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STATEMENT

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Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 10: Suitability of taxonomic units notified to EFSA until March 2019

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Abstract

The qualified presumption of safety (QPS) procedure was developed to provide a harmonised generic pre-evaluation to support safety risk assessments of biological agents performed by EFSA's Scientific Panels. The taxonomic identity, body of knowledge, safety concerns and antimicrobial resistance were assessed. Safety concerns identified for a taxonomic unit (TU) are, where possible and reasonable in number, reflected by 'qualifications' which should be assessed at the strain level by the EFSA's Scientific Panels. During the current assessment, no new information was found that would change the previously recommended QPS TUs and their qualifications. The list of microorganisms notified to EFSA from applications for market authorisation was updated with 47 biological agents, received between October 2018 and March 2019. Of these, 19 already had QPS status, 20 were excluded from the QPS exercise by the previous QPS mandate (11 filamentous fungi) or from further evaluations within the current mandate (9 notifications of *Escherichia coli*). *Sphingomonas elodea, Gluconobacter frateurii, Corynebacterium ammoniagenes, Corynebacterium casei, Burkholderia ubonensis, Phaeodactylum tricornutum, Microbacterium foliorum and Euglena gracilis* were evaluated for the first time. *Sphingomonas elodea* cannot be assessed for a possible QPS recommendation because it is not a valid species. *Corynebacterium ammoniagenes* and *Euglena gracilis* can be recommended for the QPS list with the qualification 'for production purposes only'. The following TUs cannot be recommended for the QPS list: *Burkholderia ubonensis,* due to its potential and confirmed ability to generate biologically active compounds and limited of body of knowledge; *Corynebacterium casei, Gluconobacter frateurii* and *Microbacterium foliorum,* due to lack of body of knowledge; *Phaeodactylum tricornutum*, based on the lack of a safe history of use in the food chain and limited knowledge on its potential production of bioactive compounds with possible toxic effects.

Keywords: safety, QPS, bacteria, yeast, *Corynebacterium ammoniagenes*, *Gluconobacter frateurii*, *Sphingomonas elodea*, *Burkholderia ubonensis*, *Phaeodactylum tricornutum*, *Euglena gracilis*, *Microbacterium foliorum*, *Corynebacterium casei*

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Amendment: By error, the name of an author has been omitted in the previous version and has been added in this version on pages 1 and 2 – in the 'Suggested citation' paragraph. These editorial corrections do not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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Summary

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the 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 and reasonable in number, 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 overall summary of the re-evaluation of TUs previously recommended for the QPS list is undertaken every 3 years in a scientific Opinion of the BIOHAZ Panel. Meanwhile, the list of microorganisms is maintained and re-evaluated approximately every 6 months in a Panel Statement. If new information is retrieved from extended literature searches that would change the QPS status of a microbial species or its qualifications, this is published in the Panel Statement. The Panel Statement also includes the evaluation of microbiological agents newly notified to EFSA within the 6-month period for an assessment for use as feed additives, food enzymes, food additives and flavourings, novel foods or plant protection products (PPPs). The main results of the assessments completed from 2017 onwards will be included in the scientific Opinion of the BIOHAZ Panel to be published by the end of the current mandate in December 2019. In the interim, as a result of each Panel Statement, the '2016 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA scientific Panels and Units' is extended by the inclusion of new recommendations for QPS status, and appended to the Opinion adopted in December 2016 (Appendix E).

The *first ToR* requires ongoing updates of the list of biological agents notified to EFSA, in the context of a technical dossier, for intentional use in food and/or feed or as sources of food and feed additives, enzymes and PPPs for safety assessment. The list was updated with the notifications received since the latest review in October 2018. Within this period, 47 notifications were received by EFSA, of which 32 were for feed additives, two for food enzymes, food additives and flavourings, 10 for novel foods and 3 for PPPs. The new notifications, received between October 2018 and March 2019, are included in a table appended to the current Statement (Appendix F).

The *second ToR* concerns the revision of the TUs previously recommended for the QPS list and their qualifications when new information has become available, and the updating of the information provided in the previous Opinion adopted in December 2016. According to the articles retrieved through an extensive literature search (ELS), for articles published from October 2018 to March 2019 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 TUs notified to EFSA, but not present in the current QPS list, for their suitability for inclusion in the updated list. The current Statement focuses on the assessments of the TUs that were notified to EFSA between October 2018 and March 2019. Of the 47 notifications received, 19 biological agents already had QPS status and did not require further evaluation in this Statement and 20 were not included because: 11 were notifications of filamentous fungi that were excluded from the QPS exercise; nine were notifications of *Escherichia coli* that were excluded from further QPS evaluations within the current QPS mandate. Eight new TUs were considered for the QPS assessment within this Statement: *Sphingomonas elodea, Corynebacterium ammoniagenes, Corynebacterium casei, Gluconobacter frateurii*, *Burkholderia ubonensis, Phaeodactylum tricornutum*, *Euglena gracilis and Microbacterium foliorum* which were evaluated for the first time.

Sphingomonas elodea could not be assessed for a possible QPS recommendation because it is currently not a valid species. *Corynebacterium ammoniagenes* and *Euglena gracilis* can be recommended for the QPS list with the qualification 'for production purposes only'. The following TUs cannot be recommended for the QPS list: *Burkholderia ubonensis,* due to its potential ability to generate biologically active compounds and limited body of knowledge; *Corynebacterium casei*, *Gluconobacter frateurii* and *Microbacterium foliorum,* due to lack of body of knowledge; *Phaeodactylum tricornutum*, based on the lack of a safe history of use in the food chain and limited knowledge on its potential production of bioactive compounds with toxic effects.

Pediococcus dextrinicus (Coster and White, 1964) Back, 1978 *species* has been changed to *Lactobacillus dextrinicus* (Coster and White, 1964) Haakensen et al., 2009, comb. nov. It will be updated in the QPS list.

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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 to prioritise and to harmonise risk assessment within the European Food Safety Authority (EFSA) of microorganisms intentionally introduced into the food chain, in support of the respective Scientific Panels and Units in the frame of market authorisations (EFSA, 2007). The list, first established in 2007, has been continuously revised and updated. The publication of the overall assessment of the taxonomic units (TUs) previously recommended for the QPS list is to be evaluated every 3 years through a scientific Opinion by the Panel on Biological Hazards (BIOHAZ). Intermediate deliverables in the form of a Panel Statement are produced and published for periods of around 6 months, should an assessment for a QPS classification of a microbiological agent notified to EFSA be requested by the Units dealing with feed additives, food enzymes, food additives and flavourings, novel foods, or plant protection products. These Panel Statements also include the results of the assessment of the relevant new papers related to the TUs with QPS status.

1.1. Background and Terms of Reference as provided by EFSA

1.1.1. Background 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.

Several taxonomic units (usually species for bacteria and yeasts, families for viruses) have been included in the qualified presumption of safety (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).[1] The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and published in 2007 a list of microorganisms recommended for the QPS list.[2]

In 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 Scientific Panel on Biological Hazards (BIOHAZ) took the prime responsibility for this and started reviewing annually the existing QPS list. The first annual QPS update[3] was published in 2008 and EFSA's initial experience in applying the QPS approach was included. The potential application of the QPS approach to microbial plant protection products was discussed in the 2009 update.[4] Also in 2009, bacteriophages were assessed and were not considered appropriate for the QPS list. After consecutive years of reviewing the existing scientific information, the filamentous fungi (2008 to 2013 updates) and enterococci (2010 to 2013 updates) were not recommended for the QPS list. The 2013 update[5] of the recommended QPS list included 53 species of Gram-positive non-spore-forming bacteria, 13 Gram-positive spore forming bacteria (*Bacillus* species), one Gram-negative bacterium (*Gluconobacter oxydans*), 13 yeast species, and three virus families.

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 is no longer carried out annually but over 3-year periods. From 2017, the search and revision of the possible safety concerns linked to those taxonomic units start to be done every 6 months period. The revision of the 2013 update (EFSA Biohaz Panel, 2013) was updated in 2016 (EFSA BIOHAZ Panel, 2017a)

[1] Opinion of the Scientific Committee on a request from EFSA related to a generic approach to the safety assessment by EFSA of microorganisms used in food/feed and the production of food/feed additives. The EFSA Journal 2005, 226, 1–12.

[2] Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA – Opinion of the Scientific Committee. The EFSA Journal 2007, 293, 1–85.

[3] Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on the maintenance of the list of QPS microorganisms intentionally added to food or feed. The EFSA Journal 2008, 923, 1–48.

[4] Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update). EFSA Journal 2009; 7(12):1431, 92 pp. https://doi.org/10.2903/j.efsa.2009.1431

[5] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). EFSA Journal 2013;11(11):3449, 107 pp. https://doi.org/10.2903/j.efsa.2013.3449

and the next update will be published in a scientific Opinion of the BIOHAZ Panel after its adoption in December 2019.[6] The QPS list of microorganisms has been maintained and frequently checked, based on the evaluation of extensive literature searches. In the meantime and 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 or by the Pesticides Unit, has been produced and published. In the follow up of the 2013 update[5] the Scientific Committee agreed to exclude some biological groups (filamentous fungi, bacteriophages and *Enterococcus faecium*[7]) notified to EFSA from the QPS assessment because it was considered unlikely that any taxonomical units within these groups would be granted QPS status in the foreseeable future. Thus, the assessment of members of these biological groups needs to be done at a strain level, on a case-by-case basis, by the relevant EFSA Unit.

The QPS provides a generic safety pre-assessment approach for use within EFSA that covers risks for human, animals and the environment. In the QPS concept a safety assessment of a defined taxonomic unit is considered independently of any particular specific notification in the course of an authorisation process. The QPS concept does not address hazards linked to the formulation or other processing of the products containing the microbial agents and added into the food or feed chain. 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, inhalation, ingestion) are not addressed. In the case Genetically Modified Microorganisms (GMMs) 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, 2018a).[8] Assessment of potential allergenicity to microbial residual components is beyond the QPS remit; if there is however, science-based evidence for some microbial species it is reported. Where applicable these aspects are assessed, separately by the EFSA Panel responsible for assessing the notification. Antimicrobial resistance was introduced as a possible safety concern for the assessment of the inclusion of bacterial species in the QPS list published in 2008 QPS Opinion (EFSA, 2008)[3]. In the 2009 QPS Opinion (EFSA BIOHAZ Panel, 2009)[4] a qualification regarding the absence of antimycotic resistance for yeasts was introduced.

1.1.2. Terms of Reference as provided by EFSA

The Terms of Reference, as provided by EFSA 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.

1.2. Interpretation of the Terms of Reference

The absence of acquired genes conferring resistance to clinically relevant antimicrobials is a qualification[9] applied to all QPS bacterial TUs. The verification of such qualification is under the remit of the Unit conducting the safety assessment of the organism notified to EFSA for market authorisation, and is therefore done at strain level (EFSA BIOHAZ Panel, 2017a).

[6] References updated from the original self-task mandate.

[7] The taxonomic unit was corrected from the original mandate: 'enterococci'. It is only referred to *Enterococcus faecium*, the only species which was evaluated for a possible QSP status.

[8] Sentence included, correcting the previous sentence from the original self-task mandate: 'Genetically modified microorganisms are similarly not taken into account'.

[9] Identified safety concerns, including acquired antimicrobial resistance genes, for a certain TU can be, where reasonable in number and not universally present, reflected as 'qualifications'.

In June 2017 (EFSA BIOHAZ Panel, 2017b), the BIOHAZ Panel has agreed to exclude *Escherichia coli* and any species of the genus *Streptomyces* from QPS evaluation within this mandate.

In June 2018 (EFSA BIOHAZ Panel, 2018b), the BIOHAZ Panel clarified that the qualification 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass.

2. Data and methodologies

2.1. Data

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

In reply to ToR 3, (re)assessment of the suitability of TUs notified within the time period covered by this Statement (from October 2018 to March 2019) 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, Cases Database, 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.

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 Appendices B and C.

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 47 notifications were received between October 2018 and March 2019, of which 32 were for a feed additive, 2 for food enzymes, 10 for novel foods and 3 for plant protection products (Table 1).

