STATEMENT

ADOPTED: 7 June 2018

doi: 10.2903/j.efsa.2018.5315

Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 8: suitability of taxonomic units notified to EFSA until March 2018

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Abstract

The qualified presumption of safety (QPS) was developed to provide a harmonised generic pre-evaluation procedure to support safety risk assessments of biological agents performed by EFSA's Scientific Panels. The identity, body of knowledge, safety concerns and antimicrobial resistance of valid taxonomic units were assessed. Safety concerns identified for a taxonomic unit 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 taxonomic units and their qualifications. The 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. Between September 2017 and March 2018, the QPS notification list was updated with 46 microorganisms from applications for market authorisation. From these, 28 biological agents already had QPS status, 15 were excluded of the QPS exercise from the previous QPS mandate (10 filamentous fungi and one bacteriophage) or from further evaluations within the current mandate (two notifications of *Streptomyces* spp. and one of *Escherichia coli*), and one was excluded where confirmatory data for the risk assessment of a plant protection product (PPP) was requested (*Pseudomonas* sp.). Three taxonomic units were (re)evaluated: *Paracoccus carotinifaciens* and *Paenibacillus lentus* had been previously evaluated in 2008 and 2014, respectively, and were now re-evaluated within this mandate, and *Yarrowia lipolytica,* which was evaluated for the first time. *P. carotinifaciens* and *P. lentus* cannot be granted QPS status due to lack of scientific knowledge. *Y. lipolytica* is recommended for QPS status, but only for production purpose.

Keywords: safety, QPS, bacteria, yeast, *Paenibacillus lentus*, *Paracoccus carotinifaciens*, *Yarrowia lipolytica*

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Question number: EFSA-Q-2016-00829

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Acknowledgements: The Panel wishes to thank EFSA staff members Jaime Aguilera, Rosella Brozzi, Leng Heng and Frédérique Istace, for the support provided to this Statement.

Amendment: On page 42, Appendix F, the text under the entry *Pichia pastoris* has been corrected for the information shown in the columns 'Microorganism species/strain', 'Intended use' and 'EFSA Question number and EFSA webpage link'. 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.

Suggested citation: EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Fernández Escámez PS, Girones R, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlström H, Cocconcelli PS, Peixe L, Maradona MP, Querol A, Suarez JE, Sundh I, Vlak J, Barizzone F, Correia S and Herman L, 2018. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 8: suitability of taxonomic units notified to EFSA until March 2018. EFSA Journal 2018;16(7):5315, 42 pp. https://doi.org/10.2903/j.efsa.2018.5315

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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.

The complete evaluation 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 notified to EFSA within the 6-month period for an assessment for feed additives, food enzymes, food additives and flavourings, novel foods or plant protection products (PPPs). The main results of these assessments completed from 2017 will be included in the scientific Opinion of the BIOHAZ Panel to be published by the end of the current mandate in December 2019. 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 with the inclusion of new recommendations for QPS status and the new version 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 plant protection products for safety assessment. The list was updated with the notifications received since the latest review in September 2017. The new notifications received between September 2017 and March 2018, were included in a table appended to the current Statement (Appendix F). Within this period, 46 notifications were received by EFSA, of which 34 were for feed additives, 4 for food enzymes, food additives and flavourings, 7 for PPPs and 1 for novel foods.

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 to update the information provided in the previous Opinion adopted in December 2016. According to the articles retrieved through a second extensive literature search (ELS) for articles published between June and December 2017, no new information that would affect the QPS status of those TUs and their qualifications was found.

The *third ToR* requires a (re)assessment of the suitability of TUs notified to EFSA not present in the current QPS list for their inclusion in the updated list. The current Statement focuses on the assessments of the TUs that were notified to EFSA between September 2017 and March 2018. Of the 46 notifications received, 28 biological agents already had QPS status and did not require further evaluation in this Statement and 11 were not included as they are filamentous fungi or bacteriophages that were excluded from the QPS exercise; two notifications of *Streptomyces* sp. and one of *Escherichia coli* were excluded from further QPS evaluations within the current QPS mandate and one notification of *Pseudomonas* sp. was not considered as it corresponded to a request for confirmatory data for the risk assessment of a PPP. Three new TUs were considered for the QPS assessment within this Statement: *Paracoccus carotinifaciens,* already evaluated in 2008, and *Paenibacillus lentus*, already evaluated in 2014, and were re-evaluated within this mandate and *Yarrowia lipolytica* which was evaluated for the first time. *Paracoccus carotinifaciens* and *Paenibacillus lentus* cannot be granted the QPS status due to lack of sufficient knowledge. *Yarrowia lipolytica* is recommended for QPS status but only for production purpose.

