

STATEMENT

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Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 14: suitability of taxonomic units notified to EFSA until March 2021

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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 biological agents, intended for addition to food or feed, 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, safety concerns and occurrence of antimicrobial resistance. Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at the species/strain or product level and reflected by 'qualifications'. In the period covered by this statement, no new information was found that would change the status of previously recommended QPS TUs. *Schizochytrium limacinum*, which is a synonym for *Aurantiochytrium limacinum*, was added to the QPS list. Of the 78 microorganisms notified to EFSA between October 2020 and March 2021, 71 were excluded; 16 filamentous fungi, 1 *Dyella* spp., 1 *Enterococcus faecium*, 7 *Escherichia coli*, 1 *Streptomyces* spp., 1 *Schizochytrium* spp. and 44 TUs that had been previously evaluated. Seven TUs were evaluated: *Corynebacterium stationis* and *Kodamaea ohmeri* were re-assessed because an update was requested for the current mandate. *Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi* and *Lactococcus garvieae* were assessed for the first time. The following TUs were not recommended for QPS status: *A. caldiproteolyticus* due to the lack of a body of knowledge in relation to its use in the food or feed chain, *E. hormaechei*, *L. garvieae* and *K. ohmeri* due to their pathogenic potential, *E. ashbyi* and *C. stationis* due to a lack of body of knowledge on their occurrence in the food and feed chain and to their pathogenic potential. *B. paralicheniformis* was recommended for the QPS status with the qualification 'absence of toxigenic activity' and 'absence of genetic information to synthesize bacitracin'.

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Keywords: *Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Corynebacterium stationis*, *Eremothecium ashbyi*, *Enterobacter hormaechei*, *Lactococcus garvieae*, *Kodamaea ohmeri*

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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.4917414>) was updated with the notifications received between October 2020 and March 2021. Within this period, 78 notifications were received by EFSA, of which 55 were proposed for evaluation in feed, 13 for use as food enzymes, food additives and flavourings, 8 as novel foods and 2 as plant protection products. The new notifications received between October 2020 and March 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 July until December 2020 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.5016562>) and the search strategies in Appendix C (see <https://doi.org/10.5281/zenodo.5016711>). No new information was found that would affect the QPS status of those TUs or their qualifications. *Schizochytrium limacinum*, which is a synonym for *Auranthiochytrium limacinum*, is added to the QPS list.

The third ToR requires a (re)assessment of new TUs notified to EFSA, for their suitability for inclusion in the updated QPS list at the Knowledge Junction in Zenodo (<https://doi.org/10.5281/zenodo.4917383>, Appendix E).

Seven of the 78 notifications received, corresponding to 7 TUs, were evaluated for possible QPS status; *Corynebacterium stationis* and *Kodamaea ohmeri* were re-assessed because an update was requested in relation to the current mandate. Five TUs (*Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi* and *Lactococcus garvieae*) were assessed for the first time. The following conclusions were drawn:

- *Anoxybacillus caldiproteolyticus* is not recommended for QPS status due to a lack of a body of knowledge on its occurrence in the food and feed chain.
- *B. paralicheniformis* is recommended for the QPS status with the qualification 'absence of toxigenic activity' and 'absence of genetic information to synthesize bacitracin'.
- *Corynebacterium stationis* is not recommended for QPS status due to a lack of a body of knowledge in relation to its occurrence in the food and feed chain and to possible safety concerns in relation to human health.
- *Enterobacter hormaechei* is not recommended for QPS status due to its pathogenic potential for humans and animals.
- *Eremothecium ashbyi* is not recommended for QPS status due to a lack of a body of knowledge on its occurrence in the food and feed chain and its pathogenicity for plants.
- *Kodamaea ohmeri* is not recommended for QPS status due to safety concerns in relation to human health.
- *Lactococcus garvieae* is not recommended for QPS status due to its pathogenic potential for humans and animals.

The remaining 71 notifications were excluded from QPS evaluation for the following reasons: 25 notifications were related to microorganisms that are generally excluded from QPS evaluation (16 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 7 of *Escherichia coli*, 1 *Streptomyces* spp.), 2 notifications (*Dyella* spp. and *Schizochytrium* sp. strain CABIO-A-2) were only a genus, or a

strain in the case of *Schizochytrium*, and not a species and therefore not suitable for the QPS approach and 44 (including the newly classified *Lactiplantibacillus plantarum*, previously known as *Lactobacillus plantarum*) were related to TUs that already have QPS status and did not require further evaluation.

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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 on Feed, Food Ingredients and Packaging (FIP), Nutrition, Pesticides 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

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 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 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 pathogens (*'safety'*) 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 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, 2020a,c) 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 October 2020 to March 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 organisms in the environment (EFSA BIOHAZ Panel, 2020a). 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 based on the information in the application dossier. The knowledge on relevant acquired antimicrobial resistance (AMR) is reflected in the safety sections of this document.

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched. More details on the search strategy, search keys and approach 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 78 notifications were received between October 2020 and March 2021, of which 55 were for evaluation for use in feed, 13 for use as food enzymes, food additives and flavourings, 8 as novel foods and 2 as plant protection products (Table 1).²

In response to ToR 3, seven of the 78 notifications, corresponding to seven TUs, were evaluated for possible QPS status, five of these (*Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi* and *Lactococcus garvieae*) for the first time. The other two, *Corynebacterium stationis* and *Kodamaea ohmeri*, were re-assessed because an update was requested in the current mandate. The remaining 71 notifications were excluded from QPS evaluation for the following reasons: 25 notifications were related to microorganisms that are generally excluded from QPS evaluation (16 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 7 of *Escherichia coli*, 1 *Streptomyces* spp.), two notifications were not suitable for the QPS approach, i.e. *Dyella* spp. because it is a genus and *Schizochytrium* sp. strain CABIO-A-2 because it is a strain, not a species, and 44 (including newly classified *Lactiplantibacillus plantarum*, previously known as *Lactobacillus plantarum*) were related to TUs that already had QPS status and did not require further evaluation in this mandate.

Table 1: Notifications received by EFSA, per risk assessment area and by biological group, from October 2020 to March 2021

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement ^(b)	Total
	Already QPS	Excluded in QPS ^(a)		
Biological group				
Feed	39	13	3	55
Bacteria	35	5	2	42
Filamentous fungi	0	8	0	8
Yeasts	4	0	1	5
Novel foods	2	4	2	8
Bacteria	0	3	2	5
Filamentous fungi	0	0	0	0
Protists/Algae	1	1	0	2

² *Eremothecium ashbyi* was previously considered to be a filamentous fungus and excluded from QPS assessment. However, as a result of the recently defined distinction between yeasts and filamentous fungi (EFSA BIOHAZ Panel, 2021), it is now classified as a yeast and included in the QPS assessment.

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement ^(b)	Total
	Already QPS	Excluded in QPS ^(a)		
Biological group				
Yeasts	1	0	0	1
Plant protection products	0	2	0	2
Bacteria	0	0	0	0
Filamentous fungi	0	2	0	2
Viruses	0	0	0	0
Food enzymes, food additives and flavourings	3	8	2	13
Bacteria	3	2	1	6
Filamentous fungi	0	6	0	6
Yeasts	0	0	1	1
Genetically modified organism	0	0	0	0
Bacteria	0	0	0	0
Total	44	27	7	78

QPS: qualified presumption of safety.

