

## STATEMENT

# Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 22: Suitability of taxonomic units notified to EFSA until March 2025

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

### Abstract

The qualified presumption of safety (QPS) process was developed to assess the safety of microorganisms used in food and feed chains. During the period covered by this Statement, no new information warranted changes to the status of previously recommended QPS taxonomic units. The QPS list was updated to verify the correctness of the names and the completeness of synonyms. Of the 47 microorganisms notified to EFSA between October 2024 and March 2025 (25 as feed additives, 7 as food enzymes or additives, 6 as novel foods, 8 as plant protection products and 1 as food contact materials), 41 were not evaluated. These latter included 11 filamentous fungi, 4 *Escherichia coli* and 1 *Streptomyces* spp. (all excluded from the QPS evaluation), and 25 already on the QPS list. Two of the other six notifications, *Bacillus thuringiensis* and *Ensifer adhaerens*, had been previously assessed. The remaining four were assessed for a possible QPS status. *Bacillus sonorensis* is recommended for the QPS list with the qualifications: 'absence of bacitracin production ability' and 'absence of toxigenic activity'. *Vibrio natriegens* is also recommended but for 'production purposes only'. *Corynebacterium stationis* is not recommended due to a limited body of knowledge on its occurrence in the food and feed chain and possible safety concerns in relation to human and animal health. *Papiliotrema terrestris* is not recommended due to a limited body of knowledge. Furthermore, *Lactobacillus paragasseri* (formerly included in *Lactobacillus gasseri*) is recommended for the QPS list. The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern, by means of genetic modification. For QPS yeasts, used as active agents (viable cells), the qualification 'for production purposes only' was added for when they are used as production strains or as biomass (non-viable cells).

### KEYWORDS

*Bacillus sonorensis*, *Corynebacterium stationis*, *Lactobacillus paragasseri*, *Papiliotrema terrestris*, QPS, *Vibrio natriegens*

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## SUMMARY

The European Food Safety Authority (EFSA) asked the Scientific Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the qualified presumption of safety (QPS) list. The QPS list contains microorganisms, intentionally added to food and feed, which have received QPS status. The request included three specific tasks as mentioned in the terms of reference (ToR).

The QPS process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms. Safety concerns identified for a taxonomic unit (TU) are, if possible, confirmed at strain or product level, reflected as 'qualifications' that should be assessed at the strain level by EFSA's Scientific Panels. A generic qualification for all QPS bacterial TUs applies in relation to the absence of acquired genes conferring resistance to clinically relevant antimicrobials (EFSA BIOHAZ Panel, 2023).

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

The first ToR requires ongoing updates of the list of microorganisms notified to EFSA, in the context of a technical dossier for safety assessment. The list 'Microbiological agents as notified to EFSA' (<https://doi.org/10.5281/zenodo.3607183>) was updated with the notifications received between October 2024 and March 2025 (inclusive). Within this period, 47 notifications were received by EFSA, of which 25 were proposed for use in feed, 7 as food enzymes, food additives and flavourings, 6 as novel foods, 8 as plant protection products and 1 as food contact materials. The new notifications received within that period are included in the current statement (see Appendix F).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications. At the same time, the QPS TUs' taxonomic nomenclature of bacteria, yeast, algae, protists and viruses is being verified every 6 months against their respective authoritative databases to ensure their accuracy for each Panel Statement. In the QPS list, a swap has been made between *Agrobacterium radiobacter* (correct name) and *Rhizobium radiobacter* (synonym).

It has been clarified that the QPS approach can be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification. For the revision of the QPS list TUs and their qualifications, articles published from July to December 2024 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>). Before running the searches for the current ELS, a verification of the correct names was performed. The ELS launched for this Panel Statement included any updated names/synonyms as keywords. No new information was found that would affect the QPS status or qualifications for the TUs on the QPS list. In the QPS list, the following qualification was added for all QPS status yeasts used as active agents (viable cells) for when they are used as production strains or as biomass (non-viable cells): *QPS applies for 'production purposes only' (the qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass)*.

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 update of the QPS list and also includes the links to the versions associated with each Panel Statement).

During the current period, 47 notifications were received. Of these, 41 were not evaluated for the following reasons: 16 involved microorganisms excluded from QPS evaluation (11 filamentous fungi, 1 *Streptomyces* spp. and 4 *Escherichia coli*), while 25 were related to TUs that already have QPS status and did not require further evaluation. Of the other six notifications, two (*Bacillus thuringiensis* and *Ensifer adhaerens*) had already been evaluated for possible QPS status in previous Panel Statements. The remaining four TUs were assessed for a possible QPS status in this panel statement: *Vibrio natriegens* (notified for the first time), *Papiliotrema terrestris* (EFSA BIOHAZ Panel, 2022), *Bacillus sonorensis* (notified for the first time) and *Corynebacterium stationis* (EFSA BIOHAZ Panel, 2021). The latter two TUs were included in response to an internal EFSA request. Additionally, *Lactobacillus paragasseri* was assessed due to its previous inclusion within *Lactobacillus gasseri*, a TU included in the QPS list.

The following conclusions were drawn:

- *Bacillus sonorensis* is recommended for the QPS list with the qualifications 'absence of bacitracin production ability' and 'absence of toxigenic activity'.
- *Corynebacterium stationis* is not recommended for the QPS list due to a limited body of knowledge on its occurrence in the food and feed chain and possible safety concerns in relation to human and animal health.
- *Papiliotrema terrestris* is not recommended for the QPS list due to a limited body of knowledge.
- *Vibrio natriegens* is recommended for the QPS list but for 'production purposes only'.
- *Lactobacillus paragasseri* is recommended for the QPS list.

## 1 | INTRODUCTION

The qualified presumption of safety (QPS) approach was developed by the EFSA Scientific Committee to provide a generic concept for risk assessment within the European Food Safety Authority (EFSA) for microorganisms intentionally introduced into the food and feed chains, in support of the respective Scientific Panels and Units in the context of market authorisations for their use in food and feed and the requirement for a safety assessment by EFSA (2007; Herman et al., 2019). The list, first established in 2007, has been continuously revised and updated. A Panel Statement is published approximately every 6 months. These Panel Statements include the results of the assessment of relevant new scientific articles related to the taxonomic units (TUs) with QPS status. They also contain the assessment of newly submitted TUs to the EFSA Units on Feed and Contaminants (FEEDCO), Food Ingredients and Packaging (FIP), Nutrition and Food Innovation (NIF) and Pesticides Peer Review (PREV). After 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period.

### 1.1 | Background and terms of reference as provided by the requestor

A wide variety of microorganisms are intentionally added at different stages to the food and feed chains. In the context of applications for market authorisation, EFSA is requested to assess the safety of microorganisms when used either directly or as sources of food and feed additives, food enzymes, and plant protection products.

EFSA's work on QPS activities began in 2004, when the Scientific Committee issued a Scientific opinion in continuation of the 2003 working document '*On a generic approach to the safety assessment of microorganisms used in feed/food and feed/food production*' prepared by a working group consisting of members of the former Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Committee on Plants of the European Commission.<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 stakeholders to the QPS approach. In its 2005 Opinion (EFSA, 2005), the Scientific Committee concluded that the QPS approach could provide a generic assessment system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed chains. Its introduction was intended to improve transparency and ensure consistency in the approach used across the EFSA Panels. Applications involving a TU belonging to a species that falls within a QPS group do not require a full safety assessment.

Several TUs (usually species for bacteria and yeasts; families for viruses) have been included in the QPS list, either following notifications to EFSA or proposals made initially by stakeholders during a public consultation in 2005, even if they were not yet notified to EFSA (EFSA, 2005). The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and, in 2007, published a list of microorganisms recommended for the QPS list.

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

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure; the overall assessment of the TUs previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) was no longer carried out annually but over a 3-year period. From 2017, the search and revision of the possible safety concerns linked to those TUs began instead to be carried out every 6 months through extensive literature searches (ELS). The update of the 2013 QPS list (EFSA BIOHAZ Panel, 2013) was done in 2016 (EFSA BIOHAZ Panel, 2017). From 2016 on, the QPS list (<https://doi.org/10.5281/zenodo.1146566>) and the list of notifications to EFSA (<https://doi.org/10.5281/zenodo.3607183>) are constantly updated, independent of the QPS Opinion, and are available at the Knowledge Junction in Zenodo. The most recent QPS Opinion (EFSA BIOHAZ Panel, 2023) summarises the main results of the 3-year ELS on the QPS TUs, together with an update of the process for granting QPS status. In the meantime, every 6 months a Panel Statement, compiling the assessments for a QPS status of the microorganisms notified to EFSA requested by the Feed and Contaminants (FEEDCO) Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition and Food Innovation (NIF) Unit, the Pesticides Peer Review (PREV) Unit,<sup>2</sup> as well as the summary of each 6-month ELS exercise, has been produced and published. Each QPS Panel Statement contains the evaluations of the new notifications for microorganisms submitted for possible QPS status. It also contains the result of a standardised ELS performed every 6 months regarding possible new safety concerns related to the TUs already included in

<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).

