	**2**	**2**	**5**
Bacteria			1	1
Filamentous fungi		2		2
Protists/Algae	1		1	2
Yeasts				
Plant protection products	**0**	**0**	**0**	**0**
Bacteria				
Filamentous fungi				
Viruses				
Food enzymes, food additives and flavourings	**2**	**2**	**1**	**5**
Bacteria	1		1	2
Filamentous fungi		2		2
Yeasts	1			1
Genetically modified organism	**0**	**0**	**0**	**0**
Bacteria				
Total	**20**	**14**	**4**	**38**

QPS: qualified presumption of safety.
(a): The number includes eight notifications of filamentous fungi, four of *Enterococcus faecium* (bacterium), two of *Escherichia coli* (bacterium), all excluded from QPS evaluation.
(b): Four notifications corresponding to three TU, *Anaerobutyricum soehngenii*, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*), *Nannochloropsis oculata* being evaluated for the first time and to Microorganism strain DSM 11798 already notified in 2015.

2.2.2. Monitoring of new safety concerns related to species with QPS status

In reply to ToR 2, concerning the revision of the TUs previously recommended for the QPS list and their qualifications, an extensive literature search (ELS) was conducted as described in Appendix B – ELS protocol, see https://doi.org/10.5281/zenodo.3607188, and in Appendix C Search strategies – see https://doi.org/10.5281/zenodo.3607192, respectively.

The screening of the articles identified was done at title and abstract level in parallel by two reviewers. In case of conflicts, these were solved before the references proceeded to the article evaluation step. This information will be used as a training set to feed a Classifier in DistillerSR with view to potentially using it in the next ELS cycle (i.e. run in parallel with a human reviewer).

The aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, animals or the environment, caused by QPS organisms since the previous QPS review (i.e. publications from July to December 2022).

For case reports of human infections or intoxications, important additional information includes whether any negative impacts are confined to persons with conditions favouring opportunistic infections, for example immunosuppression, and whether transmission occurred through food or other routes (e.g. medical devices), when described. Studies indicating the presence of virulence factors (e.g. toxins and enzymes that may contribute to the pathogenicity of the microorganism) in the TU are also reported as relevant when identifying potential safety concerns.

Several of the QPS–TUs are sporadically reported as causing infections in individuals with recognised predisposing conditions for the acquisition of opportunistic infections, e.g. cardiovascular

conditions associated with endocarditis, people in the lower or upper age spectrum or with other conditions which can lead to impairment of the immune system, such as patients subjected to transplants, undergoing cancer therapy, suffering from physical trauma or tissue damage or HIV patients. Moreover, gastrointestinal tract-related conditions with, for example, mucosal impairment and/or proton pump inhibitors can also be predisposing factors for infection. Previous use of the microorganisms being assessed as food supplements for humans was reported in many of these cases. Nevertheless, the QPS assessment takes into consideration these reports, extracting relevant information whenever justified.

After removal of duplicates, 6,791 records were submitted to the title and abstract screening step, which led to the exclusion of 6,730 of these. The remaining 61 records were found eligible for article evaluation step (full text), 30 were considered to report a potential safety concern and were further analysed.

The flow of records from their identification by the different search strategies (as reported in Appendix C) to their consideration as potentially relevant papers for QPS is shown in Table 2.

Table 2: Flow of records by search strategy step

Species	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
	Number of articles retrieved		
Bacteria (total)	**4,496**	**17**	**13**
Bacillus spp.	1,681	6	5
Bifidobacterium spp.	375	1	1
Carnobacterium divergens	8	0	0
Corynebacterium glutamicum	107	0	0
Gram negatives[(a)]	218[(b)]	0	0
Lactobacilli	1,425	5	5
Lactococcus lactis	216	4	1
Leuconostoc spp.	108	1	1
Microbacterium imperiale	1	0	0
Oenococcus oeni	31	0	0
Pasteuria nishizawae	0	0	0
Pediococcus spp.	186	0	0
Propionibacterium spp.	23	0	0
Streptococcus thermophilus	117	0	0
Viruses (total)	**231**	**2**	**0**
Alphaflexiviridae/ Potyviridae	117	1	0
Baculoviridae	114	1	0
Yeasts	**1,872**	**42**	**17**
Protists	**19**	**0**	**0**
Algae	**173**	**0**	**0**
Total	**6,791**	**61**	**30**
Excluded	6,730	31	

(a): *Gluconobacter oxydans/Xanthomonas campestris/Cupriavidus/Komagateibacter.*
(b): *Gluconobacter oxydans (34)/Xanthomonas campestris (109)/Cupriavidus (69)/Komagateibacter (6).*

3. Assessment

The search strategy (key words, literature databases, number of papers found) followed for the assessment of the suitability of TUs notified to EFSA for their inclusion in the updated QPS list (reply to ToR 3) can be found in Appendix A.

3.1. Taxonomic units evaluated during the previous QPS mandate and re-evaluated in the current statement

3.1.1. Bacteria

Microorganism strain DSM 11798

This microorganism had been notified before but was excluded from QPS assessment as the taxonomic unit of the strain was not identified (EFSA BIOHAZ Panel, 2015).

It was notified as a strain without taxonomic identification to a species with 'Standing in Nomenclature' and therefore not suitable for the QPS approach.

Conclusion

As the taxonomic unit of Microorganism strain DSM 11798 had not been identified, it is not suitable for the QPS approach and is therefore, not recommended for the QPS list.

