

## STATEMENT

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# Update of the list of QPS-recommended microbiological agents intentionally added to food or feed as notified to EFSA 16: suitability of taxonomic units notified to EFSA until March 2022

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## Abstract

The qualified presumption of safety (QPS) approach was developed to provide a regularly updated generic pre-evaluation of the safety of microorganisms, intended for use in the food or feed chains, to support the work of EFSA's Scientific Panels. The QPS approach is based on an assessment of published data for each agent, with respect to its taxonomic identity, the body of relevant knowledge, 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. Of the 50 microorganisms notified to EFSA in October 2021 to March 2022 (inclusive), 41 were not evaluated: 10 filamentous fungi, 1 *Enterococcus faecium*, 1 *Clostridium butyricum*, 3 *Escherichia coli* and 1 *Streptomyces* spp. because are excluded from QPS evaluation, and 25 TUs that have already a QPS status. Nine notifications, corresponding to seven TUs were evaluated: four of these, *Streptococcus salivarius*, *Companilactobacillus formosensis*, *Pseudonocardia autotrophica* and *Papiliotrema terrestris*, being evaluated for the first time. The other three, *Microbacterium foliorum*, *Pseudomonas fluorescens* and *Ensifer adhaerens* were re-assessed. None of these TUs were recommended for QPS status: *Ensifer adhaerens*, *Microbacterium foliorum*, *Companilactobacillus formosensis* and *Papiliotrema terrestris* due to a limited body of knowledge, *Streptococcus salivarius* due to its ability to cause bacteraemia and systemic infection that results in a variety of morbidities, *Pseudonocardia autotrophica* due to lack of body of knowledge and uncertainty on the safety of biologically active compounds which can be produced, and *Pseudomonas fluorescens* due to possible safety concerns.

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**Keywords:** *Companilactobacillus formosensis*, *Ensifer adhaerens*, *Microbacterium foliorum*, *Papiliotrema terrestris*, *Pseudomonas fluorescens*, *Pseudonocardia autotrophica*, QPS, *Streptococcus salivarius*

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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 microorganisms, intentionally added to food and feed, which have achieved QPS status. The request included three specific tasks as mentioned in the Terms of Reference (ToRs).

The QPS process was developed to provide a harmonised generic pre-evaluation procedure to support safety risk assessments of microorganisms performed by EFSA's scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms. Safety concerns identified for a taxonomic unit (TU) are, where possible, confirmed at strain or product level, reflected as 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. A generic qualification for all QPS bacterial TUs applies in relation to the absence of acquired genes conferring resistance to clinically relevant antimicrobials (EFSA, 2008).

The list of microorganisms is maintained and re-evaluated approximately every 6 months in a Panel Statement. The Panel Statement also includes the evaluation of microbiological agents newly notified to EFSA within the previous 6-month period.

The first ToR requires ongoing updates of the list of microbiological 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 October 2021 and March 2022. Within this period, 50 notifications were received by EFSA, of which 35 were proposed for evaluation in feed, 11 for use as food enzymes, food additives and flavourings and 4 as novel foods. The new notifications received between October 2021 and March 2022 are included in the current Statement (see Appendix F).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications. For this revision, articles published from July and December 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 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).

Fifty notifications were received; 41 of these were not evaluated for the following reasons: 16 notifications were related to microorganisms that are excluded from QPS evaluation (10 were notifications of filamentous fungi, 1 *Enterococcus faecium*, 1 of *Clostridium butyricum*, 3 of *Escherichia coli*, 1 *Streptomyces* spp.), and 25 were related to TUs that already have QPS status and did not require further evaluation.

The remaining nine notifications, corresponding to seven TUs, were evaluated for possible QPS status: four of these (*Companilactobacillus formosensis*, *Pseudonocardia autotrophica*, *Streptococcus salivarius* and *Papiliotrema terrestris*) being evaluated for the first time. The other three, *Ensifer adhaerens*, *Microbacterium foliorum* and *Pseudomonas fluorescens* were re-assessed because an update was requested in relation to the current mandate.

The following conclusions were drawn:

- *Companilactobacillus formosensis* (previously known as *Lactobacillus formosensis*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.
- *Pseudonocardia autotrophica* is not recommended for the QPS list due to lack of body of knowledge and uncertainty on the safety of biologically active compounds which can be produced.
- *Streptococcus salivarius* is not recommended for the QPS list due to its ability to cause bacteraemia and systemic infection that results in a variety of morbidities.
- *Papiliotrema terrestris* is not recommended for the QPS list due to a limited body of knowledge.
- *Ensifer adhaerens* (synonym *Sinorhizobium adhaerens*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.
- *Microbacterium foliorum* is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.
- *Pseudomonas fluorescens* is not recommended for the QPS list due to possible safety concerns.

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## 1. Introduction

The qualified presumption of safety (QPS) approach was developed by the EFSA Scientific Committee to provide a generic concept for risk assessment within the European Food Safety Authority (EFSA) for microorganisms intentionally introduced into the food chain, in support of the respective Scientific Panels and Units in the context of market authorisations for their use in food and feed and requiring 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 submitted 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 chains. In the context of applications for market authorisation of these microbiological 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.<sup>1</sup> 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, 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, 2005). The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and, in 2007, published a list of microorganisms recommended for the QPS list.

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

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

<sup>1</sup> [https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scf\\_out178\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out178_en.pdf)

2016 on, the QPS list (<https://doi.org/10.5281/zenodo.1146566>) and the list of notifications to EFSA (<https://doi.org/10.5281/zenodo.3607183>) are constantly updated, independent of the QPS opinion, and are available at the Knowledge Junction in Zenodo. The most recent QPS opinion (EFSA BIOHAZ Panel, 2020a) summarises the main results of the 3-year ELS on the QPS TUs, together with an update of the process for granting QPS status. In the meantime, every 6 months a Panel Statement, compiling the assessments for a QPS status of the 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 standardised 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 inform decisions on whether any TU may or may not remain on the QPS list, and whether any qualifications need to be revised.

Establishing a QPS status is based on four pillars: [1] the taxonomic 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 via 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, 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 relating to type and level of exposure of users handling the product (e.g. dermal contact, inhalation, ingestion) are not addressed. In the case of Genetically Modified Microorganisms (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,b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits by some strains of the taxonomic unit, therefore requiring a specific assessment for each strain for which an application is made.

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

ToR 1: Keep updated the list of microbiological 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 to verify whether any new safety concern has arisen that could require the removal of a taxonomic unit from the list, and to verify if the qualifications still effectively exclude safety concerns.

ToR 3: (Re) assess the suitability of new taxonomic units notified to EFSA for their inclusion in the QPS list. These 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 2021 to March 2022, inclusive) was carried out. The literature review considered the information on taxonomy, the body of knowledge, the potential safety concerns related to human and animal health and to the environment (EFSA BIOHAZ Panel, 2020a) for each TU. The environmental risk assessment of plant protection products is not included in the QPS assessment but is carried out by the Pesticide Peer Review (PPR) Unit based on the risk assessment in the application. Information 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. To complete the assessment an ELS-based approach may have been applied. In the current Panel Statement, this ELS approach was applied for assessing the QPS status of *Ensifer adhaerens* and *Streptococcus salivarius*. The ELS followed the same methodology as used for monitoring new safety concerns related to species with QPS status. More details on the search strategy, search keys, and approach for each of the assessments are described in Appendix A. Only the literature that is considered, based on expert judgement, to be relevant for the QPS assessment is reflected in the Statement.

Only valid TUs covered by the relevant international committees on the nomenclature for microorganisms are considered for the QPS assessment.

### 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 microbiological agents being notified to EFSA. A total of 50 notifications were received between October 2021 and March 2022, of which 35 were for evaluation for use in feed, 11 for use as food enzymes, food additives and flavourings, 4 as novel foods and 0 as plant protection products (Table 1).

