STATEMENT

ADOPTED: 3 June 2020

doi: 10.2903/j.efsa.2020.6174

Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 12: suitability of taxonomic units notified to EFSA until March 2020

EFSA Panel on Biological Hazards (BIOHAZ),
Kostas Koutsoumanis, Ana Allende, Avelino Alvarez-Ordóñez, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Robert Davies, Alessandra De Cesare, Friederike Hilbert, Roland Lindqvist, Maarten Nauta, Luisa Peixe, Giuseppe Ru, Marion Simmons, Panagiotis Skandamis, Elisabetta Suffredini, Pier Sandro Cocconcelli, Pablo Salvador Fernández Escámez, Miguel Prieto Maradona, Amparo Querol, Juan Evaristo Suarez, Ingvar Sundh, Just Vlak, Fulvio Barizzone, Michaela Hempen and Lieve Herman

Abstract

The qualified presumption of safety (QPS) was developed to provide a generic safety evaluation for biological agents to support EFSA's Scientific Panels. It is based on an assessment of the taxonomic identity, the body of knowledge, safety concerns and antimicrobial resistance. Safety concerns identified for a taxonomic unit (TU) are where possible to be confirmed at strain or product level, reflected by 'qualifications'. No new information was found that would change the previously recommended QPS TUs of the 39 microorganisms notified to EFSA between October 2019 and March 2020, 33 were excluded, including five filamentous fungi, five *Escherichia coli*, two *Enterococcus faecium*, two *Streptomyces* spp. and 19 TUs already evaluated. Six TUs were evaluated. *Akkermansia muciniphila* was not recommended for QPS status due to safety concerns. *Clostridium butyricum* was not recommended because some strains contain pathogenicity factors. This TU was excluded for further QPS evaluation. *Galdieria sulphuraria* and *Pseudomonas chlororaphis* were also rejected due to a lack of body of knowledge. The QPS status of *Corynebacterium ammoniagenes* (with the qualification 'for production purposes only') and of *Komagataella pastoris* (with the qualification 'for enzyme production') was confirmed. In relation to the taxonomic revision of the *Lactobacillus* genus, previously designated *Lactobacillus* species will be reassigned to the new species and both the old and new names will be retained in the QPS list.

Keywords: safety, QPS, bacteria, yeast, *Akkermansia muciniphila*, *Clostridium butyricum*, *Corynebacterium ammoniagenes*, *Galdieria sulphuraria*, *Komagataella pastoris*, *Pseudomonas chlororaphis*

Requestor: EFSA

Question number: EFSA-Q-2020-00077

Correspondence: biohaz@efsa.europa.eu

Panel members: Ana Allende, Avelino Alvarez-Ordóñez, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Robert Davies, Alessandra De Cesare, Lieve Herman, Friederike Hilbert, Kostas Koutsoumanis, Roland Lindqvist, Maarten Nauta, Luisa Peixe, Giuseppe Ru, Marion Simmons, Panagiotis Skandamis and Elisabetta Suffredini.

Acknowledgements: The BIOHAZ Panel wishes to thank the following for the support provided to this scientific output: Jaime Aguilera, Katrin Bote, Rosella Brozzi, Wolfgang Gelbmann, Annamaria Rossi, Patricia Romero and Frédérique Istace.

Suggested citation: EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Hilbert F, Lindqvist R, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Cocconcelli PS, Fernández Escámez PS, Maradona MP, Querol A, Suarez JE, Sundh I, Vlak J, Barizzone F, Hempen M and Herman L, 2020. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 12: suitability of taxonomic units notified to EFSA until March 2020. EFSA Journal 2020;18(7):6174, 42 pp. https://doi.org/10.2903/j.efsa.2020.6174

ISSN: 1831-4732

Summary

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the list of qualified presumption of safety (QPS) biological agents intentionally added to food or feed. The request included three specific tasks as mentioned in the Terms of Reference (ToR).

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

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

The first ToR requires ongoing updates of the list of biological agents notified to EFSA, in the context of a technical dossier for safety assessment. The overall list (https://doi.org/10.5281/zenodo.3607184) was updated with the notifications received since the latest review in October 2019. Within this period, 39 notifications were received by EFSA, of which 26 were proposed for use as Feed Additives, two as Food Enzymes, Food Additives and Flavourings, five as Novel Foods, five as Plant Protection Products and one as a Genetically Modified Organism. The new notifications received between October 2019 and March 2020 are also 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 2019 until December 2019 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.3607190) and the search strategies in Appendix C (see https://doi.org/10.5281/zenodo.3607193). No new information was found that would affect the QPS status of those TUs and their qualifications.

The third *ToR* requires a (re)assessment of new TUs notified to EFSA, for their suitability for inclusion in the updated QPS list at the Knowledge Junction in Zenodo (https://zenodo.org/record/1146566, Appendix E). The current Statement focuses on the assessments of the TUs that were notified to EFSA between October 2019 and March 2020. Of the 39 notifications received, 33 were not included for QPS evaluation. Fourteen of them were excluded from QPS evaluation (five were notifications of filamentous fungi; five of *Escherichia coli,* two of *Enterococcus faecium,* two of *Streptomyces* spp.) and 19 were already evaluated.

Six notifications, corresponding to six TUs, were evaluated for possible QPS status; two of these (*Akkermansia muciniphila* and *Galdieria sulphuraria*) for the first time. *Clostridium butyricum, Corynebacterium ammoniagenes, Pseudomonas chlororaphis* and *Komagataella pastoris* were re-assessed because the recent notifications related to a different intended use or because an update was requested in relation to the new mandate.

- *Akkermansia muciniphila* is not recommended for the QPS status due to safety concerns;
- *Galdieria sulphuraria* is not recommended for the QPS status due to a lack of body of knowledge regarding its use in the food and feed chain;
- *Clostridium butyricum* is not recommended for the QPS status because some strains contain pathogenicity factors; this TU is excluded for further QPS evaluation;
- *Pseudomonas chlororaphis* is not recommended for the QPS status due to a lack of body of knowledge;
- The QPS status with the qualification 'for production purposes only' of *Corynebacterium ammoniagenes* is confirmed;
- The QPS status with the qualification 'for enzyme production' of *Komagataella pastoris* is confirmed.

The genus *Lactobacillus* has been recently divided into 25 new genera (Zheng et al., 2020). As a consequence, the 37 species that are considered as QPS were reclassified into 13 genera. For maintenance of continuity within the QPS list, all the strains belonging to a previous designed *Lactobacillus* species will be transferred to the new species. Both the previous and new names will be retained.

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1. Introduction

The qualified presumption of safety (QPS) approach was developed by the EFSA Scientific Committee to provide a generic concept for risk assessment within the European Food Safety Authority (EFSA) for microorganisms intentionally introduced into the food chain, in support of the respective Scientific Panels and Units in the frame of market authorisations, requiring an EFSA safety assessment (EFSA, 2007). The list, first established in 2007, has been continuously revised and updated. Each 6 months a Panel Statement is published. These Panel Statements include the results of the assessment of the relevant new papers related to the TUs with QPS status. They also contain the assessment of newly arrived TUs to the EFSA Units on Feed, Food Ingredients and Packaging (FIP), Nutrition, Pesticides and Genetically Modified Organisms (GMO). After 3 years, a QPS opinion is published summarising the results of the Panel Statements published in that period.

1.1. Background and Terms of Reference as provided by EFSA

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

EFSA work on QPS activities started 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 WG consisting of members of the former Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Committee on Plants of the European Commission.[1] The document, made available for public consultation, proposed the introduction of the concept of Qualified Presumption of Safety (QPS), to be applied to selected groups of microorganisms. Microorganisms not considered suitable for QPS status would remain subject to a full safety assessment. EFSA management asked its Scientific Committee to consider whether the QPS approach could be applied to the safety assessment of microorganisms across the various EFSA scientific Panels. In doing so, the Committee was required to take into account the response of the stakeholders to the QPS approach. In its 2005 opinion (EFSA, 2005), the Scientific Committee concluded that the QPS approach could provide a generic assessment system that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed chain. Its introduction was intended to make more transparent and aid the consistency of approach across the EFSA Panels. Applications involving a taxonomic unit belonging to a species that falls within a QPS group do not require a full safety assessment.