In response to ToR 3, out of the 47 notifications, 19 were related to TUs that already had QPS status and did not require further evaluation. Of the remaining 26 notifications, 20 were related to TUs not evaluated for a QPS status for the following reasons:

- eleven notifications related to filamentous fungi, which were excluded from QPS evaluations in the follow-up of a recommendation of the QPS 2013 and 2016 updates (EFSA BIOHAZ Panel, 2013, 2014, 2016);
- nine notifications related to *E. coli*, which were recently excluded from the current mandate by the BIOHAZ Panel.

The TUs corresponding to the remaining eight notifications evaluated for a possible QPS recommendation:

- *Sphingomonas elodea*, *Gluconobacter frateurii*, *Corynebacterium ammoniagenes, Corynebacterium casei, Burkholderia ubonensis, Phaeodactylum tricornutum, Microbacterium foliorum* and *Euglena gracilis*, all evaluated for the first time.

The notifications received by EFSA, per risk assessment area, by biological group from October 2018 to March 2019, are presented in Table 1.

Table 1: Notifications received by EFSA, per risk assessment area and by biological group, from October 2018 and March 2019

Risk assessment area / Biological group	Not evaluated in this Statement: Already QPS	Not evaluated in this Statement: Excluded in QPS[(a)]	Evaluated in this Statement	Total
Feed additives	**15**	**13**	**4**	**32**
Bacteria	9	4	4	17
Filamentous fungi	0	9	0	9
Yeasts	6	0	0	6

Risk assessment area / Biological group	Not evaluated in this Statement: Already QPS	Not evaluated in this Statement: Excluded in QPS[(a)]	Evaluated in this Statement	Total
Novel foods	**2**	**5**	**3**	**10**
Bacteria	0	5	1	4
Yeasts	2	0	0	2
Algae	0	0	2	2
Plant protection products	**2**	**1**	**0**	**3**
Bacteria	1	0	0	1
Filamentous fungi	0	1	0	1
Viruses	1	0	0	1
Food enzymes, food additives and flavourings	**0**	**1**	**1**	**2**
Bacteria	0	0	1	1
Filamentous fungi	0	1	0	1
Total	**19**	**20**	**8**	**47**

QPS: qualified presumption of safety.
(a): The number includes 11 notifications of filamentous fungi excluded from QPS evaluation in the 2013 QPS Opinion and 9 notifications of *E. coli* (bacterium) already excluded in the Panel Statement adopted in December 2016 (EFSA BIOHAZ Panel et al., 2017a).

2.2.2. Use of MLT in the context of the yeasts and *Bacillus* taxonomic units

To explore the potential application of a machine learning technique (MLT) for screening papers in the context of the QPS project the performances of such technique were assessed against the previous batch of papers retrieved for the Bacillus and Yeasts 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 2 reviewers in the QPS rounds from 1 June 2016 to 31 December 2017. This is considered a conservative approach since, in the case of conflicts among the experts, the algorithm considers the paper as relevant.

The MLT predicted screening results on the batch of papers corresponding to the period January–June 2018 were obtained and compared with the results obtained by the two reviewers in the real exercise.

The results of the exercise showed that, in the case of yeasts, MLT had around 88% and 80% of sensitivity and specificity, respectively, while, in the case of *Bacillus*, MLT had 100% and about 82% of sensitivity and specificity, respectively. Moreover, it was found that in case of using the MLT algorithm as a reviewer in parallel with a human reviewer, in both projects no information relevant for the QPS status would have been missed.

On the basis of these results and considering the high number of papers retrieved for both yeasts and *Bacillus* in the context of the QPS exercise, it was decided to use the MLT in parallel with a human reviewer to screen the current batch of papers in these two TUs.

As expected, considering its specificity, the application of the MLT algorithm resulted in a high 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 potentially relevant by the human reviewer.

2.2.3. Monitoring of new safety concerns related to the QPS list

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 2018). For a detailed protocol of the process and search strategies, refer to Appendices B and C.

After removal of duplicates, 3,710 records were submitted to the *title screening* step, which led to the exclusion of 3,179 of them. The remaining 531 records were found eligible for the *Title and abstract screening* step, which led to the exclusion of 39 of these. Of the 492 articles that finally reached the *Article evaluation step* (full text), 85 were considered to be relevant for the QPS project.

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

Species	No of papers			
	Title screening step	**Title/ abstract screening step**	**Article evaluation step (screening for potential relevance)**[(a)]	**Article evaluation step (identification of potential safety concerns)**
Bacteria	**2,244**	**258**	**224**	**11**
Bacillus spp.	804	199	199[(b)]	2
Geobacillus stearothermophilus			0	0
Bifidobacterium spp.	206	21	3	1
Carnobacterium divergens			0	0
Corynebacterium glutamicum	45	0	0	0
Gluconobacter oxydans	115	1	0	0
Xanthomonas campestris			0	0
Lactobacillus spp.	555	22	12	3
Lactococcus lactis	173	6	4	3
Leuconostoc spp.	68	5	4	1
Microbacterium imperiale			0	0
Oenococcus oeni	24	1	0	0
Pasteuria nishizawae			0	0
Pediococcus spp.	146	2	2	1
Propionibacterium spp.	27	0	0	0
Streptococcus thermophilus	81	1	0	0
Viruses	**108**	**0**	**0**	**0**
Alphaflexiviridae	39	0	0	0
Potyviridae				0
Baculoviridae	69	0	0	0
Yeasts	**1,358**	**273**	**268**[(b)]	**30**[(c)]
Candida famata (teleomorph = *Debaryomyces hansenii*)	1,358	273	268	10
Candida kefyr (teleomorph = *Kluyveromyces marxianus*)				16
Candida pelliculosa (synonymus = Pichia anomala) (teleomorph = *Wickerhamomyces anomalus*)				6
*Candida utilis (*teleomorph = *Lindnera jadinii)*				1
Hanseniaspora uvarum				1
Saccharomyces cerevisiae including *Saccharomyces boulardii*				8
Kluyveromyces lactis				1
Schizosaccharomyces pombe				1
Total	**3,710**	**531**	**492**	**85**
Excluded	**3,179**	**39**	**407**	

(a): Relevant references in Appendix D.
(b): The relatively high number of hits is linked to the procedure followed for the screening of references using machine learning techniques (MLT) in parallel with experts' selection.
(c): 30 articles describing 45 studies related to different yeast species. In one case, there was no reference to any particular species.

3. Assessment

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

None.

3.2. Taxonomic units to be evaluated for the first time

3.2.1. Bacteria

3.2.1.1. *Burkholderia ubonensis*

Identity

B. ubonensis is a species with Standing in Nomenclature. *B. ubonensis* belongs to the *Burkholderia cepacia* complex (Martina et al., 2018) that was first described as *Burkholderia uboniae* (Yabuuchi et al., 2000) and later on renamed as *B. ubonensis* (Anonymous, 2000).

Body of knowledge

There are only a limited number of scientific papers published on this TU. *B. ubonensis* as well as other *Burkholderia* species, produce lipases, which are used in a broad range of industrial applications.

Safety concerns

B. ubonensis is considered to be non-pathogenic, although its virulence potential has not been extensively tested. It appears to be innocuous after a subcutaneous challenge to mice (Price et al., 2017).

Whole genome characterisation of strains within the species revealed the presence of numerous genes encoding secondary, biologically active, metabolites such as polyketides, non-ribosomal peptides, quinolines and pyrrolnitrins (Loveridge et al., 2017). Some produce monobactams (Imada et al., 1981), bulgecins (Horsman et al., 2017), which enhance the bactericidal effect of β-lactams on Gram negative bacteria, and bacteriocin-like compounds (Marshall et al., 2010).

Antimicrobial resistance aspects

Different features, namely the external membrane structure and an inducible class A β-lactamase contributes to the intrinsic resistance to diverse antibiotics (Rhodes and Schweizer, 2016)

Conclusions on a recommendation for the QPS list

B. ubonensis cannot be recommended for the QPS list due to its ability to generate biologically active compounds and limited body of knowledge.

3.2.1.2. *Corynebacterium ammoniagenes*

Identity

C. ammoniagenes is a species with Standing in Nomenclature. It was first described by Cooke and Keith (1927) as *Brevibacterium ammoniagenes,* an urea-splitting bacterium isolated from the human intestinal tract. It was transferred to the genus *Corynebacterium* by Collins (1987).

Body of knowledge

C. ammoniagenes is used for the industrial production of nucleotides, nucleosides and riboflavin (Koizumi et al., 2000; Serrano et al., 2017).

C. ammoniagenes derived single-cell protein[10] can also be used as a non-conventional protein source in animal diet such as in broilers (An et al., 2018) and growing pigs (Wang et al., 2013), without any negative effects on blood, bone characteristics or meat quality (An et al., 2018).

[10] Single-cell protein (SCP) typically refers to mixed protein extracted from pure and mixed cultures of microorganisms like yeasts, bacteria, fungi and algae, grown in large scale culture systems (Nasseri et al., 2011). SCP can be produced using a variety of raw substrates from inexpensive agro-industrial by-products and can be used in poultry feed as an alternative protein source to soya bean meal or fishmeal (El-Deek et al., 2009).

Safety concerns

No information was found in relation to pathogenicity of the organism, including when used for production of SCP for feed (Oliveira et al., 2017).

Antimicrobial resistance aspects

No information was found in relation to the AMR.

Conclusions on a recommendation for the QPS list

C. ammoniagenes can be recommended for QPS list with the qualification 'for production purposes only'.

3.2.1.3. *Corynebacterium casei*

Identity

C. casei was first isolated from the surface of a smear-ripened cheese (Brennan et al., 2001) and is a valid species according to the list of prokaryotic names with Standing in Nomenclature.

Body of knowledge

There are only a limited number of articles published on this TU. Most of the relevant articles described the microbial communities and activities in ripened cheese where *C. casei* contributes as a spontaneous contaminant to the production of the desired organoleptic properties (Brennan et al., 2002; Hannon et al., 2004; Mounier et al., 2005; Rea et al., 2007; Bockelmann, 2011; Cogan et al., 2014; Bertuzzi et al., 2017).

Safety concerns

One article described the identification of *C. casei* among 57 bacterial strains isolated during the screening of blood samples of patients with cardiovascular diseases and not having any active infection (Dinakaran et al., 2012), so no proven connection with the ongoing diseases was identified.

Antimicrobial resistance aspects

No information was found in the literature.

Conclusions on a recommendation for the QPS list

C. casei cannot be recommended to the QPS list due to lack of body of knowledge.

3.2.1.4. *Gluconobacter frateurii*

Identity

It is a species with Standing in Nomenclature (Mason and Claus, 1989). It was separated from *Acetobacter* in 1989. It has been classified as a separate cluster in the *Gluconobacter* genus according to 16S rRNA gene sequence analysis (Sievers et al., 1995) and to restriction analysis of 16S-23S rDNA internal transcribed spacer regions (Malimas et al., 2006).

Body of knowledge

There are only a limited number of articles published on this TU. It can produce high amounts of fructans and can efficiently produce glyceric acid from raw glycerol (Poljungreed and Boonyarattanakalin, 2018). It is an obligate aerobic acetic acid bacterium that is found as a spontaneous contaminant as part of the microbial community in some food processes (e.g. vinegar production and kefir, cocoa and coconut water fermentation) (Korsak et al., 2015; Ho et al., 2018). Although these foods are consumed and exposure of humans and animals to this microorganism is expected, the scientific knowledge on this species is limited.

Safety concerns

The literature search retrieved no hits on virulence, pathogenicity or disease related to this TU.

Antimicrobial resistance aspects

No information is available in the scientific literature.

Conclusions on a recommendation for the QPS list

Gl. frateurii cannot be recommended for the QPS list due to lack of body of knowledge.

3.2.1.5. *Microbacterium foliorum*

Identity

M. foliorum is a valid species name according to the List of Prokaryotic Names with Standing in Nomenclature. It was first isolated as a plant associated bacterium (Behrendt et al., 2001).

Body of knowledge

There are only a limited number of articles published on this TU. *M. foliorum* is a saprophytic organism that may become endophytic and allow cruciferous plants to grow on oil seep soils, due to its capacity to process hydrocarbons such as catechol, toluene, naphthalene, octanol and others (Lumactud et al., 2016, 2017). In addition, it is, as a spontaneous contaminant, part of the microbiota involved in production of flavour and aroma in surface-ripened cheeses, such as Limburger and Munster, due to its caseinolytic, aminopeptidase and deaminase activities (Deetae et al., 2007, 2009). Although these foods are consumed and exposure of humans to this microorganism is expected, the scientific knowledge on this species is still limited.

