Adopted: 6 December 2023

DOI: 10.2903/j.efsa.2024.8517

efsa JOURNAL

STATEMENT

Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 19: Suitability of taxonomic units notified to EFSA until September 2023

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Abstract

The qualified presumption of safety (QPS) process was developed to provide a safety assessment approach for microorganisms intended for use in food or feed chains. The QPS approach is based on an assessment of published data for each taxonomic unit (TU), with respect to its taxonomic identity, the body of relevant knowledge and safety concerns. Safety concerns identified for a 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 71 microorganisms notified to EFSA between April and September 2023 (30 as feed additives, 22 as food enzymes or additives, 7 as novel foods and 12 from plant protection products [PPP]), 61 were not evaluated because: 26 were filamentous fungi, 1 was *Enterococcus faecium*, 5 were *Escherichia coli*, 1 was a bacteriophage (all excluded from the QPS evaluation) and 28 were TUs that already have a QPS status. The other 10 notifications belonged to 9 TUs which were evaluated for a possible QPS status: *Ensifer adhaerens* and *Heyndrickxia faecalis* did not get the QPS recommendation due to the limited body of knowledge about their occurrence in the food and/or feed chains and *Burkholderia ubonensis* also due to its ability to generate biologically active compounds with antimicrobial activity; *Klebsiella pneumoniae, Serratia marcescens* and *Pseudomonas putida* due to safety concerns. *K. pneumoniae* is excluded from future QPS evaluations. *Chlamydomonas reinhardtii* is recommended for QPS status with the qualification 'for production purposes only'; *Clostridium tyrobutyricum* is recommended for QPS status with the qualification 'absence of genetic determinants for toxigenic activity'; *Candida oleophila* has been added as a synonym of *Yarrowia lipolytica*. The Panel clarifies the extension of the QPS status for genetically modified strains.

KEYWORDS

Burkholderia ubonensis, *Candida oleophila*, *Chlamydomonas reinhardtii*, *Clostridium tyrobutyricum*, *Ensifer adhaerens*, *Heyndrickxia faecalis*, *Klebsiella pneumoniae*, *Pseudomonas putida*, QPS, *Serratia marcescens*

CONTENTS

SUMMARY

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

The QPS process was developed to provide a harmonised 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, 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 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 overall list 'Microbiological agents as notified to EFSA' (https://doi.org/10.5281/zenodo.3607183) was updated with the notifications received between April and September 2023 (inclusive). Within this period, 71 notifications were received by EFSA, of which 30 were proposed for evaluation in feed, 22 for use as food enzymes, food additives and flavourings, 7 as novel foods and 12 for PPPs. The new notifications received between April and September 2023 are included in the current Statement (see Appendix F).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications. For this revision, articles published from January to June 2023 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 or the qualifications for the TUs on the QPS list.

The third ToR requires a (re)assessment of new TUs notified to EFSA, for their suitability for inclusion in the updated QPS list at the Knowledge Junction in Zenodo (https://doi.org/10.5281/zenodo.1146566, Appendix E – the link opens at the latest update of the QPS list, and also includes the links to the versions associated to each Panel Statement).

In the current period, 71 notifications were received, 61 of which were not evaluated for the following reasons: 33 notifications were related to microorganisms that are excluded from QPS evaluation (26 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 5 of *Escherichia coli*, and 1 bacteriophage) and 28 were related to TUs that already have QPS status and did not require further evaluation. The other 10 notifications belonged to 9 TUs. These were evaluated for possible QPS status: *Burkholderia ubonensis* (already notified and evaluated in 2019), *Candida oleophila*, *Chlamydomonas reinhardtii* (already notified and evaluated in 2021), *Clostridium tyrobutyricum, Ensifer adhaerens* (already notified in 2021 and evaluated in 2022), *Heyndrickxia faecalis, Klebsiella pneumoniae* (already notified and evaluated in 2016), *Pseudomonas putida* and *Serratia marcescens*.

The following conclusions were drawn:

- *B. ubonensis* was already evaluated (EFSA BIOHAZ Panel, 2019) and the new information confirms that it cannot be recommended for the QPS list due to its ability to generate biologically active compounds with antimicrobial activity, and to the limited body of knowledge for its occurrence in the food and/or feed chains.
- *C. oleophila* is included in the QPS list as a synonym of *Yarrowia lipolytica*. *Y. lipolytica* has the QPS qualification 'for production purposes only'. The synonym has been added to the QPS list.
- *C. reinhardtii* (synonym *C. smithii*) was already evaluated (EFSA BIOHAZ Panel, 2022a) and, based on new information, *C. reinhardtii* is recommended for the QPS list with the qualification 'for production purposes only'.
- *C. tyrobutyricum* is recommended for the QPS list with the qualification 'absence of genetic determinants for toxin production'.
- *E. adhaerens* (synonym *Sinorhizobium adhaerens*) was already evaluated (EFSA BIOHAZ Panel, 2022b) and the new information confirms that it cannot be recommended for the QPS list due to the limited body of knowledge for its occurrence in the food and/or feed chains.
- *H. faecalis* is not recommended for the QPS list due to the limited body of knowledge about its occurrence in the food and/or feed chains.
- *K. pneumoniae* was already evaluated (EFSA BIOHAZ Panel, 2016) and the new information confirms that it cannot be recommended for the QPS list due to safety concerns. The inappropriateness of granting a safety status *to K. pneumoniae*, has already been recognised in the previous Panel Statement (EFSA BIOHAZ Panel, 2016). In this Statement, the Panel excludes *K. pneumoniae* from future QPS evaluations.
- *P. putida* is not recommended for the QPS list due to safety concerns.
- *S. marcescens* is not recommended for the QPS list due to safety concerns.
- The Panel clarifies that 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 genetically modified strains used as production strains, biomass or active agents.

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 (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.[1] The document, made available for public consultation, proposed the introduction of the concept of Qualified Presumption of Safety (QPS), to be applied to selected groups of microorganisms. Microorganisms not considered suitable for QPS status would remain subject to a full safety assessment. EFSA management asked its Scientific Committee to consider whether the QPS approach could be applied to the safety assessment of microorganisms across the various EFSA Scientific Panels. In doing so, the Committee was required to take into account the response of stakeholders to the QPS approach. In its 2005 Opinion (EFSA, 2005), the Scientific Committee concluded that the QPS approach could provide a generic assessment system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed 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 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 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 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,[2] as well as the summary of each 6-month ELS exercise, has been produced and published. Each QPS Panel Statement contains the evaluations of the new notifications for microorganisms submitted for possible QPS status. It also contains the result of a standardised ELS performed every 6 months regarding possible new safety concerns

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

[2] Units as in December 2022.

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

Establishing a QPS status is based on four pillars: (1) the taxonomic unit (TU) for which QPS is sought ('*taxonomic identification*'); (2) whether sufficient relevant information is available about the proposed TU to conclude on human/animal exposure via food/feed ('*body of knowledge*'); (3) whether the TU proposed contains known '*safety concerns*' and, finally, (4) the intended end use ('*intended use*'). If a hazard related to a TU is identified, which can be tested at the strain or product level, a 'qualification' to exclude that hazard may be established and added. The subject of these qualifications for the microbial strain under investigation is evaluated by the EFSA Unit to which the application dossier has been allocated. Absence of acquired genes coding for resistance to antimicrobials relevant for humans and animals is a generic qualification for all bacterial TUs; the absence of antimycotic resistance should be proven if the pertinent yeasts are to be used as viable organisms in the food 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 type and level of exposure of users handling the product (e.g. dermal contact, inhalation, ingestion) are not addressed. In the case of genetically modified microorganisms (GMMs) for which the species of the recipient strain qualifies for the QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to genetically modified production strains (EFSA BIOHAZ Panel, 2018). The assessment of potential allergenic microbial residual components is beyond the QPS remit; however, it is reported if science-based evidence is available for a microbial species. These aspects are separately assessed, where applicable, by the EFSA Panel responsible for assessing the application.

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

Filamentous fungi, bacteriophages, Streptomycetes, Oomycetes, *Enterococcus faecium, Escherichia coli* and recently *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020a, 2020b) are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits by some strains of the taxonomic unit, therefore requiring a specific assessment for each strain for which an application is made.

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

ToR 1: Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units such as Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF),[3] 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.[4]

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 (between April and September 2023 [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 PPPs is not included in the QPS assessment but is carried out by the Pesticide Peer Review (PPR) Unit, based on the risk assessment in the application.

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. In the case of need, 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

[3]Units as in December 2022.

[4]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'.

with QPS status but also included 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).

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 71 notifications were received between April and September 2023 (inclusive), of which 30 were for evaluation for use in feed, 22 for use as food enzymes, food additives and flavourings, 7 as novel foods and 12 as plant protection products (Table 1).