- (a): The number includes 16 notifications of filamentous fungi, 1 of *Enterococcus faecium* (bacterium), 7 of *Escherichia coli* (bacterium) and 1 of *Streptomyces spp.* (bacterium), all excluded from QPS evaluation, as well as 1 of *Dyella spp.* and 1 of *Schizochytrium sp.* strain CABIO-A-2 which are only a genus or strain and not a species and therefore not suitable for the QPS approach.
- (b): Seven notifications corresponding to seven TUs, two were last evaluated in 2020 (*Corynebacterium stationis* and *Kodamaea ohmeri*) and five were evaluated for the first time (*Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi* and *Lactococcus garvieae*).

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.5016562>, and in Appendix C Search strategies – see <https://doi.org/10.5281/zenodo.5016711>, respectively.

The Artificial Intelligence (AI) function 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 July to December 2020).

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, when described (e.g. 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 mucosal impairment 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, 2,770 records were submitted to the title screening step, which led to the exclusion of 2,581 of these. The remaining 189 records were found eligible for the title and abstract screening step, which led to the exclusion of 113 of these. Of the 76 articles that finally reached the article evaluation step (full text), 39 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)	1,939	72	32	14
<i>Bacillus</i> spp. ^(a)	557	13	4	2
<i>Bifidobacterium</i> spp. ^(a)	150	14	8	2
<i>Carnobacterium divergens</i>	8	0	0	0
<i>Corynebacterium glutamicum</i>	34	1	0	0
<i>Gluconobacter oxydans</i> / <i>Xanthomonas campestris</i>	200	2	2	0
Lactobacilli ^(a)	423	14	7	5
<i>Lactococcus lactis</i> ^(a)	126	11	2	0
<i>Leuconostoc</i> spp.	95	10	6	5
<i>Microbacterium imperiale</i>	1	0	0	0
<i>Oenococcus oeni</i>	36	2	1	0
<i>Pasteuria nishizawae</i>	1	0	0	0
<i>Pediococcus</i> spp.	193	4	2	0
<i>Propionibacterium</i> spp.	36	0	0	0
<i>Streptococcus thermophilus</i>	79	1	0	0
Viruses (total)	74	1	0	0
Alphaflexiviridae/ Potyviridae	31	0	0	0
Baculoviridae	43	1	0	0
Yeasts^(a)	673	74	36	21
Protists/Algae	84	42	8	4
Total	2,770	189	76	39
Excluded	2,581	113	37	

(a): The numbers of references pre-screened by AI and excluded are not reported in the table and are for: *Bifidobacterium* spp. (165), lactobacilli (430), *Lactococcus lactis* (149), *Bacillus* spp. (566), yeasts (676).

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

Corynebacterium stationis

C. stationis was recently evaluated (EFSA BIOHAZ Panel, 2020b) and was not recommended as QPS due to a lack of body of relevant knowledge.

Identity

C. stationis (synonym *Achromobacter stationis*) is a valid species with standing in nomenclature. It was described by Bernard et al. (2010), grouping *Brevibacterium stationis* ATCC 14403 and *C. ammoniagenes* ATCC 6872. Those strains can be discriminated from other *Corynebacterium* species by 16S rRNA gene and *rpoB* sequencing.

Body of knowledge

The body of knowledge for *C. stationis* is limited. The type strain was isolated from seawater (Bernard et al., 2010). Other strains of this species were isolated from a human infant stool sample (Bernard et al., 2010) and found in a population community from a compost produced by different types of wastewater sludge (Tashiro et al., 2016). *C. stationis* is used in experimental trials as an indicator for improving UV seawater disinfection treatment (Rubio et al., 2013). A strain of *C. stationis* was used to produce disodium 5'-inosinate for use as a feed additive (EFSA FEEDAP Panel, 2020).

Safety concerns

Two clinical *C. stationis* isolates were obtained from blood cultures from a 62-year-old male with a chest infection, and a 66-year-old female; no further clinical information was provided (Bernard et al., 2010). In a recent article, *C. stationis* was identified among bacteria causing diabetic foot infection and presenting resistance to antibiotics (Henciya et al., 2020). *C. stationis* has been isolated from the raw milk of cows with mastitis (León-Galván et al., 2015; Anaya-López et al., 2006; Mahmmod et al., 2018) and on teat skin (Mahmmod et al., 2018); no invasion was observed in bovine mammary epithelial cells (Anaya-López et al., 2006).

Conclusion on a recommendation for QPS status

C. stationis cannot be recommended for QPS status due to a lack of body of knowledge on its occurrence in the food and feed chain and possible safety concerns in relation to human and animal health.

3.1.2. Yeasts

Kodamaea ohmeri

Kodamaea ohmeri was recently evaluated (EFSA BIOHAZ Panel, 2020b) and not recommended for QPS due to safety concerns.

Identity

K. ohmeri is a yeast within the *Saccharomycetales* order. A synonym of *K. ohmeri* is *Pichia ohmeri* and the teleomorphic form is *Candida guilliermondii* var. *membranaefaciens* (Kurtzman et al., 2011). It is a biologically under-investigated taxon and its relationship with other taxa within the Order *Saccharomycetales* is uncertain (Lumbsch and Huhndorf, 2007). Currently, it is classified in the Class *Ascomyceta* and the *Saccharomycetaceae* family. Correct identification apparently remains a challenge.

Body of knowledge

K. ohmeri has been recovered from a broad variety of sources. From a biotechnological point of view, this species is used in the production of xylitol from glucose and the conversion of xylulose to xylitol (Kurtzman et al., 2011).

Safety concerns

Up to 2020, more than 70 cases of invasive fungaemia due to the yeast *K. ohmeri* have been reported (Kanno et al., 2017; Ioannou and Papakitsou, 2020). A patient with a severe fungaemic pulmonary infection was diagnosed with *K. ohmeri* (Kanno et al., 2017).

Conclusions on a recommendation for QPS status

The above information confirms our previous Statement (EFSA BIOHAZ Panel, 2020b), that *K. ohmeri* cannot be recommended for QPS status due to safety concerns in relation to human health.

3.2. Taxonomic units to be evaluated for the first time

3.2.1. Bacteria

Anoxybacillus caldiproteolyticus

Identity

A. caldiproteolyticus is an aerobic, Gram-positive, sporulating, thermophilic bacterial species with standing in nomenclature (Coorevits et al., 2012). The type strain was isolated from sewage and initially classified as *Geobacillus caldoproteolyticus* (Chen et al., 2004).

Body of knowledge

A. caldiproteolyticus was first isolated and used for the production of a thermostable protease (Chen et al., 2004), a phenotypic trait later confirmed by another strain that generated a keratinase (Reis et al., 2020). Strains of the species have also been isolated from hot springs (Najar et al., 2018). *A. caldiproteolyticus* has been implicated in the generation of biofilms on dairy abiotic surfaces (Karaca et al., 2019).

Safety concerns

No safety concerns were reported for *A. caldiproteolyticus*.

Conclusions on a recommendation for the QPS status

A. caldiproteolyticus cannot be recommended for the QPS status due to lack of body of knowledge on its occurrence in the food and feed chain.

