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STATEMENT

Update of the list of qualified presumption of safety (QPS) recommended microbiological agents intentionally added to food or feed as notified to EFSA 20: Suitability of taxonomic units notified to EFSA until March 2024

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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. In the period covered by this statement, no new information was found that would change the status of previously recommended QPS TUs. The TUs in the QPS list were updated based on a verification, against their respective authoritative databases, of the correctness of the names and completeness of synonyms. A new procedure has been established to ensure the TUs are kept up to date in relation to recent taxonomical insights. Of 81 microorganisms notified to EFSA between October 2023 and March 2024 (45 as feed additives, 25 as food enzymes or additives, 11 as novel foods), 75 were not evaluated because: 15 were filamentous fungi, 1 was *Enterococcus faecium*, 10 were *Escherichia coli*, 1 was a *Streptomyces* (all excluded from the QPS evaluation) and 46 were TUs that already have a QPS status. Two of the other eight notifications were already evaluated for a possible QPS status in the previous Panel Statement: *Heyndrickxia faecalis* (previously *Weizmannia faecalis*) and *Serratia marcescens*. One was notified at genus level so could not be assessed for QPS status. The other five notifications belonging to five TUs were assessed for possible QPS status. *Akkermansia muciniphila* and *Actinomadura roseirufa* were still not recommended for QPS status due to safety concerns. *Rhizobium radiobacter* can be recommended for QPS status with the qualification for production purposes. *Microbacterium arborescens* and *Burkholderia stagnalis* cannot be included in the QPS list due to a lack of body of knowledge for its use in the food and feed chain and for *B. stagnalis* also due to safety concerns. *A. roseirufa* and *B. stagnalis* have been excluded from further QPS assessment.

KEYWORDS

Actinomadura roseirufa, *Akkermansia muciniphila*, *Burkholderia stagnalis*, *Microbacterium arborescens*, QPS, *Rhizobium radiobacter* (synonym *Agrobacterium radiobacter*)

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 (ToR).

The QPS process was developed to provide a harmonised safety assessment approach to support EFSA Scientific Panels and Units. This process assesses the taxonomic identity, body of relevant knowledge and safety of microorganisms. Safety concerns identified for a taxonomic unit (TU) are, 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 Biohazard Panel Statement. The Panel Statement also includes the evaluation of newly notified microorganisms to EFSA in the context of technical dossiers for safety assessment, within the previous 6-month period.

The first ToR requires ongoing updates of the list of microorganisms notified to EFSA, in the context of a technical dossier for safety assessment. The list 'Microbiological agents as notified to EFSA' (https://doi.org/10.5281/zenodo.3607183) was updated with the notifications received between October 2023 and March 2024 (inclusive). Within this period, 81 notifications were received by EFSA, of which 45 were proposed for use in feed, 25 as food enzymes, food additives and flavourings and 11 as novel foods. The new notifications received within that period are included in the current Statement (see Appendix F).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications. For this revision, articles published from July to December 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 QPS TUs of bacteria, yeasts, algae, protists and viruses were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The correct names for *Acidipropionibacterium acidipropionici* (previously *Propionibacterium acidipropionici*), *Shouchella clausii* (previously *Alkalihalobacillus claussii*), *Lederbergia lenta* (previously *Ledebergia lentus*), *Heyndrickxia coagulans* (previously *Weizmannia coagulans*) *and Phaffia rhodozyma* (previously *Xanthophyllomyces dendrorhous)* were included in the QPS list. For 25 bacteria and 9 yeast TUs, new synonyms were added. For two bacteria and four yeast Tus, previous synonyms were removed because they were no longer valid. For protists and algae, all names are correct, but one synonym was removed because it is indicated as a different species. A new procedure has been established to ensure the TUs are kept up to date in relation to recent taxonomical insights. Every 6 months, the QPS TUs of bacteria, yeast, algae, protists and viruses will be verified against their respective authoritative databases to ensure the accuracy for each Panel Statement. The next ELS cycle to review the QPS list TUs will already include the updated names/synonyms as keywords.

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

In the current period, 81 notifications were received, 75 of which were not evaluated for the following reasons: 27 notifications were related to microorganisms that are excluded from QPS evaluation (15 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 10 of *Escherichia coli*, and 1 *Streptomyces*), and 46 were related to TUs that already have QPS status and did not require further evaluation. Two of the other eight notifications were already evaluated for possible QPS status in the previous Panel Statement: *Heyndrickxia faecalis* (previously *Weizmannia faecalis*) and *Serratia marcescens*. One was notified at genus level so could not be assessed for the QPS status. The other five notifications belonging to five TUs, *Akkermansia muciniphila*, *Microbacterium arborescens*, *Rhizobium radiobacter* (synonym *Agrobacterium radiobacter*), *Actinomadura roseirufa* and *Burkholderia stagnalis* were assessed for possible QPS status.

The following conclusions were drawn:

- The evidence published since the previous evaluation precludes *Akkermansia muciniphila* from being recommended for the QPS list due to safety concerns.
- *Actinomadura roseirufa* is not recommended for QPS status due to safety concerns. The same conclusion was reached in a previous evaluation (EFSA BIOHAZ Panel, 2014). It was concluded to exclude *Actinomadura roseirufa* for further QPS assessment.
- *Microbacterium arborescens* cannot be recommended for QPS status due to lack of body of knowledge on its use in the food and feed chain.
- *Rhizobium radiobacter,* synonym *Agrobacterium radiobacter,* can be recommended for QPS status with the qualification 'for production purposes only'.
- *Burkholderia stagnalis* cannot be included in the QPS list due to a lack of body of knowledge for its use in the food and feed chain and due to possible safety concerns. It was concluded to exclude *B. stagnalis* for further QPS assessment.

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 and feed chains, in support of the respective Scientific Panels and EFSA Units in the frame of the market authorisations for their use in the food and feed chains. The same Committee recognised that there would have to be continuing provision for reviewing and modifying the QPS list and, in line with this recommendation, the EFSA Panel on Biological Hazards (BIOHAZ) took the prime responsibility for this and started reviewing annually the existing QPS list. In 2008, the first annual QPS update was published (EFSA, 2008).

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure; the overall assessment of the 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 4 pillars: [1] the taxonomic unit (TU) for which QPS is sought ('*taxonomic identification*'); [2] whether sufficient relevant information is available about the proposed TU to conclude on human/animal exposure via food/feed ('*body of knowledge*'); [3] whether the TU proposed contains known '*safety concerns*' and, finally, [4] the intended end use ('*intended use*'). If a hazard related to a TU is identified, which can be tested at the strain or product level, a 'qualification' to exclude that hazard may be established and added. The subject of these qualifications for the microbial strain under investigation is evaluated by the EFSA Unit to which the application dossier has been allocated. Absence of acquired genes coding for resistance to antimicrobials relevant for humans and animals is a generic qualification for all bacterial TUs; the absence of antimycotic resistance should be proven if the pertinent yeasts are to be used as viable organisms in the food and/or feed chains. The qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied to food and feed products based on microbial biomass (EFSA BIOHAZ Panel, 2020a).