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

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

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure; the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) was no longer carried out annually but over a 3-year period. From 2017, the search and revision of the possible safety concerns linked to those taxonomic units started instead to be carried out every 6 months through extensive literature searches (ELS). The update of the 2013 QPS list (EFSA BIOHAZ Panel, 2013) was done in 2016 (EFSA BIOHAZ Panel, 2017). From 2016 on, the QPS list (https://zenodo.org/record/1146566) and the list of notifications to EFSA (https://zenodo.org/record/3607183) are constantly updated, independent of the QPS opinion and available at the Knowledge Junction in Zenodo. The most recent QPS opinion (EFSA BIOHAZ Panel, 2020b summarises

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

the main results of the 3-year ELS on the QPS TUs, together with an update of the process for granting QPS Status. In the meantime, every 6 months a Panel Statement, compiling the assessments for a QPS status of the microbiological agents notified to EFSA requested by the Feed Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition Unit, the Pesticides Unit and the Genetically Modified Organisms (GMO) Unit, as well as the summary of each 6-month ELS exercise, has been produced and published. Each QPS Panel Statement contains the evaluations of the new notifications for microorganisms submitted for possible QPS status. It also contains the result of an Extensive Literature Search (ELS) performed every 6 months concerning possible new safety concerns related to the TUs already included in the QPS list. The data identified are used to decide whether any TU may or may not remain in the QPS list, and whether any qualifications need to be revised.

Establishing a QPS status is based on four pillars: the taxonomic grouping for which QPS is sought ("*taxonomic identification*"); whether sufficient information is available about the proposed group of organisms to conclude on human/animal exposure by food/ feed ("*body of knowledge*"); whether the grouping proposed contains known pathogens ("*safety*") and, finally, 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. 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 proved if the yeasts are to be used as viable organisms in the food or feed chains. The qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied to food and feed products based on microbial biomass (EFSA BIOHAZ Panel, 2020a,b).

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

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

Filamentous fungi, bacteriophages, Streptomycetes, Oomycetes, *Enterococcus faecium* and *Escherichia coli* are excluded from the QPS assessments based on an ambiguous taxonomic position or the possession of potentially harmful traits.

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

ToR 1: Keep updated the list of biological agents being notified in the context of a technical dossier to EFSA Units such as Feed, Pesticides, Food Ingredients and Packaging (FIP) and Nutrition, for intentional use directly or as sources of food and feed additives, food enzymes and plant protection products for safety assessment.

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

ToR 3: (Re) assess the suitability of new taxonomic units notified to EFSA for their inclusion in the QPS list. These microbiological agents are notified to EFSA and requested by the Feed Unit, the FIP Unit, the Nutrition Unit or by the Pesticides Unit.

2. Data and methodologies

2.1. Data

In reply to ToR 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.3607190, and in Appendix C Search strategies – see https://doi.org/10.5281/zenodo.3607193, respectively.

In reply to ToR 3, (re)assessment of the suitability of TUs notified within the time period covered by this Statement (from October 2019 to March 2020) is carried out. The literature review considered the identification, the body of knowledge, the potential safety concerns and the knowledge on acquired antimicrobial resistance (AMR). Relevant databases, such as PubMed, Web of Science, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched. More details on the search strategy, search keys and approach are described in Appendix A.

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

The taxonomy of the genus *Lactobacillus* has recently been revised (Zheng et al., 2020). The consequences for the QPS assessment and the QPS list are addressed in this Statement (see 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 biological agents being notified to EFSA. A total of 39 notifications were received between October 2019 and March 2020, of which 26 were for feed additives, 2 for food enzymes and food additives, 5 for novel foods, 5 for plant protection products and 1 for a genetically modified organism (Table 1).

In response to ToR 3, of the 39 notifications received, 33 were not included for QPS evaluation. Fourteen of them were excluded from QPS evaluation (five were notifications of filamentous fungi; five of *Escherichia coli*, two of *Enterococcus faecium,* two of *Streptomyces* spp.) and 19 were already evaluated.

Six notifications, corresponding to six TUs, were evaluated for possible QPS status, two of these (*Akkermansia muciniphila* and *Galdieria sulphuraria*) for the first time. *Clostridium butyricum, Corynebacterium ammoniagenes, Pseudomonas chlororaphis* and *Komagataella pastoris* were re-assessed because the recent notifications intended a different use or because an update was requested in relation to the new mandate.

Table 1: Notifications received by EFSA, per risk assessment area and by biological group, from October 2019 to March 2020

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[(b)]	Total
Biological group	**Already QPS**	**Excluded in QPS[(a)]**		
Feed additives	**16**	**8**	**2**	**26**
Bacteria	14	7	2	23
Filamentous fungi	0	1	0	1
Yeasts	2	0	0	2
Novel foods	**0**	**3**	**2**	**5**
Bacteria	0	2	1	3
Filamentous fungi	0	1	0	1
Protists/Algae	0	0	1	1
Yeasts	0	0	0	0
Plant protection products	**2**	**2**	**1**	**5**
Bacteria	2	0	1	3

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement[(b)]	Total
Biological group	**Already QPS**	**Excluded in QPS[(a)]**		
Filamentous fungi	0	2	0	2
Viruses	0	0	0	0
Food enzymes, food additives and flavourings	**1**	**1**	**0**	**2**
Bacteria	0	0	0	0
Filamentous fungi	0	1	0	1
Yeasts	1	0	0	1
Genetically modified organism	**0**	**0**	**1**	**1**
Yeasts	(1)	0	1	1
Total	**19**	**14**	**6**	**39**

QPS: qualified presumption of safety.
(a): The number includes five notifications of filamentous fungi, two of *Enterococcus faecium* (bacterium), five of *Escherichia coli* (bacterium) and two of *Streptomyces spp.,* all excluded from QPS evaluation.
(b): Six notifications corresponding to six TUs, one was last evaluated in 2015 (*Pseudomonas chlororaphis*), another one in 2014 (*Clostridium butyricum*), two already have a QPS with qualifications but were now notified for another purpose (*Corynebacterium ammoniagenes*, *Komagataella pastoris*) and two were evaluated for the first time (*Akkermansia muciniphila*, *Galdieria sulphuraria*).

2.2.2. Evaluating the use of Artificial Intelligence in the context of *Bifidobacterium, Lactobacillus* and *Lactococcus*

To explore the potential application of Artificial Intelligence (AI) for screening papers in the context of the QPS project, the performances of that technique were assessed against the previous batch of papers retrieved for the *Bifidobacterium*, *Lactobacillus* and *Lactococcus* taxonomic units.

To that purpose, the DistillerAI Toolkit included in the DistillerSR online software was used.

DistillerAI 'Preview and Rank' function was used mapping the papers from 'Title screening' to 'Article evaluation'. The SVM algorithm with 100% training set and 100% references to preview was used and the references were subsequently tagged. The algorithm was trained on the combined results of the two reviewers in the QPS rounds from 1 June 2016 to 31 December 2018. This is considered a conservative approach since, in the case of conflicts among the experts, the algorithm considers the paper as relevant.

The AI predicted screening results on the batch of papers corresponding to the period January–June 2019 were obtained and compared with the results obtained by the two reviewers in the real exercise.

The results of the exercise showed that:

- for *Bifidobacterium*, from a total number of 270 references in the batch, DistillerAI missed four papers that were considered as relevant by the experts at the end of the Title and Abstract step. These four papers were not considered relevant for QPS by the experts at the stage of Article evaluation.
- for *Lactobacillus*, from a total number of 620 references in the batch, DistillerAI missed four papers that were considered as relevant by the experts at the end of the Title and Abstract step. At the stage of Article evaluation, the experts did not consider relevant for QPS two of these four papers, while for the other two it was concluded that there was no information that could potentially lead to a change in the QPS status of the TU.
- for *Lactococcus,* from a total number of 165 references in the batch, DistillerAI did not miss any paper that was considered as relevant by the experts at the end of the Title and Abstract step.

Hence, the AI function did not miss any relevant paper for the three TUs considered.

On the basis of these results, it was decided to use the AI function in parallel with a human reviewer to screen the current batch of papers for these three TUs.

The results of the exercise showed that:

- for *Bifidobacterium*, from a total number of 253 references in the batch, DistillerAI missed one paper that was considered as relevant by the expert at the end of the Title and Abstract step. At the stage of Article evaluation, this paper was not considered as pertaining to the *Bifidobacterium* TU by the Experts.
- for *Lactobacillus*, from a total number of 661 references in the batch, DistillerAI missed two papers that were considered as relevant by one of the experts at the end of the Title and Abstract step. At the stage of Article evaluation, one of the experts judged one paper as 'not dealing with safety concerns' while the other one was assessed as 'not bringing information that could potentially lead to a change to the QPS status', since the microorganism was used as probiotics which do not fall under the remit of the QPS assessment.
- for *Lactococcus,* from a total number of 150 references in the batch, DistillerAI missed one paper that was considered as relevant by the experts at the end of the Title and Abstract step. At the stage of Article evaluation, this paper was assessed as 'not dealing with safety concerns' by the experts.

The use of AI resulted in a large number of potentially relevant papers at the end of the screening phase. On the other hand, the algorithm did not miss any paper identified as relevant by the human reviewers in the final assessment.

2.2.3. Use of Artificial Intelligence in the context of the yeast and *Bacillus* taxonomic units

The AI function alone was used for pre-screening of the large number of papers for the yeast and *Bacillus* taxonomic units, followed by a second screening by two experts of the articles retrieved by AI.