In response to ToR 3, 10 of the 71 notifications, corresponding to 9 TU, were evaluated for a possible QPS status: *Burkholderia ubonensis, Candida oleophila, Chlamydomonas reinhardtii, Clostridium tyrobutyricum, Ensifer adhaerens, Heyndrickxia faecalis, Pseudomonas putida, Klebsiella pneumoniae* and *Serratia marcescens* (2 notifications). *B. ubonensis* has already been notified and evaluated in 2019 and *E. adhaerens* in 2021. *C. reinhardtii* and *K. pneumoniae* have already been notified and evaluated before (2021 and 2016 respectively). The other 5 TUs (6 notifications) were evaluated for the first time. 61 notifications were excluded from QPS evaluation for the following reasons: 33 notifications were related to microorganisms that are generally excluded from QPS evaluation (26 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 5 of *Escherichia coli* and 1 bacteriophage) and 28 were related to TUs that already had QPS status and did not require further evaluation in this mandate.

TABLE 1 Notifications received by EFSA, per risk assessment area and by biological group, from April to September 2023.

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[b]	Total
Biological group	**Already QPS**	**Excluded in QPS[a]**		
Feed additives	**21**	**7**	**2**	**30**
Bacteria	20	2	2	24
Filamentous fungi		5		5
Yeasts	1			1
Novel foods	**0**	**3**	**4**	**7**
Bacteria		1	3	4
Filamentous fungi		2		2
Protists/Algae			1	1
Yeasts				0
Plant protection products	**2**	**8**	**2**	**12**
Bacteria	1		1	2
Filamentous fungi		7		7
Yeasts			1	1
Bacteriophages		1		1
Viruses	1			1
Food enzymes, food additives and flavourings	**5**	**15**	**2**	**22**
Bacteria	3	3	2	8
Filamentous fungi		12		12
Yeasts	2			2
Genetically modified organism	**0**	**0**	**0**	**0**
Bacteria				0
Total	**28**	**33**	**10**	**71**

Abbreviation: QPS, qualified presumption of safety.

[a]The number includes 26 notifications of filamentous fungi, 1 of *Enterococcus faecium* (bacterium), 5 of *Escherichia coli* (bacterium) and 1 bacteriophage, all excluded from QPS evaluation.

[b]10 notifications corresponding to 9 TU, *Burkholderia ubonensis, Serratia marcescens (2 notifications), Heyndrickxia faecalis, Clostridium tyrobutyricum, Ensifer adhaerens, Candida oleophila, Pseudomonas putida, Chlamydomonas reinhardtii* and *Klebsiella pneumoniae*.

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 screening of the articles identified was done at title and abstract level in parallel by two reviewers. In case of conflicts, these were solved before the references proceeded to the article evaluation step. This information will be used as a training set to feed a Classifier in DistillerSR with view to potentially using it in the next ELS cycle (i.e. run in parallel with a human reviewer).

The aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, production animals or the environment, caused by QPS organisms since the previous QPS review (i.e. scientific articles published from January to June 2023).

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

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

After removal of duplicates, 9419 records were submitted to the title and abstract screening step, which led to the exclusion of 9363 of these. The remaining 56 records were found eligible for article evaluation step (full text) and 34 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)
	Number of articles retrieved		
Bacteria (total)	**5823**	**23**	**16**
Bacillus spp.	2065	2	2
Bifidobacterium spp.	536	2	2
Carnobacterium divergens	5	0	0
Corynebacterium glutamicum	112	0	0
Gram negatives[a]	318[b]	0	0
Lactobacilli	1855	8	6
Lactococcus lactis	263	4	3
Leuconostoc spp.	151	6	3
Microbacterium imperiale	0	0	0
Oenococcus oeni	40	0	0
Pasteuria nishizawae	1	0	0
Pediococcus spp.	268	0	0
Propionibacterium spp.	45	0	0
Streptococcus thermophilus	164	1	0
Viruses (total)	**221**	**0**	**0**
Alphaflexiviridae/Potyviridae	106	0	0
Baculoviridae	115	0	0
Yeasts	**3121**	**33**	**18**
Protists	**20**	**0**	**0**
Algae	**234**	**0**	**0**

(Continues)

TABLE 1 (Continued)

Species	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
Total	**9419**	**56**	**34**
Excluded	9363	22	

[a]*Gluconobacter oxydans/Xanthomonas campestris/Cupriavidus/Komagateibacter.*

[b]*Gluconobacter oxydans (43)/Xanthomonas campestris (165)/Cupriavidus (106)/Komagateibacter (4).*

3 | ASSESSMENT

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

3.1.1 | Bacteria

Burkholderia ubonensis

Burkholderia ubonensis was already evaluated (EFSA BIOHAZ Panel, 2019).

A new evaluation of *B. ubonensis* was made because an update was requested in relation to the new QPS mandate. The scientific articles published from 2019 onwards provided limited additional information. Four relevant articles were selected describing antimicrobial activity (Cheung-Lee et al., 2020; Lau et al., 2020), lipase production (Mak & Simon, 2020), increased rice yield through the inoculation of a bacterial consortium including *B. ubonensis* (Ríos-Ruiz et al., 2020).

Conclusion on a recommendation for QPS status

The new information confirms that *Burkholderia ubonensis* cannot be recommended for the QPS list due to its ability to generate biologically active compounds with antimicrobial activity and to the limited body of knowledge for its occurrence in the food and/or feed chains.

Ensifer adhaerens synonym *Sinorhizobium adhaerens*

Ensifer adhaerens (synonym *Sinorhizobium adhaerens*) was already evaluated (EFSA BIOHAZ Panel, 2022b).

A new evaluation of *E. adhaerens* was made because an update was requested in relation to the new QPS mandate. New information concerns a biocatalytic activity (Castronovo et al., 2023). The presence of this species in the soil microbiome has also been reported associated with plant growth promoting effects (Baliyan et al., 2022; Hernández-Álvarez et al., 2022; Newberger et al., 2023). No safety concerns were reported.

Conclusion on a recommendation for QPS status

The new information confirms that *Ensifer adhaerens* cannot be recommended for the QPS list due to the limited body of knowledge for its occurrence in the food and/or feed chains.

Klebsiella pneumoniae

Klebsiella pneumoniae was already evaluated (EFSA BIOHAZ Panel, 2016).

A new evaluation of *K. pneumoniae* was made because an update was requested in relation to the new QPS mandate. An update of the scientific knowledge confirms the pathogenic nature of this TU. Recent studies confirm the clinical relevance of *K. pneumoniae* (Magobo et al., 2023). New findings point to the circulation of clinically relevant *K. pneumoniae* strains in the food production sector (Mourão et al., 2023).

Conclusion on a recommendation for QPS status

The new information confirms that *Klebsiella pneumoniae* cannot be recommended for the QPS list due to safety concerns.

The inappropriateness of granting a safety status to the species *K. pneumoniae* has already been recognised in a previous BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016). In this Statement, the Panel excludes *K. pneumoniae* from future QPS evaluations.

3.1.2 | Algae

Chlamydomonas reinhardtii synonym *Chlamydomonas smithii*

Chlamydomonas reinhardtii (synonym *Chlamydomonas smithii*) was already evaluated (EFSA BIOHAZ Panel, 2022a).

A new evaluation of *Chlamydomonas reinhardtii* was made because an update was requested in relation to the new QPS mandate.

Body of knowledge

Chlamydomonas is a genus of green algae consisting of about 150 species. They are unicellular flagellates widely distributed worldwide in soil and fresh water (Sasso et al., 2018).

C. reinhardtii, reported to derive from a single zygote isolated from a Massachusetts potato field (Harris, 2009), is of high interest in genomic research because of the advantages provided by a haploid system, its rapid growth and ability to proliferate easily on plates and in liquid media. In addition, *C. reinhardtii* is widely used to produce bio-products with potential applications in both medical and nutraceutical fields (review Masi et al., 2023). Dried biomass powder of *C. reinhardtii* (strain THN6), was evaluated and approved for use as a nutritive ingredient in food to replace other dietary proteins and received a GRAS status in the United States (GRAS, 2018).

Safety concerns

In a toxicological study dealing with *C. reinhardtii* strain TAI114, a strain rich in protoporphyrin IX and developed using an evolution and selection strategy, no evidence of mutagenicity or toxicity was observed in rats up to the maximum feasible doses of 4000 mg/kg body weight/day biomass (Murbach et al., 2022). In human volunteers with varying gastrointestinal symptoms and consuming 1 or 3 g of *C. reinhardtii* (THN6) daily for 30 days, no signs of dysbiosis or adverse effect on microbial composition were observed in stool samples (Fields et al., 2020). A 42-day oral toxicity study showed that the *C. reinhardtii* strain crAL082 (modified to express an *N*-acetylmuramoyl-L-alanine amidase and a lysozyme-type enzyme) dried biomass powder was fully tolerated by broiler chickens based on the lack of detrimental effects found in performance, mortality, haematology, blood clinical chemistry, and histopathologic results compared with those of an untreated control group, resulting in a 'No Observed Adverse Effect Level' of 5000 ppm, the highest dose tested (Lee et al., 2022). No adverse safety concerns have been identified from the toxicological studies performed.