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

In summary, the QPS evaluation provides a safety assessment approach for use within EFSA that covers safety concerns for humans, production animals and the environment. In the QPS concept, a safety assessment of a defined TU is performed independently of the legal framework under which the application is made in the course of an authorisation process. Although general human safety is part of the evaluation, specific issues relating to 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*, *Clostridium butyricum* (EFSA BIOHAZ Panel, 2020a, 2020b), *Klebsiella pneumoniae* (EFSA BIOHAZ Panel, 2024), *Actinomadura roseirufa* and *Burholderia stagnalis* (within this Panel Statement – EFSA BIOHAZ Panel, 2024) 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 and therefore, require a specific assessment for each strain for which an application is made.

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

ToR 1: Keep updated the list of microorganisms being notified in the context of a technical dossier to EFSA Units such as Feed and Contaminants (FEEDCO), Pesticides Peer Review (PREV), Food Ingredients and Packaging (FIP) and Nutrition and Food Innovation (NIF),[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 period covered by this statement (between October 2023 and March 2024 (inclusive)) was carried out. The literature review considered the information on taxonomy, the body of knowledge, the potential safety concerns related to human and animal health and to the environment (EFSA BIOHAZ Panel, 2023) for each TU. The environmental risk assessment of a TU used in PPPs, following the legal requirements, is not included in the QPS assessment but is carried out by the Pesticide Peer Review (PPR) Unit, based on the risk assessment in the application.

[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'.

Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched, based on the judgement of the experts. When needed, an ELS-based approach is applied to ensure the completeness of the information retrieved from the literature in terms of body of knowledge and possible safety concerns. The ELS follows the same methodology as used for monitoring new safety concerns related to species with QPS status but also 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). In order to validate this statement, it was decided to revise in a systematic way the TUs names and synonyms included in the current QPS list. The TUs of bacteria, yeasts, algae, protists and viruses present in the QPS list were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The results of this exercise can be found in Section 3.4.

2.2 | Methodologies

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

In response to ToR 1, the EFSA Units were asked to update the list of microorganisms being notified to EFSA. A total of 81 notifications were received between October 2023 and March 2024 (inclusive), of which 45 were for evaluation for use in feed, 25 for use as food enzymes, food additives and flavourings, 11 as infant formula/nutrition/novel foods and none as plant protection products (Table 1).

In response to ToR 3, 75 notifications were excluded from QPS evaluation for the following reasons: 27 notifications were related to microorganisms that are generally excluded from QPS evaluation (15 were notifications of filamentous fungi, 1 of *Enterococcus faecium*, 10 of *Escherichia coli* and 1 *Streptomyces* sp.) and 46 were related to TUs that already had QPS status and did not require further evaluation in this mandate. Two of the other eight notifications were already evaluated for a possible QPS status in the previous Panel Statement: *Heyndrickxia faecalis* (previously *Weizmannia faecalis*) and *Serratia marcescens*. One was notified at genus level so cannot be assessed for QPS status. Five TUs were assessed for a possible QPS status in this Panel Statement. *Akkermansia muciniphila* and *Actinomadura roseirufa* have already been notified and evaluated before (EFSA BIOHAZ Panel, 2020b, 2014) and were re-evaluated within this document. The other three TUs were evaluated for the first time (*Microbacterium arborescens*, *Rhizobium radiobacter* synonym *Agrobacterium radiobacter* and *Burkholderia stagnalis*).

TABLE 1 Notifications received by EFSA, per risk assessment area and by microbiological group, from October 2023 to March 2024.

Risk assessment area Microbiological group	Not evaluated in this statement Already QPS	 Excluded in QPS[a]	Evaluated in this statement[b]	Total
Feed additives	**32**	**11**	**2**	**45**
Bacteria	27	6	2	35
Filamentous fungi		5		5
Yeasts	5			5
Novel foods	**2**	**5**	**4**	**11**
Bacteria		4	3	7
Filamentous fungi		1		1
Protists/Algae			1	1
Yeasts	2			2
Plant protection products	**0**	**0**	**0**	**0**
Food enzymes, food additives and flavourings	**12**	**11**	**2**	**25**
Bacteria	8	2	2	12
Filamentous fungi		9		9
Yeasts	4			4
Genetically modified organism	**0**	**0**	**0**	**0**
Bacteria				0
Total	**46**	**27**	**8**	**81**

Abbreviation: QPS, qualified presumption of safety.

[a]The number includes 15 notifications of filamentous fungi, 1 of *Enterococcus faecium* (bacterium), 10 of *Escherichia coli* (bacterium) and 1 *Streptomyces* sp., all excluded from QPS evaluation.

[b]Eight notifications corresponding to eight TU, *Heyndrickxia faecalis* (previously *Weizmannia faecalis*), *Serratia marcescens*, *Schizochytrium* sp., *Akkermansia muciniphila*, *Microbacterium arborescens*, *Rhizobium radiobacter* (synonym *Agrobacterium radiobacter*), *Actinomadura roseirufa* and *Burkholderia stagnalis*.

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 aim of the ELS was to identify any publicly available scientific studies reporting on safety concerns for humans, production animals, the environment, AMR or genotoxicity caused by QPS organisms since the previous QPS review (i.e. scientific articles published from July to December 2023) that would require a change in the QPS status of the TU.

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

The title and abstract screening step in this process was supported by a machine-assisted tool (DAISY) in DistillerSR. A classifier was created de novo to answer the screening question. The training data set used consisted of 564 random references (80% of the ones included and a number excluded that was 5 times the number of the included) from the QPS batches used in Panel Statements 18 and 19 screened by two human reviewers in parallel. Conflicts were reconciled by discussion. The total number of references in each class in the training data set was: 94 in class Yes and 470 in class No. The classifier was validated against all the remaining references of the QPS batches used in Panel Statements 18 and 19. To assess the stability of the model, the entire process was run several times (23). The results of the model were compared with the combined judgement of the two experts after solving the conflicts. The specificity was always close to 0.99 and the sensitivity was in general above 0.75 with a lower value of 0.67 and a higher one of 0.88. In this context, the results of the validation were considered stable and fit for purpose even in the worst-case sensitivity scenario recorded. To predict the outcome of the title and abstract screening step of the QPS batch used in Panel Statement 20, a new classifier was then created de novo (as described before). The training data set used consisted of 702 references (all the ones included, and a random number of the ones excluded that was 5 times the number of the included) from the QPS batches used in Panel Statements 18 and 19. The classifier was validated using the DistillerSR built-in threefold cross-validation method. The performances of the classifier confirmed the results recorded when validating the initial classifier also suggesting some improvements.

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

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

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

After removal of duplicates, 8050 records were submitted to the title and abstract screening step, which led to the exclusion of 7986 of these. The remaining 64 records were found eligible for article evaluation step (full text) and 39 were considered to report a potential safety concern and were further analysed.

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

TABLE 2 Flow of records by search strategy step.

Species/microbiological groups	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)	**4667**	**31**	**21**
Bacillus spp.	1653	13	11
Bifidobacterium spp.	396	1	1
Carnobacterium divergens	10	0	0
Corynebacterium glutamicum	99	0	0
Gram negatives[a]	207[b]	0	0

(Continues)

TABLE 2 (Continued)

Species/microbiological groups	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
	Number of articles retrieved		
Lactobacilli	1510	8	5
Lactococcus lactis	223	4	2
Leuconostoc spp.	122	5	2
Microbacterium imperiale	2	0	0
Oenococcus oeni	37	0	0
Pasteuria nishizawae	0	0	0
Clostridium tyrobutyricum	30	0	
Pediococcus spp.	214	0	0
Propionibacterium spp.	32	0	0
Streptococcus thermophilus	132	0	0
Viruses (total)	**198**	**0**	**0**
Alphaflexiviridae/Potyviridae	96	0	0
Baculoviridae	102	0	0
Yeasts	**2489**	**33**	**18**
Protists	**12**	**0**	**0**
Algae	**684**	**0**	**0**
Total	**8050**	**64**	**39**
Excluded	7986	25	

[a]Gluconobacter oxydans/Xanthomonas campestris/Cupriavidus necator/Komagataeibacter sucrofermentans.