The 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.

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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 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, 2007a). 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 (2008–2013 updates) and enterococci (2010–2013 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. The revision of the 2013 update (EFSA BIOHAZ Panel, 2013) was updated in 2016 (EFSA BIOHAZ Panel, 2017a) and the next update

[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. EFSA Journal 2005;226, p. 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. EFSA Journal 2007; 293, p. 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. EFSA Journal 2008; 923, p. 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

will be published in a scientific Opinion of the BIOHAZ Panel after its adoption in December of 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 enterococci) 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. Genetically modified microorganisms are similarly not taken into account.[7] 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.

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 September 2017 to March 2018) 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.

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

[7] In the QPS Statement published on January 2018 (EFSA BIOHAZ Panel, 2018), the possibility for genetically modified microorganisms to get the QPS status was introduced when these microorganisms are used for production of food enzymes, food additives and flavourings and feed additives.

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 46 notifications were received between September 2017 and March 2018, of which 34 were for a feed additive, 4 for food enzymes, 1 for novel foods and 7 for plant protection products (Table 1).

In response to ToR 3, out of the 46 notifications, 28 were related to TUs that already had QPS status and did not require further evaluation. Of the remaining 18 notifications, 15 were related to TUs not evaluated for a QPS status for the following reasons:

- Ten notifications related to filamentous fungi and one to a bacteriophage, 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),
- One notification related to *E. coli* and other two to *Streptomyces* sp., which were recently excluded from the current mandate by the BIOHAZ Panel, and
- One notification related to *Pseudomonas* sp. corresponded to a request on confirmatory data for the risk assessment of a plant protection product (PPP).

The TUs corresponding to the remaining three notifications were now evaluated (or re-evaluated if they had been evaluated prior to 2016) for possible QPS recommendation:

- *Paracoccus carotinifaciens* (notified as a feed additive), already evaluated in 2008 and not granted QPS status (see EFSA, 2008),
- *Paenibacillus lentus* (notified as a feed additive), already evaluated in 2014 and not granted QPS status (see EFSA BIOHAZ Panel, 2014), and
- *Yarrowia lipolytica* (notified as a novel food), evaluated for the first time.

The notifications received by EFSA, per risk assessment area, by biological group from September of 2017 and March 2018 are presented in Table 1.

Table 1: Notifications received by EFSA, per risk assessment area and by biological group, from September of 2017 to March 2018

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement	Total
Biological group	**Already QPS**	**Excluded in QPS[a]**		
Feed additives	**23**	**9**	**2**	**34**
Bacteria	21	2	2	25
Filamentous fungi	0	6	0	6
Yeasts	2	0	0	2
Bacteriophages	0	1	0	1
Novel foods	**0**	**0**	**1**	**1**
Yeasts	0	0	1	1
Plant protection products	**3**	**4**	**0**	**7**
Bacteria	2	1	0	3
Filamentous fungi	0	3	0	3
Viruses	1	0	0	1
Food enzymes, food additives and flavourings	**2**	**2**	**0**	**4**
Bacteria	1	1	0	2
Filamentous fungi	0	1	0	1

Risk assessment area	Not evaluated in this Statement		Evaluated in this Statement	Total
Biological group	**Already QPS**	**Excluded in QPS[(a)]**		
Yeasts	1	0	0	1
Total	**28**	**15**	**3**	**46**

QPS: qualified presumption of safety.
(a): The number includes filamentous fungi or enterococci excluded from QPS evaluation in the 2013 QPS Opinion, other bacterial species (*E. coli*, *Streptomyces* spp.) already excluded in the Panel Statement adopted in June 2017 (EFSA BIOHAZ Panel, 2017b) and also to a notification corresponding to a request on confirmatory data for the risk assessment of a plant protection product (PPP).

2.2.2. Use of microorganisms for production purpose

The qualification 'for production purpose only' applies to TUs used for the biosynthesis of specific products for the food chain and subject to a specific authorisation (e.g. feed additives – vitamins, amino acids, polysaccharides and enzymes – and food-processing enzymes). For most of the TUs used for production, data are lacking on direct exposure to humans and animals, while there is a long history of use of their fermentation products in the food chain. This qualification implies the absence of viable cells of the production organism in the final product and is also applicable to food and feed products based on biomass of the micro-organism.

