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STATEMENT

Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 23: Suitability of taxonomic units notified to EFSA until September 2025

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The qualified presumption of safety (QPS) process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. The QPS approach assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms intentionally added to the food and feed chain. Safety concerns identified for a taxonomic unit (TU) are, where possible, reflected by 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. During the period covered by this Statement, no new information warranted changes to the status of previously recommended QPS TUs. The QPS list was updated to verify the correctness of the names and the completeness of synonyms. Of the 47 microorganisms notified to EFSA between April and September 2025 (28 as feed additives, 11 as food enzymes or additives, 6 as novel foods, none as plant protection products and 2 as food contact materials), 43 were not evaluated. These latter included 9 filamentous fungi and 9 *Escherichia coli* (all excluded from the QPS evaluation), and 25 already present on the QPS list. One of the other four notifications, *Heyndrickxia faecalis* (previously known as *Weizmannia faecalis*), had been assessed recently within this 3-years QPS cycle. The remaining 3 were assessed for a possible QPS status. *Microchloropsis gaditana*, *Bacillus thermoamylovorans* (both notified for the first time) and an additional TU, *Aurantiochytrium acetophilum*, not evaluated previously, which was included in response to an internal request. *B. thermoamylovorans* cannot be granted the QPS status due to the lack of body of knowledge. *A. acetophilum* cannot be granted the QPS status due to a limited body of knowledge. *M. gaditana* can be granted the QPS status with the qualification for '*production purpose only*'.

KEYWORDS

Aurantiochytrium acetophilum, *Bacillus thermoamylovorans*, *Microchloropsis gaditana*, QPS

CONTENTS

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 qualified presumption of safety (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 (ToR).

The QPS process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms.

Safety concerns that are identified for a taxonomic unit (TU) are, if 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 applies for all QPS bacterial TUs, '*the strains should not harbour any acquired resistance genes to therapeutic antimicrobials*' (EFSA BIOHAZ Panel, 2023a).

Every 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period. The Opinion also updates the QPS approach considering developments in microbial methodology, new scientific insights and new microbial applications in the food chain.

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

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 list '*Microbiological agents as notified to EFSA*' (https://doi.org/10.5281/zenodo.3607183) was updated with the notifications received between April to September 2025 (inclusive). Within this period, 47 notifications were received by EFSA, of which 28 were proposed for use as feed additives, 11 as food enzymes, food additives and flavourings, 6 as novel foods, none as plant protection products and 2 as food contact materials. The new notifications received within that period 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. At the same time, the QPS TUs taxonomic nomenclature of bacteria, yeasts, algae, protists and viruses are being verified every 6 months against their respective authoritative databases to ensure their accuracy for each Panel Statement. The following changes have been made: (1) a swap between correct name and synonym resulting in *Lactibacillus rhamnosus* (correct name) and *Lacticaseibacillus rhamnosus* and *Lacticaseibacillus casei* subsp. *rhamnosus* (synonyms); (2) a swap between correct name and synonym resulting in *Bacillus circulans* (correct name) and *Niallia circulans* (synonym); (3) an update related to *Bacillus coagulans*, becoming the correct name, and *Weizmannia coagulans* and *Heyndrickxia coagulans* as synonyms.

For the revision of the QPS list TUs and their qualifications, articles published from January to June 2025 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). The ELS launched for this Panel Statement included any updated names/synonyms as keywords found with the verification described above. No new information was found that would affect the QPS status or 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).[1]

During the current period, 47 notifications were received. Of these, 43 were not evaluated for the following reasons: 18 notifications involved microorganisms excluded from QPS evaluation (9 filamentous fungi and 9 *Escherichia coli*), and 25 were related to TUs that already have QPS status and did not require further evaluation. Of the other 4 notifications, one (*Heyndrickxia faecalis*, previously known as *Weizmannia faecalis*) had already been evaluated for possible QPS status in a previous Panel Statement (EFSA BIOHAZ Panel, 2024a). The remaining 3 TUs were assessed for a possible QPS status in this Panel Statement: *Nannochloropsis gaditana* (notified for the first time), *Bacillus thermoamylovorans* (notified for the first time) and an additional TU, *Aurantiochytrium acetophilum*, which was included in response to an internal request.

The following conclusions were drawn:

- *Aurantiochytrium acetophilum* cannot be granted the QPS status due to a limited body of knowledge.
- *Bacillus thermoamylovorans* (correct name of *Caldibacillus thermoamylovorans* used by the applicant in the notification) cannot be granted the QPS status due to the lack of body of knowledge.
- *Microchloropsis gaditana* (previously *Nannochloropsis* gaditana) can be granted the QPS status with the qualification for '*production purpose only*'.

[1]The link opens at the latest update of the QPS list, and also includes the links to the versions associated with each Panel Statement.

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 the requirement for 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 scientific articles 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) and 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 the requestor

A wide variety of microorganisms are intentionally added at different stages to 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, food flavourings, novel foods 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.[2] 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 TU belonging to a species that falls within a QPS group do not require a full safety assessment.

Several TUs (usually species for bacteria, protists/microalgae 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 the QPS approach should provide a generic concept to prioritise and to harmonise safety risk assessment of microorganisms intentionally introduced into the food and feed 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 TUs 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 TUs began instead to be carried out every 6 months through extensive literature searches (ELS). For instance, the update of the 2013 QPS list (EFSA BIOHAZ Panel, 2013) was done in 2016 (EFSA BIOHAZ Panel, 2017). From 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, independently from the QPS Opinion, and are available at the Knowledge Junction in Zenodo. From 2016, the QPS opinion 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[3], 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

[2] https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out178_en.pdf.

[3] Units as in December 2022.

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 4 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. Absence of acquired genes coding for resistance to therapeutic antimicrobials 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 and/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 safety assessment approach for use within EFSA that covers safety concerns for humans, production 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[4], *streptomycetes*, oomycetes, *Enterococcus faecium, Escherichia coli*, (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum (*EFSA BIOHAZ Panel, 2020b), *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024a), *Actinomadura roseirufa* and *Burkholderia stagnalis* (EFSA BIOHAZ Panel, 2024b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits by some strains of the TU and therefore, require 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)[5], 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 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.[6]

2 | DATA AND METHODOLOGIES

2.1 | Data

In reply to ToR 3, (re)assessment of the suitability of TUs notified within the period covered by this Statement (between April and September 2025 (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, 2023b) for each TU. The environmental risk assessment of a TU used in PPPs, following the legal requirements, is not included in the QPS assessment. This assessment is carried out by the Pesticide Peer Review (PPR) Unit, based on the risk assessment in the application.

[4]Bacteriophages were excluded since 2020 and within this 3-years QPS cycle (2023–25) but this exclusion has been revised within the QPS opinion (please see section 3.7, EFSA BIOHAZ Panel, 2026).

[5]Units as in December 2022.

[6]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*".

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. More details on the search strategy, search keys and approach for each of the assessments are described in Appendix A.