[b]Gluconobacter oxydans (31)/Xanthomonas campestris (107)/Cupriavidus necator (62)/Komagataeibacter sucrofermentans (7).

3 | ASSESSMENT

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

3.1.1 | Bacteria

Akkermansia muciniphila

Identity

Akkermansia muciniphila has previously been subjected to QPS evaluation (EFSA BIOHAZ Panel Statement part 12, 2020b). Its identity remains unchanged from the previous evaluation, and it is a valid species with standing in nomenclature.

Body of knowledge

A. muciniphila was not included in the QPS list because, despite the beneficial effects described in the literature, its colon concentration appeared to be increased in patients with several neuropsychiatric problems such as Parkinson's and Alzheimer's diseases, multiple sclerosis and autism spectrum disorders.

Since then, there has been a substantial increase in the number of articles dealing with neurological problems, which report higher *A. muciniphila* concentrations in affected vs. control subjects and others describing potential benefits on the symptom's severity upon administration of the organism as a probiotic or as a post-biotic derivative (pasteurised cells and extracellular vesicles among others) (Chiantera et al., 2023; Lei et al., 2023).

Safety concerns

There are new articles showing higher relative abundance of *A. muciniphila* in the guts of Parkinson (Baldini et al., 2020; Qian et al., 2018; Zapała et al., 2021), multiple sclerosis (iMSMS consortium, 2022; Kozhieva et al., 2019; Takewaki et al., 2020), Alzheimer (Khedr et al., 2022a, 2022b; Ling et al., 2020; Wang, Cai, et al., 2022; Wang, Li, et al., 2022), stroke (Li et al., 2019; Tan et al., 2021) and post-stroke depressed patients (Yao et al., 2023) with respect to the healthy controls. In addition, it has been associated with production of food allergies in mice subjected to a fibre deprived diet (Parrish et al., 2023) and its administration as a 'probiotic', was reported to exacerbate enteric infection (Ganesh et al., 2013), inflammatory bowel disease (Zhang et al., 2021) and even colon carcinogenesis (Wang, Cai, et al., 2022; Wang, Li, et al., 2022).

Finally, it has been suggested that the puzzling data available might be due to colonisation of the colon by different *A. muciniphila* strains, which would produce disparate effects (Liu et al., 2021).

EFSA performed already a safety assessment of *A. muciniphila* at the strain level within an application for market authorisation context. The product obtained by pasteurised *A. muciniphila* strain ATCC BAA-835^T was assessed by EFSA (EFSA NDA Panel, 2021) and authorised as a novel food.[5]

Conclusions on a recommendation for the QPS list

The evidence published since the previous evaluation precludes *Akkermansia muciniphila* from being recommended for the QPS list due to safety concerns.

Actinomadura roseirufa

Identity

Actinomadura roseirufa is a valid species with standing in nomenclature (Wieme et al., 2019). The only described wild-type strain of the species (ATCC53666) produces diglycoside polyether antibiotics and was classified as *Actinomadura roseorufa*. Several mutants, obtained through mutagenesis with nitrosoguanidine, were found to produce several other antibiotics of the same family. One of them synthesised semduramicin, formerly a semisynthetic anticoccidial compound used for poultry and as a growth enhancer for swine and cattle (Dirlam et al., 1991, 1992). This mutant has recently been designated as the type strain of the species (LMG 30035^T = CECT 9808^T = ATCC 53664^T) (Wieme et al., 2019); in the same paper, the species name was changed from *A. roseorufa* to *A. roseirufa*.

Body of knowledge

The search terms *Actinomadura roseorufa* and *Actinomadura roseirufa*, when introduced in PubMed, only provided four references. Two of them are on the biochemical characteristics and the spectra of action of the antibiotics produced by the mutants of the wild strain (Dirlam et al., 1991, 1992), the third is a general description of the morphology of several actinomycetes and the rheology of the broth when grown in submerged culture (Warren et al., 1995) and the fourth presents the proposal of the type strain (Wieme et al., 2019).

Safety concerns

No literature on safety, related to *A. roseirufa*, has been found. A search for clusters encoding secondary metabolites (antiSMASH version 7.1.0) in its genome (accession number: ENA-CAACVB010000000) provided multiple matches to polyketide, non-ribosomal peptides and terpene synthetases. This, most probably, places the organism among those that, like filamentous fungi and streptomycetes, present a wide potential for production of biologically active compounds and which, because of that, are excluded from the QPS evaluation (EFSA BIOHAZ Panel, 2020a).

Conclusions on a recommendation for the QPS list

Actinomadura roseirufa is not recommended for QPS status due to safety concerns. The same conclusion was reached in a previous evaluation (EFSA BIOHAZ Panel, 2014).

It was concluded to exclude *Actinomadura roseirufa* for further QPS assessment.

3.2 | Taxonomic units evaluated for the first time

3.2.1 | Bacteria

Microbacterium arborescens

Identity

Microbacterium arborescens is a species with standing in nomenclature. The species was previously known as *Flavobacterium arborescens* (Bergey et al., 1923) and was reclassified to the genus *Microbacterium* as *M. arborescens* (Imai et al., 1984).

[5]Commission implementing Regulation (EU) 2022/168 of 8 February 2022 authorising the placing on the market of pasteurised *Akkermansia muciniphila* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU). 2017/2470. L_2022028EN.01000501.xml (europa.eu).

Body of knowledge

M. arborescens is known to produce exopolysaccharides (Godinho & Bhosle, 2009), pigments with antioxidant activity (Jayaraman et al., 2020), liplanthines which are ribosomally synthesised lipopeptides with antimicrobial activity (Velasco-Belalcázar et al., 2019; Wiebach et al., 2018) and polyhydroxyalkanoates, which are potential alternatives to conventional synthetic plastics (Tan et al., 2019). The endophytic colonisation of plants with potential application for phytoremediation (Ahsan et al., 2017; Basumatary et al., 2021) and the potential application for bioremediation of environmental contamination (Ashraf et al., 2018) have been reported.

Safety concerns

Most of the *M. arborescens* strains described so far have been isolated from environmental samples. Some strains, however, were isolated from clinical samples (Funke et al., 1995; Girişgen et al., 2019; Kesarwani et al., 2021). For all cases for which details were provided, immunocompromised patients were involved.

Conclusion on a recommendation for QPS status

Microbacterium arborescens cannot be recommended for the QPS status due to lack of body of knowledge on its use in the food and feed chain.

Rhizobium radiobacter* synonym *Agrobacterium radiobacter

Identity

Rhizobium radiobacter, the homotypic synonym of *Agrobacterium radiobacter*, is a species with standing in nomenclature (Young et al., 2001).