Bacillus paralicheniformis

Identity

B. paralicheniformis is a valid species name with standing in nomenclature (Oren and Garrity, 2016). *B. paralicheniformis* are Gram-positive, facultatively anaerobic, mobile, endospore-forming rods; producing catalase but not oxidase. Based on phylogenomic analysis of all available genomes of the *B. licheniformis* group, a number of strains, originally designated as *B. licheniformis*, were reclassified as a new species; *B. paralicheniformis* (Dunlap et al., 2015). The type strain was isolated from cheonggukjang, a Korean fermented soybean food product.

Body of Knowledge

B. paralicheniformis has been isolated from the food product cheonggukjang (Dunlap et al., 2015), from kimchi, a traditionally, spontaneously fermented vegetable Korean food product (Khan et al., 2018) and from whey powder as a contaminant (McHugh et al., 2018). *B. paralicheniformis* were reported as plant-associated bacteria, displaying growth promoting abilities (Annapurna et al., 2018) and the potential to be used as phytopathogen biocontrol agents (Wang et al., 2017; Pylro et al., 2019; Jinal et al., 2020; Ramirez-Carino et al., 2020). *B. paralicheniformis* strains also have the potential to be used for biotechnological purposes and for bioremediation (Rahman et al., 2019; Khan et al., 2018; SanthaKalaikumari et al., 2021; Ganesh Kumar et al., 2021).

Ahire et al. (2020) reported the production of a bacitracin, an antimicrobial peptide active against a range of Gram-positive bacteria, by strains of *B. paralicheniformis*. The ability to produce bacitracin is reported for a subset of *B. paralicheniformis* (Du et al., 2019).

Safety concerns

No negative effects in relation to *B. paralicheniformis* were reported. All strains classified as *B. paralicheniformis* are reported to have phenotypic resistance to erythromycin as well as chromosomal erythromycin resistance genes (Lee and Jeong, 2017; Agersø et al., 2018, 2019; Jeong et al., 2020).

Conclusions on a recommendation for the QPS status

B. paralicheniformis is recommended for the QPS status with the qualification 'absence of toxigenic activity' and 'absence of genetic information to synthesize bacitracin'.

Enterobacter hormaechei

Identity

E. hormaechei is a TU with standing in nomenclature. It was first described by O'Hara et al. (1989) amended by Hoffmann et al. (2005) and updated by Oren and Garrity (2017). It is currently placed within the *E. cloacae* complex, together with five other species and six additional genovars (Hoffmann et al., 2005; Sutton et al., 2018), but further taxonomic restructuring might occur based on the description of new species and subspecies by Wu et al. (2020).

Body of Knowledge

E. hormaechei has been isolated as a contaminant from food (Indugu et al., 2020; Sadek et al., 2020), as an endophyte from plants (Khalaf and Raizada, 2020; Tshishonga and Serepa-Dlamini, 2019) and from the gastrointestinal tracts of insects (Asimakis et al., 2019). Isolates of *E. hormaechei* are able to degrade lutein, a plant carotenoid (Zhong et al., 2017). Enhancing soil fertility and P- and K-uptake by plants have been reported for *E. hormaechei* (Roslan et al., 2020).

Safety concerns

E. hormaechei is an opportunistic human pathogen, causing mainly **nosocomial** infections (Townsend et al., 2008; Roberts et al., 2020). It has frequently been reported as the cause of human disease in susceptible individuals, in association with multidrug resistance, including to critical antimicrobials located on mobile genetic elements (Yang et al., 2018; Yuan et al., 2019; Gou et al., 2020; Martins et al., 2020; Soliman et al., 2020). The virulence features of *E. hormaechei* are insufficiently studied. The genomic plasticity of this species may explain its ability to spread in hospital environments (Paauw et al., 2009; Roberts et al., 2020).

E. hormaechei has also been associated with respiratory disease in un-weaned calves (Wang et al., 2020).

Multiresistant *E. hormaechei* has been isolated from several food products. Examples are a shrimp sample from a farmers' market in the US harbouring *sul1*, *sul2*, *qnrA1*, *oqxAB*, *dfrA23*, *blaACT*, *floR*, *fosA*, *tet(A)*, *aph(6)-Id* and *aph(30)-Ib* antibiotic resistance genes and several plasmids (Indugu et al., 2020); an isolate from a raw beef patty with *bla_{VIM-1}*, *mcr-9* *aac(6')-II*, *ΔaadA22*, *aac(6')-Ib-cr*, *sul1*, *dfrA1* on a plasmid (Sadek et al., 2020).

Conclusion on a recommendation for the QPS status

Enterobacter hormaechei cannot be recommended for the QPS status due to its pathogenic potential for humans and animals.

Lactococcus garvieae

Identity

L. garvieae is a bacterial species name with standing in nomenclature (Collins et al., 1983; Schleifer et al., 1985).

Body of knowledge

This bacterial species has been isolated from a variety of terrestrial and aquatic environments. *L. garvieae* has been found in raw milk and sporadically in the bacterial communities of fermented dairy products. In a single study, *L. garvieae* has been used as a cheese starter culture (Guarcello et al., 2016).

Safety concerns

The pathogenicity of *L. garvieae* has been reviewed by Gibello et al. (2016). This species is a recognised fish pathogen responsible for high mortality haemorrhagic septicaemia in wild fish and in fish farmed in fresh and sea water (Shahi and Mallik, 2020). It has also been associated with bovine mastitis (Sorge et al., 2021). *L. garvieae* is also a rare human pathogen of increasing clinical significance, facilitated by predisposing factors, being responsible for infections such as endocarditis, urinary tract infections and septicaemia (Gibello et al., 2016; Choksi and Dadani, 2017; Lee et al., 2020).

Conclusions on a recommendation for the QPS status

L. garvieae is not recommended for the QPS status due to its pathogenic potential for humans and animals.

3.2.2. Yeast

Eremothecium ashbyi

Identity

The genus *Eremothecium* contains five species of ascomycetous yeasts or yeast-like fungi and belongs to the family *Saccharomycetaceae* (Prillinger et al., 1997; Kurtzman et al., 2011). The species *E. ashbyi* was first described in 1935 and it is a legitimate species and name (Mycobank, Index Fungorum). A synonym name is *Crebrothecium ashbyi*, which however has been little used. The species designation has repeatedly been spelled *ashbyii*; however, this is considered by Kurtzman et al. (2011) as an orthographic error.

Body of knowledge

A special feature of *E. ashbyi* (and other species of the genus) is growth predominantly as pseudo-hyphae and absence of budding. The ascospores in this genus are sickle- or needle-shaped.

Very little information is available on the ecology of *E. ashbyi*. It has been isolated mostly in cropping systems of tropical or subtropical regions, e.g. cotton and citrus fruit. Batra (1973) considered it to be a relatively rare fungus. No other information was found on the possible occurrence of the species in the food and feed chains.

Along with other species of the genus, *E. ashbyi* has been widely used in biotechnology since the 1950s for production of useful compounds. The main interest has been the overproduction of riboflavins by some strains (Kapralek, 1962; Semenova et al., 2017). Additionally, some studies report extraction of accumulated lipids and essential oils from the biomass of *E. ashbyi* (He et al., 2019; Vijayalakshmi et al., 2003).