In response to ToR 3, nine of the 50 notifications, corresponding to seven TUs, were evaluated for possible QPS status, four of these, *Companilactobacillus formosensis*, *Pseudonocardia autotrophica*, *Streptococcus salivarius*, and *Papiliotrema terrestris*, being evaluated for the first time. The other three, *Ensifer adhaerens*, *Microbacterium foliorum* and *Pseudomonas fluorescens*, were re-assessed because an update was requested in the current mandate. The remaining 41 notifications were excluded from QPS evaluation for the following reasons: 17 notifications were related to microorganisms that are excluded from QPS evaluation (10 were notifications of filamentous fungi, 1 of *Clostridium butyricum* (bacterium), 1 of *Enterococcus faecium* (bacterium), 3 of *Escherichia coli*, 1 *Streptomyces* spp.) and 25 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 microbiological group, from October 2021 to March 2022

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement <sup>(b)</sup>	Total
	Already QPS	Excluded from QPS <sup>(a)</sup>		
<b>Microbiological group</b>				
<b>Feed additives</b>	<b>22</b>	<b>7</b>	<b>6</b>	<b>35</b>
Bacteria	20	1	6	27
Filamentous fungi		6		6
Yeasts	2			2

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement <sup>(b)</sup>	Total
	Already QPS	Excluded from QPS <sup>(a)</sup>		
<b>Microbiological group</b>				
<b>Novel foods</b>	<b>0</b>	<b>4</b>	<b>0</b>	<b>4</b>
Bacteria		3		3
Filamentous fungi		1		1
Protists/Algae				
Yeasts				
<b>Plant protection products</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Bacteria				
Filamentous fungi				
Viruses				
<b>Food enzymes, food additives and flavourings</b>	<b>3</b>	<b>5</b>	<b>3</b>	<b>11</b>
Bacteria	2	2	2	6
Filamentous fungi		3		3
Yeasts	1		1	2
<b>Genetically modified organism</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Bacteria				
<b>Total</b>	<b>25</b>	<b>16</b>	<b>9</b>	<b>50</b>

QPS: qualified presumption of safety.

(a): The number includes 10 notifications of filamentous fungi, 1 of *Clostridium butyricum* (bacterium), 1 of *Enterococcus faecium* (bacterium), 3 of *Escherichia coli* (bacterium) and 1 of *Streptomyces* spp. (bacterium), all excluded from QPS evaluation.

(b): Nine notifications corresponding to seven TUs, four of these (*Companilactobacillus formosensis*, *Pseudonocardia autotrophica*, *Streptococcus salivarius*, and *Papillotrema terrestris*) being evaluated for the first time. The other three, *Ensifer adhaerens*, *Microbacterium foliorum* and *Pseudomonas fluorescens* were re-assessed because an update was requested in the current mandate.

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

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

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

The aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, animals or the environment, caused by QPS organisms since the previous QPS review (i.e. publications from July to December 2021).

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, for example mucosal impairment and/or proton pump inhibitors can also be predisposing factors for infection. Previous use of the microorganisms being assessed as food supplements for humans was reported in many of these cases. Nevertheless,



the QPS assessment takes into consideration these reports, extracting relevant information whenever justified. For a detailed protocol of the process and search strategies, refer to Appendices B and C.

After removal of duplicates, 3,290 records were submitted to the title screening step, which led to the exclusion of 3,143 of these. The remaining 190 records were found eligible for the title and abstract screening step, which led to the exclusion of 66 of these. Of the 55 articles that finally reached the article evaluation step (full text), 32 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)
<b>Number of articles retrieved</b>				
<b>Bacteria (total)</b>	<b>2,112</b>	<b>78</b>	<b>32</b>	<b>13</b>
<i>Bacillus</i> spp. <sup>(a)</sup>	676	15	9	6
<i>Bifidobacterium</i> spp. <sup>(a)</sup>	180	10	3	1
<i>Carnobacterium divergens</i>	6	0	0	0
<i>Corynebacterium glutamicum</i>	23	2	1	0
Gram negatives <sup>(b)</sup>	260	3	1	0
Lactobacilli <sup>(a)</sup>	471	25	7	3
<i>Lactococcus lactis</i> <sup>(a)</sup>	110	12	5	3
<i>Leuconostoc</i> spp.	76	5	2	0
<i>Microbacterium imperiale</i>	1	0	0	0
<i>Oenococcus oeni</i>	29	0	0	0
<i>Pasteuria nishizawae</i>	1	0	0	0
<i>Pediococcus</i> spp.	175	2	0	0
<i>Propionibacterium</i> spp.	24	0	0	0
<i>Streptococcus thermophilus</i>	80	4	4	0
<b>Viruses (total)</b>	<b>114</b>	<b>2</b>	<b>0</b>	<b>0</b>
Alphaflexiviridae/ Potyviridae	55	0	0	0
Baculoviridae	59	2	0	0
<b>Yeasts<sup>(a)</sup></b>	<b>802</b>	<b>92</b>	<b>19</b>	<b>19</b>
<b>Protists</b>	<b>22</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>Algae</b>	<b>240</b>	<b>17</b>	<b>4</b>	<b>0</b>
<b>Total</b>	<b>3,290</b>	<b>190</b>	<b>55</b>	<b>32</b>
<b>Excluded</b>	3,143	66	48	

(a): The numbers of references pre-screened by AI and excluded are not reported in the table and are for: *Bifidobacterium* spp. (179), lactobacilli (471), *Lactococcus lactis* (103), *Bacillus* spp. (740), yeasts (811).

(b): *Gluconobacter oxydans*/*Xanthomonas campestris*/*Cupriavidus*/*Komagataibacter*.

### 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

##### ***Ensifer adhaerens* synonym *Sinorhizobium adhaerens***

A new evaluation of *Ensifer adhaerens* was made because an update was requested in relation to the new QPS mandate. *E. adhaerens* was not recommended for the QPS list in the previous assessment due to a lack of body of knowledge (EFSA, 2011).

##### *Identity*

*E. adhaerens* is a valid taxonomic unit. *Sinorhizobium adhaerens* is a synonym (Cassida, 1982; Willems et al., 2003). *Sinorhizobium morelense* (Wang et al., 2002) and *Ensifer morelensis* (Wang et al., 2013, Oren and Garrity, 2015) are previously used names without nomenclature validation. All synonyms were included in the literature searches.

##### *Body of knowledge*

The literature search was concentrated on papers since 2011. *Ensifer adhaerens* is a rhizosphere inhabiting bacterium with the ability to genetically transform several plants species (Rudder et al., 2014). *E. adhaerens* strains have been isolated in relation to N<sub>2</sub> fixing (Katiyar et al., 2021), biosorption and biodegradation potential (Xu et al., 2016, Mesa et al., 2017), ligninolytic potential (Falade et al., 2017), exopolysaccharide production (Marques Alvarez et al., 2018), degradation of neonicotinoid insecticides (Sun et al., 2021, Zhao et al., 2021), vitamin B production (Thi Vu et al., 2013), mineral weathering capacity (Wang et al., 2016), alliinase production with antimicrobial activity (Yutani et al., 2011) and growth promotion potential (Zhumakayev et al., 2021).

##### *Safety concerns*

The safety of Vitamin B<sub>12</sub>, produced by a strain of *E. adhaerens* has been assessed by EFSA (EFSA FEEDAP Panel, 2020). WGS confirmed the absence of any known virulence gene and no toxic compounds are expected to be produced during fermentation. No other references addressed food safety issues.

##### *Conclusion on a recommendation for QPS status*

*E. adhaerens* (synonym *Sinorhizobium adhaerens*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.