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 June until December 2017). For a detailed protocol of the process and search strategies, refer to Appendices B and C.

After removal of duplicates, 4,190 records were submitted to the *Title screening* step, which led to the exclusion of 4,048. The remaining 142 records were found eligible for the *Title and abstract screening* step, which led to the exclusion of 58 of these. Of the 84 articles that finally reached the *Article appraisal step* (full text), 47 were considered as relevant to consider 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 QPS potentially relevant papers, is shown in Table 2.

Table 2: Flow of records by search strategy

Species	No papers (title screening)	No papers (title/abstract screening)	No papers (article appraisal)	No papers (relevant for QPS)
Alphaflexiviridae and Potyviridae	28	0	0	0
Bacillus spp.	1,107	16	8	5
Baculoviridae	70	5	3	0
Bifidobacterium spp.	204	11	2	0
Carnobacterium divergens			0	0
Corynebacterium glutamicum	42	3	0	0
Gluconobacter oxydans	155	1	0	0
Xanthomonas campestris			0	0
Lactobacillus spp.	565	14	6	6
Lactococcus lactis	152	3	2	0
Leuconostoc spp.	62	8	5	4
Microbacterium imperiale			0	0
Oenococcus oeni	37	0	0	0
Pasteuria nishizawae			0	0
Pediococcus spp.	137	4	3	0
Propionibacterium spp.	49	1	0	0
Streptococcus thermophilus	82	4	3	1

Species	No papers (title screening)	No papers (title/abstract screening)	No papers (article appraisal)	No papers (relevant for QPS)
Yeasts	1,500	72	52	31
Total	4,190	142	**84**	**47**
Excluded	**4,048**	**58**		

QPS: qualified presumption of safety.

3. Assessment

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

3.1.1. *Paenibacillus lentus*

Paenibacillus lentus has been previously evaluated and was not included in the QPS list due to lack of knowledge (EFSA BIOHAZ Panel, 2014).

3.1.1.1. Identity

Paenibacillus lentus is an aerobic, endospore-forming and rod-shaped bacterium, belonging to the phylum *Firmicutes.* This species was described by Li et al. (2014).

Paenibacillus lentus is not a synonym of *Bacillus lentus* as demonstrated by the low percentage of 16S rRNA gene sequence identity of the corresponding type strains.

3.1.1.2. Body of knowledge

Paenibacillus lentus was isolated from soil (Li et al., 2014) and is of industrial interest due to the production of endo-1,4-β-D-mannanase, which can be used as a feed additive (EFSA FEEDAP Panel, 2017, 2018).

3.1.1.3. Safety concerns

Apart from its description as a new species, information on *P. lentus* is scarce.

3.1.1.4. Antimicrobial resistance aspects

No information could be found about AMR of *P. lentus.*

3.1.1.5. Conclusions on a recommendation for the QPS list

Due to the absence of new relevant knowledge for the evaluation, *Paenibacillus lentus* cannot be proposed for the QPS list.

3.1.2. *Paracoccus carotinifaciens*

Paracoccus carotinifaciens has previously been evaluated and, due to lack of knowledge, it was not included in the QPS list (EFSA, 2008).

3.1.2.1. Identity

The genus *Paracoccus* is composed of Gram-negative bacteria that belong to the α-3-subclass of Proteobacteria. *P. carotinifaciens* was identified by DNA–DNA hybridisation and may be differentiated from other species of the genus by its motility (peritrichous flagella) and the production of astaxanthin (Tsubokura et al., 1999).

3.1.2.2. Body of knowledge

By searching in PubMed and in Thomson Reuter's Web of Science for *P. carotinifaciens*, only the paper by Tsubokura et al. (1999) on its taxonomy was considered relevant. Other papers assessed the properties of the carotenoid compounds produced by the organism (Nishioka et al., 2011; Murata et al., 2012; Katsumata et al., 2014). Moreover, EFSA evaluated the safety and efficacy of dried sterilised cells of *P. carotinifaciens*, as a source of red carotenoids to be used as a feed additive for the production of salmon and trout (EFSA, 2007b; EFSA FEEDAP Panel, 2010).

3.1.2.3. Safety concerns

There is no information on the possible toxigenicity/pathogenicity of the organism.

3.1.2.4. Antimicrobial resistance aspects

No information on the AMR of *P. carotinifaciens* is available.

