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 17: suitability of taxonomic units notified to EFSA until September 2022

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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, new information was found leading to the withdrawal of the qualification 'absence of aminoglycoside production ability' for *Bacillus velezensis.* The qualification for *Bacillus paralicheniformis* was changed to 'absence of bacitracin production ability'. For the other TUs, no new information was found that would change the status of previously recommended QPS TUs. Of 52 microorganisms notified to EFSA between April and September 2022 (inclusive), 48 were not evaluated because: 7 were filamentous fungi, 3 were *Enterococcus faecium*, 2 were *Escherichia coli*, 1 was *Streptomyces* spp., and 35 were taxonomic units (TUs) that already have a QPS status. The other four TUs notified within this period, and one notified previously as a different species, which was recently reclassified, were evaluated for the first time for a possible QPS status: *Xanthobacter* spp. could not be assessed because it was not identified to the species level; *Geobacillus thermodenitrificans* is recommended for QPS status with the qualification 'absence of toxigenic activity'. *Streptoccus oralis* is not recommended for QPS status. *Ogataea polymorpha* is proposed for QPS status with the qualification 'for production purposes only'. *Lactiplantibacillus argentoratensis* (new species) is included in the QPS list.

Keywords: *Geobacillus thermodenitrificans*, *Lactiplantibacillus argentoratensis*, *Ogataea polymorpha*, QPS, *Streptococcus oralis*, *Xanthobacter*

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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 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 (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 (https://doi.org/10.5281/zenodo.3607183) was updated with the notifications received between March and September 2022. Within this period, 52 notifications were received by EFSA, of which 36 were proposed for evaluation in feed, 7 for use as food enzymes, food additives and flavourings, 6 as novel foods and 3 as plant protection products (PPPs). The new notifications received between April 2022 and September 2022 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 January to June 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). The qualification 'absence of aminoglycoside production ability' is removed for *Bacillus velezensis* based on new information not supporting the aminoglycoside production and contradicting the original data. The qualification for *Bacillus paralicheniformis* was changed to 'absence of bacitracin production ability' to allow also phenotypic data in the assessment carried out by the respective EFSA unit. For the other TUs, no new information was found that would affect their QPS status or their qualifications.

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 version of the QPS list, and also shows the versions associated with each Panel Statement).

Fifty-two notifications were received; 48 of these were not evaluated for the following reasons: 13 notifications were related to microorganisms that are excluded from QPS evaluation (7 were notifications of filamentous fungi, 3 *Enterococcus faecium*, 2 of *Escherichia coli*, 1 *Streptomyces* spp.) and 35 were related to TUs that already have QPS status and did not require further evaluation.

The remaining four notifications, corresponding to four TUs (*Xanthobacter* spp., *Geobacillus thermodenitrificans, Streptococcus oralis, Ogataea polymorpha*) and one further TU received after taxonomic reclassification of a TU previously notified (*Lactiplantibacillus argentoratensis)* were evaluated for the first time for a possible QPS status:

The following conclusions were drawn:

- *Xanthobacter* spp. could not be further assessed because it was not identified to the species level.
- *G. thermodenitrificans* is recommended for QPS status with the qualification 'absence of toxigenic activity' based on its inability to grow at animal and human physiological temperatures and the absence of reported safety concerns.
- *S. oralis* is not recommended for QPS status due to safety concerns.
- *O. polymorpha* is recommended for QPS status with the qualification 'for production purposes only' based on the absence of safety concerns and the body of knowledge related to its use as a production organism.

- *L. argentoratensis* (previously *Lactobacillus plantarum* subsp. *argentoratensis*) is recommended for QPS status based on the absence of safety concerns and its former taxonomic position as a subspecies of *L. plantarum* which has QPS status.

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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 chain, 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 chain. 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 chain, 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 chain. 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://ec.europa.eu/food/sites/food/files/safety/docs/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, 2020a) 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. 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,c) 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 (GMM) for safety assessment.

[2] Units as in December 2022.

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.[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 (from April to September 2022, 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, 2020a) 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. To complete the assessment an ELS-based approach may be applied but it was not considered necessary in the current Panel Statement. When required, the ELS would follow the same methodology as used for monitoring new safety concerns related to species with QPS status. 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, 2020a).

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 52 notifications were received between April 2022 and September 2022 (inclusive), of which 36 were for evaluation for use in feed, 7 for use as food enzymes, food additives and flavourings, 6 as novel foods and 3 as plant protection products (Table 1).

In response to ToR 3, 4 of the 52 notifications, corresponding to 4 TU, were evaluated for the first time for a possible QPS status: *Xanthobacter*, *Ogataea polymorpha, Geobacillus thermodenitrificans* and *Streptococcus oralis*. *Xanthobacte*r could not be further assessed because it was not identified to the species level. One further TU, *Lactiplantibacillus argentoratensis*, previously notified to EFSA, was asked to be assessed due to a taxonomic reclassification (not included in Table 1). The remaining 48 notifications were excluded from QPS evaluation for the following reasons: 13 notifications were related to microorganisms that are generally excluded from QPS evaluation (7 were notifications of filamentous fungi, 3 of *Enterococcus faecium*, 2 of *Escherichia coli*, 1 *Streptomyces* spp.) and 35 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 microbiological group, from March to September 2022

Risk assessment area / Microbiological group	Not evaluated in this Statement		Evaluated in this Statement[(b)]	Total
	Already QPS	Excluded in QPS[(a)]		
Feed additives	**28**	**8**	**0**	**36**
Bacteria	24	4		28
Filamentous fungi		4		4
Yeasts	4			4
Novel foods	**1**	**3**	**2**	**6**
Bacteria		2	2	4
Filamentous fungi		1		1
Protists/Algae	1			1
Yeasts				
Plant protection products	**2**	**1**	**0**	**3**
Bacteria				
Filamentous fungi		1		1
Viruses	2			2
Food enzymes, food additives and flavourings	**4**	**1**	**2**	**7**
Bacteria	3		1	4
Filamentous fungi		1		1
Yeasts	1		1	2
Genetically modified organism	**0**	**0**	**0**	**0**
Bacteria				
Total	**35**	**13**	**4**	**52**

QPS: qualified presumption of safety.
(a): The number includes 7 notifications of filamentous fungi, 3 of *Enterococcus faecium* (bacterium), 2 of *Escherichia coli* (bacterium) and 1 of *Streptomyces* spp. (bacterium), all excluded from QPS evaluation.
(b): 4 notifications corresponding to 4 TU, *Xanthobacter, Ogataea polymorpha, Geobacillus thermodenitrificans* and *Streptococcus oralis* all being evaluated for the first time.