3.2. Taxonomic units evaluated for the first time

3.2.1. Bacteria

Anaerobutyricum soehngenii

Identity

Anaerobutyricum soehngenii is a bacterial species with Standing in Nomenclature (Shetty et al., 2018). It is phylogenetically related to *Anaerobutyricum hallii* (basonym *Eubacterium hallii*) and belongs to the family *Lachnospiraceae* of the phylum Bacillota. A bacterial strain, designated L2-7^T, was isolated from infant faeces and sequenced (Shetty et al., 2017).

Body of knowledge

A. soehngenii is a gut commensal, part of the normal microbiota of the gastrointestinal tract. It is an obligate anaerobic Gram-positive bacterium and produces butyrate and propionate as a metabolic by-product (Shetty et al., 2017; Wortelboer et al., 2022). A study of the intestinal microbiota found its presence in the faeces of healthy volunteers (Louis et al., 2010). Two studies including the administration of live cells of strain L2-7 to mice have been published (Gilijamse et al., 2020; Koopen et al., 2022). A significant positive effect on insulin sensitivity and lipid metabolism was observed (Udayappan et al., 2016), as well as an increase in faecal butyrate levels (Wortelboer et al., 2022). The body of knowledge is nearly exclusively based on studies with strain *A. soehngenii* L2-7 or its derivative.

Safety concerns

No safety concerns have been described in the scientific literature. A toxicological safety evaluation of live *A. soehngenii* strain CH106 (a tetracycline-sensitive derivative of strain L2-7) has been performed (Seegers et al., 2022), consisting of non-clinical studies assessing the potential for genotoxicity (bacterial reverse mutation and in vitro micronucleus test on mammalian cells) and subchronic toxicity in rats (90-day oral toxicity study), showing no adverse effects (Seegers et al., 2022). Oral intake of supplements to humans of up to 10^{11} live cells/day for 28 days was well tolerated without any adverse effect (Gilijamse et al., 2020). Direct administration in the duodenum of a single dose of 10^{11} live cells of *A. soehngenii* strain L2-7 showed that this kind of administration was also safe and well tolerated (Koopen et al., 2022).

Conclusion on a recommendation for QPS status

A. soehngenii is not recommended for QPS status due to a limited body of knowledge of its use in the food and feed chains.

***Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*)**

Identity

Stutzerimonas stutzeri is a bacterial species with 'Standing in Nomenclature' (Lehman and Neumann, 1896–1927). The former name is *Pseudomonas stutzeri* (Gomila et al., 2022).

Body of knowledge

S. stutzeri is a species of ubiquitous Gram-negative denitrifying bacterial strains (Lalucat et al., 2006). *S. stutzeri* is involved in environmentally important metabolic activities such as bioremediation and degradation of biogenic and xenobiotic compounds (oil derivatives – aromatic and nonaromatic hydrocarbons – and biocides) (Lalucat et al., 2006). Several biotechnological applications are envisaged based on these properties, its N2-fixing ability in soils and its beneficial effects on the rhizosphere and plant health (Lami et al., 2020). A possible application in wastewater treatment has also been reported (Chen et al., 2021). There is limited information about its occurrence in the food and feed chains and exposure of animals and humans through those chains.

Safety

S. stutzeri has been reported as a causative agent of some infections (pneumonia, meningitis, ocular infection, bacteraemia, osteomyelitis, joint infections, endocarditis), mainly in immunocompromised patients (Alwazzeh et al., 2020; Alabdely et al., 2021).

Conclusion on a recommendation for QPS status

S. stutzeri is not recommended for the QPS status based on safety concerns and limited information about the exposure of animals and humans through the food and feed chains.

3.2.2. Yeasts

None

3.2.3. Algae

Nannochloropsis oculata

Identity

Nannochloropsis oculata is a microalgal species with 'Standing in Nomenclature'. *N. oculata*, described by Hibberd (1981), is the type species (holotype) of the genus *Nannochloropsis* (Andersen et al., 1998; Guiry et al., 2018).

Body of knowledge

After an initial literature search, it was decided to run an ELS search for this TU to ensure the completeness of the retrieval of information in terms of body of knowledge and possible safety concerns. *N. oculata* is of interest for the production of high-value products such as eicosapentaenoic acid (EPA), a polyunsaturated fatty acid (Wang et al., 2012; Kagan and Matulka, 2015). *N. oculata* has been used as a supplement to the diet of laying hens in order to increase the level of omega-3 long-chain polyunsaturated fatty acids in egg yolk (Lemahieu et al., 2013) and in feed for Nile Tilapia (Abdelghany et al., 2020; Salem et al., 2022). *N. oculata* microalgae as a supplement in the diet of diabetic rats (20 mg/kg body weight, 21 days) is described as a natural anti-inflammatory and antioxidant compound (Fereidouni et al., 2022). Intestinal tissue sections from healthy rats, fed with freeze-dried *N. oculata* (50 mg/day, 6 weeks) indicated the presence of intestinal atrophy in four out of five rats, two of which had transmural necrosis. All the sections from the *N. oculata* diabetic group showed epithelium lined by extensive necrotic areas (Nuñoa et al., 2013). The dietary addition of 3% *N. oculata* increased body weight and body weight gain in sheep, while also producing significant high cytokine levels and enhancing lymphocyte transformation ability (El Hawy et al., 2022). Supplementation with *N. oculata* (5 g/animal per day) microalgae in the diet of Nubian goats reduced atherogenic index and enhanced the concentrations of unsaturated fatty acids and C20:5n-3 (α-linolenic acid) (Kholif et al., 2020).