3.1.2.5. Conclusions on a recommendation for the QPS list

Due to the absence of new relevant knowledge for the evaluation, *Paracoccus carotinifaciens* cannot be proposed for the QPS list.

3.2. Taxonomic Units to be evaluated for the first time

3.2.1. *Yarrowia lipolytica*

3.2.1.1. Identity

Yarrowia lipolytica and *Candida lipolytica* are the teleomorph and anamorph names of the same species.

3.2.1.2. Body of knowledge

The species is widespread in nature, as seen from the sources of isolation. Substrates high in lipids are a common source of this species. *Y. lipolytica* has several physiological properties of industrial significance. The species is well-known for production of proteases and lipases. It is also a widely reported contaminant in dairy and meat products, and is common on raw poultry products and in traditional sausages (Kurtzman et al., 2011).

3.2.1.3. Safety concerns

Hazen (1995) paid special attention to *C. lipolytica*, since the species had been implicated as the cause of human infection in one study and it was therefore considered an 'emerging pathogen'. Pfaller and Diekema (2004) reported four *C. lipolytica* isolates among 6,082 *Candida spp*. isolates (i.e. less than 0.1%) from human bloodstream infections. Shin et al. (2000) reported a temporal outbreak of hospital-acquired infections with *C. lipolytica* in five patients during 3 months in a paediatric ward in a hospital in Korea. All patients had suppressed immune systems and all but one had a catheter fitted. All recovered from the infection after chemotherapy. Tumbarello et al. (1996) reported the presence of *C. lipolytica* in one out of 64 HIV patients with oral candidiasis. The comprehensive review of Groenewald et al. (2013) concluded that all described human infections with this species have occurred in immunocompromised patients with underlying disease and that the majority were catheter-related. Antifungal therapy invariably resulted in clearance of the pathogen. In the last 5 years, several reports confirm that *C. lipolytica* can behave as an opportunistic pathogen (e.g.: Trabelsi et al., 2015; Abbes et al., 2017; Boyd et al., 2017).

3.2.1.4. Antimicrobial resistance aspects

No relevant information was found.

3.2.1.5. Conclusions on a recommendation for the QPS list

Based on the available information, *Y. lipolytica* is a commonly occurring species in many habitats/environments. It may behave as an opportunistic pathogen for immunocompromised patients, especially for those that are using catheters.

Yarrowia lipolytica is recommended for the QPS list but only for production purpose.

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

The summaries of the search and 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 June and December 2017, 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.

Two papers (Morovic et al., 2017; Smilowitz et al., 2017) were selected for *Bifidobacterium*; for one the full text could not be obtained and for the other, no safety concern was identified. Consequently, the QPS status of *Bifidobacterium* spp. is not changed.

3.3.1.2. *Carnobacterium divergens*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *C. divergens* is not changed.

3.3.1.3. *Corynebacterium glutamicum*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *C. glutamicum* is not changed.

3.3.1.4. *Lactobacillus* spp.

Six articles were found to raise possible safety concerns involving lactobacilli. The cases described involved *L. gasseri* (two papers), *L. rhamnosus*, *L. salivarius*, *L. paracasei* and *L. zeae* (*L. casei*). However, identification of *L. gasseri* on the Elikowski et al. (2017) reference was performed by phenotypic methods, which are not considered as completely reliable. The patients described in the remaining papers (Aaron et al., 2017; Esquibel et al., 2017; Pararajasingam and Uwagwu, 2017; Stroupe et al., 2017; Wang et al., 2017; respectively) presented underlying health problems (e.g. mitral regurgitation, uncontrolled diabetes, alcoholism, periodontal abscesses, etc.). In the case of the *L. paracasei* infection, the same strain was isolated from a fermented milk product and from the patient (Pararajasingam and Uwagwu, 2017). Based on the evidence described above, the QPS status of the *Lactobacillus* species involved in the reported cases and, by extension, of all other lactobacilli included in the QPS list, is not changed.

3.3.1.5. *Lactococcus lactis*

Two papers (Camperio et al., 2017; Matsuda et al., 2017) reached the final stage of evaluation but no safety concerns were identified. Consequently, the QPS status of *Lactococcus lactis* is not changed.

3.3.1.6. *Leuconostoc* spp.