##### ***Microbacterium foliorum***

A new evaluation of *Microbacterium foliorum* was made because an update was requested in relation to the new QPS mandate. *M. foliorum* was not recommended for the QPS list due to lack of body of knowledge (EFSA BIOHAZ Panel, 2019b). In the period between 2019 and 2022, only one relevant article was found related to the safety of *M. foliorum*. Fu et al. (2021) studied the microbiological load of urban air dust by a metagenomic approach and found an association of *M. foliorum* with the occurrence of wheeze, rhinitis and rhinoconjunctivitis; a causal relationship was not investigated.

##### *Conclusion on a recommendation for QPS status*

*M. foliorum* is not to be recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.

##### ***Pseudomonas fluorescens***

A new evaluation of *Pseudomonas fluorescens* was made because an update was requested in relation to the new QPS mandate. *P. fluorescens* was considered as unsuitable for QPS in 2016 and 2019 assessments because some strains raise safety concerns (EFSA BIOHAZ Panel, 2016, 2019a).

In recent years, it was recognised that many strains, reported to be *P. fluorescens*, are incorrectly identified (Morimoto et al., 2020). Moreover, several studies reporting safety concerns do not mention the method used for identification of the pathogen or used, only 16S rRNA sequence as identification tool which has been shown to be insufficiently discriminative.

Studies, based on correct identification of *P. fluorescens*, are lacking to clarify the possible safety concerns reported in relation to *P. fluorescens*.

### Conclusion on a recommendation for QPS status

*P. fluorescens* is not recommended for the QPS list due to possible safety concerns.

## 3.2. Taxonomic units to be evaluated for the first time

### 3.2.1. Bacteria

#### ***Companilactobacillus formosensis* previously known as *Lactobacillus formosensis***

##### *Identity*

*Companilactobacillus formosensis* is a bacterial species of heterofermentative Lactobacillaceae with standing in nomenclature (Chang et al., 2015; Zheng et al., 2020). It was originally described as *Lactobacillus formosensis* by Chang et al. (2015) and then assigned to the genus *Companilactobacillus* by Zheng et al. (2020).

##### *Body of knowledge*

Very limited information is available on the *C. formosensis* species, other than the taxonomical identification. The type strain of this species (strain S215) has the potential to be used as a sweet potato vine silage inoculant because of its ability to improve fermentability and aerobic stability (Mangwe et al., 2016).

##### *Safety concerns*

No information has been published.

##### *Conclusion on a recommendation for QPS status*

*C. formosensis* (previously known as *Lactobacillus formosensis*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.

#### ***Pseudonocardia autotrophica***

##### *Identity*

*P. autotrophica* is a filamentous actinomycete that was initially classified into the genus *Streptomyces* (Takamiya and Tubaki, 1956) and later transferred to the genus *Pseudonocardia* (Warwick et al., 1994). It is a valid species with standing in Nomenclature.

##### *Body of knowledge*

*P. autotrophica* has been reported to produce an antifungal compound belonging to the tetraene-family, nystatin-like *Pseudonocardia* polyene A1 (NPP A1) (Lee et al., 2012; Han et al., 2019; Park et al., 2020). It is also used for the production of biosurfactants (Kuznetsov et al., 2020), and as a biocatalyst for the commercial production of a cytochrome P-450 hydroxylase of vitamin D3 (Fujii et al., 2009).

##### *Safety concerns*

The genome sequences of two *P. autotrophica* isolates have been published (Grumaz et al., 2017; Yoshida et al., 2018) and, in addition, another two have been deposited in the data bases. A search done by the QPS WG for secondary metabolite gene-clusters using the antiSmash platform (Blin et al., 2021) revealed a cluster corresponding to a nystatin-like polyene in one of the strains, DSM 43083 (GenBank: MIFY01000001.1), similar to the one previously described in *P. autotrophica* KCTC9441 (GenBank: EU108007.1), whose characterisation revealed antifungal activity against *Candida albicans* (Kim et al., 2009). Additionally, over 10 clusters that encoded potential polyketides and non-ribosomally synthesized peptides (NRP) related to known biologically active compounds were identified, albeit with different degrees of similarity to the original genomic sequences. Among them, a 100% similarity was found to an alkylresorcinol polyketide (Genbank: AP009493.1) and 72% and 45% to the NRPs heterobactin (GenBank: AP008957.1) and coelibactin (GenBank: AL645882.2) respectively. There is lack of information on the safety of these secondary metabolites.

### Conclusion on a recommendation for QPS status

*P. autotrophica* is not recommended for the QPS list due to lack of body of knowledge and uncertainty on the safety of biologically active compounds which can be produced.

### ***Streptococcus salivarius***

#### Identity

*Streptococcus salivarius* is a species with standing in nomenclature (Farrow and Collins, 1984). During the period 1984–1995, the species *S. salivarius* included also *S. thermophilus* as a subspecies (*S. salivarius* subsp. *thermophilus*). Later studies based on 16S rRNA gene comparison showed that, although being closely related to *S. salivarius*, *S. thermophilus* is a different species (Kawamura et al., 1995; Pombert et al., 2009). Genome analyses confirmed this view (Delorme et al., 2015).

#### Body of knowledge

This species is a human and animal commensal. Some strains are used as oral probiotics to limit nasopharyngeal infections, as supported by several papers in peer-reviewed journals (Zupancic et al., 2017; Wilcox et al., 2019). Recent scientific articles focus on the safety assessment of some of the probiotic strains (Li et al., 2021; Hale et al., 2022).

#### Safety concerns

*S. salivarius* is a common inhabitant of the oropharynx and, as such, has been associated with halitosis and caries (Sterer and Rosenberg, 2006; Gross et al., 2012). From this and other sources, it can result in bacteraemia (Corredoira et al., 2005; Molinaro et al., 2014; Akbulut et al., 2018), which can be followed by meningitis (Srinivasan et al., 2012), endocarditis (Knudtzen et al., 2015), peritoneal/gallbladder (Urade et al., 2018) and brain (Mandapat et al., 2011) abscesses and prosthesis-associated infections (Olson et al., 2019) among other morbidities. These diseases were found in immunocompromised and immunocompetent patients.

#### Antimicrobial resistance

Transmissible resistances to macrolides, phenicols, penicillins and tetracyclines have been reported, their determinants being allocated to transposons, and other mobile and integrative genetic elements (Chaffanel et al., 2015; Palma et al., 2016).

### Conclusion on a recommendation for QPS status

*S. salivarius* is not recommended for the QPS list due to its ability to cause bacteraemia and systemic infection that results in a variety of morbidities.

## 3.2.2. Yeasts

### ***Papiliotrema terrestris* synonym *Cryptococcus terrestris***

#### Identity

*Papiliotrema terrestris* is a basidiomycetous yeast belonging to the Tremellaceae in the subphylum Agaricomycotina. The genus *Papiliotrema* was first proposed in 2002 to accommodate the new species *Papiliotrema bandonii* (Sampaio et al., 2002), and it has been revised in 2015 by Liu et al. (2015). The species *P. terrestris* was described by Crestani et al. (2009) as *Cryptococcus terrestris*. It was ubiquitously found in the soil and the species has recently been reclassified as *Papiliotrema terrestris* (Miccoli et al., 2020; Li et al., 2020).

#### Body of knowledge

Since the species is rather recently described the body of knowledge is limited. Some strains of this species are proposed as biocontrol agents and the majority of the strains are isolated from plants, fruits and soil. The type strain CBS 101036 is patented under the name *C. nodaensis* to produce salt-tolerant and thermostable glutaminase (US Patent US006063409A; Sato et al., 1999). Isolate CBS 942 (NRRL Y-1401, cited as *C. laurentii* or *C. laurentii* var. *flavescens*) produces an acidic extracellular polysaccharide, which contains D-xylose, D-mannose, D-glucuronic acid and O-acetyl (Abercrombie et al., 1960; Slodki et al., 1966; De Baets and Vandamme, 2001, De Baets et al., 2002).