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

The aim of the ELS carried out in response to ToR 2 (review of the recommendations for the QPS list and specific qualifications) was to identify any publicly available studies reporting on safety concerns for humans, animals or the environment caused by QPS organisms since the previous QPS review (i.e. publications from July to December 2019).

For case reports of human infections or intoxications, additional important information is whether any negative impacts are confined to affected persons with conditions favouring opportunistic infections, e.g. immunosuppression, and whether transmission occurred through food or other routes (e.g. medical devices). Studies indicating the presence of virulence factors (e.g. toxins and enzymes that may contribute to the pathogenicity of the microorganism) in the TU are also reported as relevant for the identification of 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 favouring endocarditis, people in the extreme lower or upper age spectrum or other conditions which can lead to impairment of the immunological system, such as patients submitted to transplants, undergoing cancer therapy, with physical trauma or tissue damage or HIV patients. Moreover, gastrointestinal tract-related conditions with mucosal impairment can also be predisposing factors for infections. Previous use of the microorganisms as food supplements for humans was reported in many of these cases. The living microorganism used as a food supplement does not fall under the remit of the QPS assessment. Nevertheless, QPS assessment takes into consideration these reports, extracting relevant information whenever justified. For a detailed protocol of the process and search strategies, refer to Appendices B and C.

After removal of duplicates, 2,557 records were submitted to the *title screening* step, which led to the exclusion of 2,327 of them. The remaining 230 records were found eligible for the Title and abstract screening step, which led to the exclusion of 83 of these. Of the 147 articles that finally reached the Article evaluation step (full text), 37 were considered to be relevant for the QPS project and were further analysed.

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

Table 2: Flow of records by search strategy step

Species	Title screening step	Title/abstract screening step	Article evaluation step (screening for potential relevance)	Article evaluation step (identification of potential safety concerns)
	Number of articles retrieved			
Bacteria (total)	**2,159**	**156**	**100**	**7**
Bacillus	443	11	6	3
Bifidobacterium/ Carnobacterium divergens	253	65	48	1
Corynebacterium glutamicum	47	1	0	0
G-: Gluconobacter oxydans/Xanthomonas campestris	247	3	0	0
Lactobacilli	661	39	33	3
Lactococcus lactis	150	13	10	0
Leuconostoc/ Microbacterium imperiale	65	8	2	0
Oenococcus/Pasteuria nishizawae	35	0	0	0
Pediococci	178	9	0	0
Propionibacterium	25	0	0	0
Streptococcus thermophilus	55	7	1	0
Viruses (total)	**106**	**4**	**1**	**0**
Alphaflexiviridae	42	2	0	0
Baculoviridae	64	2	1	0
Yeasts	**292**	**70**	**46**	**29**
Total	**2,557**	**230**	**147**	**36**
Excluded	**2,327**	**83**	**111**	

3. Assessment

The search strategy (key words, literature databases, number of papers found) followed for the assessment of the suitability of TUs notified to EFSA for their inclusion in the updated QPS list (reply to ToR 3) can be found in Appendix A.

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

3.1.1. Bacteria

3.1.1.1. *Clostridium butyricum*

A new evaluation of *Clostridium butyricum* was made because an update was requested in relation to the new QPS mandate. *C. butyricum* was considered as unsuitable for QPS in 2008, 2011 and 2014 assessments because some strains can produce botulinum toxin E (EFSA, 2008; EFSA BIOHAZ Panel, 2011, 2014).

Identity

Clostridium butyricum is a valid taxonomic species with standing in nomenclature. It is a Gram-positive, sporulating, strictly anaerobic bacterium, able to produce butyric acid.

Body of knowledge

C. butyricum occurs in a variety of environments and is a common human and animal gut commensal bacterium. In recent years, several papers describing the beneficial effects of some strains of *C. butyricum* as probiotics in animals and humans have been published (Cassir et al., 2016) and a single strain has been assessed by EFSA as a feed additive (EFSA BIOHAZ Panel, 2014). This species has also been studied for use in biotechnological processes, such as dechlorination of trichloroethene (Lo et al., 2020), as well as the production of hydrogen (Ortigueira et al., 2019) and butyrate (Detman et al., 2019).

Safety concerns

Some strains of *C. butyricum* are able to form botulinum neurotoxin type E (BoNT/E) (Hauser et al., 1992; Peck, 2009). Toxigenic strains of this species are responsible for infant botulism (Fenicia et al., 1999; Abe et al., 2008) and can be involved in food-borne intoxications. The gene coding for botulinum neurotoxin type E was detected only in a minority of *C. butyricum* strains (Hauser et al., 1992). The genetic locus coding for BoNT/E is generally harboured by megaplasmids (bigger than 500 Kb) as also confirmed by WGS (Halpin et al., 2017). *C. butyricum* has been identified as an aetiological cause of necrotising enterocolitis in preterm neonates (Cassir et al., 2016; Schönherr-Hellec et al., 2018; Hosny et al., 2019a,b) and in adults (Sato et al., 2018). The strains isolated from necrotising enterocolitis harbour four genes encoding polypeptides similar to haemolysins (Cassir et al., 2016). An additional concern is indicated by one report of bacteraemia in a drug addict who very likely injected himself with a drug contaminated with *C. butyricum* (Gardner et al., 2008). Occasionally, an enterotoxin-producing *C. butyricum* was associated with antibiotic-associated diarrhoea (Kwok et al., 2014).

Antimicrobial resistance aspects

Acquired resistance to beta-lactams (due to b-lactamase production), tetracyclines (*tet* genes), macrolides (*erm* genes) and clindamycin (*lmrB*) has been reported (Ferraris et al., 2010).

Conclusions on a recommendation for the QPS list

The information collected reveals that some strains can harbour pathogenicity factors. Therefore, *C. butyricum* is not recommended for the QPS list, confirming the previous conclusion on this species attained in 2008, 2011 and 2014.

Since the inappropriateness of granting a safety status to the species *C. butyricum* has been recognised in several EFSA Opinions (EFSA, 2008; EFSA BIOHAZ Panel, 2011, 2014), the Panel confirms the exclusion of this species from future QPS evaluations.

3.1.1.2. *Corynebacterium ammoniagenes*

A new evaluation of *Corynebacterium ammoniagenes* was made following its notification as a sensory additive in feed. It was recently evaluated (EFSA BIOHAZ Panel, 2019) and included in the QPS list with the qualification 'for production purposes only'.

Identity

C. ammoniagenes is a species with standing in nomenclature. It is a Gram-positive, non-spore forming, non-motile, rod-shaped, facultatively anaerobic bacterium.

Body of knowledge

It is widely used for the industrial production of nucleotides, and its use as single-cell protein diets in shrimp, pigs and chicken has been reported (Wang et al., 2013; An et al., 2018; Hamidoghli et al., 2018), without any negative effects on blood, bone characteristics or meat quality (An et al., 2018). Additionally, the use of this TU for riboflavin synthesis was reported (Koizumi et al., 2000). It has recently been used for the production of riboflavin and related cofactors using whole-cell biocatalytic processes (Liu et al., 2020).

No information about the use of viable cells in food or feed was found in the scientific literature.

Safety concerns

No additional information was found in relation to the pathogenicity of the organism.

Antimicrobial resistance aspects

No additional information was found in relation to antimicrobial resistance.

Conclusions on a recommendation for the QPS list

The QPS status of *C. ammoniagenes* is confirmed with the qualification 'for production purposes only'.

3.1.1.3. *Pseudomonas chlororaphis*

A new evaluation of Pseudomonas chlororaphis was made because an update was requested in relation to the new QPS mandate. *P. chlororaphis* was considered as unsuitable *for* QPS in 2009 and 2013 (EFSA BIOHAZ Panel, 2009, 2013)

Identity

Pseudomonas chlororaphis is a valid species name with standing in nomenclature (Johnson and Palleroni, 1989). It is a Gram-negative strictly aerobic flagellated rod. The species contains four subspecies *P. clororaphis* subsp. *chlororaphis,* subsp. *aureofaciens,* subsp. *aurantiaca* (Peix et al., 2007) and subsp. *piscium* (Burr et al., 2010). *P. chlororaphis* strains have been isolated from the wider environment but also in association with plants and fish intestines. It is closely related to *P. protegens* which was also isolated from the plant rhizosphere (Ramette et al., 2011).

Body of knowledge

P. chlororaphis is typically an aerobic heterotroph, but has also been shown to perform denitrification within the rhizosphere, thus having biogeochemical significance in terms of producing dinitrogen gas from nitrate (Palleroni, 2005). It is mesophilic with an ideal growth temperature range between 20°C and 28°C and grows best around a pH of 6.3–7.5 (EFSA BIOHAZ Panel, 2015).