Only valid TUs covered by the relevant international committees on the nomenclature for microorganisms are considered for the QPS assessment (EFSA BIOHAZ Panel, 2023b). In order to validate this Panel Statement, the TUs of bacteria, yeasts, algae, protists and viruses present in the QPS list were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms (see EFSA BIOHAZ Panel, 2024b for more details). The results of this exercise can be found in Section 3.3.

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 notified to EFSA. A total of 47 notifications were received between April and September 2025 (inclusive), of which 28 were for evaluation for use as feed additives, 11 for use as food enzymes, food additives and flavourings, 6 as novel foods, none as plant protection product and 2 as food contact materials (Table 1).

In response to ToR 3, 43 notifications were not included in the current QPS evaluation for the following reasons: 18 notifications were related to microorganisms generally excluded from QPS evaluation (9 of filamentous fungi, 9 of *Escherichia coli*) and 25 were related to TUs that already had QPS status and did not require further evaluation. Of the remaining 4 notifications, 1 *Heyndrickxia faecalis* (previously *Weizmannia faecalis*) had already been evaluated for a possible QPS status in a previous Panel Statement (EFSA BIOHAZ Panel, 2024a). The other two TUs included: *Microchloropsis gaditana* and *Bacillus thermoamylovorans*, both notified for the first time, were assessed for a possible QPS status in this Panel Statement. An additional TU, *Aurantiochytrium acetophilum*, was included in response to an internal request.

TABLE 1 Notifications received by EFSA, per risk assessment area and by microbiological group, from April until September 2025.

Risk assessment area	Not evaluated in this statement		Evaluated in this statement[b]	Total
Microbiological group	Already QPS	Excluded in QPS[a]		
Feed additives	**21**	**5**	**2**	**28**
Bacteria	14	5	2	21
Filamentous fungi	0	0	0	0
Yeasts	7	0	0	7
Novel foods	**1**	**3**	**2**	**6**
Microalgae	1	0	1	1
Bacteria	0	2	0	2
Filamentous fungi	0	1	0	1
Protists	0	0	1[c]	1
Yeasts		0	0	1
Plant protection products	**0**	**0**	**0**	**0**
Bacteria	0	0	0	0
Filamentous fungi	0	0	0	0
Yeasts	0	0	0	0
Viruses	0	0	0	0
Food enzymes, food additives and flavourings	**3**	**8**	**0**	**11**
Bacteria	2	0	0	2
Filamentous fungi	0	8	0	8
Yeasts	1	0	0	1
Genetically modified organism	**0**	**0**	**0**	**0**
Bacteria	0	0	0	0
Food contact materials	**0**	2	0	**2**
Bacteria	0	2	0	2
Total	**25**	**18**	**4**	**47**

Abbreviation: QPS, qualified presumption of safety.

[a]The number includes nine notification of filamentous fungi, nine of *Escherichia coli*, all excluded from QPS evaluation.

[b]1 was already assessed recently (*Heyndrickxia faecalis* previously *Weizmannia faecalis)* so that was not reassessed in this statement and 2 notifications corresponding to 2 TU, *Nannochloropsis gaditana* and *Bacillus thermoamylovorans (*notified as *Caldibacillus thermoamylovorans)* were assessed in this Statement.

[c]1 TU requested through an internal request from EFSA Nutrition and Food Innovation Unit: *Aurantiochytrium acetophilum*.

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 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.

The aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, production animals, the environment, AMR or genotoxicity caused by QPS organisms since the previous QPS review that would require a change in the QPS status of the TU. The current ELS covered the scientific articles published from January to June 2025. Because of issues with the database platform, the results were filtered using the date of publication rather than the indexation date on the database. Any papers not captured will be included in the next search iteration scheduled for January 2026.

The ELS was done in DistillerSR starting with a screening based on the title and the abstract followed by evaluation of the full texts of the selected abstracts.

The Title and Abstract screening step of this Panel Statement was performed by a Classifier in DistillerSR. Before applying the Classifier an assessment of its performance was done. The specificity of the Classifier was 0.99, while its sensitivity was >0.98 when considering the results of the process up to the Article Evaluation step. Taking into account this background it was considered safe to use the Classifier as the only reviewer at Title and Abstract screening.

The taxonomic nomenclature of QPS TUs including bacteria, yeasts, algae, protists and viruses was verified against their respective authoritative databases to ensure their accuracy and the QPS list has been updated (EFSA BIOHAZ Panel, 2024b) (see Section 3.3). Before conducting searches for the current ELS, the correctness of names was checked. The ELS launched for this Panel Statement incorporated updated names/synonyms as keywords.

For case reports of human infections or intoxications, important additional information includes whether adverse effects were limited to individuals with conditions that increase susceptibility to opportunistic infections, for example immunosuppression. Whether transmission occurred through ingestion of food, intake of probiotics or other routes (e.g. medical devices), was also included 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 opportunistic infections such as cardiovascular conditions associated with endocarditis, people in the lower or upper age spectrum, or conditions that impair immune function. Examples of these conditions are 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/probiotics for humans was reported in many of these cases. The QPS assessment takes into consideration these reports, extracting relevant information where justified.

After removal of duplicates, 6820 records proceeded to the title and abstract screening step, resulting in the exclusion of 6676 records. The remaining 144 records were deemed eligible for article evaluation step (full text), of which 37 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 scientific articles for QPS is shown in Table 2.

One paper (Brannen et al., 2025) was not picked by the search although it was dealing with a possible safety concern related to the QPS species '*Bacillus velezensis*'. The paper was not retrieved because it does not contain the keywords specified in the search. For future ELS, this will be taken into account, and the keywords used for the search will be revised. An impact assessment has been conducted to identify the eventual missed articles from the last 3 years for the *Bacillus* TUs in case terms associated to 'Food-borne outbreak' would have been included. It was shown that in a total of 167 extra articles, only the above-mentioned article would have been identified.

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)	**4222**	**79**	**20**
Bacillus spp.	1350	20	4
Geobacillus stearothermophilus	5	0	
Bifidobacterium spp.	426	8	2
Carnobacterium divergens	0	0	
Corynebacterium glutamicum	67	1	0
Gram negatives[a]	331[b]	1	1
Lactobacilli	1291	29	12
Lactococcus lactis	217	12	1
Leuconostoc spp.	113	6	0
Microbacterium imperiale	0	0	
Oenococcus oeni	28	0	
Pasteuria nishizawae	0	0	
Clostridium tyrobutyricum	17	0	
Pediococcus spp.	259	1	0
Propionibacterium spp.	18	0	
Streptococcus thermophilus	100	1	0
Viruses (total)	**202**	**1**	**0**
Alphaflexiviridae/Potyviridae	116	1	0
Baculoviridae	86	0	
Yeasts	**1827**	**64**	**17**
Protists	**21**	**0**	
Microalgae	**548**	**0**	
Total	**6820**	**144**	**37**
Excluded	6676	107	

[a]*Gluconobacter oxydans/Xanthomonas campestris/Cupriavidus necator/Komagataeibacter sucrofermentans/Agrobacterium radiobacter/Vibrio natrigens*.
[b]*Gluconobacter oxydans* (36)/*Xanthomonas campestris* (106)/*Cupriavidus necator* (90)/*Komagataeibacter sucrofermentans* (8)/*Agrobacterium radiobacter* (61)/*Vibrio natrigens* (30).