Literature searches did not provide any evidence for a safety concern for human or animal health for any use.

Conclusion on a recommendation for QPS status

Chlamydomonas reinhardtii (synonym *Chlamydomonas smithii*) is recommended for the QPS list with the qualification 'for production purposes only'.

3.2 | Taxonomic units evaluated for the first time

3.2.1 | Bacteria

Clostridium tyrobutyricum

Identity

Clostridium tyrobutyricum is a species with Standing in Nomenclature. It was first described by Van Beynum and Pette (1935) and approved in 1980 (Skerman et al., 1980). It is a Gram-positive anaerobic, spore-forming bacterium that belongs to cluster 1 subgroup 2 of the *Clostridium* genus. Genomic analysis showed that this subgroup is phylogenetically separated from those containing the pathogenic and toxigenic species *C. botulinum, C. perfringens* and *Clostridioides difficile* (Cruz-Morales et al., 2019).

Body of knowledge

C. tyrobutyricum is considered to be one of the main causative agents for spoilage of hard and semi-hard cheeses. Raw milk becomes contaminated mainly due to cross contamination with bovine faeces during milking or from soil. The spores germinate and the outgrowth during ripening of cheeses coincides with excessive production of gas and butyric acid causing late blown cheese (Mosconi et al., 2023; Podrzaj et al., 2020). The body of knowledge indicates a regular exposure of humans and animals.

Biotechnological applications investigated *n*-butanal and butyrate production (Bao et al., 2020). Probiotic effects, generally associated with butyric acid production, were explored relating to the effect on the gut microbiome composition,

the regulation of the intestinal immune system and the inhibition of the inflammatory response (Liang et al., 2020; Xiao et al., 2021; Yang et al., 2022).

Safety concerns

No safety concerns were reported related to *C. tyrobutyricum*. No cytotoxigenic strains of *C. tyrobutyricum* were found (Schallehn & Wolff, 1988). This was confirmed by a more recent study (Podrzaj et al., 2022) on *C. tyrobutyricum* genomes indicating that so far this bacterium does not possess genes coding for toxins and virulence factors.

Conclusion on a recommendation for QPS status

C. tyrobutyricum is recommended for the QPS list with the qualification 'absence of genetic determinants for toxin production'.

S erratia marcescens

Identity

Serratia marcescens is a species with Standing in Nomenclature. It was first described by Bizio in 1823. It was included in the approved list (Skerman et al., 1980) and the synonymy of this taxon was mentioned in an IJSEM list (Oren & Garrity, 2020). It is a species of rod-shaped, Gram-negative bacteria in the family Yersiniaceae and order Enterobacterales.

Body of knowledge

S. marcescens is a ubiquitous bacterium displaying a high genetic plasticity that allows it to adapt and persist in multiple niches including soil, water and plants. It has been recently described for the production of serratiopeptidase, a proteolytic enzyme extensively used as an anti-inflammatory and analgesic drug (Chander et al., 2021). Prodigiosin, a red pigment produced by this species, demonstrated toxigenic effects on chick embryos and antimicrobial activity (Kalesperis et al., 1975).

Safety concerns

S. marcescens is an important opportunistic pathogen, mainly affecting patients previously taking antibiotics or hosts with a weakened immune system. A diversity of infections (e.g. pneumonia, sepsis, meningitis, peritonitis, endocarditis, arthritis, and urinary tract and skin infections), difficult to treat due to host susceptibility conditions and *S. marcescens* multidrug resistance, has been described (Bartlett et al., 2022).

Conclusion on a recommendation for QPS status

S. marcescens is not recommended for the QPS list due to safety concerns.

***Heyndrickxia faecalis* (previously *Weizmannia faecalis*)**

Identity

Heyndrickxia faecalis, a species with Standing in Nomenclature, is the homotypic synonym of *Weizmannia faecalis* (Narsing Rao et al., 2023, Kieu et al., 2022). A single strain (Marseille-P8953^{T}) was isolated from the faeces of a healthy subject and consisted of Gram-positive, spore-forming, motile rod-shaped cells.

Body of knowledge

As the species has been very recently described, the body of knowledge is limited to the only strain and type strain, which was isolated from the faeces of a healthy subject.

Safety concerns

There is no information on safety.

Conclusion on a recommendation for QPS status

Heyndrickxia faecalis is not recommended for the QPS list due to the limited body of knowledge about its occurrence in the food and/or feed chains.

Pseudomonas putida

Identity

Pseudomonas putida is a Gram-negative bacterium with Standing in Nomenclature (Skerman et al., 1980).

Body of knowledge

P. putida is found mostly in temperate soil and aquatic habitats. Strains of *P. putida* have plant growth promoting abilities (Costa-Gutierrez et al., 2022) and biofilm forming capacities (Espinosa-Urgel & Ramos-González, 2023). The metabolic versatility of *P. putida* makes this organism attractive for biotechnological applications and it has been developed as a useful microbial chassis for synthetic biology applications (Martin-Pascual et al., 2021). A further application of *P. putida* was for the biodegradation of environmental pollutants and synthesis of added-value chemicals starting from industry-derived wastes (Kivisaar, 2020, Son et al., 2023).

Safety concerns

P. putida is considered an opportunistic pathogen that primarily causes nosocomial infections. Several cases of bacteraemia are reported, mainly in immunocompromised patients (Yoshino et al., 2011). The organism is also reported as responsible for wound infections (Carpenter et al., 2008).

Conclusion on a recommendation for QPS status

Pseudomonas putida is not recommended for the QPS list due to safety concerns.

3.2.2 | Yeasts

Candida oleophila

C. oleophila is a synonym of Yarrowia lipolytica (Kurtzman et al., 2011).
Y. lipolytica has QPS status with the qualification 'for production purposes only'.
C. oleophila is included in the QPS list as a synonym of *Yarrowia lipolytica*.

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. scientific articles published between January and June 2023 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 scientific articles potentially relevant for QPS-listed *Bifidobacterium* spp. (*B. adolescentis, B. animalis, B. bifidum, B. breve* and *B. longum*) provided 536 references. Title and abstract screening left two references, which were found to be relevant for full article appraisal (Acuna-Gonzalez, 2023; Takeda et al., 2023). The first reference described a case of a bacteraemia linked to a routine probiotic treatment of *B. longum* in an extremely low birth weight preterm infant (Acuna-Gonzalez, 2023). The second described a case of necrotizing fasciitis due to *B. breve* in a man suffering from several underlying factors (diabetes mellitus, obesity, cellulitis of the back and subcutaneous abscess) (Takeda et al., 2023). Based on the available evidence, the QPS status of *Bifidobacterium* spp. is not changed.

Carnobacterium divergens

A search for potentially relevant scientific articles on *C. divergens* provided five references. None of these articles was considered relevant at the level of title and abstract; consequently, the QPS status of *C. divergens* is not changed.

Corynebacterium glutamicum

A search for scientific articles potentially relevant to the QPS evaluation of *C. glutamicum* provided 112 references. None of these articles was considered relevant at the level of title and abstract screening and therefore, no new safety concerns were identified and the QPS status of *C. glutamicum* is not changed.

Lactobacilli

A search of scientific articles referring to any of the QPS species, formerly belonging to the genus *Lactobacillus* (EFSA BIOHAZ Panel, 2020b), provided 1855 references. After title and abstract screening, eight were selected for the full article appraisal. One of them was not dealing with these TUs and another one was not related to safety concerns; therefore, six articles were relevant for the QPS exercise. In two cases (Hui et al., 2023; Rahman et al., 2023), no indication on the methods used for identification of *Lacticaseibacillus casei* and *Lactobacillus acidophilus* respectively, were provided; in another (Kell et al., 2023) it is stated that culture, which is unreliable to identify lactobacilli, revealed *Lacticaseibacillus rhamnosus*. In the communication to a meeting by Kolimas et al. (2022) culture of a clinical sample produced a mix of *L. acidophilus*/*Lactobacillus gasseri*. In the paper by Itoh et al. (2023) MALDI-TOF MS identification of a *Ligilactobacillus salivarius* strain was performed; that methodology gives a more accurate identification than phenotypic methods. Itoh et al. (2023) described a case of a patient suffering from laryngeal and oesophageal cancer that also presented dyslipidaemia and hypertension, among other comorbidities. Upon pharyngo-oesophageal anastomosis subsequent to laryngectomy, he developed an abscess from which *Bacteroides denticanum*, a well-known pathogen, *L. salivarius* and *Streptococcus anginosus* were isolated. Since the two last organisms are normal inhabitants of the oropharyngeal cavity, the authors suggested that they might be just accompanying organisms to the real pathogen. In the last report (Hovan et al., 2023), the use of 16S RNA gene sequencing plus WGS, revealed an infection by *L. rhamnosus*. Hovan et al. (2023) reported a case of endocarditis and cerebral stroke after dental surgery in a patient suffering from Marfan's syndrome, a hereditary condition that affects the connective tissue and that provoked his previous aorta valve replacement; this syndrome may be considered as a relevant predisposing situation for the infection.