Safety concerns

M. foliorum has been associated with clinical samples. Laffineur et al. (2003) reported the isolation of 30 *Microbacterium* spp. specimens 'during the past decades' one of which was classified as *M. foliorum*, with no further indication of its source or the conditions of the patient. Gneiding et al. (2008) identified 50 isolates as belonging to the genus *Microbacterium* in a survey of bacteria obtained during the previous 5 years from pathological samples and processed in a German Coryneform reference laboratory. Unfortunately, only the origin of the samples was reported, with no indication of the patient conditions or the procedures to which they were subjected. Of these isolates, seven were ascribed to *M. foliorum*, their origin being wound swabs (5), pleural fluid (1) and blood (1).

A toxicological study was made on lysed cultures from a single strain without adverse effects, but the results cannot be extrapolated to the species (Kim et al., 2018a).

Antimicrobial resistance aspects

One paper (Gneiding et al., 2008) reported susceptibility profiles of *M. foliorum* but without reference to transmissibility of resistances.

Conclusions on a recommendation for the QPS list

M. foliorum cannot be recommended for the QPS list due to lack of body of knowledge.

3.2.1.6. *Sphingomonas elodea*

Identity

S. elodea was described as a Gram-negative bacterium, initially named as *Pseudomonas elodea* (Kang et al., 1982). This species has not been taxonomically validated according to the List of Prokaryotic Names with Standing in Nomenclature (LPSN) (Euzéby, 2013) (http://www.bacterio.net/-allnamesdl.html) and the modifications that appear in the International Journal of Systematic and Evolutionary Microbiology (IJSEM) (Oren and Garrity, 2015).

Body of knowledge

Not applicable.

Safety concerns

Not applicable.

Antimicrobial resistance aspects

Not applicable.

Conclusions on a recommendation for the QPS list

S. elodea could not be assessed for a possible QPS recommendation because it is not a valid species.

3.2.2. *Algae*

3.2.2.1. *Euglena gracilis*

Identity

E. gracilis belongs to the genus *Euglena,* phototrophic euglenoid flagellates possessing complex chloroplasts. The taxonomy of *E. gracilis* and closely related species has not been amended so far based on molecular phylogenetic analyses (Zakryś et al., 2017). The whole genome of the *E. gracilis* strain Z1 was recently sequenced (Ebenezer et al., 2019).

Body of knowledge

There are an extended amount of scientific papers published on this TU. *E. gracilis* is found in many freshwater habitats, especially in shallow eutrophic ponds. The species is able to synthesise biotechnologically relevant compounds such as polyunsaturated fatty acids, vitamins, β-glucans and tyrosine used in cosmetics and food supplements. *E. gracilis* is also used for bioremediation of heavy metals in contaminated water and as a toxicity bioindicator (Krajčovič et al., 2015).

E. gracilis biomass, generally based on dried cells, is used as a feed additive in aquaculture and in animal feed as well as in human food (Suzuki, 2017). Food products containing *E. gracilis* are marketed in Japan as cookies, cereal bars and nutritional drinks.

Safety concerns

Using dried preparations of non-viable *E. gracilis*, no genotoxicity was observed in bacterial reverse mutation and mammalian micronucleus tests. Moreover, subchronic toxicity tests in rats did not show any adverse effect and a no-observed-adverse-effect-level (NOAEL) of 50,000 ppm was determined. (Simon et al., 2016).

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

Antimicrobial resistance aspects

Not applicable.

Conclusions on a recommendation for the QPS list

E. gracilis may be recommended for the QPS list with the qualification 'for production purposes only'.

3.2.2.2. *Phaeodactylum tricornutum*

Identity

The unicellular, photosynthetic alga *P. tricornutum* was first isolated and described as a new species by the end of the 19th century (Bohlin, 1897). It is a pennate diatom (class Bacillariophyceae) and the only known species in the genus. It is an unusual diatom since it is pleiomorphic (fusiform, oval or triradiate morphology) and production of a silica frustule is facultative. Identification has recently been made by 18S rRNA gene sequencing (Demirel, 2016; Haro et al., 2017). The genome of one isolate has been sequenced (Bowler et al., 2008; Rastogi et al., 2018).

Body of knowledge

There are an extended amount of scientific papers published on the TU. *P. tricornutum* has been isolated from marine or brackish locations, often in benthic habitats, and appears to have a global distribution (De Martino et al., 2007). However, it is not a dominant species of algal communities and relatively little is known about its ecology.

It is of biotechnological interest, for studies within algal physiology and metabolism and as a model test species in toxicology. The potential of *P. tricornutum* as a source of biomass for biofuels, antimicrobial agents, health-promoting substances and food or feed components in general is subject to intensive study (Bajpai, 2016; Garcia et al., 2017; Haro et al., 2017; Shah et al., 2018). For example, the alga produces many compounds of high nutritional value, such as essential fatty acids and carotenoids (Zhang et al., 2015; Garcia et al., 2017). It has also been shown that *P. tricornutum* biomass can be used as a feed supplement (Skrede et al., 2011; Cerezuela et al., 2012; Sørensen et al., 2016).

Although several scientific studies are available, there appears to be no history of use of *P. tricornutum* in food or feed in practice, since no evidence was found that *P. tricornutum*, or substances produced by it, have yet been commercialised and/or widely consumed.

Safety concerns

The literature search did not reveal any studies reporting infection or intoxication by *P. tricornutum*.

Niccolai et al. (2017) tested *in vitro* toxicity of water- or methanol extracts of *P. tricornutum* (strain F&M-M40) and found them to be toxic to fibroblasts. Neumann et al. (2018a) showed cytotoxic effects on human peripheral mononuclear cells.

In another study, Neumann et al. (2018b) investigated the bioavailability and toxicity of disrupted and freeze-dried cells of *P. tricornutum* in a mouse model and no adverse effect was reported.

Recent studies suggest that *P. tricornutum* can produce β-*N*-methylamino-L-alanine (BMAA) (Réveillon et al., 2016; Lage et al., 2019), which is a neurotoxin produced by certain cyanobacteria, diatoms and dinoflagellates. BMAA occurs ubiquitously in marine environments and can be transferred in food-webs to fish and seafood (Salomonsson et al., 2015; Lance et al., 2018).

Antimicrobial resistance aspects

Not applicable.

Conclusions on a recommendation for the QPS list

P. tricornutum is not recommended for QPS status based on the lack of a safe history of use in the food chain and on its potential for production of bioactive compounds with toxic effects.

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 caused by QPS organisms described and published since the previous ELS (i.e. between January and June 2018, as described in Appendices B and C) and the references 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

3.3.1.1. *Bifidobacterium* spp.

A search for papers potentially relevant for the QPS consideration of *Bifidobacterium* spp. and *Carnobacterium divergens*[11] provided 206 references. The analysis of their title left 21 articles; the rest were discarded because they did not deal with safety concerns. Three articles were found relevant for the QPS consideration of *Bifidobacterium* spp. at the level of title and abstract screening. For one article, the full text was not available (conference proceedings) (Magistrelli et al., 2018). For one of the two other articles (Suzuki et al., 2018), the study was not considered because of study design shortcomings in relation to QPS assessment. For the third article (Kim et al., 2018a,b), no safety concern was identified for both *Bifidobacterium bifidum* and *Bifidobacterium longum*.

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

3.3.1.2. *Carnobacterium divergens*

A search for papers potentially relevant for the QPS consideration of *Bifidobacterium* spp. and *Carnobacterium divergens* provided 206 references. The analysis of their title/abstracts left 21 articles; the rest were discarded because they did not deal with safety concerns. No article arrived to the final stage for this TU. Consequently, the QPS status of *C. divergens* is not changed.

3.3.1.3. *Corynebacterium glutamicum*

A search for papers potentially relevant for the QPS consideration of *Corynebacterium glutamicum* provided 45 references. No paper reached the final selection phase, therefore no new safety concerns were identified.

[11] These 2 TUs were searched together for practical reasons.

3.3.1.4. *Lactobacillus* spp.

A search for papers potentially relevant for the QPS consideration of any of the 35 *Lactobacillus* species included in the list provided 555 references. Analysis of their title left 22 articles; the rest were discarded because they did not deal with safety concerns. Inspection of their abstracts allowed the selection of 12 papers that might raise safety concerns. After analysing the full texts, nine were considered to be not relevant, while the other three described safety concerns linked to *L. paracasei* (Kao et al., 2018) and *L. rhamnosus* (Naqvi et al., 2018; Zeba et al., 2018). In one case (Kao et al., 2018), no indication is provided on how the identification of the pathogen was done, while in Zeba et al. (2018) an automated phenotypical method was used, known not to reliably identify lactobacilli. Patients in the three studies (Kao et al., 2018; Naqvi et al., 2018; Zeba et al., 2018) presented with clear predisposing conditions.

Based on the available evidence as described above, the QPS status of the lactobacilli involved in the reported cases and, by extension, of all others included in the QPS list, is not changed.

3.3.1.5. *Lactococcus lactis*

A search for papers potentially relevant for the QPS consideration of *Lactococcus lactis* provided 173 references. Analysis of their title/abstracts left six articles; the rest were discarded because they did not deal with safety concerns. Analysis of the abstracts allowed selection of four papers that might raise safety concerns. After analysing the full texts, one was found not to deal with safety concerns (Kato et al., 2018) while the other three (Chen et al., 2018; Kaboré et al., 2018; Shimizu et al., 2019) did. In two of them (Chen et al., 2018; Kaboré et al., 2018) phenotypical methods for identification of the etiological agent were used, which are known not to be reliable for this species. In addition, two of the papers (Chen et al., 2018; Shimizu et al., 2019) described cases in which clear predisposing conditions were identified. Shimizu et al. (2019) describes a patient suffering from a cholangiocarcinoma that blocked bile evacuation, reason why a bilioduodenal catheter was inserted. This might have been the source of the *L. lactis* cholangitis (predisposing condition) that appeared just 2 days later. The last reference (Kaboré et al., 2018) described the microbiota associated to 125 cases of endodontitis, out of which five contained *L. lactis* as part of a polymicrobial community, which is suggestive of colonisation of the oral cavity rather than aetiology of the infections.

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

3.3.1.6. *Leuconostoc citreum, Leuconostoc lactis, Leuconostoc mesenteroides, Leuconostoc pseudomesenteroides*

A search for papers potentially relevant for the QPS consideration of *Leuconostoc* spp. and *Microbacterium imperiale*[11] provided 68 references. The analysis of their title left five articles; the rest were discarded because they did not deal with safety concerns. One paper lacked information on the identification procedures used to identify the infectious agents. Four papers arrived to the full text phase. Three were immediately excluded as they were not dealing with a safety concern or with these TUs. In the article of Menegueti et al. (2018), a 67-year-old female patient with chronic Chagas disease was submitted to several surgical interventions, and presented complications such as hypotension and hypoxemia. The identification of cultures was performed using automated phenotypical method known not to reliably identify *Leuconostoc* spp.

The safety concern identified was linked to severe underlying health conditions and the identification of strain was not reliable due to the use of phenotypic tests. Consequently the QPS status of *Leuconostoc* spp. is not changed.

3.3.1.7. *Microbacterium imperiale*

A search for papers potentially relevant for the QPS consideration of *Leuconostoc* and *Microbacterium imperiale*[11] provided 68 references. The analysis of their title left five articles; one paper lacked information on the identification procedures used to identify the infectious agents. The rest were discarded because they did not deal with safety concerns. None of the remaining four articles dealt with this TU. Consequently, the QPS status of *M. imperiale* is not changed.

3.3.1.8. *Oenococcus oeni*

A search for papers potentially relevant for the QPS consideration of *Oenococcus oeni* and *Pasteuria nishizawae*[11] provided 24 references. The analysis of their title/abstracts left one article for consideration. No paper reached the final selection phase, no new safety concern was found. Consequently, the QPS status of *O. oeni* is not changed.

3.3.1.9. *Pasteuria nishizawae*

A search for papers potentially relevant for the QPS consideration of *Oenococcus oeni* and *Pasteuria nishizawae*[11] provided 24 references. The analysis of their title/abstracts left one article for consideration. No paper reached the final selection phase, no new safety concern was found. Consequently, the QPS status of *P. nishizawae* is not changed.

3.3.1.10. *Pediococcus* spp.