Safety concerns

There are no reports indicating that *E. ashbyi* might be pathogenic to humans or any other animals. However, some studies characterise it as a plant pathogen, since it has been shown to be able to cause stigmatomycosis (or 'yeast spot') in citrus fruit (Batra, 1973), soybean (Kimura et al., 2008a) and azuki bean (Kimura et al., 2009). A likely route of transmission to new places of infection is via stink bugs that have fed on infected plants or plant material (Kimura et al., 2008b).

Conclusions on a recommendation for the QPS status

E. ashbyi is not recommended for the QPS list due to its plant pathogenicity and lack of body of knowledge on its occurrence in the food and feed chains.

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

The summaries of the evaluation of the possible safety concerns for humans, animals or the environment described and published since the previous ELS exercise (i.e. articles published between July 2020 and December 2020 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. Gram-positive non-sporulating bacteria

3.3.1. *Bifidobacterium* spp.

A search for papers potentially relevant for QPS-listed *Bifidobacterium* spp. provided 315 references. The artificial intelligence (AI) analysis left 150. Title screening left 14 references for abstract inspection, then 8 for a full article appraisal. This last step identified two articles (Pillai et al., 2020; Takiguchi et al., 2021) dealing with safety concerns. The first article (Pillai et al., 2020) described a case of bacteraemia in a premature baby girl who was given a probiotic mixture containing, amongst other organisms, *Bifidobacterium longum*. The isolated strain from blood culture was compared to the one from the probiotic and was indistinguishable, but the methods of isolation and genotyping were not provided. The authors concluded that the infection was a likely adverse event of the probiotic supplementation. In the second article (Takiguchi et al., 2021), the authors described a case of an old woman hospitalised with an infection in the peribronchial connective tissue caused by *Bifidobacterium longum* and *Veillonella* species, cultured from a transbronchial needle aspirate. However, the role of *B. longum* in the infection was not elucidated since it was identified together with *Veillonella* species.

Based on the available evidence, the QPS status of the QPS-listed *Bifidobacterium* spp. is not changed.

Carnobacterium divergens

A search for potentially relevant papers on *C. divergens* provided eight references. 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 34 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 split into 13 new genera, provided 853 references. The AI analysis left 423 articles. Title screening of these provided 14 references for abstract inspection, which further reduced their number to 5. However, full paper review excluded all of them, either because no reliable microorganism identification procedures were described or due to uncertainty on the aetiology of the cases described.

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

Lactococcus lactis

A search for papers potentially relevant for the QPS status of *L. lactis* provided 275 references. The AI analysis left 126 papers. Title and abstract screenings of these reduced their number to 11. Two papers reached full article evaluation but neither of them dealt with a possible safety concern pertaining to *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 95 references. The analysis of their titles left 10 articles for title/abstract screening. Six articles, of which one was not in English, reached full text evaluation, and five dealt with possible safety concerns. These were excluded because either the isolation procedure or 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 one reference. The analysis of the title led to this reference being discarded. 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 36 references. The analysis of their titles left two articles for title/abstract screening. One article reached full text evaluation but did not raise any safety concerns. 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 193 references. The analysis of their titles left four articles for the title/abstract phase. Two articles reached the full text evaluation stage but neither of them identified 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 36 references. Following the analysis of their titles, no articles were selected for abstract screening or the full article evaluation phase; thus, no new 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 79 references. The analysis of their titles left one article for title and abstract screening that 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 1,123 references. The AI analysis left 557 articles. The analysis of their titles by two experts left 13 articles for the abstract phase and, from these, four articles passed to the full text phase for further analysis. Two papers did not deal with safety concerns. Two papers were further analysed. Song et al. (2020) described *Bacillus licheniformis* as possibly involved in bovine mastitis. The paper had methodological flaws in relation to strain identification and did not document source attribution. Princess et al. (2020) described the isolation of *B. clausii* from the blood of a patient, who had been treated with a *B. clausii* probiotic. The identification via the blood isolate was performed by MALDI-TOF and the link to the probiotic strain was not confirmed. The authors reported the patient as immunocompetent, but the patient had underlying diseases, being a type II diabetic who had undergone several surgical procedures and was being treated for a tracheal infection while taking the probiotic.

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 1,123 references. The AI analysis left 557 articles. The analysis of their titles by two experts left 13 articles and for four of these the full text was analysed. None dealt with this species. Consequently, the QPS status *G. stearothermophilus* is not changed.

Pasteuria nishizawae

A search for papers potentially relevant for the QPS evaluation of *P. nishizawae* provided one reference, which was excluded during title screening. Consequently, the QPS status of *P. nishizawae* is not changed.

3.3.3. Gram-negative bacteria

Gluconobacter oxydans

A search for papers potentially relevant to the QPS evaluation of *G. oxydans* and *Xanthomonas campestris* provided 200 references.

The analysis of their titles left two articles, but these were excluded following the title and abstract screening; therefore, no paper reached the final selection phase for this TU. Consequently, the QPS status of *G. oxydans* is not changed.

Xanthomonas campestris

The search for papers potentially relevant for the QPS evaluation of *Gluconobacter oxydans* and *X. campestris* provided 200 references. The analysis of their titles left two articles, which reached the evaluation phase for this TU, but neither eventually dealt with health nor 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 1,349 references. The AI analysis left 673 articles. After title screening by two experts, 74 studies remained for the title/abstract phase, and from these 36 articles passed to the full article appraisal. Out of these, 21 reported a possible safety concern.

Two studies were considered relevant for the QPS evaluation but did not directly report safety concerns. Boontham et al. (2020) proposed a name change of the QPS species *Candida cylindracea* to *Limtongozyma cylindracea*. Libkind et al. (2020) discussed the use of full genome sequencing for taxonomic identification of yeasts.

Twenty-one studies discussed potentially relevant safety concerns for QPS yeast species, which are discussed below.

For the species ***Candida cylindracea*, *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.

Cyberlindnera jadinii

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

In a retrospective study for 1999–2018, Kaur et al. (2020) identified 7927 yeast isolates (out of 602,963 isolates in total) from patients with suspected sepsis in intensive care units in a hospital in India. They reported that *C. jadinii* represented 2.8% of the yeasts and 0.03% of total isolates (identification by conventional methods and MALDI-TOF MS, but no confirmation with DNA-based molecular methods). Yamin et al. (2020) found in a retrospective study (2001–2018) on isolates from patients with candidaemia in a hospital in Malaysia, that a very low incidence (one isolate or 0.1%) was *C. jadinii*. In a retrospective study of isolates from patients with fungaemia in 12 hospitals in Italy (Prigitano et al., 2020), one of the isolates (0.3%) was *C. jadinii* (identification by conventional methods and MALDI-TOF MS). The incidence was very low and identification by MALDI-TOF was not further confirmed by a DNA-based molecular methodology.

The inconsistency of the identification, together with the scarcity of linkage of this organism to pathology, resulted in the decision that the QPS status of *C. jadinii* is not changed.

Hanseniaspora uvarum

The anamorph name of *H. uvarum* is *Kloeckera apiculata*.

Zalewski et al. (2020) investigated the causes of cranberry fruit rot (CFR) in a cranberry farm in Wisconsin, USA. They show that in rare cases (CFR is usually caused by filamentous fungi), *H. uvarum* can cause CFR and thus cause spoilage of harvested cranberries.

This new report 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*.