Body of knowledge

It encompasses the strains which are causing plant tumours, previously assigned to a different species *Agrobacterium tumefaciens* (Flores-Félix et al., 2020; Sawada et al., 1993). *R. radiobacter* contains also strains which are not pathogenic for plants. Extensive literature reports *A. tumefaciens* for its ability to transfer DNA into plant cells, a capacity intensively exploited to deliver recombinant DNA into plants (Azizi-Dargahlou & Pouresmaeil, 2024; Thomson et al., 2024). *R. radiobacter* was detected as a food contaminant (Casalinuovo et al., 2015; Williams et al., 2023). *R. radiobacter* was also reported for its capacity for bioremediation of soils (Atuchin et al., 2023) and the biodegradation of chlorpyrifos (Uniyal et al., 2021).

Safety concerns

Although *R. radiobacter* has been reported as a source of pathogenicity in immunosuppressed individuals frequently handling soil, these reports are rare (Williams et al., 2023, Hashiba et al., 2021, Hartman et al., 2023, Wang & An, 2022).

Conclusion on a recommendation for QPS status

Rhizobium radiobacter, synonym *Agrobacterium radiobacter*, can be recommended for QPS status with the qualification 'for production purposes only'.

Burkholderia stagnalis

Identity

Burkholderia stagnalis is a species with standing in nomenclature (https://lpsn.dsmz.de/species/burkholderia-stagnalis). It has been described in 2015 (De Smet et al., 2015) as a novel species belonging to the *Burkholderia cepacia* complex.

Body of knowledge

Some strains of the *B. cepacia* complex show biotechnological potential for bio-control, bioremediation and plant growth promotion (De Smet et al., 2015).

Safety concerns

B. stagnalis strain was used as production organism for a food enzyme; in the strain, several putative virulence factors occurring in pathogenic *Burkholderia* species were found (EFSA CEP Panel, 2023a). Strains from the species were isolated from respiratory specimens taken from patients suffering from cystic fibrosis (De Smet et al., 2015).

Conclusion on a recommendation for QPS status

Burkholderia stagnalis cannot be included in the QPS list due to a lack of body of knowledge for its use in the food and feed chain and due to possible safety concerns.

It was concluded to exclude *B. stagnalis* for further QPS assessment.

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 July and December 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 396 references. Title and abstract screening left one reference which was found to be relevant for full article appraisal (Nishio et al., 2023). The article described a case of bacteraemia and obstructive pyelonephritis due to *B. breve* in an aged woman suffering from several underlying factors (diabetes mellitus and dementia). 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 10 references. None of these articles were 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 99 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, 2020a, 2020b), provided 1510 references. After title and abstract screening, 8 were selected for the full article appraisal. One of them was not dealing with these TUs and two were not related to safety concerns; therefore, 5 articles were relevant for the QPS exercise. Two of them dealt with *L. paracase*i infections (Carrega et al., 2023; Kim et al., 2023), one was on *L. casei* (Guzek et al., 2023) and the last ones referred to *L. rhamnosus* cases (Sweedan et al., 2023; Zayet et al., 2023). The identification methodology was not clear in two papers (Kim et al., 2023; Sweedan et al., 2023) while MALDI-TOF MS was used in the other three. All cases occurred in aged people with important previous morbidities that included serious cardiac problems (Guzek et al., 2023; Kim et al., 2023), neurological disabilities (Sweedan et al., 2023) or radiation enteritis of the small bowel wall (Zayet et al., 2023), which are clearly predisposing factors for opportunistic 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 223 references. Title and abstract screenings reduced their numbers to 4. None of these were relevant for its evaluation as a QPS organism, either because the papers did not deal with safety concerns or, in two cases (Meng et al., 2023; Wu et al., 2023) because the first was a meeting abstract and the second a review that did not provide new original data. Based on this available evidence, 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 122 references. The analysis of their titles and abstracts left five articles for full-text evaluation. One article is not related to this TU and two of them are not dealing with safety concerns, meaning that only two were found to be relevant for the QPS exercise. One article reported a case of bacteraemia in an immunocompromised patient (Azghar et al., 2023). The second article involved the identification of strains isolated from mastitis cases in cows (Manoj et al., 2022). Both references presented problems related to the identification of the causative strains (performed using phenotypic tests, Azghar et al., 2023; Manoj et al., 2022) and, in the first article, to the immune status of the patient, who suffered from osteopetrosis with bone marrow aplasia (Azghar et al., 2023).

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 two references. Neither of these articles was considered relevant at the level of title and abstract screening. 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 37 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 214 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 32 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 132 references. Following the analysis of their titles and abstracts, no articles passed to the full article evaluation phase. Consequently, the status of QPS-listed *S. thermophilus* is not changed.

3.3.2 | Gram-positive spore-forming bacteria

A search for scientific articles potentially relevant for *Bacillus* spp., related species and *Geobacillus stearothermophilus* provided 1662 references.

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

One thousand six hundred and fifty-three articles were found for Bacillus. The 13 scientific articles that passed to the full-text phase for further analysis were related to *Bacillus* spp.. For one the full text was not in English, and one was not concerning a TU in the QPS list; therefore, 11 were relevant for the QPS exercise. Two (Ancuelo et al., 2023; Kitchen et al., 2023) had methodological problems related to the identification of the causative agent and to source attribution. Two papers confirmed the need for the qualification of the absence of toxigenic potential and the antimicrobial resistance genes for *Bacillus pumilus* (Ma et al., 2023) and the absence of production potential for bacitracin of *Bacillus paralicheniformis* (EFSA CEP Panel, 2023b) and the absence of antimicrobial resistance genes in *Bacillus subtilis* (Youssif et al., 2023). Probiotic usage of *Shouchella clausii* (*Bacillus clausii*) (Erbas et al., 2023) and of *Bacillus licheniformis* (Zou et al., 2024) leads to bacteraemia in an immunocompromised patient. Bacteraemia related to *Bacillus subtilis* (Hashimoto et al., 2023; Kato et al., 2022; Ochi et al., 2023; Tokano et al., 2023) was diagnosed in immunocompromised patients.

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

Geobacillus stearothermophilus

None of the nine 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 no references. Consequently, the QPS status of *P. nishizawae* is not changed.

Clostridium tyrobutyricum

A search for scientific articles potentially relevant for *C. tyrobutyricum* provided 30 references. Following the analysis of its title and abstract, none was selected for the full-text analysis phase. Consequently, the QPS status of *C. tyrobutyricum* is not changed.

3.3.3 | Gram-negative bacteria

A search for scientific articles potentially relevant to the QPS evaluation of *Gluconobacter oxidans*, *Xanthomonas campestris, Cupriavidus necator* and *Komagataeibacter sucrofermentans* provided in total 207 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 62 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 31 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 seven 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 107 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 2489 references. After the title/abstract screening phase, 33 articles passed to the full article appraisal phase. Out of these, six are not related to safety concerns, four are not related to the QPS yeast group and five are not in English, therefore, only 18 reported a possible safety concern. The 18 articles are discussed below.