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 scientific articles potentially relevant for the QPS status of *L. lactis* provided 263 references. Title and abstract screenings reduced their numbers to four. One of them did not deal with safety concerns leaving three relevant articles for the QPS exercise: in one (An et al., 2023), no indication on how the identification of the organism isolated from an urinary tract infection was provided; in the second report (Lahlou et al., 2023), only cultivation was used for identification, which is not reliable for *L. lactis*. Finally, the report by Giuliano et al. (2023) described a fatal *L. lactis* infection in an 82 year-old man who suffered from thrombocytopenia and had to receive blood and platelet transfusions weekly, in addition to further underlying diseases. One of the platelet bags was contaminated with the same strain of *L. lactis* isolated from the patient as shown by whole genome sequence.

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

Leuconostoc spp.

A search for scientific articles potentially relevant for the QPS evaluation of *Leuconostoc* QPS species (*L. citreum, L. lactis, L. mesenteroides, L. pseudomesenteroides*) provided 151 references. The analysis of their titles and abstracts left 6 articles for full-text evaluation. Two are not related to this TU and another is not dealing with safety concerns, meaning that only three were found to be relevant for the QPS exercise. These articles (Botan et al., 2023, Ghobrial et al., 2023; Immel & Widmer, 2023) presented methodological problems with reference to the identification of the causative agent.

Consequently, the status of QPS-listed *Leuconostoc* species is not changed.

Microbacterium imperiale

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

Oenococcus oeni

A search for scientific articles potentially relevant for the QPS evaluation of *Oenococcus oeni* provided 40 references. The title/abstract screening left no articles for the full-text phase. Consequently, the QPS status of *O. oeni* is not changed.

***Pediococcus* spp.**

A search for scientific articles potentially relevant for the QPS evaluation of *Pediococcus* spp. provided 268 references. The analysis of their title/abstract left no articles for the full-text evaluation stage; consequently, the articles reviewed did not identify any information that would change the status of QPS-listed *Pediococcus* spp.

***Propionibacterium* spp.**

A search for scientific articles potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 45 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 164 references. The analysis of their title and abstract screening left 1 article for the full-text evaluation phase but this did not report any safety concerns and the QPS status of *S. thermophilus* is therefore not changed.

3.3.2 | Gram-positive spore-forming bacteria

A search for scientific articles potentially relevant for *Bacillus* spp. and *Geobacillus stearothermophilus* provided 2065 references. The analysis of their titles and abstract phase left 2 articles for the full-text phase of analysis.

***Bacillus* spp.**

The two scientific articles that passed to the full-text phase for further analysis were related to *Bacillus* spp. and both were relevant for the QPS exercise. One reference (Aoyagi et al., 2023), described a statistical association of children receiving cancer chemotherapy with bacteraemia caused by *B. subtilis* related to the consumption of natto (soybeans fermented with *B. subtilis* strain 'natto'). The paper shows two major methodological problems. The first issue pertains to the identification of the causative agent. The existing methodology lacks reliability when it comes to identifying the specific strain. Additionally, it is worth noting that patients with compromised immune systems are already known to be susceptible hosts for infections, even by bacteria usually considered to be safe. A second methodological problem relates to the uncertainty that the patients in which the *B. subtilis* strain 'natto' was isolated consumed natto. The second article (EFSA CEP Panel, 2023) described the presence of bacitracin in the enzyme product obtained from *B. paralicheniformis*. This confirms the need of the qualification of this TU on the QPS list 'absence of bacitracin production ability'.

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

Geobacillus stearothermophilus

Neither of the two 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 for *P. nishizawae* provided one reference. Following the analysis of its title and abstract, it was not selected for the full-text analysis phase. Consequently, the QPS status of *P. nishizawae* 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* and *Komagataeibacter sucrofermentans* provided in total 318 references. The analysis of the titles left no articles to be checked at abstract level.

Cupriavidus necator

A search for scientific articles potentially relevant for *C. necator* provided 106 references. Following the analysis of their titles and abstract, none was 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 43 references. Following the analysis of their titles and abstracts, none was 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 four references. Following the analysis of their titles and abstracts, none was 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 165 references. Following the analysis of their titles and abstracts, none was selected for the full-text phase. Consequently, the QPS status of *X. campestris* is not changed.

3.3.4 | Yeasts

The ELS searches for potentially relevant scientific articles on the yeasts with QPS status provided 3121 references. After the title/abstract screening phase, 33 articles passed to the full article appraisal phase. Out of these, 11 are not related to safety concerns, 3 are not related to the yeast group and 1 is not in English; therefore, only 18 reported a possible safety concern. The 18 articles are discussed below.

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

Cyberlindnera jadinii

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

One scientific article contributed with information related to human safety concerns: a retrospective study of 751 clinical yeast isolates from a hospital in India (Umamaheshwari & Sumana, 2023) reported a low incidence of *C. jadinii* (three isolates, i.e., 0.4%). There were limitations regarding methods for species identification, and any (likely) predisposing factors were not specified.

The study 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*.

Two scientific articles contributed with information related to human safety concerns. A retrospective study of 751 clinical yeast isolates from a hospital in India (Umamaheshwari & Sumana, 2023) reported a low incidence of *C. famata* (seven isolates, i.e., 0.9%). There were identification problems and predisposing factors in the patients, but they are not specified. Alam et al. (2023) analysed the incidence of fungal infection of the external ear (Otomycosis) from 2021 to 2022 at Mymensingh Medical College Hospital, Bangladesh. Out of 60 samples, 3 of them were identified as *D. hansenii*.

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

Kluyveromyces marxianus

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

Six scientific articles contributed with information related to human safety concerns: a retrospective study of 751 clinical yeast isolates from a hospital in India (Umamaheshwari & Sumana, 2023) reported a low incidence of *C. kefir* (four isolates, i.e., 0.5%). There were limitations regarding methods for species identification and any predisposing factors in the patients were not specified. In a study of COVID-19 patients with oral candidiasis in Iran (Babamahmoodi et al., 2023), *K. marxianus* made up 11% of the yeast isolates. It is unlikely that *K. marxianus* was the primary etiological agent, however, since it was always isolated together with established opportunistic yeasts, e.g., *Candida albicans*, *Candida tropicalis* and *Candida glabrata*. Mohammadi et al. (2023) reported that 9% of the yeasts isolated from the oral mucosa of haemodialysis patients in a hospital in Iran was *K. marxianus*. The patients had underlying disease, were receiving hospital treatment and had not developed infections. In a study in Bangladesh (Sathi, 2023), one of the yeast isolates from vaginal swabs of 175 women with suspected vulvovaginitis was *K. marxianus*. In a retrospective study, Calle-Miguel et al. (2023) reported that one out of five yeast strains that had been recovered from children with candidaemia at a hospital in Spain was *K. marxianus*. The methods used for species identification were not described, and the children underwent chemotherapy or haematopoietic

stem cell transplant. Youn et al. (2023) reported potential virulence attributes and in vivo safety concerns in a mouse model of two potentially probiotic strains of *K. marxianus* isolated from Korean kefir. Most potential virulence attributes of the two *K. marxianus* were comparable to those of the negative control, a probiotic strain of *Saccharomyces cerevisiae* var. *boulardii*.

One article contributed information related to animal safety concerns: Ricardo-González et al. (2022) recovered nine yeast isolates from milk of cows showing clinical mastitis. The isolates were identified to *K. marxianus*, however there were shortcomings in the species identification, only by traditional tests. Bacterial isolates were also obtained from the milk, and it is very uncertain whether yeasts contributed to mastitis.

New studies confirm that in rare cases, *K. marxianus* can cause opportunistic or superficial infections. 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. A synonym of this species is *Saccharomyces boulardii*.

Five scientific articles are associated with human safety concerns. Two of them present problems in the method used for the identification, MALDI-TOF MS (Furuya, 2023; Spiliopoulou et al., 2023). Ramos et al. (2023) reported a blood infection associated with *S. cerevisiae* in a 75-year-old woman with several serious predisposing factors. A systematic, global, review (Vinayagamoorthy et al., 2023) studied risk factors for *S. cerevisiae* fungaemia in patients receiving *S. boulardii* probiotic, compared to a control group. They concluded that probiotic therapy may have contributed to an increase in the number of cases of *S. cerevisiae* fungaemia and that clinicians have to be aware of this risk. Finally, Morard et al. (2023), by comparative genomic analysis using a group of *S. cerevisiae* strains of various origins but documented virulence/infection attributes and a control group of food strains, concluded that food related, or dietary supplemental strains may be the origin of opportunistic infections in predisposed subjects, in case the strains are capable of adapting to the new, human habitat. The study provides new information on what can be the origin of *S. cerevisiae* in opportunistic human infections.