P. chlororaphis strains are used as biocontrol agents due to their complex interactions with plant metabolism (Ciancio et al., 2016). Strains are described to produce molecules with antifungal activity such as phenazines (Mercado-Blanco and Bakker, 2007), with antibacterial activity (Dorosky et al., 2018) and with insecticidal activity (Anderson et al., 2018). Also, the ability to colonise the plant and stimulate the root system, increasing nutrient uptake, has been reported; a feature linked to the biosynthetic gene cluster for indole-3-acetic acid metabolism (Flury et al., 2016). *P. chlororaphis* has also been used in industrial acrylamide production, producing nitrile hydrases that hydrate nitriles to amides (Yamada and Kobayashi, 1996).

Comparative genome analysis indicates the absence of genes coding for plant virulence factors such as those located in the genome islands PAPI-1 and PAPI-2, the presences of genes required for the biosynthesis of phytotoxins (syringomycin, syringopeptine, coronatine) and exoenzymes (cellulases, pectinases and pectin lyases) involved in the degradation of plant cell walls (EFSA BIOHAZ Panel, 2015).

Safety concerns

P. chlororaphis has only rarely been reported as a cause of human infection. Montaña et al. (2018) recovered a *P. chlororaphis* strain resistant to several beta-lactam antibiotics from a respiratory tract and anal mucous sample from a 63-year-old man suffering from aspirate pneumonia and being HIV positive.

A metallo-beta-lactamase-producing *P. chlororaphis* was also reported from a blood culture of a 59-year-old male who suffered from a prolonged febrile syndrome and was suspected of having endocarditis (Faccone et al., 2014). The strain was identified based on partial 16S rDNA gene sequence analysis (803 bp), leaving some doubts about its identity.

Antimicrobial resistance aspects

No relevant further information was found in relation to antimicrobial resistance.

Conclusions on a recommendation for the QPS list

P. clororaphis is not recommended for the QPS list due to a lack of body of knowledge.

3.1.2. Yeasts

3.1.2.1. *Komagataella pastoris*

A new evaluation of *Komagataella pastoris* was made following its notification as a sensory additive. The anamorph of *K. pastoris* is not described. It was recently evaluated (EFSA BIOHAZ Panel, 2020a,b) and included in the QPS list. The previous name of this species was *Pichia pastoris.*

Identity

K. pastoris is a species with standing in nomenclature.

Body of knowledge

A search with *Komagataella pastoris* and *Pichia pastoris* was conducted including the last 10 years. None of the articles referred to the use of this TU as viable cells or uses other than enzyme production.

Safety concerns

No additional information was found in relation to pathogenicity of the organism.

Antimicrobial resistance aspects

No additional information was found in relation to antimicrobial resistance.

Conclusions on a recommendation for the QPS list

No references reporting possible concerns for human or animal safety, or other related aspects were identified. Therefore, the QPS status does not change. The qualification is unchanged, QPS only applies when the species is used for enzyme production because of a lack of knowledge for other uses.

3.2. Taxonomic units to be evaluated for the first time

3.2.1. Bacteria

3.2.1.1. *Akkermansia muciniphila*

Identity

Akkermansia muciniphila is a valid species with standing in nomenclature. It belongs to the Phylum Verrucomicrobia (Oren and Garrity, 2017). The type strain is MucT (Derrien et al., 2004). Its GC-content is 55.8%, as determined through whole genome sequencing (Hahnke et al., 2016). *A. muciniphila* is a Gram-negative, strictly anaerobic, non-motile bacterium that grows optimally in media with mucin but that can also be propagated on a limited number of sugars. The genomes of 23 *Akkermansia* spp. strains (Xing et al., 2019) and of 39 strains of *A. muciniphila* (Guo et al., 2017) were compared and revealed phylogenetic and phenotypical relationships, suggesting that *Akkermansia* is a monophyletic genus.

Body of knowledge

A. muciniphila is abundant in the colon of humans and animals but has also been detected in human milk samples (Collado et al., 2007; Geerlings et al., 2018). It has been associated with health promotion (Gomez-Gallego et al., 2016; Derrien et al., 2017) because its prevalence appears to be decreased in gut microbiota samples of people suffering from the 'metabolic syndrome', which includes obesity, diabetes, cardiometabolic disease and low-grade inflammation. In addition, *A. muciniphila* is postulated to increase the efficacy of cancer immunotherapy and to ameliorate the symptoms of alcohol-related liver disease (Grander et al., 2018; Zheng et al., 2019). These data prompted research aiming to the use of *A. muciniphila* as a probiotic organism (Gomez-Gallego et al., 2016; Zhang et al., 2019).

Safety concerns

Depommier et al. (2019) performed a human volunteer study with a daily oral administration of 10^{10} *A. muciniphila*, either alive or pasteurised, to 32 overweight/obese insulin-resistant volunteers for 3 months. The administration was demonstrated to be safe and well tolerated for both live and pasteurised cells, while a decrease in total plasma cholesterol and insulinaemia was observed. This study confirmed the results of a previous study of administration for 2 weeks of live and pasteurised *A. muciniphila* to humans (Plovier and Cani, 2017) and a collection of other reports on safety upon dispensation to rodents (see Gomez-Gallego et al., 2016, for a comprehensive review). However, *A. muciniphila* might contribute to progression of neural diseases, possibly through its ability to degrade mucin, which would induce local inflammation, increase of gut permeability, loss of mucosal integrity (Radisavljevic et al., 2018) and, eventually, endotoxaemia. The prevalence of *A. muciniphila* has been found to be increased in Parkinson's disease (Hill-Burns et al., 2017; Heintz-Buschart et al., 2018), multiple sclerosis (Berer et al., 2017; Cekanaviciute et al., 2017), Alzheimer's disease (Vogt et al.,

2017; Zhuang et al., 2018) and autism spectrum disorders (Finegold et al., 2010; De Angelis et al., 2013), although for autism, depletion of the microorganism was reported as well (Wang et al., 2011).

Antimicrobial resistance aspects

Whole genome analysis of 39 *A. muciniphila* strains revealed the presence of several antimicrobial resistance genes (*sul2* for sulfonamides and *aph(6)-Id* and *aph(3")-Ib* for aminoglycosides resistance) (Guo et al., 2017).

Conclusions on a recommendation for the QPS list

A. muciniphila cannot be recommended for the QPS list due to safety concerns.

3.2.2. Protists/Algae

3.2.2.1. *Galdieria sulphuraria*

Identity

Galdieria sulphuraria is a mixotrophic, unicellular, red microalgae (Graziani et al., 2013) from the Cyanidiophyceae class, order Cyanidiales, family Galdieriaceae, genus *Galdieri*.[2] It is a valid taxonomic species.

Body of knowledge

G. sulphuraria has so far only been isolated from volcanic soils; it is thermotolerant (up to 56°C), acidophilic (down to pH 0), and is more resistant to salt, arsenic and toxic metals than most other microorganisms. Its genome harbours up to 5% of genes most likely acquired through horizontal gene transfer, probably contributing to its adaptation to extreme habitats (Rossoni et al., 2019). Its use has been explored for different biotechnological applications: e.g. for production of energy (Cheng et al., 2019), bioactive food ingredients (thermotolerant phycocyanin and phytochemicals, Eriksen, 2008; Sorensen et al., 2013; Sloth et al., 2017; Massa et al., 2019; Rahman et al., 2019), carotenoids (Graziani et al., 2013), highly branched glycogen (Martinez-Garcia et al., 2017) and for wastewater treatment (Selvaratnam et al., 2014; Henkanatte-Gedera et al., 2015; Ju et al., 2016; Cheng et al., 2020). Besides cultivation in bioreactors, also cultivation in open pond systems, wastewater and waste streams from the food industry have been explored (Hirooka and Miyagishima, 2016; Sloth et al., 2017; Massa et al., 2019). Information on human exposure is limited.

The body of knowledge concerns mainly the description of the characteristics of the strains, the genetic basis of their adaptation to extreme conditions and their potential in biotechnological applications. Modeste et al. (2019) performed a safety study of the dried biomass of a particular strain, using an Ames bacterial reverse mutation test, an *in vitro* mammalian cell micronucleus test and an oral toxicity study in rats. No toxicity was observed and the no observed adverse effect level (NOAEL) was established as 5,000 mg/kg per day.

Safety concerns

No reports in relation to safety concerns were found

Antimicrobial resistance aspects

Not applicable

Conclusions on a recommendation for the QPS list

G. sulphuraria is not recommended for the QPS status due to a lack of body of knowledge regarding its use in the food or feed chain.

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

The summaries of the evaluation of the possible safety concerns for humans, animals or the environment described and published since the previous ELS exercise (i.e. articles published between July and December 2019, 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.

[2] https://www.gbif.org

3.3.1. Gram-positive non-sporulating bacteria

3.3.1.1. *Bifidobacterium* spp.