3 | ASSESSMENT

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

None.

3.2 | Taxonomic units evaluated for the first time

3.2.1 | Bacteria

Bacillus thermoamylovorans*, correct name of *Caldibacillus thermoamylovorans

Identity

Caldibacillus thermoamylovorans has no Standing in Nomenclature. The valid name is *Bacillus thermoamylovorans*, a species of thermophilic bacilli with optimum temperature for growth around 50 degrees (Combet-Blanc et al., 1995).

Body of knowledge

Only a few papers have been published. *Bacillus thermoamylovorans* has been recognised for its ability to produce thermostable enzymes, such as lipases (Sharma et al., 2018) and polyhydroxyalkanoates (Saharan et al., 2024).

Safety concerns

The only possible safety concern identified relates to a strain isolated from metastatic tumour that, when cultured on cells lines, significantly increases the metastatic burden (Gerbec et al., 2025). The results of Gerbec et al. do not provide definitive evidence of a safety hazard, given that there is a growth-temperature mismatch, a potential for contamination of cell cultures and no proper identification of the strain. This proper identification is hampered by the fact that no WGS is available for the type strain of *B. thermoamylovorans*.

Conclusion

B. thermoamylovorans cannot be granted the QPS status due to the lack of body of knowledge.

3.2.2 | Protists

Aurantiochytrium acetophilum

Identity

Aurantiochytrium acetophilum is a protist described by Ganuza et al. (2019) as a new species. The species belongs to the genus *Aurantiochytrium* containing before only the species *A. limacinum*. The nucleotide and protein sequences comparisons between *A. acetophilum* HS-399 and *A. limacinum* type species strain SR21 showed 90.44% similarity at the nucleotide level and 94.62% at the protein level.

Body of knowledge

A. acetophilum strain HS-399 was isolated from a mangrove swamp in Biscayne Bay (Florida, USA) and selected for its capacity to accumulate lipids and in particular docosahexaenoic acid (Ganuza et al., 2019). Compared to the type species *A. limacinum* strain SR21, morphological differences were found. *A. acetophiulum* HS-399 showed a lipid accumulation level and a lipid profile quite similar to *A. limacinum* strain SR21 (D. Honda & Yokochi) when grown on glycerol. The substrate assimilation profiles of *A. acetophilum* and *A. limacinum* were also very similar. Both strains consumed hexoses but did not assimilate pentoses, disaccharides or longer polysaccharides. Strain HS-399, however, demonstrated an extraordinary tolerance to acetate toxicity, growing on acetate as sole carbon source at a pH level as low as 5 without showing any organic acid inhibition (Ganuza et al., 2019).

In day-old male chicks fed for 6 weeks with a basal diet supplemented with DHA-rich *A. acetophilum* biomass, supplementation at less than 2% improved growth performance and breast muscle mass accumulation, whereas 4% had deleterious effects (Sun et al., 2022). The use of *A. acetophilum* as 12% (Ruiz et al., 2024) or 20% whole cell biomass in fish feed decreased digestibility in juvenile Atlantic salmon (Ruiz et al., 2022). Biomass cell disruption affected digestibility.

Another article described *A. acetophilum* as a platform for production of monoclonal antibodies and other biotherapeutic proteins (Dahmen et al., 2023).

Safety concerns

No articles were found regarding safety aspects of *A. acetophilum*.

Conclusion

A. acetophilum cannot be granted the QPS status due to a limited body of knowledge.

3.2.3 | Microalgae

***Microchloropsis gaditana* (previously *Nannochloropsis gaditana*)**

Identity

Phylogenetic analyses based on *rbcL* and 18S rDNA sequencing data, has reclassified *Nannochloropsis gaditana* and *Nannochloropsis salina* into a new genus named *Microchloropsis* (Fawley et al., 2015). The two species are very closely related sharing up to 98% of their chloroplastic genome and 97% of their mitochondrial genome (Starkenburg et al., 2014).

Body of knowledge

M. gaditana is investigated for a lot of biotechnological purposes and as a feed ingredient.

M. gaditana is used for its ability to accumulate large amounts of polyunsaturated fatty acids (PUFA's), high levels of vitamin D3 (Ljubic et al., 2020) and for the production of carotenoids (Zazirna et al., 2024). *M. gaditana* produces bioactive lipid metabolites as oxylipins, with anti-inflammatory properties (Ávila-Román et al., 2018; de Reyes et al., 2014) and with a cytotoxic activity against human cancer cell lines (Ávila-Román et al., 2016; Castejón & Marko, 2022), and eicosapentaenoic fatty acid (EPA), with antimicrobial activity (Díaz et al., 2025). *M. gaditana* biomass is used as feed ingredient in aquaculture, partially replacing fishmeal and fish oil and has shown also bioactive properties promoting skin pigmentation (Sales et al., 2021), immunostimulation (Sánchez et al., 2023) and preventing lipid oxidation (Camacho-Rodríguez et al., 2014). The addition of 5% hydrolysed microalgal biomass to feed for carnivorous fish (Sparus aurata) did not affect the bacterial composition of the intestinal microbiota and the expression of integrity and permeability genes in the intestine (Cerezo-Ortega et al., 2021). A toxicological evaluation in rat models, including studies on acute oral toxicity, genotoxicity, teratogenicity and subchronic toxicity of a commercial *M. gaditana* oil showed no significant changes compared to negative controls at levels of 2.8 g/kg body weight (Qu et al., 2025). The complete genome sequence of the strain CCMP1894 is available (Schwartz Ariel et al., 2018). Proteomics has identified a protein from the prohibitin family with potential anticancer activity (Carrasco-Reinado et al., 2021). In 2021 NHC (China)[7] has approved the microalgae *Nannochloropsis gaditana* for use in foods with a limit of 2 grams per day on a dry weight basis.

Safety concerns

No safety concerns were reported related to *M. gaditana*.

Conclusion

M. gaditana can be granted the QPS status with the qualification for production purposes only.

3.3 | Update of the QPS list related to taxonomic update

The taxonomic nomenclature of QPS TUs including bacteria, yeasts, algae, protists and viruses was verified against their respective authoritative databases to ensure their accuracy (EFSA BIOHAZ Panel, 2024b).