Safety concerns

No safety concerns have been described in the scientific literature. Toxicological studies (Kafaie et al., 2012; Kagan and Matulka, 2015) did not indicate negative effects.

Conclusion on a recommendation for QPS status

N. oculata is not recommended for the QPS status due to a limited body of knowledge of its use in the food and feed chain.

3.3. Monitoring of new safety concerns related to organisms on the QPS list

The summaries of the evaluation of the possible safety concerns for humans, animals or the environment described and published since the previous ELS exercise (i.e. articles published between July and December 2022 as described in Appendices B and C) with reference to the articles selected as potentially relevant for the QPS exercise (Appendix D) for each of the TUs or groups of TUs that are part of the QPS list (Appendix E), are presented below.

3.3.1. Gram-positive non-sporulating bacteria

***Bifidobacterium* spp.**

A search for papers potentially relevant for QPS-listed *Bifidobacterium* spp. provided 375 references. Title and abstract screening left one reference for full article appraisal which was found to be relevant (Wakabayashi, 2022). The paper described a case of necrotizing fasciitis and bacteraemia caused by *Bifidobacterium breve* of a 43-year-old Japanese female with type 2 diabetes that led to leg amputation (Wakabayashi, 2022). There is a methodological shortcoming concerning the source attribution and furthermore an immunosuppressive status due to diabetes was mentioned as a predisposing condition. Based on the available evidence, the QPS status of *Bifidobacterium* spp. is not changed.

Carnobacterium divergens

A search for potentially relevant papers on *C. divergens* provided eight references. None of these articles was considered relevant at the level of title and abstract, consequently, the QPS status of *C. divergens* is not changed.

Corynebacterium glutamicum

A search for papers potentially relevant to the QPS evaluation of *C. glutamicum* provided 107 references. None of these papers was considered relevant at the level of title and abstract screening and therefore, no new safety concerns were identified and the QPS status of *C. glutamicum* is not changed.

Lactobacilli

A search of papers referring to any of the QPS species, formerly belonging to the genus *Lactobacillus* and recently split into 13 new genera, provided 1,425 references. After title and abstract screening, five were screened at the full-text phase and all five were found relevant for the QPS exercise (Mikucka (2022), Aydogan (2022), Bergas (2022), Ming-Cho, (2021), for *Lacticaseibacillus rhamnosus* and Neonakis, (2022) for *Lactobacillus delbrueckii*). In Mikucka et al. (2022) and Aydogan et al. (2022) important comorbidities occurred and infection by important pathogens preceded, remained and eventually, contributed to the death of the patients. Despite these debilitating conditions, the patients were fed probiotic preparations that might have provoked transient bacteraemia caused by *L. rhamnosus* (the identification procedure is not completely reliable) that responded well to antibiotics. The other two papers dealing with *L. rhamnosus* infections describe the cases of two elders (Bergas et al, 2022) and a premature newborn (Ming-Chou, 2021). Both have in common an adequate identification of the microorganism, the presence of important comorbidities and a successful recovery following antibiotic treatment. The paper on *L. delbrueckii* (Neonakis et al., 2022) describes a urinary tract infection occurring in a patient suffering from prostatic hyperplasia that required frequent catheter implantation, which might have been the origin of the infection The problem was resolved with an ambulatory antibiotic regime. In addition, the identification methodology was not completely discriminative.

Based on the available evidence as described above, the status of any of the QPS species included in the group of lactobacilli is not changed.

Lactococcus lactis

A search for papers potentially relevant for the QPS status of *L. lactis* provided 216 references. Title and abstract screenings reduced their numbers to four. Only one, describing an infectious endocarditis, was found relevant for the QPS exercise (Mitchell (2022) for *Lactococcus lactis*). There are some

shortcomings in the identification procedure and the patient presented multi-morbidities that led to immunosuppression. Based on the available evidence as described above, the QPS status of *L. lactis* is not changed.

***Leuconostoc* spp.**

A search for papers potentially relevant for the QPS evaluation of *Leuconostoc* species provided 108 references. The analysis of their titles and abstract left one article for full-text evaluation, which was found to be relevant for the QPS exercise (Mohta, 2022) for (*Leuconostoc mesenteroides*). The article reported an infection caused by *L. mesenteroides* in a patient with predisposing conditions (oral carcinoma and diabetes). The identification methodology was considered inadequate (phenotypic identification using Vitek 2). Consequently, the status of QPS-listed *Leuconostoc* spp. is not changed.

Microbacterium imperiale

A search for papers potentially relevant for the QPS evaluation of *Microbacterium imperiale* provided one reference for title/abstract screening which did not reach the full-text phase. Consequently, the QPS status of *M. imperiale* is not changed.

Oenococcus oeni

A search for papers potentially relevant for the QPS evaluation of *Oenococcus oeni* provided 31 references. The title/abstract screening left no articles for the full-text phase. Consequently, the QPS status of *O. oeni* is not changed.

***Pediococcus* spp.**

A search for papers potentially relevant for the QPS evaluation of *Pediococcus* spp. provided 186 references. The analysis of their title/abstract left no articles for the full-text evaluation stage, consequently, the papers reviewed did not identify any information that would change the status of QPS-listed *Pediococcus* spp.

***Propionibacterium* spp.**

A search for papers potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 23 references. Following the analysis of their titles and abstracts, none passed to the full article evaluation phase, consequently, the status of QPS-listed *Propionibacterium* spp. is not changed.

Streptococcus thermophilus

A search for papers potentially relevant for the QPS evaluation of *Streptococcus thermophilus* provided 117 references. The analysis of their title and abstract screening left no article to the full-text evaluation phase, and therefore, the QPS status of *S. thermophilus* is not changed.