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 artificial intelligence (AI) function of DistillerSR was used for pre-screening of papers for *Bifidobacterium* spp., lactobacilli, *Lactococcus lactis*, *Bacillus* spp. and yeasts, followed by a second screening of those articles carried out by two experts.

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 January to June 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, 3,715 records were submitted to the title screening step, which led to the exclusion of 3,563 of these. The remaining 152 records were found eligible for the title and abstract screening step, which led to the exclusion of 69 of these. Of the 82 articles that finally reached the article evaluation step (full text), 36 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/family	Title screening step	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)	**2,424**	**60**	**36**	**20**
Bacillus spp.[(a)]	672	15	11	7
Bifidobacterium spp.[(a)]	198	18	5	2
Carnobacterium divergens	6	1	1	0
Corynebacterium glutamicum	44	0	0	0
Gram negatives[(b)]	307	1	0	0
Lactobacilli[(a)]	511	11	10	7
Lactococcus lactis[(a)]	116	3	2	1
Leuconostoc spp.	112	5	5	2
Microbacterium imperiale	0	0	0	0
Oenococcus oeni	46	0	0	0
Pasteuria nishizawae	1	0	0	0
Pediococcus spp.	252	4	2	1
Propionibacterium spp.	55	1	0	0
Streptococcus thermophilus	104	1	0	0
Viruses (total)	**122**	**2**	**0**	**0**
Alphaflexiviridae/ Potyviridae	55	1	0	0
Baculoviridae	67	1	0	0
Yeasts[(a)]	**846**	**77**	**44**	**16**
Protists	**28**	**2**	**0**	**0**
Algae	**295**	**11**	**3**	**0**
Total	**3,715**	**152**	**83**	**36**
Excluded	3,563	69	47	

(a): The numbers of references pre-screened by AI and excluded are not reported in the table and are for: *Bifidobacterium* spp. (214), lactobacilli (531), *Lactococcus lactis* (118), *Bacillus* spp. (705), yeasts (855).
(b): *Gluconobacter oxydans /Xanthomonas campestris/Cupriavidus/Komagateibacter.*

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

None.

3.2. Taxonomic units to be evaluated for the first time

3.2.1. Bacteria

Lactiplantibacillus argentoratensis

Identity

Lactobacillus plantarum subsp. *argentoratensis* was isolated from vegetables (Bringel et al., 2005). As a subspecies of *L. plantarum*, it had QPS status. Recently, it was renamed to *Lactiplantibacillus plantarum* subsp. *argentoratensis*, as part of the general lactobacilli genera expansion within the family Lactobacillaceae (Zheng et al., 2020). At about the same time, the taxonomic status of the subspecies was raised to the species *Lactobacillus argentoratensis* (Li et al., 2020). Finally, Liu et al. (2020) renamed it as *Lactiplantibacillus argentoratensis*.

Body of knowledge

L. argentoratensis strains have been isolated from sourdoughs (Syrokou et al., 2022), kimchi (Jin et al., 2018), white cocoa (*Theobroma grandiflorum*) (Tenea and Ortega, 2021) and other fermenting matrices. The production of anti-inflammatory and anti-oxidative compounds has been reported after fermentation of *Alnus* sap by strains of this bacterium (Le et al., 2017). Furthermore, two low mass metabolites with antibiofilm properties appear to be synthesised by another strain (Mohapatra et al., 2022).

Safety concerns

No reports on safety concerns have been highlighted for *L. argentoratensis* or *L. plantarum* subsp. *argentoratensis*.

Conclusion on a recommendation for QPS status

L. argentoratensis is commonly present in food matrices and there are no safety concerns identified. It was a subspecies of *L. plantarum*, which had the QPS status. Therefore, *L. argentoratensis* is recommended for QPS status.

Geobacillus thermodenitrificans

Identity

Geobacillus thermodenitrificans is a valid taxonomic species with Standing in Nomenclature (Nazini et al., 2001). It was first described as a validated species with the name *Bacillus thermodenitrificans* by Manachini et al. (2000). The description of the species was completed by Coorevits et al. (2012).

Body of knowledge

G. thermodenitrificans is a thermophilic spore-forming bacterial species growing at 50–65°C and some strains, including the type strain, are capable of growing at 45–70°C. G. *thermodenitrificans* has been reported for the production of several compounds of biotechnological interest such as antibiotics (Garg et al., 2012), α-glucosidase (Cihan et al., 2011), thermophilic enzymes such as esterase (Chen et al., 2020) and lignocellulose-degrading enzymes (Ma et al., 2020). *G. thermodenitrificans* strains were reported to be able to produce exopolysaccharides (Panosyan et al., 2018) with antiviral properties (Arena et al., 2009). *G. thermodenitrificans* has been isolated from heat-treated food products and can produce biofilm in simulated dairy conditions (Karaca et al., 2019, 2020, 2022).

Safety concerns

No safety concerns were reported related to *G. thermodenitrificans* in relation to human and animal health.

Conclusion on a recommendation for QPS status

G. thermodenitrificans is recommended for QPS status with the qualification 'absence of toxigenic activity' based on its inability to grow at animal and human physiological temperatures and the absence of reported safety concerns.

Streptococcus oralis

Identity

Streptococcus oralis is a bacterial species with Standing in Nomenclature (Bridge and Sneath, 1982). Based on whole genome sequence analysis three subspecies are recognised: *S. oralis* subsp. *dentisani*, *S. oralis* subsp. *tigurinus* and *S. oralis* subsp. *oralis* (Jensen et al., 2016; Oren and Garrity, 2017).

Body of knowledge

S. oralis is part of the normal microbiota of the oropharyngeal, nasal, gastrointestinal and genitourinary tracts and has a 'probiotic' effect providing protection against invading pathogens in the oral cavity (reviewed by Okahashi et al., 2022a; Bidossi et al., 2018). Strains of this species are used as oral 'probiotics', but strains of the same species are responsible for human infections.

Safety concerns

S. oralis may cause various diseases such as meningitis, endocarditis and bloodstream infections in which streptococcal surface proteins and other virulence factors might be involved (Basaranoglu et al., 2019; Cruz Cardoso et al., 2021; Nakamura et al., 2021; Okahashi et al., 2022b).

Conclusion on a recommendation for QPS status

S. oralis is not recommended for QPS status due to safety concerns.

3.2.2. Yeasts

Ogataea polymorpha

Identity

Synonyms: *Hansenula polymorpha, Candida thermophila*.

The genus *Ogataea* contains 25 species of ascomycetous yeasts (Kurtzman et al., 2011) from which many were initially described in the genus *Pichia*, or before that, in the former genus *Hansenula*. *Ogataea* has been described based on partial sequences of the large and small subunits rRNAs, and the phenotypic property of methanol utilisation (for a review see Kurtzman et al. (2011)).

