STATEMENT

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Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 6: suitability of taxonomic units notified to EFSA until March 2017

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Abstract

The qualified presumption of safety (QPS) concept was developed to provide a harmonised generic pre-evaluation 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 as 'qualifications' which should be assessed at the strain level by the EFSA's scientific Panels. No new information was found that would change the previously recommended QPS taxonomic units and their qualifications. Between the end of September 2016 and March 2017, the QPS notification list was updated with 87 applications for market authorisation. From these, 32 biological agents already had a QPS status, and 37 were not included in the evaluation as they are filamentous fungi or enterococci. *Streptomyces* species (*Streptomyces cinnamonensis, Streptomyces mobaraensis* and *Streptomyces violaceoruber), Bacillus circulans* (three notifications) and *Escherichia coli* (seven notifications) were re-confirmed not suitable for QPS. *Streptomyces rubiginosus* and *Streptomyces netropsis*, not evaluated within the previous mandate, were also not recommended for QPS. *Streptomyces* spp. and *E. coli* will be excluded from further QPS evaluations within the current QPS mandate. *Hyphomicrobium denitrificans,* which has never been evaluated before, was not recommended for the QPS list and for *Pseudomonas amyloderamosa,* the QPS assessment was not applicable because it is not a validated species. *Lactobacillus animalis* was a new taxonomic unit recommended to have the QPS status.

Keywords: safety, QPS, bacteria, yeast, *Hyphomicrobium denitrificans*, *Lactobacillus animalis*, *Pseudomonas amyloderamosa*

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Amendment: An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. In Appendix B the text has been revised so as to clarify that the 2016 updated list of QPS status recommended biological agents in support of EFSA risk assessment will be published in the 2016 Scientific Opinion of the BIOHAZ Panel and on the Knowledge Junction at: https://doi.org//10.5281/zenodo.1146566. 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 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 and antimicrobial resistance of biological agents are assessed. Safety concerns identified for a taxonomic unit are, where possible and reasonable in number, reflected as 'qualifications' which should be assessed at the strain level by the EFSA's scientific Panels. A generic qualification for all QPS bacterial taxonomic units applies in relation to the absence of acquired genes conferring resistance to clinically relevant antimicrobials and therefore this needs to be checked at strain level.

The evaluation is undertaken every 3 years in a scientific Opinion of the BIOHAZ Panel. Meanwhile, the list of microorganisms is maintained and around every 6 months re-evaluated in a Panel Statement. If new information would be retrieved from extended literature search or expert knowledge that would change the QPS status of a microbial species or its qualifications, this would be 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. The main results of these assessments done 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. Appended to 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 updated with the inclusion of new recommendations for QPS status (Appendix B).

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 of 2016. The new notifications received since then and March 2017, were included in a table appended to the current Statement (Appendix C). Within this period, 87 notifications were received by EFSA, of which 35 were from feed additives, 49 from food enzymes, food additives and flavourings, one from novel foods, and two from plant protection products.

The *second ToR* concerns the revision of the taxonomic units 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. Although the main work for replying to this ToR will be published in an Opinion in December of 2019, according to experts' knowledge, no new information that would affect those QPS taxonomic units and their qualifications was found.

The *third ToR* requires a (re)assessment of the suitability of taxonomic units 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 taxonomic units that were notified to EFSA between the end of September 2016 and March 2017. Of the 87 notifications received, 32 biological agents already had the QPS status and did not require further evaluation in this Statement. From the remaining 55 (without a QPS status), 37 were not further assessed as they are filamentous fungi or enterococci, which have been excluded from QPS. Eleven notifications related to seven taxonomic units dealing with food enzymes, food additives and flavourings, six related to three taxonomic units dealing with feed additives and one dealing with a novel food were evaluated for the QPS status. Three *Streptomyces* species (*Streptomyces cinnamonensis, Streptomyces mobaraensis* and *Streptomyces violaceoruber), Bacillus circulans* (three notifications) and *Escherichia coli* (seven notifications) were previously considered not suitable for QPS status and now re-confirmed. Two *Streptomyces* species not evaluated previously (*Streptomyces rubiginosus* and *Streptomyces violaceoruber)* were also not recommended for a QPS status. It was agreed that *Streptomyces* spp. and *E. coli* will be excluded from further QPS status evaluations within the current mandate. *Hyphomicrobium denitrificans* which has never been evaluated before is not recommended for the QPS list, and *Pseudomonas amyloderamosa,* for which does not exist a validated taxonomic unit name, the QPS assessment is not applicable. *Lactobacillus animalis* is a new taxonomic unit recommended to have a QPS status.