A search for papers potentially relevant for the QPS evaluation of *Bifidobacterium* species and *Carnobacterium divergens*[3] provided 253 references. The analysis of their titles left 65 articles; the rest were discarded because they did not deal with safety concerns. Forty-eight articles were found relevant for the QPS evaluation of *Bifidobacterium* spp. at the level of title and abstract screening. Forty-seven of these articles were not in English or not dealing with safety concerns. One article was considered for further evaluation (Pruccoli et al., 2019). The paper described a case of bacteraemia in a 5-month child with a diagnosis of heart disease. Although the composition of the probiotics that the child received was checked and revealed the presence of *Bifidobacterium longum*, the bacterial isolation from the patients referred only to a positive blood culture for *Bifidobacterium* spp. without further identification and specifications.

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

Carnobacterium divergens

A search for papers potentially relevant for the QPS evaluation of QPS *Bifidobacterium* species and *Carnobacterium divergens*[13] provided 253 references. The analysis of their titles left 65 articles; the rest were discarded because they did not deal with safety concerns. No article was considered relevant at the level of title and abstract screening for this TU. Consequently, the QPS status of *C. divergens* is not changed.

3.3.1.2. *Corynebacterium glutamicum*

A search for papers potentially relevant for the QPS evaluation of *Corynebacterium glutamicum* provided 47 references. One paper reached the level of title and abstract screening but did not reach full text evaluation. Therefore, no new safety concerns were identified and the QPS status of *C. glutamicum* is not changed.

3.3.1.3. *Lactobacillus* spp.

The search for papers on the 37 *Lactobacillus* spp. included in the QPS list that might raise safety concerns provided a total of 661 references. Title screening left 39 references for abstract inspection, which reduced their number to 33. Full paper review allowed the recognition of three articles dealing with safety concerns. Two of them dealt with *L. rhamnosus* infections linked to probiotic consumption (Cavicchiolo et al., 2019; Yelin et al., 2019) while the third described a prosthetic aortic valve endocarditis that was associated with *L. paracasei* in a patient with no history of probiotic intake (Ajam et al., 2019). The ascription of this last case is doubtful; the organism was isolated from blood and identified 'by culture' with no further specification. Moreover, culture implies phenotypical identification, which is known not to be reliable for lactobacilli. All three papers dealt with infections that occurred in patients with underlying illnesses that probably compromised their immunological responses. The case described in the paper by Ajam et al. (2019) was a 75-year-old woman suffering from the Birt–Hogg–Dube syndrome, which is associated with skin and kidney tumours and lung cysts development that predispose for pneumothorax. In addition, she had suffered an aortic stenosis 9 years previously that needed to be replaced by the prosthetic valve that became colonised. The paper from Cavicchiolo et al. (2019) describes bacteraemia in three premature babies due to *L. rhamnosus*. One of them, a girl born at 31 weeks gestation and weighing 770 g at birth, had been fed with a probiotic supplement from her third day onwards. The two other affected patients were two boys, admitted to the same open intensive care unit, but not having received the probiotic supplement (no details on these two boys are provided, other than stating that all three were presented with central catheters). All of them developed bacteraemia due to a *L. rhamnosus* strain that was indistinguishable from the lactobacilli in the probiotic supplement. Finally, Yelin et al. (2019) presented a retrospective study relating probiotic use with *Lactobacillus* infection in ICU patients, having found that about 1% of these developed bacteraemia by a *Lactobacillus* strain that was identical to that included in the probiotic preparation based on WGS comparison.

Case reports related to the administration of living microorganisms used as probiotics are reported but do not fall under the remit of the QPS assessment, as explained in Section 2.2.4.

[3] These two TUs were searched together for practical reasons.

The ELS did not identify any information that would change the status of the *Lactobacillus* species included in the QPS list.

3.3.1.4. *Lactococcus lactis*

A search for papers potentially relevant for the QPS evaluation of *Lactococcus lactis* provided 150 references. Thirteen papers qualified for screening at the title/abstract level. Three were discarded and the remaining 10 papers were assessed as full texts. None of them dealt with safety concerns.

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

3.3.1.5. *Leuconostoc* spp.

A search for papers potentially relevant for the QPS evaluation of QPS *Leuconostoc* species and *Microbacterium imperiale*[14] provided 65 references. The analysis of their title/abstracts left eight articles; six were discarded because they did not deal with safety concerns. Two articles reached full text evaluation, but one was dealing with another TU and the other was not available in English. Consequently, the QPS status of *Leuconostoc* spp. is not changed.

3.3.1.6. *Microbacterium imperiale*

A search for papers potentially relevant for the QPS evaluation of QPS *Leuconostoc* species and *Microbacterium imperiale*[14] provided 65 references. The analysis of their title/abstracts left eight articles; six were discarded because they did not deal with safety concerns. No article was considered relevant for this TU. Consequently, the QPS status of *M. imperiale* is not changed.

3.3.1.7. *Oenococcus oeni*

A search for papers potentially relevant for the QPS evaluation of *Oenococcus oeni* and *Pasteuria nishizawae*[14] (see Section 3.3.2.3) provided 35 references. The analysis of their title/abstracts left no article for consideration. Consequently, the QPS status of *O. oeni* is not changed.

3.3.1.8. *Pediococcus* spp.

A search for papers potentially relevant for the QPS evaluation of *Pediococcus* spp. provided 178 references. The analysis of their title/abstracts left nine articles for the evaluation phase which were not related to this TU or not dealing with safety concerns. No article reached the full text evaluation stage. Consequently, the QPS status of *Pediococcus* spp. is not changed.

3.3.1.9. *Propionibacterium*

A search for papers potentially relevant for the QPS evaluation of *Propionibacterium* spp. provided 25 references. Following the analysis of their title/abstracts, no articles were selected for the full article evaluation phase; thus, no new safety concerns were identified. Consequently, the QPS status of *Propionibacterium* spp. is not changed.

3.3.1.10. *Streptococcus thermophilus*

A search for papers potentially relevant for the QPS evaluation of *Streptococcus thermophilus* provided 55 references. The analysis of their titles left seven articles for title and abstract screening. One reached the evaluation phase but was not dealing with safety concerns. Therefore, the QPS status of *S. thermophilus* is not changed.

3.3.2. Gram-positive spore-forming bacteria

3.3.2.1. *Bacillus* spp.

A search for papers potentially relevant for *Bacillus* spp. and *Geobacillus stearothermophilus* provided 924 references. The AI analysis left 443 articles. The analysis of their titles by two experts left 11 articles for the title/abstracts phase, and from these six articles passed to the full text phase for further analysis. For one reference, no full paper was retrieved, and two papers did not deal with safety concerns. Three papers had serious methodological problems in relation to strain identification and source attribution and were not food related (Al-Tulaibawi, 2019; Nadăş et al., 2019; Thanganadar Appapalam et al., 2019). Al-Tulaibawi (2019) described the isolation of *B. subtilis* from a urinary tract infection of diabetic patients; Thanganadar Appapalam et al. (2019) the isolation of *B. subtilis* from diabetic foot ulcers; Nadăş et al. (2019) the isolation of *B. pumilus* from dogs with conjunctivitis.

The ELS did not come up with any information that would change the status of the *Bacillus* species included in the QPS list and confirmed the qualification 'absence of cytotoxicity'.

3.3.2.2. *Geobacillus stearothermophilus*

A search for papers potentially relevant *Bacillus* spp. and *Geobacillus stearothermophilus*[14] provided 924 references. The AI analysis left 443 articles. The analysis of their titles by two experts left 11 articles, for six of which the full texts were analysed. None dealt with this species. Consequently, the QPS status *G. stearothermophilus* is not changed.

3.3.2.3. *Pasteuria nishizawae*

A search for papers potentially relevant for the QPS evaluation of *Oenococcus oeni* and *Pasteuria nishizawae*[14] provided 35 references. The analysis of their title/abstracts left no article for consideration. Consequently, the QPS status of *P. nishizawae* is not changed.

3.3.3. Gram-negative bacteria

3.3.3.1. *Gluconobacter oxydans*

A search for papers potentially relevant for the QPS evaluation of *Gluconobacter oxidans* and *Xanthomonas campestris*[14] provided 247 references. The analysis of their titles left three articles, which were discarded following the title and abstract screening. No paper reached the final selection phase for this TU. Consequently, the QPS status of *G. oxydans* is not changed.

3.3.3.2. *Xanthomonas campestris*

A search for papers potentially relevant for the QPS evaluation of *Gluconobacter oxidans* and *Xanthomonas campestris*[14] provided 247 references.

The analysis of their titles left three articles which were discarded in the title and abstract screening.

The analysis of their titles left one article. No paper reached the evaluation phase for this TU. Consequently, the QPS status of *X. campestris* is not changed.

3.3.4. Yeasts

The ELS searches for potentially relevant studies on the yeasts with QPS status provided 1,253 references. The AI analysis left 292 articles. After title screening by two experts, 70 studies remained for the title/abstract phase, and from these 46 articles passed to the full article appraisal.