Five papers arrived to the final stage of the evaluation. One was not found relevant as it was not food-borne related (Camperio et al., 2017). For the other four papers, two papers were related to infections due to *Leuconostoc* spp.: in the first case, a 44-year-old woman with acute myeloid leukaemia under myelosuppression, had bacteraemia by *Leuconostoc lactis* (Matsuda et al., 2017); in the second case, *Leuconostoc mesenteroides* was isolated from a 50-day old baby hospitalised with diarrhoea, presenting catheter-related septicaemia. In this latter study, a phenotypic identification procedure was performed (Karbuz et al., 2017). In both cases, the patients had underlying diseases and the infections were not food-borne and in relation to the second case, there was uncertainty linked to the species identification. For another paper (Ananieva et al., 2017), the identification was done using biochemical methods, and the last article concerns the AMR of a small number of *Leuconostoc* spp. strains (Cai et al., 2017). Based on the available evidence as described above, the QPS status of the *Leuconostoc* species involved in the reported cases and, by extension, of all other *Leuconostoc* spp. included in the QPS list is not changed.

3.3.1.7. *Microbacterium imperiale*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Microbacterium imperiale* is not changed.

3.3.1.8. *Oenococcus oeni*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Oenococcus oeni* is not changed.

3.3.1.9. *Pasteuria nishizawae*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Pasteuria nishizawae* is not changed.

3.3.1.10. *Pediococcus* spp.

Three papers (Nero et al., 2017; Rzepkowska et al., 2017; Sirichokchatchawan et al., 2017) reached the final selection phase but were not considered relevant. Consequently, the QPS status of *Pediocooccus* spp. is not changed.

3.3.1.11. *Propionibacterium*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Propionibacterium* spp. is not changed.

3.3.1.12. *Streptococcus thermophilus*

Three papers (Bonham et al., 2017; Flórez and Mayo, 2017; Gong et al., 2017) reached the final selection phase. One article (Flórez and Mayo, 2017) describes the AMR of a few strains of *S. thermophilus* strains not linked to safety concerns to humans and that were not related to currently-in-use *S. thermophilus* starters. They were not considered relevant for further QPS assessment because none of them reported safety concerns related to this species. Therefore, the QPS status of *Streptococcus thermophiles* is not changed.

3.3.2. Gram-positive spore-forming bacteria

3.3.2.1. *Bacillus* spp.

Eight papers concerning *Bacillus* spp. reached the final selection phase and were analysed in-depth. Three of these papers were considered not relevant for the QPS context: two papers because they are not dealing with *Bacillus* spp. on the QPS list (Broussolle et al., 2017; Bzdil et al., 2017), one paper because it does not deal with safety concerns (Lakshmi et al., 2017). The remaining five articles were considered relevant as they described potential safety concerns but were not considered: one paper because of methodological shortcomings on source attribution (Allam et al., 2017), two papers because of methodological shortcomings on strain identification (Danilova et al., 2017; Garcia-Ramon et al., 2018), two papers because they are dealing with intrinsic AMR not associated with any known genetic element able to mobilise resistance genes (Glenwright et al., 2016; Jeong et al., 2017) and with strain specific acquired antimicrobial resistance genes (Jeong et al., 2017). The ELS did not come up with any information that would change the *Bacillus* species included in the QPS list.

3.3.3. Gram-negative bacteria

3.3.3.1. *Gluconobacter oxydans*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Gluconobacter oxydans* is not changed.

3.3.3.2. *Xanthomonas campestris*

No paper reached the final selection phase, so no new safety concern was found. Consequently, the QPS status of *Xanthomonas campestris* is not changed.

3.3.4. Yeasts

Fifty-two papers reached the final stage of the ELS (please refer to Appendix D for the complete list of references). Several of the yeasts on the QPS list occasionally were reported associated with fungal and nosocomial infections in immunocompromised or post-surgery patients. Collectively, the ELS identified 31 articles with 38 studies referring to different yeast species with QPS status, of which 15 referred to *Candida kefyr* (teleomorph = *Kluyveromyces marxianus*), five to *Saccharomyces cerevisiae* of which five were identified as *Saccharomyces boulardii*, seven to *Candida famata* (teleomorph = *Debaryomyces hansenii*) and six to *Candida pelliculosa* (synonymus = *Pichia anomala,* teleomorph = *Wickerhamomyces anomalus*). For the other yeast species with QPS status, no relevant studies were identified through the ELS. Several of the papers identified had methodological shortcomings in the species identification, reducing the value of the results. The ELS did not come up with any information that would change the yeast species included in the QPS list.