<sup>2</sup>Units as in December 2022.

the QPS list. The data identified are used to inform decisions on whether any TU may or may not remain on the QPS list, and whether any qualifications need to be revised.

Establishing a QPS status is based on 4 pillars: (1) the taxonomic unit (TU) for which QPS is sought ('*taxonomic identification*'); (2) whether sufficient relevant information is available about the proposed TU to conclude on human/animal exposure via food/feed ('*body of knowledge*'); (3) whether the TU proposed contains known '*safety concerns*' and, finally, (4) the intended end use ('*intended use*'). If a hazard related to a TU is identified, which can be tested at the strain or product level, a 'qualification' to exclude that hazard may be established and added. The subject of these qualifications for the microbial strain under investigation is evaluated by the EFSA Unit to which the application dossier has been allocated. Absence of acquired genes coding for resistance to 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 and/or feed chains. The qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied to food and feed products based on microbial biomass (EFSA BIOHAZ Panel, 2020a).

Because the QPS evaluation is, after its initial creation, only triggered through an application dossier notified to EFSA, the QPS list is not exhaustive.

In summary, the QPS evaluation provides a safety assessment approach for use within EFSA that covers safety concerns for humans, production animals, and the environment. In the QPS concept, a safety assessment of a defined TU is performed independently of the legal framework under which the application is made in the course of an authorisation process. Although general human safety is part of the evaluation, specific issues relating to the type and level of exposure of users handling the product (e.g. dermal contact, inhalation, ingestion) are not addressed. In the case of Genetically Modified Microorganisms (GMMs) for which the species of the recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to genetically modified production strains (EFSA BIOHAZ Panel, 2018). The assessment of potential allergenic microbial residual components is beyond the QPS remit; however, it is reported if science-based evidence is available for a microbial species. These aspects are separately assessed, where applicable, by the EFSA Panel responsible for assessing the application.

The lowest TU for which the QPS status is granted is the species level for bacteria, yeasts, and protists/algae, and family for viruses.

Filamentous fungi, bacteriophages, streptomycetes, oomycetes, *Enterococcus faecium*, *Escherichia coli* (EFSA BIOHAZ Panel, 2020a), *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020b), *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024a), *Actinomyces roseirufa* and *Burkholderia stagnaralis* (EFSA BIOHAZ Panel, 2024b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits by some strains of the TU and therefore, require a specific assessment for each strain for which an application is made.

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

ToR 1: Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units such as Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF),<sup>3</sup> for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products (PPPs) and Genetically Modified Microorganisms (GMO) for safety assessment.

ToR 2: Review taxonomic units previously recommended for the QPS list and their qualifications when new information has become available. The latter is based on an update of the ELS aiming to verify whether any new safety concern has arisen that could require the removal of a taxonomic unit from the list, and to verify if the qualifications still effectively exclude safety concerns.

ToR 3: (Re) assess the suitability of new taxonomic units notified to EFSA for their inclusion in the QPS list. These microorganisms are notified to EFSA in the context of technical dossiers for safety assessment and trigger a QPS assessment.<sup>4</sup>

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

In reply to ToR 3, (re)assessment of the suitability of TUs notified within the period covered by this statement (between October 2024 and March 2025 (inclusive)) was carried out. The literature review considered the information on taxonomy, the body of knowledge, the potential safety concerns related to human and animal health and to the environment (EFSA BIOHAZ Panel, 2023) for each TU. The environmental risk assessment of a TU used in PPPs, following the legal requirements, 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.

<sup>3</sup>Units as in December 2022.

<sup>4</sup>Previous text 'These microorganisms are notified to EFSA and requested by the Feed Unit, the FIP Unit, the Nutrition Unit or by the Pesticides Unit'.

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. When needed, an ELS-based approach is applied to ensure the completeness of the information retrieved from the literature in terms of body of knowledge and possible safety concerns. The ELS follows the same methodology as used for monitoring new safety concerns related to species with QPS status but also includes information on the body of knowledge. More details on the search strategy, search keys and approach for each of the assessments are described in Appendix A. Only the literature that is considered, based on expert judgement, to be relevant for the QPS assessment is reflected in the Statement.

Only valid TUs covered by the relevant international committees on the nomenclature for microorganisms are considered for the QPS assessment (EFSA BIOHAZ Panel, 2023). In order to validate this statement, it was decided to revise in a systematic way the TU names and synonyms included in the current QPS list. The TUs of bacteria, yeasts, algae, protists and viruses present in the QPS list were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The results of this exercise can be found in Section 3.4.

## 2.2 | Methodologies

### 2.2.1 | Evaluation of a QPS recommendation for taxonomic units notified to EFSA

In response to ToR 1, the EFSA units were asked to update the list of microorganisms being notified to EFSA. A total of 47 notifications were received between October 2024 and March 2025 (inclusive), of which 25 were for evaluation for use in feed, 7 for use as food enzymes, food additives and flavourings, 6 as novel foods, 8 as plant protection product and 1 as food contact materials (Table 1).

In response to ToR 3, 41 notifications were excluded from the current QPS evaluation for the following reasons: 16 notifications were related to microorganisms that are generally excluded from QPS evaluation (including 11 were notifications of filamentous fungi, 4 of *Escherichia coli*, 1 of *Streptomyces* spp.) and 25 were related to TUs that already had QPS status and did not require further evaluation in this mandate. Of the remaining six notifications, two (*Bacillus thuringiensis* and *Ensifer adhaerens*) had already been evaluated for a possible QPS status in previous Panel Statements. The other four TUs included: *Vibrio natriegens* (notified for the first time), *Papiliotrema terrestris* (EFSA BIOHAZ Panel, 2022), *Bacillus sonorensis* (notified for the first time) and *Corynebacterium stationis* (EFSA BIOHAZ Panel, 2021) will be assessed for a possible QPS status in this Panel Statement. The latter two TUs were included in response to an internal request. *Lactobacillus paragasseri* was also assessed because it was formerly included in *Lactobacillus gasseri*, a TU included in the QPS list.

**TABLE 1** Notifications received by EFSA, per risk assessment area and by biological group, from October 2024 to March 2025.

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement <sup>a</sup>	Total
	Already QPS	Excluded in QPS <sup>b</sup>		
<b>Biological group</b>				
<b>Feed additives</b>	<b>14</b>	<b>10</b>	<b>1</b>	<b>25</b>
Bacteria	12	3	1	16
Filamentous fungi		7		7
Yeasts	2			2
<b>Novel foods</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>6</b>
Bacteria	1	1	1	3
Filamentous fungi				0
Protists/Algae	1			1
Yeasts	2			2
<b>Plant protection products</b>	<b>2</b>	<b>4</b>	<b>2</b>	<b>8</b>
Bacteria	1	1	1	3
Filamentous fungi		3		3
Yeasts			1	1
Viruses	1			1
<b>Food enzymes, food additives and flavourings</b>	<b>4</b>	<b>1</b>	<b>2</b>	<b>7</b>
Bacteria	3		2 <sup>c</sup>	5
Filamentous fungi		1		1
Yeasts	1			1
<b>Food contact materials</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>
Bacteria	1			1

TABLE 1 (Continued)

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement <sup>a</sup>	Total
	Already QPS	Excluded in QPS <sup>b</sup>		
<b>Biological group</b>				
<b>Genetically modified organism</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Bacteria				0
<b>Total</b>	<b>25</b>	<b>16</b>	<b>6</b>	<b>47</b>

Abbreviation: QPS, qualified presumption of safety.

<sup>a</sup>Two were already assessed recently (*Bacillus thuringiensis* and *Ensifer adhaerens*), so they were not assessed in this Statement and four notifications corresponding to four TUs, *Vibrio natriegens*, *Papiliotrema terrestris*, *Bacillus sonorensis* and *Corynebacterium stationis* are assessed in this Statement.

<sup>b</sup>The number includes 11 notifications of filamentous fungi, 4 of *Escherichia coli* and 1 of *Streptomyces* spp., all excluded from QPS evaluation.

<sup>c</sup>Two TUs requested through an internal request from Food Ingredients and Packaging Unit: *Bacillus sonorensis* and *Corynebacterium stationis*.

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

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

The aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, production animals, the environment, AMR or genotoxicity caused by QPS organisms since the previous QPS review that would require a change in the QPS status of the TU. The current ELS covered the scientific articles published from July to December 2024.

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

The title and abstract screening step in this process was supported by a machine-assisted tool (DAISY) in DistillerSR. Details of the process followed can be found in a previous QPS Panel Statement (EFSA BIOHAZ Panel, 2024b).

