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STATEMENT

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Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 15: suitability of taxonomic units notified to EFSA until September 2021

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Abstract

The qualified presumption of safety (QPS) approach was developed to provide a generic pre-evaluation of the safety of biological agents. 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 are, where possible, confirmed at the species/strain or product level and reflected by 'qualifications'. The QPS list was updated in relation to the revised taxonomy of the genus *Bacillus*, to synonyms of yeast species and for the qualifications 'absence of resistance to antimycotics' and 'only for production purposes'. *Lactobacillus cellobiosus* has been reclassified as *Limosilactobacillus fermentum*. In the period covered by this statement, no new information was found that would change the status of previously recommended QPS taxonomic units (TU)s. Of the 70 microorganisms notified to EFSA, 64 were not evaluated: 11 filamentous fungi, one oomycete, one *Clostridium butyricum*, one *Enterococcus faecium*, five *Escherichia coli*, one *Streptomyces* sp., one *Bacillus nakamurai* and 43 TUs that already had a QPS status. Six notifications, corresponding to six TUs were evaluated: *Paenibacillus lentus* was reassessed because an update was requested for the current mandate. *Enterococcus lactis* synonym *Enterococcus xinjiangensis*, *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei*, *Schizochytrium aggregatum*, *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii* and *Haematococcus lacustris* synonym *Haematococcus pluvialis* were assessed for the first time. The following TUs were not recommended for QPS status: *P. lentus* due to a limited body of knowledge, *E. lactis* synonym *E. xinjiangensis* due to potential safety concerns, *A. mangrovei* synonym *S. mangrovei*, *S. aggregatum* and *C. reinhardtii* synonym *C. smithii*, due to lack of a body of knowledge on its occurrence in the food and feed chain. *H. lacustris* synonym *H. pluvialis* is recommended for QPS status with the qualification 'for production purposes only'.

Keywords: *Aurantiochytrium mangrovei*, *Chlamydomonas reinhardtii*, *Enterococcus lactis*, *Haematococcus lacustris*, *Paenibacillus lentus*, *QPS*, *Schizochytrium aggregatum*

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Amendment: The link mentioned for Appendix E has been updated in the document, with a clarification added on the versions of the QPS list.

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Summary

The European Food Safety Authority (EFSA) asked the 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 biological agents, intentionally added to food and feed, which have achieved 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 generic pre-evaluation procedure to support safety risk assessments of biological agents performed by EFSA's scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of biological agents. 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 microbiological agents newly notified to EFSA within the previous 6-month period.

The first ToR requires ongoing updates of the list of biological agents 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 April and September 2021. Within this period, 70 notifications were received by EFSA, of which 42 were proposed for evaluation in feed, 17 for use as food enzymes, food additives and flavourings, nine as novel foods and two as plant protection products. The new notifications received between April and September 2021 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 until June 2021 were assessed. The articles were retrieved and assessed through an extensive literature search (ELS) protocol available in Appendix B (see https://doi.org/10.5281/zenodo.3607188) and the search strategies in Appendix C (see https://doi.org/10.5281/zenodo.3607192). No new information was found that would affect the QPS status of those TUs or their qualifications.

The QPS list was updated for the following items:

- Related to the recent revision of the taxonomy of the genus *Bacillus*, all the TUs belonging to a previously designated *Bacillus* species are transferred to the new species and both the previous and new names are included in the QPS list.
- *Lactobacillus cellobiosus* was first reclassified to as *Lactobacillus fermentum*, more recently renamed *Limosilactobacillus fermentum*.
- The qualification 'QPS only applies when the species is used for production purposes with absence of viable cells in the product' has been harmonised among the different TUs concerned.
- Synonyms of yeast species were added and the qualification 'absence of resistance to antimycotics' has been deleted for those yeast TUs for which the QPS status only qualifies for production purposes.
- The warning for the probiotic use of *Saccharomyces cerevisiae* has been deleted because this is out of the scope of the QPS assessment.

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 to each Panel Statement).

Six of the 70 notifications received, corresponding to six TUs, were evaluated for possible QPS status; *Paenibacillus lentus* was reassessed because an update was requested in relation to the current mandate. *Enterococcus lactis* synonym *Enterococcus xinjiangensis*, *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei*, *Schizochytrium aggregatum*, *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii* and *Haematococcus lacustris* synonym *Haematococcus pluvialis* were assessed for the first time. The following conclusions were drawn:

- *Paenibacillus lentus* is not recommended for QPS status due to a limited body of knowledge.
- *Enterococcus lactis;* synonym *Enterococcus xinjiangensis*, is not recommended for QPS status due to potential safety concerns.
- *Aurantiochytrium mangrovei;* synonym *Schizochytrium mangrovei*, is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.

- *Schizochytrium aggregatum* is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.
- *Chlamydomonas reinhardtii;* synonym *Chlamydomonas smithii;* is not recommended for QPS status due to a limited body of knowledge on its use in the food and feed chain.
- *Haematococcus lacustris* synonym *Haematococcus pluvialis* is recommended for QPS status with the qualification 'for production purposes only'.

Of the remaining 64 notifications, 43 notifications were related to TUs that already had QPS status and did not require further evaluation in this mandate. Twenty-one notifications were not included in the assessment because they were related to microorganisms that are generally excluded from QPS evaluation (11 were notifications of filamentous fungi, one of oomycetes, one of *Clostridium butyricum* (bacterium), one of *Enterococcus faecium* (bacterium), five of *Escherichia coli* (bacterium), one of *Streptomyces* sp. (bacterium)) or because the TU was not valid (one *Bacillus nakamurai*).

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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, requiring an EFSA safety assessment (EFSA, 2007). 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 TUs with QPS status. They also contain the assessment of newly arrived TUs to the EFSA Units currently dealing with feed additives, food enzymes, food additives and flavourings, novel foods, plant protection products and Genetically Modified Organisms (GMO). 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 chain. In the context of applications for market authorisation of these biological agents used, either directly or as sources of food and feed additives, food enzymes and plant protection products, EFSA is requested to assess their safety.

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 the stakeholders to the QPS approach. In its 2005 opinion (EFSA Scientific Committee, 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 taxonomic units (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 Scientific Committee, 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 started 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 2016 on, the QPS

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

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 available at the Knowledge Junction in Zenodo. The most recent QPS opinion (EFSA BIOHAZ Panel, 2020) 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 microbiological agents notified to EFSA requested by the Feed Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition Unit, the Pesticides Unit and the Genetically Modified Organisms (GMO) Unit, 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 standardized extensive literature search 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 decide 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 grouping (TU) for which QPS is sought ('*taxonomic identification*'); [2] whether sufficient relevant information is available about the proposed group of organisms to conclude on human/animal exposure by food/ feed ('*body of knowledge*'); [3] whether the grouping 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, 2020).

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 taxonomic unit 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 connected 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 (GMM) for which the species of the recipient strain qualifies for the QPS status, and for which the genetically modified state 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, if there is science-based evidence for a microbial species it is reported. 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 also *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits.

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

ToR 1: Keep updated the list of biological agents being notified in the context of a technical dossier to EFSA Units such as Feed, Pesticides, Food Ingredients and Packaging (FIP) and Nutrition, for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products 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 a review of the updated literature aiming at verifying if 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 efficiently exclude safety concerns.

ToR 3: (Re) assess the suitability of new taxonomic units notified to EFSA for their inclusion in the QPS list. These microbiological agents are notified to EFSA and requested by the Feed Unit, the FIP Unit, the Nutrition Unit or by the Pesticides Unit.