The following changes have been found and consequently, changes have been made in the QPS list: (1) a swap between correct name and synonym resulting in *Lactibacillus rhamnosus* (correct name) and *Lacticaseibacillus rhamnosus* and *Lacticaseibacillus casei* subsp. *rhamnosus* (synonyms); (2) a swap between correct name and synonym resulting in *Bacillus circulans* (correct name) and *Niallia circulans* (synonym); (3) an update related to *Bacillus coagulans*, becoming the correct name and *Weizmannia coagulans* and *Heyndrickxia coagulans* as synonyms.

3.4 | Monitoring of new safety concerns related to organisms on the QPS list

The summaries of the evaluation regarding potential safety concerns for humans, animals or the environment based on scientific articles published since the previous ELS exercise 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. The current ELS covered the scientific articles published from January to June 2025.

3.4.1 | Gram-positive non-sporulating bacteria

***Bifidobacterium* spp.**

A search for scientific articles potentially relevant for QPS-listed *Bifidobacterium* spp. (*B. adolescentis, B. animalis, B. bifidum, B. breve* and *B. longum*) provided 426 references. After title and abstract screening, eight were selected for the full text inspection (see Appendix D for all references). From these, six did not describe safety concerns. The other two (Muramatsu et al., 2025, Abda et al., 2025) were considered relevant. Muramatsu et al. (2025) reported a case of *B. breve* bacteraemia in an 80-year-old man presenting cardiopulmonary arrest, despite no use of probiotics. His medical history included diabetes mellitus, Alzheimer's disease and anorexia. It was concluded, that *B. breve* bacteraemia is uncommon in adults, but can occur in patients with chronic intestinal disorders and the case reported emphasised the importance of considering *B. breve* as a potential pathogen in such contexts. However, limitations in the identification method were found. The paper

[7] https://www.cirs-group.com/en/food/nhc-approved-four-new-food-raw-materials.

of Abda et al. (2025) described a single-centre retrospective study, in infants born preterm, for more than 10 years, to assess the incidence of bacteraemia related to multistrain probiotic formulations (MPFs) containing *Bifidobacterium* spp. and *Lactobacillus* spp.. Although 0.4% of bacteraemia with *Bifidobacterium* spp. were identified (9 out of 2109 exposed infants), the authors concluded that there were no cases of mortality directly attributed to bacteraemia in preterm infants.

Consequently, the QPS status of *Bifidobacterium* spp. remains unchanged.

Carnobacterium divergens

A search for potentially relevant scientific articles on *C. divergens* provided no references. Consequently, the QPS status of *C. divergens* remains unchanged.

Corynebacterium glutamicum

A search for scientific articles potentially relevant to the QPS evaluation of *C. glutamicum* provided 67 references. One of these articles passed to the full text phase but didn't describe any safety concern. Consequently, the QPS status of *C. glutamicum* remains unchanged.

Lactobacilli

A search of papers referring to any of the QPS species, formerly belonging to the genus *Lactobacillus* and in 2020 split into several new genera, provided 1291 references. After title and abstract screening, 29 were selected for the full text phase inspection (see Appendix D for all references). From these, 15 did not describe safety concerns and one was not in English, from which one was not related to lactobacilli QPS TUs. The other 12 were describing a possible safety concern (Hernandez et al., 2025, Xiao et al., 2025, Qi et al., 2025, Ren et al., 2025, Guerin et al., 2025, Chukamnerd et al., 2025, Farella et al., 2025, Mannavola et al., 2025, Wagers et al., 2025, Wasuwanich et al., 2025, Adi et al., 2025; Abda et al., 2025).

The paper of Abda et al. (2025) described a single-centre retrospective study, in which multistrain probiotic formulations have been used in infants born preterm for more than 10 years, to assess the incidence of bacteraemia related to MPFs containing *Bifidobacterium* spp. and *Lactobacillus* spp. Although 0.1% of bacteraemia with *Lactobacillus* spp. were identified (3 out of 2109 exposed infants), the authors concluded that there were no cases of mortality directly attributed to bacteraemia in preterm infants.

The remaining 11 papers described single cases occurring in people with severe systemic pathologies and underlying diseases (bioprosthetic mitral valve replacement, splenectomy, irritable bowel syndrome, cancer, heart diseases) or in preterm infant leading to immunodepression. The species involved included *Lactobacillus paracasei*, *Lactiplantibacillus plantarum, Lactobacillus plantarum*, *Lactobacillus delbrueckii*, *Lactobacillus johnsonii*, *Lactobacillus rhamnosus* and *Lactobacillus fermentum*.

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

The search for papers dealing with *L. lactis* associated with safety concerns provided 217 references. After title and abstract screening, 12 articles arrived at the full-text phase, but from these, 2 were related to a different TU and nine did not describe a safety concern (see Appendix D for all references). Only one was considered to be relevant after full text inspection (Wongkaew et al., 2025). These authors identified, by 16S rDNA gene and *gyrB* partial sequences, strains of *Lactococcus lactis* as cause of lactococcosis, a fish infection, in red tilapia. This paper has some problems for the species identification as the type strain has not been included as reference.

Based on the available evidence as described above, the QPS status of *Lactococcus lactis* is not changed but the involvement of *L. lactis* on fish pathogenicity will be the object of further follow up.

Leuconostoc spp.

A search for scientific articles potentially relevant for the QPS evaluation of *Leuconostoc* QPS species (*L. citreum, L. lactis, L. mesenteroides, L. pseudomesenteroides*) provided 113 references. The analysis of their titles and abstracts left six articles for full text evaluation (see Appendix D for all references), but none of them was considered relevant for the QPS (3) or was not dealing with this TU (3). The information from the ELS did not lead to a change in the status of QPS-listed *Leuconostoc* species.

Microbacterium imperiale

A search for scientific articles potentially relevant for the QPS evaluation of *Microbacterium imperiale* provided no references. Consequently, the QPS status of *M. imperiale* is not changed.

Oenococcus oeni

A search for scientific articles potentially relevant to the QPS evaluation of *Oenococcus oeni* provided 28 references. Following title and abstract screening, no articles were selected for full-text evaluation. Consequently, the QPS status of *O. oeni* remains unchanged.

***Pediococcus* spp**.

A search for scientific articles potentially relevant for the QPS evaluation of *Pediococcus* spp. provided 259 references. The title/abstract screening left no articles for the full text phase. Consequently, the status of QPS-listed *Pediococcus* spp. remains unchanged.

***Propionibacterium* spp**.

A search for scientific articles potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 18 references. Following the analysis of their titles and abstracts, no articles passed to the full article evaluation phase. Consequently, the status of QPS-listed *Propionibacterium* spp. is not changed.

Streptococcus thermophilus

A search for scientific articles potentially relevant for the QPS evaluation of *Streptococcus thermophilus* provided 100 references. Following the analysis of their titles and abstracts, one article passed to the full article evaluation phase which was not considered relevant for the QPS exercise (see Appendix D for reference). Consequently, the status of QPS-listed *S. thermophilus* is not changed.

3.4.2 | Gram-positive spore-forming bacteria

A search for scientific articles potentially relevant for *Bacillus* spp., related species and *Geobacillus stearothermophilus* provided 1355 references.