The complete genome sequence of the biocontrol yeast *P. terrestris* strain LS28P is available in GenBank.

#### *Safety concerns*

According to Crestani et al. (2009) and Kurtzman et al. (2011), *P. terrestris* is phylogenetically closely related to *C. laurentii* and *C. flavescens* (*syn. C. laurentii*) which has been associated with some infections (Kurtzman 2011; Intra et al., 2021; Zono et al., 2021).

#### *Conclusion on a recommendation for QPS status*

*P. terrestris* is not recommended for the QPS list due to a limited body of knowledge.

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

The summaries of the evaluation of the possible safety concerns for humans, animals or the environment described and published since the previous ELS exercise (i.e. articles published between July and December 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 359 references. The AI analysis left 180. Title screening left 10 references for abstract screening, then 3 for a full article appraisal. This last step discarded two articles because no safety concern was found. One was found relevant (D'Agostin et al., 2021) but because it is a study review referring to articles that have been already part of previous ELS exercises, it was not further considered. Consequently, the QPS status of these species is not changed.

##### ***Carnobacterium divergens***

A search for potentially relevant papers on *C. divergens* provided six 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 23 references. Two papers reached the level of title and abstract screening and one reach full-text evaluation but 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 942 references. The AI analysis left 471 articles. Title screening of these provided 25 references for abstract screening, which further reduced their number to 7. Three of them did not raise safety concerns, one was on *L. paragasseri*, which is not a QPS organism, and the other three (Aydogan et al., 2021; Miwa et al., 2021; Pietrangelo et al., 2021) although relevant, were excluded because no reliable microorganism identification procedures were described, or due to uncertainty on the aetiology of the cases described. Moreover, the patients affected were a newborn baby that presented a congenital hypoplastic left heart syndrome, an 88-year-old lady with terminal pancreatitis and uncontrolled diabetes and a middle-aged alcoholic man, i.e.: all of them presented serious morbidities that might have allowed the opportunistic infections described.

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

### ***Lactococcus lactis***

A search for papers potentially relevant for the QPS status of *L. lactis* provided 213 references. The AI analysis left 110 papers. Title and abstract screenings reduced their numbers to 12 and 5, respectively. One of them did not raise safety concerns, another did not deal with *L. lactis*, and identification of the causal microorganism was not reliable for two of the remaining cases, only phenotypical methods were used (Ahmed et al., 2021; Gurley et al., 2021). The third (Rowe et al., 2021) was on comparison of different algorithms to predict occurrence of cow mastitis.

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 76 references. The analysis of their titles left five articles for title/abstract screening. Two articles reached full text evaluation, but neither dealt with possible safety concerns. Consequently, the status of QPS-listed *Leuconostoc* spp. is not changed.

### ***Microbacterium imperiale***

A search for papers potentially relevant for the QPS evaluation of *M. imperiale* provided 1 reference but was not relevant 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 29 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 175 references. The analysis of their titles left two articles for the title/abstract phase. No article reached the full text evaluation stage, 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 24 references. Following the analysis of their titles, no article was selected for abstract screening or the full article evaluation phase, consequently, the status of QPS-listed *Propionibacterium* spp. is not changed.

### ***Streptococcus thermophilus***

A search for papers potentially relevant for the QPS evaluation of *Streptococcus thermophilus* provided 80 references. The analysis of their titles left 4 articles for title and abstract screening, which did not deal with safety concerns. Therefore, no article reached the evaluation phase, and the QPS status of *S. thermophilus* is not changed.

## **3.3.2. Gram-positive spore-forming bacteria**

A search for papers potentially relevant for *Bacillus* spp. and *Geobacillus stearothermophilus* provided 1,416 references. The AI analysis left 676 articles. The analysis of their titles left 15 articles for the abstract phase and, from these, 9 articles passed to the full-text phase for further analysis.

### ***Bacillus* spp.**

All nine articles that passed to the full text phase for further analysis were related to *Bacillus* spp. Three papers did not deal with safety concerns. Six papers were further analysed. One paper (D'Agostin et al., 2021) reviewed human case reports related to probiotic intake of *B. clausii* which were already discussed in previous EFSA statements. Four papers had methodology problems related to the identification methodology used (Garcia et al., 2021; Severiche-Bueno et al., 2021; Lampropoulos et al., 2021) and/or the source attribution (Konate et al., 2021; Severiche-Bueno et al., 2021). Three papers described predisposing factors for the infection (Garcia et al., 2021; Konate et al., 2021; Lampropoulos et al., 2021). One paper (Liu et al., 2021) presented phylogenetic and phylogenomic results based on the genome sequences of 96 *B. amyloliquefaciens* strains from different sources, mentioning the presence of possible virulence genes in strains. For most of these genes there

is no information of a direct link with the enhancement of the capacity to cause infection. One strain (MBGja9) was shown to carry genes from the *isd* cluster that were previously described to be connected with virulence of *Staphylococcus* sp. (Naushad et al., 2019). Publicly available genome (assembly number ASM291526v1) of this strain revealed an assembly anomaly, not allowing the confirmation of the linkage of these genes with *B. amyloliquefaciens*.<sup>2</sup>

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

### ***Geobacillus stearothermophilus***

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

### ***Pasteuria nishizawae***

A search for papers potentially relevant for the QPS evaluation of *P. nishizawae* provided 1 reference that did not reach the full text stage. Consequently, the QPS status of *P. nishizawae* is not changed.

### **3.3.3. Gram-negative bacteria**

A search for papers potentially relevant to the QPS evaluation of *Gluconobacter oxidans*, *Xanthomonas campestris*, *Cupriavidus necator* and *Komagataeibacter sucrofermentans* provided in total 260 references.

#### ***Cupriavidus necator***

A search for papers potentially relevant for *C. necator* provided 73 references. The analysis of the titles left three papers, but none dealt with this species. Consequently, the QPS status of *C. necator* is not changed.

#### ***Gluconobacter oxydans***

A search for papers potentially relevant for *G. oxydans* provided 32 references. The analysis of the titles left three papers, but none dealt with this species. Consequently, the QPS status of *G. oxydans* is not changed.

#### ***Komagataeibacter sucrofermentans***

A search for papers potentially relevant for *K. sucrofermentans* provided 16 references. The analysis of the titles left three papers, but none dealt with this species. Consequently, the QPS status of *K. sucrofermentans* is not changed.

#### ***Xanthomonas campestris***

A search for papers potentially relevant for *X. campestris* provided 139 references. The analysis of the titles left 3 articles, 1 reached the full-text phase but no safety concern was identified. 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 1,613 references. The AI analysis left 802 articles. After title screening, 92 studies remained for the title/abstract phase, and from these 19 articles passed to the full article appraisal. All of these 19 reported a possible safety concern.

The 19 studies that discussed potentially relevant safety concerns for QPS yeast species are discussed below.

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

<sup>2</sup> An assembly anomaly is registered on this genome. Accordingly, to the information from "Assembly" (NIH) ([https://www.ncbi.nlm.nih.gov/assembly/GCF\\_002915265.1/#/qa](https://www.ncbi.nlm.nih.gov/assembly/GCF_002915265.1/#/qa)) the best is *Staphylococcus warneri*.

### **Cyberlindnera jadinii**

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

Three references related to possible concerns for human safety were identified by Mohzari (2021), Sreelekshmi et al. (2021) and Sharma and Chauhan (2020).

Mohzari et al. (2021) reported a case of nosocomial meningitis by *C. jadinii* and the bacterium *Stenotrophomonas maltophilia* in a patient that had been subject to neurosurgery. The yeast identification by MALDI-TOF MS was not confirmed by molecular analyses.