The title and abstract screening step was performed in parallel by one expert and the same classifier used for the QPS batch of references processed in Panel Statement part 20 (EFSA BIOHAZ Panel, 2024b). An assessment of the performances of the classifier on the above-mentioned batch of references was performed. The specificity of the classifier was 0.99 while, when considering the results of the process up to the Article Evaluation step, the sensitivity was 0.86. Against this background, the classifier was considered useful when put into production as one of the reviewers at title and abstract screening.

To allow the potential expansion of the training set for the DistillerSR Classifier and hence continuously improve the performance of the algorithm in subsequent QPS batches, conflicts between the Experts and the classifier were solved. In case of conflicts where the answer of the classifier had to be changed (after consultation with the Expert concerned), the reply was changed manually by the EFSA Scientific Officer in charge of the assessment who had administration rights on the DistillerSR project.

The taxonomic nomenclature of QPS TUs including bacteria, yeast, algae, protists and viruses is verified every 6 months against their respective authoritative databases to ensure their accuracy for each Panel Statement (EFSA BIOHAZ Panel, 2024b). Before conducting searches for the current ELS, the correctness of names was checked. The ELS launched for this Panel Statement incorporated updated names/synonyms as keywords. In the QPS list, *Agrobacterium radiobacter* (the correct name) and *Rhizobium radiobacter* (a synonym) were swapped.

The CoMiCProN (Ad Hoc Committee for Mitigating Changes in Prokaryotic Nomenclature) prepared Guidelines on Bacterial Nomenclature concerning the (increasing) number of bacterial name changes which have serious implications for, among other fields, medical microbiology. The activities of the CoMiCProN will be followed as it may have consequences for the Nomenclature used in the QPS list.

For case reports of human infections or intoxications, important additional information includes whether any negative impacts are limited to people with conditions that leave the person susceptible to opportunistic infections, for example immunosuppression, and whether transmission occurred through ingestion of food, intake of probiotics or other routes (e.g. medical devices), when described. Studies indicating the presence of virulence factors (e.g. toxins and enzymes that may contribute to the pathogenicity of the microorganism) in the TU are also reported as relevant when identifying potential safety concerns.

Several of the QPS-TUs are sporadically reported as causing infections in individuals with recognised predisposing conditions for the acquisition of opportunistic infections, e.g. cardiovascular conditions associated with endocarditis, people in the lower or upper age spectrum, or with other conditions which can lead to impairment of the immune system, such as patients subjected to transplants, undergoing cancer therapy, suffering from physical trauma or tissue damage, or HIV patients. Moreover, gastrointestinal tract-related conditions with, for example, mucosal impairment and/or proton pump inhibitors can also be predisposing factors for infection. Previous use of the microorganisms being assessed as food supplements/probiotics for humans was reported in many of these cases. The QPS assessment takes into consideration these reports, extracting relevant information whenever justified.

After removal of duplicates, 9000 records proceeded to the title and abstract screening step, resulting in the exclusion of 8943 records. The remaining 57 records were deemed eligible for the article evaluation step (full text), of which 31 were considered to report a potential safety concern and were further analysed.

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

**TABLE 2** Flow of records by search strategy step.

Species	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
<b>Number of articles retrieved</b>			
<b>Bacteria (total)</b>	<b>6297</b>	<b>29</b>	<b>14</b>
<i>Bacillus</i> spp.	2647	14	7
<i>Geobacillus stearothermophilus</i>	3	0	0
<i>Bifidobacterium</i> spp.	404	2	1
<i>Carnobacterium divergens</i>	4	0	0
<i>Corynebacterium glutamicum</i>	73	0	0
Gram negatives <sup>a</sup>	764 <sup>b</sup>	1	0
Lactobacilli	1580	6	3
<i>Lactococcus lactis</i>	292	4	2
<i>Leuconostoc</i> spp.	119	2	1
<i>Microbacterium imperiale</i>	0	0	0
<i>Oenococcus oeni</i>	28	0	0
<i>Pasteuria nishizawae</i>	0	0	0
<i>Clostridium tyrobutyricum</i>	21	0	0
<i>Pediococcus</i> spp.	200	0	0
<i>Propionibacterium</i> spp.	40	0	0
<i>Streptococcus thermophilus</i>	122	0	0
<b>Viruses (total)</b>	<b>199</b>	<b>0</b>	<b>0</b>
Alphaflexiviridae/Potyviridae	104	0	0
Baculoviridae	95	0	0
<b>Yeasts</b>	<b>2035</b>	<b>28</b>	<b>17</b>
<b>Protists</b>	<b>8</b>	<b>0</b>	<b>0</b>
<b>Algae</b>	<b>461</b>	<b>0</b>	<b>0</b>
<b>Total</b>	<b>9000</b>	<b>57</b>	<b>31</b>
<b>Excluded</b>	<b>8943</b>	<b>26</b>	

<sup>a</sup>*Gluconobacter oxydans*/*Xanthomonas campestris*/*Cupriavidus necator*/*Komagataeibacter sucrofermentans*/*Agrobacterium radiobacter*.

<sup>b</sup>*Gluconobacter oxydans* (23)/*Xanthomonas campestris* (545)/*Cupriavidus necator* (66)/*Komagataeibacter sucrofermentans* (8)/*Agrobacterium radiobacter* (122).

## 3 | ASSESSMENT

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

#### 3.1.1 | Bacteria

##### *Corynebacterium stationis*

The QPS assessment of *Corynebacterium stationis* was initiated by an internal ad hoc request from the Food additives and Flavourings Team (FAF),<sup>5</sup> FIP Unit.

*C. stationis* was recently evaluated (EFSA BIOHAZ Panel, 2021) and was not recommended for the QPS list due to a limited body of knowledge on its occurrence in the food and feed chain and possible safety concerns in relation to human and animal health. The literature was checked for additional information published from 2021 to 2024.

<sup>5</sup>It concerns the manufacturing process of the already permitted food additives E 627 (EFSA-Q-2011-00692), E 631 (EFSA-Q-2011-00696) and E 635 (EFSA-Q-2011-00700) (disodium guanosine-5'-monophosphate, disodium inosine-5'-monophosphate and disodium 5'-ribonucleotides (mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate), respectively). According to Regulation (EU) No 257/2010, these were requested to be re-evaluated for safety. To this aim, the public call for data Call for data for the re-evaluation of ribonucleotides (E 626–635) as food additives' was launched by EFSA on 28 June 2023. <https://www.efsa.europa.eu/en/call/call-data-re-evaluation-ribonucleotides-e-626-635-food-additives>.

### 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

Five articles, published from 2021 till 2024, were selected as relevant for the extension of the body of knowledge. Two relate to the safety assessment by EFSA of a strain of *C. stationis*, used to produce disodium 50-inosinate for use as a feed additive (EFSA FEEDAP Panel, 2022, 2023). Two papers relate to *C. stationis* fermentation of compost and the resulting improvement of its use as an organic fertiliser by increasing the indole-3-acetic-acid (IAA) content (Cai et al., 2022; Li,Zhou, et al., 2022). One paper concerns the isolation of *C. stationis* from Chinese soybean paste and the associated biosynthesis of aldehydes (Ling et al., 2022).

### 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). *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 (Anaya-López et al., 2006; Leon-Galvin et al., 2015; 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

No new information was found to change the previous conclusion on the QPS assessment of *C. stationis*. *C. stationis* is not recommended for the QPS list due to a limited 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

### ***Papiliotrema terrestris***

*Papiliotrema terrestris* has already been evaluated in 2022 (EFSA BIOHAZ Panel, 2022) and was not recommended for the QPS list due to a limited body of knowledge.

Since 2022, few new articles have been available, most of which propose this species as a biocontrol agent.

### Conclusion

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

## 3.2 | Taxonomic units evaluated for the first time

### 3.2.1 | Bacteria

#### ***Bacillus sonorensis***

*Bacillus sonorensis* was never notified to EFSA. The QPS assessment of *Bacillus sonorensis* was initiated by an internal ad hoc request from the Food enzymes Team,<sup>6</sup> FIP Unit.

### Identity

*Bacillus sonorensis* is a bacterial species with Standing in Nomenclature (Anonymous, 2001). It was described by Palmisano et al. (2001) as a close relative of *Bacillus licheniformis*. *B. sonorensis* strains were distinguished from *B. licheniformis* by a lower salt tolerance, a different pigmentation and sequence differences in protein-coding genes and 16S rRNA gene (Kim

<sup>6</sup>It is related to an application (EFSA-Q-2023-00215) encompassing several food enzymes ('joint dossier') in which the production strain was initially allocated as *B. licheniformis*. Production of food enzyme subtilisin. Individual data packages from joint dossiers are not subjected to completeness check, and for this reason, it was not notified to EFSA by FDP.

et al., 2015; Palmisano et al., 2001). Despite high 16S rRNA gene similarity (> 99.5%) with related species (*B. licheniformis* and *B. paralicheniformis*), a phylogenomic analysis based on the core genome sequence data (799 genes) (Dunlap et al., 2015; Jeong et al., 2018) and average nucleotide identity (ANI) analysis (performed by MoPs at EFSA)<sup>7</sup> showed that *B. sonorensis* is a distinct standalone species within the *B. subtilis* group.