3.3.5. Viruses used for plant protection

3.3.5.1. Alphaflexiviridae and Potyviridae

No paper reached the final selection phase, so no new safety concern was found. The ELS did not come up with any information that would change the current QPS status of any member of the Alphaflexiviridae and Potyviridae families.

3.3.5.2. Baculoviridae

Three papers (Lacey, 2017; Maciel-Vergara and Ros, 2017; van Oers et al., 2017) reached the final stage of evaluation but no safety concerns were identified. The ELS did not come up with any information that would change the current QPS status of any member of the Baculoviridae family.

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 September 2017 and March 2018, the list was updated with 46 notifications that were received by EFSA, of which 34 were for feed additives, four for food enzymes, food additives and flavourings, one for nutrition and seven 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 afety 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 28 out of the 46 notifications received already had a QPS status.
- The TUs corresponding to 15 out of 18 notifications without a QPS status were: 10 notifications related to filamentous fungi and 1 to a bacteriophage which were excluded from QPS activities in the follow-up of a recommendation of the QPS 2013 update (EFSA BIOHAZ Panel, 2013, 2014, 2016), 1 notification related to *E. coli* and 2 to *Streptomyces* spp. which were recently excluded from the current mandate by the BIOHAZ Panel, 1 notification related to *Pseudomonas* spp. was not considered as it corresponded to a request on confirmatory data concerning the risk assessment of a PPP which should not be assessed for a possible QPS status.
- Three TUs, corresponding to 3 notifications out of those 46, were evaluated for potential QPS recommendation: *Paracoccus carotinifaciens,* which was evaluated in 2008, and *Paenibacillus lentus*, previously evaluated in 2014, both not granted the QPS status at that time (see EFSA BIOHAZ Panel, 2014) were now re-evaluated within this mandate. *Yarrowia lipolytica* was evaluated here for the first time.
- The 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.

5. Recommendations

- *Paracoccus carotinifaciens* and *Paenibacillus lentus* cannot be granted QPS status due to lack of knowledge.
- *Yarrowia lipolytica* is recommended for the QPS status but only for production purpose.

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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Wang HK, Teng LJ, Chen YC, Du SH and Hsueh PR, 2017. *Lactobacillus salivarius* empyema with respiratory failure. Journal of Microbiology, Immunology and Infection, 50, 923–925. https://doi.org/10.1016/j.jmii.2016.06.001

Glossary and Abbreviations

Antimicrobial compounds	antibiotics, bacteriocins and/or small peptides
AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
ELS	extensive literature search
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FIP	EFSA Food ingredients and packaging Unit
FSTA	Food Science Technology Abstracts
GMM	genetically modified microorganisms
QPS	qualified presumption of safety
PPP	plant protection product
ToR	Term of Reference
TU	taxonomic unit

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)

Paenibacillus lentus

A literature search was performed in PubMed for the body of knowledge using the search terms "*Paenibacillus lentus*", considering all years available: 4 hits were identified and screened. Another search was done in Web of Science. In total, 6 studies were identified and screened.

Paracoccus carotinifaciens

A literature search was performed in PubMed and the Thomson Reuter Web of Science, using the search term "Paracoccus carotinifaciens": 9 hits were identified and screened.

Yarrowia lipolytica

A literature search was performed in PubMed and the Web of Science, using the search term "Yarrowia lipolytica" or "Candida lipolytica" combined with terms related to "infection", "opportunist" and "human disease", concentrating especially on papers from 2013 onwards: 22 papers were identified and screened.

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, 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 2017
CAB Abstracts	Web of Science, Thomson Reuters 2017
BIOSIS Citation Index	Web of Science, Thomson Reuters 2017
MEDLINE	Web of Science, Thomson Reuters 2017
Food Science Technology Abstracts (FSTA)	Web of Science, Thomson Reuters 2017

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[8] 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).

B.4.1. Screening for potential relevance at title level

Articles will initially be screened at title level in parallel by two reviewers by experts 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).

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

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 relevant for the QPS project?

- 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 relevant: 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: Please report any safety concern with an impact on human health

- Free text

Question 4: Please report any safety concern with an impact on animal health

- Free text

Question 5: Please report any safety concern with an impact on the environment

- Free text

Question 6: Please report any safety concern related to AMR

- Free text

Question 7: Other safety concerns (please specify)

- Free text

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/sub-group 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. Antmicrobial/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**
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*

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	
"Propionibacterium acidipropionici" OR "Propionibacterium freudenreichii" OR "P acidipropionici" OR "P freudenreichii"	
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 "Lindnerajadinii" 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 "S cerevisiae" OR "S boulardii"	
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 June to December 2017 (reply to ToR 2)

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium

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None.