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1. Introduction

A wide variety of microorganisms is intentionally added at different stages into the food chain, either directly or as a source of food and feed additives, enzymes or plant protection products. In the context of applications for market authorisation of these biological agents, EFSA is requested by the European Commission, National Competent Authorities or Applicants to assess their safety. 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 authorisations (EFSA, 2007). The list, first established in 2007, has continuously been revised and updated. The publication of the overall assessment of the taxonomic units previously recommended for the QPS list is carried out every 3 years through a scientific Opinion by the Panel on Biological Hazards (BIOHAZ). The recommendations provided concerning that list of microorganisms will be maintained and every 6 months re-evaluated based on extensive literature reviews and experts knowledge. Intermediate deliverables in the form of a Panel Statement will be produced and published, 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, and plant protection products. Evaluations of these notifications will be compiled in single Panel Statements for periods of around 6 months. The main results of these assessments will also be included in the scientific opinion to be published in December of 2019.

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 (2005).[1] The EFSA Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and in (2007) published a list of microorganisms recommended for the QPS list.[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 BIOHAZ Panel took the prime responsibility for this and started reviewing annually the existing QPS list. In 2008, the first annual QPS update[3] was published and EFSA's initial experience in applying the QPS approach 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 update) and enterococci (2010–2013 update) 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, 13 yeast species and three virus families.

[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

In 2014, the BIOHAZ Panel, in consultation with the Scientific Committee, decided to change the revision procedure: the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013)[5] was no longer carried out annually but over the last 3-year period and it was adopted in a scientific Opinion of the BIOHAZ Panel in December of 2016 (EFSA BIOHAZ Panel (2017a,b). 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. Assessment of potential allergenicity to microbial residual components is beyond the QPS remit; however, if there is science-based evidence for some microbial species it is reported. These aspects are assessed, where applicable, 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

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 product 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 taxonomic units (TUs) covered by the relevant international committees on the nomenclature for microorganisms are considered for the QPS assessment.

For the TUs associated with the notifications compiled within the time period covered by this Statement (from end of September 2016 until March 2017), the literature review considered the identification, the body of knowledge, history of use, the antimicrobial resistance and the potential safety concerns.

Relevant databases such as PubMed, Web of Science, CasesDatabase, 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.

2.2. Methodologies

In response to ToR1, the EFSA Units have been asked to update the list of biological agents being notified to EFSA. Eighty-seven (87) notifications were received between the end of September 2016 and the beginning of March 2017, of which 35 were from a feed additive, 49 from food enzymes, one from a novel food and two from plant protection products (Table 1).

In response to ToR3, out of 87 notifications, 32 biological agents already had the QPS status and did not require further evaluation; neither did the 37 filamentous fungi or enterococci, which have been excluded from QPS activities in the follow up of a recommendation of the QPS 2013 update (EFSA BIOHAZ Panel, 2013, 2014). A total of eighteen notifications were considered in the current Statement. Three notifications for *Streptomyces* species (*Streptomyces cinnamonensis, Streptomyces mobaraensis* and *Streptomyces violaceoruber*), three for *Bacillus circulans* and seven for *Escherichia coli* were evaluated for QPS status during the last QPS mandate and were considered not suitable for QPS status but were re-evaluated within the current mandate. Five notifications related to five taxonomic units were evaluated for QPS status for the first time: *Streptomyces rubiginosus*, *Streptomyces netropsis, Hyphomicrobium denitrificans*, *Lactobacillus animalis* and *Pseudomonas amyloderamosa*. They were notified for an assessment by the food enzymes/food additives/flavourings area (*B. circulans*, *E. coli*, *P. amyloderamosa*, *S. mobaraensis*, *S. netropsis*, *S. rubiginosus*, *S. violaceoruber*), by the feed additives area (*E. coli*, *L. animalis*, *S. cinnamonensis*) and by the novel foods area (*H. denitrificans*).

Table 1: Notifications received by EFSA, per risk assessment area, by biological group from September 2016 until March 2017

Risk assessment area / Biological group	Not evaluated in this Statement		Evaluated in this Statement	Total
	Already QPS	Excluded in QPS[(a)]		
Feed additives	**22**	**7**	**6**	**35**
Bacteria	19	1	6	26
Filamentous fungi		6		6
Yeasts	3			3
Novel foods			**1**	**1**
Bacteria			1	1
Plant protection products		**2**		**2**
Filamentous fungi		2		2
Food enzymes, food additives and flavourings	**10**	**28**	**11**	**49**
Bacteria	10		11	21
Filamentous fungi		28		28
Total	**32**	**37**	**18**	**87**

(a): The number includes filamentous fungi and enterococci excluded from QPS evaluation in the 2013 QPS Opinion.