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*.

Three scientific articles contributed with information related to human safety concerns: Aboutalebian et al. (2023) describe a case of bloodstream infection and sepsis caused by *W. anomalus* in an immunodeficient child in a hospital in Iran. The five-year-old boy suffered from Griscelli and hemophagocytic syndromes and was admitted to the paediatric intensive care unit. Ira et al. (2023) reported that one out of 315 yeast isolates from superficial samples (mainly vaginal swabs) from 227 outpatients in a hospital in Cote d'Ìvoire was *W. anomalus*. A retrospective study of 751 clinical yeast isolates from a hospital in India (Umamaheshwari & Sumana, 2023) reported a low incidence of *W. anomalus* (eight isolates, i.e. 1%). There were limitations regarding methods for species identification, and any predisposing factors in the patients were not specified.

One scientific article contributed with information related to animal safety concerns: Duggan et al. (2023) reported a case in Ireland of a horse with problems in the left tarsocrural joint. After arthroscopic lavage and a subsequent operation of the joint, the horse was ultimately diagnosed with an infection with *W. anomalus*. However, methods used for species identification were not specified. The joint did not recover after antifungal treatment and after developing partial lameness, the horse was put down.

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

Yarrowia lipolytica

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

Two scientific articles contributed information related to human safety concerns and both present identification problems and predisposing factors. Umamaheshwari and Sumana (2023) is a retrospective study of 751 clinical yeast isolates from a hospital in India. The authors reported a low incidence of *Y. lypolitica* (six isolates, i.e. 0.8%). but the methods for species identification are not well described and the cases were also associated with predisposing factors in the patients, but they were not specified. Simonetti et al. (2023) report a case of fungaemia caused by *Y. lipolytica* in a patient with predisposition factors, COVID-19 infection and a history of alcohol syndrome. The literature update did not identify any new information that would change the QPS status of *Y. lipolytica*.

3.3.5 | Protists

Aurantiochytrium limacinum (*Schizochytrium limacinum*)

A search for scientific articles potentially relevant for *A. limacinum* provided 20 articles. Following the analysis of their titles and abstract, none was 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 234 articles. Following the analysis of their titles and abstract, none was 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 pluvialis

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 106 references. Following the analysis of their titles and abstract, none was 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 115 references. Following the analysis of their titles and abstract, none was selected for the full-text phase. Therefore, the current QPS status remains unchanged.

3.4 | QPS and genetically modified microorganisms

In the Statement (EFSA BIOHAZ Panel, 2018) the following was stated: '*For 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*.'

In the frame of the EFSA safety assessment GMMs may need to be assessed not only when they are used as production strain but also when used as biomass and active agents. Biomass covers products in which the microbial cells and their genetic material may still be detected, but cells are not viable; active agents cover products containing viable microorganisms or viruses.

Here we clarify that for 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 genetically modified strains used as production strains, biomass and active agents.

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)[5]), for intentional use in feed and/or food or as sources of food and feed additives, enzymes, plant protection products for safety assessment***

- Between April and September 2023 (inclusive) the list of notifications was updated with 71 notifications that were received by EFSA, of which 30 were proposed for evaluation as feed additives, 22 for use as food enzymes, food additives and flavourings, 7 as novel foods and 12 as plant protection products.

[5]Units as in December 2022.

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

- 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.

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 71 notifications received between April and September 2023, 28 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 61 notifications, 33 notifications were related to microorganisms that are generally excluded from QPS evaluation (26 were notifications of filamentous fungi, 1 of *Enterococcus faecium* (bacterium), 5 of *Escherichia coli* (bacterium) and 1 bacteriophage).
- Ten of the 71 notifications received, corresponding to 9 TUs (*Burkholderia ubonensis* (already notified and evaluated in 2019), *Candida oleophila*, *Chlamydomonas reinhardtii* (already notified and evaluated in 2021), *Clostridium tyrobutyricum, Ensifer adhaerens* (already notified in 2021 and evaluated in 2022), *Heyndrickxia faecalis, Klebsiella pneumoniae* (already notified and evaluated in 2016), *Pseudomonas putida* and *Serratia marcescens*) were assessed for possible QPS status.

The following conclusions were drawn:

- *B. ubonensis* was already evaluated (EFSA BIOHAZ Panel, 2019) and the new information confirms that it cannot be recommended for the QPS list due to its ability to generate biologically active compounds with antimicrobial activity and to the limited body of knowledge for its occurrence in the food and/or feed chains.
- *C. oleophila* is included in the QPS list as a synonym of *Yarrowia lipolytica*. *Y. lipolytica* has QPS status with the qualification 'for production purposes only'. The synonym has been added to the QPS list.
- *C. reinhardtii* (synonym *C. smithii*) was already evaluated (EFSA BIOHAZ Panel, 2022a) and, based on new information, *C. reinhardtii* is recommended for the QPS list with the qualification 'for production purposes only'.
- *C. tyrobutyricum* is recommended for the QPS list with the qualification 'absence of genetic determinants for toxin production'.
- *E. adhaerens* (synonym *Sinorhizobium adhaerens*) was already evaluated (EFSA BIOHAZ Panel, 2022b) and the new information confirms that it cannot be recommended for the QPS list due to the limited body of knowledge for its occurrence in the food and/or feed chains.
- *H. faecalis* is not recommended for the QPS list due to the limited body of knowledge about its occurrence in the food and/or feed chains.
- *K. pneumoniae* was already evaluated (EFSA BIOHAZ Panel, 2016) and the new information confirms that it cannot be recommended for the QPS list due to safety concerns. The inappropriateness of granting a safety status to *K. pneumoniae*, has already been recognised in the previous BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016). In this Statement, the Panel excludes *K. pneumoniae* from future QPS evaluations.
- *P. putida* is not recommended for the QPS list due to safety concerns.
- *S. marcescens* is not recommended for the QPS list due to safety concerns.
- The Panel clarifies that for GMMs for which the species of the parental/recipient strain qualifies for QPS status, and for which the genetic modification does not give rise to safety concerns, the QPS approach can be extended to genetically modified strains used as production strains, biomass or active agents.

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
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
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group

ACKNOWLEDGMENTS

The BIOHAZ Panel wishes to thank Estefanía Noriega Fernández, Frédérique Istace, Irene Baratto, Irene Guajardo, Jaime Aguilera and Rosella Brozzi, for the support provided to this scientific output.

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

EFSA

QUESTION NUMBER

EFSA-Q-2021-00771

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How to cite this article: EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Alvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Nonno, R., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Prieto-Maradona M, … Herman, L. (2024). Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 19: Suitability of taxonomic units notified to EFSA until September 2023. *EFSA Journal*, *22*(1), e8517. https://doi.org/10.2903/j.efsa.2024.8517

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. | *Burkholderia ubonensis*

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

- "Burkholderia ubonensis": 24 hits between 2019 and 2023; 9 relevant for this assessment.

A.2. | *Ensifer adhaerens* synonym *Sinorhizobium adhaerens*

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

- "Ensifer adhaerens": 76 hits published in 2022 and 2023, all checked.
- "Sinorhizobium adhaerens": 78 hits published in 2022 and 2023, all checked.

A.3. | *Klebsiella pneumoniae*

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

- "Klebsiella pneumoniae" AND "infection": 1622 hits published in 2023 until now.

A.4. | *Chlamydomonas reinhardtii*

The search on Pubmed (Title & abstract) for the following terms led to the number of hits indicated below:

- "Chlamydomonas reinhardtii" AND (safety OR infect* OR diseas* OR toxi* OR antimicrobial resistance): 157 hits published from 2020-2023, all checked.

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

- "Chlamydomonas reinhardtii" AND (safety OR infect* OR diseas* OR toxi* OR antimicrobial resistance): 249 hits published from 2020-2023, all checked.

A search for "Chlamydomonas smithii" did not result in additional relevant references.

A.5. | *Clostridium tyrobutyricum*

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

- "Clostridium tyrobutyricum": 292 hits.
- "Clostridium tyrobutyricum" AND "taxonomy": 27 hits, all checked.
- "Clostridium tyrobutyricum" AND "safety": 28 hits, all checked.
- "Clostridium tyrobutyricum" AND "toxin": 6 hits, all checked.
- "Clostridium tyrobutyricum" AND "infection": 12 hits, all checked.

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

- "Clostridium tyrobutyricum" AND "safety": 22 hits. No safety concerns.

A.6. | *Serratia marcescens*

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

- "Serratia marcescens" AND "infection": 4001 hits published until now.