Body of knowledge

O. polymorpha is one of several methanol assimilating yeasts that has become biotechnologically important for protein expression. This yeast is used in Asian countries for the production of various traditionally fermented products (Rhee et al., 2003). Today it has been successfully established as producer of vaccines (Chhatwal et al., 2017) and industrial enzymes, e.g. phytases (Mayer et al., 1999), glucoamylase (Gellissen et al. 1991) and various microbial enzymes (Poeta et al., 2018). For a review see Rebello et al., (2018).

Safety concerns

The incidence of mycoses due to *O. polymorpha* is very limited and always linked to patients with predisposing factors (Bar-Meir et al., 2006).

Conclusion on a recommendation for QPS status

There are no safety concerns reported. The number of references associated with its use as viable organism in food and feed is limited and most of the references are related to the use of

O. polymorpha as production organism. Therefore, *O. polymorpha* is recommended for QPS status with the qualification 'for production purposes only'.

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 January and June 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 418 references. The AI analysis left 204. Title screening left 18 references for abstract inspection, then 5 for a full article appraisal. This last step discarded 3 articles because no safety concern was found. One was found relevant, describing bacteraemia cases due to *Bifidobacterium breve* in preterm infants and children with congenital surgical conditions (Sakurai et al., 2022). The authors concluded that the incidence of *B. breve* bacteraemia was higher than reported previously. Ileus and intestinal mucosal damage can cause *B. breve* bacteraemia. It was associated with a good prognosis after treating the patients with antibiotics. Another (Kulkarni, 2022) was a review paper in pre-term neonates. 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 6 references. One article was considered relevant at the level of title screening and one for article evaluation, but no safety concerns were found for this TU. 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 44 references. No papers reached 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

Analysis of papers referring to any of the QPS species, formerly belonging to the genus *Lactobacillus* and recently split into 13 new genera, provided 1,042 references. The AI analysis left 511 articles. Title screening of these provided 11 references for abstract inspection, which further reduced their number to 10. Three of them did not raise safety concerns; in four of the remaining papers/poster communications no reference to the identification procedures were provided. The remaining three papers dealt with *Lacticaseibacillus casei* (Tang et al., 2022) and *Lacticaseibacillus rhamnosus* presumptive infections (Karime et al., 2022; Rubin et al., 2022). All three cases affected patients with important previous morbidities. The first one was an intravenous drug user that suffered a mitral valve replacement complicated by a *Candida* spp. related endocarditis and presented multiple abscesses in the spleen and pelvic and gluteal regions that were positive for *L. casei*. The authors related these infections to numerous superficial scratches and injuries that might have become contaminated by the saliva of the patient's dogs. The other two papers refer to the isolation of *L. rhamnosus* from the blood of two extremely debilitated patients that followed probiotic courses. Karime et al. (2022) presents the case of a man that had been subjected to an aortic valve replacement that became complicated by acute respiratory distress syndrome requiring tracheostomy and extracorporeal membrane oxygenation. In addition, he suffered from ulcerative colitis, the reason why he was taking a course of multiple probiotics among which there was a strain of *L. rhamnosus*. Rubin et al. (2022) describes the case of a woman on specialised neurorehabilitation after a multi-trauma with severe intra-abdominal injuries and widespread, hypoxic cerebral injury. The patient was receiving probiotics via a nasogastric tube, for reasons not reported in the paper. The *L. rhamnosus* isolate was subjected to whole genome sequencing (WGS) and confirmed to be identical to a popular probiotic strain. These cases further confirm the danger associated with the administration of living organisms, even those with no virulence determinants described, to people that suffer from life threatening illnesses.

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 234 references. The AI analysis left 116 papers. Title and abstract screenings reduced their numbers to 3 and 2 respectively. One of them did not raise safety concerns, while in the other, identification of the organism was done by biochemical methods, which are considered to be unreliable for *L. lactis*.

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 112 references. The analysis of their titles left five articles for title/abstract screening. Five articles reached full-text evaluation, and two passed to the final phase (Hussein et al., 2022, Modaweb et al., 2022) One of them (Hussein et al., 2022) did not raise safety concerns. Modaweb et al. (2022) describes the case of a central venous catheter infection in an ex-preterm baby with low birth weight with a biliary atresia which was considered relevant. In both papers the identification of the organism was unreliable. 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 no reference for title/abstract screening. 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 46 references. The analysis of their titles left no articles for title/abstract screening. 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 252 references. The analysis of their titles left four articles for the title/abstract phase. Two articles reached the full-text evaluation stage, one passed to the final phase (Tachikawa et al., 2022) and the other was considered not relevant for QPS purposes. The article describes a self-limiting infection by *P. acidilactici* in an immunocompromised patient. 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 55 references. Following the analysis of their titles, one article was selected for abstract screening and none for 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 104 references. The analysis of their titles left one article for title and abstract screening, which did not deal with safety concerns. Therefore, no article reached the evaluation phase, and 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 *G. stearothermophilus* provided 1,377 references. The AI analysis left 672 articles. The analysis of their titles left 15 articles for the abstract phase and, from these, 11 articles passed to the full-text phase for further analysis.

***Bacillus* spp.**

All 11 articles that passed to the full-text phase for further analysis were related to *Bacillus* spp. and 7 of them had a potential safety concern. Of these seven papers, four did not deal with safety

concerns related to QPS TUs. Three papers had problems related to the identification methodology used (Bae et al., 2022; Dabire et al., 2022; Yeak et al., 2022) and/or source attribution (Aly et al., 2022; Bae et al., 2022; Dorsch et al., 2022). The paper of Bae et al. (2022) reported an endocarditis which could be due to infection by *B. amyloliquefaciens*; a link with the probiotic use of *B. amyloliquefaciens* spores was hypothesised although not experimentally confirmed. Some strains of *B. licheniformis* isolated from food products showed the production of the surfactant lichenysin, a feature which would not comply with the QPS qualification 'absence of cytotoxic activity'. Bacteraemia was diagnosed in a highly immunocompromised patient suffering from gut dysbiosis with a *B. subtillis* strain also present in fermented soya (natto), which was consumed daily by the patient (Kato et al., 2022). Haemolytic activity was discovered in some *B. amyloliquefaciens* (Dabire et al., 2022; Gauri et al., 2022) and *B. subtilis* (Dabire et al., 2022) strains; a property which is covered by the qualification 'absence of toxigenic activity' for *Bacillus* spp.

Through the ELS, the WG did not identify any information that would change the status of members of *Bacillus* spp. included in the QPS list.

Geobacillus stearothermophilus

None of the 11 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 307 references. The analysis of the titles left one article to be checked at abstract level but it did not report any safety concerns.