A search for papers potentially relevant for the QPS consideration of *Pediococcus* spp. provided 146 references. The analysis of their title left two articles (Chen et al., 2018; Singla et al., 2018). The latter does not describe a safety concern. Chen et al. (2018) describes an infectious endocarditis caused by *L. lactis* subsp. *Lactis* and *Pediococcus pentosaceus*. *P. pentosaceus* was identified after levofloxacin treatment in blood cultures, but the phenotypical method used for its identification is known not to be reliable for this species. In addition, the papers describe a case in which clear predisposing conditions were identified.

Consequently, the QPS status of *Pediococcus* spp. is not changed.

Pediococcus dextrinicus (Coster and White, 1964) Back, 1978, species, the name was changed to *Lactobacillus dextrinicus* (Coster and White, 1964) Haakensen et al., 2009, comb. nov. It will be updated in the QPS list.

3.3.1.11. *Propionibacterium* spp.

A search for papers potentially relevant for the QPS consideration of *Propionibacterium* spp. provided 27 references. Following the analysis of their title/abstracts, no articles were selected for the final selection phase, thus no new safety concerns were identified. Consequently, the QPS status of *Propionibacterium* spp. is not changed.

3.3.1.12. *Streptococcus thermophilus*

A search for papers potentially relevant for the QPS consideration of *Streptococcus thermophilus* provided 81 references. The analysis of their title/abstracts left one article that did not reach the final selection phase; thus, no new safety concern was found. 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 the QPS consideration of *Bacillus* spp. and *Geobacillus stearothermophilus*[11] provided 804 references. The analysis of their titles left 199 articles. A first round has been conducted using the MLT as a co-assistant; the second round of analysis of the 199 articles by two experts left two articles for more in-depth analysis. The remaining articles were discarded because they did not deal with safety concerns. The paper of Osman et al. (2018) concerns the enterotoxinogenic potential of *Bacillus pumilus* strains, a topic covered by the current qualification for *Bacillus* spp. The paper of Tsonis et al. (2018) concerns the description of a cerebral abscess due to *Bacillus subtilis* in an immunocompetent patient. For both papers there were methodological shortcomings on the identification methods of the bacterial strains and therefore the data presented were not included for further assessment.

The ELS did not come up with any information that would change the status of the *Bacillus* species included in the QPS list.

3.3.2.2. *Geobacillus stearothermophilus*

A search for papers potentially relevant for the QPS consideration of *Bacillus* spp. and *Geobacillus stearothermophilus*[11] provided 804 references. The analysis of their titles/abstract left 199 articles. None was dealing with this species. Consequently, the QPS status *Geobacillus stearothermophilus* is not changed.

3.3.3. Gram-negative bacteria

3.3.3.1. *Gluconobacter oxydans*

A search for papers potentially relevant for the QPS consideration of *Gluconobacter oxidans* and *Xanthomonas campestris*[11] provided 115 references. The analysis of their titles left one article; the rest were discarded because they did not deal with safety concerns. 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 consideration of *Gluconobacter oxidans* and *Xanthomonas campestris*[11] provided 115 references. The analysis of their titles left one article; the rest were discarded because they did not deal with safety concerns. No paper reached the final selection phase for this TU. Consequently, the QPS status of *X. campestris* is not changed.

3.3.4. Yeasts

A search for papers potentially relevant for the QPS consideration of the yeasts' species included in the QPS list provided 1,358 references. The analysis of their titles left 268 articles. A first round has been conducted using the MLT as a co-assistant; 229 of these were immediately excluded because they were not in English or because they were not dealing with safety concerns. Thus, the ELS identified 30 articles relevant for different yeast species with QPS status (please refer to Appendix D for the complete list of references).

These 30 articles included description of 45 studies related to different yeast species with QPS status, of which 16 referred to *Candida kefyr* (teleomorph = *Kluyveromyces marxianus*) (Afsarian et al., 2018; Awad et al., 2018; Bharathi, 2018; Diba et al., 2018; García-Agudo et al., 2018; Hasan and Yassein, 2018; Kaur et al., 2018; Kesmen et al., 2018; Khedri et al., 2018; Nagy et al., 2018; Okmen et al., 2018; Omran and Mansori, 2018; de Paula et al., 2018; Sadrossadati et al., 2018; Shokohi et al., 2018; Simi et al., 2019), 8 to *Saccharomyces cerevisiae* including *Saccharomyces boulardii* (corresponding to 7 articles: Lazo-Vélez et al., 2018; Ruelle et al., 2018; Hasan and Yassein, 2018; Kara et al., 2018; Kesmen et al., 2018; Ochiai et al., 2018; Teblick et al., 2018), 10 to *Candida famata* (teleomorph = *Debaryomyces hansenii*) (Afsarian et al., 2018; Alobaid and Khan, 2018; Awad et al., 2018; Cen et al., 2018; Das et al., 2018; Diba et al., 2018; Hasan and Yassein, 2018; Kesmen et al., 2018; de Paula et al., 2018; Simi et al., 2019), 6 to *Candida pelliculosa* (synonymus = *Pichia anomala*, teleomorph = *Wickerhamomyces anomalus*) (Ahmadsah et al., 2018; Arendrup et al., 2018; Cen et al., 2018; Jung et al., 2018; Kesmen et al., 2018; Soman et al., 2018), 1 to *Candida utilis* (teleomorph = *Lindnera jadinii*) (Treguier et al., 2018), 1 to *Hanseniaspora uvarum* (Kesmen et al., 2018), 1 *Kluyveromyces lactis* (Kesmen et al., 2018) and 1 to *Schizosaccharomyces pombe* (Kesmen et al., 2018). One of these articles was considered relevant (Pfaller et al., 2018) to evaluate since it presented new data on antimycotic MIC breakpoints for azoles but it is not associated to any specific yeast TU.

For the other yeast species with QPS status, no relevant studies were identified through the ELS.

Methodological problems were identified in 30 out of those 45 studies (corresponding to 22 articles – see Table 3). In 17 of those 30 studies (corresponding to 11 articles: Alobaid and Khan, 2018; Awad et al., 2018; Bharathi, 2018; de Paula et al., 2018; Hasan and Yassein, 2018; Kaur et al., 2018; Okmen et al., 2018; Ruelle et al., 2018; Soman et al., 2018; Treguier et al., 2018; Simi et al., 2019), a problem was found in respect to the methodology used for identity confirmation of the microorganism, therefore the value of these results and conclusions were very limited. In 2 of those 30 studies (corresponding to 1 article, Awad et al., 2018), the problem was due to a lack of information regarding the source attribution. In 19 studies (corresponding to 15 articles: Afsarian et al., 2018; Alobaid and Khan, 2018; Bharathi, 2018; Diba et al., 2018; Das et al., 2018; Hasan and Yassein, 2018; Jung et al., 2018; Kara et al., 2018; Khedri et al., 2018; Kaur et al., 2018; Nagy et al., 2018; Omran and Mansori, 2018; Sadrossadati et al., 2018; Shokohi et al., 2018; Teblick et al., 2018), the problem was due to predisposing factors in the exposed subject.

For 32 of those 45 studies, no potential safety concern was reported, while a potential safety concern was described in the other 13 studies (corresponding to 11 articles: Diba et al., 2018; Das et al., 2018; Jung et al., 2018; Kara et al., 2018; Khedri et al., 2018; Nagy et al., 2018; Omran and Mansori, 2018; Sadrossadati et al., 2018; Afsarian et al., 2018; Shokohi et al., 2018; Teblick et al., 2018): 3 for *C. famata* (Das et al., 2018; Diba et al., 2018; Shokohi et al., 2018), 7 for *C. kefyr* (Afsarian et al., 2018; Diba et al., 2018; Khedri et al., 2018; Nagy et al., 2018; Omran and Mansori, 2018; Sadrossadati et al., 2018;

Shokohi et al., 2018), 1 for *C. pelliculosa* (Jung et al., 2018) and 2 for *Saccharomyces cerevisiae* (Kara et al., 2018; Teblick et al., 2018). All these studies reported isolation of the QPS yeasts from opportunistic infections in patients with serious predisposing factors.

In short, the ELS did not identify any information that would change the status for the yeast species included in the QPS list.

Table 3: Articles that arrived to the evaluation phase (final step of the extensive literature search) for the QPS status yeasts group (30 articles with 45 studies)

Relevant to the QPS exercise[(a),(b)]	Articles not describing safety concerns	19 articles (32 studies)	**Any methodological problem identified?**	*Yes*	11 articles (17 studies)	*Methodology used for identity confirmation of the microorganism*	11 articles (17 studies)	Alobaid and Khan (2018); Awad et al. (2018); Bharathi (2018); de Paula et al. (2018); Hasan and Yassein (2018); Kaur et al. (2018); Okmen et al. (2018); Ruelle et al. (2018); Simi et al. (2019); Soman et al. (2018); Treguier et al. (2018)
						Reliability of the source attribution	1 article (2 studies)	Awad et al. (2018)
						Misuse of the microorganism	None	
						Predisposing factors in the exposed subjects	4 articles (6 studies)	Alobaid and Khan (2018); Bharathi (2018); Hasan and Yassein (2018); Kaur et al. (2018)
						Other reasons	1 article (2 studies)	de Paula et al. (2018)
				No	8 articles (15 studies)			Arendrup et al. (2018); Ahmadsah et al. (2018); Cen et al. (2018); García-Agudo et al. (2018); Lazo-Vélez et al. (2018); Kesmen et al. (2018); Ochiai et al. (2018); Pfaller et al. (2018)
	Articles dealing with safety concerns	11 articles (13 studies)	**Any methodological problem identified?**	*Yes*	11 articles (13 studies)	*Methodology used for identity confirmation of the microorganism*	None	
						Reliability of the source attribution	None	
						Misuse of the microorganism	None	
						Predisposing factors in the exposed subjects	11 articles (13 studies)	Afsarian et al. (2018); Diba et al. (2018); Das et al. (2018); Jung et al. (2018); Kara et al. (2018); Khedri et al. (2018); Nagy et al. (2018); Omran and Mansori (2018); Sadrossadati et al. (2018); Shokohi et al. (2018); Teblick et al. (2018)
						Other reasons	None	
				No	None			

(a): Please refer to Appendix D for the complete list of references.
(b): Number of references (articles and studies) indicated for each step.

3.3.5. Viruses used for plant protection

3.3.5.1. *Alphaflexiviridae*

A search for papers potentially relevant for the QPS consideration of *Alphaflexiviridae* and *Potyviridae*[11] provided 39 references. No paper reached the final selection phase, thus no new safety concern was found.

3.3.5.2. *Potyviridae*

A search for papers potentially relevant for the QPS consideration of *Alphaflexiviridae* and *Potyviridae*[11] provided 39 references. No paper 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 consideration of *Baculoviridae* provided 69 references. No article reached the final selection phase, thus no new safety concern was found.

The ELS did not come up with any information that would change the current QPS status of any of the above virus families.

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 (FIP), Nutrition Unit and Pesticides Unit), for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products for safety assessment*:

- Between October 2018 and March 2019, the list was updated with 47 notifications that were received by EFSA, of which 32 were for feed additives, 2 for food enzymes, food additives and flavourings, 10 for novel foods and 3 for plant protection products.

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

- In relation to the results of the monitoring of possible new safety concerns related to the QPS list, there were no results that justify removal of any TU 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*:

- The TUs corresponding to 19 out of the 47 notifications received, already had a QPS status.
- Of the 28 notifications without a QPS status, 11 notifications related to filamentous fungi which were excluded from QPS activities in the follow-up of a recommendation of the QPS 2013 update (EFSA BIOHAZ Panel, 2013, 2014, 2016), 9 notifications related to *E. coli*, which was recently excluded from the current mandate by the BIOHAZ Panel (EFSA BIOHAZ Panel, 2018a).
- The remaining eight TUs, *Burkholderia ubonensis, Corynebacterium ammoniagenes, Corynebacterium casei, Euglena gracilis, Gluconobacter frateurii, Microbacterium foliorum, Phaeodactylum tricornutum* and *Sphingomonas elodea,* were evaluated for potential QPS recommendation for the first time.

5. Recommendations

- *Burkholderia ubonensis* cannot be recommended for the QPS list due to its ability to generate biologically active compounds and limited of body of knowledge.
- *Corynebacterium ammoniagenes* can be recommended for QPS list status with the qualification 'for production purposes only'.
- *Corynebacterium casei* cannot be recommended to the QPS list due to lack of body of knowledge.
- *Euglena gracilis* may be recommended for the QPS list with the qualification 'for production purposes only'.