### Body of knowledge

*B. sonorensis* strains were reported for their ability to produce the bacteriocin sonorensin (Chopra et al., 2015), the enzymes L-asparaginase (Aly et al., 2020), pectinase (Mohandas et al., 2018), xylanase (Kiribayeva et al., 2022), endoglucanase (Raza et al., 2019), lipase (Bhosale et al., 2016), cellulase (Azadian et al., 2017) and exopolysaccharides (Abdelnasser & Abu-Shahba, 2024; Abdelnasser & Ahmed, 2022).

*B. sonorensis* strains have shown plant growth promoting ability (Ankati et al., 2018) and antagonistic activity against the fungal plant disease causing charcoal rot (Pandya & Saraf, 2014).

*B. sonorensis* was isolated from the fermentation brine of Chinese soya sauce (Yin et al., 2012) and the Korean meju (basis for the production of soy sauce and soybean paste) (Jang et al., 2021), from starters used for the production of Sudanese bread (Adimpong et al., 2012) and for the production of the Sudanese snack Gergoush (Abban et al., 2013; Thorsen et al., 2011) and from fermented grains used for the production of Chinese liquor (Yin et al., 2024).

*B. sonorensis* was isolated from the rumen of buffalo (Wang et al., 2021), from tank milk samples on dairy farms (Buehner et al., 2014) and from concentrated milk (Martinez et al., 2017). It was also isolated from gelatin (Heckler et al., 2024).

### Safety concerns

The whole genome sequence of *B. sonorensis* strain L12 carries gene clusters for de novo biosynthesis of bacitracin (Adimpong et al., 2013). The bacitracin biosynthetic cluster was detected in the *B. sonorensis* type strain genome (NBRC 101234<sup>T</sup>) using MoPS (antiSMASH genome mining tool). In the study by Adimpong et al. (2012), the bacitracin biosynthetase gene *bacA* and the transporter gene *bcrA* were both detected in all 18 *B. sonorensis* strains including the type strain. The bacitracin synthetase genes *bacB* and *bacC*, as well as the transporter genes *bcrB* and *bcrC*, were not detected in any of the *B. sonorensis* strains. Bacitracin A production was detected in 9% of the *B. sonorensis* strains. No other safety concerns have been reported related to *B. sonorensis*.

### Conclusion

*B. sonorensis* is recommended for the QPS list with the qualifications 'absence of bacitracin production ability' and 'absence of toxigenic activity'.

## ***Vibrio natriegens***

*Vibrio natriegens* was never notified earlier to EFSA. It has now been notified as a production strain for a hydrolysate intended as a novel food.

### Identity

*Vibrio natriegens* is a bacterial species with Standing in Nomenclature (Anonymous, 1981). The species was described by Baumann et al. (1980). It is a facultative anaerobic microorganism (Li, Liang, et al., 2022).

### Body of knowledge

*V. natriegens* is a ubiquitous, marine fast-growing bacterium (Müller & Blombach, 2019), accelerating the corrosion of steel materials (Wu et al., 2023) and gaining attention as a chassis organism (Gong et al., 2023; Hoff et al., 2020; Hong et al., 2024; Lima et al., 2024; Thoma & Blombach, 2021). *V. natriegens* strains may promote the growth of unicellular algae as *Euglena gracilis* (Kim et al., 2019) and are known to produce exopolysaccharides (Schulze et al., 2024), neuraminic acid (Peng et al., 2023) and pyruvate (Wu et al., 2023). *V. natriegens* can utilise a wide range of substrates, displays a range of enzymatic activities and is capable of nitrate reduction and nitrogen fixation (Coyer et al., 1996; Ellis et al., 2019; He et al., 2024; Hoffart et al., 2017). It is also capable of breaking down polyethylene terephthalate microplastics under saltwater conditions (Li et al., 2023).

<sup>7</sup><https://mopsportal.efsa.europa.eu/>.

### Safety concerns

No safety concerns to humans were reported in literature. Two publications report pathogenicity towards molluscs. *V. natriegens* strains, identified by molecular methods, were isolated as causing agent of mortality in juvenile abalones (*Haliotis discus hannai Ino*) (Li, Zhou, et al., 2022), in oysters (*Crassostrea gigas*) (Zhang et al., 2023) and it was found in the bacterial community composition among coral diseases in Biawak Island (Agung et al., 2020).

### Conclusion

*Vibrio natriegens* is recommended for the QPS status but for 'production purposes only'.

## **Lactobacillus paragasseri**

### Identity

*L. paragasseri* is a valid species according to the List of Prokaryotic Names with Standing in Nomenclature (Tanizawa et al., 2018). This species is related to *L. gasseri*, to the point that 16S rRNA gene sequencing does not distinguish between them. However, analysis of nucleotide-level genomic similarity by average nucleotide identity (ANI), in silico DNA hybridisation and comparison of some specific genes such as *rpoA* and *pheS*, clearly delineates both species (Ene et al., 2022; Tanizawa et al., 2018; Zhou et al., 2020).

### Body of knowledge

Most papers dealt with the presence of *L. paragasseri* among the genitourinary and intestinal autochthonous microbiota (Atkins et al., 2024; Ding et al., 2022; Ksiezarek et al., 2021). Some strains are claimed as having a 'probiotic' positive effect on digestive (Yamada et al., 2024) and urogenital problems (Nilsen et al., 2020), on pre-menstrual tension relieve (Sato et al., 2023) and on viral and bacterial infections (Kobatake et al., 2023; Xu et al., 2023). It has also been developed as a 'post-biotic' for cosmetic use (Lee et al., 2025). Kusada et al. (2022) identified in vitro penicillin acylase (PA) activity in the bile salt hydrolase (BSH) of *Lactobacillus paragasseri* and other gut microbiota members. While this bifunctional enzyme degraded penicillin G in purified form, the whole-cell susceptibility of *L. paragasseri* to penicillins remained high (low MICs), indicating that PA activity does not confer resistance in vivo. The observed higher MICs for cephalosporins in these strains were not linked to BSH-mediated PA activity, and alternative mechanisms – such as altered penicillin-binding proteins (PBPs) – remain plausible but unconfirmed.

### Safety concerns

Toyoshima et al. (2021) have published a report in which *L. paragasseri* appeared to be the aetiological agent of a cavernosal abscess in a 63-year-old man. Predisposing agents were an uncontrolled type 2 diabetes and a foreign body (a pearl) inserted in the urethra. No other references on possible safety concerns of *L. paragasseri* have been found.

### Conclusions on a recommendation for the QPS list

Based on the outcome of the above assessment, *L. paragasseri* is recommended for the QPS list.

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

The summaries of the evaluation regarding potential safety concerns for humans, animals or the environment based on scientific articles published since the previous ELS exercise, as described in Appendices B and C, with reference to the articles selected as potentially relevant for the QPS exercise (Appendix D) for each of the TUs or groups of TUs that are part of the QPS list (Appendix E), are presented below. The current ELS covered the scientific articles published from July to December 2024.

### 3.3.1 | Gram-positive non-sporulating bacteria

#### **Bifidobacterium spp.**

A search for scientific articles potentially relevant for QPS-listed *Bifidobacterium* spp. (*B. adolescentis*, *B. animalis*, *B. bifidum*, *B. breve* and *B. longum*) provided 404 references. Two of these articles (Graspeuntner et al., 2024; Imataki & Uemura, 2024) were considered relevant based on their title and abstract screening. Graspeuntner et al. (2024) did not describe any safety concern. The paper of Imataki and Uemura (2024) described a case of *Bifidobacterium breve* bloodstream infection in a

lymphoma patient undergoing chemotherapy (Imataki & Uemura, 2024). There is a lack of description of the methodology used to identify the bacteria. Consequently, the QPS status of *Bifidobacterium* spp. remains unchanged.

### ***Carnobacterium divergens***

A search for potentially relevant scientific articles on *C. divergens* provided four references. None of these articles were considered relevant based on their title and abstract screening. Consequently, the QPS status of *C. divergens* remains unchanged.

### ***Corynebacterium glutamicum***

A search for scientific articles potentially relevant to the QPS evaluation of *C. glutamicum* provided 73 references. None of these articles were considered relevant based on their title and abstract screening. Consequently, the QPS status of *C. glutamicum* remains unchanged.