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

3.1. *Bacillus circulans*

3.1.1. Identity

Bacillus circulans is a valid species name (Skerman et al., 1980), belonging to the genus *Bacillus*. It is a facultative anaerobe, motile, Gram-positive, endospore forming, rod-shaped bacterium. Spores are ellipsoidal and produced in swelling sporangia. *B. circulans* is phylogenetically closely related to *Bacillus firmus* (Logan and De Vos, 2009).

Nakamura and Swezey (1983) noted that *B. circulans* species contained many misclassified strains. This was confirmed by Guinebretière et al. (2001) and Berge et al. (2002) who showed that many strains identified as *B. circulans* using phenotypic features actually belonged to *Paenibacillus* spp. The body of knowledge on *B. circulans* and related safety concerns should be considered cautiously, their reliability strongly depending on the methods used for strain identification.

3.1.2. Body of knowledge

A search for the body of knowledge on *B. circulans* was done in the Web of Science Core collection, using a range of search terms in relation to food and feed, combined with '*Bacillus circulans*' (search strings in Appendix A). One hundred and six references were screened. Most publications concerned synthesis of enzymes for production or modification of polysaccharides that could be used in foods (e.g. Li et al., 2014). Some publications reported the use of *B. circulans* strains as a probiotic in fish (Ghosh et al., 2003; Bandyopadhyay and Mohapatra, 2009; Geraylou et al., 2013; Naseri et al., 2013). Another set of publications report the presence of *B. circulans* in fermented foods, beverages and condiments, typically from tropical countries (Sarkar et al., 2002; Coulin et al., 2006; Almeida et al., 2007; Agbobatinkpo et al., 2013; Chakrabarty et al., 2014). *B. circulans* was also identified in pasteurised milk, raw milk and fermented sausages (Dommett, 1992; Encinas et al., 1996; Matta and Punj, 1999; Mayr et al., 1999; Coorevits et al., 2008). Some of these studies used only phenotypic identification methods and the strains may have been misidentified. In particular, the cold tolerant *B. circulans* may rather be *Paenibacillus* spp., as Guinebretière et al. (2001) found that among food isolates, *B. circulans* were mesophilic whereas the *Paenibacillus* erroneously identified as *B. circulans* by phenotypic systems were cold-tolerant. *B. circulans* has been described to produce the antimicrobial butirosin, a 2-deoxystreptamine aminoglycoside (Kudo et al., 2005).

3.1.3. Safety concerns

A search for safety concerns was done in the Web of Science Core collection, using a range of search terms in relation to toxins and diseases (search strings in Appendix A), combined with '*Bacillus circulans*'. Eighteen articles were found, and they demonstrated that *B. circulans* has been isolated from several cases of human infection. Examples were fatal sepsis, endophthalmitis, endocarditis, interphalangeal joint infection, cholecystitis, and wound infections, with some but not all in immunocompromised individuals (Gatermann et al., 1991; Goudswaard et al., 1995; Khatib et al., 1995; Krause et al., 1999; Tandon et al., 2001). None of these cases was linked to food consumption. *B. circulans* was also reported to produce lipopeptides (Das et al., 2008) and butirosin, an aminoglycoside antimicrobial (Howells et al., 1972; Kudo et al., 2005). In other *Bacillus* species, some lipopeptides are suspected to be the cause of food-borne poisoning (EFSA FEEDAP Panel, 2014). *B. circulans* has been reported to produce the same enterotoxins as *Bacillus cereus* (Phelps and McKillip, 2002; Manzano et al., 2010). *B. circulans* has also been considered as a plant pathogen causing diseases on date palm seedlings (Leary and Chun, 1989). The uncertainties on the identity of strains identified as *B. circulans* mentioned in the 'body of knowledge' also apply to the safety concerns.

3.1.4. Antimicrobial resistance

The aminoglycoside phosphotransferase gene was described in butirosin-producing *B. circulans* strains (Dowding and Davies, 1975; Herberts et al., 1986), indicating the possibility of antimicrobial-producing strains to act as a source of certain resistance determinants (Herberts et al., 1986; Trieucuot and Courvalin, 1986). Moreover, the acquisition of a *vanA* gene cluster conferring resistance to glycopeptides was reported on a clinical isolate identified as *B. circulans* by conventional biochemical methods (Ligozzi et al., 1998).

3.1.5. Conclusions on a recommendation for the QPS list

As with many other *Bacillus* species, *B. circulans* is a rare cause of opportunistic human infections, although presumably not linked to the food chain. It also seems to have the potential of infecting wounds in human tissues. Its presence in foods has been shown in a few studies, with some uncertainties due to the identification methods used. *B. circulans* has been widely studied as a producer of enzyme with potential application as food additives, but there are no reports of its particular usage in human food or animal feed that could indicate an absence of safety concerns. *B. circulans* was also reported to produce butirosin, an aminoglycoside antimicrobial. Some evidence support the possibility that *B. circulans* strains can act as a source of an aminoglycoside phosphotransferase for other bacteria.