3.3.2. Gram-positive spore-forming bacteria

A search for papers potentially relevant for *Bacillus* spp. and *Geobacillus stearothermophilus* provided 1681 references. The analysis of their titles and abstract phase left six articles for the full-text phase of analysis.

***Bacillus* spp.**

All six articles that passed to the full-text phase for further analysis were related to *Bacillus* spp. and five were relevant for the QPS exercise. One reference (Wang et al., 2022), was not related to safety concerns. The other four described a potential safety concern. In the four papers there were problems related to the identification methodology used (Yeltekin et al., 2022, Fugaban et al., 2022, Tokana et al., 2022, Tanaka et al., 2022). The paper of Yeltekin et al. (2022) reported a negative effect of *B. subtilis* infection on trout health but there was no clear link between the infectious agent and the trout affected, making the source attribution unclear. The presence of toxin genes reported in the paper of Fugaban et al. for two *B. subtilis* strains and one *B. velezensis* strain are considered by the general qualification for *Bacillus* spp. 'absence of toxigenic activity' and would therefore need to be assessed at strain level by the respective EFSA Unit. Tokana et al. (2022) and Tanaka et al. (2022) reported bacteraemia with *B. subtilis* in humans with predisposing conditions. The isolated strains were also present in natto, a soybean fermented product which was regularly consumed by the patients.

Through the ELS, no information was identified that would change the status of members of *Bacillus* spp. included in the QPS list.

Geobacillus stearothermophilus

None of the six articles that passed to the full-text phase (see above) for further analysis dealt with this species. Consequently, the QPS status of *G. stearothermophilus* is not changed.

Pasteuria nishizawae

A search for papers potentially relevant for the QPS evaluation of *P. nishizawae* provided no reference that reached the full-text stage. Consequently, the QPS status of *P. nishizawae* is not changed.

3.3.3. Gram-negative bacteria

A search for papers potentially relevant to the QPS evaluation of *Gluconobacter oxidans*, *Xanthomonas campestris, Cupriavidus necator* and *Komagataeibacter sucrofermentans* provided in total 218 references. The analysis of the titles left no article to be checked at abstract level.

Cupriavidus necator

A search for papers potentially relevant for *C. necator* provided 69 references. Following the analysis of their titles and abstract, none was selected for the full-text analysis phase. Consequently, the QPS status of *C. necator* is not changed.

Gluconobacter oxydans

A search for papers potentially relevant for *G. oxydans* provided 34 references. Following the analysis of their titles and abstract, none was selected for the full-text phase. Consequently, the QPS status of *G. oxydans* is not changed.

Komagataeibacter sucrofermentans

A search for papers potentially relevant for *K. sucrofermentans* provided six references. Following the analysis of their titles and abstract, none was selected for the full-text phase. Consequently, the QPS status of *K. sucrofermentans* is not changed.

Xanthomonas campestris

A search for papers potentially relevant for *X. campestris* provided 109 references. Following the analysis of their titles and abstract, none was selected for the full-text phase. Consequently, the QPS status of *X. campestris* is not changed.

3.3.4. Yeasts

The ELS searches for potentially relevant studies on the yeasts with QPS status provided 1,872 references. After the title/abstract screening phase, 42 articles passed to the full article appraisal phase. Out of these, 17 reported a possible safety concern.

The 17 studies that discussed potentially relevant safety concerns for QPS yeast species are discussed below.

For the species ***Hanseniaspora uvarum***, ***Komagataella pastoris***, ***Komagataella phaffi***, ***Limtongozyma cylindracea***, ***Ogataea angusta***, ***Ogataea polymorpha***, ***Saccharomyces bayanus***, ***Saccharomyces pastorianus***, ***Schizosaccharomyces pombe***, ***Xanthophyllomyces dendrorhous*** and ***Zygosaccharomyces rouxii***, no safety concerns were reported. Consequently, the QPS status does not change for these species.

Kumar et al. (2022) is a systematic review and summary of reports of infections caused by rare '*Candida*' species for the periods 2000–2010 and 2011–2021. The QPS species *C. kefyr* (=*K. marxianus*), *C. famata* (=*D. hansenii*), *C. lipolytica* (=*Y. lipolytica*) and *C. pelliculosa* (=*W. anomalus*) are covered in the review. The paper summarises the number of reports, types of infections and reported antimycotic susceptibilities. The review does not present new information on any QPS yeast species. There was no information on potential changes in the rates of antimycotic resistance.

Cyberlindnera jadinii

The anamorph name of *C. jadinii* is *Candida utilis*.

Reda et al. (2022) reported that two (2%) of 'candida' strains isolated from patients with septicemia at two hospitals in Egypt were identified as *C. jadinii*. The species identification was by traditional biochemical growth tests and thus uncertain, and information on clinical history and underlying risk factors are lacking.

The study on *C. jadinii* did not add any new information that would change the current QPS status of this species.

Debaryomyces hansenii

The anamorph name of *D. hansenii* is *Candida famata*.