For the species ***Hanseniaspora uvarum***, ***Komagataella pastoris***, ***Komagataella phaffi***, ***Limtongozyma cylindracea***, ***Ogataea polymorpha***, ***Saccharomyces bayanus***, ***Saccharomyces pastorianus***, ***Schizosaccharomyces pombe***, ***Phaffia rhodozyma***, 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*. Synonyms of this species are *Hansenula jadinii, Pichia jadinii, Lindnera jadinii.*

One scientific article (Li et al., 2023) was related to human safety concerns. In this retrospective study of a neonatal intensive care unit in Beijing, China, yeasts isolated from blood cultures of neonatal children were identified as *C. jadinii*. Information regarding methods used for species identification is missing and there were predisposing conditions (hospitalised neonates).

One new paper was relevant regarding identification methods. Sariguzel et al. (2023) reported that phenotypic methods indicated that 29 clinical yeast isolates were *C. jadinii*. However, both sequencing of ITS genes and MALDI-TOF MS showed that they all instead belonged to the more common opportunist *Cyberlindnera fabianii*. Thus, molecular methods have to be used for reliable identification of *C. jadinii*.

The studies 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*. Synonyms of this species are *Debaryozyma hansenii, Pichia hansenii, Torulaspora hansenii, Debaryomyces hansenii var. hansenii, Debaryomyces tyrocola var. hansenii*.

Three scientific articles (Afsarian et al., 2023, Al-Manei et al., 2023, Belloch et al., 2023) contributed with information related to human safety concerns. Al-Manei et al. (2023) present identification problems and predisposing factors (head and neck cancer patients). Afsarian et al. (2023) described a low presence of *D. hansenii* in the infected nails of 51 patients, but apart from this superficial fungal infection, no illness is reported. Finally, Belloch et al. (2023) concluded in a study that analysed the virulence factors of a collection of 60 strains of this species that most strains displayed no virulence trait or only presented the capability to produce biofilm.

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

Kluyveromyces lactis

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

One article (Saied et al., 2023) contributed with information related to human safety concerns. One out of 24 yeast isolates from a hospital in Egypt was identified as *K. lactis*. However, species identification is not entirely reliable, there is no evidence that the isolate contributed to disease, and information on any pre-disposing factors is missing.

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

Kluyveromyces marxianus

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

Six scientific articles (Aboueldahab et al., 2023, Afsarian et al., 2023, Al-Manei et al., 2023, Bektas et al., 2023, Schwarz et al., 2022, Sig et al., 2023) contributed information related to human safety concerns. Three of the studies reported clinical isolates of *K. marxianus* (Aboueldahab et al. 2023; Bektas et al. 2023; Sig et al. 2023). Identification methods, however, used conventional morphological or physiological approaches and there were pre-disposing factors. Al-Manei et al. (2023) used MALDI-TOF MS species identification and reported *K. marxianus* in the oral microbiome of cancer patients; however, it is uncertain whether the yeasts caused an infection. In a medical mycology laboratory in Iran, Afsarian et al. (2023) isolated *K. marxianus* from infected nails of 51 human subjects. Apart from this superficial fungal infection, there is no information on any other illness.

Schwarz et al. (2022) reported the response of six clinical isolates of *K. marxianus* to the antimycotic isavuconazole. The MICs were similar to those reported before.

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*.

Ogataea angusta

The anamorph of *O. angusta* is not described. A synonym of this species is *Pichia angusta*.

A review article (Gil et al., 2023) was related to human safety concerns. This review analyses demographic and clinical data from 495 cases of infections caused by rare yeasts in eight Latin American countries. *O. angusta* is reported as one of the identified species. No conclusions could be made since the species identification method was not specified for the reported cases.

The study on *O. angusta* did not add any new information that would change the current QPS status of this species.

Saccharomyces cerevisiae

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

Eight scientific articles were associated with human safety concerns (Al-Manei et al., 2023; Gil et al., 2023; Jabbar et al., 2022; Mayer et al., 2023; Menu et al., 2023; Nawaz et al., 2022; Osset-Trénor et al. 2023 Sig et al., 2023) and all of them present identification problems and/or predisposing factors with one exception (Osset-Trénor et al., 2023). This publication is a review where the authors discuss the mechanisms for developing antimycotic resistance in pathogenic fungi and the prospects of developing new strategies and antimycotics to combat this problem. The seven publications reporting some problem (Al-Manei et al. 2023, Gil et al., 2023, Jabbar et al., 2022, Mayer et al., 2023, Menu et al., 2023, Nawaz et al., 2022, Sig et al., 2023), all have identification problems, three of them are associated with predisposition factors (Al-Manei et al., 2023, Jabbar et al., 2023, Nawaz et al., 2023).

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

Wickerhamomyces anomalus

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

Four scientific articles contributed information related to human safety concerns (Galván Ledesma et al., 2023, Gil et al., 2023, Higgins et al., 2023, Warghade et al., 2023). Galván Ledesma et al. (2023) describe a postoperative fungal endophthalmitis caused by *W. anomalus* in a 77-year-old male who had undergone surgery for a right eye cataract. The other three publications present identification problems (Gil et al., 2023; Higgins et al. 2023; Warghade et al., 2023). 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* and *Candida oleophila*. A synonym of this species is *Saccharomycopsis lipolytica*.

One scientific article contributed information about human safety concerns (Bektas et al., 2023). However, the identification was not well performed, and the patients presented pre-disposing factors. There was no new information that would change the QPS status of *Y. lipolytica*.

Zygosaccharomyces rouxii

The anamorph form of *Z. rouxii* is not described. A synonym of this species is *Torulaspora rouxii*.

One scientific article contributed information about human safety concerns (Jabbar, 20 et al., 2023). The authors identified only one strain of this species in a collection of yeast isolates from invasive fungal infections in kidney transplant recipients and there were shortcomings in the identification method used.

The literature update did not identify any new information that would change the QPS status of *Z. rouxii*.

3.3.5 | Protists

Aurantiochytrium limacinum (Schizochytrium limacinum)

A search for scientific articles potentially relevant for *A. limacinum* provided 12 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 684 articles. Following the analysis of their titles and abstract, none were selected for the full-text phase.

Euglena gracilis

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

Haematococcus lacustris* synonym *Haematococcus 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.

Chlamydomonas reinhardtii

No scientific articles dealt with potential safety concerns for *C. reinhardtii*. Therefore, the current QPS status of *C. reinhardtii* 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 96 references. Following the analysis of their titles and abstract, none were selected for the full-text phase. Therefore, the current QPS status remains unchanged.

Baculoviridae

A search for scientific articles potentially relevant for the QPS evaluation of the *Baculoviridae* family provided 102 references. Following the analysis of their titles and abstract, none were selected for the full-text phase. Therefore, the current QPS status remains unchanged.

3.4 | Update of the QPS list with changes in nomenclature and taxonomic insights of QPS TUs

3.4.1 | Adding the correct name/synonyms to the QPS list

The TUs of bacteria, yeasts, algae, protists and viruses present in the QPS list were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. The QPS list was updated based on these taxonomical insights.

Bacterial nomenclature was verified using the expert-curated authoritative database – *List of Prokaryotic Names with Standing in Nomenclature* (LPSN) database.[6] Upon review, it was found that four names were incorrect. Consequently, the corrected names were integrated into the QPS list (Table 3). Furthermore, synonyms were updated, retaining valid synonyms from the database. For 25 bacterial TUs, a total of 33 new synonyms were added.[7] In contrast, for two TUs, two synonyms were removed. *Acidipropionibacterium acidipropionici* was swapped as a synonym as it is the correct name for the TU, and *Brevibacterium lactofermentum* (previously a synonym of *Corynebacterium glutamicum*) was excluded because it is not a validly published name in the database.