### **Lactobacilli**

A search of papers referring to any of the QPS species, formerly belonging to the genus *Lactobacillus* and, in 2020, split into several new genera, yielded 1580 references. After title and abstract screening, six were selected for the full-text phase inspection. Of these, one did not describe safety concerns (Santoemma et al., 2024), and two were not in English (Cabrera et al., 2024; Cornacchiari et al., 2024). Only three described a possible safety concern (Christ et al., 2024; Ito et al., 2024; Ukai et al., 2025). All of them described single cases occurring in individuals with severe systemic pathologies leading to immunodepression. Despite this, the first two were administered probiotics. Ukai et al. (2025) reported a case of *Lacticaseibacillus paracasei* bacteraemia in an 8-month-old girl following a jejunostomy for hypoganglionosis. She had been taking a probiotic preparation containing a *L. paracasei* strain, which was most likely the same strain isolated from her blood. Ito et al. (2024) described a case of endocarditis in a man with predisposing conditions, including previous aortic valve regurgitation and mycotic aneurysms in both abdominal and cranial arteries, suggestive of immunodeficiency. Blood cultures rendered *Lacticaseibacillus rhamnosus*, and, since the patient took probiotics regularly, this was taken as evidence of *L. rhamnosus* endocarditis. However, the composition of the probiotic preparation was not reported, nor were attempts made to link both facts. Finally, Christ et al. (2024) described the case of an immunocompromised patient who suffered from non-controlled type 2 diabetes (level of glycosylated haemoglobin 13.2) that presented an abscess on his left leg, out of which a *Lactobacillus gasseri* isolate was obtained.

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

### ***Lactococcus lactis***

The search for publications addressing potential safety concerns related to *L. lactis* provided 292 references. Following title and abstract screening, four articles arrived at the full-text phase, but 2 were related to another TU (Pena-Mosca et al., 2024; Tripathy et al., 2024). Only two articles were identified that might pose safety concerns (Magro et al., 2024; Prabhala et al., 2024). However, none of them were considered to be relevant after full text inspection because in the first of them, on cow mastitis, *L. lactis* was scarcely found on positive samples, suggesting that this is not the agent causing mastitis, while in the second, identification was only done through phenotypical methods.

Based on the available evidence as described above, the QPS status of *Lactococcus lactis* is not changed.

### ***Leuconostoc* spp.**

A search for scientific articles potentially relevant to the QPS evaluation of *Leuconostoc* QPS species (*L. citreum*, *L. lactis*, *L. mesenteroides*, *L. pseudomesenteroides*) provided 119 references. The analysis of their titles and abstracts left 2 articles for full text evaluation. One of these was not related to *Leuconostoc* QPS TUs (Prabhala et al., 2024). The second article by Karnaker et al. (2024) described a lower respiratory tract infection in a hospitalised patient but was considered unsuitable due to the use of phenotypic tests for the identification of *L. pseudomesenteroides*. The information obtained from the ELS did not lead to any change in the status of QPS-listed *Leuconostoc* species.

### ***Microbacterium imperiale***

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

### ***Oenococcus oeni***

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

### ***Pediococcus* spp.**

A search for scientific articles potentially relevant for the QPS evaluation of *Pediococcus* spp. provided 200 references. The title and abstract screening left no articles for the full-text phase. Consequently, the status of QPS-listed *Pediococcus* spp. remains unchanged.

### ***Propionibacterium* spp.**

A search for scientific articles potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 40 references. Following the analysis of their titles and abstracts, no articles passed to the full article evaluation phase. Consequently, the status of QPS-listed *Propionibacterium* spp. is not changed.

### ***Streptococcus thermophilus***

A search for scientific articles potentially relevant for the QPS evaluation of *Streptococcus thermophilus* provided 122 references. Following the analysis of their titles and abstracts, no articles passed to the full article evaluation phase. Consequently, the QPS status of *S. thermophilus* is not changed.

## 3.3.2 | Gram-positive spore-forming bacteria

A search for scientific articles potentially relevant for *Bacillus* spp., related species and *Geobacillus stearothermophilus* provided 2650 references. Some of the references (883) were still from the previous ELS period but because of a problem in the search process identified during this ELS cycle, were included in this batch.

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

2647 articles were found for *Bacillus* spp. and related species. Of the 14 scientific articles that passed to the full-text phase for further analysis, six do not describe a safety concern (EFSA CEP Panel 2023a, 2023b; Jin et al., 2024; Sermkaew et al., 2024; Sylvester et al., 2024; Viera et al., 2024), one was not in English (Lotti et al., 2023) and seven were reporting a possible safety concern. Three papers reported *B. licheniformis* involved in peritonitis (Ali et al., 2024) and endocarditis (Plata-Corona et al., 2023) and *Priestia megaterium* (Guo et al., 2024) involved in pulmonary proteinosis but did not include information on the identification method. The identification methods reported in the papers of Nayeri Fasaei et al. (2023) considering *B. licheniformis*, Ugras and Bahat (2024) considering *Bacillus pumilus* and Cismasiu et al. (2023) considering *Shouchella clausii* (formerly *B. clausii*) were found to be insufficiently discriminative at the species level.

The article of Moreno-Muñoz et al. (2024) reported a case of a 4-month-old infant who died due to septicaemia 12 days after administration of a probiotic containing a formulation of antibiotic-resistant *S. clausii* strains. It has to be stressed that probiotic use in humans is out of the remit of QPS.

Through the ELS, no information was identified that would change the status of members of *Bacillus* spp. included in the QPS list.

### ***Geobacillus stearothermophilus***

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

### ***Pasteuria nishizawae***

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

### ***Clostridium tyrobutyricum***

A search for scientific articles potentially relevant to *C. tyrobutyricum* provided 21 references. Following an analysis of the title and abstract, none were selected for the full-text analysis phase. Consequently, the QPS status of *C. tyrobutyricum* is not changed.

### 3.3.3 | Gram-negative bacteria

A search for scientific articles potentially relevant to the QPS evaluation of *Gluconobacter oxidans*, *Xanthomonas campestris*, *Cupriavidus necator*, *Komagataeibacter sucrofermentans* and *Rhizobium radiobacter* provided in total 764 references. The analysis of the titles left one article to be evaluated at abstract level.

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

A search for scientific articles potentially relevant for *C. necator* provided 66 references. Following the analysis of their titles and abstract, none were selected for the full-text analysis phase. Consequently, the QPS status of *C. necator* is not changed.

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

A search for scientific articles potentially relevant for *G. oxydans* provided 23 references. Following the analysis of their titles and abstracts, none were selected for the full-text phase. Consequently, the QPS status of *G. oxydans* is not changed.

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

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

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

A search for scientific articles potentially relevant for *X. campestris* provided 545 references. Following the analysis of their titles and abstracts, one article was selected for the full-text phase but did not describe a safety concern (Chang et al., 2023). Consequently, the QPS status of *X. campestris* is not changed.

#### ***Agrobacterium radiobacter* synonym *Rhizobium radiobacter***

A search for scientific articles potentially relevant for *A. radiobacter* provided 122 references. Following the analysis of their titles and abstracts, none were selected for the full-text phase. Consequently, the QPS status of *X. campestris* *A. radiobacter* is not changed.

### 3.3.4 | Yeasts

The ELS searches for potentially relevant scientific articles on yeasts with QPS status provided 2035 references. After the title/abstract screening phase, 28 articles proceeded to the full article appraisal phase. Out of these, six were not related to safety concerns (Delma et al., 2024; Liu et al., 2024; Schaefer et al., 2024; Van Genechten et al., 2024; Zhou et al., 2024; Zonna et al., 2024), three were not related to the QPS yeast group (Al Janabi et al., 2025; de Moraes et al., 2024; Murante et al., 2024) and two were not available (Alshawi et al., 2024; Tabuena et al., 2024). Therefore, only 17 reported a possible safety concern. These 17 articles are cited and discussed below. For the species ***Komagataella pastoris*, *Komagataella phaffi*, *Limtongozyma cylindracea*, *Ogataea angusta*, *Ogataea polymorpha*, *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.

#### ***Hanseniaspora uvarum***

The anamorph name of *H. uvarum* is *Kloeckera apiculata*. No obligate synonyms are described.

Ehrlich-Fein and Patel (2024) report a case study of a nail infection (onychomycosis) in an otherwise healthy 32-year-old male, but no actual illness. It is very rare that the widespread and common yeast *H. uvarum* causes infections in humans.

This study did not add any new information that would change the current QPS status of this species.

#### ***Cyberlindnera jadinii***

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

Rai et al. (2024) isolated yeasts from the blood of neonates with suspected bloodstream infection at a tertiary care centre in North India. Yeasts were initially identified by standard phenotypic methods followed by MALDI-TOF MS. From a total of 107 suspected candidaemia events, surprisingly *C. jadinii* was the most isolated species with 57 cases (53%). However,

species identification was not confirmed with a molecular method and information is lacking regarding what could be the possible source to the putative *C. jadinii*. The susceptibilities of the isolates to fluconazole, itraconazole and amphotericin B were largely in accordance from previous studies.