Six publications contributed with information related to human safety concerns and five of them present identification problems and/or predisposing factors (Caria et al., 2022; Erfaninejad et al., 2022; Gautam et al., 2022; Reda et al., 2022; Saha et al., 2022). Caria et al., (2022) reported a case of central nervous system infection caused by *D. hansenii* in a 60-year-old patient with HIV-1. Erfaninejad et al., (2022) studied the prevalence of oral candidiasis and *Candida* species among HIV-infected patients. From 154 isolates, seven of them were identified as *D. hansenii*. Gautam et al. (2022) isolated yeasts from 0 to 1-month-old neonates, infants and children in the age range of 1–17 years. Among isolates from a total of 116 blood samples, *D. hansenii* made up 9.48%. Reda et al. (2022) identified by traditional growth-based tests four strains (4%) of *D. hansenii* isolated from patients with septicaemia at two hospitals in Egypt in a retrospective study about fungaemia incidence but without background info on the patients.

Khaksar et al. (2022) was the only publication without uncertainties regarding species identification and predisposing factors. The authors described vulvovaginal candidiasis in a retrospective study of 119 females in Iran. Out of 52 *Candida* isolated one was *D. hansenii*. There is some uncertainty about whether *D. hansenii* was the etiological agent since the microbiological analysis was only for yeasts and not for other fungi or bacteria.

Badiee et al. (2022) tested the antifungal activities of eight antifungal agents of a total of 598 *Candida* strains isolated from 10 hospitals in Iran. The strains were identified by PCR restriction fragment length polymorphism (RFLP) and sequencing methods. The isolates included 31 *D. hansenii* (*Candida famata*) strains. No information about antifungal resistance was presented.

The studies on *D. hansenii* did not add any new information that would change the current QPS status of this species.

Kluyveromyces lactis

The anamorph name of *K. lactis* is *Candida spherica*.

Gautam et al. (2022) reported 116 'candida' isolates from blood samples from 33,445 suspected cases of septicaemia in hospitals in New Delhi, India. An unspecified number (but less than 9%) of isolates were *K. lactis*. Species identification was only by traditional growth-based tests, and information on underlying risk factors is lacking.

The study on *K. lactis* did not add any new information that would change the current QPS status of this species.

Kluyveromyces marxianus

The anamorph name of *K. marxianus* is *Candida kefyr*.

A study in Iran reported that out of 154 *Candida* spp. isolated from the mouth of HIV patients that had developed oral candidiasis, four isolates were *K. marxianus* (Erfaninejad et al., 2022). Hosukoglu et al. (2022) reported that five (=5%) of 'candida' strains isolated from the vaginas of women with suspected vulvovaginal candidiasis were *K. marxianus*. Species identification, however, was by morphological and growth-based tests. Three retrospective studies of 'candida' isolates from patients with opportunistic infections (or lacking information regarding clinical history) reported low incidence (1–2%) of *K. marxianus* (Alshawi et al., 2022; Eksi et al., 2022; Reda et al., 2022). Species identification in these studies was by traditional tests and not sequencing.

Badiee et al. (2022) measured susceptibility to amphotericin B, caspofungin and six azoles of 11 *K. marxianus* isolates from hospitals in Iran. All isolates were susceptible to all eight antimycotic substances.

New studies confirm that in rare cases, *K. marxianus* can cause opportunistic or superficial infections. The papers did not identify any information that would change the QPS status of *K. marxianus*.

Saccharomyces cerevisiae

The anamorph form of *S. cerevisiae* is not described. A synonym of this species is *Saccharomyces boulardii*.

Only one publication (Little et al., 2022) reported yeast infections in patients that had received haematopoietic cell transplantation, mostly due to acute myelogenous leukaemia. One isolate has been identified as *S. cerevisiae*, but only using morphological tests.

The literature update did not identify any information that would change the current QPS status of *S. cerevisiae*.

Wickerhamomyces anomalus

The anamorph name of *W. anomalus* is *Candida pelliculosa*.

A case of postoperative fungal endophthalmitis (eye infection) caused by *W. anomalus* was reported by Galvan Ledesma et al. (2022). However, species identification was only performed using traditional tests and is therefore uncertain. Two retrospective studies from India reported the presence of *W. anomalus* in clinical yeast collections from patients with varying predisposing conditions (Gautam et al. 2022; Saha et al. 2022). Both studies employed traditional biochemical tests for species identification, but no molecular confirmation. Shubham et al. (2021) reported two cases of nosocomial blood infection with *W. anomalus* in a neonatal unit in India. Both patients required mechanical ventilation and other supportive measures.

Bilal et al. (2022) reviewed reports of antimycotic susceptibility profiles of clinical isolates of *Candida* spp. from mainland China, published 2011–2021. For *W. anomalus* (3% of the isolates), only data for two azoles were presented. Fifty per cent of the isolates (n = 131) were not susceptible to fluconazole.

The literature update did not identify any information that would change the current QPS status of *W. anomalus*.

Yarrowia lipolytica

The anamorph form of *Y. lipolytica* is *C. lipolytica*.

Three publications contribute with information related to human safety concerns and the three present identification problems and/or predisposing factors. Lona-Reyes et al. (2022) describe the incidence and factors associated with invasive infection by *Candida* spp. in a neonatal intensive care unit in Mexico. The incidence of infection was 2.27 events/1,000 live newborns. From a total of 85 *Candida* strains, two were identified as *Y. lipolytica*. Invasive interventions (central catheter, mechanical ventilation and parenteral nutrition) and the use of antimicrobials increase the risk of neonatal *Candida* spp.. Murtiastutik et al. (2022) isolated 149 yeast strains from 114 HIV/AIDS patients in a hospital in Indonesia. One of the isolates was identified as *Y. lipolytica*, however, a strain of *Candida albicans* was also isolated from the same patient. The yeast species was identified by morphological and biochemical growth tests. Toxqui-Munguia et al. (2022) reported the isolation of *Y. lipolytica* from cows with subclinical mastitis in Mexico. Additionally, the species identification was identified by morphological and biochemical growth.