Seth-Smith et al. (2020) reported bloodstream infection with *K. marxianus* in a 61-year-old male. He was immunocompromised due to acute myeloid leukaemia and chemotherapy and prophylactic antibiotic treatment, and species identification (growth on chromogenic media and MALDI-TOF MS) did not apply DNA-based molecular methods. A study in a hospital in India (Sankari et al., 2020) reported that 2% of yeasts recovered from the saliva of patients with oral squamous cell carcinoma were *K. marxianus*. The patients, however, had not been diagnosed with fungal infection. Yamin et al. (2020) found in a retrospective study (2001–2018) on isolates from patients with candidaemia in a hospital in Malaysia, that one of the isolates (incidence only 0.1%) was *K. marxianus*. In a retrospective study of isolates from patients with fungaemia in 12 hospitals in Italy (Prigitano et al., 2020), one of the isolates (low incidence of 0.3%) was *K. marxianus* (identification by conventional methods and MALDI-TOF MS). Eghtedar Nejad et al. (2020) identified yeast isolates from HIV patients in a hospital in Iran and a non-HIV control group. One isolate in each group (corresponding to only 1% of isolates) was *K. marxianus*. A study of isolates from women in Iran diagnosed with vulvovaginal infection (Farahyar et al., 2020) showed that *K. marxianus* may in rare cases (prevalence 1.6%) cause vulvovaginal infections. The results of two additional studies reporting a low prevalence (< 2%) of *K. marxianus* in vulvovaginal infections (Ignjatović et al., 2020) and nosocomial fungal infections in patients that had undergone abdominal surgery (Kilic et al., 2020) could not be appropriately evaluated since there were uncertainties in the species identification.

In conclusion, the literature update mentioned mainly the isolation of *K. marxianus* from patients who are immunocompromised and/or have underlying disease and there is a scarcity of linkage of this organism to pathology. The prevalence of *K. marxianus* in the retrospective studies was very low. 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*.

Chi et al. (2021) report a case where a 44-year-old man in Taiwan treated for gastric adenocarcinoma by gastric surgery and chemotherapy developed fungaemia caused by *Y. lipolytica*. Predisposing conditions were a central venous catheter and an infection with *Acinetobacter baumannii*. Yamin et al. (2020) found in a retrospective study (2001–2018) on isolates from patients with candidaemia in a hospital in Malaysia, that four of the isolates (incidence only 0.3%) were *Y. lipolytica*. In a retrospective taxonomic study on 85 'uncommon *Candida* species' isolates from patients with candidaemia in hospitals in Taiwan (Huang et al., 2020), three isolates were identified as *Y. lipolytica* by conventional methods, MALDI-TOF MS and DNA sequencing. However, no information was given on pathology or any predisposing factors for infection. Huang et al. (2020) also showed that conventional methods often led to misidentification, especially of *Candida sake* and the QPS species *D. hansenii*.

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*.

Six references related to possible concerns for human safety were identified. Sankari et al. (2020) reported the prevalence of *Candida* species in the saliva of patients with oral squamous cell carcinoma, other oral potentially malignant disorders and healthy cohorts in a hospital in India and 17% were identified as *C. famata*. Yamin et al. (2020) found in a retrospective study (2001–2018) on isolates from patients with candidaemia in a hospital in Malaysia, that 1.7% of the isolates were *C. famata* from patients with oral squamous cell carcinoma. All these patients had disorders that could predispose them to infection. In a retrospective taxonomic study on 85 'uncommon *Candida* species' isolates from patients with candidaemia in hospitals in Taiwan (Huang et al., 2020), four isolates were identified as *C. famata* by conventional methods, MALDI-TOF MS and DNA sequencing. Huang et al. (2020) also showed that conventional methods often led to misidentification, especially of *Candida sake* and the QPS species *D. hansenii*. In this study, no information was given on pathology or any predisposing factors for infection. Vasileiou et al. (2020) report the cases of candidaemia in paediatric patients with malignancies in hospitals in Greece, and 15.8% of the isolates were described as *C. famata*. Almasadi et al. (2020) report five isolates of *C. famata* from a total of 79 microbial isolates from patients with nosocomial, opportunistic infections in a paediatric intensive care unit at a hospital in Saudi Arabia. The report of Mello et al. (2021) also has problems with the identification methodology

used; the yeast isolates were identified only by using conventional growth-based tests and not confirmed by molecular approaches. This study indicates that *C famata* might contribute to dermatomycosis or onychomycosis in humans. In these three reports, species identification is unclear. The retrospective studies did not provide further information on the cases reported.

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*.

Four references reported safety concerns for humans and, in all of them, the identification is uncertain. Ventoulis et al. (2020) report that two cases of critically ill patients who had to be hospitalised in an ICU due to Sars-CoV-2 infection received *S. cerevisiae* supplementation because of diarrhoea and subsequently developed a *S. cerevisiae* bloodstream infection. The identification was done using a morphological approach and API ID 32C. In a retrospective study of isolates from patients with fungaemia in 12 hospitals in Italy (Prigitano et al., 2020), three of the isolates (0.3%) were *S. cerevisiae* (identification by conventional methods and MALDI-TOF MS). Ignjatović et al. (2020) describe six cases (2%) of vulvovaginal infection caused by *S. cerevisiae* from a hospital in Serbia using only traditional growth-based methods for the species identification. Finally, Noni et al. (2020) describe a 12-year retrospective study of fungal infections at a children's hospital in Greece. All patients had a serious underlying disease and had acquired an opportunistic fungal infection. Six of 416 subjects (1.4%) had *S. cerevisiae* infection. It is not possible to know which specific method(s) was used to identify *S. cerevisiae*. The retrospective studies did not provide further information on the cases reported.

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*.

Kaur et al. (2020), in a retrospective study, from a total of 602,963 blood samples from patients with suspected sepsis, identified in intensive care units in a hospital in India, that *W. anomalus* constituted 13.1% of yeast isolates (identification by conventional methods and MALDI-TOF MS). In a retrospective taxonomic study on 85 'uncommon *Candida* species' isolated from patients with candidaemia in hospitals in Taiwan (Huang et al., 2020), 15 isolates were identified as *W. anomalus* by conventional methods and MALDI-TOF MS. Pandey et al. (2020) report the identification of 119 yeast isolates from patients diagnosed with blood-stream candidiasis in an intensive care unit of a hospital in India. Using MALDI-TOF MS, 15 isolates were identified as *W. anomalus*. In these three reports, species identification is uncertain because of the low resolution of the methods used for yeast identification. Sankari et al. (2020) reported the prevalence of *Candida* species in the saliva of patients with oral squamous cell carcinoma, oral potentially malignant disorders and healthy cohorts in a hospital in India, and 33% were identified as *C. pelliculosa* in patients with oral squamous cell carcinoma. Yamin et al. (2020) found in a retrospective study (2001–2018) on isolates from patients with candidaemia in a hospital in Malaysia, that four of 1,175 isolates (0.3%) *C. pelliculosa*. The retrospective studies did not provide further information on the cases reported.

Finally, Dutra et al. (2020) report a case of infection by *W. anomalus* in a 19-month-old Brazilian female who had a previous history of prematurity, cardiac surgery due to patent ductus arteriosus and a long period of hospital stay.

The reports assessed in this period showed inconsistency in the identification, predisposing factors for human infection and/or a lack of information on the cases reported.