Cupriavidus necator

A search for papers potentially relevant for *C. necator* provided 87 references. Following the analysis of their titles, none was selected for abstract screening. Consequently, the QPS status of *C. necator* is not changed.

Gluconobacter oxydans

A search for papers potentially relevant for *G. oxydans* provided 44 references. Following the analysis of their titles, none was selected for abstract screening. Consequently, the QPS status of *G. oxydans* is not changed.

Komagataeibacter sucrofermentans

A search for papers potentially relevant for *K. sucrofermentans* provided 4 references. Following the analysis of their titles, none was selected for abstract screening. Consequently, the QPS status of *K. sucrofermentans* is not changed.

Xanthomonas campestris

A search for papers potentially relevant for *X. campestris* provided 172 references. The analysis of the titles left one article to be checked at abstract level but it did not deal with safety concerns. 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 1701 references. The AI analysis left 846 articles. After title screening, 77 studies remained for the title/ abstract phase, and from these 44 articles passed to the full article appraisal. Out of these, 16 reported a possible safety concern. The study of Ko et al. (2022) was not considered because the paper only studied methodological aspects.

The 15 studies that discussed potentially relevant safety concerns for QPS yeast species are discussed below.

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

Debaryomyces hansenii

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

Three studies reported possible concerns regarding human safety. Al-Khairallah and Al-Yasiri (2022) found that out of 25 'Candida' isolates that had caused nail infections at a hospital in Iraq, three were *D. hansenii*. However, species identification was only by morphologic and physiological tests and is therefore uncertain. In a retrospective study (3,800 clinical samples from suspected opportunistic candidemia) in Iran, Ranjbar-Mobarake et al. (2021) report that out of the 46 cases deemed positive, two were *D. hansenii*. The isolates were considered resistant to fluconazole, but susceptible to all six other antifungals tested. Belloch et al. (2022) screened 60 strains of *D. hansenii* from assorted foods for potential as starters in dry-cured sausages and for physiological properties associated with virulence. Most strains were negative for all virulence traits, except that some were positive for biofilm production.

Segundo Zaragoza et al. (2021) found that 24% of 221 '*Candida*' isolates from the milk of healthy goats were *D. hansenii*. However, the isolates had not caused disease and the species identification is uncertain. Spampinato et al. (2022) did not describe safety concerns.

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*.

Three studies on *K. marxianus* related to possible human concerns. In a systematic review, Bayoumy et al. (2021) collected information about microorganisms that have been reported to contribute to gut fermentation syndrome. All reported cases were associated with different predisposing conditions, e.g. coeliac disease or thyroid disease. One paper reported a case with presence of *K. marxianus* (and *S. cerevisiae*). A case study (Spiliopoulou et al., 2022) described pyelonephritis (kidney infection) in a 41-year-old, previously immunocompetent, patient who was hospitalised in a covid-19 intensive care unit. Catheterisation was hypothesised to be the origin of infection and antimycotic treatment was successful. Unequivocal molecular identification of the etiological fungus is missing (but MALDI-TOF-MS supported that it was *K. marxianus*) and there were strong predisposing factors after the hospitalisation. Youn et al. (2022) investigated virulence attributes of two *K. marxianus* isolates from Korean kefir. They were negative for gelatinase and haemolytic activity but could produce pseudohyphae.

Segundo Zaragoza et al. (2021) found that 36% of 221 'Candida' isolates from the milk of healthy goats were *K. marxianus*. However, the isolates had not caused disease and the species identification is uncertain.

Srimahaeak et al. (2022) demonstrated a dairy products spoilage potential of three *K. marxianus* strains isolated from skyr (an Icelandic dairy product similar to yoghurt).

The papers did not identify any information that would change the QPS status of *K. marxianus*.

Komagataella pastoris

Becerril-Garcia et al. (2022) evaluate the immune response raised by *K. pastoris*, confirming its innocuous nature.

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

Saccharomyces cerevisiae

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

Five publications reported safety concerns for humans. Arnoriaga-Rodriguez et al. (2021) hypothesised that the presence of *S. cerevisiae* in the gut microbiota could be associated with chronic

low-grade endogenous hyperproduction of alcohol. By sequencing, the authors detected the presence of *S. cerevisiae* in the microbiome of 15% of subjects, presenting some impairment in attention and executive functions, similar to individuals with chronic ethanol abuse. In the other four papers, the identification was uncertain, and/or the reports were associated with different predispositions in the patients. Bayoumy et al. (2020) did a systematic review of the micro-organisms, diagnostics, and possible treatments of patients with gut fermentation syndrome (GFS), also known as the endogenous alcohol fermentation syndrome or auto-brewery syndrome. From a total of 17 publications included in their review, 9 described the presence of *S. cerevisiae* and 8 of various *Candida* species. In all the reports the syndrome was associated with predispositions like obesity, or alcohol abuse. The remaining three manuscripts described the presence of *S. cerevisiae* in patients with risk factors. Abomughaid et al. (2021) in patients with diabetes; Gun et al. (2022) in a 6-month-old boy with risk factors and Kulkarni et al. (2022) in preterm neonates in intensive care units.

Two manuscripts (Abomughaid et al., 2021; Delma et al., 2021) analysed antifungal activity but did not provide new relevant information.

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*.

Two studies reported possible concerns for human health associated with *W. anomalus*. In a retrospective study from a hospital in Turkey, Eren et al. (2022) reported that out of 279 'Candida' isolates from various clinical samples, one (0.36%) was *W. anomalus*. However, species identification was only performed by traditional methods and therefore uncertain. Inoue et al. (2022) investigated 42 'yeast-like' isolates from 41 patients with keratitis (eye infection), collected from several health centres in Japan for 3 years. One strain was *W. anomalus*, isolated from a patient with predisposing factors, e.g. physical trauma, ocular surgery and systemic diseases.

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

3.3.5. Protists

***Aurantiochytrium limacinum* (*Schizochytrium limacinum*)**

A search for papers potentially relevant for *A. limacinum* provided 28 articles. The analysis of their titles left two articles, but these papers did not reach the full article evaluation stage, thus no new safety concern was identified. Therefore, the current QPS status of *A. limacinum* is not changed.

3.3.6. Algae

A search for papers potentially relevant for algae provided 295 articles. The analysis of their titles left 11 articles and for 3 of these the full text was analysed.

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* provided 55 references. After title screening, no paper reached the title/abstract

screening stage, thus no new safety concern was identified. Therefore, the current QPS status remains unchanged.

Baculoviridae

A search for papers potentially relevant for the QPS evaluation of *Baculoviridae* provided 67 references. No articles dealing with *Baculoviridae* passed the title screening stage, thus no new safety concern was identified. Therefore, the current QPS status remains unchanged.