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 2021) was carried out. The literature review considered the identification, the body of knowledge, the potential safety concerns related to human and animal health and to the environment (EFSA BIOHAZ Panel, 2020). The environmental risk assessment of plant protection products is not included in the QPS assessment but carried out by the Pesticide Peer Review (PPR) Unit. The knowledge on relevant acquired antimicrobial resistance (AMR) is reflected in the safety sections.

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 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.

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 biological agents being notified to EFSA. A total of 70 notifications were received between April and September 2021, of which 42 were for evaluation for use in feed, 17 for use as food enzymes, food additives and flavourings, nine as novel foods and two as plant protection products (Table 1).

In response to ToR 3, six of the 70 notifications, corresponding to six TUs, were evaluated for possible QPS status, five of these (*Enterococcus lactis* synonym *Enterococcus xinjiangensis*, *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei* and *Schizochytrium aggregatum*, *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii*, *Haematococcus lacustris* synonym *Haematococcus pluvialis*,) being evaluated for the first time. The other, *Paenibacillus lentus* was re-assessed because an update was requested in the current mandate.

Of the remaining 64 notifications, 43 notifications were related to TUs that already had QPS status and did not require further evaluation in this mandate. A further 21 notifications were not included in the assessment because they were related to microorganisms that are generally excluded from QPS evaluation (11 were notifications of filamentous fungi, one of oomycetes, one of *Clostridium butyricum* (bacterium), one of *Enterococcus faecium* (bacterium), five of *Escherichia coli* (bacterium), one *Streptomyces* sp. (bacterium)) or because the TU was not valid (one *Bacillus nakamurai*).

Table 1: Notifications received by EFSA, per risk assessment area and by biological group, from April to September 2021

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[(b)]	Total
Biological group	**Already QPS**	**Excluded in QPS[(a)]**		
Feed	32	8	2	42
Bacteria	20	4	2	26
Filamentous fungi	0	4	0	4
Yeasts	12	0	0	12
Novel foods	1	4	4	9
Bacteria	0	2	0	2
Filamentous fungi	0	2	0	2
Protists/Algae	0	0	4	4
Yeasts	1	0	0	1

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[b]	Total
Biological group	**Already QPS**	**Excluded in QPS[a]**		
Plant protection products	0	2	0	2
Bacteria	0	1	0	1
Oomycetes	0	1	0	1
Viruses	0	0	0	0
Food enzymes, food additives and flavourings	10	7	0	17
Bacteria	7	2	0	9
Filamentous fungi	0	5	0	5
Yeasts	3	0	0	3
Genetically modified organism	0	0	0	0
Bacteria	0	0	0	0
Total	43	21	6	70

QPS: qualified presumption of safety.
(a): The number includes 11 notifications of filamentous fungi, one of oomycetes, one of *Clostridium butyricum* (bacterium), one of *Enterococcus faecium* (bacterium), five of *Escherichia coli* (bacterium) and one of *Streptomyces sp*. (bacterium), all excluded from QPS evaluation, as well as one of *Bacillus nakamurai*, a TU that is not valid and therefore not suitable for the QPS approach.
(b): 6 notifications corresponding to six TUs, one of which was last evaluated in 2018 (*Paenibacillus lentus*) and five were evaluated for the first time *(Enterococcus lactis* synonym *Enterococcus xinjiangensis*, *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei* and *Schizochytrium aggregatum*, *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii*, *Haematococcus lacustris* synonym *Haematococcus pluvialis*).

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 search strategies were updated to include the following synonyms:

- *Bacillus clausii: Alkalihalobacillus clausii*
- *Bacillus coagulans: Weizmannia coagulans*
- *Bacillus flexus: Priestia flexa*
- *Bacillus fusiformis: Lysinibacillus fusiformis*
- *Bacillus lentus: Lederbergia lentus*
- *Bacillus megaterium: Priestia megaterium*
- *Candida cylindracea: Limtongozyma cylindracea*
- *Lindnera jadinii: Cyberlindnera jadinii*
- *Yarrowia lipolytica: Candida lipolytica*

The search period for *Cyberlindnera jadinii* and *Candida lipolytica* was extended to include articles from 2010 onwards, the other synonyms were searched for the period covering January–June 2021.

The Artificial Intelligence (AI) function was used for prescreening 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 2021).

For case reports of human infections or intoxications, important additional information includes whether specific negative health outcomes are confined to persons with conditions favouring opportunistic infections, e.g. immunosuppression, and whether transmission occurred through food or other routes (e.g. through medical devices). 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 immunological 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 proton pump inhibitors can also be a predisposing factor for infection. Previous use of the microorganisms being assessed as food supplements for humans was reported in many of these cases. A living microorganism used as a food supplement does not fall under the remit of the QPS assessment because regulation does not require an EFSA assessment. Nevertheless, the QPS assessment takes into consideration these reports, extracting relevant information whenever justified. For a detailed protocol of the process and search strategies, refer to Appendices B and C.

After removal of duplicates, 2,478 records were submitted to the title screening step, which led to the exclusion of 2,291 of these. The remaining 187 records were found eligible for the title and abstract screening step, which led to the exclusion of 118 of these. Of the 69 articles that finally reached the article evaluation step (full text), 27 were considered to report a potential safety concern and were further analysed.

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

Table 2: Flow of records by search strategy step

Species	Title 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)	**1713**	**94**	**25**	**10**
Bacillus spp.[(a)]	249	25	5	3
Bifidobacterium spp.[(a)]	141	8	2	0
Carnobacterium divergens	1	1	1	0
Corynebacterium glutamicum	26	1	0	0
Gluconobacter oxydans/ Xanthomonas campestris	265	3	0	0
Lactobacilli[(a)]	299	16	7	5
Lactococcus lactis[(a)]	69	2	2	1
Leuconostoc spp.	88	8	5	1
Microbacterium imperiale	0	0	0	0
Oenococcus oeni	43	0	0	0
Pasteuria nishizawae	0	0	0	0
Pediococcus spp.	189	7	1	0
Propionibacterium spp.	32	2	0	0
Streptococcus thermophilus	311	21	2	0
Viruses (total)	**69**	**0**	**0**	**0**
Alphaflexiviridae/Potyviridae	42	0	0	0
Baculoviridae	27	0	0	0
Yeasts[(a)]	**500**	**62**	**39**	**17**
Protists	**28**	**12**	**4**	**0**
Algae	**168**	**19**	**1**	**0**
Total	**2478**	**187**	**69**	**27**
Excluded	**2291**	**118**	**42**	

(a): The numbers of references pre-screened by AI and excluded are not reported in the table and are for: *Bifidobacterium* spp. (142), lactobacilli (296), *Lactococcus lactis* (69), *Bacillus* spp. (271), yeasts (504).

3. Assessment

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

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

3.1.1. Bacteria

Paenibacillus lentus

Paenibacillus lentus has been previously evaluated and was not included in the QPS list due to lack of body of knowledge (EFSA BIOHAZ Panel, 2014, 2018).

Identity

P. lentus is an aerobic, endospore-forming and rod-shaped bacterium, belonging to the phylum *Firmicutes*. This species was described by Li et al. (2014). *P. lentus* is not a synonym of *Bacillus lentus* as demonstrated by the low percentage of 16S rRNA gene sequence identity of the corresponding type strains.

Body of knowledge

The type strain of *P. lentus* shows β-mannanase activity and was isolated from soil. The endo-1,4-β-D-mannanase is of industrial interest and can be used as a feed additive (EFSA FEEDAP Panel, 2017, 2018). No new body of knowledge was found.

Safety concerns

No relevant information on *P. lentus* was found.