***Bacillus* spp. and related species**

1350 articles were found for *Bacillus* spp. and related species. Of the 20 scientific articles that passed to the full text phase for further analysis, 15 do not describe a safety concern (see Appendix D for all references), 4 were reporting a possible safety concern (Qi et al., 2025, Tabrizi et al., 2025, Gallego Aristizabal et al., 2025, Mohamed et al., 2025) and one was not available. One extra paper, not picked up by the ELS because of the keywords (Brannen et al., 2025) was also included in this assessment.

The paper of Brannen et al. (2025) reported an outbreak, most probably due to consumption of cake which showed roping spoilage. The paper indicates *Bacillus velezensis* as the possible etiological agent and the source attribution was only based on epidemiological investigation. The microbiological identification showed some methodological problems. The strain was also not analysed for cytotoxic activity, a qualification for all QPS *Bacillus* spp. The paper of Tabrizi et al. (2025) reported the increased presence of *B. velezensis* strains in urine samples of patients with chronic prostatitis/chronic pelvic pain syndrome, but the causal relationship with the disease remains unclear. The paper of Qi et al. (2025) reported a bacteraemia with a *B. licheniformis* and a *Lactiplantibacillus plantarum* strain, both used as probiotic in a man suffering from different predisposing conditions. Bacteraemia with *Shouchella clausii* was reported in two papers (Gallego Aristizabal et al., 2025, Mohamed et al., 2025) each in a patient with several predisposing conditions after treatment with the probiotic product. The strain was in both cases identified by MALDI-TOF MS, not allowing confirmation of the link with the probiotic strain(s).

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 5 scientific 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 scientific articles potentially relevant for *P. nishizawae* provided no references. Consequently, the QPS status of *P. nishizawae* is not changed.

Clostridium tyrobutyricum

A search for scientific articles potentially relevant for *C. tyrobutyricum* provided 17 references. Following the analysis of its title and abstract, none was selected for the full text analysis phase. Consequently, the QPS status of *C. tyrobutyricum* is not changed.

3.4.3 | Gram-negative bacteria

A search for scientific articles potentially relevant to the QPS evaluation of *Gluconobacter oxidans*, *Xanthomonas campestris, Cupriavidus necator, Komagataeibacter sucrofermentans, Rhizobium radiobacter* and *Vibrio natriegens* provided in total 331 references. The analysis of the titles left one article to be checked at abstract level (Casazza et al., 2025).

Cupriavidus necator

A search for scientific articles potentially relevant for *C. necator* provided 90 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 scientific articles potentially relevant for *G. oxydans* provided 36 references. Following the analysis of their titles and abstracts, none was selected for the full text phase. Consequently, the QPS status of *G. oxydans* is not changed.

Komagataeibacter sucrofermentans

A search for scientific articles potentially relevant for *K. sucrofermentans* provided 36 references. Following the analysis of their titles and abstracts, none was selected for the full text phase. Consequently, the QPS status of *K. sucrofermentans* is not changed.

Xanthomonas campestris

A search for scientific articles potentially relevant for *X. campestris* provided 106 references. Following the analysis of their titles and abstracts, none was selected for the full text phase. Consequently, the QPS status of *X. campestris* is not changed.

Agrobacterium radiobacter* synonym *Rhizobium radiobacter

A search for scientific articles potentially relevant for *A. radiobacter* provided 61 references. Following the analysis of their titles and abstracts, one article (Casazza et al., 2025) was selected for the full text phase but no safety concern was reported. Consequently, the QPS status of *X. campestris A. radiobacter* is not changed.

Vibrio Natriegens

A search for scientific articles potentially relevant for *Vibrio natriegens* provided 30 references. Following the analysis of their titles and abstracts, none was selected for the full text phase. Consequently, the QPS status of *Vibrio natriegens* remains unchanged.

3.4.4 | Yeasts

The ELS searches for potentially relevant scientific articles on the yeasts with QPS status provided 1827 references. After the title/abstract screening phase, 64 articles passed to the full article appraisal phase. Out of these, 27 are not related to safety concerns (see Appendix D for all references), 18 are not related to the QPS yeast group, 1 not in English and 1 not available, therefore, only 17 reported a possible safety concern. The 17 articles are cited and discussed below. For the species ***Hanseniaspora uvarum, Kluyveromyces lactis, 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.

Cyberlindnera jadinii

The anamorph name of *C. jadinii* is *Candida utilis*. Synonyms of this species are *Hansenula jadinii, Pichia jadinii and Lindnera jadinii*.

One paper is related to safety concerns. Yavuz et al. (2025) is a retrospective study of isolates from a medical laboratory in Turkey. Two out of 57 isolates were identified (with MALDI–TOF MS) to *C. jadinii*. The patients from which yeasts were isolated were hospitalised with various predisposing conditions, e.g. cancer treatment, organ transplantations, central venous catheter and parenteral nutrition. The two isolates of *C. jadinii* were moderately susceptible to fluconazole but susceptible to the other seven tested antimycotics.

This study did not add any new information that would change the current QPS status of *C. jadinii*.

Debaryomyces hansenii

The anamorph name of *D. hansenii* is *Candida famata*. Synonyms of this species are *Debaryozyma hansenii, Pichia hansenii, Torulaspora hansenii, Debaryomyces hansenii* var. *hansenii, Debaryomyces tyrocola* var. *hansenii*.

Two papers are related to safety concerns. Ejaz et al. (2025) investigated clinical yeast isolates from hospitalised patients of special and intensive care units of a hospital in Pakistan, showing different symptoms of fungal infection. Patients had various diseases and predisposing conditions. Five out of 474 isolates (1%) were identified to *D. hansenii*. All isolates of *D. hansenii* were susceptible to all three tested antimycotics (amphotericin B, fluconazole and voriconazole). A French study of yeast fungemia in intravenous injection drug users (Paccoud et al., 2025), reported that *D. hansenii* was present in 1% of the cases. However, there were predisposing conditions and methods used for yeast species identification were not reported.

The studies on *D. hansenii* 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*. Synonyms of this species are *Dekkeromyces marxianus, Guilliermondella marxiana, Zygofabospora marxiana, Zygorenospora marxiana, Zygosaccharomyces marxianus*.