Yeast nomenclature was checked against the MycoBank database,[8] revealing one incorrect name. Consequently, the corrected name was added to the QPS list (Table 3). Additionally, synonyms were updated to include obligate synonyms from the database and the names of the complementary forms (anamorph or teleomorph). The complementary form name is significant because the context determines its use. For example, in clinical studies, the anamorph form is predominantly used. For yeast TUs 30 synonyms were added and for fourTUs, four synonyms were removed. The synonyms *Torulopsis utilis* (previously a synonym of *Cyberlindnera jadinii*), *Saccharomyces carlsbergensis* (previously a synonym of *Saccharomyces pastorianus*) and *Saccharomyces anomalus* (previously a synonym of *Wickerhamomyces anomalus*) were removed because they are not obligate synonyms. Additionally, *Phaffia rhodozyma* was swapped as a synonym as it is the correct name for the TU.

Microalgae and protists nomenclature was checked against the AlgaeBase database[9] and the NCBI taxonomy browser[10], respectively. All listed names were correct. For one algae TU, *Chlamyodomans smithii* was removed as synonym of *Chlamydomonas reinhardtii* because it is indicated as a different species.

The nomenclature for viruses' family was checked against database of International Committee on Taxonomy of Viruses (ICTV, 2021)[11] and no updates were required.

[6] https://www.bacterio.net/.

[7] Synonyms added in the QPS list are noted in blue – updated QPS list at the Knowledge Junction in Zenodo. https://doi.org/10.5281/zenodo.1146566.

[8] https://www.mycobank.org/.

[9] https://www.algaebase.org.

[10] https://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi.

[11] https://ictv.global/taxonomy.

TABLE 3 List of amendments done in the QPS List concerning the correct names.

Microbiological group	Previous name in QPS list	Corrected name integrated in the QPS list
Bacteria	*Propionibacterium acidipropionici*	*Acidipropionibacterium acidipropionici*
Bacteria	*Alkalihalobacillus clausii*	*Shouchella clausii*
Bacteria	*Lederbergia lentus*	*Lederbergia lenta*
Bacteria	*Weizmannia coagulans*	*Heyndrickxia coagulans*
Yeast	*Xanthophyllomyces dendrorhous*	*Phaffia rhodozyma*

3.4.2 | Establishment of a procedure to check correct name and synonyms for the QPS list

A new procedure will be established for regular updates of the QPS list based on recent taxonomic insights. Every 6 months, the QPS TUs of bacteria, yeast, algae, protists and viruses will be verified against their respective authoritative databases to ensure the accuracy for each Panel Statement. These checks will be conducted before the ELS exercise to review the TUs on the QPS list being launched so that the most recent names/synonyms can be included in the keywords for the literature searches.

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

- Between October 2023 and March 2024 (inclusive), the list of notifications was updated with 83 notifications that were received by EFSA, of which 47 were proposed for evaluation as feed additives, 25 for use as food enzymes, food additives and flavourings and 11 as novel foods.

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.
- The QPS TUs of bacteria, yeast, algae, protists and viruses were checked against their respective authoritative databases to verify the correctness of the names and completeness of synonyms. Some incorrectness of the names and incompleteness of synonyms were found. Changes were made in the QPS list to include the latest taxonomic insights.
- A new procedure has been established to ensure the TUs are kept up to date in relation to recent taxonomical insights. Every 6 months, the QPS TUs of bacteria, yeast, algae, protists and viruses will be verified against their respective authoritative databases to ensure the accuracy for each Panel Statement. The next ELS cycle to review the QPS list TUs will already include the updated names/synonyms as keywords.

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 81 notifications received between October 2023 and March 2024, 46 were related to TUs that already had QPS status and therefore did not require further evaluation.
- Of the remaining 35 notifications, 27 notifications were related to microorganisms that are generally excluded from QPS evaluation (15 were notifications of filamentous fungi, 1 of *Enterococcus faecium* (bacterium), 10 of *Escherichia coli* (bacterium) and 1 *Streptomyces*).
- 2 of the other 8 notifications, corresponding to 2 TU, had already been evaluated for a possible QPS status in the previous Panel Statement: *Heyndrickxia faecalis* (previously *Weizmannia faecalis)* and *Serratia marcescens*.
- One was notified at genus level so cannot be assessed for the QPS status.
- The other five notifications belonging to five TUs, were assessed for a possible QPS status *Akkermansia muciniphila, Microbacterium arborescens, Rhizobium radiobacter* (synonym *Agrobacterium radiobacter*), *Actinomadura roseirufa* and *Burkholderia stagnalis*.

[12]Units as in December 2022.

The following conclusions were drawn:

- The evidence published since the previous evaluation precludes *Akkermansia muciniphila* from being recommended for the QPS list due to safety concerns.
- *Actinomadura roseirufa* is not recommended for QPS status due to safety concerns. The same conclusion was reached in a previous evaluation (EFSA BIOHAZ Panel, 2014). It was concluded to exclude *Actinomadura roseirufa* for further QPS assessment.
- *Microbacterium arborescens* cannot be recommended for QPS status due to lack of body of knowledge on its use in the food and feed chain.
- *Rhizobium radiobacter,* synonym *Agrobacterium radiobacter,* can be recommended for QPS status with the qualification 'for production purposes'.
- *Burkholderia stagnalis* cannot be included in the QPS list due to a lack of body of knowledge for its use in the food and feed chain and due to possible safety concerns. It was concluded to exclude *B. stagnalis* for further QPS assessment.

GLOSSARY

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

ABBREVIATIONS

AI	artificial intelligence
AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
ELS	extensive literature search
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FIP	EFSA Food ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
GMO	EFSA Unit on Genetically Modified Organisms
MALDI-TOF MS	matrix-assisted laser desorption/ionisation (MALDI), time-of-flight (TOF) mass spectrometry (MS)
QPS	qualified presumption of safety
PPR	Pesticide Peer Review Unit
ToR	Term(s) of reference
TU	taxonomic unit
WG	working group

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AMENDMENT

Some descriptive data related to the notifications received have been corrected in Appendix F. Reference to those notifications in abstract, summary, sections 2.2.2 and conclusions have been corrected accordingly without any impact on the scientific content of the statement. To avoid confusion, the original version of the output has been removed from the EFSA Journal, but is available on request.

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-2021-00772

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APPENDIX A

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

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

A.1 | *Akkermansia muciniphila*

The search on PubMed for the following terms led to the number of hits indicated below:
- 'Akkermansia muciniphila': 134 hits between 2020 and 2024, all checked.

A.2 | *Actinomadura roseirufa*

The search on PubMed for the following terms led to the number of hits indicated below:
- 'Actinomadura roseirufa' AND 'Actinomadura roseorufa': 4 hits, all checked.

A.3 | *Microbacterium arborescens*

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

- 'Microbacterium arborescens': 26 hits published, all checked.
- 'Flavoabacterium arborenscens': 29 hits all checked.

A.4 | *Rhizobium radiobacter, synonym Agrobacterium radiobacter*

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

- 'Rhizobium radiobacter' taxonomy review: 23 hits, all checked.
- 'Rhizobium radiobacter': review 2023 14 hits, all checked.
- 'Rhizobioum radiobacter' AND 'safety': 71 hits, all checked, nothing relevant found.
- 'Rhizobium radiobacter' AND 'genotoxicity': 2 hits, all checked.
- 'Rhizobium radiobacter' AND 'food contamination': 28 hits all checked.