In a retrospective study in a hospital in India (Sreelekshmi et al., 2021), three of the "Candida spp." Blood culture isolates (1.5% of total Candida) were *C. jadinii*. Two patients were neonates and one a four-day-old baby. All three cases shared a risk factor of intensive care unit stay, but the sources of the infections were not known. Two of the patients responded well to treatment. One was first treated for meningitis (caused by unidentified *Pseudomonas*), but then developed endocarditis with blood cultures growing *Staphylococcus aureus* and *C. jadinii*.

Sharma and Chauhan (2020) report a case of osteomyelitis (bone infection) by *C. jadinii* in a 9-month old boy, who was immunosuppressed. However, the species identification is uncertain since no information was provided about which methods were used.

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

### **Debaryomyces hansenii**

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

One reference related to possible concerns for human safety was identified. Sakamoto et al. (2021) reported that five (3.3%) of the 'Candida' isolates from the blood of hospitalised patients with underlying disease or other predisposing conditions in a hospital in Japan were *D. hansenii*. However, species identification was only by standard biochemical growth test and is therefore very uncertain.

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

### **Hanseniaspora uvarum**

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

One reference related to possible concerns for human safety was identified. Sanchez-Cardenas et al. (2021) reported onychomycosis (nail infection) with *H. uvarum* in a woman with multiple sclerosis, but the species identification is not definite, since standard CHROMagar showed *Candida glabrata* and MALDI-TOF MS suggested *H. uvarum*. No molecular confirmation was performed.

The report on *H. uvarum* 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 kefyri*.

Three publications contribute with information related to human safety concerns, and all three present identification problems (Singh et al., 2020; Jain et al., 2021;; Zyrek, 2021). Singh et al. (2020) claim that 2 clinical isolates from patients with suspected candidiasis in a hospital in India were *Candida kefyri*. Since the species identification is very uncertain and the paper lacks information regarding any predisposing conditions in the patients, the importance of the results cannot be appropriately assessed. Zyrek et al. (2021) provided no relevant information about this species.

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

### **Saccharomyces cerevisiae**

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

Five publications reported safety concerns for humans and in four of them, the identification is uncertain. Four of them published fungaemia cases linked to the use of *S. boulardii* as a probiotic. Pinto et al., (2021) described a case of a fungal infection caused by *S. cerevisiae* in a critically ill COVID-19 patient in an intensive care unit (ICU) after supplementation with *Saccharomyces*. Rannikko et al. (2021) also reported fungaemia cases linked to the use of *S. boulardii* probiotic in Finland hospitals from 2009 to 2018. Wombwell et al., (2021) report a retrospective study of 16.404 hospitalised patients in a medical care centre in the US. All subjects received *S. boulardii* as a



preventative probiotic and were investigated for *S. cerevisiae*/*S. boulardii* in blood. Even though the subjects were hospitalised with underlying disease or trauma, and the majority of the patients admitted to intensive care had a central catheter, the fungaemia incidence was very low (0.1%). D'Agostin et al. (2021) make a systematic review of fungal infections due to intake of *S. boulardii* as a probiotic. Each of the 14 patients in the cited studies reporting infection with *S. boulardii* had underlying conditions.

Imre et al., (2021) compared the general phenotypic and virulence factors of 14 *S. boulardii* isolates, four from probiotic products and 10 clinical isolates, of which two were from patients diagnosed with mycosis. The authors conclude that some strains in probiotic products possess features that enable them to act as pathogens when conditions are permissive, and whether they can enter the bloodstream is mainly due to factors related to the host.

These new reports of *S. cerevisiae* did not add any new information that indicates change in the current QPS status of this species. The current QPS status of *S. cerevisiae* is not changed.

### ***Wickerhamomyces anomalus***

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

Four references related to possible concerns for human safety were identified: Zhang et al. (2021), Yasuj et al. (2021), Koutserimpas et al. (2021), Yang (2021).

Zhang et al. (2021) reported 13 cases of *W. anomalus* fungaemia (positive blood cultures) in a 2.5-year retrospective study in a hospital in China. Identification was by MALDI-TOF MS but no further molecular confirmation was provided. All patients were hospitalised and had underlying disease and/or other predisposing conditions. There are uncertainties regarding *W. anomalus* as the etiological agent, since eight of the 13 subjects had mixed bacterial/*Candida* infection and four mixed candidemia. The isolates' susceptibility to azoles were comparatively low and other classes of antimycotics were therefore recommended for treatment.

In a retrospective study in a hospital in Iran (2016–2019), blood samples were taken from 800 patients (Yasuj et al., 2021). One of the 27 with confirmed candidemia (in intensive care unit because of urinary tract infection with unknown agent) showed growth of *W. anomalus*. The isolate was susceptible to all tested antimycotics (fluconazole, amphotericin B and caspofungin).

Koutserimpas et al. (2021) reviewed reports of 'non-*Candida*' opportunistic infections after prosthetic joint arthroplasty. Out of the 42 retrieved cases globally for the period 1981–2018, five were *W. anomalus*. A thorough evaluation of the implications of this review cannot be performed since no details are provided regarding identification methods.

*W. anomalus* has occasionally caused nosocomial outbreaks of opportunistic infections in neonatal intensive care units. Yang et al. (2021) provides two additional cases of fungaemia in 2012 and 2013 in a hospital in China. All isolates were susceptible to all five tested antimycotic substances and infections were successfully treated.

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 22 articles. The analysis of their titles left 1 article, but this paper did not reach the full article evaluation stage, thus no new safety concern was identified. Therefore, the current QPS status of *A. limacinum* is not changed.

### **3.3.6. Algae**

A search for papers potentially relevant for algae provided 240 articles. The analysis of their titles left 17 articles and for 4 of these the full text was analysed.

#### ***Euglena gracilis***

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

### ***Haematococcus lacustris* synonym *Haematococcus pluvialis***

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

### ***Tetraselmis chuii***

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

## **3.3.7. Viruses used for plant protection**

### ***Alphaflexiviridae* and *Potyviridae***

A search for papers potentially relevant for the QPS evaluation of viruses of the *Alphaflexiviridae* and *Potyviridae* provided 55 references. After title screening, no paper reached the title/abstract screening stage, thus no new safety concern was identified. Therefore, the current QPS status remains unchanged.

### ***Baculoviridae***

A search for papers potentially relevant for the QPS evaluation of *Baculoviridae* provided 59 references. Two articles 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 microbiological 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 2021 and March 2022 (inclusive), the list of notifications was updated with 50 notifications that were received by EFSA, of which 36 were proposed for evaluation as feed additives, 10 for use as food enzymes, food additives and flavourings, 4 as novel foods, and none as plant protection products.

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

- In relation to the results of the monitoring of possible new safety concerns relevant for the QPS list, there were no results that would justify removal of any TUs from 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 50 notifications received between October 2021 and March 2022, 25 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 25 notifications, 16 notifications were related to microorganisms that are excluded from QPS evaluation (10 were notifications of filamentous fungi, 1 of *Clostridium butyricum* (bacterium), 1 of *Enterococcus faecium* (bacterium), 3 of *Escherichia coli* (bacterium), 1 of *Streptomyces* sp. (bacterium).
- Nine of the 50 notifications received, corresponding to 7 TUs, were evaluated for possible QPS status: four of these (*Companilactobacillus formosensis*, *Pseudonocardia autotrophica*, *Streptococcus salivarius* and *Papiliotrema terrestris*) being evaluated for the first time. The other three, *Ensifer adhaerens*, *Microbacterium foliorum* and *Pseudomonas fluorescens* were re-assessed because an update was requested in relation to the current mandate. The following conclusions were drawn:
  - *Companilactobacillus formosensis* (previously known as *Lactobacillus formosensis*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.