A.7. | *Heyndrickxsia faecalis* (previously *Weizmannia faecalis*)

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

- "Weizmannia faecalis": 2 hits, checked.

A.8. | *Pseudomonas putida*

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

- "Pseudomonas putida" AND "infection" OR "disease": 530 hits.

A.9. | *Candida oleophila*

It was not needed as it is a synonym of a QPS TU.

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 (EFSA-Q-2021-00770) 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 January to June 2023 (reply to ToR 2)

Gram-positive non-sporulating bacteria

Bifidobacterium spp.

Acuna-Gonzalez, A., Kujawska, M., Youssif, M., Atkinson, T., Grundy, S., Hutchison, A., Tremlett, C., Clarke, P., & Hall, L. J. (2023). Bifidobacterium bacteraemia is rare with routine probiotics use in preterm infants: A further case report with literature review. Anaerobe, 80, 102713. https://doi.org/10.1016/j.anaerobe.2023.102713

Takeda, Y., Ota, K., Kondo, A., Nishii, T., Onishi, N., Yokoyama, H., Yamakawa, K., & Takasu, A. (2022). A case of necrotizing fasciitis caused by Bifidobacterium breve. IDCases, 31, e01667. https://doi.org/10.1016/j.idcr.2022.e01667

Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

Hui, J., Ren, Y., Wang, Y., & Han, Q. (2023). Lactobacillus acidophilus Endophthalmitis postcataract operation: A case report with a literature review. Ocular Immunology and Inflammation. https://doi.org/10.1080/09273948.2023.2202736

Hovan, M., & Mandler, A. (2023). Lactobacillus rhamnosusendocarditis associated with dental procedure in a patient with Marfan's variant and prior aortic root replacement. BMJ Case Reports, 16(3). https://doi.org/10.1136/bcr-2022-252699

Kell, M., Lee, Z. C., Hernandez, M., Crader, M., & Norwood, J. (2023). A case report of bacteremia due to a symptomatic and rare lactobacillus rhamnosus infected splenic hematoma and the ultimate treatment model. Cureus, 15(3), e36128. https://doi.org/10.7759/cureus.36128

Kolimas, A. M., Ajmal, M., Avila, D. D., Kotagiri, R., Kazui, T., Moynahan, K. J., & Corban, M. T. (2022). Abstract 14522: Infective mitral valve endocarditis in an immunocompetent patient caused by lactobacillus species transmitted by intranasal cocaine use. Circulation, 146(Suppl_1), A14522–A14522. https://doi.org/10.1161/circ.146.suppl_1.14522

Itoh, N., Akazawa, N., & Tanaka, T. (2023). A mixed infection involving Bacteroides denticanum, Lactobacillus salivarius, and Streptococcus anginosus as causative agents of abscess around a pharyngo-oesophageal anastomosis and acute vertebral osteomyelitis: Identification by ribosomal RNA sequencing of bacterial isolates. Journal of Infection and Chemotherapy, 29(8), 816–819. https://doi.org/10.1016/j.jiac.2023.04.017

Hovan, M., & Mandler, A. (2023). Lactobacillus rhamnosus endocarditis associated with dental procedure in a patient with Marfan's variant and prior aortic root replacement. BMJ Case Reports, 16(3). https://doi.org/10.1136/bcr-2022-252699

Lactococcus lactis

An, Y., Cao, Q., Liu, Y., Lei, L., Wang, D., Yang, Y., Kong, W., An, D., & Liu, D. (2023). Sigmoido-vesical fistula secondary to sigmoid colon cancer presenting as urinary tract infection with Lactococcus lactis: A case report. Frontiers in Oncology, 13. https://doi.org/10.3389/fonc.2023.1054978. PMID: 36937404; PMCID: PMC10016092.

Lahlou, W., Bourial, A., Maaouni, T., Bensaad, A., Bensahi, I., Sabry, M., & Miguil, M. (2023). Lactococcus lactis endocarditis and liver abscess in an immunocompetent patient: a case report and review of the literature. Journal of Medical Case Reports, 17, 115. https://doi.org/10.1186/s13256-022-03676-1

Giuliano, S., Scatena, A., Sbrana, F., Martini, L., Manetti, A. C., Tascini, C., & Di Paolo, M. (2023). Lactococcus lactis blood products contamination resulting in fatal human case: insights from a forensic case. The New Microbiologica, 46(2), 219–222. PMID: 37247245.

Leuconostoc spp.

Immel, S., & Widmer, K. (2023). Leuconostoc mesenteroides bacteremia in a patient with exposure to unpasteurised raw milk. BMJ Case Reports, 16(3). https://doi.org/10.1136/bcr-2022-252034

Ghobrial, M., Ibrahim, M., Streit, S. G., Staiano, P. P., & Seeram, V. (2023). A rare case of Leuconostoc pseudomesenteroides bacteremia and refractory septic shock. Cureus, 15(4), e38312. https://doi.org/10.7759/cureus.38312

Botan, E., Aydin, B., & Gultekin, C. (2023). Leuconostoc lactis as an early-onset neonatal sepsis agent: A case Report with the current literature review. Haseki Tip Bulteni, 61(1), 69–71.

Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

None.

Propionibacterium spp.

None.

Streptococcus thermophilus
None.

Gram-positive spore-forming bacteria

Bacilli
Aoyagi, R., Okita, K., Uda, K., Ikegawa, K., Yuza, Y., & Horikoshi, Y. (2023). Natto intake is a risk factor of Bacillus subtilis bacteremia among children undergoing chemotherapy for childhood cancer: A case-control study. Journal of Infection and Chemotherapy, 29(3), 329–332. https://doi.org/10.1016/j.jiac.2022.12.010

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré, C., Barat Baviera, J. M., Bolognesi, C., Cocconcelli, P. S., Crebelli, R., Gott, D. M., Grob, K., Lampi, E., Mengelers, M., Mortensen, A., Rivière, G., Steffensen, I.-L., Tlustos, C., Van Loveren, H., Vernis, L., Zorn, H., Herman, L., Roos, Y., … Chesson, A. (2023). Scientific Opinion on the safety evaluation of the food enzyme subtilisin from the non-genetically modified Bacillus paralicheniformis strain LMG S-30155. EFSA Journal, 21(6), 7910. https://doi.org/10.2903/j.efsa.2023.7910

Geobacillus stearothermophilus
None.

Pasteuria nishizawae
None.

Gram-negative bacteria

Cupriavidus necator
None.

Gluconobacter oxydans
None.

Komagataeibacter sucrofermentans
None.

Xanthomonas campestris
None.

Yeasts
Aboutalebian, S., Mirhendi, H., Eshaghi, H., Nikmanesh, B., & Charsizadeh, A. (2023). The first case of Wickerhamomyces anomalus fungemia in Iran in an immuneodeficient child, a review on the literature. Journal de Mycologie Medicale, 33(1). https://doi.org/10.1016/j.mycmed.2022.101351

Alam, M. M., Biplob, J. A., Sathi, F. A., Nila, S. S., Paul, A., Khanam, J., Chowdhury, C. S., & Khan, M. S. (2023). Ear infections by non albicans Candida Species with isolation of rare drug resistant species in a tertiary care Hospital of Bangladesh. Mymensingh Medical Journal, 32(3), 644–648.

Babamahmoodi, F., Rezai, M. S., Ahangarkani, F., Mohammadi Kali, A., Alizadeh-Navaei, R., Alishahi, A., Najafi, N., Haddadi, A., Davoudi, A., Azargon, L., Daftarian, Z., Kordi, S., & Abbasi, K. (2022). Multiple Candida strains causing oral infection in COVID-19 patients under corticosteroids and antibiotic therapy: An observational study. Frontiers in Cellular and Infection Microbiology, 12, 1103226. https://doi.org/10.3389/fcimb.2022.1103226

Calle-Miguel, L., Garrido-Colino, C., Santiago-García, B., Moreno Santos, M. P., Gonzalo Pascual, H., Ponce Salas, B., Beléndez Bieler, C., Navarro Gómez, M., Guinea Ortega, J., & Rincón-López, E. M. (2023). Changes in the epidemiology of invasive fungal disease in a Paediatric Haematology and Oncology Unit: the relevance of breakthrough infections. BMC Infectious Diseases, 23(1), 348. https://doi.org/10.1186/s12879-023-08314-9

Duggan, M., Gibbons, J., Offereins, H., Fogarty, U., & Schofield, W. (2023). Diagnosis and unsuccessful management of iatrogenic fungal septic arthritis caused by Wickerhamomyces anomalous (formerly Candida pelliculosa) and concurrent osteochondral lesion in Ireland. Equine Veterinary Education, 35, e571–e578. https://doi.org/10.1111/eve.13807