There was no new information that would change the QPS status of *Y. lipolytica*.

3.3.5. Protists

Aurantiochytrium limacinum (Schizochytrium limacinum)

A search for papers potentially relevant for *A. limacinum* provided 19 articles. Following the analysis of their titles and abstract, none was selected for the full-text phase. Therefore, the current QPS status of *A. limacinum* is not changed.

3.3.6. Algae

A search for papers potentially relevant for algae provided 173 articles. Following the analysis of their titles and abstract, none was selected for the full text phase.

Euglena gracilis

No article dealt with potential safety concerns of *E. gracilis*. Therefore, the current QPS status of *E. gracilis* is not changed.

Haematococcus lacustris* synonym *Haematococcus pluvialis

No article dealt with potential safety concerns of *H. lacustris*. Therefore, the current QPS status of *H. lacustris* is not changed.

Tetraselmis chuii

No article dealt with potential safety concerns of *T. chuii*. Therefore, the current QPS status of *T. chuii* is not changed.

3.3.7. Viruses used for plant protection

Alphaflexiviridae* and *Potyviridae

A search for papers potentially relevant for the QPS evaluation of viruses of the *Alphaflexiviridae* and *Potyviridae* families provided 117 references. Following the analysis of their titles and abstract, one was selected for the full text phase but was not found relevant for the QPS exercise, therefore, the current QPS status remains unchanged.

Baculoviridae

A search for papers potentially relevant for the QPS evaluation of the *Baculoviridae* family provided 114 references. Following the analysis of their titles and abstract, one was selected for the full text phase but was not found relevant for the QPS exercise, therefore, the current QPS status remains unchanged.

Conclusions

ToR 1: *Keep updated the list of microorganisms being notified, in the context of a technical dossier to EFSA Units (Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF)[2]), for intentional use in feed and/or food or as sources of food and feed additives, enzymes, plant protection products for safety assessment*:

- Between October 2022 and March 2023 (inclusive) the list of notifications was updated with 38 notifications that were received by EFSA, of which 28 were proposed for evaluation as feed additives, 5 for use as food enzymes, food additives and flavourings, 5 as novel foods, and none as plant protection products.

ToR 2: *Review taxonomic units previously recommended for the QPS list and their qualifications when new information has become available*:

- In relation to the results of the monitoring of possible new safety concerns relevant for the QPS list, there were no results that would affect the QPS status or the qualifications for the TUs on the QPS list.

ToR 3: *(Re)assess the suitability of taxonomic units notified to EFSA not present in the current QPS list for their inclusion in that list*:

- Out of the 38 notifications received between October 2022 and March 2023, 20 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 18 notifications, 14 notifications were related to microorganisms that are generally excluded from QPS evaluation (8 were notifications of filamentous fungi, 4 of *Enterococcus faecium* (bacterium), 2 of *Escherichia coli* (bacterium)).
- Four of the 38 notifications received, corresponding to 4 TUs (*Anaerobutyricum soehngenii*, Microorganism strain DSM 11798, *Stutzerimonas stutzeri* (former *Pseudomonas stutzeri*), *Nannochloropsis oculata*) were evaluated in this Panel statement for the first time (exception for Microorganism strain DSM 11798 which has also been notified in 2015).

The following conclusions were drawn:

- *A. soehngenii* is not recommended for QPS status due to a limited body of knowledge of its use in the food and feed chains.

- *S. stutzeri* is not recommended for inclusion in the QPS list based on safety concerns and limited information about the exposure of animals and humans through the food and feed chains.
- *N. oculata* is not recommended for the QPS status due to a limited body of knowledge of its use in the food and feed chains.
- As the taxonomic unit of Microorganism strain DSM 11798 is notified as a strain, not a species, it is not suitable for the QPS approach.

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Abbreviations

BIOHAZ	EFSA Panel on Biological Hazards
ELS	extensive literature search
FIP	EFSA Food ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
GMO	EFSA Unit on Genetically Modified Organisms
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group

Glossary

Anamorph name	Valid name of a fungus based on the asexual reproductive state (morphologically)
Antimicrobial compounds	Antibiotics, bacteriocins and/or small peptides with antimicrobial activity
Atherogenic index	The atherogenic index is calculated using a ratio between SFA (C12:0, C14:0 and C16:0) and the sum of MUFA and PUFA. Typically, the lower the atherogenic index, the less atherogenic the food, that is, the healthier the food (Bermingham et al., 2021).
Basonym name	the earliest validly published name of a taxon
Synonymous name/ Homotypic synonym	have the same type (specimen) and the same taxonomic rank.
Teleomorph name	Valid name of a fungus based on the sexual reproductive state (morphologically)

Appendix A – Search strategy followed for the (re)assessment of the suitability of TUs notified to EFSA not present in the current QPS list for their inclusion in the updated list (reply to ToR 3)

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. Details on the search strategy, search keys and approach for each of the assessments of the TUs evaluated in the statement may be found below.

A.1. *Anaerobutyricum soehngenii*

The search on Pubmed for the following terms led to the number of hits indicated below:

- "Anaerobutyricum soehngenii" – 7 hits
- "Anaerobutyricum soehngenii" OR "Eubacterium hallii" – 129 hits

Body of knowledge is limited. No report of infections. *A. soehngenii*, generally positive role in the gut.