Conclusion on a recommendation for QPS status

Due to a limited body of knowledge, *P. lentus* is not recommended for QPS status.

3.2. Taxonomic units to be evaluated for the first time

3.2.1. Bacteria

Enterococcus lactis synonym *Enterococcus xinjiangensis*

Identity

Enterococcus lactis was originally isolated from dairy products and described by Morandi et al. (2012). The species *Enterococcus xinjiangensis* (Ren et al., 2016; Oren and Garrity, 2020) was accepted as a heterotypic synonym of *E. lactis* (Li and Gu, 2021). Belloso Daza et al. (2021) reassigned the strains of *Enterococcus faecium* clade B to *E. lactis*.

Body of knowledge

E. lactis was isolated from traditional chickpea liquid starter and dough samples for bakeries in Turkey (Gunduz et al., 2020), from traditional (raw) milk cheeses (Morandi et al., 2012; Mangia et al., 2016), artisanal animal rennet pastes (Cruciata et al., 2014) and a traditional cereal based Indian product (idli batter) (Thumu and Halami, 2012). Recent evidence supports the presence of *E. lactis*, which was previously identified as *E. faecium* clade B, in the human and animal gut (Belloso Daza et al., 2021).

Several strains of *E. lactis* show biotechnological properties, probiotic potential and bacteriocinogenic activities for application as starter, adjunct, protective or probiotic cultures in the food industry (Bauer et al., 2009; Sharma et al., 2012; Nami et al., 2015; Albano et al., 2018, 2020; Braïek et al., 2018a,b, 2019).

Safety concerns

There are insufficient data on the role in human infections and the presence of virulence genes of current ampicillin susceptible *E. faecium* clade B, that correspond to *E. lactis* (Freitas et al., 2018; Belloso Daza et al., 2021).

Conclusions on a recommendation for QPS status

Due to potential safety concerns, *E. lactis* is not recommended for QPS status.

3.2.2. Protists

Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei

Identity

Schizochytrium mangrovei isolated on decaying mangrove leaves from Goa, India was described in 1988 by Raghu-Kumar. Yokoyama and Honda (2007) described *Schizochytrium sensu lato* and proposed three different genera, i.e. *Schizochytrium sensu stricto*, *Aurantiochytrium* and *Oblongichytrium* gen. nov. *Aurantiochytrium mangrovei* was proposed as the new name for *S. mangrovei*. The division into three genera was supported by 18S rRNA gene phylogenetic analysis (Yokoyama and Honda, 2007).

Many references still use the name *S. mangrovei*.

Body of knowledge

A. mangrovei is cultivated heterotrophically and is often tested for the production of omega-3 fatty acids, squalene (Jiang et al., 2004; Unagul et al., 2005; Hoang et al., 2016, 2018; Hien et al., 2017) or biodiesel (Hong et al., 2013). Hoang et al. (2016) concluded that squalene isolated from *A. mangrovei* is a peroxisome proliferator-activated receptor-α agonist. Furthermore, studies showed potential effect on anti-aging of *A. mangrovei* for *Drosophila melanogaster* (Huangfu et al., 2013), on anti-inflammation of an ethanol extract on murine macrophage RAW264 cells (Takahashi et al., 2018) and on enrichment of highly unsaturated fatty acid rich freeze-dried biomass of *A. mangrovei* for the rotifer *Brachionus plicatilis* (Estudillo-del Castillo et al., 2009).

Safety concerns

Thom and Hong (2021) concluded that *A. mangrovei* TB17 bio-oil met the Vietnamese food safety standard. According to the results of assessment of the acute toxicity in mice and the subchronic oral toxicity in rats for 90 days, the bio-oil rich in omega 3–6 fatty acids is safe.

Conclusion on a recommendation for QPS status

A. mangrovei, synonym *S. mangrovei*, is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.

Schizochytrium aggregatum

Identity

Schizochytrium aggregatum was first described by Goldstein and Belsky (1964). *S. aggregatum* divides by successive bi-partitioning to form tetrads of zoosporangia (Goldstein and Belsky, 1964). Eventually, the vegetative cells undergo a progressive cleavage to form zoospores (Moss, 1986). *S. aggregatum* can produce up to 64 zoospores, reniform to ovoid in shape, while the zoosporangium can reach up to 140 μm (Dick, 2001; Fossier Marchan et al., 2018). Yokoyama and Honda (2007) described *Schizochytrium* sensu lato as showing large pale-yellow colonies due to the production of β-carotene, which are characterised by successive binary divisions of its vegetative cells. The authors proposed three different genera, i.e. *Schizochytrium sensu stricto*, *Aurantiochytrium* and *Oblongichytrium gen. nov. S. aggregatum* is the only species within the genus *Schizochytrium*.

The division into three genera was supported by 18S rRNA gene phylogenetic analysis (Yokoyama and Honda, 2007).

Body of knowledge

S. aggregatum is a heterotrophic microorganism with industrial applications to produce omega-3 fatty acids.

Safety concerns

No specific information regarding safety in relation to food or feed was found in literature for *S. aggregatum*.

Conclusion on a recommendation for QPS status

S. aggregatum is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.

3.2.3. Algae

Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii

Identity

Chlamydomonas reinhardtii (heterotypic synonym *Chlamydomonas smithii*) is a freshwater green alga belonging to the family *Chlamydomonadaceae* and has a standing nomenclature (ITIS - Report: *Chlamydomonas reinhardtii*). *C. reinhardtii* is of high interest in genomic research because of rapid growth and ability to grow easily on plates and in liquid media. *C. reinhardtii* can grow autotrophically with CO_2 as the carbon source, or heterotrophically by consuming acetate or mixotrophically when utilising CO_2 and acetate as the carbon source.

Body of knowledge

An extensive literature screening resulted in one relevant article addressing toxicological aspects of *C. reinhardtii*. Murbach et al. (2018) investigated the safety of *C. reinhardtii* for use as a nutritional human food ingredient. No evidence of mutagenicity or genotoxic activity, or toxicity was observed.

Safety concerns

The only toxicological study dealt with a single strain; no safety concerns were identified (Murbach et al., 2018).

Conclusion on a recommendation for QPS status

C. reinhardtii, synonym *C. smithii*, is not recommended for QPS status due to limited body of knowledge for its use in the food and feed chain.

Haematococcus lacustris* synonym *Haematococcus pluvialis

Haematococcus lacustris was evaluated in 2008 (EFSA, 2008) and was not recommended for QPS due to a lack of a body of relevant knowledge.

Identity

H. lacustris is a freshwater, unicellular green microalga described by Nakada and Ota (2016). Buchheim et al. (2013) indicated that *Haematococcus* isolates from diverse localities belonged to a single species based on similarities in their 18S and ITS2 rDNA sequences and currently, only one species is recognised in the genus. Confusingly, two names, *Haematococcus lacustris* and *H. pluvialis*, are currently used for this species. Nakada and Ota (2016) indicated H. *lacustris* as the correct name, however both names are used and are considered appropriate.

Body of knowledge

H. lacustris strains are well known producers of astaxanthin (Mota et al., 2021). Several studies assessed the safety of astaxanthin derived from *H. lacustris* and no adverse effects were observed within the use levels (Guerin et al., 2003; Spiller and Dewell, 2003; Satoh et al., 2009; Katagiri et al., 2012; EFSA NDA Panel, 2014; Régnier et al., 2015; Brendler and Williamson, 2019).