Corynebacterium glutamicum

None.

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Microbacterium imperiale

None.

Oenococcus oeni

None.

Pasteuria nishizawae

None.

Pediococci

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None.

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Gram-Positive Spore-forming Bacteria

Bacillus

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Geobacillus stearothermophilus

None.

Gram-negative bacteria

Gluconobacter oxydans

None.

Xanthomonas campestres

None.

Yeasts

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Viruses used for plant protection

Alphaflexiviridae and Potyviridae

None.

Baculoviridae

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Appendix E – The 2016 updated list of QPS Status recommended biological agents in support of EFSA risk assessments (reply to ToRs 2 and 3)

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) available at https://doi.org//10.2903/j.efsa.2017.4664 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 September 2017 and March 2018 (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?[(c)]	To be evaluated? yes or no[(d)]
Bacteria						
Feed additives	*Bacillus amyloliquefaciens*	Zootechnical additive	EFSA-Q-2017-00722		Yes	No
Feed additives	*Bacillus amyloliquefaciens*	Zootechnical additive	EFSA-Q-2018-00060		Yes	No
Feed additives	*Bacillus amyloliquefaciens*	Zootechnical additive	EFSA-Q-2017-00746		Yes	No
Plant protection products	*Bacillus amyloliquefaciens* strain IT-45	Plant protection product	EFSA-Q-2017-00824	Pesticide risk assessment and peer review of *Bacillus amyloliquefaciens* IT-45 in accordance with Article 12 of Regulation (EC) No 1107/2009 (application for approval)	Yes	No
Plant protection products	*Bacillus pumilus* strain QST 2808	Plant protection product	EFSA-Q-2017-00267 http://www.efsa.europa.eu/en/supporting/pub/en-1218	Request for EFSA to finalise the reporting table on confirmatory data concerning the risk assessment of *Bacillus pumilus* QST 2808	Yes	No
Feed additives	*Bacillus subtilis*	Production of xylanase	EFSA-Q-2017-00749		Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2017-00716 http://www.efsa.europa.eu/en/efsajournal/pub/5204		Yes	No
Feed additives	*Bacillus subtilis*	Technological additive	EFSA-Q-2017-00745		Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2017-00746		Yes	No
Feed additives	*Bacillus subtilis*	Technological additive	EFSA-Q-2017-00744		Yes	No
Feed additives	*Bacillus subtilis*	Production of xylanase	EFSA-Q-2018-00253		Yes	No
Feed additives	*Corynebacterium glutamicum*	Production of threonine	EFSA-Q-2018-00084		Yes	No
Feed additives	*Corynebacterium glutamicum*	Production of lysine	EFSA-Q-2018-00266		Yes	No
Feed additives	*Corynebacterium glutamicum*	Production of histidine	EFSA-Q-2018-00438		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?[c]	To be evaluated? yes or no[d]
Food additives, food enzymes, flavourings	*Corynebacterium glutamicum* strain FIS002	Production of food enzyme D-psicose 3-epimerase	EFSA-Q-2018-00115		Yes	No
Feed additives	*Escherichia coli* K12 KCCM80152	Zootechnical additive	EFSA-Q-2017-00693		No	No
Feed additives	*Lactobacillus farciminis*	Zootechnical additive	EFSA-Q-2017-00756		Yes	No
Feed additives	*Lactobacillus farciminis*	Technological additive	EFSA-Q-2017-00754		Yes	No
Feed additives	*Lactobacillus farciminis*	Zootechnical additive	EFSA-Q-2017-00755		Yes	No
Feed additives	*Lactobacillus plantarum* DSM 8862	Zootechnical additive	EFSA-Q-2018-00268		Yes	No
Feed additives	*Lactobacillus plantarum* DSM 8866	Zootechnical additive	EFSA-Q-2018-00268		Yes	No
Feed additives	*Lactobacillus rhamnosus*	Zootechnical additive	EFSA-Q-2017-00756		Yes	No
Feed additives	*Lactobacillus rhamnosus*	Technological additive	EFSA-Q-2017-00754		Yes	No
Feed additives	*Lactobacillus rhamnosus*	Zootechnical additive	EFSA-Q-2017-00755		Yes	No