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

### ***Debaryomyces hansenii***

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

All six publications of *D. hansenii* related to safety concerns showed identification problems. Three of them are retrospective reviews of candidaemia. Welagedara et al. (2024) is a retrospective review at the Mycology Reference Laboratory in Sri Lanka over 5 years. They identified isolates causing candidaemia from blood samples, their antifungal susceptibility patterns and associated factors. No information about the methodology used for yeast identification is included. Of the 13 *C. famata* isolates (1.3%), 9 had low MIC values ( $\leq 1 \mu\text{g/mL}$ ) for amphotericin B. Shelke et al. (2024) is a retrospective study of yeasts and yeast-like fungi in the strain collection of a hospital in India. Two of the isolates (2%) were identified as *D. hansenii*. However, there is uncertainty regarding the identification method and whether the fungi caused the disease. Pinho et al. (2024) is a review associated with emergent uncommon *Candida* species responsible for invasive infections in adult patients (from 2001 to 2023). Similar to the two previous reviews, no information is available on the methodology used for species identification. From 1567 publications, the authors selected 36, excluding non-invasive fungal infection, pathogenic *Candida* species and studies with no patient clinical information and identified the presence of *C. famata* only in Asia.

The remaining three publications are related to studies of resistance to antifungals. Sigei et al. (2024) analysed the itraconazole and voriconazole antifungal sensitivity profiles of *Candida* isolates from clinical specimens from candidiasis patients in Nairobi County. Two isolates were identified as *D. hansenii*: one strain was sensitive to itraconazole and the other to voriconazole. Corbu et al. (2024) studied resistance and virulence markers in *Candida* spp. isolated from community-acquired infections in Bucharest outpatients during 2021, at phenotypic and molecular levels. A total of 62 *Candida* spp. strains were isolated from dermatomycoses, identified using chromogenic culture media and MALDI-TOF MS, and investigated for their antimicrobial resistance and virulence markers. Of the 62 strains, 1.66% were *D. hansenii*. All the isolates of this species were resistant to the antimicrobial tested. Ali et al. (2024) analysed the frequency and antifungal susceptibility of *Candida albicans* and non-*albicans* species in diabetic foot infections from samples collected in a tertiary care hospital in the district of Peshawar. Of 600 samples, 200 patients had diabetic foot ulcers with positive fungal culture, and 19 (9.5%) corresponded to *D. hansenii*. Two samples presented resistance to amphotericin, one to caspofungin, one to fluconazole, nine to flucytosine, one to itraconazole, six to micafungin and five to voriconazole.

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

### ***Kluyveromyces lactis***

The anamorph form of *K. lactis* is *Candida spherica*. Synonyms of this species are: *Guilliermondella lactis*, *Zygodabospora lactis*, *Zygorenospora lactis*, *Kluyveromyces marxianus* var. *lactis*, *Dekkeromyces lactis*.

Only one publication addresses safety concerns (Baniodeh et al., 2024). In this retrospective study from two hospitals in Palestine, only one isolate (0.2%) was identified as *K. lactis*. However, there is uncertainty regarding species identification, and clinical information is missing.

The study on *K. lactis* did not add any new information that would change this species' current QPS status.

### ***Kluyveromyces marxianus***

The anamorph name of *K. marxianus* is *Candida kefyr*. Synonyms of this species are *Dekkeromyces marxianus*, *Guilliermondella marxiana*, *Zygodabospora marxiana*, *Zygorenospora marxiana*, *Zygosaccharomyces marxianus*.

Seven publications are related to safety concerns. The new studies confirm that, in rare cases, *K. marxianus* can cause opportunistic or superficial infections. One of the isolates from 413 cases of fungal head or neck infection at a hospital in the USA was reported to be *K. marxianus* (Hou et al. 2024). However, the paper provides no clinical information about the case or the method used for yeast identification. Corbu et al. (2024) investigated antimycotic susceptibility and virulence markers in *Candida* spp. isolated from outpatients with dermatomycosis at Romanian hospitals during 2021. One (out of 62) strain was identified to *K. marxianus* (by chromogenic culture media and MALDI-TOF MS), but no specific information on antifungal susceptibility and virulence of that strain was given. Belgacem et al. (2024) defined the profile of uncommon, clinical yeast species at a hospital in Tunisia using phenotypic, molecular and proteomic methods and determined their antifungal susceptibility profile. Out of 2402 yeast isolates, 30 (1.3%) were considered 'uncommon', of which five were *K. marxianus*. All five had low MIC values for echinocandins. Pinho et al. (2024) reviewed cases of uncommon *Candida* sp. responsible for invasive infections in adult patients from 2001 to 2023, focusing on epidemiological, clinical and microbiological data. In their data, *K. marxianus* was predominantly recorded in North America, Europe and Asia.

In a retrospective study by Baniodeh et al. (2024) from two hospitals in Palestine, only two isolates (0.4%) from a collection of clinical yeast isolates were identified as *K. marxianus*. However, there is uncertainty regarding species identification, and clinical information is missing.

Zareshahrabadi et al. (2024) determined antimycotic susceptibility profiles to caspofungin, fluconazole, itraconazole, voriconazole and amphotericin B in dairy and clinical (plus a healthy control group) isolates of *K. marxianus* and reported epidemiological cut-off values. Interestingly, the frequency of non-wild-type isolates (reduced susceptibility) was highest in the control group from healthy individuals, which is difficult to explain. Sánchez Quitian et al. (2024) reported that one out of 10 isolates of *K. marxianus* from artisanal cheeses in Colombia had intermediate susceptibility to 5-fluorocytosine.

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

### ***Saccharomyces cerevisiae***

The anamorph form of *S. cerevisiae* is not described. An exceptional synonym of this species is *Saccharomyces boulardii*. Other synonyms are *Mycokluyveria cerevisiae*, *Eutorulopsis cerevisiae*, *Eutorula cerevisiae*, *Kloeckera cerevisiae*.

Two publications are related to safety concerns. Yan et al. (2024) conducted a retrospective study of the antimycotic susceptibility of *S. cerevisiae* isolates from a university hospital in Southwest China. The isolates were from patients with vulvovaginal candidiasis, pneumonia and diarrhoea. Only MALDI-TOF MS was used for yeast identification, and no confirmation was obtained using molecular methods. The *S. cerevisiae* isolates were not considered the primary pathogen in any of the pneumonia cases, and there was no clear clinical evidence that *S. cerevisiae* was the primary pathogen in any of the diarrhoea cases. Additionally, the minimum inhibitory concentrations of the isolates were generally within the same order of magnitude as in previous studies and were lower than those of *Candida albicans* isolates from the same collection. Belgacem et al. (2024) aimed to define the profile of uncommon yeast species at Fattouma Bourguiba University Hospital, collected from 2018 to 2021. These isolates were further identified using phenotypic methods (ID32C (R) system and Vitek2 (R) YST), MALDI-TOF MS and sequencing. Only through sequencing did the authors find one isolate identified as *S. cerevisiae*. No information about this strain's antifungal susceptibility is available.

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

### ***Wickerhamomyces anomalus***

The anamorph name of *W. anomalus* is *Candida pelliculosa*. Synonyms of this species are *Endomyces anomalus*, *Pichia anomala*, *Willia anomala*, *Hansenula anomala*.

One scientific article contributed with information related to human safety concerns (Mpakosi et al., 2024). This is a global, systematic review of cases of neonatal fungaemia caused by 'non-*Candida*' yeasts and yeast-like fungi. Of the 342 cases from 89 publications included in the study, the most common species causing neonatal fungaemia was *W. anomalus*, with 31% of the cases. 62% of the cases occurred in Asia. Low birth weight, use of central catheters, use of antibiotics and premature birth were the main risk factors in fatal cases. The study confirms that *W. anomalus* may cause opportunistic infections in neonates and that early diagnosis and species identification are critical for selecting effective treatment.

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

## 3.3.5 | Protists

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

A search for scientific articles potentially relevant for *A. limacinum* provided eight articles. Following the analysis of their titles and abstract, none were selected for the full-text phase. Therefore, the current QPS status of *A. limacinum* is not changed.

## 3.3.6 | Algae

A search for scientific articles potentially relevant for algae provided 461 articles. Following the analysis of their titles and abstract, none were selected for the full-text phase.

### ***Euglena gracilis***

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

### ***Haematococcus lacustris* synonym *Haematococcus pluviialis***

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

### ***Tetraselmis chuii***

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

### 3.3.7 | Viruses used for plant protection

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

A search for scientific articles potentially relevant for the QPS evaluation of viruses of the *Alphaflexiviridae* and *Potyviridae* families provided 104 references. Following the analysis of their titles and abstract, none were selected for the full-text phase. Therefore, the current QPS status remains unchanged.