A.2. *Stutzerimonas stutzeri (former Pseudomonas stutzeri)*

The search on Pubmed for the following terms led to the number of hits indicated below:

- "Pseudomonas stutzeri"- 143 hits
- "Pseudomonas stutzeri" AND "infection" AND "review"- 15 hits
- "Pseudomonas stutzeri" AND "infection"- 179 hits
- "Stutzerimonas"- 7 hits, 3 related to *S. stutzeri*, none of them with relevance for QPS.

A.3. *Nannochloropsis oculata*

The search on Pubmed for the term "Nannochloropsis oculata" led to 206 hits from which 21 were manually selected as possibly relevant for QPS.

A search on Scopus did not extend the number of new references.

Some additional references were found on the intranet.

As explained in 2.1, an ELS was also performed to ensure the completeness of the retrieval of information in terms of body of knowledge and possible safety concerns.

ELS for *Nannochloropsis oculata*

Search date: 4 December 2023
Timespan: 2011–2023
Sources of information: WoS CC, CABI, FSTA, MEDLINE, BIOSIS
Option 2. Using terms related to general toxicity or toxins

Set	Query	Result	Comment
#4	#3 AND PY = (2011–2023)	139	TU AND Toxins and time limit
#3	#1 AND #2	172	TU AND Toxins
#2	TS = (safe* OR *toxic OR toxic* OR *toxin OR *toxins)	7,046,643	Toxins
#1	TS = ("Nannochloropsis oculata" OR "N oculata" OR "Nannochloropsis oculate" OR "N oculate" OR "Nannochloropsis occulata" OR "N occulata" OR "Nannochloropsis occulate" OR "N occulate")	1,480	TU

Appendix B – Protocol for Extensive literature search (ELS), relevance screening and article evaluation for the maintenance and update of list of QPS-recommended microorganisms (reply to ToR 2)

The protocol for extensive literature search (ELS) used in the context of the EFSA mandate on the list of QPS-recommended microorganisms intentionally added to the food or feed (EFSA-Q-2021-00770) is available on the EFSA Knowledge Junction community on Zenodo, at: https://doi.org/10.5281/zenodo.3607188

Appendix C – Search strategies for the maintenance and update of list of QPS-recommended microorganisms (reply to ToR 2)

The search strategies for each taxonomic unit (TU), i.e. the string for each TU and the search outcome, are available on the EFSA Knowledge Junction community on Zenodo at: https://doi.org/10.5281/zenodo.3607192

Appendix D – References selected from the ELS exercise with potential safety concerns for searches July to December 2022 (reply to ToR 2)

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Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

Cilingir Yeltekin A, 2022. Toxic Effects of Lactococcus garvieae, Staphylococcus epidermidis, and Bacillus subtilis Bacteria on the Physiology of Rainbow Trout. Biology Bulletin, 49.

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Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

None.

Propionibacterium spp.

None.

Streptococcus thermophilus

None.

Gram-Positive Spore-forming Bacteria

Bacilli

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Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Gram-negative bacteria

Cupriavidus necator

None.

Gluconobacter oxydans

None.

Komagataeibacter sucrofermentans

None.

Xanthomonas campestris

None.

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Hosukoglu FG, Eksi F, Erinmez M and Ugur MG, 2022. An epidemiologic analysis of vulvovaginal candidiasis and antifungal susceptibilities. Infectious Microbes and Diseases, 4.

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Protists

None.

Algae

None.

Viruses used for plant protection

Alphaflexiviridae

None.

Potyviridae

None.

Baculoviridae

None.

Appendix E – Updated list of QPS Status recommended microorganisms in support of EFSA risk assessments

The list of QPS status recommended microorganisms (EFSA BIOHAZ Panel, 2023) is being maintained in accordance with the mandate of the BIOHAZ Panel. Possible additions to this list are included approximately every 6 months, with this Panel Statement (18) adopted in June 2023. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2023); the updated QPS list is available at https://doi.org/10.5281/zenodo.1146566 (the link opens at the latest version of the QPS list, and also shows the versions associated to each Panel Statement).

Appendix F – Microbial species as notified to EFSA, received between October 2022 and March 2023 (reply to ToR 1)

The overall list of microorganisms being notified to EFSA in the context of a technical dossier to EFSA Units (for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products for safety assessment), is kept updated in accordance with the mandate of the BIOHAZ Panel and can be found in https://doi.org/10.5281/zenodo.3607183.

The list was updated with the notifications received between October 2022 and March 2023, listed in the Table below.

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[(a)]	Previous QPS status of the respective TU[(b)]	Assessed in this Statement? Yes or no
Algae							
Nannochloropsis oculata	CCMP525	Feed additives	Novel Food	The novel food consists of an extracted oil derived from *N. oculata*. Not GMM	EFSA-Q-2023-00013	No	Yes
Schizochytrium limacinum	FCC-3204	Novel foods	Novel Food	Production of DHA 550 oil as novel food. Not GMM	EFSA-Q-2022-00734	Yes	No
Bacteria							
Anaerobutyricum soehngenii	CH106	Novel foods	Novel Food	Food supplement. Not GMM	EFSA-Q-2022-00552	No	Yes
Bacillus subtilis	MAM DS 79893	Food enzymes, food additives and flavourings	Enzyme production	Production of the food enzyme glucan 1,4-α-maltohydrolase. GMM	EFSA-Q-2022-00603	Yes	No
Bacillus velezensis	ATCC PTA-6737	Feed additives	Zootechnical additives	Not GMM	EFSA-Q-2022-00746	Yes	No
Bacillus Licheniformis	DSM 34315	Feed additives	Zootechnical additives	Production of alpha-amylase as feed additive. GMM	EFSA-Q-2023-00043	Yes	No
Corynebacterium glutamicum	KCCM 80346	Feed additives	Nutritional additives	Production of L-tryptophan through fermentation. Not GMM	EFSA-Q-2022-00882	Yes	No
Corynebacterium glutamicum	KCCM 80366	Feed additives	Nutritional additives	Production of L-valine through fermentation. Not GMM	EFSA-Q-2022-00874	Yes	No
Corynebacterium glutamicum	KCCM 80367	Feed additives	Nutritional additives	Production of L-threonine through fermentation. GMM	EFSA-Q-2022-00873	Yes	No
Corynebacterium glutamicum	CGMCC 20437	Feed additives	Nutritional additives	All animal species. Not GMM	EFSA-Q-2023-00207	Yes	No
Enterococcus faecium	NCIMB 11181	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00553	No	No