Seven papers are related to safety concerns. Ejaz et al. (2025) investigated clinical yeast isolates from hospitalised patients of special and intensive care units of a hospital in Pakistan, showing different symptoms of fungal infection. Patients had various diseases and predisposing conditions. Nineteen out of 474 isolates (4%) were identified to *K. marxianus*. All isolates of *K. marxianus* were susceptible to all three tested antimycotics (amphotericin B, fluconazole and voriconazole). In a retrospective study of isolates from a medical laboratory in Turkey (Yavuz et al., 2025), 12 out of 57 isolates were identified (with MALDI-TOF MS) to *K. marxianus*. The patients were hospitalised with various predisposing factors, e.g. cancer treatment, organ transplantations, central venous catheter and parenteral nutrition. All 12 isolates were susceptible to amphotericin B whereas for fluconazole, voriconazole and anidulafungin, 6 to 8 of the isolates were susceptible. El-Dawy et al. (2025) identified and characterised 79 yeasts isolated from 172 neonatal children in an intensive care ward with symptoms of oral candidiasis in a hospital in Egypt. One of the isolates was identified to *K. marxianus*. Among enzymatic activities related to virulence, the isolate showed low phospholipse and proteinase activity, but high hemolytic activity. There is no direct evidence that the *K. marxianus* strain actually caused the infection. A French study of yeast fungemia in intravenous injection drug users (Paccoud et al., 2025), reported that *K. marxianus* was present in 1% of the cases. However, there were predisposing conditions and methods for yeast species identification were not reported. Elkefy et al. (2025) determined antimycotic susceptibility of 60 clinical yeast isolates from Egypt of which one had been identified to *K. marxianus*, however only using traditional methods.

Buonanno et al. (2025) investigated safety factors in a new isolate of *K. marxianus* from sourdough. Thus, there are no indications that the strain may cause disease. The isolate showed no hemolytic effect, it was susceptible to the tested antimycotics (fluconazole, caspofungin, ketoconazole and amphotericin B) and it had no inhibiting effect on *Galleria mellonella* larvae. Authors concluded that it was safe.

Turedi et al. (2025) isolated yeasts from the milk of healthy Anatolia buffaloes and buffalo cows with 'sub-clinical' mastitis in Turkey. No cows with confirmed mastitis were included in the study. Sixteen out of the 76 yeast isolates were identified to *K. marxianus* (with MALDI–TOF MS). However, these isolates were evenly distributed on the healthy and 'sub-clinical' buffaloes.

The articles 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. An exceptional synonym of this species is *Saccharomyces boulardii*. Other synonyms are *Mycokluyveria cerevisiae, Eutorulopsis cerevisiae, Eutorula cerevisiae, Kloeckera cerevisiae*.

Six papers are related to safety concerns. Hwang et al. (2025) report seven cases from South Korea where administration of *S. cerevisiae* (*S. boulardii*) to children of 4–10 months of age caused food protein-induced enterocolitis syndrome. Vomiting and diarrhoea rapidly ceased when the administration was terminated. Mingo et al. (2025) present a rare case of pyelonephritis caused by *S. cerevisiae* in an immunosuppressed patient with a prior history of exposure to Baker's yeast through sourdough breadmaking and *Candida glabrata* and *S. cerevisiae* vaginitis. No information is given about methods used for species confirmation. Neal et al. (2025) describe a case of a 61-year-old woman with recurrent vaginitis caused by *S. cerevisiae* while consuming a daily probiotic supplement comprised of '*Saccharomyces* species', with no further details given on the probiotic or on methods used for species identification.

A retrospective study in Queensland, Australia (Stewart et al., 2025), summarised cases of human bloodstream infections caused by 'non-*Candida* non-*Cryptococcus* yeasts', who received care at the public hospitals or health services ($n = 70$) in years 2000 to 2019. Fifteen percent of infections with 'non-*Candida* non-*Cryptococcus* yeasts' were caused by *S. cerevisiae*. They noted that these infections are more likely to be hospital-onset and concluded that increased awareness is essential on infections with these organisms in patients with predisposing conditions. Yavuz et al. (2025) is a retrospective study of isolates from a medical laboratory in Turkey. One out of their 57 isolates were identified (with MALDI–TOF MS) to *S. cerevisiae*. The patients from which yeasts were isolated were hospitalised with various predisposing conditions, e.g. cancer treatment, organ transplantations, central venous catheter and parenteral nutrition. The isolate of *S. cerevisiae* was not susceptible to fluconazole, voriconazole and anidulafungin but was moderately susceptible to the other tested antimycotics.

In a global systematic review, Li et al. (2025) summarised published cases of infection with *S. cerevisiae* in HIV patients. They concluded that *S. cerevisiae* is a rare but clinically important opportunistic pathogen in HIV patients who have epidemiological risk factors.

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*. Synonyms of this species are *Endomyces anomalus, Pichia anomala, Willia anomala, Hansenula anomala*.

Five papers are related to safety concerns. A French study of yeast fungemia in intravenous injection drug users (Paccoud et al., 2025), reported that *W. anomalus* was present in 6% of the cases. However, there were obvious predisposing conditions and methods used for yeast species identification were not reported. In a retrospective study of isolates from a medical laboratory in Turkey (Yavuz et al., 2025), four out of 57 isolates were identified (with MALDI-TOF MS) to *W. anomalus*. The patients were hospitalised with various predisposing factors, e.g. cancer treatment, organ transplantations, central venous catheter and parenteral nutrition. The four *W. anomalus* isolates were susceptible to amphotericin B, voriconazole and anidulafungin, whereas they had high (4 mg/L) minimum inhibitory concentration (MICs) for fluconazole. In a study from Iran, Jabrodini et al. (2025) show that *W. anomalus* may in very rare cases cause (or at least be involved in) nail infections in humans. This is a superficial infection and not related with food intake.

Luo et al. (2025) determined antimycotic susceptibility of 307 clinical isolates of *W. anomalus* from blood samples of a national survey in China from 2009 to 2021. The identification methodology used was MALDI–TOF MS. The isolates whose identification was uncertain were further investigated with rDNA internal transcribed spacer (ITS) sequencing. So not all the strains were unequivocally identified. *W. anomalus* isolates in this study were highly susceptible to echinocandins (MIC50/90, 0.25 mg/L). However, it was concluded that azole susceptibility of *W. anomalus* in China has exhibited a concerning downward trend.

There was no new information that would change the QPS status of *W. anomalus*.

Yarrowia lipolytica

The anamorph name of *Y. lipolytica* are *Candida lipolytica* and *Candida oleophila*. Synonym of this species is *Saccharomycopsis lipolytica*.

Three papers are related to safety concerns. Major et al. (2025) describe a very uncommon case of fungal nail infection by *Y. lipolytica* in a 20-year-old woman with persistent nail shedding that was unresponsive to standard antifungal treatments. The isolate was resistant to several tested azole antimycotics. This is a superficial infection, however, and it could not be completely ruled out that other fungi also contributed to the nail infection. Yavuz et al. (2025) is a retrospective study of isolates from a medical laboratory in Turkey. One out of their 57 isolates were identified (with MALDI–TOF MS) to *Y. lipolytica*. The patients from which yeasts were isolated were hospitalised with various predisposing conditions, e.g. cancer treatment, organ transplantations, central venous catheter and parenteral nutrition. The isolate of *Y. lipolytica* showed reduced susceptibility to the azoles but was moderately susceptible to the other tested antimycotics.