#### ***Baculoviridae***

A search for scientific articles potentially relevant for the QPS evaluation of the *Baculoviridae* family provided 95 references. Following the analysis of their titles and abstract, none were selected for the full-text phase. Therefore, the current QPS status remains unchanged.

## 3.4 | QPS and genetically modified microorganisms (GMMs)

In this Panel Statement, the relation between QPS and genetically modified microorganisms, originally described in EFSA BIOHAZ Panel (2018) and clarified in EFSA BIOHAZ Panel (2024b), has been amended as follows: *'For genetically modified microorganisms (GMMs) for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents. The QPS approach can also be followed if the qualifications for QPS are met due to the removal/ inactivation of a gene(s) of concern (e.g. AMR genes) by means of genetic modification.'*

## 3.5 | Inclusion of both yeasts' qualifications for some TUs

For all QPS status yeasts used as active agents (viable cells), it has been agreed to add the qualification when they are used as production strains or as biomass (non-viable cells): *QPS applies for 'production purposes only' (the qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass).*

## 4 | CONCLUSIONS

**ToR 1: Keep updated the list of microorganisms being notified, in the context of a technical dossier to EFSA Units (Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF)<sup>8</sup>), 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 2024 and March 2025 (inclusive), the list of notifications was updated with 47 notifications that were received by EFSA, of which 25 were proposed for evaluation as feed additives; 7 for use as food enzymes, food additives and flavourings; 6 as novel foods; 8 as plant protection products; and 1 as food contact materials.

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

- The ELS cycle to review the QPS list TUs included the updated names/synonyms verified in the previous Panel Statement as keywords. In relation to the results of the monitoring of possible new safety concerns relevant for the QPS list, there were no results that would affect the QPS status or the qualifications for the TUs on the QPS list.
- The taxonomic nomenclature of the QPS TUs was verified against their respective authoritative databases to ensure its accuracy. In the QPS list, a swap has been made between *Agrobacterium radiobacter* (correct name) and *Rhizobium radiobacter* (synonym).

<sup>8</sup>Units as in December 2022.

- In this Panel Statement, the relation between QPS and genetically modified microorganisms has been amended as follows: *'For genetically modified microorganisms (GMMs) for which the species of the parental/recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to the genetically modified strain(s) used as production strains, biomass or active agents. The QPS approach can also be followed if the qualifications for QPS are met due to the removal of a gene(s) of concern (e.g. AMR genes) by means of genetic modification.'*
- For all QPS status yeasts used as active agents (viable cells), the following qualification was added for when they are used as production strains or as biomass (non-viable cells): *QPS applies for 'production purposes only' (the qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass).*

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

- Out of the 47 notifications received between October 2024 and March 2025, 25 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 22 notifications, 16 were related to microorganisms that are generally excluded from QPS evaluation (11 were notifications of filamentous fungi, 4 of *Escherichia coli* and 1 of *Streptomyces* spp.).
- Two of the other six notifications were already evaluated for a possible QPS status in previous Panel Statements: *Bacillus thuringiensis* and *Ensifer adhaerens*.
- The other four TU were assessed for a possible QPS status in this Panel Statement: *Vibrio natriegens* (notified for the first time), *Papiliotrema terrestris* (EFSA BIOHAZ Panel, 2022), *Bacillus sonorensis* (notified for the first time) and *Corynebacterium stationis* (EFSA BIOHAZ Panel, 2021). The latter two were received through an internal request from EFSA FIP Unit (Food Enzymes and Food Additives and Flavourings Teams, respectively).
- *Lactobacillus paragasseri* was also assessed because it was formerly included in *Lactobacillus gasseri*, a TU included in the QPS list.

#### Conclusions:

- *Bacillus sonorensis* is recommended for the QPS list with the qualifications 'absence of bacitracin production ability' and 'absence of toxigenic activity'.
- *Corynebacterium stationis* is not recommended for the QPS list due to a limited body of knowledge on its occurrence in the food and feed chain and possible safety concerns in relation to human and animal health.
- *Papiliotrema terrestris* is not recommended for the QPS list due to a limited body of knowledge.
- *Vibrio natriegens* is recommended for the QPS list but for 'production purposes only'.
- *Lactobacillus paragasseri* is recommended for the QPS list.

### **ABBREVIATIONS**

AI	artificial intelligence
AMR	antimicrobial resistance
ANI	Average Nucleotide Identity
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 MS	matrix-assisted laser desorption/ionisation (MALDI), time-of-flight (TOF) mass spectrometry (MS)
PPR	Pesticide Peer Review Unit
QPS	qualified presumption of safety
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group

### **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)

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## REQUESTOR

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## APPENDIX A

### Search strategy followed for the (re)assessment of the suitability of TUs notified to EFSA not present in the current QPS list for their inclusion in the updated list (reply to ToR 3)

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. Details on the search strategy, search keys and approach for each of the assessments of the TUs evaluated in the Statement may be found below.

#### A.1 | *Corynebacterium stationis*

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

- '*Corynebacterium stationis*': (only for 2021–2024): 21 hits, all checked.

#### A.2 | *Papiliotrema terrestris*

The search on PubMed (only for 2022 to March 25) for the following terms led to the number of hits indicated below:

- '*Papiliotrema terrestris*': 10 hits, all checked.

#### A.3 | *Bacillus sonorensis*

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

- '*Bacillus sonorensis*': 60 hits, all checked.

#### A.4 | *Vibrio natriegens*

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

- '*Vibrio natriegens*': 184 hits, all checked.

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

- '*Vibrio natriegens*': 232 hits, all checked.

#### A.5 | *Lactobacillus paragasseri*

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

- '*Lactobacillus paragasseri*': 32 hits, all checked.

## APPENDIX B

### **Protocol for extensive literature search (ELS), relevance screening and article evaluation for the maintenance and update of the list of QPS-recommended microorganisms (reply to ToR 2)**

The protocol for extensive literature search (ELS) used in the context of the EFSA mandate on the list of QPS-recommended microorganisms intentionally added to the food or feed is available on the EFSA Knowledge Junction community on Zenodo at <https://doi.org/10.5281/zenodo.3607188>

## APPENDIX C

### Search strategies for the maintenance and update of the list of QPS-recommended microorganisms (reply to ToR 2)

The search strategies for each taxonomic unit (TU), i.e. the string for each TU and the search outcome, are available on the EFSA Knowledge Junction community on Zenodo at: <https://doi.org/10.5281/zenodo.3607192>

## APPENDIX D

### References selected from the ELS exercise with potential safety concerns for searches done from July to December 2024 (reply to ToR 2)

#### **Gram-Positive Non-Sporulating Bacteria**

##### ***Bifidobacterium* spp.**

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

None.

##### ***Corynebacterium glutamicum***

None.

##### **Lactobacilli**

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##### ***Microbacterium imperiale***

None.

##### ***Oenococcus oeni***

None.

***Pediococci* spp.**

None.

***Propionibacterium* spp.**

None.

***Streptococcus thermophilus***

None.

**Gram-Positive Spore-forming Bacteria*****Bacilli***

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- Cismasiu, R. S., Birlutiu, R. M., & Preotescu, L. L. (2023). Uncommon septic arthritis of the hip joint in an immunocompetent adult patient due to *Bacillus pumilus* and *Paenibacillus barengoltzii* managed with long-term treatment with linezolid: A case report and short literature review. *Pharmaceuticals (Basel, Switzerland)*, 16(12), 1743. <https://doi.org/10.3390/ph16121743>
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- Muñoz, M., Castaño G, E., Esquivel Suman, R., & Alvarado, M. (2023). Septicemia due to *Bacillus clausii* after the use of probiotics. A complication to keep in mind. Septicemia por *Bacillus clausii* posterior al uso de probióticos. Una complicación para tener presente. *Andes pediátrica: Revista Chilena de pediatría*, 94(3), 379–385. <https://doi.org/10.32641/andespediatr.v94i3.4417>
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***Geobacillus stearothermophilus***

None.

***Pasteuria nishizawae***

None.

**Gram-negative bacteria*****Cupriavidus necator***

None.

## ***Gluconobacter oxydans***

None.

## ***Komagataeibacter sucrofermentans***

None.