- *Gluconobacter frateurii* cannot be recommended to the QPS list due to lack of body of knowledge.
- *Microbacterium foliorum* cannot be recommended to the QPS list due to lack of body of knowledge.
- *Phaeodactylum tricornutum* cannot be recommended for QPS status, based on the lack of a safe history of use in the food chain and on its potential production of bioactive compounds with toxic effects based on the lack of a safe history of use in the food chain and a limited knowledge on its potential production of bioactive compounds with toxic effects.
- *Sphingomonas elodea* could not be assessed for a possible QPS recommendation because it is not a valid species.

Pediococcus dextrinicus (Coster and White, 1964) Back, 1978 species has been changed to *Lactobacillus dextrinicus* (Coster and White, 1964) Haakensen et al., 2009, comb. nov.

This new QPS recommendation will be included as an addition to the list of QPS status recommended biological agents (EFSA BIOHAZ Panel, 2016), published both as an update to the Scientific Opinion (EFSA BIOHAZ Panel, 2016) and as supporting information available on the Knowledge Junction at https://doi.org/10.5281/zenodo.1146566.

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Glossary and Abbreviations

Antimicrobial compounds	Antibiotics, bacteriocins and/or small peptides with antimicrobial activity
AMR	antimicrobial resistance

BIOHAZ	EFSA Panel on Biological Hazards
BMAA	β-*N*-methylamino-L-alanine
ELS	Extensive Literature Search
FIP	EFSA Food Ingredients and Packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganism
IJSEM	International Journal of Systematic and Evolutionary Microbiology
LPSN	List of Prokaryotic Names with Standing in Nomenclature
MLT	machine learning technique
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)

Burkholderia ubonensis

A literature search was performed in PubMed database using the search term: "Burkholderia ubonensis": 18 citations were identified and screened.

Corynebacterium ammoniagenes

A literature search was performed in PubMed database using the search term: "Corynebacterium ammoniagenes": 112 citations were identified and screened.

Corynebacterium casei

A literature search was performed in Scopus database using the search term: "Corynebacterium casei": 125 citations were identified and screened from which, 40 were relevant for the assessment.

Euglena gracilis

Pub Med search; "Euglena gracilis", taxonomy; 88 references screened for relevance; two selected: Zakryś et al. (2017) for taxonomy and Krajčovič et al. (2015) for body of knowledge as review article

A literature search was performed in PubMed database using the search term:

- "E. gracilis" biotechnology 49 references.
- "E. gracilis" biomass 26 references.
- "E. gracilis" and safety, 5 references, Simon et al. (2016) as relevant.
- "E. gracilis" and illness: no references.
- "E. gracilis" and hospitalization: no references
- "E. gracilis" and infectivity: 6 references, Ebenezer et al. (2019) as relevant.
- "E. gracilis" and tox: 1 reference, not relevant.
- "E. gracilis" and health: 30 references, none relevant.
- "E. gracilis" and environment and concern: 1 reference, not relevant.
- "E. gracilis" and environment: 245 references, Suzuki et al. (2018) as relevant.

Gluconobacter frateurii

A literature search was performed in Web of Science core collection and in Pubmed using the search term: "Gluconobacter frateurii": 74 and 45 citations were identified and screened respectively.

Microbacterium foliorum

A search using the species name "Microbacterium foliorum" in the Web of Science core collection provided 29 hits.

Phaeodactylum tricornutum

Literature searches were performed in the Web of Science Core Collection. Using only the species name "Phaeodactylum tricornutum" gave 2,917 references. Using refined search terms gave the following numbers of references, which were all scanned at title level:

- "Phaeodactylum tricornutum" and (species characterization): 55 references.
- "Phaeodactylum tricornutum" and taxonom*: 55 references.
- "Phaeodactylum tricornutum" and ecology: 50 references.
- "Phaeodactylum tricornutum" and (secondary metabolit*): 17 references.
- "Phaeodactylum tricornutum" and infect*: 14 references.
- "Phaeodactylum tricornutum" and toxi*: 299 references.
- "Phaeodactylum tricornutum" and safety: 14 references.
- "Phaeodactylum tricornutum" and BMAA: 3 references.

Sphingomonas elodea

A literature search was performed in PubMed database using the search term: "Sphingomonas elodea": 26 hits were identified and screened, mainly dealing with the gellan gun production and the molecular characterisation of the enzymes and genes involved in this production.

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 following protocol for extensive literature search (ELS) will be used in the context of the EFSA self-task mandate on the list of QPS-recommended biological agents intentionally added to the food or feed (EFSA-Q-2016-00684).

B.1. Description of the process

An ELS of studies related to safety concerns for humans, animals, plants and/or the environment of microorganisms recommended for the Qualified Presumption of Safety (QPS) 2019 list will be performed.

The process will be performed according to the following main steps:

- ELS for potentially relevant citations;
- Relevance screening to select the citations identified by the literature search, based on titles and abstract and then full-text;
- Evaluation of articles according to pre-specified categories of possible safety concerns;
- Discussion between experts to come to collective expert evaluation of the outcome, reflected in the QPS Opinion and Panel Statements.

Considering the purpose of the QPS approach, a broad search will be performed.

The review questions will be broken down into key elements using the PECO conceptual model:

- Population of interest (P);
- Exposure of interest (E);
- Comparator (C);
- Outcomes of interest (O).

B.1.1. Objective

The aim is to identify any publicly available studies reporting on safety concerns for humans, animals or the environment caused by microorganisms on the QPS recommended list (see Appendix E).

B.1.2. Target population

The populations of interest are humans, animals, plants and the environment.

B.1.3. Exposure

Citations must report on at least one species included in one of the five groups of named species specified in the EFSA QPS recommended list of the QPS 2016 update ((see Table A.1 in Appendix A to (EFSA BIOHAZ Panel, 2017a)):

a) Gram-positive non-spore-forming bacteria;
b) Gram-positive spore-forming bacteria;
c) Gram-negative bacteria;
d) Viruses used for plant protection;
e) Yeasts.

In more detail:

a) Gram-positive non-spore forming bacteria:

Bifidobacterium adolescentis, Bifidobacterium animalis, Bifidobacterium bifidum, Bifidobacterium breve, Bifidobacterium longum, Carnobacterium divergens, Corynebacterium glutamicum, Lactobacillus acidophilus, Lactobacillus amylolyticus, Lactobacillus animalis, Lactobacillus amylovorus, Lactobacillus alimentarius, Lactobacillus aviaries, Lactobacillus brevis, Lactobacillus buchneri, Lactobacillus casei, Lactobacillus cellobiosus, Lactobacillus collinoides, Lactobacillus coryniformis, Lactobacillus crispatus, Lactobacillus curvatus, Lactobacillus delbrueckii, Lactobacillus diolivorans Lactobacillus farciminis, Lactobacillus fermentum, Lactobacillus gallinarum, Lactobacillus gasseri, Lactobacillus helveticus, Lactobacillus hilgardii, Lactobacillus johnsonii, Lactobacillus kefiranofaciens, Lactobacillus kefiri, *Lactobacillus mucosae, Lactobacillus panis, Lactobacillus paracasei, Lactobacillus paraplantarum, Lactobacillus pentosus, Lactobacillus plantarum, Lactobacillus pontis, Lactobacillus reuteri, Lactobacillus rhamnosus, Lactobacillus sakei, Lactobacillus salivarius, Lactobacillus sanfranciscensis, Lactococcus lactis, Leuconostoc citreum, Leuconostoc lactis, Leuconostoc mesenteroides, Leuconostoc pseudomesenteroides, Microbacterium imperiale, Oenococcus oeni, Pasteuria nishizawae, Pediococcus acidilactici, Pediococcus dextrinicus, Pediococcus parvulus, Pediococcus pentosaceus, Propionibacterium freudenreichii, Propionibacterium acidopropionici, Streptococcus thermophilus;*

b) Gram-positive spore-forming bacteria:

Bacillus amyloliquefaciens, Bacillus atrophaeus, Bacillus clausii, Bacillus coagulans, Bacillus flexus, Bacillus fusiformis, Bacillus lentus, Bacillus licheniformis, Bacillus megaterium, Bacillus mojavensis, Bacillus pumilus, Bacillus smithii, Bacillus subtilis, Bacillus vallismortis, Geobacillus stearothermophilus;

c) Gram-negative bacteria:

Gluconobacter oxydans; *Xanthomonas campestris*;

d) Viruses used for plant protection:

Plant viruses (Family): *Alphaflexiviridae*, *Potyviridae*;
Insect viruses (Family): *Baculoviridae*;

e) Yeasts:

Candida cylindracea, Debaryomyces hansenii, Hanseniaspora uvarum, Kluyveromyces lactis, Kluyveromyces marxianus, Komagataella pastoris, Lindnera jadinii, Ogataea angusta, Saccharomyces bayanus, Saccharomyces cerevisiae, Saccharomyces pastorianus, Schizosaccharomyces pombe, Wickerhamomyces anomalus, Xanthophyllomyces dendrorhous.

For the yeast species, as previously, the name of the teleomorphic form is used in the list of QPS species, when available. Important synonyms and older names were also included in the searches. For instance, names of the anamorphic growth forms were included, when such a form is known:

- *Debaryomyces hansenii*: anamorph *Candida famata*;
- *Hanseniaspora uvarum*: anamorph *Kloeckera apiculata*;
- *Kluyveromyces lactis*: anamorph *Candida spherica*;
- *Kluyveromyces marxianus*: anamorph *Candida kefyr*;
- *Komagataella pastoris*: synonym *Pichia pastoris*;
- *Lindnera jadinii*: synonyms *Pichia jadinii*, *Hansenula jadinii*, *Torulopsis utilis*, anamorph *Candida utilis*;
- *Ogataea angusta*: synonym *Pichia angusta*;
- *Saccharomyces cerevisiae*: synonym *Saccharomyces boulardii*;
- *Saccharomyces pastorianus*: synonym *Saccharomyces carlsbergensis*;
- *Wickerhamomyces anomalus*: synonyms *Hansenula anomala*, *Pichia anomala*, *Saccharomyces anomalus*, anamorph *Candida pelliculosa*;
- *Xanthophyllomyces dendrorhous*: anamorph *Phaffia rhodozyma*.

B.1.4. Comparator

It is expected that the prevalent study designs will be case reports or case series and studies based on surveys or isolate collections. The remaining study designs may include: studies using laboratory isolates; randomised controlled trials, field trials or experimental designs in the laboratory; experimental designs in live animals with a deliberate disease challenge; observational study designs; animal or insect models; investigations to identify or to understand the causes of safety concerns (e.g. identification, characterisation of toxic factors, virulence mechanisms); studies to demonstrate beneficial effects but with reporting of unwanted side-effects.

Since it is expected that in the majority of the study designs relevant for the review question, the comparator will not be available, the latter will not be included as a key element in the search strategy.

B.1.5. Outcomes of interest

The outcomes of interest to this ELS are:

Question 1:

- potential harms;
- safety issues;
- virulence or infectivity;
- intoxication.

Question 2:

- (acquired/intrinsic) antimicrobial resistance (AMR) covering phenotypic and genotypic aspects.

The QPS concept does not address hazards linked to the formulation or processing of the products based on biological agents added into the food or feed chain. Neither the safety of users handling the product nor the genetic modifications are taken into account.

B.1.6. Identification of the review questions

The following research questions will be addressed:

- Is there evidence of any safety concerns, including virulence features and toxin production, for humans, animals, plants and/or the environment associated with microbial species currently recommended for the QPS list since the previous QPS review (i.e. published from June 2016 until June 2019)?
- Is there evidence related to the presence or absence of antimicrobial resistance or antimicrobial resistance genes for the same microbial species published during the same time period?

B.2. Eligibility criteria for study selection

The selection of studies relevant to questions 1 and 2 will be performed applying the eligibility criteria described in Table B.1 below.

Table B.1: Eligibility criteria for questions 1 and 2

	Criteria
Study design	No specific type of study design will be used to include/exclude relevant studies, although it is expected that the prevalent study designs will be case reports or case series and studies based on surveys or isolate collections
Study characteristics:	No exclusion will be based on study characteristics
Population	Humans, animals, plants, environment
Exposure	Studies must report on at least one TU as identified in Section B.1.3
Outcome of interest	Outcomes as listed in Section B.1.5
Language	English
Time	From June 2016 until end June 2019
Publication type	Primary research studies and secondary studies reporting previously unpublished primary studies

B.3. Literature searches

Searches will be conducted in a range of relevant information sources to identify any evidence of safety concerns and AMR regarding the target microbial species.