B. circulans is not recommended for the QPS list due to the possible production of metabolites with antimicrobial activity and uncertainty on virulence features.

3.2. *Escherichia coli*

3.2.1. Identity

Escherichia coli are Gram-negative, facultative anaerobic bacteria, belonging to the family Enterobacteriaceae, which are taxonomically placed within the gamma subdivision of the Proteobacteria phylum.

E. coli isolates have been divided into subgroups attending to various criteria, either related to pathogenicity towards the human host, serology (e.g. serotypes O127:H7 or K1) or, mainly for population genetic purposes, phylogenetic properties of particular housekeeping genes (subdivided in seven major phylogenetic groups A, B1, B2, C, D, E and F) (Jaureguy et al., 2008). The *E. coli* core genome corresponds to less than half the pangenome, with most of the *E. coli* genes in any given genome being found in some strains, but missing in others (Fukiya et al., 2004; Lukjancenko et al., 2010).

3.2.2. Body of knowledge

A search for the body of knowledge on *E. coli* was done in the Web of Science Core collection (search strings in Appendix A) and 854 references were found and screened.

E. coli is a versatile bacterium, both retrieved from the environment or as a commensal of the intestinal tract of humans and animals. Beside these habitats, certain strains have the potential to cause a wide spectrum of intestinal and extra-intestinal diseases such as urinary tract infection, septicaemia, meningitis and pneumonia in humans and animals. *E. coli* is a well-recognised food-borne enteropathogen and cases and outbreaks are monitored/reported in the 2015 EFSA and ECDC annual Zoonoses Report (EFSA and ECDC, 2016).

E. coli, the most extensively studied prokaryote, was introduced into laboratories almost a century ago to become one of the most important model organisms. Some of these laboratory *E. coli* strains, (e.g. *E. coli* K-12) and its derivatives are widely used as organisms for producing amino acids and vitamins used in the food chain.

3.2.3. Safety concerns

The ability of an *E. coli* strain to behave as a commensal or an extra-intestinal pathogen is determined by a complex balance between many factors, e.g. presence of virulence determinants, production of toxins, portal of entry, inoculum dose, genetic background of the bacterium and immune status of the host. Several virulence determinants are recognised, either involved in enteric infection (e.g. enterotoxins and pili) and/or in extra-intestinal infections (e.g. siderophores, mucinase, cytotoxins, immunomodulators, lectin-like haemagglutinin and colibactin) (Pacheco and Sperandio, 2012; Ruiz-Perez and Nataro, 2014). Recently, worrying observations about the potential implication of these determinants in colon cancer were described, although apparently associated to a specific phylogenetic subgroup (Nowrouzian and Oswald, 2012). Moreover, an incomplete understanding of the virulence factors triggering all clinical disease presentations, including for neonatal meningitis-causing *E. coli*, still persists (Wijetunge et al., 2014). These considerations prevent the proposal of a set of precise qualifications for QPS status.

3.2.4. Antimicrobial resistance

The (β)-lactamase bla_{AmpC} gene with ability when overexpressed to confer resistance to several ß-lactams is intrinsic for *E. coli* (Paltansing et al., 2015). Moreover, this species has the ability to acquire a plethora of different antimicrobial resistance genes (Krizman et al., 2017).

3.2.5. Conclusions on a recommendation for the QPS list

E. coli cannot be proposed for the QPS list as the safety evaluation has to be done on strain level. No further knowledge supports a revision of the previous conclusion attained in 2009 and confirmed in 2014. The Panel has agreed to exclude this species from QPS evaluation within this mandate.

3.3. *Streptomyces cinnamonensis*

3.3.1. Identity

A search in Pub-Med using the key word *S. cinnamonensis*, retrieved 70 articles, the vast majority of which dealt with different aspects of monensin production (Day et al., 1973; Hüttel et al., 2014; Zhang et al., 2016). No paper on *S. cinnamonensis* taxonomic characteristics was found, apart from some that justified classification of *S. cinnamonensis* 16S rRNA-related strains into a new species *S. cinnamonensis* is a valid species, as it is included in the List of Prokaryotic Names with Standing in Nomenclature. No strain belonging to the species has been fully sequenced according to NCBI (Microbial Genomes, online).