Steward et al. (2008) determined the no-observed adverse-effect-levels (NOAEL) of the astaxanthin-rich biomass from *H. lacustris* for male and female rats as 14,161 and 17,076 mg/kg body weight per day, or 465 and 557 mg astaxanthin/kg per day, respectively. For mice, no adverse effects of administration of astaxanthin from *H. lacustris* throughout pregnancy on mice were reported (Niu et al., 2020). In a recent study, sea bass fed with *H. lacustris* biomass-containing diets did not show negative effects and results indicated that dietary supplementation with the suitable level (0.4–0.6%) of *H. lacustris* could promote certain performance parameters (Yu et al., 2021).

Safety concerns

No safety concerns on application of astaxanthin from *H. lacustris* and of the astaxanthin containing biomass were found in the literature.

Conclusion on a recommendation for QPS status

H. lacustris, synonym *H. pluvialis*, 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 to June 2021 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 283 references. The artificial intelligence (AI) analysis left 141. Title screening left eight references for abstract inspection, then two for a full article appraisal. This last step discarded the articles because no safety concerns were identified in these papers.

No articles were identified describing possible safety concerns related to the QPS-listed *Bifidobacterium* species. Consequently, the QPS status of these species is not changed.

Carnobacterium divergens

A search for potentially relevant papers on *C. divergens* provided one reference. No article was considered relevant at the level of title screening 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 26 references. One paper reached the level of title and abstract screening but did not reach full text evaluation. 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 divided into 13 new genera, provided 595 references. The AI analysis left 299 articles. Title screening of these provided 16 references for abstract inspection, which further reduced their number to seven. One of them was not in English, another did not describe safety concerns, two (Jimenez-Gutierrez et al., 2021; Tang et al., 2021) did not provide any information on the microbial identification methods used and one (Campisciano et al., 2020) tried to link vaginal *Lactobacillus gasseri* colonisation to infertility, but no data on the presence/absence of the organism in the vaginas of fertile women were provided. The two remaining articles described the case of a patient with pyogenic liver abscesses that rendered *L. gasseri* (Ramos-Coria et al., 2021) and two cases of bacteraemia by *Lacticaseibacillus rhamnosus* (Bergas et al., 2021). These last two cases affected old patients with a history of cardiac comorbidities, while the *L. gasseri* infection occurred in a person that suffered previous multiple abdominal interventions (cholecystectomy, distal pancreatectomy, splenectomy and pancreaticojejunal anastomosis), all of which might have been predisposing conditions leading to the opportunistic infections described. Based on the available evidence as described above, the QPS status of any of the QPS species included in the former genus *Lactobacillus* is not changed.

Lactococcus lactis

A search for papers potentially relevant for the QPS status of *L. lactis* provided 138 references. The AI analysis left 69 papers. Title and abstract screenings of these reduced their number to two. No

safety concerns were raised by one paper, while the other (El Hattabi et al., 2021) described a liver abscess in an immunocompetent 27-year-old person without co-morbidities. However, the article does not describe how identification was performed and doubts on the correct assignation to *L. lactis* remain.

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 88 references. The analysis of their titles left eight articles for title/abstract screening. Five articles reached full text evaluation, and one dealt with possible safety concerns (Gagliardo et al., 2021). It was excluded because the identification procedures were considered 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 references 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 43 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 189 references. The analysis of their titles left seven articles for the title/abstract phase. One article reached the full text evaluation stage but did not identify a safety concern. Consequently, the status of QPS-listed *Pediococcus* spp. is not changed.

***Propionibacterium* spp.**

A search for papers potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 32 references. Following the analysis of their titles, two articles were selected for abstract screening or the full article evaluation phase, but no safety concerns were identified. 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 311 references. The analysis of their titles left 21 articles for title and abstract screening. The two selected articles 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

***Bacillus* spp.**

A search for papers potentially relevant for *Bacillus* spp. provided 520 references. The AI analysis left 249 articles. The analysis of their titles left 25 articles for the abstract phase and, from these, five articles passed to the full text phase for further analysis. Two papers did not deal with safety concerns. Three papers were further analysed. Russo et al. (2021) reported a spondylodiscitis caused by *Bacillus circulans* (*Niallia circulans*) in a 65-year-old patient with hypertension without a link to food intake. The identification occurred by MALDI-TOF MS and no further information, e.g. on cytotoxic properties, was provided. The paper of Khatri et al. (2021) described a bacteraemia case after probiotic use of *Bacillus clausii* by a 17- year-old person. The identification to the species level was performed by MALDI-TOF MS and confirmed by a 'state reference laboratory' without further details. Basit et al. (2021) reported the isolation of *Bacillus subtilis* strains from burn wounds in 11 patients without documenting the identification method.

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

Geobacillus stearothermophilus

A search for papers potentially relevant for *G. stearothermophilus* provided 520 references. The AI analysis left 249 articles. The analysis of their titles by two experts left 25 articles and for five of these the full text was analysed. None 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. 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 *G. oxydans* and *X. campestris* provided 265 references.

Gluconobacter oxydans

The analysis of the titles left no paper. Consequently, the QPS status of *G. oxydans* is not changed.

Xanthomonas campestris

The analysis of the titles left three articles, which reached the evaluation phase for this TU, but neither eventually dealt with health or 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 1004 references. The AI analysis left 500 articles. After title screening, 62 studies remained for the title/abstract phase, and from these 39 articles passed to the full article appraisal. Out of these, 17 reported a possible safety concern.

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

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

Kluyveromyces marxianus

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

Several studies reported opportunistic infections with *K. marxianus* in humans with various predisposing conditions but could not be appropriately evaluated due to uncertainties regarding methodology for species identification (Nurdin et al., 2021; Alp et al., 2021; Pedaci et al., 2021; Jyothi et al., 2021). Aldejohann et al. (2021) reported eye infection with *K. marxianus* following surgery (transplantation of a lamellar endothelial corneal graft). In a literature review, Bayoumi et al. (2021) found that *K. marxianus* was one of several yeasts that had been reported to cause gut fermentation syndrome (GFS), where consumed carbohydrates are converted to alcohol by the gut microbiota. Perez-Traves et al. (2021) investigated factors potentially related to virulence in opportunistic strains of *K. marxianus*. All strains, but one, were positive in most virulence related factors and there were no general differences between strains of environmental/food origin and strains of clinical origin. Additionally, the extent to which the investigated properties actually contribute to the ability of *K. marxianus* to cause opportunistic infections is uncertain. In a study of virulence-related properties of yeasts isolated from bovine milk, a minor fraction (eight of 66 isolates) were *K. marxianus*. These cows had subclinical signs of infection, but no signs of disease. Thus, it is uncertain whether the isolated strains can actually cause disease. Desnos-Ollivier et al. (2021) reported in a retrospective study of antimycotic susceptibility in a collection of clinical yeasts that the *K. marxianus* strains (ca 1% of the more than 9,000 isolates) were susceptible to fluconazole, voriconazole and posaconazole.

In conclusion, the literature update showed mainly the isolation of *K. marxianus* from patients who are immunocompromised and/or have underlying disease. Also, methodological problems concerning

identification (no confirmation by use of DNA-based molecular methods) and source attribution were noted. Thus, the papers did not identify any information that would change the QPS status of *K. marxianus*.

Yarrowia lipolytica

The anamorph name of *Y. lipolytica* is *Candida lipolytica*.

Desnos-Ollivier et al. (2021) reported in a retrospective study of antimycotic susceptibility in a collection of clinical yeasts that the *Y. lipolytica* strains (0.3% of more than 9,000 isolates) showed intermediate susceptibility to fluconazole.