Furuya, K., Ito, K., Sugiyama, K., Tokuda, S., Kanemoto, H., Kamei, K., & Shimada, T. (2023). A case of bloodstream co-infection of Saccharomyces cerevisiae and Candida glabrata while using micafungin. BMC Infectious Diseases, 23(1), 329. https://doi.org/10.1186/s12879-023-08287-9

Ira, A. V. B., Krasteva, D., Kouadjo, F., Roger, F., Bellet, V., Koffi, D., Pottier, C., Toure, O. A., Drakulovski, P., Djaman, A. J., Ranque, S., & Bertout, S. (2023). Four uncommon clinical fungi, Lodderomyces elongisporus, Kodamaea ohmeri, Cyberlindnera fabianii and Wickerhamomyces anomalus, isolated in superficial samples from Côte d'Ivoire. Journal de Mycologie Medicale, 33(3), 101410. https://doi.org/10.1016/j.mycmed.2023.101410

Mohammadi, F., Charkhchian, M., & Mirzadeh, M. (2023). Phenotypic and genotypic characterisation of virulence markers and antifungal susceptibility of oral Candida species from diabetic and non-diabetic haemodialysis patients. BMC Oral Health, 23(1), 261. https://doi.org/10.1186/s12903-023-02970-8

Morard, M., Pérez-Través, L., Perpiñá, C., Lairón-Peris, M., Collado, M. C., Pérez-Torrado, R., & Querol, A. (2023). Comparative genomics of infective Saccharomyces cerevisiae strains reveals their food origin. Scientific Reports, 13(1), 10435. https://doi.org/10.1038/s41598-023-36857-z

Ramos, L. S., Mokus, L., Frota, H. F., Santos, M. V., Oliveira, S. S. C., Oliveira, M. M. E., Costa, G. L., Alves, A. L., Bernardes-Engemann, A. R., Orofino-Costa, R., Aor, A. C., Branquinha, M. H., & Santos, A. L. S. (2023). SARS-CoV-2 Post-infection and sepsis by Saccharomyces cerevisiae: A fatal case report-focus on fungal susceptibility and potential virulence attributes. Tropical Medicine and Infectious Disease, 8(2), 99. https://doi.org/10.3390/tropicalmed8020099

Ricardo-Gonzalez, I. D., Hernandez-Andrade, L., Monte-Rodriguez, A. L.d., Santillan-Flores, M. A., Blanco Ochoa, M. A., Campuzano-Reyes, L. O., & Jimenez-Saavedra, A. (2022). Interaction in the production of biofilm and drug susceptibility of Candida kefyr with Escherichia coli and Streptococcus dysgalactiae isolated from bovine mastitis. Journal of Veterinary Medicine and Animal Health, 14(3), 62–69. https://doi.org/10.5897/jvmah2022.0975

Sathi, F. A., Alam, M. M., Paul, S. K., Nasrin, S. A., Ahmed, S., Haque, N., Khan, M. S., Mamun, A. A., Khan, S., & Arafa, P. (2023). Species identification and antifungal susceptibility pattern of Candida isolates in patients with Vulvovaginitis from Mymensingh, Bangladesh. Mymensingh Medical Journal, 32(3), 638–643.

Shoukat, M., Ullah, F., Tariq, M. N., Din, G., Khadija, B., & Faryal, R. (2023). Profiling of potential pathogenic candida species in obesity. Microbial Pathogenesis, 174. https://doi.org/10.1016/j.micpath.2022.105894

Simonetti, O., Zerbato, V., Sincovich, S., Cosimi, L., Zorat, F., Costantino, V., Di Santolo, M., Busetti, M., Di Bella, S., Principe, L., & Luzzati, R. (2023). Candida lipolytica bloodstream infection in an adult patient with COVID-19 and alcohol use disorder: a unique case and a systematic review of the literature. Antibiotics (Basel, Switzerland), 12(4), 691. https://doi.org/10.3390/antibiotics12040691

Spiliopoulou, A., Lekkou, A., Vrioni, G., Leonidou, L., Cogliati, M., Christofidou, M., Marangos, M., Kolonitsiou, F., & Paliogianni, F. (2023). Fungemia due to rare non-Candida yeasts between 2018 and 2021 in a Greek tertiary care university hospital. Journal de Mycologie Medicale, 33(3), 101386. https://doi.org/10.1016/j.mycmed.2023.101386

Umamaheshwari, S., & Sumana, M. N. (2023). Retrospective analysis on distribution and antifungal susceptibility profile of Candida in clinical samples: A study from Southern India. Frontiers in Public Health, 11. https://doi.org/10.3389/fpubh.2023.1160841

Vinayagamoorthy, K., Pentapati, K. C., & Prakash, H. (2023). Epidemiology of Saccharomyces fungemia: A systematic review. Medical Mycology, 61(2). https://doi.org/10.1093/mmy/myad014

Youn, H. Y., Kim, D. H., Kim, H. J., Jang, Y. S., Song, K. Y., Bae, D., Kim, H., & Seo, K. H. (2023). A combined in vitro and in vivo assessment of the safety of the yeast strains Kluyveromyces marxianus A4 and A5 isolated from Korean Kefir. Probiotics and Antimicrobial Proteins, 15(1), 129–138. https://doi.org/10.1007/s12602-021-09872-7

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 (19) adopted in December 2023. 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 April and September 2023 (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 April and September 2023, listed in the Table below.

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Algae							
Chlamydomonas reinhardtii		Novel foods	Novel foods	Dried biomass powder	EFSA-Q-2023-00301	NO	YES
Bacteria							
Bacillus amyloliquefaciens	AT-332	Plant protection products	Plant Protection Product	Fungicide to control damage from fungal disease caused by *Botrytis cinerea* in grapes and in tomato, eggplant, bell and sweet pepper in greenhouses.	EFSA-Q-2021-00465	YES	NO
Bacillus licheniformis	ATCC-127113	Feed additives	Zootechnical additives	Gut flora stabilisers. No GMM	EFSA-Q-2023-00325	YES	NO
Bacillus licheniformis	DSM 34099	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme beta-galactosidase. GMM	EFSA-Q-2023-00443	YES	NO
Bacillus paralicheniformis	DSM 33902	Feed additives	Zootechnical additives	Gut flora stabilisers	EFSA-Q-2023-00454	YES	NO
Bacillus subtilis	AR-155	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme endo-1,4-b-xylanase. GMM	EFSA-Q-2023-00307	YES	NO
Bacillus subtilis	DSM 33864	Feed additives	Technological additives	Silage additives	EFSA-Q-2023-00631	YES	NO
Bacillus subtilis	DSM 33903	Feed additives	Zootechnical additives	Gut flora stabilisers	EFSA-Q-2023-00454	YES	NO
Bacillus subtilis	LMG S-25520	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme aqualysin-1 (protease). GMM	EFSA-Q-2023-00303	YES	NO
Bacillus velezensis	ATCC PTA-127114	Feed additives	Zootechnical additives	Gut flora stabilisers. No GMM	EFSA-Q-2023-00325	YES	NO
Bacillus velezensis	ATCC PTA-6737	Feed additives	Zootechnical additives	Gut flora stabilisers. No GMM	EFSA-Q-2023-00325	YES	NO
Burkholderia ubonensis	AE-LRE	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme triacylglycerol lipase. No GMM	EFSA-Q-2023-00361	NO	YES
Clostridium tyrobutyricum	ASM#19	Novel foods	Novel Food	Production of novel food Clostridium protein. No GMM	EFSA-Q-2023-00291	NO	YES