3.3.2. Body of knowledge

There is a long record of using monensin as an anticoccidial additive (McDougald, 1976; Chapman et al., 2010; Pirali Kheirabadi et al., 2014). Cases of accidental monensin intoxication of chickens, horses and other farm animals that may involve internal organ compromise, including myocardial and neurological damage and even death, have been reported (Matsuoka, 1976; Oehme and Pickrell, 1999; Zavala et al., 2011). There are no clinical reports involving *S. cinnamonensis* in human disease.

3.3.3. Safety concerns

Apart from the toxicity of monensin, there are two other reasons for concern:

- Monensin is being tested as a possible anticancer agent, although the studies are not as advanced as with salinomycin, another polyether ionophore with a similar mode of antimicrobial action (Choi et al., 2013; Tumova et al., 2014).
- The biosynthetic capacity of *S. cinnamonensis* cannot be assessed due to lack of information on its genome. The common occurrence of multiple pathways encoding secondary metabolites among the streptomycetes whose genomes are known indicates that this might also be the case for *S. cinnamonensis*. Many of these secondary metabolites act as antimicrobials.

Knowledge of the strain and, by extension, of the species it belongs to, is not sufficient to ensure safe application. Especially important is the ability to produce secondary metabolites appears to be strain-specific. Finally, monensin seems to have moderate toxicity to man and animals.

3.3.4. Antimicrobial resistance

No reports of antimicrobial resistance in *S. cinnamonensis* have been found.

3.3.5. Conclusions on a recommendation for the QPS list

S. cinnamonensis is not recommended for the QPS list, because the body of knowledge is limited and safety concerns cannot be excluded.

Streptomycetes are essentially non-virulent, with the exception of some plant pathogens such a *S. scabies* (a search on PubMed in May 2017, using the keywords actinomycetoma and *Streptomyces*, retrieved 106 articles; out of the 45 published from 1990, 12 were considered as relevant, the vast majority of which reported opportunistic single infectious cases). They produce antimicrobials and may thus contribute to selection for resistant bacteria. Other secondary metabolites have diverse biological activities that go from depressors of the immune system to herbicides (Butaye et al., 2003). Genome sequencing has confirmed that streptomycetes carry several gene clusters for the production of secondary metabolites, many of which may be toxic, or select for antimicrobial resistance. Furthermore, the presence of specific clusters varies on a strain basis. All this precludes granting QPS status to any species of the genus *Streptomyces*. No further knowledge supports a revision of the previous conclusion attained in December 2014 (EFSA BIOHAZ Panel, 2014). The Panel decides to exclude this species from QPS evaluation within this QPS mandate.

3.4. *Streptomyces mobaraensis*

3.4.1. Identity

A search in PubMed using the key word *S. mobaraensis*, retrieved 58 articles. The species, previously considered to belong to the genus *Streptoverticillium*, is part of the subgroup of streptomycetes that form whorls and has been separated from others of the same subgroup by DNA-DNA hybridisation and *gyrB* sequence comparison (Hatano et al., 2003). A draft genome from a transglutaminase-producing strain has been reported (Yang et al., 2013).

3.4.2. Body of knowledge

S. mobaraensis is best known by its ability to synthesise a transglutaminase (more than half of the papers quoted above deal with the enzyme and its properties and only a handful are devoted to the biology of the organism). The enzyme is mainly used for protein cross-linking to improve their colloidal stability and foaming properties, as well as for consolidation of meat fibres (Nivala et al., 2017; Santhi et al., 2017).

3.4.3. Safety concerns

At least one strain of the species produces bleomycin (Hindra et al., 2017) and a penicillin acylase has been isolated from another (Zhang et al., 2007). This last enzyme catalyses joining/breaking the bond between the nucleus and the lateral chain of β-lactam antimicrobials. It may be considered as part of the corresponding biosynthesis pathway (many streptomycetes synthesise antimicrobials of this family) or as a resistance determinant.

3.4.4. Antimicrobial resistance

A β-lactamase has been isolated from one of the transglutaminase producing strains (Zindel et al., 2016).

3.4.5. Conclusions on a recommendation for the QPS list

S. mobaraensis cannot be recommended for the QPS list, due to insufficient knowledge of its biology and safety concerns cannot be excluded. For a general conclusion on *Streptomyces* spp., refer to Section 3.3.5.

3.5. *Streptomyces violaceoruber*

3.5.1. Identity

A search in PubMed using the key word *S. violaceoruber*, retrieved 54 articles. This is a valid species and the most known of all streptomycetes (*S. coelicolor*) is a *S. violaceoruber* derivative (Glauert and Hopwood, 1961).

3.5.2. Body of knowledge

S. violaceoruber is best known by its ability to produce granaticin and phospholipase A2 (Ichinose et al., 1998; Sugiyama et al., 2002).