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

Debaryomyces hansenii

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

Two references related to possible concerns for human safety were identified. Ghaith et al. (2021) is a retrospective taxonomic study of a yeast collection from intensive care units of a hospital in Egypt but could not be evaluated appropriately regarding the methodology for species identification by conventional methods and MALDI-TOF MS. Perez-Traves et al. (2021) investigated factors potentially related to virulence in a collection of clinical and food/environmental isolated strains of *D. hansenii*, *K. marxianus* and *W. anomalous*. All the tested *D. hansenii* strains were positive for sporadic virulence-related properties but there were no statistically significant differences between the clinical and the food/environmental isolates. As has been described above for *K. marxianus*, it is uncertain whether the strains can cause disease.

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

Saccharomyces cerevisiae

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

In a literature review, Bayoumi et al. (2021) found that *S. cerevisiae* was one of several yeasts that had been reported to be able to cause the gut fermentation syndrome (GFS), where consumed carbohydrates are converted to alcohol by the gut microbiota. In a retrospective study of cases of *S. cerevisiae* fungaemia, Poncelet et al. (2021) noted that in rare cases, administration of *S. boulardii* probiotics to patients with gastrointestinal diseases might lead to dissemination of the yeast across the epithelial barriers, and subsequent fungaemia. In a retrospective study, Desnos-Ollivier et al. (2021) reported antimycotic susceptibility in a collection of clinical yeasts. The *S. cerevisiae* strains (61 of more than 9,000 isolates) had intermediate susceptibility to fluconazole.

The reports on *S. cerevisiae* did not add any new information that would change the current QPS status of this species.

Wickerhamomyces anomalus

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

Seven publications reported potential safety concerns. Several studies reported opportunistic infections with *W. anomalus* in humans or neonate children with various predisposing conditions but could not be evaluated appropriately due to uncertainties or problems with the methodology used for identification of yeasts (Alp et al., 2021; Shubham et al., 2021; Zhang et al., 2021). Desnos-Ollivier et al. (2021) reported antimycotic susceptibility of 36 strains of *W. anomalus* in a retrospective study of more than 9.000 clinical strains. Cai et al. (2021) reported a case of *C. pelliculosa* fungaemia in a neonatal boy. Due to several disease symptoms at birth, he immediately received airway pressure-assisted ventilation, vitamin supplementation and intravenous fluid. He developed a fever after six days and was diagnosed with fungaemia after 24 days. *C. pelliculosa* was identified as the causative organism using blood culture, DNA sequencing and mass spectrometric analysis. He recovered after fluconazole therapy. Kaur et al. (2021) performed a systematic epidemiologic study on fungaemia caused by rare yeasts, and from a total of 127 isolates, 43 were identified as *W. anomalous*. Perez-Traves et al. (2021) investigated factors potentially related to virulence and pathogenicity in a *Galleria mellonella* model for a collection of clinical and food/environmental isolates of *D. hansenii*, *K. marxianus* and *W. anomalous*. The *W. anomalous* clinical isolates were positive in several properties (growth to high temperatures, pseudohyphal growth and agar invasion) and differed statistically

significantly from the food/environmental isolates with regard to such properties. The results suggest that these factors are likely to contribute to virulence in strains of *W. anomalus* causing opportunistic infections.

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

3.3.5. Protists

Aurantiochytrium limacinum

A search for papers potentially relevant for *A. limacinum* provided 28 articles. The analysis of their titles left 12 articles and for four of these the full text was analysed. No article indicated a safety concern, therefore the current QPS status of *A. limacinum* is not changed.

3.3.6. Algae

A search for papers potentially relevant for algae provided 168 articles. The analysis of their titles left 19 articles and for one 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.

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 42 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 27 references. One article dealing with *Baculoviridae* passed the title screening but did not reach the full article evaluation stage, thus no new safety concern was identified. Therefore, the current QPS status remains unchanged.

4. Update of the QPS List

4.1. Taxonomic changes in bacilli included in the QPS list

Bacilli are an extremely heterogeneous group within the phylum Firmicutes, exhibiting great phylogenetic and phenotypic diversity. The species traditionally included important agents in industrial microbiology (antibiotic and enzyme producers), food (pathogens, spoilage and fermentation agents) and feed additives or plant protection products.

The systematics of the genus *Bacillus* has been recently revised (Gupta et al., 2020; Patel and Gupta, 2020) and several changes have been proposed to clarify the evolutionary relationships and taxonomic structure.

Reclassification of a number of TU, which are not related to the Subtilis or the Cereus clades, into other genera has been carried out. Based on phylogenetic and molecular evidence after studying more than 300 *Bacillus/Bacillaceae* genomes, Gupta et al. (2020) proposed 17 *Bacillus* species clades that are now recognised as novel genera. Additionally, Patel and Gupta (2020) proposed a transfer of species from several clades into 6 novel *Bacillaceae* genera.

In Table 3, the previous and current designations of the QPS *Bacillus* species are presented. To maintain continuity within the QPS list, all the TUs belonging to a previously designated *Bacillus* species are transferred to the new species. Both the previous and new names are included in the QPS list.

Table 3: Previous and current designations of the QPS Bacillus species

Species included in the QPS list	New nomenclature
Bacillus amyloliquefaciens	
Bacillus atrophaeus	
Bacillus circulans	*Niallia circulans*
Bacillus clausii	*Alkalihalobacillus clausii*
Bacillus coagulans	*Weizmannia coagulans*
Bacillus flexus	*Priestia flexa*
Bacillus fusiformis	*Lysinibacillus fusiformis*
Bacillus lentus	*Lederbergia lentus*
Bacillus licheniformis	
Bacillus megaterium	*Priestia megaterium*
Bacillus mojavensis	
*Bacillus paralicheniformis**	
Bacillus pumilus	
Bacillus smithii	
Bacillus subtilis	
Bacillus vallismortis	
*Bacillus velezensis***	

*: Qualification: 'absence of genetic information to synthesize bacitracin'.
**: Qualification: 'absence of aminoglycoside production'.

4.2. Reassignment of *Lactobacillus cellobiosus*

Lactobacillus cellobiosus, originally described by Rogosa et al. (1953) has been deleted from the QPS list because the strains belonging to this species were first reclassified as *Lactobacillus fermentum* (Dellaglio et al., 2004), and more recently renamed *Limosilactobacillus fermentum* (Zheng et al., 2020).

4.3. Qualification 'QPS only applies when the species is used for production purposes'

The qualification 'QPS only applies when the species is used for production purposes' has been updated for consistency (Table 4).

Table 4: Update on QPS qualifications

Taxonomic unit	Original qualification	Updated qualification
Gluconobacter oxydans	QPS only applies when the species is used for vitamin production	QPS applies for 'production purposes only'*
Xanthomonas campestris	QPS only applies when the species is used for the production of xanthan gum.	QPS applies for 'production purposes only'*
Candida cylindracea	QPS only applies when the species is used for enzyme production.	QPS applies for 'production purposes only'*
Ogataea angusta	QPS only applies when the species is used for enzyme production.	QPS applies for 'production purposes only'*
Microbacterium imperiale	QPS only applies when the species is used for enzyme production.	QPS applies for 'production purposes only'*
Niallia circulans	'For production purposes only…'	QPS applies for 'production purposes only'*
Cyberlindnera jadinii	QPS only applies when the species is used for enzyme production	QPS applies for 'production purposes only'*
Komagataella pastoris	QPS only applies when the species is used for enzyme production	QPS applies for 'production purposes only'*
Komagataella phaffii	QPS only applies when the species is used for enzyme production	QPS applies for 'production purposes only'*

Taxonomic unit	Original qualification	Updated qualification
Wickerhamomyces anomalus	QPS only applies when the species is used for enzyme production	QPS applies for 'production purposes only'*

*: 'QPS applies for 'production purposes only' (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 for food and feed products based on microbial biomass)'.