## ***Xanthomonas campestris***

Chang, Y., Jiang, K., Zhang, L., Yang, F., & Huang, J. (2023). Application of next-generation sequencing technology in the detection of pathogenic bacteria of the periprosthetic joint infection after arthroplasty. *International Wound Journal*, 20(6), 2121–2128. <https://doi.org/10.1111/iwj.14087>

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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 microorganisms in support of EFSA risk assessments

The list of QPS status recommended microorganisms (EFSA BIOHAZ Panel, 2023) is being maintained in accordance with the mandate of the BIOHAZ Panel. Possible additions to this list are included approximately every 6 months, with this Panel Statement (22) adopted in June 2025. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2023); the updated QPS list is available at <https://doi.org/10.5281/zenodo.1146566> (the link opens at the latest version of the QPS list, and also shows the versions associated to each Panel Statement).

## APPENDIX F

## Microbial species as notified to EFSA, received between from October 2024 and March 2025 (reply to ToR 1)

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

The list was updated with the notifications received between October 2024 and March 2025, listed in the table below.

Species	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 amyloliquefaciens</i>	Food enzymes, food additives and flavourings	Food enzyme	Production of the food enzyme nuclease. GMM	EFSA-Q-2025-00150	Yes	No
<i>Bacillus licheniformis</i>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of the feed enzyme alpha-amylase. GMM	EFSA-Q-2025-00019	Yes	No
<i>Bacillus licheniformis</i>	Feed additives	Zootechnical additives	Other zootechnical additives (improvement of zootechnical performance). Preparation of <i>Bacillus licheniformis</i> and its protease. Non-GMM	EFSA-Q-2025-00175	Yes	No
<i>Bacillus licheniformis</i>	Food contact materials	Food contact material	To produce the enzyme subtilisin to be incorporated in plastic material to facilitate plastic degradation. GMM	EFSA-Q-2025-00005	Yes	No
<i>Bacillus licheniformis</i>	Food enzyme, food additives and flavourings	Food enzyme	Production of the food enzyme transglutaminase. GMM	EFSA-Q-2024-00545	Yes	No
<i>Bacillus sonorensis</i>	Food enzymes, food additives and flavourings <sup>c</sup>	Enzyme production	Production of food enzyme subtilisin.	EFSA-Q-2023-00215	No	Yes
<i>Bacillus subtilis</i>	Feed additives	Zootechnical additives	Production of the enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2024-00563	Yes	No
<i>Bacillus subtilis</i>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of the feed enzyme protease. GMM	EFSA-Q-2025-00019	Yes	No
<i>Bacillus subtilis</i>	Food enzymes, food additives and flavourings	Food enzyme	To produce the food enzyme AMP deaminase. GMM	EFSA-Q-2024-00731	Yes	No
<i>Bacillus thuringiensis</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2023-00825	No	No
<i>Bacillus velezensis</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2023-00772	Yes	No
<i>Corynebacterium glutamicum</i>	Feed additives	Nutritional additives and Sensory additives	Amino acid, their salts and analogues. Production of L-leucine. All animal species and categories. GMM	EFSA-Q-2024-00696	Yes	No
<i>Corynebacterium glutamicum</i> <sup>d</sup>	Feed additives	Nutritional additives and sensory additives	Amino acid, their salts and analogues. Production of L-lysine. GMM	EFSA-Q-2024-00723	Yes	No

(Continues)

(Continued)

Species	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>Corynebacterium glutamicum</i> <sup>d</sup>	Feed additives	Nutritional additives and sensory additives	Amino acid, their salts and analogues. Production of L-lysine. GMM	EFSA-Q-2024-00723	Yes	No
<i>Corynebacterium glutamicum</i>	Feed additives	Nutritional additives	Amino acid, their salts and analogues. Production of L-arginine. GMM	EFSA-Q-2025-00011	Yes	No
<i>Corynebacterium glutamicum</i> <sup>d</sup>	Feed additives	Nutritional additives and sensory additives	Amino acid, their salts and analogues. Production of L-lysine. GMM	EFSA-Q-2025-00012	Yes	No
<i>Corynebacterium glutamicum</i> <sup>d</sup>	Feed additives	Nutritional additives and sensory additives	Amino acid, their salts and analogues. Production of L-lysine. GMM	EFSA-Q-2025-00012	Yes	No
<i>Corynebacterium glutamicum</i>	Novel foods	Novel foods	Production of 2'-fucosyllactose. GMM	EFSA-Q-2025-00169	Yes	No
<i>Corynebacterium stationis</i>	Food enzymes, food additives and flavourings <sup>c</sup>	Food additive	Ribonucleotides as food additives. Production of disodium guanosine-5'-monophosphate (E 627), disodium inosine-5'-monophosphate (E 631) and disodium 5'-ribonucleotides (mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate) (E 635) respectively.	EFSA-Q-2011-00692, EFSA-Q-2011-00696, EFSA-Q-2011-00700	No	Yes
<i>Ensifer adhaerens</i>	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect. Production of vitamin B12 (cyanocobalamin). Non-GMM	EFSA-Q-2024-00521	No	No
<i>Escherichia coli</i>	Feed additives	Nutritional additives	Amino acid, their salts and analogues. Production of L-threonine. GMM	EFSA-Q-2024-00695	No	No
<i>Escherichia coli</i>	Feed additives	Nutritional additives	Amino acid, their salts and analogues. Production of L-valine. GMM	EFSA-Q-2024-00697	No	No
<i>Escherichia coli</i>	Feed additives	Nutritional additives	Amino acid, their salts and analogues. Production of L-tryptophan. GMM	EFSA-Q-2025-00009	No	No
<i>Escherichia coli</i>	Novel foods	Novel foods	Production of L-β-aminoisobutyric acid as a novel food. GMM	EFSA-Q-2024-00569	No	No
<i>Lactiplantibacillus plantarum</i>	Feed additives	Technological additives	Active agent. Non-GMM	EFSA-Q-2024-00580	Yes	No
<i>Pediococcus pentosaceus</i>	Feed additives	Technological additives	Active agent. Non-GMM	EFSA-Q-2024-00580	Yes	No
<i>Streptomyces lydicus</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2023-00782	No	No
<i>Vibrio natriegens</i>	Novel foods	Novel foods	Production strain. Microbial hydrolysate. Non-GMM	EFSA-Q-2024-00600	No	Yes
<b>Protists</b>						
<i>Schizochytrium</i> sp. <sup>e</sup>	Novel foods	Novel foods	Production of DHA algal oil. Non-GMM	EFSA-Q-2024-00727	Yes	No

(Continued)

Species	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>Filamentous fungi</b>						
<i>Aspergillus niger</i>	Food enzymes, food additives and flavourings	Food enzyme	Production strain. Non-GMM	EFSA-Q-2024-00425	No	No
<i>Beauveria bassiana</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2023-00179	No	No
<i>Beauveria bassiana</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2023-00237	No	No
<i>Paecilomyces fumosoroseus</i>	Plant protection products	Plant protection products	Active substance. Non-GMM	EFSA-Q-2022-00515	No	No
<i>Talaromyces versatilis</i>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of feed enzyme cellulase. Non-GMM	EFSA-Q-2025-00019	No	No
<i>Trichoderma reesei</i>	Feed additives	Zootechnical additives	Digestibility enhancer for laying hens and other laying poultry species. Production of 6-phytase. GMM	EFSA-Q-2024-00680	No	No
<i>Trichoderma reesei</i>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of feed enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2024-00726	No	No
<i>Trichoderma reesei</i> <sup>d</sup>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of feed enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2025-00019	No	No
<i>Trichoderma reesei</i> <sup>d</sup>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of feed enzyme cellulase. Non-GMM	EFSA-Q-2025-00019	No	No
<i>Trichoderma reesei</i>	Feed additives	Zootechnical additives	Digestibility enhancer. Production of feed enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2025-00041	No	No
<i>Trichoderma reesei</i>	Feed additives	Zootechnical additives	Production of endo-1,4-beta-xylanase. GMM	EFSA-Q-2025-00142	No	No
<b>Yeasts</b>						
<i>Komagataella phaffii</i>	Food enzymes, food additives and flavourings	Food enzyme	Production of the food enzyme protein-glutamine glutaminase. GMM	EFSA-Q-2024-00709	Yes	No
<i>Komagataella phaffii</i>	Novel foods	Novel foods	Production of human-equivalent lactoferrin $\alpha$ as novel food. GMM	EFSA-Q-2025-00170	Yes	No
<i>Papiliotrema terrestris</i>	Plant protection products	Plant Protection products	Active substance. Non-GMM	EFSA-Q-2023-00792	No	Yes
<i>Saccharomyces cerevisiae</i>	Feed additives	Zootechnical additives	Gut flora stabiliser. Active agent. Non-GMM	EFSA-Q-2024-00725	Yes	No
<i>Saccharomyces cerevisiae</i>	Feed additives	Zootechnical additives	Gut flora stabiliser. Active agent. Non-GMM	EFSA-Q-2025-00010	Yes	No
<i>Saccharomyces cerevisiae</i>	Novel foods	Novel foods	Production strain. GMM	EFSA-Q-2024-00629	Yes	No

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