3.5.3. Safety concerns

Granaticin is an aminoacyl tRNA synthetase inhibitor with antibacterial and anticancer properties (Heinstein, 1982) while phospholipase A may present a membrane disrupting activity. *S. coelicolor*, a *S. violaceoruber* derivative, harbours more than twenty secondary metabolite synthesis pathways, several of which present antimicrobial activity (Challis and Hopwood, 2003).

3.5.4. Antimicrobial resistance

No reports of antimicrobial resistance in *S. violaceoruber* have been found.

3.5.5. Conclusions on a recommendation for the QPS list

S. violaceoruber cannot be recommended for the QPS list because safety concerns cannot be excluded. For a general conclusion on streptomycetes, refer to Section 3.3.5.

4. Taxonomic Units to be evaluated for the first time

4.1. *Hyphomicrobium denitrificans*

4.1.1. Identity

The genus *Hyphomicrobium* belongs to the class Alphaproteobacteria and it is composed of Gram-negative cells which are facultative methylotrophs that reproduce by budding at the tip of a polar prostheca.

Hyphomicrobium denitrificans, was proposed as a new species based on physiological characteristics, DNA-DNA hybridisation data and 16S rDNA sequencing with TK 0415 as the type strain (Urakami et al., 1995).

4.1.2. Body of knowledge

A search for the body of knowledge on *H. denitrificans* was done in the Web of Science Core collection (search strings in Appendix A) and a total of 55 papers were retrieved, of which two were considered as relevant for QPS. Most of the existing body of knowledge was related to its nitrite reductase activity.

Hyphomicrobium spp. are common inhabitants of habitats as freshwater reservoirs, brackish water, seawater, sewage treatment plants and soil, and considered normally avirulent (Famurewa et al., 1983). They are not commonly isolated from foods. Some strains are characterised by their denitrification capacities, and their presence is associated with high denitrification rates. They utilise methanol and monomethylamine, but not methane, by the serine pathway with activated formaldehyde incorporation. Genome sequences are publicly available for *H. denitrificans* ATCC 51888 and *H. denitrificans* 1NES1.

H. denitrificans has been proposed as a production organism of a novel food ingredient and is supposed not to be present in the final product.

4.1.3. Safety concerns

No information on the safety of this microorganism was identified.

4.1.4. Antimicrobial resistance

No reports of antimicrobial resistance in *H. denitrificans* have been found.

4.1.5. Conclusions on a recommendation for the QPS list

No safety concerns have been described but the body of knowledge can be considered limited and therefore, *H. denitrificans* cannot be taken into consideration for QPS.

4.2. *Lactobacillus animalis*

4.2.1. Identity

Lactobacillus animalis strains have been isolated from the oral cavity and the gastrointestinal tract of animals (Dent and Williams, 1982) and from kimchi, a fermented vegetable traditional Korean dish (Nam et al., 2011). The type strain is *L. animalis* NCDO 2425. *L. animalis* is an obligate homofermentative organism that produces mainly L-(+) lactic acid and is closely related to *Lactobacillus acidophilus* and *L. ruminis*. DNA base composition is between 41.3 and 44.4% G + C.

4.2.2. Body of knowledge

A search for the body of knowledge on *L. animalis* was done in the Web of Science Core collection (search strings in Appendix A) and a total of 9 papers were retrieved, with 1 considered relevant for QPS (Dent and Williams, 1982). Another literature search was performed in PubMed, 289 papers were identified, from which only 8 or 9 were considered relevant.

L. animalis strain TMW 1.971 has been shown to improve the water holding and gas retention ability of gluten-free doughs by production of exopolysaccharides (Rühmkorf et al., 2012; Ruhmkorf et al., 2013). Effects of *L. animalis* strain LA4 on the composition and the metabolism of the intestinal microbiota in dogs indicate that it might be considered as a potential probiotic for dogs (Biagi et al., 2007). *L. animalis* DPC6134 (Hayes et al., 2007) generated peptides with angiotensin-converting enzyme inhibitory activity from bovine caseinate containing media, with a potential to reduce blood pressure and antihypertensive effects. Bacteriocin production has been characterised for *L. animalis* strain TSU4 (Sahoo et al., 2015).

The genome sequence of *L. animalis* P38, isolated from the cecum content of chicken (Rezvani et al., 2016), of *L. animalis* 381-IL-28, a component of a multistrain commercial food biopreservative (Sturino et al., 2014) and of *L. animalis* KCTC 3501, isolated from kimchi (Nam et al., 2011), have been determined and not found to harbour any genes encoding obvious virulence factors.