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

3.3.5. Protists/Algae

ELS was performed for all three species together, as indicated below.

A search for papers potentially relevant for the QPS evaluation of protists/algae provided 84 references. The analysis of their titles left 42 articles for title/abstract screening. Eight articles reached full text evaluation. Four of eight articles dealt with potential safety concerns of which two were on *A. limacinum*, one on *Schizochytrium limacinum* and one on *T. chuii* (see below).

Aurantiochytrium limacinum

A. limacinum is a member of the *Thraustochytriaceae* and is a protist. The taxonomic classification of the genus *Schizochytrium* has been subject to discussion in 2007 (Yokoyama and Honda, 2007). Based on genetic and phenotypic analysis, the authors proposed changes in the classification. The genus *Schizochytrium* was amended and new genera such as *Aurantiochytrium* and *Oblongichytrium* were defined. The species *Schizochytrium limacinum* can also be referred to as *Aurantiochytrium limacinum*.

No article indicated a safety concern; therefore, the current QPS status of *A. limacinum* is not changed.

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

One article on *T. chuii* dealt with a potential safety concern, however, this concern was not confirmed after full text evaluation. Therefore, the current QPS status of *T. chuii* is not changed.

3.3.6. 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 31 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 43 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.

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 October 2020 and March 2021, the list of notifications was updated with 78 notifications that were received by EFSA, of which 55 were proposed for evaluation as feed additives, 13 for use as food enzymes, food additives and flavourings, 8 as novel foods and 2 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. *Schizochytrium limacinum*, which is a synonym for *Aurantiochytrium limacinum*, is added to the QPS list.

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

- Out of the 78 notifications received, 44 were related to TUs that already had QPS status and did not require further evaluation.
- Of the remaining 34 notifications, 27 were related to TUs excluded from QPS evaluation: 16 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 7 of *Escherichia coli*, 1 of *Streptomyces* spp. and 2 notifications (*Dyella* spp. and *Schizochytrium* sp. strain CABIO-A-2)

were only a genus, or a specific strain, and not a species and were therefore not eligible for QPS evaluation.

- Seven notifications, corresponding to 7 TUs, were evaluated for possible QPS status. *Corynebacterium stationis* and *Kodamaea ohmeri* were re-assessed because an update was requested in relation to the current mandate. Five TUs (*Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi* and *Lactococcus garvieae*) were assessed for the first time.
- *Corynebacterium stationis* is not recommended for QPS status due to a lack of body of knowledge in relation to its occurrence in the food and feed chain and to possible safety concerns in relation to human health.
- *Kodamaea ohmeri* is not recommended for QPS status due to safety concerns in relation to human health.
- *Anoxybacillus caldiproteolyticus* is not recommended for QPS status due to a lack of body of knowledge on its occurrence in the food and feed chain.
- *Bacillus paralicheniformis* is recommended for the QPS status with the qualifications 'absence of toxigenic activity' and 'absence of genetic information to synthesize bacitracin'.
- *Enterobacter hormaechei* is not recommended for QPS status due to its pathogenic potential for humans and animals.
- *Eremothecium ashbyi* is not recommended for QPS status due to a lack of body of knowledge on its occurrence in the food and feed chain and its plant pathogenicity.
- *Lactococcus garvieae* is not recommended for QPS status due to its pathogenic potential for humans and animals.

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Glossary

Anamorph name	Valid name of a fungus based on the asexual reproductive state (morphologically).
Antimicrobial compounds	Antibiotics, bacteriocins and/or small peptides with antimicrobial activity.
Basonym name	the earliest validly published name of a taxon.
Synonymous name/Homotypic synonym	have the same type (specimen) and the same taxonomic rank.
Teleomorph name	Valid name of a fungus based on the sexual reproductive state (morphologically).

Abbreviations

AI	artificial intelligence
AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
BMECs	bovine mammary epithelial cells
CFR	cranberry fruit rot
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)
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
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. *Enterobacter hormaechei*

The search on PubMed led to 168 hits with the keyword 'hormoachei' 168 hits. All hits were screened for their relevance.

A.2. *Corynebacterium stationis*

The search on Scopus led to 17 hits related to *Corynebacterium stationis*. Among them, seven were considered appropriate for the assessment.

A.3. *Lactococcus garvieae*

A search for the body of knowledge on *L. garvieae* was done in the databases mentioned above, considering all years available in these databases, using a range of search terms in relation to food and feed, combined with *L. garvieae*.

lactococcus AND garvieae AND (infect* OR disease* OR pathog* OR mastit*): 277 hits,
lactococcus AND garvieae AND cheese: 23 hits
lactococcus AND garviae AND (food OR feed OR ferment*): 13 hits
lactococcus AND garvieae AND fish: 213 hits
lactococcus AND garvieae AND mastit*: 18 hits

A.4. *Eremothetium ashbyi*

Searches were made on Web of Science core collection. '(*Eremothecium ashbyi*) or (*E. ashbyi*) or (*Eremothecium ashbyii*) or (*E. ashbyii*)' gave 150 hits, which were all scanned on title level. A similar search was also done with the synonym *Crebrothecium ashbyi*, resulting in no additional hits.

A.5. *Bacillus paralicheniformis*

A search was made on PubMed with the key word 'Bacillus paralicheniformis'. All 43 hits were screened.

A.6. *Anoxybacillus caldiproteolyticus*

Search in Pub-Med for the terms "caldiproteolyticus" and "caldoproteolyticus" provided eight hits. Five of them were on taxonomy/properties of the organism, while the other three were on description of related, new *Anoxybacillus* species.

A.7. *Kodamaea ohmeri*

Search in Pub-Med for the terms "Kodamaea" and "ohmeri" for the years 2019, 2020 and 2021 resulted in 15 papers, 7 papers and 1 paper, respectively. Collectively, out of these 23 papers one is a review, two are previous QPS statements, three are related to bioremediation/biochemistry, seven are related to plant pathology/ecology and 10 are related to (treatment of) opportunistic *K. ohmeri* infections in mostly immunocompromised human individuals. Other databases, including Web of Science core collection, searched for the same terms gave less papers, but with full overlap with the Pub-Med collection of papers.

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-2020-00079) is available on the EFSA Knowledge Junction community on Zenodo, at: <https://doi.org/10.5281/zenodo.5016562>

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.5016711>

Appendix D – References selected from the ELS exercise with potential safety concerns for searches July–December 2020 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium spp.

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Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

- Albarillo FS, Shah U, Joyce C and Slade D, 2020. *Lactobacillus rhamnosus* infection: a single-center 4-year descriptive analysis. *Journal of Global Infectious Diseases*, 12, 119–123.
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Lactococcus lactis

None.

Leuconostoc spp.

- Bog ES, Erturk O and Yaman M, 2020. Pathogenicity of aerobic bacteria isolated from honeybees (*Apis mellifera*) in Ordu Province. *Turkish Journal of Veterinary and Animal Sciences*, 44, 714–719.
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- Omori R, Fujiwara S, Ishiyama H, Kuroda H and Kohara N, 2020. *Leuconostoc lactis*- A Rare Cause of Bacterial Meningitis in an Immunocompromised Host. *Internal Medicine*, 59, 2935–2936.

Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

None.

Propionibacterium spp.

None.

Streptococcus thermophilus

None.