3.4. Qualifications for *Bacillus velezensis* and *Bacillus paralicheniformis*

Bacillus velezensis was recommended for the QPS list with the following qualifications: (1) the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antimicrobials; (2) absence of toxigenic activity; (3) absence of aminoglycoside production ability (EFSA BIOHAZ Panel, 2020b). The last qualification on the absence of aminoglycoside production ability was introduced based on the publication of Pournejati et al. (2019). The paper reported that a strain of this species produces an antimicrobial substance that, based on structural analysis, is classified as an aminoglycoside. In 2022 a letter to the editor was published contesting the results (Süssmuth et al., 2022). The authors considered the analytical data of the antimicrobial substance produced insufficient to allow for a structure elucidation as an aminoglycoside. Furthermore, the strain was identified by 16 S rRNA gene sequencing, which is not considered a reliable method for *Bacillus* species identification (ref.).

Upon assessment of both papers, the Panel confirmed the uncertainty regarding the data supporting the possible aminoglycoside production of the *B. velezensis* strain and concluded that the qualification 'absence of aminoglycoside production ability' should be removed.

Bacillus paralicheniformis was recommended for the QPS list with the following qualifications: (1) the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antimicrobials; (2) absence of toxigenic activity; (3) absence of genetic information to synthesise bacitracin (EFSA BIOHAZ Panel, 2021). The introduction of the last qualification was based on the papers of Ahire et al. (2020) and Du et al. (2019) who reported the presence of the bacitracin operon in a subset of strains of *B. paralicheniformis*, caused by transferable genetic information. Bacitracin is an antimicrobial peptide active against a range of Gram-positive bacteria. There is, however, a possibility that some *B. paralicheniformis* strains would not show phenotypic bacitracin activity even though bacitracin homologous gene sequences would be present.

The inclusion of a phenotypic test would support the genotypic analysis and facilitate the assessment. Therefore, the qualification for *B. paralicheniformis* was changed to 'absence of bacitracin production ability'.

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)[3]), 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 2022 (inclusive), the list of notifications was updated with 52 notifications that were received by EFSA, of which 36 were proposed for evaluation as feed additives, 7 for use as food enzymes, food additives and flavourings, 6 as novel foods, and 3 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 justify removal of any TUs from the QPS list.
- The qualification 'absence of aminoglycoside production ability' is withdrawn for *Bacillus velezensis* based on recent information not supporting aminoglycoside production, thereby contradicting the original data.

- The qualification 'absence of genetic information to synthesize bacitracin' for *B. paralicheniformis* was replaced by 'absence of bacitracin production ability' to allow also phenotypic data in the assessment at the level of the EFSA units.

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 52 notifications received between April and September 2022, 35 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 17 notifications, 13 notifications were related to microorganisms that are generally excluded from QPS evaluation (7 were notifications of filamentous fungi, 3 of *Enterococcus faecium* (bacterium), 2 of *Escherichia coli* (bacterium), 1 of *Streptomyces* spp. (bacterium)).
- Four of the 52 notifications received, corresponding to 4 TUs (*Xanthobacter* spp., *Geobacillus thermodenitrificans, Streptococcus oralis, Ogataea polymorpha*) and one further TU received after taxonomic reclassification of a TU previously notified (*Lactiplantibacillus argentoratensis)*, were being evaluated for the first time. The following conclusions were drawn:
  - *Xanthobacter* spp. could not be further assessed because it was not identified to the species level.
  - *G. thermodenitrificans* is recommended for QPS status with the qualification 'absence of toxigenic activity' based on its inability to grow at animal and human physiological temperatures and the absence of safety concerns reported.
  - *S. oralis* is not recommended for QPS status due to safety concerns.
  - *O. polymorpha* is recommended for QPS status with the qualification 'for production purposes only' based on the absence of safety concerns, and the body of knowledge related to its use as production organism.
  - *L. argentoratensis* (previously *Lactobacillus plantarum* subsp. *argentoratensis*) is recommended for QPS status based on the absence of safety concerns and its former taxonomic position as a subspecies of *L. plantarum* which has QPS status.

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Abbreviations

AI	artificial intelligence
AMR	antimicrobial resistance
BIOHAZ Panel	EFSA Panel on Biological Hazards
ELS	extensive literature search
FEEDCO	EFSA Feed and Contaminants Unit
FIP	EFSA Food Ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
MALDI-TOF-MS	matrix-assisted laser desorption/ionisation (MALDI), time-of-flight (TOF), Mass Spectrometry (MS)
NIF	EFSA Nutrition and Food Innovation Unit
PREV	EFSA Pesticides Peer Review Unit
QPS	qualified presumption of safety
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group
WGS	Whole Genome Sequencing

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)

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. *Lactiplantibacillus argentoratensis*

The search on Scopus led to 8 hits for the terms "Lactiplantibacillus argentoratensis" or "Lactobacillus plantarum subsp. argentoratensis".

A.2. *Streptococcus oralis*

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

- "Streptococcus oralis": 1252 hits
- with "review": 39 hits, all checked
- with "probiotic": 37 hits, all checked
- with "food": 70 hits, all checked
- with "taxonomy": 245 hits

Checked on LPSN website for taxonomic information.

A.3. *Ogataea polymorpha*

The search on Pubmed led to 840 hits for the terms "Hansenula polymorpha" or "Candida thermophila".

A.4. *Geobacillus thermodenitrificans*

The search on Pubmed led to 126 hits with the term "Geobacillus thermodenitrificans". None of them addresses health concerns for human and animals. Several papers refer to the production of thermostable enzymes.

The search (geobacillus OR bacillus) AND thermodenitrificans AND (infect* OR intoxic* OR toxi* OR disease*) resulted in 8 hits, none of them of concern.

LPSN site for taxonomic information Species: "Geobacillus thermodenitrificans" (dsmz.de).

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-2020-00083) 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 January to June 2022 (reply to ToR 2)

Gram-positive non-sporulating bacteria

Bifidobacterium spp.

Kulkarni, T., Majarikar, S., Deshmukh, M., Ananthan, A., Balasubramanian, H., Keil, A., & Patole, S. (2022). Probiotic sepsis in preterm neonates-a systematic review. European Journal of Pediatrics, 181(6).

Sakurai, Y., Watanabe, T., Miura, Y., Uchida, T., Suda, N., Yoshida, M., & Nawa, T. (2022). Clinical and Bacteriologic Characteristics of Six Cases of Bifidobacterium breve Bacteremia Due to Probiotic Administration in the Neonatal Intensive Care Unit. Pediatric Infectious Disease Journal, 41(1).

Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

Achuthanandan, S., Dhaliwal, A., Lu, T., & Sharma, K. (2022). Brain Abscess Due to Lactobacillus Fermentum in an Uncontrolled Diabetic. Cureus, 14(6).

Karime, C., Barrios, M. S., Wiest, N. E., & Stancampiano, F. (2022). Lactobacillus rhamnosus sepsis, endocarditis and septic emboli in a patient with ulcerative colitis taking probiotics. BMJ case reports, 15(6).

Rubin, I. M. C., Stevnsborg, L., Mollerup, S., Petersen, A. M., & Pinholt, M. (2022). Bacteraemia caused by Lactobacillus rhamnosus given as a probiotic in a patient with a central venous catheter: a WGS case report. Infection prevention in practice, 4(1).

Stoffer, J. N., Slingsby, T. J., & Giuliari, G. P. (2022). Lactobacillus acidophilus endophthalmitis after intravitreal bevacizumab injection requiring intraocular lens explantation. Canadian Journal of Ophthalmology-Journal Canadien D Ophtalmologie, 57(1).

Tang, W., Comianos, M., & Sarvepalli, S. (2022). Prolonged Lactobacillus Bacteremia With Abdominal Abscesses Secondary to Traumatic Injuries From Pet Dogs: A Case Report. Journal of medical cases, 13(3).

Tu, J., MacDonald, M., & Mansfield, D. (2022). Pulmonary actinomycosis and polymicrobial empyema in a patient with ABPA and bronchocoele. Respirology Case Reports, 10(6).

Ubaid, A., Sammour, Y., Hasan, S., Thomas, M., & Robert, T. (2022). WHEN THE DREADED HAPPENS: ATRIO-ESOPHAGEAL FISTULA POST RADIOFREQUENCY ABLATION FOR ATRIAL FIBRILLATION. Journal of the American College of Cardiology, 79(9).

Lactococcus lactis

Slaoui, A., Benmouna, I., Zeraidi, N., Lakhdar, A., Kharbach, A., & Baydada, A. (2022). Lactococcus lactis cremoris intra-uterine infection: About an uncommon case report. International Journal of Surgery Case Reports, 94.

Leuconostoc spp.

Hussein, S. A. M., Kareem, R. A., Al-Dahbi, A. M. H., & Birhan, M. (2022). Investigation of the Role of Leuconostoc mesenteroides subsp. cremoris in Periodontitis around Abutments of Fixed Prostheses. BioMed Research International, 2022.

Modaweb, A., Mansoor, Z., Alsarhan, A., & Abuhammour, W. (2022). A Case of Successfully Treated Central LineAssociated Bloodstream Infection Due to Vancomycin-Resistant Leuconostoc Citreum in a Child With Biliary Atresia. Cureus Journal of Medical Science, 14(1).

Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

Tachikawa, J., Aizawa, Y., Izumita, R., Shin, C., Imai, C., & Saitoh, A. (2022). Resolution of Pediococcus acidilactici bacteremia without antibiotic therapy in a 16-year-old adolescent with leukemia receiving maintenance chemotherapy. Idcases, 27.

Propionibacterium spp.

None.

Streptococcus thermophilus

None.

Gram-positive spore-forming bacteria

Bacilli

Aly, A. A., El-Mahdy, O. M., Habeb, M. M., Elhakem, A., Asran, A. A., Youssef, M. M., ... Hanafy, R. S. (2022). Pathogenicity of Bacillus Strains to Cotton Seedlings and Their Effects on Some Biochemical Components of the Infected Seedlings. Plant Pathology Journal, 38(2). Retrieved from: https://doi.org/10.5423/PPJ.OA.11.2021.0173

Bae, H., Hwang, T.-S., Lee, H.-C., Jung, D.-I., Kim, S.-H., & Yu, D. (2022). Successful treatment of canine infective endocarditis caused by Bacillus amyloliquefaciens. Veterinary Quarterly, 42(1).

Dabire, Y., Somda, N. S., Somda, M. K., Mogmenga, I., Traore, A. K., Ezeogu, L. I.,... Dicko, M. H. (2022). Molecular identification and safety assessment of Bacillus strains isolated from Burkinabe traditional condiment "soumbala". Annals of Microbiology, 72(1).

Dorsch, M. A., Francia, M. E., Tana, L. R., Gonzalez, F. C., Cabrera, A., Calleros, L., ... Giannitti, F. (2022). Diagnostic Investigation of 100 Cases of Abortion in Sheep in Uruguay: 2015–2021. Frontiers in Veterinary Science, 9.

Gauri, K., Rachatida, D.-U., Pinidphon, P., & Cheunjit, P. (2022). Probiogenomic analysis and safety assessment of Bacillus isolates using Omics approach in combination with In-vitro. LWT -- Food Science and Technology, 159.

Kato, A., Yoshifuji, A., Komori, K., Aoki, K., Taniyama, D., Komatsu, M., ... Ryuzaki, M. (2022). A case of Bacillus subtilis var. natto bacteremia caused by ingestion of natto during COVID-19 treatment in a maintenance hemodialysis patient with multiple myeloma. J Infect Chemother, 28(8).

Yeak, K. Y. C., Perko, M., Staring, G., Fernandez-Ciruelos, B. M., Wells, J. M., Abee, T., & Wells-Bennik, M. H. J. (2022). Lichenysin Production by Bacillus licheniformis Food Isolates and Toxicity to Human Cells. Frontiers in Microbiology, 13.

Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Gram-negative bacteria

Cupriavidus necator

None.

Gluconobacter oxydans.

None.

Komagataeibacter sucrofermentans

None.

Xanthomonas campestris

None.

Yeasts

Abomughaid, M. M. (2021). Isolation and Identification of Fungi from Clinical Samples of Diabetic Patients and Studying the Anti-Fungal Activity of Some Natural Oils on Isolated Fungi. Baghdad Science Journal, 18(3), 462–470.

Al-Khairallah, H. A., & Al-Yasiri, M. H. (2022). Molecular Detection of the Two Virulence Genes Hwp1 and Als1 in Candida Species Isolated from Onychomycosis. Wiadomosci lekarskie (Warsaw, Poland: 1960), 75(5 pt 2), 1,295–1,298.

Al-Otibi, F. O., Alrumaizan, G. I., & Alharbi, R. I. (2022). Evaluation of anticandidal activities and phytochemical examination of extracts prepared from Vitex agnus-castus: a possible alternative in treating candidiasis infections. Bmc Complementary Medicine and Therapies, 22(1).