For some TUs, data are lacking on the direct exposure of humans and animals to viable cells, while there is a long history of use of their fermentation products and/or their biomasses in the food and/or feed chain. This qualification implies the absence of viable production organisms in the final product and is also applicable to food and feed products based on the non-viable biomass of the microorganism (EFSA BIOHAZ Panel, 2018).

4.4. Synonyms for yeast species

In the QPS list the following synonyms for yeast species were added: *Candida lipolytica* as the anamorph of *Yarrowia lipolytic*a; *Lindnera jadinii* as a synonym to the new name *Cyberlindnera jadinii*; and *Candida cylindracea* as a synonym to the new name *Limtongozyma cylindrac*ea.

4.5. Qualification 'absence of resistance to antimycotics'

The qualification 'absence of resistance to antimycotics used for medical treatment of yeast infections in cases where viable cells are added to the food or feed chain' has been deleted in those cases where the taxonomic unit is only qualified for QPS in the case of production purposes. This is because this qualification implies the absence of viable yeast cells in the product. This was the case for: *Cyberlindnera jadinii*, *Komagataella pastoris*, *Komagataella phaffii*, *Limtongozyma cylindracea*, *Ogataea angusta*, *Wickerhamomyces anomalus*, *Yarrowia lipolytica*.

In the case of *Saccharomyces cerevisiae* the qualification 'absence of resistance to antimycotics used for medical treatment of yeast infections in cases where viable cells are added to the food or feed chain' applies not only for strains able to grow at 37°C and above but to all strains that are used as viable cells.

4.6. Deletion of the note about *Saccharomyces cerevisiae* related to its probiotic use

The note '*Saccharomyces cerevisiae*, subtype *boulardii* is contraindicated for persons with fragile health, as well as for patients with a central venous catheter in place' has been deleted. This concern is related to the probiotic use of this TU, which is out of the scope of the QPS assessment.

Conclusions

ToR 1: *Keep updated the list of biological agents being notified, in the context of a technical dossier to EFSA Units (such as Feed, Food Ingredients and Packaging, Nutrition, Pesticides, Genetically Modified Microorganisms), 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 2021, the list of notifications was updated with 70 notifications that were received by EFSA, of which 42 were proposed for evaluation as feed additives, 17 for use as food enzymes, food additives and flavourings, nine as novel foods and two 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 in the period January to June 2021, there were no results that would justify changing the status of any TU from the QPS list.
- The QPS list was updated for the following items:

- Related to the recent revision of the taxonomy of the genus *Bacillus*, all the TUs belonging to a previously designated *Bacillus* species are transferred to the new species and both the previous and new names are included in the QPS list.
- *Lactobacillus cellobiosus* (formerly *Lactobacillus fermentum*) has been deleted from the QPS list because the strains belonging to this species were reclassified as *Limosilactobacillus fermentum*.
- The qualification 'QPS only applies when the species is used for production purposes with absence of viable cells in the product' has been harmonised among the different TUs concerned.
- The QPS list was updated in relation to synonyms of yeast species.
- The qualification 'absence of resistance to antimycotics' has been deleted for those yeast TUs for which the QPS status only qualifies for production purposes.
- The warning for the probiotic use of *Saccharomyces cerevisiae* has been deleted because this is out of the scope of the QPS assessment.

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 70 notifications received between April and September 2021, 43 were related to TUs that already had QPS status and did not require further evaluation.
- Of the remaining 27 notifications, 21 notifications were related to microorganisms that are generally excluded from QPS evaluation (11 were notifications of filamentous fungi, one of oomycetes, one of *Clostridium butyricum* (bacterium), one of *Enterococcus faecium* (bacterium), five of *Escherichia coli* (bacterium), one of *Streptomyces* sp. (bacterium)), and one notification for *Bacillus nakamurai* was not suitable for the QPS approach because it is not a valid TU.
- Six notifications, corresponding to six TUs, were evaluated for possible QPS status. *Paenibacillus lentus* was re-assessed because an update was requested in relation to the current mandate. *Enterococcus lactis* synonym *Enterococcus xinjiangensis*, *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei*, *Schizochytrium aggregatum*, *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii* and *Haematococcus lacustris* synonym *Haematococcus pluvialis* were assessed for the first time:
  - *Paenibacillus lentus* is not recommended for QPS status due to a limited body of knowledge.
  - *Enterococcus lactis*, synonym *Enterococcus xinjiangensis*, is not recommended for QPS status due to potential safety concerns.
  - *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei* is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.
  - *Schizochytrium aggregatum* is not recommended for QPS status due to lack of a body of knowledge on its occurrence in the food and feed chain.
  - *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii* is not recommended for QPS status due to a limited body of knowledge for its use in the food and feed chain.
  - *Haematococcus lacustris* synonym *Haematococcus pluvialis* is recommended for QPS status with the qualification 'for production purposes only'.

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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
MALDI-TOF	matrix-assisted laser desorption/ionization (MALDI), time-of-flight (TOF)
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
rDNA	ribosomal deoxyribonucleic acid
rRNA	ribosomal ribonucleic acid
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group

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)

A.1. *Paenibacillus lentus*

The search on PubMed led to 168 hits related to "Paenibacillus lentus". All hits were screened for their relevance.

A.2. *Enterococcus lactis*

The search on PubMed led to 26 hits related to "Enterococcus lactis". All hits were screened for their relevance.

A.3. *Aurantiochytrium mangrovei* synonym *Schizochytrium mangrovei*

A search on PubMed and Scopus ("Schizochytrium mangrovei") or ("S. mangrovei") or ("Aurantiochytrium mangrovei") or ("A. mangrovei") led to 21 and 48 hits of which 1 was considered relevant for the assessment.

A.4. *Schizochytrium aggregatum*

A search on PubMed, Scopus and 'web of science' ("Schizochytrium aggregatum") or ("S. aggregatum") or ("S. aggregatum") led to 33, 30 and 11 documents, respectively, of which none were considered relevant for the assessment.

A.5. *Chlamydomonas reinhardtii* synonym *Chlamydomonas smithii*

A search on PubMed (14.10.2021, Title and abstract, ("Chlamydomonas reinhardtii" or "C. reinhardtii") AND (safety OR infect* OR diseas* OR toxi* OR antimicrobial resistance) led to 597 results of which 1 was considered appropriate for the assessment.

A.6. *Haematococcus lacustris* synonym *Haematococcus pluvialis*

A search on PubMed (12.8.2021, ("H. pluvialis" OR "Haematococcus pluvialis") AND (safety OR infect* OR diseas* OR toxi* OR antimicrobial resistance) led to 58 results of which 11 were considered appropriate for the assessment. Scopus and "Web of science" searches did not yield relevant new information. A search on *(*"Haematococcus lacustris" OR "H. lacustris") *AND* (safety OR infect* OR diseas* OR toxi* OR antimicrobial resistance) in PubMed and Scopus did not yield information relevant for the assessment.

Appendix B – Protocol for Extensive literature search (ELS), relevance screening, and article evaluation for the maintenance and update of list of QPS-recommended biological agents (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 biological agents intentionally added to the food or feed (EFSA-Q-2020-00080) 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 biological agents (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 2021 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium spp.

None.

Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

Bergas A, Rivera S, Torrecillas M and Cuervo G, 2021. Native and prosthetic transcatheter aortic valve infective endocarditis due to Lactobacillus rhamnosus. Enfermedades infecciosas y microbiologia clinica.