Feed additives	*Paenibacillus lentus*	Production of mannanase	EFSA-Q-2018-00050 http://www.efsa.europa.eu/en/efsajournal/pub/5270		No	Yes
Feed additives	*Paracoccus carotinifaciens*	Production of carotenoid	EFSA-Q-2017-00694		No	Yes
Feed additives	*Pediococcus acidilactici*	Zootechnical additive	EFSA-Q-2018-00268		Yes	No
Plant protection products	*Pseudomonas* sp. strain DSMZ 13134	Plant protection product	EFSA-Q-2017-00267 http://www.efsa.europa.eu/en/supporting/pub/en-1218	Request for EFSA to finalise the reporting table on confirmatory data concerning the risk assessment of *Pseudomonas* sp. strain DSMZ 13134	No	No
Feed additives	*Streptomyces albus*	Production of salinomycin sodium (coccidiostat)	EFSA-Q-2017-00661 http://www.efsa.europa.eu/en/efsajournal/pub/5209		No	No
Food additives, food enzymes, flavourings	*Streptomyces mobaraensis* strain DSM40587	Production of food enzyme transglutaminase	EFSA-Q-2017-00615		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?[c]	To be evaluated? yes or no[d]
Bacteriophages						
Feed additives	3sent1, 8sent65, 8sent1748 & 5sent1	Zootechnical additive	EFSA-Q-2017-00724		No	No
Filamentous fungi						
Plant protection products	*Ampelomyces quisqualis* strain AQ10	Plant protection product	EFSA-Q-2015-00021 http://www.efsa.europa.eu/en/efsajournal/pub/5078	Request for an EFSA peer review (EFSA Conclusion) on the active substance *Ampelomyces quisqualis* strain AQ10 according to Article 13 of Regulation (EU) No 844/2012 (application for renewal) (first application to COM only, not to EFSA)	No	No
Feed additives	*Aspergillus niger*	Production of glucanase	EFSA-Q-2017-00651		No	No
Feed additives	*Aspergillus niger*	Production of beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase	EFSA-Q-2018-00001 http://www.efsa.europa.eu/en/efsajournal/pub/5271		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (NZYM-BF)	Production of food enzyme glucoamylase	EFSA-Q-2018-00265		No	No
Feed additives	*Aspergillus tubingensis*	Production of alpha-galactosidase	EFSA-Q-2017-00837		No	No
Plant protection products	*Beauveria bassiana* 203	Plant protection product	EFSA-Q-2017-00593	Pesticide risk assessment and peer review of *Beauveria bassiana* 203 in accordance with Article 12 of Regulation (EC) No 1107/2009 (application for approval)	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?[c]	To be evaluated? yes or no[d]
Plant protection products	*Lecanicillium muscarium* strain Ve6	Plant protection product	EFSA-Q-2017-00055	Request for an EFSA peer review (EFSA Conclusion) on the active substance *Lecanicillium muscarium* Ve6 according to Article 13 of Regulation (EU) No 844/2012 (application for renewal)	No	No
Feed additives	*Trichoderma citrinoviride*	Production of xylanase	EFSA-Q-2017-00747		No	No
Feed additives	*Trichoderma reesei*	Production of glucanase, alpha-amylase and protease	EFSA-Q-2017-00717		No	No
Feed additives	*Trichoderma reesei*	Production of xylanase	EFSA-Q-2017-00682		No	No
Yeasts						
Feed additives	*Komagataella pastoris*	Production of phytase	EFSA-Q-2017-00650		Yes	No
Food additives, food enzymes, flavourings	*Pichia pastoris* (strains UGT-a and UGT-b)	Production of food additives steviol glycosides (E 960)	EFSA-Q-2018-00242	GMM strain	Yes	No
Novel foods	*Yarrowia lipolytica* yeast biomass	As a novel food (NF)	EFSA-Q-2018-00223	Request for a scientific opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2018/0208) (NF application)	No	Yes
Viruses						
Plant protection products	*Pepino mosaic virus*, strain CH2, isolate 1906	Plant protection product	EFSA-Q-2015-00483 http://www.efsa.europa.eu/en/efsajournal/pub/4458	Review of MRLs (Maximum Residue Limits)	Yes	No

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

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

(c): Included in the QPS list as adopted in December 2016 (EFSA BIOHAZ Panel, 2017) and respective updates which include new additions (latest: EFSA BIOHAZ Panel, 2018).

(d): In the current Panel Statement.