A.5 | *Burkholderia stagnalis*

The search on PubMed for the following terms led to the number of hits indicated below:
- 'Burkholderia stagnalis': 4 hits. All checked.

APPENDIX B

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

The protocol for extensive literature search (ELS) used in the context of the EFSA mandate on the list of QPS-recommended microorganisms intentionally added to the food or feed (EFSA-Q-2021-00772) is available on the EFSA Knowledge Junction community on Zenodo, at: https://doi.org/10.5281/zenodo.3607188

APPENDIX C

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

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

APPENDIX D

References selected from the ELS exercise with potential safety concerns for searches done from July to December 2023 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium spp.

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Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

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Lactococcus lactis

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Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci spp.

None.

Propionibacterium spp.

None.

Streptococcus thermophilus

None.

Gram-Positive Spore-forming Bacteria

Bacilli

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Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Clostridium tyrobutyricum

None.

Gram-negative bacteria

Cupriavidus necator

None.

Gluconobacter oxydans

None.

Komagataeibacter sucrofermentans

None.

Xanthomonas campestris

None.

Yeasts

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Protists

None.

Algae

None.

Viruses used for plant protection

Alphaflexiviridae

None.

Potyviridae

None.

Baculoviridae

None.

APPENDIX E

Updated list of QPS Status recommended microorganisms in support of EFSA risk assessments

The list of QPS status recommended microorganisms (EFSA BIOHAZ Panel, 2023) is being maintained in accordance with the mandate of the BIOHAZ Panel. Possible additions to this list are included approximately every 6 months, with this Panel Statement (20) adopted in June 2024. 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 with each Panel Statement)

APPENDIX F

Microbial species as notified to EFSA, received between October 2023 and March 2024 (reply to ToR 1)

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

The list was updated with the notifications received between October 2023 and March 2024, listed in the table below.

Species	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						
Schizochytrium sp.	Novel foods	Infant formula/Follow on formula	Production of oil rich in docosahexaenoic acid (DHA)	EFSA-Q-2023-00750	No	No
Bacteria						
Actinomadura roseirufa	Feed additives	Coccidiostats and histomonostats	Production of semduramicin. Avi-Carb (semduramicin 3% and nicarbazin 8%). Non GMM	EFSA-Q-2024-00004	No	Yes
Akkermansia muciniphila	Novel foods	Novel foods	Pasteurised *Akkermansia muciniphila*. Non GMM	EFSA-Q-2023-00893	No	Yes
Bacillus amyloliquefaciens	Feed additives	Zootechnical additives	Gut flora stabiliser. Ecobiol®, Ecobiol® 500, Ecobiol® Plus -. GMM	EFSA-Q-2024-00008	Yes	No
Bacillus amyloliquefaciens	Feed additives	Zootechnical additive – Gut flora stabiliser	Non GMM	EFSA-Q-2023-00867	Yes	No
Bacillus amyloliquefaciens	Food enzymes, food additives and flavourings	Food enzyme	Production of enzyme bacillolysin. GMM	EFSA-Q-2023-00905	Yes	No
Bacillus licheniformis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme alpha-amylase. GMM	EFSA-Q-2024-00087	Yes	No
Bacillus licheniformis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme alpha-amylase. GMM	EFSA-Q-2024-00067	Yes	No
Bacillus licheniformis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme glucan 1,4-α-maltotetraohydrolase. GMM	EFSA-Q-2024-00068	Yes	No
Bacillus licheniformis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme pullulanase. GMM	EFSA-Q-2024-00088	Yes	No
Bacillus licheniformis	Feed additives	Zootechnical additives	Gut flora stabiliser. Feed additive (B-act®). Non GMM	EFSA-Q-2024-00035	Yes	No
Bacillus licheniformis	Feed additives	Zootechnical additives	Gut flora stabiliser	EFSA-Q-2023-00667	Yes	No
Bacillus licheniformis	Feed additives	Zootechnical additives	Digestibility enhancer. Feed additive RONOZYME® RumiStar (alpha-amylase). Non GMM	EFSA-Q-2024-00081	Yes	No

(Continued)

Species	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question No[a]	Previous QPS status of the respective TU[b]	Assessed in this statement? Yes or no
Bacillus subtilis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme endo-1,4-beta-xylanase. Non GMM	EFSA-Q-2024-00079	Yes	No
Bacillus subtilis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme acetolactate decarboxylase. GMM	EFSA-Q-2024-00069	Yes	No
Bacillus subtilis	Feed additives	Zootechnical additives	Gut flora stabiliser. Non GMM	EFSA-Q-2023-00867	Yes	No
Bacillus subtilis	Feed additives	Zootechnical additives	Gut flora stabiliser. Non GMM	EFSA-Q-2023-00867	Yes	No
Bacillus subtilis	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00631	Yes	No
Bacillus subtilis	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme endo-1,4-β-xylanase. GMM	EFSA-Q-2023-00878	Yes	No
Bacillus subtilis	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect. Production of riboflavin. GMM	EFSA-Q-2023-00898	Yes	No
Bifidobacterium animalis	Feed additives	Zootechnical additives	Gut flora stabilisers, Other zootechnical additives. FlorEquilibre Chat (preparation of microorganisms). GMM	EFSA-Q-2024-00090	Yes	No
Bifidobacterium longum	Feed additives	Zootechnical additives	Gut flora stabilisers, Other zootechnical additives. FlorEquilibre Chat (preparation of microorganisms). Non GMM	EFSA-Q-2024-00090	Yes	No
Burkholderia stagnalis	Food enzymes, food additives and flavourings	Food enzyme	Production of the food enzyme triacylglycerol lipase. GMM	EFSA-Q-2024-00084	No	Yes
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production strain of L-valine. Non GMM	EFSA-Q-2023-00551	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-lysine sulphate Non GMO	EFSA-Q-2023-00712	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-lysine monohydrochloride. GMM	EFSA-Q-2023-00723	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-lysine sulphate. GMM	EFSA-Q-2023-00865	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-tryptophan. GMM	EFSA-Q-2023-00866	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-valine. GMM	EFSA-Q-2024-00032	Yes	No