None of the studies that reached the full article evaluation phase concerned the QPS yeast species ***Candida cylindracea*, *Hanseniaspora uvarum*, *Komagataella pastoris*, *Komagataella phaffi*, *Ogataea angusta*, *Saccharomyces bayanus*, *Saccharomyces pastorianus*, *Schizosaccharomyces pombe*, *Xanthophyllomyces dendrorhous*** **and** ***Zygosaccharomyces rouxii*.** Consequently, their QPS status does not change.

3.3.4.1. *Debaryomyces hansenii*

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

A total of nine articles reached the final stage and were evaluated. For two of them, no safety concerns were identified. Chen et al., 2019 performed a statistical study about the reported candidiasis cases with patients with haematological malignancies and Hamzavi et al., 2019 described the presence of *D. hansenii* in hospitalised persons although fungal infection had not been diagnosed. Seven reports include safety concerns for humans; however, four of them had limitations in the species identification (de Paula Menezes et al., 2018; Ali et al., 2019; Alobaid and Khan, 2019; Bignoumba et al., 2019). Two of them presented retrospective studies (Taverna et al., 2019; Pandey et al., 2020) reporting *D. hansenii* among fungal isolates from hospitalised patients with underlying disease/immunosuppression. Finally, Ghazi et al. (2019) summarised epidemiological data regarding *Candida* infections in the Mediterranean area, including the presence of *D. hansenii*. The article did not include any new data, not evaluated in previous QPS evaluations.

In conclusion, the literature update did not identify any information that would change the QPS status of *D. hansenii*.

3.3.4.2. *Kluyveromyces lactis*

The anamorph name of *K. lactis* is *Candida spherica*.

One clinical study reached the full article evaluation phase (Bignoumba et al., 2019). However, the paper had limitations in the methods for species identification. The literature update thus did not identify any information that would change the QPS status.

3.3.4.3. *Kluyveromyces marxianus*

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

A total of 11 studies reached the full article evaluation phase. Three of these had limitations in the species identification (de Paula Menezes et al., 2018; Rodrigues et al., 2019; Prigitano et al., 2020). One did not report a safety concern, since the hospitalised persons from which *K. marxianus* was isolated had not been diagnosed with fungal infection (Hamzavi et al., 2019). Tóth et al. (2019) reported the response of clinical isolates of *K. marxianus* to a novel echinocandin, rezafungin. Five retrospective studies of clinical isolate collections, often from specific hospitals, reported opportunistic infections in immunocompromised patients, or nosocomial infections in hospitalised patients with underlying disease (Hamzehee et al., 2019; Maheronnaghsh et al., 2019; Nemer et al., 2019; Önal et al., 2019; Pandey et al., 2020). The numbers of isolates confirmed as *K. marxianus* were low, between one and three, corresponding to between < 1% and 8% of the total number of fungal isolates obtained. Seth-Smith et al. (2019) reported bloodstream infection by *K. marxianus* in a male patient diagnosed with acute myeloid leukaemia and undergoing chemotherapy. They hypothesised that consumption of dairy products might have caused the infection, since the patient had regularly consumed fermented dairy products and the single-nucleotide polymorphism phylogenetic analysis including the 24 strains available in Genbank showed that the isolate was most similar to some dairy strains of *K. marxianus*. However, it was not unequivocally shown that the infection was food-borne.

In conclusion, the literature update did not identify any information that would change the QPS status of *K. marxianus*.

3.3.4.4. *Cyberlindnera jadinii*

The anamorph name of *Cyberlindnera jadinii* is *Candida utilis*. The previous official name of *Lindnera jadinii* was changed to *C. jadinii* (Minter, 2009).

Four studies reached the full article evaluation phase. Three of these were clinical studies but had limitations in the methods used for species identification (O'Reilly et al., 2019; Rodrigues et al., 2019; Prigitano et al., 2020). Park et al. (2019) did not indicate safety concerns but showed that traditional identification with biochemical growth tests may misidentify the opportunistic species *Cyberlindnera/Lindnera fabianii* as *L. jadinii*. Thus, earlier clinical studies relying on growth tests might have overestimated the occurrence of *L. jadinii*.

The literature update did not identify any information that would change the QPS status.

3.3.4.5. *Saccharomyces cerevisiae*

Four studies have reported safety concerns for humans. In three of them (Chakravarty et al., 2019; Gupta et al., 2019; Lee and Jang, 2019), no information about the identification method is described. Daliri et al. (2019) described information that has been described by other authors, that *S. cerevisiae* (var *boulardii*), may in rare cases cause infection when administered as a probiotic to patients with gastrointestinal diseases. Raghavan et al. (2019) provided a general review on *S. cerevisiae* with no new relevant information in relation to QPS status.

In conclusion, the literature update did not identify any information that would change the QPS status of *S. cerevisiae*.

3.3.4.6. *Wickerhamomyces anomalus*

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

Five studies reached the full article evaluation phase. One clinical case study (Marwah et al., 2019) could not be properly evaluated since it did not report the methods used for species identification. Three retrospective studies (Liu et al., 2019; Xu et al., 2019; Pandey et al., 2020) reported *W. anomalus* among fungal isolates from hospitalised patients with underlying disease/immunosuppression, with a prevalence of 6–13% of the isolates. Park et al. (2019) showed that traditional species identification with biochemical growth tests may misidentify the opportunistic species *Cyberlindnera/Lindnera fabianii* as *W. anomalus*.

Thus, earlier clinical studies relying on morphological or growth test identification might have overestimated the prevalence of *W. anomalus*.

The literature update did not identify any information that would change the QPS status.

3.3.4.7. *Yarrowia lipolytica*

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

Four studies reached the full article evaluation phase. One clinical (Bignoumba et al., 2019) and one veterinary study (Tesfaye et al., 2019) had limitations regarding methods for species identification. Zieniuk and Fabiszewska (2018) present a review and synthesis of the possible pathogenicity, epidemiology and antifungal drugs susceptibility of this yeast that may be associated with opportunistic infections. Finally, Liu et al. (2019) found in a retrospective study that one isolate (prevalence 3%) from hospitalised patients with candidaemia was *Y. lipolytica*.

No new information was found that would change the QPS status of *Y. lipolytica*.

3.3.5. Viruses used for plant protection

3.3.5.1. *Alphaflexiviridae*

A search for papers potentially relevant for the QPS evaluation of viruses of the *Alphaflexiviridae* and *Potyviridae* [14] provided 42 references. No paper dealing with *Alphaflexiviridae* reached the final selection phase; thus, no new safety concern was found.

3.3.5.2. *Potyviridae*

No paper dealing with *Potyviridae* reached the final selection phase; thus, no new safety concern was found.

3.3.5.3. *Baculoviridae*

A search for papers potentially relevant for the QPS evaluation of *Baculoviridae* provided 64 references. One article reached the final selection phase, but the full text was not in English. The ELS did not reveal any information that would change the current QPS status of any of the above virus families.

3.4. Taxonomic revision of the *Lactobacillus* genus for the QPS assessment and the QPS list

The genus *Lactobacillus* has been recently divided into 25 new genera, based on phylogenetic, phenotypical and habitat differences shown by its 261 member species, while their species names are retained (Zheng et al., 2020). As a consequence, the 37 species that are considered as QPS became classified into 13 genera, of which 10 species are now included in the new genus *Lactobacillus* (homonym to the previous genus appellation), five belong to the genus *Limosilactobacillus*, four *to Lentilactobacillus*, three to each of *Ligilactobacillus*, *Lacticaseibacillus* and *Lactiplantibacillus*, two to *Companilactobacillus* and *Latilactobacillus* and one to each of the genera *Levilactobacillus*, *Secundilactobacillus*, *Loigolactobacillus*, *Fructilactobacillus* and *Lapidilactobacillus*. In the following table, the previous and new designations of the QPS species are presented, following the alphabetical order of their specific names.