4.2.3. Safety concerns

A case of chronic hip prosthetic joint infection caused by *L. animalis* has been described (Somayaji et al., 2016). This occurred in a 70-year-old patient, 5 years after a transient bacteraemia by the same organism as deduced through whole genome sequencing of both causal agents. The patient presented a medical history of type 2 diabetes mellitus and pancreatic cancer.

4.2.4. Antimicrobial resistance

No reports of antimicrobial resistance in *L. animalis* have been found.

4.2.5. Conclusions on a recommendation for the QPS list

The species *L. animalis* is a natural component of bacterial communities of the animal oral cavity and gastro intestinal tract and is also a common starter for fermented vegetables. A single case of human infection by the organism has been reported but it was linked to life-compromising predisposing factors. It is therefore concluded that *L. animalis* does not pose a health risk for the consumer. Consequently, the QPS status can be granted for this species.

4.3. *Pseudomonas amyloderamosa*

Pseudomonas amyloderamosa was isolated from soil for its ability to produce isoamylase (Harada, 1983). It is a patented organism (ATCC number 21216) and not officially recognised as a species. It has no type strain and therefore is not considered for the QPS assessment.

P. amyloderamosa is not a valid TU and therefore cannot be taken into consideration for QPS.

4.4. *Streptomyces netropsis*

4.4.1. Identity

A search in PubMed using the key word *S. netropsis*, retrieved seven articles. The species is part of the subgroup of streptomycetes that form whorls and has been separated from others of the same subgroup by DNA–DNA hybridisation and *gyrB* sequence comparison (Hatano et al., 2003).

4.4.2. Body of knowledge

A search in PubMed for *S. netropsis* retrieved seven articles. *S. netropsis* produces a mix of three pyrrolamide antimicrobials (congocidine, also called netropsin, distamycin and disgocidine, a hybrid of both) which bind to the minor groove of DNA and, consequently, have some potential as leader molecules for the design of anticancer drugs, although the ones known are as yet too toxic for therapeutic use (Hao et al., 2014; Vingadassalon et al., 2015). Some strains produce a transglutaminase with potential in food processing (Yu et al., 2008).

4.4.3. Safety concerns

Safety concerns are related to the generation of toxic anticancer compounds by members of the species, together with the recognised ability of streptomycetes to produce diverse secondary metabolites with strong biological activities.

4.4.4. Antimicrobial resistance

No reports of antimicrobial resistance in *S. netropsis* have been found.

4.4.5. Conclusions on a recommendation for the QPS list

S. netropsis cannot be recommended for the QPS list, due to insufficient knowledge of its biology and because safety concerns cannot be excluded. For a general conclusion on streptomycetes, refer to Section 3.3.5.

4.5. *Streptomyces rubiginosus*

4.5.1. Identity

The organism has been selected on its capacity to generate a D-xylose isomerase (Wong et al., 1991). The enzyme has been thoroughly studied (Carrell et al., 1984; Waltman et al., 2014).

4.5.2. Body of knowledge

A search in PubMed for *S. rubiginosus*, retrieved 33 articles. Knowledge of the species characteristics is extremely scarce.

4.5.3. Safety concerns

Although no biologically-active secondary metabolites have been reported to be produced by *S. rubiginosus*, it may be assumed that the species has the capacity to produce them, as it happens with all the streptomycetes whose genome is known and that this ability is a strain-linked trait.

4.5.4. Antimicrobial resistance

No reports of antimicrobial resistance in *S. rubiginosus* have been found.

4.5.5. Conclusions on a recommendation for the QPS list

S. rubiginosus cannot be recommended for the QPS list, due to insufficient knowledge of its biology and because safety concerns cannot be excluded. For a general conclusion on streptomycetes, refer to Section 3.3.5.

5. 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 the end of September 2016 and March 2017, the list was updated with 87 notifications, of which 35 were dealing with feed additives, 49 with food enzymes, food additives and flavourings, one with novel foods, and two with plant protection products.

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

- No new information was found that would change the QPS TUs and their 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*:

- From the 55 notifications without a QPS status, 37 were not further assessed as they are filamentous fungi or enterococci, which have been excluded from QPS activities. Eighteen notifications corresponding to 10 taxonomic units were considered for the assessment of the suitability of the respective taxonomic units for inclusion in the QPS list.
- From the 10 taxonomic units assessed, seven were notified for an assessment on the food enzymes, food additives and flavourings area (*B. circulans, E. coli, P. amyloderamosa, S. mobaraensis, S. netropsis, S. rubiginosus* and *S. violaceoruber*), three on the feed additives

area (*E. coli, L. animalis* and *Streptomyces cinnamonensis*) and one on novel foods area (*H. denitrificans*).

- After re-evaluation, the Panel has agreed that *E. coli* and *Streptomyces* spp. will be excluded from further QPS evaluations within the current mandate.