- *Ensifer adhaerens* (synonym *Sinorhizobium adhaerens*) is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.
- *Microbacterium foliorum* is not recommended for the QPS list due to lack of body of knowledge for its occurrence in the food and feed chain.
- *Pseudonocardia autotrophica* is not recommended for the QPS list due to lack of body of knowledge and uncertainty on the safety of biologically active compounds which can be produced.
- *Pseudomonas fluorescens* is not recommended for the QPS list due to possible safety concerns.
- *Papiliotrema terrestris* is not recommended for the QPS list due to a limited body knowledge.
- *Streptococcus salivarius* is not recommended for the QPS list due to its ability to cause bacteraemia and systemic infection that results in a variety of morbidities.

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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
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/ionisation (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)

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. To complete the assessment an ELS-based approach may have been applied. In the current Panel Statement, this ELS approach was applied for assessing the QPS status of *Ensifer adhaerens* and *Streptococcus salivarius*. The ELS followed the same methodology as used for monitoring new safety concerns related to species with QPS status. Details on the search strategy, search keys, and approach for each of the assessments of those 2 TU may be found below.

### A.1. *Ensifer adhaerens*

The ELS for the keywords listed below, from 2011–2022, led to 73 hits (after de-duplication).

String for species	
"Ensifer adhaerens" OR "e adhaerens" OR "Sinorhizobium adhaerens" OR "s adhaerens" OR "Sinorhizobium morelense" OR "s morelense" OR "Ensifer morelensis" OR "e morelensis"	
OUTCOME	String
1) Antimicrobial/antibiotic/antimycotic	"antimicrobial resistan*" OR "antibiotic resistan*" OR "antimicrobial susceptibil*"
2) Infection/bacteremia/fungemia/sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3) Type of disease	endocarditis OR meningitis OR clinical*
4) Mortality/morbidity	death* OR morbidit* OR mortalit*
5) Disease risk	disease* OR illness* OR opportunistic OR virulen*

### A.2. *Microbacterium foliorum*

The search on Pub Med led to 30 hits related to "Microbacterium foliorum". All hits were screened for their relevance.

### A.3. *Pseudomonas fluorescens*

The search on Pub-Med led to 46 hits for the terms "Pseudomonas fluorescens" AND "virulence" between 2019 and present). One of them was considered relevant (Quintieni et al., 2020).

### A.4. *Companilactobacillus formosensis* previously known as: *Lactobacillus formosensis*

The search on Pubmed Search led to 6 hits for the terms "lactobacillus" OR "companilactobacillus" AND "formosensis", between 2015 and 2020. Two of them are relevant (Zhang et al., 2015; Mangwe et al., 2016).

The search on Scopus search led to 1 reference (Jung et al., 2021).

### A.5. *Pseudonocardia autotrophica*

The search on Pub-Med and the Thomson Reuter Web of Science led to 39 hits for the terms "Pseudonocardia autotrophica" and 7 for "Streptomyces autotrophicus".

The search on Scopus led to 56 hits for TITLE-ABS-KEY ("pseudonocardia" AND "autotrophica").

### A.6. *Streptococcus salivarius*

The ELS for the keywords listed below, from 2011–2022, led to 936 hits (after de-duplication).

After de-duplication 936.

<b>String for species</b>	
"Streptococcus salivarius" OR "s salivarius"	
<b>OUTCOME</b>	<b>String</b>
1) Antimicrobial/antibiotic/antimycotic	"antimicrobial resistan*" OR "antibiotic resistan*" OR "antimicrobial susceptibil*"
2) Infection/bacteremia/fungemia/sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3) Type of disease	endocarditis OR meningitis OR clinical*
4) Mortality/morbidity	death* OR morbidit* OR mortalit*
5) Disease risk	disease* OR illness* OR opportunistic OR virulen*

#### **A.7. *Papiliotrema terrestris* (*Cryptococcus terrestris*)**

The search on Pub-Med led to 146 hits for the terms terms "*Papiliotrema terrestris*", "*Cryptococcus terrestris*", "*Cryptococcus laurentii*" or "*Cryptococcus flavescens*" and "infections", "virulence" or "pathogen".

## **Appendix B – Protocol for Extensive literature search (ELS), relevance screening, and article evaluation for the maintenance and update of list of QPS-recommended microbiological 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 microbiological 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 microbiological 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 July to December 2021 (reply to ToR 2)

### Gram-Positive Non-Sporulating Bacteria

#### *Bifidobacterium* spp.

D'Agostin M, Squillaci D, Lazzerini M, Barbi E, Wijers L, Da Lozzo P, 2021. Invasive infections associated with the use of probiotics in children: a systematic review. *Children*, 8, 924. <https://doi.org/10.3390/children8100924>

#### *Carnobacterium divergens*

None.

#### *Corynebacterium glutamicum*

None.

#### *Lactobacilli*

Aydoğan S, Dilli D, Özyazici A, Aydın N, Şimşek H, Orun UA and Aksoy ON, 2021. Lactobacillus rhamnosus Sepsis associated with probiotic therapy in a term infant with congenital heart disease. *Fetal and Paediatric Pathology*, <https://doi.org/10.1080/15513815.2021.1966144>

Miwa T, Tanaka H and Shiojiri T, 2021. *BMJ Case Report*, 14, e243936. <https://doi.org/10.1136/bcr-2021-243,936>

Pietrangelo M, Hess J and Ellis L, 2021. When probiotics attack: hemorrhagic shock complicated by Lactobacillus rhamnosus septic shock. *Southern Medical Journal*, 114, #Pages#.

#### *Lactococcus lactis*

Gurley A, O'Brien T, Garland JM and Finn A, 2021. *BMJ Case Report*, 14, e243915. <https://doi.org/10.1136/bcr-2021-243915>

Ahmed I, Aziz K, Tareen H and Ahmed MA, 2021. Brain abscess caused by Lactococcus Lactis in a young male. *Journal of the College of Physicians and Surgens-Pakistan*, 31, 852–854.

Rowe SM, Vasquez AK, Godden SM, Nydam DV, Royster E, Timmerman J and Boyle M, 2021. Evaluation of 4 predictive algorithms for intramammary infection status in late-lactation cows. *Journal of Dairy Science*, 104, 11035–11046.

#### *Leuconostoc* spp.

None.

#### *Microbacterium imperiale*

None.

#### *Oenococcus oeni*

None.

#### *Pediococci* spp.

None.

#### *Propionibacterium* spp.

None.

#### *Streptococcus thermophilus*

None.

### Gram-Positive Spore-forming Bacteria

#### *Bacilli*

Garcia JP, Alzate JA, Hoyos JA and Edilberto C, 2021. Bacteremia after *Bacillus clausii* administration for the treatment of acute diarrhoea: a case report. *Biomedica*, 41, 13–20.

D'Agostin M, Squillaci D, Lazzerini M, Barbi E, Wijers L and Da Lozzo P, 2021. Invasive infections associated with the use of probiotics in children: a systematic review. *Children*, 8, 924. <https://doi.org/10.3390/children8100924>

Konaté S, Zgheib R, Camara A, Doumbo O, Djimé A, Koné AK, Théra MA, Fournier P-E, Tidjani Alou M, Raoult D and Million M, 2021. Draft genome sequence of *Bacillus velezensis* strain Marseille-Q1230, isolated from a stool

sample from a severely malnourished child. *Microbiocidal Resource Announcement*, 10, e00514–e00521. <https://doi.org/10.1128/MRA.00514-21>

Severiche-Bueno DF, Insignares-Niño DA, Severiche-Bueno DF, Vargas-Cuervo MT and Varón-Vega FA, 2021. Lemierre's syndrome by *Bacillus circulans*, *Fusobacterium nucleatum* and *Staphylococcus aureus* with involvement of the internal and external jugular vein. *Germs*, 11, 314–318. <https://doi.org/10.18683/germs.2021.1267>

Liu H, Prajapati V, Prajapati S, Bais H and Lu J, 2021. Comparative genome analysis of *Bacillus amyloliquefaciens* focusing on phylogenomics, functional traits, and prevalence of antimicrobial and virulence genes. *Frontiers of Genetics*, 12, 724217. <https://doi.org/10.3389/fgene.2021.724217>

Lampropoulos PK, Gkentzi D, Tzifas S and Dimitriou G, 2021. Neonatal sepsis due to *Bacillus subtilis*. *Cureus*, 13, e17692. <https://doi.org/10.7759/cureus.17692>

### ***Geobacillus stearothermophilus***

None.