Gram-Positive Spore-forming Bacteria

Bacilli

Princess I, Natarajan T and Ghosh S, 2020. When good bacteria behave badly: a case report of *Bacillus clausii* sepsis in an immunocompetent adult. *Accessed Microbiology*, 2, acmi000097. <https://doi.org/10.1099/acmi.0.000097>

Song X, Huang X, Xu H, Zhang C, Chen S, Liu F, Guan S, Zhang S, Zhu K and Wu C, 2020. The prevalence of pathogens causing bovine mastitis and their associated risk factors in 15 large dairy farms in China: an observational study. *Veterinary Microbiology*, 247, 108757. <https://doi.org/10.1016/j.vetmic.2020.108757>

Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Gram-negative bacteria

Gluconobacter oxydans

None.

Xanthomonas campestris

None.

Yeasts

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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, 2020a) 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 (13) adopted in December 2020 (EFSA BIOHAZ Panel, 2021). These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2020a); the updated QPS list is available at <https://doi.org//10.2903/j.efsa.2021.6689> and, as of January 2018, also as supporting information linked to every Panel Statement available on the Knowledge Junction at <https://doi.org/10.5281/zenodo.4428353>.

Appendix F – Microbial species as notified to EFSA, received between October 2020 and March 2021 (reply to ToR 1)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
Algae							
<i>Schizochytrium limacinum</i>		Novel foods	Novel Food	Production of docosahexaenoic acid (DHA)-rich oil as novel food	EFSA-Q-2020-00850	Y	No
<i>Schizochytrium sp.</i>	CABIO-A-2	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	N	No
Bacteria							
<i>Anoxybacillus caldiproteolyticus</i>	ST88	Food enzymes, food additives and flavourings	Enzyme production	Production of a cyclomaltodextrin glucanotransferase	EFSA-Q-2015-00230	N	Yes
<i>Bacillus licheniformis</i>	Ca63 – DSM 9552 GMM, NZYM-CY	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme maltogenic alpha-amylase	EFSA-Q-2021-00137	Y	No
<i>Bacillus licheniformis</i>	Ca63 – DSM 9552 GMM, NZYM-SD	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme maltogenic alpha-amylase	EFSA-Q-2021-00138	Y	No
<i>Bacillus licheniformis</i>	Ca63 – DSM 9552 GMM, NZYM-FR	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme maltogenic alpha-amylase	EFSA-Q-2021-00142	Y	No
<i>Bacillus paralicheniformis</i>	DSM 5749	Feed additives	Zootechnical additives	Zootechnical additive	EFSA-Q-2019-00736	N	Yes
<i>Bacillus subtilis</i>	KCCM-10445	Feed additives	Nutritional additives	Production of Vitamin B2	EFSA-Q-2020-00838	Y	No
<i>Bacillus velezensis</i>	deposited as <i>Bacillus amyloliquefaciens</i> , NRRL-B-50910	Feed additives	Technological additives	Acidity regulator/preservative	EFSA-Q-2021-00099	Y	No
<i>Corynebacterium glutamicum</i>	C. glutamicum KCCM 80227 (DK257RN)	Feed additives	Nutritional additives	Nutritional additives: c) amino acids, their salts and analogues	EFSA-Q-2020-00708	Y	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Corynebacterium glutamicum</i>	KCCM 80245	Feed additives	Nutritional additives	Production of L-methionine (2-amino-4-(methylthio)-butanoic acid)	EFSA-Q-2021-00154	Y	No
<i>Corynebacterium stationis</i>	KCCM 80235	Feed additives	Sensory additives	Flavouring compound	EFSA-Q-2021-00084	N	Yes
<i>Dyella</i> sp. (previous name: <i>Pseudomonas amyloclavata</i>)	MU 1174	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme isoamylase	EFSA-Q-2021-00067	N	No
<i>Enterobacter hormaechei</i>	Subsp. Steigerwaltii	Novel foods	Novel Food	Production of L-fucose as novel food	EFSA-Q-2020-00774	N	Yes
<i>Enterococcus faecium</i>	NBIMCC 8270	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	N	No
<i>Escherichia coli</i>	BL21 (DE3)	Novel foods	Novel Food	Lacto-N-tetraose production by fermentation	EFSA-Q-2020-00630	N	No
<i>Escherichia coli</i>	NITE SD 00329	Feed additives	Nutritional additives	Nutritional and sensory additive: Production of L-histidine monohydrochloride monohydrate	EFSA-Q-2020-00808	N	No
<i>Escherichia coli</i>	BL21 (DE3)-Genetically modified to express the enzyme SD16	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme D-tagatose-3-epimerase SD16	EFSA-Q-2021-00065	N	No
<i>Escherichia coli</i>	K-12	Novel foods	Novel Food	Production of 2'-Fucosyllactose	EFSA-Q-2021-00088	N	No
<i>Escherichia coli</i>	K-12 DH1	Novel foods	Novel Food	Production of 2'-Fucosyllactose/Difucosyllactose mixture	EFSA-Q-2021-00091	N	No
<i>Escherichia coli</i>	KCCM 80246	Feed additives	Nutritional additives	Production of L-methionine (2-amino-4-(methylthio)-butanoic acid)	EFSA-Q-2021-00154	N	No
<i>Escherichia coli</i>	K-12 DH1	Feed additives	Zootechnical additives	Production of Lacto-N-fucopentaose I /2'-fucosyllactose mixture (LNFP-I /2'-FL)	EFSA-Q-2021-00170	N	No
<i>Lactiplantibacillus plantarum</i>	E-98 NCIMB 30236	Feed additives	Technological additives	Silage Additive	EFSA-Q-2021-00076	N	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Lactobacillus acidophilus</i>	NBIMCC 8242	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	Y	No
<i>Lactobacillus acidophilus</i>	D2/CSL (CECT 4529)	Feed additives	Zootechnical additives	Gut flora stabiliser	EFSA-Q-2020-00847	Y	No
<i>Lactobacillus brevis</i>	DSM 12835	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00691	Y	No
<i>Lactobacillus buchneri</i>	DSM 16774	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00654	Y	No
<i>Lactobacillus buchneri</i>	DSM 12856	Feed additives	Technological additives	Silage additive	EFSA-Q-2020-00769	Y	No
<i>Lactobacillus buchneri</i>	DSM 12856	Feed additives	Technological additives	Silage additive	Not yet registered	Y	No
<i>Lactobacillus buchneri</i>	DSM 12856	Feed additives	Technological additives	Silage Additive	EFSA-Q-2021-00127	Y	No
<i>Lactobacillus delbrueckii ssp. bulgaricus</i>	NBIMCC 8244	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	Y	No
<i>Lactobacillus delbrueckii ssp. lactis</i>	NBIMCC 8250	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	Y	No
<i>Lactobacillus helveticus</i>	NBIMCC 8269	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	Y	No
<i>Lactobacillus paracasei</i>	DSM 16245	Feed additives	Technological additives	Silage additive	EFSA-Q-2020-00707	Y	No
<i>Lactobacillus plantarum</i>	DSM 8862	Feed additives	Technological additives	Silage Additive	EFSA-Q-2021-00131	Y	No
<i>Lactobacillus plantarum</i>	DSM 8866	Feed additives	Technological additives	Silage Additive	EFSA-Q-2021-00131	Y	No
<i>Lactobacillus plantarum</i>	IMI 507026	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00695	Y	No