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Corynebacterium glutamicum	KCCM 80058	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production strain L-valine. GMM	EFSA-Q-2023-00551	YES	NO
Corynebacterium glutamicum	KCCM 80368	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production strain L-lysine. GMM	EFSA-Q-2023-00484	YES	NO
Ensifer adhaerens	CGMCC 21299	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having a similar effect. Production of cyanocobalamin. No GMM	EFSA-Q-2023-00409	NO	YES
Enterococcus faecium	DSM 22502	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00252	NO	NO
Escherichia coli	DSM 34230 strain WCM208 x pMS5-plsC1-bCGTase-tet	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme beta-cyclomaltodextrin glucanotransferase. GMM	EFSA-Q-2023-00434	NO	NO
Escherichia coli	EB011067	Novel foods	Novel foods	Production of 2′-fucosyllactose (2′-FL). GMM	EFSA-Q-2023-00637	NO	NO
Escherichia coli	EBASSC W3112	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme alternansucrase. GMM	EFSA-Q-2023-00555	NO	NO
Escherichia coli	K12 DSM 34229 strain WCM195 x pMS2-plsC1-aCGTase-tet-	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme cyclomaltodextrin glucanotransferase. GMM	EFSA-Q-2023-00435	NO	NO
Escherichia coli	K12 DSM 34232	Feed additives	Nutritional additives	Amino acids, their salts and analogues. Production of L-cystine	EFSA-Q-2023-00436	NO	NO
Klebsiella pneumoniae	AE-PUL	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme pullalanase (pullulan 6-α-glucanohydrolase)	EFSA-Q-2023-00567	NO	YES
Lacticaseibacillus paracasei	NCIMB 30151 i	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00544	YES	NO
Lactiplantibacillus plantarum	DSM 16627	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00543	YES	NO
Lactiplantibacillus plantarum	DSM 34271	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00250	YES	NO
Lactobacillus plantarum	14D/CSL – CECT 4530	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00298	YES	NO
Lactococcus lactis	DSM 34262	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00249	YES	NO
Lentilactobacillus buchneri	BioCC 228 DSM 32651	Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2023-00392	YES	NO
Lentilactobacillus buchneri	DSM 12858	Feed additives	Technological additives	Silage additives	EFSA-Q-2023-00631	YES	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Levilactobacillus brevis	DSM 16680	Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2023-00355	YES	NO
Levilactobacillus brevis	DSM 23231	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00276	YES	NO
Limosilactobacillus fermentum		Feed additives	Technological additives	Silage additive. No GMM	EFSA-Q-2023-00363	YES	NO
Loigolactobacillus coryniformis	DSM 34345	Feed additives	Technological additives	Silage additives. No GMM	EFSA-Q-2023-00362	YES	NO
Pediococcus acidilactici	NCIMB 30005	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00548	YES	NO
Pseudomonas putida	B2017 CECT8538	Plant protection products	Plant Protection Product	Active substance used to control Powdery mildew in courgette, tomato, pepper, Late blight and Bacterium speck in tomato, Downy mildew in lettuce and Rhizoctonia rot in potato.	EFSA-Q-2021-00789	NO	YES
Serratia marcescens	ATCC 21076	Novel foods	Novel foods	Production of enzyme serratiopeptidase	EFSA-Q-2023-00517	NO	YES
Serratia marcescens	NPSC	Novel foods	Novel Food	Production of enzyme serratiopeptidase. No GMM	EFSA-Q-2023-00205	NO	YES
Weizmannia faecalis		Feed additives	Zootechnical additives	Gut flora stabilisers (originally identified as *W. coagulans*)	EFSA-Q-2022-00221/ FEED-2022-3991 and EFSA-Q-2022-00316/ FEED-2022-3470	NO	YES
Bacteriophages							
	Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE)	Plant protection products	Plant protection products	Active substance with soil and foliar application to potato crops against blackleg disease and tuber soft rots of potato, caused by members of the genera *Pectobacterium* spp. and *Dickeya* spp.	EFSA-Q-2021-00670	NO	NO
Filamentous fungi							
Aspergillus niger	PLN	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme phospholipase A1/ lysophospholipase. GMM	EFSA-Q-2023-00460	NO	NO
Aspergillus niger	XYL	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme endo-1,4-β-xylanase. GMM	EFSA-Q-2023-00522	NO	NO
Aspergillus oryzae	NZYM-HH-ENZ-001	Novel foods	Novel Food	Production of food enzyme laccase. GMM	EFSA-Q-2023-00405	NO	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Aspergillus oryzae	FUA	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme alpha-amylase. No GMM	EFSA-Q-2023-00360	NO	NO
Aspergillus tubingensis	ATCC SD674	Feed additives	Zootechnical additives	Digestibility enhancers. Production of alpha-galactosidase	EFSA-Q-2023-00262	NO	NO
Metarhizium brunneum	BNL102	Plant protection products	Plant Protection Product	Entomopathogenous fungus ubiquitous to the soil and plant rhizosphere -used to control vine weevil (*Otiorhynchus sulcatus*).	EFSA-Q-2021-00493	NO	NO
Metarhizium pingshaense	CF62	Plant protection products	Plant Protection Product	Entomopathogenic fungus with ubiquitous appearance in soil – used to control aphids (Hemiptera: *Aphididae*) in strawberries.	EFSA-Q-2021-00234	NO	NO
Metarhizium pingshaense	CF69	Plant protection products	Plant Protection Product	Entomopathogenic fungus ubiquitous to the soil and plant rhizosphere – used to control thrips (Thysanoptera: *Thriphidae*) in strawberries.	EFSA-Q-2021-00235	NO	NO
Metarhizium pingshaense	CF78	Plant protection products	Plant Protection Product	Entomopathogenic fungus with ubiquitous appearance in soil – used to control spider mites (Acarida: *Tetranychidae*) in strawberries.	EFSA-Q-2021-00236	NO	NO
Mortierella alpina	TKA-1	Novel foods	Novel Food	Arachidonic acid-rich oil extracted. No GMM	EFSA-Q-2023-00161	NO	NO
Thalaromyces versatilis	IMI 378536	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00253	NO	NO
Trichoderma afroharzianum	Th2RI99 ARS NRRL 67990	Plant protection products	Plant Protection Product	Control of seed-borne plant pathogenic fungi in winter cereals.	EFSA-Q-2021-00661	NO	NO
Trichoderma atroviride	I-1237	Plant protection products	Plant Protection Product	Pesticide active substance controlling wood decay caused by fungi in grapevine.	EFSA-Q-2020-00601	NO	NO
Trichoderma atroviride	NCF – PPRI 9088 DSMZ – 77B DSM 32801	Plant protection products	Plant Protection Product	Pesticide active substance used to control phytopathogenic fungi including *Rhizoctonia solani* and *Botrytis cinerea* in tomato, pepper, strawberry and grapevine.	EFSA-Q-2020-00328	NO	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Trichoderma longibrachiatum	CBS 139997	Feed additives	Zootechnical additives	Digestibility enhancers. Production of 1,4-beta-xylanase	EFSA-Q-2023-00262	NO	NO
Trichoderma reesei	AR-201	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme serine endopeptidase. GMM	EFSA-Q-2023-00367	NO	NO
Trichoderma reesei	AR-414	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme polygalacturonase. GMM	EFSA-Q-2023-00372	NO	NO
Trichoderma reesei	AR-414	Food enzymes, food additives and flavourings	Enzyme production	Production of enzyme polygalacturonase. GMM	EFSA-Q-2023-00372	NO	NO
Trichoderma reesei	AR-822	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme triacylglycerol lipase. GMM	EFSA-Q-2023-00529	NO	NO
Trichoderma reesei	AR-996	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme invertase. GMM	EFSA-Q-2023-00366	NO	NO
Trichoderma reesei	CBS 126897	Feed additives	Zootechnical additives	Digestibility enhancer. Production of 6-Phytase	EFSA-Q-2023-00254	NO	NO
Trichoderma reesei	DP-Nyc81	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme lysophospholipase. GMM	EFSA-Q-2023-00449	NO	NO
Trichoderma reesei	RF8055	Feed additives	Zootechnical additives	Digestibility enhancer. Production of endo-1,3(4)-beta-glucanase	EFSA-Q-2023-00251	NO	NO
Trichoderma reesei	AR-766, CBS 126897	Food enzymes, food additives and flavourings	Enzyme production	Produce the food enzyme 6-phytase. GMM	EFSA-Q-2023-00525	NO	NO
Trichoderma reesei	AR-577	Food enzymes, food additives and flavourings	Enzyme production	Production of enzyme fructanase. GMM	EFSA-Q-2023-00423	NO	NO
Trichoderma reesei	AR-715 (RF11412)	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme endo-1,4-beta-glucanase	EFSA-Q-2023-00422	NO	NO
Viruses							
Cryptophlebia peltastica Nucleopolyhedrovirus	strain South Africa	Plant protection products	Plant Protection Product	Active substance used to control codling moth in pome fruit.	EFSA-Q-2021-00589	YES	NO

Species	Strain	EFSA risk assessment area	Category Regulated product	Intended usage	EFSA Question No[a]	Previous QPS status of the respective TU[b]	Assessed in this Statement? Yes or no
Yeasts							
Candida oleophila	strain O	Plant protection products	Plant Protection Product	Horticultural fungicide (post-harvest use) against storage diseases *Botrytis cinerea* (grey mould) and *Penicillium expansum* (blue mould) on apples and pears.	EFSA-Q-2022-00216	NO	YES
Pichia pastoris		Food enzymes, food additives and flavourings	Food additive	Production of food additive rebaudioside M. GMM	EFSA-Q-2023-00379	YES	NO
Saccharomyces cerevisiae	LALL-MA+	Food enzymes, food additives and flavourings	Enzyme production	Production of food enzyme maltogenic alpha-amylase. GMM	EFSA-Q-2023-00533	YES	NO
Saccharomyces cerevisiae	NCYC R618	Feed additives	Zootechnical additives	Gut flora stabilisers	EFSA-Q-2023-00255	YES	NO

[a]To find more details on specific applications please access the EFSA website – openEFSA at https://open.efsa.europa.eu/questions.

[b]Included in the QPS list as adopted in December 2022 (EFSA BIOHAZ Panel, 2023).