### ***Pasteuria nishizawae***

None.

## **Gram-negative bacteria**

### ***Cupriavidus necator***

None.

### ***Gluconobacter oxydans***

None.

### ***Komagataeibacter sucrofermentans***

None.

### ***Xanthomonas campestris***

None.

## **Yeasts**

D'Agostin M, Squillaci D, Lazzerini M, Barbi E, Wijers L and Da Lozzo P, 2021. Invasive infections associated with the use of probiotics in children: a systematic review. *Children*, 8, 924. <https://doi.org/10.3390/children8100924>

Imre A, Rácz HV, Antunovics Z, Rádai Z, Kovács R, Lopandic K, Pócsi I and Pfliegler WP, 2019. A new, rapid multiplex PCR method identifies frequent probiotic origin among clinical *Saccharomyces* isolates. *Microbiological Research*, 227, 126298. <https://doi.org/10.1016/j.micres.2019.126298>

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Kermani F, Sadeghian M, Shokohi T, Hashemi S, Moslemi D, Davodian S, Abastabar M, Bandalizadeh Z, Faeli L, Seifi Z, Fami Zaghrani M and Haghani I, 2021. Molecular identification and antifungal susceptibility testing of *Candida* species isolated from oral lesions in patients with head and neck cancer undergoing radiotherapy. *Current Medical Mycology*, 7, 44–50. <https://doi.org/10.18502/cmm.7.1.6242>

Khalaf SA and Nelson T, 2021. A woman with abdominal pain while being treated with steroid. *Journal of Investigative Medicine*, 69, 1119–1120.

Koutserimpas C, Chamakioti I, Zervakis S, Raptis K, Alpantaki K, Kofteridis DP, Vrioni G and Samonis G, 2021. Non-candida fungal prosthetic joint infections. *Diagnostics*, 11, 1410. <https://doi.org/10.3390/diagnostics11081410>

Mohzari Y, Al Musawa M, Asdaq S, Alattas M, Qutub M, Bamogaddam RF, Yamani A and Aldabbagh Y, 2021. *Candida utilis* and *Stenotrophomonas maltophilia* causing nosocomial meningitis following a neurosurgical procedure: a rare co-infection. *Journal of infection and public health*, 14, 1715–1719. <https://doi.org/10.1016/j.jiph.2021.10.004> Pinto, (2021).

Pinto G, Lima L, Pedra T, Assumpção A, Morgado S and Mascarenhas L, 2021. Bloodstream infection by *Saccharomyces cerevisiae* in a COVID-19 patient receiving probiotic supplementation in the ICU in Brazil. *Access microbiology*, 3, 000250. <https://doi.org/10.1099/acmi.0.000250>

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## Protists

None.

## Algae

None.

## Viruses used for plant protection

### *Alphaflexiviridae*

None.

### *Potyviridae*

None.

### *Baculoviridae*

None.



## **Appendix E – Updated list of QPS Status recommended microbiological agents in support of EFSA risk assessments**

The list of QPS status recommended microbiological 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 this Panel Statement (16) adopted in June 2022. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2020a); the updated QPS list is available at <https://doi.org/10.5281/zenodo.1146566> (the link opens at the latest version of the QPS list, and also shows the versions associated to each Panel Statement).

## Appendix F – Microbial species as notified to EFSA, received between October 2021 and March 2022 (reply to ToR 1)

The overall list of microbiological agents being notified to EFSA in the context of a technical dossier to EFSA Units (for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products for safety assessment), is kept updated in accordance with the mandate of the BIOHAZ Panel (2020–2022) and can be found in <https://doi.org/10.5281/zenodo.3607183>.

The list was updated with the notifications received between October 2021 and March 2022, listed in the Table below.

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No <sup>(a)</sup>	Previous QPS status of the respective TU <sup>(b)</sup>	Assessed in this Statement? Yes or no
<b>Bacteria</b>							
<i>Bacillus licheniformis</i>	NRRL B-67649	Feed additives	Zootechnical additives	Gut flora stabiliser. No GMM	EFSA-Q-2021-00449	YES	NO
<i>Bacillus pumilus</i>	NRRL B-67648	Feed additives	Zootechnical additives	Gut flora stabiliser. No GMM	EFSA-Q-2021-00449	YES	NO
<i>Bacillus subtilis</i>	XAN DS 77805	Food enzymes, food additives and flavourings	Enzyme production	Production of endo-1,4- $\beta$ -xylanase. GMM	EFSA-Q-2022-00189	YES	NO
<i>Bacillus velezensis</i>	AR-112	Food enzymes, food additives and flavourings	Enzyme production	Production of the 1,4-beta-xylanase. GMM	EFSA-Q-2022-00194	YES	NO
<i>Bacillus velezensis</i>	ATCC PTA-6737	Feed additives	Technological additives	Gut flora stabilisers. No GMM, isolated from intestinal tract of a Salmonella-free chicken	EFSA-Q-2021-00778	YES	NO
<i>Bacillus velezensis (amyloliquefaciens)</i>	NRRL B-67647	Feed additives	Zootechnical additives	Gut flora stabiliser. No GMM	EFSA-Q-2021-00449	YES	NO
<i>Clostridium butyricum</i>	TO-A (FERM BP-10866)	Novel foods	Novel Food	Food supplement containing a viable microorganism. No GMO	EFSA-Q-2022-00010	NO	NO
<i>Companilactobacillus formosensis</i>		Feed additives	Zootechnical additives	Other zootechnical additives.	EFSA-Q-2021-00535	NO	YES
<i>Companilactobacillus formosensis</i>		Feed additives	Zootechnical additives	Other zootechnical additives.	EFSA-Q-2021-00536	NO	YES
<i>Companilactobacillus formosensis</i>		Feed additives	Technological additives	Silage additives.	EFSA-Q-2021-00539	NO	YES