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Species	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	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-valine. GMM	EFSA-Q-2023-00547	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-lysine sulphate containing non-viable biomass. GMM	EFSA-Q-2023-00484	Yes	No
Corynebacterium glutamicum	Feed additives	Sensory additives/Nutritional additives	Amino acids, their salts and analogue/ flavouring compounds. Production of L-arginine. GMM	EFSA-Q-2024-00005	Yes	No
Corynebacterium glutamicum	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-isoleucine. GMM	EFSA-Q-2024-00091	Yes	No
Corynebacterium glutamicum	Feed additives	Sensory additives/Nutritional additives	Amino acids, their salts and analogue/ flavouring compounds. Production of L-histidine and L-histidine monohydrochloride monohydrate. GMM	EFSA-Q-2024-00031	Yes	No
Enterococcus lactis	Feed additives	Zootechnical additives	Gut flora stabiliser. Non GMM	EFSA-Q-2023-00857	No	No
Escherichia coli	Food enzymes, food additives and flavourings	Food enzymes	To produce 3 enzymes (CDX-044 sucrose synthase; CDX-045 glycosyltransferase; CDX-047 glycosyltransferases) to be used in the manufacturing process of the food additive steviol glycosides (rebaudioside D and M). GMM	EFSA-Q-2023-00749	No	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-valine. GMM	EFSA-Q-2023-00739	No	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-arginine. Non-GMM	EFSA-Q-2023-00868	No	No
Escherichia coli	Novel foods	Novel foods	Production of 2′-fucosyllactose GMM	EFSA-Q-2023-00637	No	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-isoleucine. GMM	EFSA-Q-2024-00033	No	No
Escherichia coli	Feed additives	Nutritional additives	Amino acids, their salts and analogue. Production of L-valine. GMM	EFSA-Q-2024-00121	No	No
Escherichia coli	Novel foods	Novel foods	Production of 6′-Sialyllactose sodium salt (6′-SL). GMM	EFSA-Q-2023-00710	No	No
Escherichia coli	Novel foods	Novel foods	Production of 3′-Sialyllactose sodium salt (3′-SL). GMM	EFSA-Q-2024-00002	No	No
Escherichia coli	Novel foods	Novel foods	Production of Lacto-N-tetraose. GMM	EFSA-Q-2023-00671	No	No
Escherichia coli	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme maltogenic amylase. GMM	EFSA-Q-2024-00034	No	No

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Species	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
Lacticaseibacillus rhamnosus	Feed additives	Silage additive	Non GMM	EFSA-Q-2023-00715	Yes	No
Lactobacillus acidophilus	Feed additives	Zootechnical additives	Gut flora stabiliser. FlorEquilibre Chat (preparation of microorganisms). Non GMM	EFSA-Q-2024-00090	Yes	No
Lactobacillus paracasei	Feed additives	Zootechnical additives	Gut flora stabiliser. FlorEquilibre Chat (preparation of microorganisms). Non GMM	EFSA-Q-2024-00090	Yes	No
Lentilactobacillus buchneri	Feed additives	Technological additives	Silage additive	EFSA-Q-2023-00631	Yes	No
Ligilactobacillus salivarius	Feed additives	Zootechnical additives	Gut flora stabiliser. FlorEquilibre Chat (preparation of microorganisms). Non GMM	EFSA-Q-2024-00090	Yes	No
Microbacterium arborescens	Novel foods	Food supplements	Production of xylose isomerase. Non GMM	EFSA-Q-2024-00015	No	Yes
Rhizobium radiobacter, synonym *Agrobacterium radiobacter*	Food enzymes, food additives and flavourings	New food additive	Used in the production process of a new food additive used as firming, gelling, stabilising and/or thickening agent in many food categories. Non-GMM	EFSA-Q-2017-00024	No	Yes
Serratia marcescens	Novel foods	Food supplements	Non-GMM	EFSA-Q-2023-00205	No	No
Streptomyces aureofaciens	Feed additives	Coccidiostats and histomonostats	Production of Narasin. Interban® (10 % Narasin and 0.2 % Diclazuril). Non-GMM	EFSA-Q-2023-00748	No	No
Weizmannia faecalis	Feed additives	Zootechnical additive	Gut flora stabilisers	EFSA-Q-2023-00667	No	No
Filamentous fungi						
Aspergillus niger	Novel foods	Food supplements/ Dietary foods for special medical purposes	Non GMM	EFSA-Q-2023-00411	No	No
Aspergillus niger	Feed additives	Technological additives	Preservative and acidity regulator. For production of citric acid. Non-GMM	EFSA-Q-2024-00006	No	No
Aspergillus tubingensis	Food enzymes, food additives and flavourings	Food enzymes	Production of food enzyme polygalacturonase and β-glucosidase. Non GMM	EFSA-Q-2023-00657	No	No
Eremothecium ashbyi	Feed additives	Nutritional additives	Vitamins, pro-vitamins and chemically well-defined substances having similar effect. Production of vitamin B2/Riboflavin	EFSA-Q-2023-00693	No	No
Talaromyces versatilis	Feed additives	Zootechnical additives	Digestibility enhancers. Production of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase	EFSA-Q-2023-00520	No	No

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Species	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
Talaromyces versatilis	Feed additives	Zootechnical additives	Digestibility enhancers. Production of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase	EFSA-Q-2023-00520	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme aminopeptidase Y. GMM	EFSA-Q-2024-00089	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme chymosin. GMM	EFSA-Q-2023-00907	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme glucan 1,4-α-maltohydrolase. GMM	EFSA-Q-2024-00014	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme prolyl oligopeptidase. GMM	EFSA-Q-2023-00906	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme endo 1,4-beta-xylanase GMM	EFSA-Q-2023-00653	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme endo-1,4-beta-xylanase. GMM	EFSA-Q-2024-00085	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme phospholipase A1. GMM	EFSA-Q-2024-00065	No	No
Trichoderma reesei	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme 1,4-α-glucan 6-α-glucosyltransferase. GMM	EFSA-Q-2024-00066	No	No
Trichoderma reesei	Feed additives	Technological additives	Digestibility enhancers. Production of 6-phytase. ROVABIO® PHYPLUS 5000L and ROVABIO® PHYPLUS 20000 T. GMM	EFSA-Q-2023-00899	No	No
Yeasts						
Kluyveromyces lactis	Novel foods	Novel foods	Production of oligosaccharide Lacto-N-triose II (LNT II). GMM	EFSA-Q-2024-00142	Yes	No
Komagataella phaffii	Food enzymes, food additives and flavourings	Food enzyme	Production of food enzyme triacylglycerol lipase. GMM	EFSA-Q-2024-00083	Yes	No
Komagataella phaffii	Novel foods	Food supplements	GMM	EFSA-Q-2023-00404	Yes	No
Saccharomyces cerevisiae	Food enzymes, food additives and flavourings	Food enzyme	Production of the food enzyme asparaginase. GMM	EFSA-Q-2024-00076	Yes	No
Saccharomyces cerevisiae	Feed additives	Zootechnical additives	Gut flora stabilisers YEA-SACC, YEA-SACC TS Fit 10. Non GMM	EFSA-Q-2023-00887	Yes	No
Saccharomyces cerevisiae	Feed additives	Zootechnical additives	Digestibility enhancers/Gut flora stabiliser. Non GMM	EFSA-Q-2023-00724	Yes	No
Saccharomyces cerevisiae	Feed additives	Zootechnical additives	Gut flora stabilisers. Non GMM	EFSA-Q-2023-00486	Yes	No
Saccharomyces cerevisiae	Feed additives	Zootechnical additives	Other zootechnical additives	EFSA-Q-2023-00694	Yes	No

(Continued)

Species	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question No[a]	Previous QPS status of the respective TU[b]	Assessed in this statement? Yes or no
Saccharomyces cerevisiae	Feed additives	Technological additives	Silage additive. Non-GMM	EFSA-Q-2023-00715	Yes	No
Saccharomyces cerevisiae	Food enzymes, food additives and flavourings	Food enzymes	Production of food enzyme asparaginase. Non-GMM	EFSA-Q-2023-00656	Yes	No
Yarrowia lipolytica	Food enzymes, food additives and flavourings	Food enzymes	Production of food enzyme fructosyltransferase. GMM	EFSA-Q-2024-00010	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).

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