<i>Lactobacillus plantarum</i>	IMI 507027	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00696	Y	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Lactobacillus plantarum</i>	IMI 507028	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00697	Y	No
<i>Lactobacillus rhamnosus</i>	NCIMB 30121	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00706	Y	No
<i>Lactobacillus rhamnosus</i>	IMI 507023	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00692	Y	No
<i>Lactococcus garvieae</i>	20-92	Novel foods	Novel Food	Lactococcus 20-92 is used to produce SE5-OH [®] , a soy-based product produced by selective fermentation of soy germ powder	EFSA-Q-2021-00092	N	Yes
<i>Lactococcus lactis</i>	DSM 11037	Feed additives	Technological additives	Silage additive	EFSA-Q-2020-00846	Y	No
<i>Lactococcus lactis</i>	NCIMB 30160	Feed additives	Technological additives	Silage additive	EFSA-Q-2021-00082	Y	No
<i>Pediococcus acidilactici</i>	Pediococcus acidilactici CNCM I-4622	Feed additives	Technological additives	Acidity regulators and hygiene condition enhancer	EFSA-Q-2020-00839	Y	No
<i>Pediococcus acidilactici</i>	DSM 16243	Feed additives	Technological additives	Silage additive	EFSA-Q-2020-00814	Y	No
<i>Pediococcus acidilactici</i>	NRRL-B-50595	Feed additives	Technological additives	Acidity regulator/preservative	EFSA-Q-2021-00099	Y	No
<i>Pediococcus acidilactici</i>	NRRL-B-50964	Feed additives	Technological additives	Acidity regulator/preservative	EFSA-Q-2021-00099	Y	No
<i>Pediococcus pentosaceus</i>	IMI 507024	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00693	Y	No
<i>Pediococcus pentosaceus</i>	IMI 507025	Feed additives	Technological additives	Silage Additive	EFSA-Q-2020-00694	Y	No
<i>Pediococcus pentosaceus</i>	DSM 12834	Feed additives	Technological additives	Silage additive	EFSA-Q-2020-00845	Y	No
<i>Propionibacterium freudenreichii</i>	DSM 33189	Feed additives	Technological additives	Silage additive	Not yet registered	Y	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Propionibacterium freudenreichii</i>	DSM 33189	Feed additives	Technological additives	Silage Additive	EFSA-Q-2021-00127	Y	No
<i>Streptococcus thermophilus</i>	NBIMCC 8253	Feed additives	Nutritional additives	Gut flora stabiliser in pets and other non-food-producing animals	EFSA-Q-2020-00690	Y	No
<i>Streptomyces cinnamonensis</i>	26862	Cocciostats and histomonostats	Cocciostats and histomonostats	Production of monensin sodium as cocciostat, by fermentation.	EFSA-Q-2020-00837	N	No
Filamentous Fungi							
<i>Aspergillus aculeatus</i>	CBS 589.94	Feed additives	Zootechnical additives	Production of polygalacturonase. Zootechnical additive – digestibility enhancer.	EFSA-Q-2020-00840	N	No
<i>Aspergillus niger</i>	C3085 GMM, NZYM-NM	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme mannanase	EFSA-Q-2021-00123	N	No
<i>Aspergillus oryzae</i>	GD-FAL	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme beta-galactosidase	EFSA-Q-2020-00710	N	No
<i>Aspergillus oryzae</i>	RF31782	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme pectin esterase	EFSA-Q-2021-00072	N	No
<i>Aspergillus oryzae</i>	RF31782	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme polygalacturonase	EFSA-Q-2021-00066	N	No
<i>Paecilomyces fumosoroseus</i>	Fe9901	Plant protection products	Plant Protection Product	Insecticide, intended for biological control of whitefly	EFSA-Q-2020-00813	N	No
<i>Thermothelomyces thermophilus</i>	HC LU19287	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2021-00075	N	No
<i>Trichoderma citrinoviride</i>	Bisset IM SD 142	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2021-00157	N	No
<i>Trichoderma harzanium</i>	B97	Plant protection products	Plant Protection Product	Fungicide on rapeseed, to control soil-borne plant-pathogenic fungi Sclerotinia sclerotiorum	EFSA-Q-2020-00784	N	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Trichoderma longibrachiatum</i>	MUCL 49754	Feed additives	Zootechnical additives	Digestibility enhancer – Production of endo-1,3(4)- β -glucanase	EFSA-Q-2020-00807	N	No
<i>Trichoderma longibrachiatum</i>	MUCL 49755	Feed additives	Zootechnical additives	Digestibility enhancer – Production of endo-1,4- β -xylanase	EFSA-Q-2020-00807	N	No
<i>Trichoderma reesei</i>	CRC2836-13885 LVS_ETD MB#2 (GICC03538)	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2020-00767	N	No
<i>Trichoderma reesei</i>	MUCL 49754	Feed additives	Zootechnical additives	Production of endo-1,3(4)- β -glucanase. Zootechnical additive – digestibility enhancer.	EFSA-Q-2020-00840	N	No
<i>Trichoderma reesei</i>	MUCL 49755	Feed additives	Zootechnical additives	Production of endo-1,4- β -xylanase Zootechnical additive – digestibility enhancer.	EFSA-Q-2020-00840	N	No
<i>Trichoderma reesei</i>	BTR213 GMM, NZYM-GV	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme arabinofuranosidase	EFSA-Q-2021-00120	N	No
<i>Trichoderma reesei</i>	BTR213 GMM, NZYM-ER	Food enzymes, food additives and flavourings	Enzyme production	Used for the production of the enzyme xylanase	EFSA-Q-2021-00140	N	No
Yeasts							
<i>Eremothecium ashbyii</i>	CCTCCM 2019833	Feed additives	Nutritional additives	Vitamin B2 (Riboflavin) for all animal species	EFSA-Q-2020-00323	N	Yes
<i>Kodamaea ohmeri</i>	Po165	Food enzymes, food additives and flavourings	Enzyme production	Used in an improved manufacturing process to produce the food additive xylitol (E967)	EFSA-Q-2021-00078	N	Yes
<i>Komagataella phaffii</i>	GS1115-KI	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2021-00098	Y	No
<i>Komagataella phaffii</i>	DSM 23036	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2021-00152	Y	No
<i>Yarrowia lipolytica</i>		Novel foods	Novel Food	Production of biomass as novel food	EFSA-Q-2020-00655	Y	No

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA Question no ^(a) and EFSA webpage link ^(b)	Previous QPS status of the respective TU ^(c)	Assessed in this Statement? Yes or no
<i>Yarrowia lipolytica</i>	GM strain	Feed additives	Sensory additives	Production of Canthaxanthin (sensory additive, colourant and technological additive)	EFSA-Q-2021-00149	Y	No
<i>Yarrowia lipolytica</i>	GM strain	Feed additives	Sensory additives	Production of Canthaxanthin (sensory additive, colourant and technological additive)	EFSA-Q-2021-00150	Y	No

(a): To find more details on specific applications please access the EFSA website – [openEFSA](#).

(b): Where no link is given, this means that the risk assessment has not yet been published.

(c): Included in the QPS list as adopted in December 2019 (EFSA BIOHAZ Panel, 2020b) and respective updates which include new additions (latest: EFSA BIOHAZ Panel, 2021).