Considering the results of the previous QPS exercise, to handle the high number of studies identified in each group, 20 search strategies were prepared: three for yeasts, one for insect viruses, one for plant viruses, 13 for Gram-positive bacteria and two for Gram-negative bacteria according to named species specified by EFSA in the QPS recommended list of the QPS 2016 update (see Table A.1 in Appendix A to (EFSA BIOHAZ Panel, 2017a)).

The 20 subgroups of target microbial species will be searched separately.

Each search strategy will comprise two elements: the search terms (Section B.3.1) and the information sources (Section B.3.2) to be searched.

B.3.1. Search terms

The search strategies used to identify studies are given in Appendix C.
Each strategy will comprise two key elements:

- Target microbial species as described in Section B.1.3 ('Exposure')
- Safety issues as described in Section B.1.5 ('Outcomes').

In order to maximise the sensitivity of the search for the species for which the number of overall publications in the relevant time period is expected to be low, the search strategy will not include outcome-related terms.

The population of interest (humans, animals, plants or the environment) will not be included as a key element in the search strategies, as it is often not explicitly described within a title or abstract. It would also have been difficult to describe adequately such a broad population using title/abstract words and/or subject headings. Population information will be captured at the time of evaluating the articles (see Section B.1 above).

Search terms for safety issues were identified in close collaboration with the information specialist; example of such terms, are the following: 'toxin*', 'disease*', 'infection*', 'clinical*', 'virulen*', 'antimicrobial resistan*', 'endocarditis'.

The 20 subgroups of target microbial species will be entered on separate search lines. The search line for each group will be combined with the safety terms individually.

The searches will not be limited by language or study design.

The review period will be from June 2016 to June 2019.

B.3.2. Information sources searched

The same information sources used for the previous QPS exercise (EFSA BIOHAZ Panel et al., 2017a) will be searched for studies reporting safety concerns regarding the target microbial species (see Table B.2 below).

Table B.2: Information sources to be searched to identify relevant studies

Information source	Interface
Web of Science Core Collection	Web of Science, Thomson Reuters 2018
CAB Abstracts	Web of Science, Thomson Reuters 2018
BIOSIS Citation Index	Web of Science, Thomson Reuters 2018
MEDLINE	Web of Science, Thomson Reuters 2018
Food Science Technology Abstracts (FSTA)	Web of Science, Thomson Reuters 2018

Search results will be downloaded from the information sources and imported into EndNote® X8 bibliographic management software. For each of the 20 species groups, within-group removal of duplicate entries will be done in EndNote® X8. Following uploading of the species groups into the DistillerSR[12] online software, removal of duplicates will again be undertaken, using the Duplicate Detection feature.

B.4. Study selection and article evaluation

To identify potentially relevant studies to be included in the review the studies will be selected by a three -step procedure using the DistillerSR online software.

The results of the different phases of the study selection process will be reported in a flowchart as recommended in the PRISMA statement on preferred reporting items for systematic reviews and meta-analyses (Moher et al., 2009).

[12] DistillerSR, Evidence Partners, Ottawa, Canada. https://www.evidencepartners.com/products/distillersr-systematic-review-software/

B.4.1. Screening for potential relevance at title level

Articles will initially be screened at title level in parallel by two Working Group (WG) expert reviewers and, if needed, EFSA staff.

If the information in the title is not relevant for the research objectives, the article will not proceed to the next step (Section B.4.2).

Articles that will be excluded during screening at this step will be stored in Distiller SR.

In case of doubts or divergences between the reviewers, the paper will proceed to step 2.

B.4.2. Screening for potential relevance at title and abstract level

The articles passing the first step will undergo a screening at abstract level in parallel by two experts.

If the information in title and abstract is not relevant for the research objectives, the article will not proceed to the next step (Section B.4.3).

Articles that will be excluded during screening at this step will be stored in Distiller SR.

In case of doubts or divergences between the reviewers, the paper will proceed to step 3.

B.4.3. Article evaluation

The aim of this step will be to confirm that the article is relevant for the QPS project and, in case it is, to evaluate it. It will be carried out at full text level.

The articles passing the second step will undergo a validation procedure carried out by two experts. One reviewer will initially be tasked with the evaluation of a paper. The evaluation will be then forwarded to another reviewer for the validation of the appraisal received.

In case of disagreement with the initial appraisal, the second reviewer will write down their comments. The reviewers will initially try to solve the disagreement. In case this will not be possible, the conflicting information will be presented for collective expert evaluation of the ELS outcome (see Section B.5).

If the information contained in the article is not relevant for the research objectives, the article will not be evaluated. Articles that will not be considered relevant will be stored in Distiller SR.

B.4.3.1. Questions for study selection and article evaluation

STEP 1 (Screening for potential relevance):

Question 1: Is the full-text available, in English and dealing with safety concerns?

- Yes: Include and continue to Article evaluation form;
- Full text not available: Exclude;
- Full text not in English: Exclude;
- Full text in English but not dealing with safety concerns: Exclude.

STEP 2 (Article evaluation):

Question 2: Identification of the microorganisms

- The article will be characterised in terms of the microorganisms involved;
  Single choice question: the Experts will identify the microorganism/s described in the article. In case more than one microorganism is described in the paper, the form will be repeated for each microorganism.

Question 3: Is there any "methodological" problem identified in the paper under consideration?

- No problems identified;
- Yes some problems were identified.

Question 4: Which "methodological" problems were identified in the paper under consideration? (this question will appear in case in question 3 the option "Yes some problems were identified" will be selected)

- Methodology used for identity confirmation of the microorganism;
- Reliability of the source attribution;
- Misuse of the microorganism (e.g. parenteral exposure);
- Predisposing factors in the exposed subjects;
- Others.

When one of the above options will be selected a dedicated free text box will appear to describe the problem identified.

Question 5: Is there any safety concern identified? (this question will appear in case in question 3 the option "No problems identified" will be selected)

- No safety concerns identified;
- Yes some safety concerns were identified.

Question 6: Which safety concerns were identified? (this question will appear in case in question 5 the option "Yes some safety concerns were identified" will be selected)

- On human health;
- On animal health;
- On the environment;
- On AMR;
- On other aspects.

When one of the above options will be selected a dedicated free text box will appear to describe the safety concern identified.

Question 7: Overall, is there any information that could potentially lead to a change in the QPS status of the microorganism? (this question will appear in case in question 5 the option "Yes some safety concerns were identified" will be selected)

- No;
- Yes.

In case the option "Yes" will be selected a dedicated free text box will appear to describe the information that could potentially lead to a change in the QPS status of the microorganism.

B.5. Collective expert evaluation of the ELS outcome and presentation in the QPS opinion

The overall results of the searches and evaluations of individual articles will be presented in tabular format for each group/subgroup and species. These results will be further evaluated collectively by the working group and the outcome will be reflected in the QPS opinion.

B.6. Update of the process

The literature search, study selection and collective expert evaluation will be repeated every 6 months.

References

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal 2017;15(1):4664, 177 pp. https://doi.org/10.2903/j.efsa.2017.4664

Moher D, Liberati A, Tetzlaff J, Altman DG and the PRISMA Group, 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med, 6, e1000097.

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

Gram-Positive Non-Spore-forming Bacteria

Bifidobacterium spp.

String for species	
"Bifidobacterium adolescentis" OR "Bifidobacterium animalis" OR "Bifidobacterium bifidum" OR "Bifidobacterium breve" OR "Bifidobacterium longum" OR "B adolescentis" OR "B animalis" OR "B bifidum" OR "B breve" OR "B longum"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Carnobacterium divergens

String for species	
"Carnobacterium divergens" OR "C divergens"	
OUTCOME	**String**
6. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
7. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
8. Type of disease	*Not applied*
9. Mortality/Morbidity	*Not applied*
10. Disease Risk	*Not applied*

Corynebacterium glutamicum

String for species	
"Corynebacterium glutamicum" OR "C glutamicum" OR "Brevibacterium lactofermentum" OR "B lactofermentum"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin* OR pathogen*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

***Lactobacillus* spp.**

String for species	
"Lactobacillus acidophilus" OR "Lactobacillus amylolyticus" OR "Lactobacillus amylovorus" OR "Lactobacillus alimentarius" OR "Lactobacillus animalis" OR "Lactobacillus aviaries" OR "Lactobacillus brevis" OR "Lactobacillus buchneri" OR "Lactobacillus casei" OR "Lactobacillus zeae" OR "Lactobacillus cellobiosus" OR "Lactobacillus coryniformis" OR "Lactobacillus crispatus" OR "Lactobacillus curvatus" OR "Lactobacillus delbrueckii" OR "Lactobacillus diolivorans" OR "Lactobacillus farciminis" OR "Lactobacillus fermentum" OR "Lactobacillus gallinarum" OR "Lactobacillus gasseri" OR "Lactobacillus helveticus" OR "Lactobacillus hilgardii" OR "Lactobacillus johnsonii" OR "Lactobacillus kefiranofaciens" OR "Lactobacillus kefiri" OR "Lactobacillus mucosae" OR "Lactobacillus panis" OR "Lactobacillus collinoides" OR "Lactobacillus paracasei" OR "Lactobacillus paraplantarum" OR "Lactobacillus pentosus" OR "Lactobacillus plantarum" OR "Lactobacillus pontis" OR "Lactobacillus reuteri" OR "Lactobacillus rhamnosus" OR "Lactobacillus sakei" OR "Lactobacillus salivarius" OR "Lactobacillus sanfranciscensis" OR "L acidophilus" OR "L amylolyticus" OR "L amylovorus" OR "L alimentarius" OR "L animalis" OR "L aviaries" OR "L brevis" OR "L buchneri" OR "L casei" OR "L zeae" OR "L cellobiosus" OR "L coryniformis" OR "L crispatus" OR "L curvatus" OR "L delbrueckii" OR "L diolivorans" OR "L farciminis" OR "L fermentum" OR "L gallinarum" OR "L gasseri" OR "L helveticus" OR "L hilgardii" OR "L johnsonii" OR "L kefiranofaciens" OR "L kefiri" OR "L mucosae" OR "L panis" OR "L collinoides" OR "L paracasei" OR "L paraplantarum" OR "L pentosus" OR "L plantarum" OR "L pontis" OR "L reuteri" OR "L rhamnosus" OR "L sakei" OR "L salivarius" OR "L sanfranciscensis"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	opportunistic OR virulen*

Lactococcus lactis

String for species	
"Lactococcus lactis" OR "L lactis"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Leuconostoc spp.

String for species	
"Leuconostoc mesenteroides" OR "Leuconostoc lactis" OR "Leuconostoc pseudomesenteroides" OR "Leuconostoc citreum" OR "L mesenteroides" OR "L lactis" OR "L pseudomesenteroides" OR "L citreum"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Microbacterium imperiale

String for species	
"Microbacterium imperiale" OR "M imperiale"	
OUTCOME	**String**
6. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
7. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
8. Type of disease	*Not applied*
9. Mortality/Morbidity	*Not applied*
10. Disease Risk	*Not applied*

Oenococcus spp.

String for species	
"Oenococcus oeni" OR "O oeni"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

Pasteuria nishizawae

String for species	
"Pasteuria nishizawae" OR "P nishizawae"	
OUTCOME	**String**
11. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
12. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
13. Type of disease	*Not applied*
14. Mortality/Morbidity	*Not applied*
15. Disease Risk	*Not applied*

Pediococcus spp.

String for species	
"Pediococcus pentosaceus" OR "Pediococcus dextrinicus" OR "Pediococcus acidilactici" OR "Pediococcus parvulus" OR "P pentosaceus" OR "P dextrinicus" OR "P acidilactici" OR "P parvulus"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

Propionibacterium spp.

String for species	Number papers retrieved and notes
"Propionibacterium acidipropionici" OR "Propionibacterium freudenreichii" OR "P acidipropionici" OR "P freudenreichii"	**176**
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

Streptococcus thermophilus

String for species	
"Streptococcus thermophilus" OR "S thermophilus" "Streptococcus thermophilus" OR "S thermophilus"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Gram-positive spore-forming bacteria

Bacillus spp.