Yu et al. (2025) investigated the infection characteristics of *Y. lipolytica* in a mouse model. Immunocompetent and immunosuppressed BALB/c mice were intravenously challenged by injecting fungal cells directly into the bloodstream. In immunocompetent mice, *Y. lipolytica* was effectively cleared even at the highest dose of 1×10^8 cells. Three days after infection, the fungal burden was highest in the lungs followed by the spleen, kidneys, liver and brain. In immunosuppressed mice, the mortality rate following *Y. lipolytica* infection significantly increased, with the highest fungal burden consistently observed in the lungs. In the immunosuppressed model, clinical isolates exhibited a greater lung fungal burden compared to the industrial isolate. The authors concluded that *Y. lipolytica* is a low-virulence fungus that can hardly cause fatal infection in immunocompetent hosts but exhibits a marked tropism for the lungs. Authors also conclude that the model can be useful for studying fungal pulmonary infection pathogenesis and the infection dynamics of *Y. lipolytica*.

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

3.4.5 | Protists

Aurantiochytrium limacinum (Schizochytrium limacinum)

A search for scientific articles potentially relevant for *A. limacinum* provided 21 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.

3.4.6 | Algae

A search for scientific articles potentially relevant for algae provided 548 articles. Following the analysis of their titles and abstract, none were selected for the full text phase.

Euglena gracilis

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

Haematococcus lacustris* synonym *Haematococcus pluvialis

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

Tetraselmis chuii

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

3.4.7 | Viruses used for plant protection

Alphaflexiviridae* and *Potyviridae

A search for scientific articles potentially relevant for the QPS evaluation of viruses of the *Alphaflexiviridae* and *Potyviridae* families provided 116 references. Following the analysis of the title and abstract, none were selected for the full text phase. Therefore, the current QPS status remains unchanged.

Baculoviridae

A search for scientific articles potentially relevant for the QPS evaluation of the *Baculoviridae* family provided 86 references. Following the analysis of their titles and abstract, none were selected for the full text phase. Therefore, the current QPS status remains unchanged.

4 | 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)*** [8]***), for intentional use in feed and/or food or as sources of food and feed additives, enzymes, plant protection products for safety assessment***

- Between April and September 2025 (inclusive) the list of notifications was updated with 47 notifications that were received by EFSA, of which 28 were proposed for evaluation as feed additives, 11 for use as food enzymes, food additives and flavourings, 6 as novel foods, 2 as food contact materials 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***

- The ELS cycle to review the QPS list TUs included the updated names/synonyms verified in the previous Panel Statement

[8]Units as in December 2022.

as keywords. 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.
- The following changes have been made: (1) a swap between correct name and synonym resulting in *Lactibacillus rhamnosus* (correct name) and *Lacticaseibacillus rhamnosus* and *Lacticaseibacillus casei* subsp. *rhamnosus* (synonyms); (2) a swap between correct name and synonym resulting in *Bacillus circulans* (correct name) and *Niallia circulans* (synonym); (3) an update related to *Bacillus coagulans*, becoming the correct name, and *Weizmannia coagulans* and *Heyndrickxia coagulans* as synonyms.

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 47 notifications received between April and September 2025, 25 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 22 notifications, 18 were related to microorganisms that are generally excluded from QPS evaluation (9 were notifications of filamentous fungi and 9 of *Escherichia coli*).
- One of the other four notifications was already evaluated for a possible QPS status in a previous recent Panel Statement: *Heyndrickxia faecalis*, previously known as *Weizmannia faecalis*.
- The other three TUs were assessed for a possible QPS status in this Panel Statement: *Nannochloropsis gaditana* (notified for the first time), *Caldibacillus thermoamylovorans* (notified for the first time) and an additional TU, *Aurantiochytrium acetophilum*, which was included in response to an internal request from EFSA Nutrition and Food Innovation Unit.
- *Aurantiochytrium acetophilum* cannot be granted the QPS status due to a limited body of knowledge.
- *Bacillus thermoamylovorans* (correct name of *Caldibacillus thermoamylovorans*) cannot be granted the QPS status due to the lack of body of knowledge
- *Microchloropsis gaditana* (previously *Nannochloropsis* gaditana) can be granted the QPS status with the qualification for 'production purpose only'.

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
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)

ABBREVIATIONS

AI	artificial intelligence
AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
ELS	extensive literature search
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FIP	EFSA Food ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
GMO	EFSA Unit on Genetically Modified Organisms
ITS	internal transcribed spacer
MALDI–TOF MS	matrix-assisted laser desorption/ionisation–time-of-flight mass spectrometry
MPFs	multistrain probiotic formulations
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
ToR	Term(s) of Reference
TU	taxonomic unit
WG	working group

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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. | *Bacillus thermoamylovorans*, correct name of *Caldibacillus thermoamylovorans*

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

- "Caldibacillus thermoamylovorans" only: 5 hits, all checked.
- "Bacillus thermoamylovorans" and "Caldibacillus thermoamylovorans": 56 hits, all checked

A.2. | *Aurantiochytrium acetophilum*

The search on PubMed for the following terms led to the number of hits indicated below:
- "Aurantiochytrium acetophilum": 4 hits, all checked.

A.3. | *Microchloropsis gaditana* (previously *Nannochloropsis gaditana*)

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

- "Microchloropsis gaditana" only: 20 hits, all checked.
- "Nannochloropsis gaditana": 203 hits, all checked.

APPENDIX B

Protocol for extensive literature search (ELS), relevance screening and article evaluation for the maintenance and update of the 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 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 the 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 done from July to December 2024 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium spp.

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Carnobacterium divergens

None.

Corynebacterium glutamicum

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Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

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Propionibacterium spp.

None.

Streptococcus thermophilus

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Gram-Positive Spore-forming Bacteria

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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.

Agrobacterium radiobacter synonym *Rhizobium radiobacter*

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Protists

None.

Algae

None.

Viruses used for plant protection

Alphaflexiviridae

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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, 2023a) 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 (23) adopted in 3 December of 2025. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2023x); 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 from April 2025 and September 2025 (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 April and September 2025, as shown in the Table below.