Arnoriaga-Rodriguez, M., Mayneris-Perxachs, J., Coll, C., Perez-Brocal, V., Ricart, W., Moya, A., ... Fernandez-Real, J. M. (2021). Subjects with detectable Saccharomyces cerevisiae in the gut microbiota show deficits in attention and executive function. Journal of Internal Medicine, 290(3), 740–743.

Bayoumy, A. B., Mulder, C. J. J., Mol, J. J., & Tushuizen, M. E. (2021). Gut fermentation syndrome: A systematic review of case reports. United European Gastroenterology Journal, 9(3), 332–342.

Becerril-Garcia, M. A., Flores-Maldonado, O. E., Gonzalez, G. M., Garcia-Gonzalez, G., Hernandez-Bello, R., & Palma-Nicolas, J. P. (2022). Safety profile of intravenous administration of live Pichia pastoris cells in mice. Fems Yeast Research, 22(1).

Belloch, C., Perea-Sanz, L., Gamero, A., & Flores, M. (2022). Selection of Debaryomyces hansenii isolates as starters in meat products based on phenotypic virulence factors, tolerance to abiotic stress conditions and aroma generation. Journal of applied microbiology.

Delma, F. Z., Al-Hatmi, A. M. S., Bruggemann, R. J. M., Melchers, W. J. G., e Hoog, S., Verweij, P. E., & Buil, J. B. (2021). Molecular Mechanisms of 5-Fluorocytosine Resistance in Yeasts and Filamentous Fungi. Journal of Fungi, 7(11).

Eren, E., Sav, H., & Dursun, Z. B. (2022). The epidemiology and antifungal susceptibilityof Candida species isolated from patients in intensive care units of a research hospital. Turk Hijyen ve Deneysel Biyoloji Dergisi, 79(1), 93–102.

Gun, E., Ozdemir, H., Celik, D. B., Botan, E., & Kendirli, T. (2022). Saccharomyces cerevisiae fungemia due to an unexpected source in the pediatric intensive care unit. The Turkish journal of pediatrics, 64(1), 138–141.

Inoue, Y., Ohashi, Y., Shimomura, Y., Sotozono, C., Hatano, H., Fukuda, M., ... Makimura, K. (2022). Multicenter prospective observational study of fungal keratitis in Japan: analyses of culture-positive cases. Japanese Journal of Ophthalmology, 66(3), 227–239.

Kulkarni, T., Majarikar, S., Deshmukh, M., Ananthan, A., Balasubramanian, H., Keil, A., & Patole, S. (2022). Probiotic sepsis in preterm neonates-a systematic review. European Journal of Pediatrics, 181(6), 2,249–2,262.

Orlandini, R. K., Rocha, A. C. S. D., Silva, G. A., Watanabe, E., Motta, A. C. F., Silva-Lovato, C. H., ... Lourenco, A. G. (2021). Increased diversity, fungal burden, and virulence of oral Candida spp. in patients undergoing anti-tuberculosis treatment. Microbial Pathogenesis, 161.

Ranjbar-Mobarake, M., Nowroozi, J., Badiee, P., Mostafavi, S. N., & Mohammadi, R. (2021). Cross-Sectional Study of Candidemia from Isfahan, Iran: Etiologic Agents, Predisposing Factors, and Antifungal Susceptibility Testing. Journal of research in medical sciences: the official journal of Isfahan University of Medical Sciences, 26, 107–107.

Segundo Zaragoza, C., Lopez Ortiz, I., Contreras Caro del Castillo, D. A., Dominguez Hernandez, Y. M., & Rodriguez Garcia, J. A. (2021). Characterization, enzymatic activity and biofilm formation of Candida species isolated from goat milk. Revista Iberoamericana De Micologia, 38(4), 175–179.

Spiliopoulou, A., Kolonitsiou, F., Vrioni, G., Tsoupra, S., Lekkou, A., & Paliogianni, F. (2022). Invasive Candida kefyr infection presenting as pyelonephritis in an ICU hospitalized COVID-19 patient: Case report and review of the literature. Journal De Mycologie Medicale, 32(2).

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 is being maintained in accordance with the ongoing mandate of the BIOHAZ Panel, extended for the following years (2023–2025). Possible additions to this list are included approximately every 6 months, with this Panel Statement (17) adopted in December 2022. These additions are published as updates to the latest 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 with each Panel Statement).

Appendix F – Microbial species as notified to EFSA, received between April and September 2022 (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 ongoing 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 2022, 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							
Haematococcus pluvialis	ACO32	Novel foods	Novel foods	Production of astaxanthin-rich oleoresin. Not GMM	EFSA-Q-2022-00588	YES	NO
Bacteria							
Bacillus amyloliquefaciens	DSM 25840	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00325	YES	NO
Bacillus subtilis	AR-513 (deposited as CBS 141004)	Food enzymes, food additives and flavourings	Enzyme production	Production of maltogenic amylase. GMM	EFSA-Q-2022-00530	YES	NO
Bacillus subtilis	DSM 32324	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00325	YES	NO
Bacillus subtilis	DSM 32325	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00325	YES	NO
Bacillus subtilis	DSM 33862	Feed additives	Technological additives	Silage additive	EFSA-Q-2022-00510	YES	NO
Bacillus velezensis	ATCC PTA-6737	Feed additives	Zootechnical additives	Gut flora stabilisers	EFSA-Q-2022-00320	YES	NO
Bifidobacterium animalis	DSM 16284	Feed additives	Zootechnical additives	Gut flora stabilisers. Mixture of viable cells of 5 lactic acid producing bacteria. Not GMM	EFSA-Q-2022-00321	YES	NO
Bifidobacterium animalis	DSM 16284	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00374	YES	NO
Enterococcus faecium	DSM 21913	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00374	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 33761	Feed additives	Zootechnical additives	Gut flora stabilisers. Mixture of viable cells of 5 lactic acid producing bacteria. Not GMM	EFSA-Q-2022-00321	NO	NO
Enterococcus faecium	DSM 7134	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00531	NO	NO
Escherichia coli	BL21 (DE3)	Novel foods	Novel Food	Production of L-3-aminoisobutyric acid. GMM	EFSA-Q-2022-00493	NO	NO
Escherichia coli	K12 MG1655 INB-6SL02 (deposition nr. LMBP 12506)	Novel foods	Novel Food	Production of 6'-sialyllactose sodium salt (6'-SL*Na). GMM	EFSA-Q-2022-00086	NO	NO
Geobacillus thermodenitrificans	TRBE14	Food enzymes, food additives and flavourings	Enzyme production	Production of 1,4-alpha-glucan branching enzyme	EFSA-Q-2016-00100	NO	YES
Lacticaseibacillus paracasei	ATCC PTA-6135	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00199	YES	NO
Lactiplantibacillus argentoratensis[4]		Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00131	NO	YES
Lactiplantibacillus plantarum	NCIMB 30083	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00317	YES	NO
Lactiplantibacillus plantarum	NCIMB 30084	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00322	YES	NO
Lactiplantibacillus plantarum	NCIMB 30094	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00324	YES	NO
Lactiplantibacillus plantarum	NCIMB 30148	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00342	YES	NO
Lactiplantibacillus plantarum	NCIMB 41028	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00343	YES	NO

[4] New species due to change in taxonomic classification. Already notified to EFSA before. One of the strains not yet in the QPS list (DSM 8866), as its current TU is *L. argentoratensis* (formerly *Lactobacillus plantarum* subsp. *argentoratensis*).