'Classical' denomination	'Updated' denomination
Lactobacillus acidophilus	*Lactobacillus acidophilus*
Lactobacillus alimentarius	*Companilactobacillus alimentarius*
Lactobacillus amylolyticus	*Lactobacillus amylolyticus*
Lactobacillus amylovorus	*Lactobacillus amylovorous*
Lactobacillus animalis	*Ligilactobacillus animalis*
Lactobacillus aviarius	*Ligilactobacillus aviarius*
Lactobacillus brevis	*Levilactobacillus brevis*
Lactobacillus buchneri	*Lentilactobacillus buchneri*
Lactobacillus casei	*Lacticaseibacillus casei*
Lactobacillus collinoides	*Secundilactobacillus collinoides*
Lactobacillus coryniformis	*Loigolactobacillus coryniformis*

'Classical' denomination	'Updated' denomination
Lactobacillus crispatus	*Lactobacillus crispatus*
Lactobacillus curvatus	*Latilactobacillus curvatus*
Lactobacillus delbrueckii	*Lactobacillus delbrueckii*
Lactobacillus dextrinicus	*Lapidilactobacillus dextrinicus*
Lactobacillus diolivorans	*Lentilactobacillus dioliovorans*
Lactobacillus farciminis	*Companilactobacillus farciminis*
Lactobacillus fermentum	*Limosilactobacillus fermentum*
Lactobacillus gallinarum	*Lactobacillus gallinarum*
Lactobacillus gasseri	*Lactobacillus gasseri*
Lactobacillus helveticus	*Lactobacillus helveticus*
Lactobacillus hilgardii	*Lentilactobacillus hilgardii*
Lactobacillus johnsonii	*Lactobacillus johnsonii*
Lactobacillus kefiranofaciens	*Lactobacillus kefiranofaciens*
Lactobacillus kefiri	*Lentilactobacillus kefiri*
Lactobacillus mucosae	*Limosilactobacillus mucosae*
Lactobacillus panis	*Limosilactobacillus panis*
Lactobacillus paracasei	*Lacticaseibacillus paracasei*
Lactobacillus paraplantarum	*Lactiplantibacillus paraplantarum*
Lactobacillus pentosus	*Lactiplantibacillus pentosus*
Lactobacillus plantarum	*Lactiplantibacillus plantarum*
Lactobacillus pontis	*Limosilactobacillus pontis*
Lactobacillus reuteri	*Limosilactobacillus reuteri*
Lactobacillus rhamnosus	*Lacticaseibacillus rhamnosus*
Lactobacillus sakei	*Latilactobacillus sakei*
Lactobacillus salivarius	*Ligilactobacillus salivarius*
Lactobacillus sanfranciscensis	*Fructilactobacillus sanfranciscensis*

To maintain continuity within the QPS list, all the strains belonging to a previous designed *Lactobacillus* species will be transferred to the new species. Both the previous and new names will be retained.

4. Conclusions

ToR 1: *Keep updated the list of biological agents being notified, in the context of a technical dossier to EFSA Units (such as Feed, Food Ingredients and Packaging, Nutrition, Pesticides, Genetically Modified Microorganisms), for intentional use in feed and/or food or as sources of food and feed additives, enzymes, plant protection products for safety assessment*:

- Between October 2019 and March 2020, the QPS list was updated with 39 notifications that were received by EFSA, of which 26 were for feed additives, two for food enzymes and food additives, five for novel foods, five for plant protection products and one for genetically modified organisms.

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 related to the QPS list, there were no results that justify removal of any TUs from the QPS list or changes in their respective qualifications.

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*:

- Of the 39 notifications received, 19 were related to TUs that already had QPS status and did not require further evaluation.

- Of the remaining 20 notifications, 14 were related to TUs excluded from QPS evaluation: five were notifications of filamentous fungi, five of *Escherichia coli,* two of *Enterococcus faecium,* two of *Streptomyces* spp. (one *Streptomyces aureofaciens* and one *Streptomyces lasaliensis*).
- Six notifications, corresponding to six TUs, were evaluated for possible QPS status, two of these (*Akkermansia muciniphila* and *Galdieria sulphuraria*) for the first time. *Clostridium butyricum, Corynebacterium ammoniagenes, Pseudomonas chlororaphis* and *Komagataella pastoris* were re-assessed because the recent notifications related to a different intended use or because an update was requested in relation to the new mandate.
    - *Akkermansia muciniphila* is not recommended for QPS status due to safety concerns;
    - *Galdieria sulphuraria* is not recommended for QPS status due to a lack of body of knowledge regarding its use in the food and feed chain;
    - *C. butyricum* is not recommended for QPS status because some strains contain pathogenicity factors; this species is excluded for further QPS evaluation;
    - *P. chlororaphis* is not recommended for QPS status due to a lack of body of knowledge;
    - The QPS status with the qualification 'for production purposes only' of *C. ammoniagenes* is confirmed;
    - The QPS status with the qualification 'for enzyme production' of *K. pastoris* is confirmed.
- The genus *Lactobacillus* has been recently divided into 25 new genera. As a consequence, the 37 species that are considered as QPS were reclassified into 13 genera. To maintain continuity within the QPS list, all the strains belonging to a previous designed *Lactobacillus* species will be transferred to the new species. The previous and new names will both be retained.

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Glossary

Anamorph name	Valid name of a fungus based on the asexual reproductive state (morphologically)
Antimicrobial compounds	Antibiotics, bacteriocins and/or small peptides with antimicrobial activity
Basonym name	The earliest validly published name of a Staxon Have the same type (specimen) and the same taxonomic rank

Synonymous name/Homotypic synonym	
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 (FEEDAP)
FIP	EFSA Food ingredients and packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
IJSEM	International Journal of Systematic and Evolutionary Microbiology
NOAEL	no observed adverse effect level
QPS	qualified presumption of safety
PPP	plant protection product
SCP	single cell protein
ToR	Terms of Reference
TU	taxonomic unit
WG	Working Group

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

A.1. *Clostridium butyricum*

PubMed; Clostridium butyricum AND toxi*: 40 hits

A.2. *Corynebacterium ammoniagenes*

A search was conducted using the taxonomic unit name for the last 5 years in WoS (core collection). The time frame of the literature search was restricted because this TU was re-assessed during this mandate. A total of 24 references were found and they were all screened.

A.3. *Pseudomonas chlororaphis*

PubMed; Pseudomonas chlororaphis: 365 hits.

A.4. *Komagataella pastoris*

A search was conducted including the last 10 years and it provided 142 references in PubMed with Komagataella pastoris and Pichia pastoris. The time frame of the literature search was restricted because this TU was re-assessed during this mandate.

A.5. *Galdieria sulphuraria*

PubMed; Galdieria sulphuraria: 86 hits; all screened.

A.6. *Akkermansia muciniphila*

Akkermansia muciniphila, (present in title), 160 hits.
Akkermansia muciniphila and pathogenic, 36 hits.
PubMed and Web of Science core collection.

Appendix B – Protocol for Extensive literature search (ELS), relevance screening and article evaluation for the maintenance and update of list of QPS-recommended biological agents (reply to ToR 2)

The protocol for extensive literature search (ELS) used in the context of the EFSA mandate on the list of QPS-recommended biological agents intentionally added to the food or feed (EFSA-Q-2020-00077) is available on the EFSA Knowledge Junction community on Zenodo, at: https://doi.org/10.5281/zenodo.3607190

Appendix C – Search strategies for the maintenance and update of list of QPS-recommended biological agents (reply to ToR 2)

The search strategies for each taxonomic unit (TU), i.e. the string for each TU and the search outcome, are available on the EFSA Knowledge Junction community on Zenodo at: https://doi.org/10.5281/zenodo.3607193

Appendix D – References selected from the ELS exercise as relevant for the QPS for searches from July to December 2019 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium

Pruccoli G, Silvestro E, Pace Napoleone C, Aidala E, Garazzino S and Scolfaro C, 2019. Are probiotics safe? Bifidobacterium bacteremia in a child with severe heart failure. Infez. Medicine, 27, 175–178.

Carnobacterium divergens

None.

Corynebacterium glutamicum

None.

Lactobacilli

Ajam M, Adam O, Yeddi A, Kahlid M, Shokr M and Afonso L, 2019. Prosthetic aortic valve endocarditis in a patient with birt-hogg-dube syndrome due to Lactobacillus Paracasei. Cardiology Research, 10, 245–248. https://doi.org/10.14740/cr901

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Lactococcus lactis

None.

Leuconostoc

None.

Microbacterium imperiale

None.

Oenococcus oeni

None.

Pediococci

None.

Propionibacterium

None.

Streptococcus thermophilus

None.

Gram-Positive Spore-forming Bacteria

Bacillus

Al-Tulaibawi N, 2019. Prevalence and sensitivity of bacterial urinary tract infection among adult diabetic patients in misan province, Iraq. Journal of Pure and Applied Microbiology, 13, 847–853. https://doi.org/10.22207/jpam.13.2.20

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Geobacillus stearothermophilus

None.

Pasteuria nishizawae

None.

Gram-negative bacteria

Gluconobacter oxydans

None.

Xanthomonas campestris

None.

Yeasts

Ali R, Hameed ZH, Hussain AF and Hamu A, 2019. Evaluation effectiveness of fluconazole and mirabilis jalapa extract against some pathological fungi. Biochemistry Cellular Archives, 19, 2467–2473. https://doi.org/10.35124/bca.2019.19.s1.2467

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Viruses used for plant protection

Alphaflexiviridae

None.

Potyviridae

None.

Baculoviridae

None.