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No <sup>(a)</sup>	Previous QPS status of the respective TJ <sup>(b)</sup>	Assessed in this Statement? Yes or no
<i>Ensifer adhaerens</i>	CGMCC 19596	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect. Production of vitamin B12/ Cyanocobalamin. No GMM	EFSA-Q-2021-00571	NO	YES
<i>Enterococcus faecium</i>	WF-3	Feed additives	Zootechnical additives	Gut flora stabilisers. Consisting of four viable bacterial strains. No GMM	EFSA-Q-2021-00383	NO	NO
<i>Escherichia coli</i>	BL21(DE3) #1540	Novel foods	Novel Food	Production of 2'-fucosyllactose (2'-FL). GMM	EFSA-Q-2021-00643	NO	NO
<i>Escherichia coli</i>	K12 MG1655 INB-LNT_01 (deposition number LMBP 12730)	Novel foods	Novel Food	Production of Lacto-N-Trealose. GMM	EFSA-Q-2022-00085	NO	NO
<i>Escherichia coli</i>	Waksman (ATCC 9637) pGEX-4 T1-GT5	Food enzymes, food additives and flavourings	Food flavouring	Production of L-Menthol-β-D-glucoside. GMM.	EFSA-Q-2021-00683	NO	NO
<i>Lactiplantibacillus plantarum</i>	DSM 11520	Feed additives	Technological additives	Acidity regulator. No GMM, isolated from a healthy horse	EFSA-Q-2021-00687	YES	NO
<i>Lactiplantibacillus plantarum</i>	DSM 3676	Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2021-00635	YES	NO
<i>Lactiplantibacillus plantarum</i>	DSM 3677	Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2021-00635	YES	NO
<i>Lactiplantibacillus plantarum</i>	LMG P-21295	Feed additives	Technological additives	Silage additives. no GMM, isolated from plant	EFSA-Q-2021-00738	YES	NO
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	ATCC PTA-6139	Feed additives	Technological additives	Silage additives. No GMO	EFSA-Q-2022-00022	YES	NO
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	DSM 4785 - DSM 18113	Feed additives	Technological additives	Silage additives. No GMO	EFSA-Q-2022-00020	YES	NO
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	DSM 4786 - DSM 18114	Feed additives	Technological additives	Silage additives. Contains a viable microorganism. No GMO	EFSA-Q-2022-00019	YES	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No <sup>(a)</sup>	Previous QPS status of the respective TU <sup>(b)</sup>	Assessed in this Statement? Yes or no
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	DSM 4787 - ATCC 55943	Feed additives	Technological additives	Silage additives. Contains a viable microorganism. No GMO	EFSA-Q-2022-00018	YES	NO
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	DSM 5284 - ATCC 55944	Feed additives	Technological additives	Silage additives. Contains a viable microorganism. No GMO	EFSA-Q-2022-00017	YES	NO
<i>Lactobacillus (Lactiplantibacillus) plantarum</i>	DSM4784- ATCC53187- DSM18112	Feed additives	Technological additives	Silage additives. No GMO	EFSA-Q-2022-00021	YES	NO
<i>Lactobacillus casei</i>	K9-1	Feed additives	Zotechnical additives	Gut flora stabilisers. Consisting of four viable bacterial strains. No GMM	EFSA-Q-2021-00383	YES	NO
<i>Lactobacillus diolivorans</i>	DSM 33625	Feed additives	Technological additives	Silage additives. No GMM, isolated from natural silage	EFSA-Q-2021-00590	YES	NO
<i>Lentilactobacillus buchneri</i>	DSM 13573	Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2021-00635	YES	NO
<i>Levilactobacillus brevis</i>	WF-1B	Feed additives	Zotechnical additives	Gut flora stabilisers. Consisting of four viable bacterial strains. No GMM.	EFSA-Q-2021-00383	YES	NO
<i>Limosilactobacillus fermentum</i>	K9-2	Feed additives	Zotechnical additives	Gut flora stabilisers. Consisting of four viable bacterial strains. No GMM	EFSA-Q-2021-00383	YES	NO
<i>Microbacterium foliorum</i>	SYG27B	Food enzymes, food additives and flavourings	Enzyme production	Production of D-psicose 3-epimerase. No GMM	EFSA-Q-2021-00653	NO	YES
<i>Pediococcus pentosaceus</i>	DSM 23376 (5 M-1P)	Feed additives	Technological additives	Silage additives. Contains a viable microorganism. No GMO	EFSA-Q-2022-00006	YES	NO
<i>Pseudomonas fluorescens</i>	PIC or BD27719	Food enzymes, food additives and flavourings	Enzyme production	Production of Phosphoinositide phospholipase C. GMM.	EFSA-Q-2021-00654	NO	YES
<i>Pseudonocardia autotrophica</i>	M301	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect. Production of 25-hydroxycholecalciferol as nutritional feed additive. No GMM	EFSA-Q-2021-00641	NO	YES

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No <sup>(a)</sup>	Previous QPS status of the respective TJ <sup>(b)</sup>	Assessed in this Statement? Yes or no
<i>Streptococcus salivarius</i>	K12 (ATCC BAA-1024, DSM 13084)	Feed additives	Technological additives	Acidity regulators. Viable cells to be used as technological additive. No GMM	EFSA-Q-2021-00501	NO	YES
<i>Streptomyces mobaraensis</i>	M2020197	Food enzymes, food additives and flavourings	Enzyme production	Production of transglutaminase. No GMM	EFSA-Q-2021-00651	NO	NO
<b>Filamentous Fungi</b>							
<i>Aspergillus niger</i>	CBS 120604	Feed additives	Zootechnical additives	Digestibility enhancers. Production of $\beta$ -mannanase. No GMM	EFSA-Q-2021-00549	NO	NO
<i>Aspergillus niger</i>	CBS120604	Feed additives	Zootechnical additives	Digestibility enhancers. Production of endo-1,4- $\beta$ -D-glucanase. No GMM	EFSA-Q-2021-00128	NO	NO
<i>Aspergillus niger</i>	GT147	Food enzymes, food additives and flavourings	Enzyme production	Production of glutaminase. No GMM	EFSA-Q-2021-00652	NO	NO
<i>Aspergillus niger</i>	NPH	Food enzymes, food additives and flavourings	Enzyme production	Production of 3-phytase. GMM	EFSA-Q-2022-00193	NO	NO
<i>Aspergillus oryzae</i>	DSM33737	Food enzymes, food additives and flavourings	Enzyme production	Production of the enzyme 6-phytase. GMM	EFSA-Q-2022-00082	NO	NO
<i>Fusarium flavolapis</i>	PTA-10698	Novel foods	Novel Food	Nutritional fungi protein to be used as an animal protein alternative. It consists of a mat of mycelial biomass. No GMM	EFSA-Q-2021-00519	NO	NO
<i>Trichoderma longibrachiautum</i> (T. resei)	MUCL 49754. GICC03480	Feed additives	Zootechnical additives	Production of Endo-1,3(4)- $\beta$ -glucanase. No GMM	EFSA-Q-2021-00673	NO	NO
<i>Trichoderma longibrachiautum</i> (T. resei)	MUCL 49755. GICC03483	Feed additives	Zootechnical additives	Production of Endo-1,4- $\beta$ -xylanase. No GMM	EFSA-Q-2021-00673	NO	NO
<i>Trichoderma reesei</i>	ATCC 74444	Feed additives	Zootechnical additives	Digestibility enhancers. Production of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase. No GMM, generated by classical mutation selection.	EFSA-Q-2021-00498	NO	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No <sup>(a)</sup>	Previous QPS status of the respective TJ <sup>(b)</sup>	Assessed in this Statement? Yes or no
<i>Trichoderma reesei</i>	RF5427	Feed additives	Zotechnical additives	Digestibility enhancer. Production of endo-1,4-beta-xylanase. GMM	EFSA-Q-2022-00027	NO	NO
<b>Yeasts</b>							
<i>Komagataella phaffii</i> (synonym <i>Pichia pastoris</i> )	MXV0541	Food enzymes, food additives and flavourings	Food additive	Production of soy leghemoglobin. GMM	EFSA-Q-2022-00031	YES	NO
<i>Papiliotrema terrestris</i> ( <i>Cryptococcus laurentii</i> )	AE-BLC NITE SD 00411	Food enzymes, food additives and flavourings	Enzyme production	Production of beta-galactosidase. No GMM	EFSA-Q-2022-190	NO	YES
<i>Saccharomyces cerevisiae</i>	CBS 615.94 (carrying a gene from <i>Cyamopsis tetragonoloba</i> guar)	Feed additives	Zotechnical additives	Digestibility enhancers. Production of $\alpha$ -galactosidase. GMM	EFSA-Q-2021-00128	YES	NO
<i>Saccharomyces cerevisiae</i>	NCYC Sc 47 (CNCM I-4407)	Feed additives	Zotechnical additives	Gut flora stabiliser. Viable cells to be used. Non GMM	EFSA-Q-2021-00382	YES	NO

(a): To find more details on specific applications please access the EFSA website – openEFSA at <https://open.efsa.europa.eu/>.

(b): Included in the QPS list as adopted in December 2019 (EFSA BIOHAZ Panel, 2020b) and respective updates which include new additions (latest: EFSA BIOHAZ Panel, 2022)