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Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

None.

Propionibacterium spp.

None.

Streptococcus thermophilus

None.

Gram-Positive Spore-forming Bacteria

Bacilli

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Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Gram-negative bacteria

Gluconobacter oxydans

None.

Xanthomonas campestris

None.

Yeasts

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Pedaci FA, Filippeschi C, Giovannini M, Dolce D and Oranges T, 2021. Kerion-Like Scalp Mycosis Caused by *Candida kefyr*. The Journal of Pediatrics, 235, 298–300.

Perez-Traves L, e Llanos R, Flockhart A, Garcia-Domingo L, Groenewald M, Perez-Torrado R and Querol A, 2021. Virulence related traits in yeast species associated with food; *Debaryomyces hansenii*, *Kluyveromyces marxianus*, and *Wickerhamomyces anomalus*. Food Control, 124.

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Zhang Z, Cao Y, Li Y, Chen X, Ding C and Liu Y, 2021. Risk factors and biofilm formation analyses of hospital-acquired infection of Candida pelliculosa in a neonatal intensive care unit. Bmc Infectious Diseases, 21, 620.

Protists/algae

None.

Viruses used for plant protection

Alphaflexiviridae

None.

Potyviridae

None.

Baculoviridae

None.

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

The list of QPS status recommended biological agents (EFSA BIOHAZ Panel, 2020) is being maintained in accordance with the mandate of the BIOHAZ Panel (2020–2022), extended for the following years. Possible additions to this list are included approximately every 6 months, with the last Panel Statement (15) adopted in December 2021 (EFSA BIOHAZ Panel, 2022). These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2020); 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 April 2021 and September 2021 (reply to ToR 1)

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							
Chlamydomonas reinhardtii		Novel foods	Novel Food		EFSA-Q-2021-00476	No	**Yes**
Haematococcus pluvialis		Novel foods	Novel Food	Production of algal meal and oleoresin as novel foods	EFSA-Q-2021-00319	No	**Yes**
Schizochytrium aggregatum		Novel foods	Novel Food	Production of docosahexaenoic acid (DHA; 4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoic acid; CAS# 6217-54-5)-rich oil	EFSA-Q-2021-00168	No	**Yes**
Schizochytrium mangrovei		Novel foods	Novel Food	Production of docosahexaenoic acid (DHA; 4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoic acid; CAS# 6217-54-5)-rich oil	EFSA-Q-2021-00168	No	**Yes**
Bacteria							
Bacillus amyloliquefaciens	Ba-BPD1 (DSM 21836)	Feed additives	Zootechnical additives	Digestibility enhancer and gut flora stabiliser Preparation containing 3 active substances, one enzyme (endo-1,4-β-xylanase) and 2 viable *Bacillus* spp. (*B. amyloliquefaciens* Ba-BPD1 (DSM 21836) and *B. licheniformis* PWD-1 (ATCC 53757)).	EFSA-Q-2021-00312	Yes	**No**
Bacillus licheniformis	Ca63 - DSM 9552, NZYM-AY (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme alpha amylase	EFSA-Q-2021-00292	Yes	**No**

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Bacillus licheniformis	Ca63 - DSM 9552, NZYM-CB (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme subtilisin	EFSA-Q-2021-00295	Yes	**No**
Bacillus licheniformis	Ca63 - DSM 9552, NZYM-DI (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme Phosphoinositide Phospholipase C	EFSA-Q-2021-00225	Yes	**No**
Bacillus licheniformis	Ca63 - DSM 9552, NZYM-JQ (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme glutaminase	EFSA-Q-2021-00290	Yes	**No**
Bacillus licheniformis	Ca63 - DSM 9552, NZYM-LU (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme pullulanase	EFSA-Q-2021-00222	Yes	**No**
Bacillus licheniformis	PWD-1 (ATCC 53757)	Feed additives	Zootechnical additives	Digestibility enhancer and gut flora stabiliser Preparation containing 3 active substances, one enzyme (endo-1,4-β-xylanase) and 2 viable *Bacillus* spp. (*B. amyloliquefaciens* Ba-BPD1 (DSM 21836) and *B. licheniformis* PWD-1 (ATCC 53757))	EFSA-Q-2021-00312	Yes	**No**
Bacillus nakamurai	F727	Plant protection products	Plant Protection Product	Fungicide against plant pathogenic fungi (e.g. foliar spray applications in grape, legume vegetable crops, application in the furrow lanes for planting potatoes). In particular, *Plasmopara viticola*, *Sclerotinia spp*., *Rhizoctonia solani* and *Phytophthora erythroseptica*	EFSA-Q-2021-00027	No	**No**
Bacillus subtilis	RH1018b, AR-453 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme maltogenic amylase	EFSA-Q-2021-00299	Yes	**No**

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Bacillus subtilis	RH1018b, AR-651 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme alpha amylase	EFSA-Q-2021-00307	Yes	**No**
Bacillus velezensis	ABS1704	Feed additives	Zootechnical additives	Gut flora stabiliser for chickens for fattening, turkeys for fattening, chickens reared for laying, minor poultry species and turkeys reared for breeding	EFSA-Q-2021-00240	Yes	**No**
Bacillus velezensis	DSM 15544 (previously *B. subtilis* C-3102)	Feed additives	Zootechnical additives	Gut flora stabiliser for chickens reared for laying; breeding chickens; turkeys for rearing/fattening and breeding/ laying; minor poultry species and all other avian species for rearing/fattening and laying/ breeding	EFSA-Q-2021-00169	Yes	**No**
Bacillus velezensis	DSM 15544 (previously *B. subtilis* C-3102)	Feed additives	Zootechnical additives	Gut flora stabiliser for dairy cows and other dairy ruminants	EFSA-Q-2021-00206	Yes	**No**
Clostridium butyricum	FERM BP-2789	Feed additives	Zootechnical additives	Gut flora stabiliser Zootechnical feed additive for chickens for fattening, chickens reared for laying and minor avian species (excluding laying birds)	EFSA-Q-2021-00384	No	**No**
Corynebacterium glutamicum	CGMCC 17927 (GMM)	Feed additives	Nutritional additives	Amino acids, their salts and analogues Enhance L-lysine production efficacy	EFSA-Q-2021-00439	Yes	**No**
Corynebacterium glutamicum	CGMCC 20516	Feed additives	Nutritional additives	Amino acids, their salts and analogues Production of L-Arginine	EFSA-Q-2021-00494	Yes	**No**
Enterococcus faecium	strain WF-3	Feed additives	Zootechnical additives	Gut flora stabiliser for dogs	EFSA-Q-2021-00383	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 lactis	NCIMB 10415	Feed additives	Zootechnical additives	Gut flora stabiliser	EFSA-Q-2020-00391	No	**Yes**
Escherichia coli	K12, NITE BP-02917 (AJ111507) (GMM)	Feed additives	Nutritional additives	As nutritional (amino acids, their salts and analogues) and as sensory feed additives (flavouring compound). Production of L-lysine	EFSA-Q-2021-00462	No	**No**
Escherichia coli	K12, (DH1 MDO) MAP 1834 DSM 33416 (GMM)	Novel foods	Novel Food	Production of 3-fucosyllactose	EFSA-Q-2021-00354	No	**No**
Escherichia coli	K12, LE1B109_pPB129 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme sucrose phosphorylase	EFSA-Q-2021-00291	No	**No**
Escherichia coli	K12, LE1B109_pPB130 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme cellobiose phosphorylase	EFSA-Q-2021-00297	No	**No**
Escherichia coli	W (SGR5) (ATCC 9637 – ATCC, 2020)	Novel foods	Novel Food	Production of 2′-fucosyllactose from glucose and lactose	EFSA-Q-2021-00407	No	**No**
Lacticaseibacillus casei	K9-1	Feed additives	Zootechnical additives	Gut flora stabiliser for dogs	EFSA-Q-2021-00383	Yes	**No**
Lactiplantibacillus plantarum	CNCM I-3235 (DSM 11672)	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Lactiplantibacillus plantarum	CNCM I-3736 (DSM 11672)	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Lactococcus lactis	NCIMB 30117	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00237	Yes	**No**
Lentilactobacillus buchneri	CNCM I-4323 (NCIMB 40788)	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Lentilactobacillus hilgardii	CNCM I-4785	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Levilactobacillus brevis	WF-1B	Feed additives	Zootechnical additives	Gut flora stabiliser for dogs	EFSA-Q-2021-00383	Yes	**No**