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
Lentilactobacillus buchneri	DSM 12856	Feed additives	Technological additives	Silage additive	EFSA-Q-2022-00510	YES	NO
Lentilactobacillus buchneri	DSM 19455	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00524	YES	NO
Lentilactobacillus buchneri	NCIMB 30139	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00198	YES	NO
Ligilactobacillus salivarius	DSM 16351	Feed additives	Zootechnical additives	Gut flora stabilisers. Mixture of viable cells of 5 lactic acid producing bacteria. Not GMM	EFSA-Q-2022-00321	YES	NO
Ligilactobacillus salivarius	DSM 16351	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00374	YES	NO
Limosilactobacillus reuteri	DSM 33751	Feed additives	Zootechnical additives	Gut flora stabilisers. Mixture of viable cells of 5 lactic acid producing bacteria. Not GMM	EFSA-Q-2022-00321	YES	NO
Pediococcus acidilactici	CNCM I-4622	Feed additives	Zootechnical additives	Physiological condition stabilisers. Not GMM	EFSA-Q-2022-00340	YES	NO
Pediococcus acidilactici	DSM 33758	Feed additives	Zootechnical additives	Gut flora stabilisers. Mixture of viable cells of 5 lactic acid producing bacteria. Not GMM	EFSA-Q-2022-00321	YES	NO
Pediococcus pentosaceus	NCIMB 30168	Feed additives	Technological additives	Silage additive. Not GMM	EFSA-Q-2022-00204	YES	NO
Propionibacterium acidipropionici		Food enzymes, food additives and flavourings	Food additive	Production of propionate. Not GMM	EFSA-Q-2022-00462	YES	NO
Propionibacterium freudenreichii		Food enzymes, food additives and flavourings	Food additive	Production of propionate. Not GMM	EFSA-Q-2022-00462	YES	NO
Streptococcus oralis	89A	Novel foods	Novel Food	Not GMM	EFSA-Q-2022-00492	NO	YES
Streptomyces aurefocaciens	C735.15	Feed additives	Coccidiostats and histomonostats	Production of narasin (coccidiostat). Not GMM	EFSA-Q-2022-00354	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
Weizmannia coagulans	DSM 32016	Feed additives	Zootechnical additive	Not GMM	EFSA-Q-2022-00221	YES	NO
Weizmannia coagulans	DSM 32016	Feed additives	Zootechnical additives	Gut flora stabilisers. Preparation with viable spores. Not GMM	EFSA-Q-2022-00316	YES	NO
Xanthobacter	SoF2	Novel foods	Novel Food	Production of bacterial biomass. Not GMM	EFSA-Q-2022-00140	NO	YES
Filamentous fungi							
Aspergillus niger	DSM 25770 (LU17257)	Feed additives	Zootechnical additives	Digestibility enhancer. Production of 6-phytase. GMM	EFSA-Q-2022-00509	NO	NO
Aspergillus oryzae	DSM 33700	Feed additives	Zootechnical additives	Digestibility enhancers. Production of the enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2022-00156	NO	NO
Mortierella alpina	CNCM I-4642	Novel foods	Novel Food	Production of arachidonic acid-rich oil	EFSA-Q-2022-00315	NO	NO
Trichoderma asperellum	T34 (CECT No. 20417)	Plant protection products	Plant Protection Product	Fungicide (biofungicide) that protects ornamental and carnation plants and increases their defences against *Fusarium oxysporum* f.sp. *dianthi*	EFSA-Q-2020-00633	NO	NO
Trichoderma citrinoviride	DSM 33578 (B-125)	Feed additives	Zootechnical additives	Production of endo-1,4-β-xylanase, cellulase, xyloglucan-specific endo-β-1,4-glucanase. Not GMM	EFSA-Q-2022-00326	NO	NO
Trichoderma reesei	AR-715 (RF11412)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme endo-1,4-beta-glucanase. GMM	EFSA-Q-2022-00228	NO	NO
Trichoderma reesei	DSM 32338	Feed additives	Zootechnical additives	Production of muramidase. GMM	EFSA-Q-2022-00318	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
Yeasts							
Komagataella phaffii		Feed additives	Zootechnical additives	Digestibility enhancer. Production of endo-1, 4-β-xylanase. GMM	EFSA-Q-2022-00323	YES	NO
Ogataea polymorpha	DP-Jza21 (deposited as CBS 141004)	Food enzymes, food additives and flavourings	Enzyme production	Production of hexose oxidase. GMM	EFSA-Q-2022-00406	NO	YES
Saccharomyces cerevisiae	Canobios-BL	Feed additives	Zootechnical additives	Gut flora stabilisers. Not GMM	EFSA-Q-2022-00373	YES	NO
Saccharomyces cerevisiae	DSM 34129 (LALL-LI)	Food enzymes, food additives and flavourings	Enzyme production	Production of triacylglycerol lipase. GMM	EFSA-Q-2022-00529	YES	NO
Saccharomyces cerevisiae	MUCL 39885 (deposited as CBS 141004)	Feed additives	Zootechnical additives	Gut flora stabilisers. GMM	EFSA-Q-2015-00513	YES	NO
Viruses							
Helicoverpa armigera nucleopolyhedrovirus	HearNPV BV-0003	Plant protection products	Plant Protection Product	Insecticide for biological control of the cotton bollworm, *Helicoverpa armigera* with HearNPV	EFSA-Q-2020-00515	YES	NO
Spodoptera littoralis Nucleopolyhedrovirus	SpliNPV-BV0005	Plant protection products	Plant Protection Product	Insecticide on *Spodoptera littoralis* in tomatoes. Only the larval stages of the hosts are sensitive to infections with SpliNPV BV-0005	EFSA-Q-2020-00516	YES	NO

(a): To find more details on specific applications please access the EFSA website – openefsa at https://open.efsa.europa.eu/.
(b): Included in the QPS list as adopted in December 2019 (EFSA BIOHAZ Panel, 2020a) and respective updates which include new additions (latest: EFSA BIOHAZ Panel, 2022).