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Enterococcus faecium	DSM 7134	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00820	No	No
Enterococcus faecium	NCIMB 10415	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00817	No	No
Escherichia coli	CGMCC 7.460	Feed additives	Nutritional additives	Production of L-tryptophan. Not GMM	EFSA-Q-2023-00048	No	No
Escherichia coli	CGMCC 7.455	Feed additives	Nutritional additives	Production of L-threonine. GMM	EFSA-Q-2023-00049	No	No
Enterococcus faecium	NCIMB 11181	Feed additives	Zootechnical additives	Gut flora stabilisers for all growing poultry and ornamental birds.	EFSA-Q-2022-00876	No	No
Lentilactobacillus buchneri	DSM 22501	Feed additives	Technological additives	Silage additive. Formerly *Lactobacillus buchneri*	EFSA-Q-2022-00789	Yes	No
Levilactobacillus brevis	DSMZ 21982	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00581	Yes	No
Lacticaseibacillus rhamnosus	DSM 7133	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00820	Yes	No
Lentilactobacillus buchneri	ATCC PTA-2494	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00778	Yes	No
Lentilactobacillus buchneri	ATCC PTA-6138	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00780	Yes	No
–	DSM 11798	Feed additives	Technological additives	Substance for reduction of the contamination of feed by mycotoxins. No GMM	EFSA-Q-2022-00793	No	Yes
Pediococcus pentosaceus	DSM 23689	Feed additives	Technological additives	Silage additives. All animal species	EFSA-Q-2023-00162	Yes	No
Pediococcus pentosaceus	DSM 23688	Feed additives	Technological additives	Silage additives. All animal species	EFSA-Q-2023-00163	Yes	No
Pediococcus pentosaceus	DSM 14021	Feed additives	Technological additives	Silage additives. All animal species	EFSA-Q-2023-00164	Yes	No
Pseudomonas stutzeri	MO-19	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme glucan 1,4 alpha maltotetraohydrolase. Not GMM	EFSA-Q-2022-00831	No	Yes

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[(a)]	Previous QPS status of the respective TU[(b)]	Assessed in this Statement? Yes or no
Filamentous fungi							
Aspergillus niger	CBS 109.713	Feed additives	Zootechnical additives	Production of endo-1,4-beta-xylanase. GMM	EFSA-Q-2023-00042	No	No
Aspergillus niger	DSM 18404	Feed additives	Zootechnical additives	Production of endo-1,4-beta-glucanase. GMM	EFSA-Q-2023-00042	No	No
Lentinula edodes	WC 1008	Novel foods	Novel Food	Used for the fermentation of pea protein. Not GMM	EFSA-Q-2022-00618	No	No
Penicillium citrinum	AE-RPE	Food enzymes, food additives and flavourings	Enzyme production	Production of the food enzyme ribonuclease P. Not-GMM	EFSA-Q-2022-00822	No	No
Trichoderma citrinoviride	HBI-TX01	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme endo-1,4-beta-xylanase. Not GMM	EFSA-Q-2022-00533	No	No
Trichoderma reesei	QM6a	Novel foods	Novel Food	Production of β-lactoglobulin. GMM	EFSA-Q-2022-00591	No	No
Trichoderma longibrachiatum Rifai aggr. (aka Trichoderma reesei)	MUCL 49754	Feed additives	Zootechnical additives	Production of the feed enzyme beta-glucanase. Not GMM	EFSA-Q-2022-00800	No	No
Trichoderma longibrachiatum Rifai aggr. (aka Trichoderma reesei)	MUCL 49755	Feed additives	Zootechnical additives	Production of the feed enzyme xylanase. Not GMM	EFSA-Q-2022-00801	No	No
Yeasts							
Komagataella phaffii	DSM33835	Feed additives	Technological additives	Reduction of the contamination of feed by mycotoxins for all animal species. GMM	EFSA-Q-2023-00203	Yes	No
Saccharomyces cerevisiae	Y1242	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00819	Yes	No
Saccharomyces cerevisiae	LALL-GO	Food enzymes, food additives and flavourings	Enzyme production	Production of the food enzyme glucose oxidase. GMM	EFSA-Q-2022-00842	Yes	No

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[(a)]	Previous QPS status of the respective TU[(b)]	Assessed in this Statement? Yes or no
Saccharomyces cerevisiae	CEN.PK113-7D	Feed additives	Nutritional additives	Production of riboflavin. GMM	EFSA-Q-2022-00846	Yes	No

(a): To find more details on specific applications please access the EFSA website – openEFSA at https://open.efsa.europa.eu/questions.
(b): Included in the QPS list as adopted in December 2022 (EFSA BIOHAZ Panel, 2023).