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Limosilactobacillus fermentum	K9-2	Feed additives	Zootechnical additives	Gut flora stabiliser for dogs	EFSA-Q-2021-00383	Yes	**No**
Paenibacillus lentus	CMG3376 (DSM 33618) (GMM)	Feed additives	Technological additives	Digestibility enhancers Production of endo-1,4-Beta-D-mannanase	EFSA-Q-2021-00346	No	**Yes**
Pediococcus acidilactici	CNCM I-3237 (DSM 11673)	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Pediococcus acidilactici	CNCM I-4622 (DSM 11673)	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Pediococcus pentosaceus	DSM 32292	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00530	Yes	**No**
Pediococcus pentosaceus	NCIMB 12455	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Acidipropionibacterium acidipropionici	CNCM I-4661	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00426	Yes	**No**
Streptomyces cinnamonensis	28682	Feed additives	Coccidiostat	Coccidiostat to be used for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breading. Monensin sodium (Carrier Perlite, Calcium Carbonate)	EFSA-Q-2020-00405	No	**No**
Filamentous Fungi							
Aspergillus oryzae	A1560 (IFO 04177), NZYM-BU (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme leucyl aminopeptidase	EFSA-Q-2021-00224	No	**No**
Aspergillus oryzae	A1560 (IFO 04177), NZYM-MK (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme carboxypeptidase D	EFSA-Q-2021-00223	No	**No**
Aspergillus oryzae	A1560 (IFO 04177), NZYM-LJ (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme phospholipase A1	EFSA-Q-2021-00226	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
Aspergillus oryzae	DMS 33699	Feed additives	Zootechnical additives	Digestibility enhancer Production of 6-phytase	EFSA-Q-2021-00342	No	**No**
Fusarium spp.	*Fusarium strain flavolapis*	Novel foods	Novel food	Production of a nutritional fungi protein	EFSA-Q-2021-00519	No	**No**
Mortierella alpina		Novel foods	Novel Food	Production of arachidonic acid-rich oil	EFSA-Q-2021-00317	No	**No**
Trichoderma citrinoviride	B-125	Feed additives	Zootechnical additives	Digestibility enhancer Production of endo 1,4 betaxylanase endo 1,4 betaglucanase(cellulase) xyloglucan-specific-endo-beta-1,4-glucanase (xyloglucanase)	EFSA-Q-2021-00308	No	**No**
Trichoderma citrinoviride	Bisset IM SD 135	Feed additives	Zootechnical additives	Digestibility enhancer Production of endo-1,4-beta-xylanase	EFSA-Q-2021-00153	No	**No**
Trichoderma reesei	RF4847 (mutant deriving from Rut-C30), AR-352 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme glucose oxidase	EFSA-Q-2021-00298	No	**No**
Trichoderma reesei	RF4847 (mutant deriving from Rut-C30), AR-852 (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme cellulase	EFSA-Q-2021-00306	No	**No**
Trichoderma reesei	RF7727 (GMM)	Feed additives	Zootechnical additives	Digestibility enhancer Production of 6-phytase	EFSA-Q-2021-00313	No	**No**
Oomycetes							
Pythium oligandrum	B301	Plant protection products	Plant Protection Product	Plant protection product on grapevine against *Phaeomoniella chlamydospora*	EFSA-Q-2021-00027	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							
Kluyveromyces lactis	DS 00332 (parental strain), DS 38549 (recipient strain), KLA (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme β-galactosidase	EFSA-Q-2021-00311	Yes	**No**
Komagataella pastoris	SUNHY 002 (DSM 25376) and SUNHY 004 (DSM 26469) (GMM)	Feed additives	Zootechnical additives	Digestibility enhancer Production of xylanase and β-glucanase	EFSA-Q-2021-00314	Yes	**No**
Komagataella phaffii	GS115-VTR 001 (CGMCC 7.370) (GMM)	Feed additives	Zootechnical additives	Digestibility enhancer Production of 6-phytase	EFSA-Q-2021-00425	Yes	**No**
Komagataella phaffii	GS115-VTR001 (GMM)	Feed additives	Zootechnical additives	Digestibility enhancer Production of 6-phytase	EFSA-Q-2021-00417	Yes	**No**
Komagataella phaffii	GS115-VTR002 (CGMCC 7.371) (GMM)	Feed additives	Zootechnical additives	Digestibility enhancer Production of the enzyme endo-β-1,4-xylanase	EFSA-Q-2021-00442	Yes	**No**
Komagataella phaffii	NCAIM Y001485	Feed additives	Technological additives	Substances for reduction of the contamination of feed by mycotoxins Production of fumonisin esterase	EFSA-Q-2021-00152	Yes	**No**
Komagataella phaffii	NCAIM Y001485 (GMM)	Feed additives	Technological additives	Substances for reduction of the contamination of feed by mycotoxins Production of fumonisin esterase	EFSA-Q-2021-00470	Yes	**No**
Komagataella phaffii	Xyl-2 (DSM 33574)	Feed additives	Zootechnical additives	Digestibility enhancer and gut flora stabiliser Production of Endo-1, 4-β-xylanase	EFSA-Q-2021-00312	Yes	**No**
Saccharomyces cerevisiae		Feed additives	Zootechnical additives	Gut flora stabiliser for rabbits	EFSA-Q-2021-00382	Yes	**No**

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Saccharomyces cerevisiae		Feed additives	Technological additives	Substances for reduction of the contamination of feed by mycotoxins	EFSA-Q-2021-00470	Yes	**No**
Saccharomyces cerevisiae	CEN.PK113-7D (GMM)	Food enzymes, food additives and flavourings	Enzyme production	Production of the food additive steviol glycosides (E960)	EFSA-Q-2021-00357	Yes	**No**
Saccharomyces cerevisiae	CEN.PK113-7D (GMM)	Novel foods	Novel Food	Production of 2′-fucosyllactose	EFSA-Q-2021-00415	Yes	**No**
Saccharomyces cerevisiae	CNCM I-1079	Feed additives	Zootechnical additives	Digestibility enhancers and gut flora stabilisers	EFSA-Q-2021-00429	Yes	**No**
Saccharomyces cerevisiae	SC0639 (DS 67494) (GMM)	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect Production of 5,7,24-cholestatrienol (precursor of 25-hydroxyvitamin D3)	EFSA-Q-2021-00341	Yes	**No**
Saccharomyces cerevisiae	Y03-0	Feed additives	Nutritional additives	Compounds of trace elements Production of selenised yeast	EFSA-Q-2021-00309	Yes	**No**
Yarrowia lipolytica	GMM	Food enzymes, food additives and flavourings	Enzyme production	Production of the food additive steviol glycosides (E960)	EFSA-Q-2021-00356	Yes	**No**

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