Species	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
Bacteria						
Bacillus licheniformis	Food enzymes, food additives and flavourings	Food enzyme	Production of alkaline protease. Non GMM	EFSA-Q-2025-00514	Yes	No
Bacillus smithii	Feed additives	Technological additives	Production of lactic acid. Non GMM	EFSA-Q-2025-00288	Yes	No
Bacillus subtilis	Feed additives	Technological additives	Acidity regulator. Active agent. Non GMM.	EFSA-Q-2025-00295	Yes	No
Bacillus subtilis	Feed additives	Zootechnical additives	Improvement of zootechnical /performance parameters of all aquatic species. Non GMM	EFSA-Q-2025-00501	Yes	No
Bacillus subtilis	Food enzymes, food additives and flavourings	Food enzyme	Production of glutaminase. GMM	EFSA-Q-2025-00232	Yes	No
Bacillus velezensis	Feed additives	Zootechnical additives	Gut flora stabiliser. Non GMM	EFSA-Q-2025-00414	Yes	No
Bacillus velezensis	Feed additives	Zootechnical additives	Improvement of zootechnical /performance parameters of all aquatic species. Non GMM	EFSA-Q-2025-00502	Yes	No
Caldibacillus thermoamylovorans	Feed additives	Technological additives	Production of lactic acid. Non GMM	EFSA-Q-2025-00288	No	Yes
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production of L-lysine monohydrochloride. Non GMM	EFSA-Q-2025-00354	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production of L-arginine	EFSA-Q-2025-00495	Yes	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production of L-histidine monohydrochloride monohydrate. GMM	EFSA-Q-2025-00262	No	No
Escherichia coli	Feed additives	Nutritional additives	Production of calcium D-pantothenate. GMM	EFSA-Q-2025-00438	No	No
Escherichia coli	Feed additives	Nutritional additives	Production of calcium D-pantothenate	EFSA-Q-2025-00438	No	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production of L-threonine. GMM	EFSA-Q-2025-00499	No	No
Escherichia coli	Feed additives	Technological additives	Production of zearalenone hydrolase. GMM	EFSA-Q-2025-00401	No	No

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Species	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
Escherichia coli	Food contact materials	Food contact material	Production of butanoic acid, 3-hydroxy-, (3R)-, polymer with 4-hydroxybutanoic acid, containing up to 15 weight percent 4-hydroxybutanoic acid to be used as a monomer to produce plastic. GMM	EFSA-Q-2025-00264	No	No
Escherichia coli	Food contact materials	Food contact material	Production of biopolymer 'amorphous butanoic acid, 3-hydroxy-, (3R), polymer with 4-hydroxybutanoic acid, containing 4-hydroxybutanoic acid' to be used as an additive in plastic food contact material. GMM	EFSA-Q-2025-00305	No	No
Escherichia coli	Novel foods	Novel foods	Production of 2′-fucosyllactose (2′-FL). GMM	EFSA-Q-2025-00435	No	No
Escherichia coli	Novel foods	Novel foods	Production of hydroxytyrosol	EFSA-Q-2025-00469	No	No
Heyndrickxia coagulans	Feed additives	Technological additives	Production of lactic acid. Non GMM	EFSA-Q-2025-00288	Yes	No
Heyndrickxia faecalis	Feed additives	Zootechnical additives	Gut flora stabilisers. To produce TechnoSpore 50 as a zootechnical additive for calves and other bovines, ovines, caprines, cervids and camelids. Non GMM	EFSA-Q-2025-00272	No	No
Lactiplantibacillus plantarum	Feed additives	Technological additives	Acidity regulator for all animal species. Non GMM	EFSA-Q-2025-00284	Yes	No
Lactococcus lactis	Feed additives	Technological additives	Acidity regulator for all animal species. Non GMM	EFSA-Q-2025-00285	Yes	No
Lentilactobacillus buchneri	Feed additives	Technological additives	Acidity regulator. Active agent. Non GMM	EFSA-Q-2025-00295	Yes	No
Ligilactobacillus salivarius	Feed additives	Zootechnical additives	Gut flora stabiliser. Active agent. Non GMM	EFSA-Q-2025-00315	Yes	No
Parageobacillus thermoglucosidasius	Feed additives	Technological additives	Production of lactic acid. Non GMM	EFSA-Q-2025-00288	Yes	No
Parageobacillus thermoglucosidasius	Feed additives	Technological additives	Production of lactic acid. GMM	EFSA-Q-2025-00288	Yes	No
Protists						
Aurantiochytrium acetophilum	Novel foods	Novel foods	Production of DHA algal oil. Non GMM	EFSA-Q-2024-00272	No	Yes
Filamentous fungi						
Antrodia camphorata	Novel foods	Novel foods	For use as freeze dried mycelia	EFSA-Q-2025-00449	No	No
Aspergillus niger	Food enzymes, food additives and flavourings	Food enzyme	Production of glucoamylase. GMM	EFSA-Q-2025-00524	No	No
Moniliella pollinis	Food enzymes, food additives and flavourings	Food additive	Production of xylitol. GMM	EFSA-Q-2025-00517	No	No

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Species	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
Rhizopus arrhizus	Food enzymes, food additives and flavourings	Food enzyme	Production of triacylglycerol lipase. Non GMM	EFSA-Q-2025-00357	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of beta-glucosidase. GMM	EFSA-Q-2025-00235	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of triacylglycerol lipase. GMM	EFSA-Q-2025-00374	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of 4-phytase. GMM	EFSA-Q-2025-00377	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of glucan 1,4-alpha-glucosidase. GMM	EFSA-Q-2025-00433	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of glucan 1,4-alpha-glucosidase. GMM	EFSA-Q-2025-00434	No	No
Yeasts						
Kluyveromyces marxianus	Novel foods	Novel foods	For use in processed food products (excluding infant formulas and meat and poultry products) as a source of non-animal protein.	EFSA-Q-2025-00445	Yes	No
Komagataella phaffi	Feed additives	Zootechnical additives	Digestibility enhancers. Production of 6-phytase for all avian and porcine species	EFSA-Q-2025-00287	Yes	No
Komagataella phaffi	Feed additives	Zootechnical additives	Digestibility enhancers. Production of the 6-phytase for fish. GMM	EFSA-Q-2025-00353	Yes	No
Komagataella phaffi	Feed additives	Zootechnical additives	Digestibility enhancers. Production of xylanase and beta-glucanase as zootechnical additive for pigs for fattening. GMM	EFSA-Q-2025-00376	Yes	No
Komagataella phaffi	Feed additives	Zootechnical additives	Digestibility enhancers. Production of xylanase and beta-glucanase for pigs for fattening. GMM	EFSA-Q-2025-00376	Yes	No
Komagataella phaffi	Feed additives	Zootechnical additives	Digestibility enhancers. Production of the 6-phytase for chickens for fattening, all avian species other than turkeys for fattening and reared for breeding, piglet, pigs for fattening, sows and minor porcine species. GMM	EFSA-Q-2025-00287	Yes	No
Komagataella phaffii	Feed additives	Technological additives	Production of fumonisin esterase enzyme	EFSA-Q-2025-00489	Yes	No

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Species	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
Komagataella phaffii	Food enzymes, food additives and flavourings	Food enzyme	Production of phospholipase A1. GMM	EFSA-Q-2025-00516	Yes	No
Yarrowia lipolytica	Feed additives	Sensory additives	Colourants substances which, when fed to animals, add colours to food of animal origin. Production of astaxanthin diacetate. GMM	EFSA-Q-2025-00368	Yes	No
Algae						
Nannochloropsis gaditana	Novel foods	Novel foods	Production of oleoresin. Non GMM	EFSA-Q-2025-00291	No	Yes

[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, 2023b).

[c]Different strains from same species in the same application.