String for species	
"Bacillus amyloliquefaciens" OR "Bacillus coagulans" OR "Bacillus clausii" OR "Bacillus atrophaeus" OR "Bacillus flexus" OR "Bacillus fusiformis" OR "Lysinibacillus fusiformis" OR "Bacillus licheniformis" OR "Bacillus lentus" OR "Bacillus mojavensis" OR "Bacillus megaterium" OR "Bacillus vallismortis" OR "Bacillus smithii" OR "Bacillus subtilis" OR "Bacillus pumilus" OR "Geobacillus stearothermophilus" OR "B amyloliquefaciens" OR "B coagulans" OR "B clausii" OR "B atrophaeus" OR "B flexus" OR "B fusiformis" OR "L fusiformis" OR "B licheniformis" OR "B lentus" OR "B mojavensis" OR "B megaterium" OR "B vallismortis" OR "B smithii" OR "B subtilis" OR "B pumilus" OR "G stearothermophilus"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antibiotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	opportunistic OR virulen*

Gram-negative bacteria

Gluconobacter oxydans

String for species	
"Gluconobacter oxydans" OR "G oxydans"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

Xanthomonas campestris

String for species	
"Xanthomonas campestris" OR "X campestris"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

Yeasts

TUs without keywords for OUTCOME

String for species	
"Candida cylindracea" OR "Debaryomyces hansenii" OR "Candida famata" OR "Hanseniaspora uvarum" OR "Kloeckera apiculata" OR "Ogataea angusta" OR "Pichia angusta" OR "Saccharomyces bayanus" OR "Saccharomyces pastorianus" OR "Saccharomyces carlsbergensis" OR "Wickerhamomyces anomalus" OR "Hansenula anomala" OR "Pichia anomala" OR "Saccharomyces anomalus" OR "Candida pelliculosa" OR "Xanthophyllomyces dendrorhous" OR "Phaffia rhodozyma" OR "C cylindracea" OR "D hansenii" OR "C famata" OR "H uvarum" OR "K apiculata" OR "O angusta" OR "P angusta" OR "S bayanus" OR "S pastorianus" OR "S carlsbergensis" OR "W anomalus" OR "H anomala" OR "P anomala" OR "S anomalus" OR "C pelliculosa" OR "X dendrorhous" OR "P rhodozyma"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	*Not applied*

TUs with keywords for OUTCOME except for type of disease and morbility/mortality

String for species	
"Kluyveromyces lactis" OR "Candida spherica" OR "Kluyveromyces marxianus" OR "Candida kefyr" OR "Komagataella pastoris" OR "Pichia pastoris" OR "Lindnera jadinii" OR "Pichia jadinii" OR "Hansenula jadinii" OR "Torulopsis utilis" OR "Candida utilis" OR "Schizosaccharomyces pombe" OR "K lactis" OR "C spherica" OR "K marxianus" OR "C kefyr" OR "K pastoris" OR "P pastoris" OR "L jadinii" OR "P jadinii" OR "H jadinii" OR "T utilis" OR "C utilis" OR "S pombe"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antimycotic resistan* OR antimicrobial susceptibil*
2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR fungemia OR fungaemia OR mycos*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	*Not applied*
5. Disease Risk	opportunistic OR virulen*

TUs with keywords for OUTCOME except for type of disease

String for species	
"Saccharomyces cerevisiae" OR "Saccharomyces boulardii" OR "Scerevisiae" OR "Sboulardii"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	antimicrobial resistan* OR antimycotic resistan* OR antimicrobial susceptibil*

2. Infection/Bacteremia/Fungemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR fungemia OR fungaemia OR mycos*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Viruses used for plant protection

Alphaflexiviridae

String for species	
"Alphaflexiviridae" OR "Potyviridae"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	necros*
3. Type of disease	*Not applied*
4. Mortality/Morbidity	mortalit* OR safety concern* OR "health hazard"
5. Disease Risk	virulen*

Baculoviridae

String for species	
"Nuclear polyhedrosis virus" OR "granulovirus" OR "baculoviridae"	
OUTCOME	**String**
1. Antimicrobial/Antibiotic/Antimycotic	*Not applied*
2. Infection/Bacteremia/Fungemia/Sepsis	*Not applied*
3. Type of disease	"nuclear polyhedrosis" OR granulosis
4. Mortality/Morbidity	mortalit* OR safety concern* OR "health hazard"
5. Disease Risk	*Not applied*

Appendix D – References selected from the ELS exercise as relevant for the QPS for searches from July to December 2018 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium spp.

Kim MJ, Seockmo K, Sun Young K, Hyun Ha L, Hui J, Sini K, Rui L, Johnston TV, Myeong Soo P and Geun Eog J, 2018. Safety evaluations of *Bifidobacterium bifidum* BGN4 and *Bifidobacterium longum* BORI. International Journal of Molecular Sciences, 19, 1422–1422.

Magistrelli L, Amoruso A, Milner AV, Mogna L, Cantello R, Pane M and Comi C, 2018. Effects of probiotic bacterial strains on peripheral inflammation in Parkinson's disease. European Journal of Neurology, 25, 428–428.

Suzuki S, Campos-Alberto E, Morita Y, Yamaguchi M, Toshimitsu T, Kimura K, Ikegami S, Katsuki T, Kohno Y and Shimojo N, 2018. Low Interleukin 10 Production at Birth Is a Risk Factor for Atopic Dermatitis in Neonates with *Bifidobacterium* Colonization. International Archives of Allergy and Immunology, 177, 342–349.

Carnobacterium divergens

None

Corynebacterium glutamicum

None

Lactobacilli spp.

Arokiyaraj S, Seo SS, Kwon M, Lee JK and Kim MK, 2018. Association of cervical microbial community with persistence, clearance and negativity of Human Papillomavirus in Korean women: a longitudinal study. Scientific Reports, 8, 15479.

Costa RL, Moreira J, Lorenzo A and Lamas CC, 2018. Infectious complications following probiotic ingestion: a potentially underestimated problem? A systematic review of reports and case series. Bmc Complementary and Alternative Medicine, 18, 329.

Esaiassen E, Hjerde E, Cavanagh JP, Pedersen T, Andresen JH, Rettedal SI, Stoen R, Nakstad B, Willassen NP and Klingenberg C, 2018. Effects of Probiotic Supplementation on the Gut Microbiota and Antibiotic Resistome Development in Preterm Infants. Frontiers in Pediatrics, 6, 347.

Griff PM, Schleper A, Lynch CA, Sun Y and Butler TR, 2018. CHRONIC ADMINISTRATION OF PROBIOTIC L. RHAMNOSUS AFFECTS ANXIETY-LIKE BEHAVIOR IN A MODEL OF ALCOHOL USE DISORDER VULNERABILITY. Alcoholism-Clinical and Experimental Research, 42, 35A–35A.

Hojsak I, Fabiano V, Pop TL, Goulet O, Zuccotti GV, Cokugras FC, Pettoello-Mantovani M and Kolacek S, 2018. Guidance on the use of probiotics in clinical practice in children with selected clinical conditions and in specific vulnerable groups. Acta Paediatrica, 107, 927–937.

Kao, B-Z, Lin H-J, Chen M-Y, Wu C-S, Lin S-T, Lee M-H, Lai Y-X and Hu P-J, 2018. *Lactobacillus paracasei* as cause of liver abscess: Case report. Journal of Gastroenterology and Hepatology, 33, 433–433.

Kawai K, Kamochi R, Oiki S, Murata K and Hashimoto W, 2018. Probiotics in human gut microbiota can degrade host glycosaminoglycans. Scientific Reports, 8, 10674.

Maillet F, Passeron A, Podglajen I, Ranque B and Pouchot J, 2018. *Lactobacillus delbrueckii* urinary tract infection in a male patient. Medecine et maladies infectieuses.

Naqvi SSB, Nagendra V and Hofmeyr A, 2018. Probiotic related *Lactobacillus rhamnosus* endocarditis in a patient with liver cirrhosis. IDCases, 13, e00439–e00439.

Okba A, Shahin R, Attallah A, Sheha D, Mkawy M and Farag M, 2018. ROLE OF INTESTINAL MICROBIOTA IN CARDIOVASCULAR DISEASE RISK IN END STAGE RENAL DISEASE PATIENTS. Nephrology Dialysis Transplantation, 33, 573–574.

Zawistowska-Rojek A and Tyski S, 2018. Are Probiotic Really Safe for Humans? Polish Journal of Microbiology, 67, 251–258.

Zeba F, Yirerong J, Assali M, Tewary G and Noska A, 2018. A Double Whammy: *Lactobacillus acidophilus* Bacteremia and Subsequent *Lactobacillus rhamnosus* Prosthetic Valve Infective Endocarditis in an Elderly Diabetic Patient. Rhode Island Medical Journal (2013), 101, 32–35.

Lactococcus lactis

Chen F, Zhang Z and Chen J, 2018. Infective endocarditis caused by *Lactococcus lactis* subsp. *lactis* and *Pediococcus pentosaceus*: A case report and literature review. Medicine, 97, e13658–e13658.

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Microbacterium imperiale

None

Oenococcus oeni

None

Pasteuria nishizawae

None

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None

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None

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Geobacillus stearothermophilus

None

Gram-negative bacteria

Gluconobacter oxydans

None

Xanthomonas campestris

None

Yeasts

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Viruses used for plant protection

Alphaflexiviridae

Potyviridae

Baculoviridae

None.

Appendix E – The 2016 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, 2016) is being maintained in accordance with the self-task mandate of the BIOHAZ Panel (2017–2019). Possible additions to this list are included around every 6 months, with the first Panel Statement adopted in June 2017 and the last Panel Statement planned for adoption in December 2019. These additions are published as updates to the Scientific Opinion (EFSA BIOHAZ Panel, 2016); the latest update is available at https://doi.org//10.2903/j.efsa.2018.5315 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 2018 and March 2019 (reply to ToR 1)