Appendix E – The 2020 updated list of QPS Status recommended biological agents in support of EFSA risk assessments

The list of QPS status recommended biological agents (EFSA BIOHAZ Panel, 2020a,b) is being maintained in accordance with the mandate of the BIOHAZ Panel (2020–2022), extended for the following years. Possible additions to this list are included around every 6 months, with the latest Panel Statement adopted in December 2019. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2020a,b); the updated QPS list is available at https://doi.org/10.2903/j.efsa.2020.5966 and, as of January 2018, also as supporting information linked to every Panel Statement available on the Knowledge Junction at https://doi.org/10.5281/zenodo.1146566

Appendix F – Microbial species as notified to EFSA, received between October 2019 and March 2020 (reply to ToR 1)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question no[a] and EFSA webpage link[b]	Previous QPS status of the respective TU[c]	Assessed in this Statement? Yes or no
Algae							
Galdieria sulphuraria		Novel foods	Novel food	Biomass	EFSA-Q-2019-00660	N	Yes
Bacteria							
Akkermansia muciniphila	ATCC BAA-835	Novel foods	Novel Food	To be used as a food supplement Human gut commensal bacteria	EFSA-Q-2019-00767	N	Yes
Bacillus licheniformis	DSM 5749	Feed additives	Zootechnical additives	Zootechnical additives: Gut flora stabiliser	EFSA-Q-2019-00736	Y	No (already QPS)
Bacillus licheniformis	FMCH001	Plant protection products	Plant Protection Product	Fungicide and nematicide	EFSA-Q-2019-00602	Y	No (already QPS)
Bacillus subtilis	DSM 5750	Feed additives	Zootechnical additives	Zootechnical additives: Gut flora stabiliser	EFSA-Q-2019-00736	Y	No (already QPS)
Bacillus subtilis	ABS747	Feed additives	Zootechnical additives	Gut flora stabiliser	EFSA-Q-2019-00803	Y	No (already QPS)
Bacillus subtilis	LMG S-27588 (Anuα 3101)	Feed additives	Zootechnical additives	Digestibility enhancer	EFSA-Q-2020-00004	Y	No (already QPS)
Bacillus subtilis	ABS1781	Feed additives	Zootechnical additives	Gut flora stabiliser	EFSA-Q-2020-00006	Y	No (already QPS)
Bacillus subtilis	KCCM-10445/ CJKB0001	Feed additives	Nutritional additives	Vitamin	EFSA-Q-2020-00160	Y	No (already QPS)
Bacillus subtilis	CNCM I-4606	Feed additives	Technological additives	Hygiene condition enhancer: Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609	EFSA-Q-2020-00202 (FAD-201-0090)	Y	No (already QPS)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question no[a] and EFSA webpage link[b]	Previous QPS status of the respective TU[c]	Assessed in this Statement? Yes or no
Bacillus subtilis	CNCM I-5043	Feed additives	Technological additives	Hygiene condition enhancer: Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609	EFSA-Q-2020-00202 (FAD-201-0090)	Y	No (already QPS)
Bacillus subtilis	CNCM I-4607	Feed additives	Technological additives	Hygiene condition enhancer: Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609	EFSA-Q-2020-00202 (FAD-201-0090)	Y	No (already QPS)
Bacillus subtilis	FMCH002	Plant protection products	Plant Protection Product	Fungicide and nematicide	EFSA-Q-2019-00603	Y	No (already QPS)
Clostridium butyricum	FERM BP-2789	Feed additives	Zootechnical additives	Gut flora stabilisers	EFSA-Q-2019-00802	N	Yes
Corynebacterium ammoniagenes	KCCM 10530	Feed additives	Sensory additives	GMP (disodium 5′-guanylate) produced by fermentation with *Corynebacterium ammoniagenes* KCCM 10530 and *Escherichia coli* K12 KFCC 11067 as a flavouring compound	EFSA-Q-2020-00267 (FAD-2019-0085)	Y	Yes
Corynebacterium glutamicum	CG MCC 7.358	Feed additives	Nutritional additives	Production of L-Valine	EFSA-Q-2019-00788	Y	No (already QPS)
Corynebacterium glutamicum	KCCM 80185	Feed additives	Nutritional additives	Production of L-Isoleucin	EFSA-Q-2020-00007	Y	No (already QPS)
Corynebacterium glutamicum	KCCM 80187	Feed additives	Sensory additives	Flavouring compound	EFSA-Q-2020-00155	Y	No (already QPS)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question no[a] and EFSA webpage link[b]	Previous QPS status of the respective TU[c]	Assessed in this Statement? Yes or no
Corynebacterium glutamicum	KCCM 80216 (LU13544)	Feed additives	Nutritional additives	Amino acid	EFSA-Q-2020-00134	Y	No (already QPS)
Enterococcus faecium	DSM 7134	Feed additives	Zootechnical additives/Gut flora stabilisers Renewal application	Bonvital® (*Enterococcus faecium* strain DSM 7134) is an additive already authorised	EFSA-Q-2019-00741	N	No (excluded)
Enterococcus faecium	DSM 7134	Feed additives	Zootechnical additives	Functional group: b	EFSA-Q-2019-00156	N	No (excluded)
Escherichia coli	BL21 (DE3) ZenA070#1147	Feed additives	Technological additives	Reduction of the contamination of feed by mycotoxins	EFSA-Q-2020-00008	N	No (excluded)
Escherichia coli	KCCM 80212	Feed additives	Nutritional additives	Production of L-histidine monohydrochloride monohydrate	EFSA-Q-2020-00189 (FAD-2019-0016)	N	No (excluded)
Escherichia coli	K12 KFCC 11067	Feed additives	Sensory additives	GMP (disodium 5′-guanylate) produced by fermentation with *Corynebacterium ammoniagenes* KCCM 10530 and *Escherichia coli* K12 KFCC 11067 as a flavouring compound	EFSA-Q-2020-00267 (FAD-2019-0085)	N	No (excluded)
Escherichia coli	GMO	Novel foods	Novel Food	Processing aid in the production of 3-fucosyllactose	EFSA-Q-2019-00666	N	No (excluded)
Escherichia coli	BL21 (DE3)	Novel foods	Enzyme production	Production of D-tagatose-3-epimerase (dt3) used for the production of allulose	EFSA-Q-2020-00141	N	No (excluded)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question no[a] and EFSA webpage link[b]	Previous QPS status of the respective TU[c]	Assessed in this Statement? Yes or no
Lactococcus lactis	CNCM I-4609	Feed additives	Technological additives	Hygiene condition enhancer: Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609	EFSA-Q-2020-00202 (FAD-201-0090)	Y	No (already QPS)
Pseudomonas chlororaphis	MA342	Plant protection products	Plant Protection Product	Fungicide, in particular against soil-borne plant pathogenic fungi used for seed treatment on cereals and peas.	Q-2020-00116	N	Yes
Streptomyces aureofaciens	strain C735.15	Feed additives	Coccidiostats and histomonostats	Production of narasin	EFSA-Q-2019-00739	N	No (excluded)
Streptomyces lasaliensis	subsp. lasaliensis PF2-7-WI-49V	Feed additives	Coccidiostats and histomonostats	Production of lasalocid A sodium	EFSA-Q-2019-00745	N	No (excluded)
Filamentous Fungi							
Aspergillus niger	Genetically modified strain NZYM-FP	Food enzymes, food additives and flavourings	Production of the food enzyme phospholipase A1		EFSA-Q-2019-00639	N	No (excluded)
Antrodia camphorata		Novel foods	Freeze-dried mycelia	The novel food consists of freeze-dried mycelia to be used as a food supplement	EFSA-Q-2019-00759	N	No (excluded)
Trichoderma atroviride	AT10	Plant protection products	Plant Protection Product	Fungicide	EFSA-Q-2019-00113	N	No (excluded)
Talaromyces versatilis	DSM 26702 (GM strain) and IMI 378536 (Non-GM strain)	Feed additives	Zootechnical additives	Functional group: a	EFSA-Q-2020-00147	N	No (excluded)
Metarhizium brunneum	Cb15-III	Plant protection products	Plant Protection Product	Insecticide to control wireworms (Agriotes spp.) in potatoes	EFSA-Q-2019-00697	N	No (excluded)

Species	Strain	EFSA risk assessment area	Category regulated product	Intended usage	EFSA question no[(a)] and EFSA webpage link[(b)]	Previous QPS status of the respective TU[(c)]	Assessed in this Statement? Yes or no
Yeasts							
Saccharomyces cerevisiae	cell wall of yeast or inactivated yeast	Food enzymes, food additives and flavourings	Food contact material	As active material in food contact material, as oxygen scavenger (for wine bottles and bag-in-box)	EFSA-Q-2019-00588	Y	No (already QPS)
Saccharomyces cerevisiae	Sc 47/CNCM I-4407	Feed additives	Zootechnical additives	Zootechnical additives: Gut flora stabilisers	EFSA-Q-2019-00740	Y	No (already QPS)
Pichia pastoris	GMO strain	GMO	Sensory additives	Production of flavouring (Soy Leghaemoglobin)	EFSA-Q-2019-00651	Y	Yes
Komagataella phaffii	(CECT 13171)	Feed additives	Zootechnical additives	Functional group: a, c	EFSA-Q-2020-00161	Y	No (already QPS)

(a): To find more details on specific applications please access the EFSA website – Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL

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

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