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Bacteria						
Feed additives	*Bacillus amyloliquefaciens* CBS143954	Zootechnical additives/Digestibility enhancer endo-1,4-beta-xylanase (EC 3.2.1.8) produced by GMM *Trichoderma reesei*, subtilisin protease (EC 3.4.21.62) produced by GMM *Bacillus subtilis* and alpha-amylase (EC 3.2.1.1) produced by GMM *Bacillus amyloliquefaciens*	EFSA-Q-2018-01040		Yes	No
Plant protection products	*Bacillus amyloliquefaciens* FZB42	Fungicide	EFSA-Q-2019-00096		Yes	No
Feed additives	*Bacillus licheniformis* DSM 19670	Zootechnical additives/Digestibility enhancers RONOZYME® ProAct (serine protease produced by a GMM strain of *Bacillus licheniformis* DSM 19670)	EFSA-Q-2019-00156		Yes	No
Feed additives	*Bacillus licheniformis* ENV01/DSM 32457	Technological additives/Silage additive	EFSA-Q-2018-00690		Yes	No
Feed additives	*Bacillus subtilis* CBS143946	Zootechnical additives/Digestibility enhancer? endo-1,4-beta-xylanase (EC 3.2.1.8) produced by GMM *Trichoderma reesei*, subtilisin protease (EC 3.4.21.62) produced by GMM *Bacillus subtilis* and alpha-amylase (EC 3.2.1.1) produced by GMM *Bacillus amyloliquefaciens*	EFSA-Q-2018-01040		Yes	No
Feed additives	*Bacillus subtilis* DSM32324, *Bacillus subtilis* DSM32325 and *Bacillus amyloliquefaciens* DSM25840	Zootechnical feed additive/Flora stabiliser	EFSA-Q-2019-00117	*Bacillus subtilis* DSM32324, *Bacillus subtilis* DSM32325 and *Bacillus amyloliquefaciens* DSM25840 are non-GMM, and are all three of natural origin	Yes	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Food enzymes, food additives and flavourings	*Burkholderia ubonensis*	Food enzyme triacylglycerol lipase produced by *Burkholderia ubonensis*	EFSA-Q-2019-00056	*Burkholderia ubonensis* has been used for over 20 years for the production of the food enzyme	No	Yes
Feed additives	*Corynebacterium ammoniagenes* KCCM 80161	Sensory additives/ Flavouring compounds IMP (disodium 5′-inosinate) produced by fermentation with *Corynebacterium ammoniagenes* KCCM 80161	EFSA-Q-2019-00040	Disodium 5′-inosinate feed grade is a highly purified product and does not contain any microorganisms. After the fermentation, the cells of the production strain *Corynebacterium ammoniagenes* KCCM80161 are eliminated by filtration and centrifugation from the fermentation broth	No	Yes
Feed additives	*Corynebacterium casei* KCCM80190	Nutritional Additives/Amino Acids, their salts and analogues. L-lysine produced by fermentation with a GMM *Corynebacterium casei* KCCM80190	EFSA-Q-2019-00195		No	Yes
Feed additives	*Corynebacterium glutamicum* KCCM 80184	Nutritional additives/Amino acids/ Production of L-methionine	EFSA-Q-2018-01017		Yes	No
Feed additives	*Corynebacterium glutamicum* KCCM80188	Sensory additives/ Flavouring compounds MSG (monosodium L-glutamate) produced by fermentation with *Corynebacterium glutamicum* KCCM80188	EFSA-Q-2019-00037		No	No
Feed additives	*Corynebacterium glutamicum* KFCC11043	Nutritional Additives/Amino Acids, their salts and analogues L-lysine sulphate feed grade produced by fermentation with *Corynebacterium glutamicum* KFCC11043 (GMM)	EFSA-Q-2019-00194		Yes	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Novel foods	*Escherichia coli* BL21 (DE3) strain	Production of a recombinant protein (novel food) for food supplements	EFSA-Q-2018-00316	GMM *E. coli* Summary of the application under "APOAEQUORIN" at https://ec.europa.eu/food/safety/novel_food/authorisations/summary-ongoing-applications-and-notifications_en	No	No
Novel foods	*Escherichia coli* DSM 32833	Production of novel food 6-SL (6′-sialyllactose sodium salt)	EFSA-2019-0169	GMM *E. coli* (K12-DH1 derivative)	No	No
Novel foods	*Escherichia coli* DSM 32834	Production of novel food 3-SL (3′-sialyllactose sodium salt)	EFSA-2019-0204	GMM *E. coli* (K12-DH1 derivative)	No	No
Feed additives	*Escherichia coli* K12 KCCM 80096	Nutritional additives/Amino acids/ Production of L-methionine	EFSA-Q-2018-01017		No	No
Feed additives	*Escherichia coli KCCM* 80109 *Escherichia coli KCCM* 80197	Sensory additives/ Flavouring compounds/ L-cysteine hydrochloride monohydrate by fermentation with *Escherichia coli* KCCM 80109 and *Escherichia coli* KCCM 80197	EFSA-Q-2019-00041	L-cysteine hydrochloride monohydrate feed grade is a highly purified product and does not contain any microorganisms. After the fermentation, the cells of the production strain *E. coli* K12 KCCM 80109 and KCCM 80197 are removed by filtration and centrifugation from the fermentation broth	No	No
Novel foods	*Escherichia coli* strain K12 DH1 (DSM 32774)	Production of 2′-fucosyllactose/ difucosyllactose (novel food)	EFSA-Q-2018-00374 http://www.efsa.europa.eu/en/efsajournal/pub/5717	GMM *E. coli* (K12-DH1 derivative) Summary of application: https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_2fl-dfl.pdf	No	No
Novel foods	*Escherichia coli* K12 derivative	For the production of allulose (novel food); a recombinant derivative of *Escherichia coli* strain K-12 is used in the fermentation process to produce D-psicose 3-epimerase	EFSA-Q-2018-00756	Summary of application: https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_sum_ongoing-app_allulose_sum.pdf	No	No
Feed additives	*Escherichia coli* K12 KCCM 80159 (C 001)	Nutritional additives/Amino acids/ Production of L-valine	EFSA-Q-2018-00712		No	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Feed additives	*Escherichia coli NITE* BP-02526	Nutritional additives/Amino acids/ Flavouring compounds/Sensory additives/Production of L-histidine monohydrochloride monohydrate	EFSA-Q-2018-00782		No	No
Feed additives	*Gluconobacter frateurii* NBRC 103465	Zootechnical additives/ *Gluconobacter frateurii* NBRC 103465 is a glyceric acid producing strain. Used for the production of the active ingredient: 2,3-dihydroxy propanoic acid/glyceric acid (GA), D-enantiomer (D-GA)	EFSA-Q-2018-00999	Other Zootechnical additives/Draft Genome Sequence of *Gluconobacter frateurii* NBRC 103465, has been published online by Sato et al. in 2013 Jul 25. https://doi.org/10.1128/genomea.00369-13	No	Yes
Feed additives	*Lactobacillus buchneri* DSM 29026	Technological Additives/Silage Additives	EFSA-Q-2019-00180	This is a non-holder specific additive. The strain has also been designated MFLBU1 or LBU1	Yes	No
Feed additives	*Microbacterium foliorum* SYG27B-MF	Production of the novel food D-allulose	EFSA-Q-2018-00797	Non-GMM strain of *Microbacterium foliorum*	No	Yes
Feed additives	*Sphingomonas elodea* PS-60 ATCC 31461	Technological additives/Gelling agents, Stabilisers, Thickeners/ Production of Gellan Gum	EFSA-Q-2018-00815		No	Yes
Filamentous fungi						
Food enzymes, food additives and flavourings	*Aspergillus niger* (DSM 25770)	Zootechnical additives Digestibility enhancers 6-phytase produced by a GMM strain of *Aspergillus niger* (DSM 25770)	EFSA-Q-2019-00042	Natuphos® E is a preparation of 6-phytase produced by *Aspergillus niger*, LU17257 (DSM 25770)		
Food enzymes, food additives and flavourings	*Aspergillus niger* DSM 32805	Food enzyme chymosin IUBMB name and number of the enzyme protein: 3.4.23.4; Chymosin from GMM strain of *Aspergillus niger* DSM 32805. This strain was previously known under the name *A. niger* var. awamori	EFSA-Q-2019-00125		No	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Feed additives	*Aspergillus niger* strain ATCC 26550 and NRC A-1-233	Zootechnical functional group/ Performance enhancer AviPlus® is a preparation based on a mixture of sorbic acid, citric acid, thymol and vanillin	EFSA-Q-2019-00154	The production of citric acid process is via fermentation of a stable non-GMM *Aspergillus niger* strain	No	No
Feed additives	*Aspergillus niger* strain ATCC 26550/ NRC A-1-233	Zootechnical additive/Performance enhancer AviPlus® is a preparation based on a mixture of sorbic acid, citric acid, thymol and vanillin	EFSA-Q-2019-00157	The production of citric acid process is via fermentation of a stable non-GMM *Aspergillus niger* strain	No	No
Plant protection products	*Trichoderma atroviride* AGR2	Plant protection product	EFSA-Q-2018-00476	Pesticide risk assessment and peer review of *Trichoderma atroviride* AGR2 in accordance with Article 12 of Regulation (EC) No 1107/2009 (application for approval)	No	No
Feed additives	*Trichoderma longibrachiatum* MUCL 49754 /*Trichoderma longibrachiatum* MUCL 49755	Zootechnical additives/Production of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase	EFSA-Q-2018-00762		No	No
Feed additives	*Trichoderma reesei* CBS143953	Zootechnical additives/endo-1,4-beta-xylanase (EC 3.2.1.8) produced by GMM *Trichoderma reesei*, subtilisin protease (EC 3.4.21.62) produced by GMM *Bacillus subtilis* and alpha-amylase (EC 3.2.1.1) produced by GMM *Bacillus amyloliquefaciens*	EFSA-Q-2018-01040		No	No
Feed additives	*Trichoderma reesei* DSM 32338	Zootechnical additives/Production of muramidase	EFSA-Q-2018-00952		No	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Feed additives	*Trichoderma reesei* MUCL 49755	Zootechnical additives/Digestibility enhancers Used for the production of endo-1,4-beta-xylanase (Bergazym® P 100)	EFSA-Q-2019-00097	The strain used for the production of the xylanase is *Trichoderma reesei* MUCL 49755		
Feed additives	*Trichoderma reesei* RF5427 strain	Zootechnical additives/Digestibility enhancers/Production of endo-1,4-beta-xylanase	EFSA-Q-2018-00824		No	No
Feed additives	*Trichoderma reesei* strain Morph-Y5#2 (CBS143953)	Zootechnical additives/Digestibility enhancers/Production of Xylanase by GMM *Trichoderma reesei*	EFSA-Q-2018-01039		No	No
Yeasts						
Feed additives	*Komagataella pastoris* appaT75 (CGMCC 12056) previously known as *Pichia pastoris*	Zootechnical feed additive/ Digestibility enhancer APSA PHYTAFEEDR 20,000 is a preparation of 6-phytase produced in two formulations. APSA PHYTAFEEDR 20,000 is produced by fermentation of a GMM yeast	EFSA-Q-2019-00188		Yes	No
Feed additives	*Komagataella pastoris* appaT75 (CGMCC 12056) previously known as *Pichia pastoris*	Zootechnical feed additive/ Digestibility enhancer APSA PHYTAFEEDR 20,000 is a preparation of 6-phytase produced in two formulations. APSA PHYTAFEEDR 20,000 is produced by fermentation of a GMM yeast	EFSA-Q-2019-00192		Yes	No
Feed additives	*Pichia pastoris*	Nutrase P (6-phytase) belongs to the category 4 'zootechnical additives' in its functional group 'digestibility enhancers'	EFSA-Q-2019-00155	The strain used for the production is a GMM *Pichia pastoris*	Yes	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(C)]	To be evaluated? yes or no[(d)]
Feed additives	*Saccharomyces cerevisiae*	Nutritional additives/vitamins, pro-vitamins and chemically well-defined substances having a similar effect 25-hydroxycholecalciferol (25-OH-D3)	EFSA-Q-2019-00155	25-OH-D3 is obtained from the raw material 5,7,24-cholestatrienol ('trienol'). Trienol is produced by a fermentation process using a GMM *Saccharomyces cerevisiae* strain number SC0639		
Feed additives	*Saccharomyces cerevisiae* CBS 493.94	Zootechnical additives/Digestibility enhancers	EFSA-Q-2018-00893		Yes	No
Feed additives	*Saccharomyces cerevisiae* CNCM I-3399	Nutritional additives/Selenium-enriched yeast	EFSA-Q-2018-00908	Trace elements	Yes	No
Novel foods	*Yarrowia lipolytica* A-101	As a novel food production of yeast biomass/Chromium enriched	EFSA-Q-2018-00769	Application from same applicant as *Yarrowia lipolytica* biomass (see above)/Summary of application: NA Qualification: 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass	Yes	No
Novel foods	*Yarrowia lipolytica* A-101	As a novel food production of yeast biomass/Selenium enriched	EFSA-Q-2018-00796	Application from same applicant as *Yarrowia lipolytica* biomass (See above)/Summary of application: NA Qualification: 'for production purpose only' implies the absence of viable cells of the production organism in the final product and can also be applied for food and feed products based on microbial biomass	Yes	No

EFSA risk assessment area	Microorganism species/strain	Intended use	EFSA Question number[(a)] and EFSA webpage link[(b)]	Additional information provided by the EFSA Scientific Unit	Previous QPS status of the respective TU?[(c)]	To be evaluated? yes or no[(d)]
Viruses						
Plant protection products	*Spodoptera exigua multicapsid nucleopolyhedrovirus* (SeMNPV)	Plant protection product	EFSA-Q-2018-00726	Pesticide risk assessment and peer review of *Spodoptera exigua multicapsid nucleopolyhedrovirus* (SeMNPV) in accordance with Article 12 of Regulation (EC) No 1107/2009 (application for approval)	Yes	No
Algae						
Novel foods	*Euglena gracilis*	As a novel food consisting on dried whole cells of *Euglena gracilis*	EFSA-Q-2019-00043	A minimally processed dried biomass of *E. gracilis* preparation, containing a minimum of 50% algae beta-glucan	No	Yes
Novel foods	*Phaeodactylum tricornutum*	PhaeoSOL is a novel food consisting on an extract of the microalgae *Phaeodactylum tricornutum* to be uses as a source of the naturally occurring carotenoid, fucoxanthin	EFSA-Q-2019-00091	PhaeoSOL consists of an ethanolic extraction of microalgae dried biomass	No	Yes

(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 at the time of the publication of this Panel Statement.
(c): Included in the QPS list as adopted in December 2016 (EFSA BIOHAZ Panel, 2017) and respective updates which include new additions (latest: EFSA BIOHAZ Panel, 2018).
(d): In the current Panel Statement.