6. Recommendations

- *B. circulans, S. mobaraensis, S. violaceoruber, S. cinnamonensis* and *E. coli, which have been evaluated before,* are confirmed as not recommended for the QPS list.
- *H. denitrificans, P. amyloderamosa, S. rubiginosus* and *S. netropsis,* which have never been evaluated before, are not recommended for the QPS list.
- *L. animalis* is recommended for the QPS list.

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Glossary and Abbreviations

antimicrobial substances	antibiotics, bacteriocins and/or small peptides
BIOHAZ	EFSA Panel on Biological Hazards
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
QPS	Qualified Presumption of Safety
ToR	Term of Reference
TU	Taxonomic unit

Appendix A – Search strategy for the evaluated microorganisms

Bacillus circulans

A literature search was performed in Web of Science Core collection. for the body of knowledge using the search terms "Bacillus circulans", and a range of search terms in relation to "food" and "feed", considering all years available: 106 hits were identified and screened. Another search was done for the safety concerns using instead search terms in relation to "toxins" and "diseases". 18 hits were identified and screened.

Escherichia coli

A literature search was performed in Web of Science Core collection, using the search terms "Escherichia coli" for 2017: 854 hits were identified and screened.

Hyphomicrobium denitrificans

A literature search was performed in Web of Science Core collection, using the search terms "Hyphomicrobium denitrificans" considering all years available: 55 references were found and screened.

Lactobacillus animalis

A literature search was performed in Web of Science Core collection, using the search terms "Lactobacillus animalis", considering all years available: 9 references were found and screened. Another literature search was performed in PubMed, using the search terms "Lactobacillus animalis", considering all years available: 289 papers from which only 9 or 8 were considered relevant (if related to bacteriocin production it was not included).

Pseudomonas amyloderamosa

A literature search was performed in PubMed, using the search terms "Pseudomonas amyloderamosa", considering all years available: only hits related to isoamylase production; no hits on identity. Identity status traced back from ATCC website (ATCC number 21216 in Google search found).

Streptomyces cinnamonensis

A literature search was performed in PubMed, using the search terms "Streptomyces cinnamonensis", considering all years available: 70 hits were identified and screened.

Streptomyces mobaraensis

A literature search was performed in PubMed, using the search terms "Streptomyces mobaraensis", considering all years available: 58 hits were identified and screened.

Streptomyces netropsis

A literature search was performed in PubMed, using the search terms "Streptomyces netropsis", considering all years available: 7 hits were identified and screened.

Streptomyces rubiginosus

A literature search was performed in PubMed, using the search terms "Streptomyces rubiginosus", considering all years available: 33 hits were identified and screened.

Streptomyces violaceoruber

A literature search was performed in PubMed, using the search terms "Streptomyces violaceoruber", considering all years available: 54 hits were identified and screened.

Appendix B – The 2016 updated list of QPS Status recommended biological agents in support of EFSA risk assessments

Update 24 January 2018: 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.**

Table B.1: The 2016 updated list of QPS status recommended biological agents to support the safety risk assessments carried out by EFSA Scientific Panels and Units – **please see the paragraph above for the updated version of this table**

Bacteria			
Gram-positive non-spore forming bacteria			
Species			**Qualifications[a]**
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
Carnobacterium divergens[f]			
Corynebacterium glutamicum[b]			QPS only applies when the species is used for amino acid production
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus animalis*[k] *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei*[c] *Lactobacillus cellobiosus* *Lactobacillus collinoides* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus curvatus*	*Lactobacillus delbrueckii* *Lactobacillus diolivorans*[i] *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[f]			QPS only applies when the species is used for enzyme production
Oenococcus oeni			
Pasteuria nishizawae[h]			
Pediococcus acidilactici *Pediococcus dextrinicus*	*Pediococcus parvulus*[i]	*Pediococcus pentosaceus*	
Propionibacterium acidipropionici	*Propionibacterium freudenreichii*		
Streptococcus thermophilus			

Gram-positive spore-forming bacteria			
Bacillus			
Species			**Qualifications**[a]
Bacillus amyloliquefaciens *Bacillus atrophaeus* *Bacillus clausii* *Bacillus coagulans* *Bacillus flexus*[i]	*Bacillus fusiformis* *Bacillus lentus* *Bacillus licheniformis* *Bacillus megaterium*	*Bacillus mojavensis* *Bacillus pumilus* *Bacillus smithii*[j] *Bacillus subtilis* *Bacillus vallismortis*	Absence of toxigenic activity
Geobacillus stearothermophilus			Absence of toxigenic activity
Gram-negative bacteria			
Species			**Qualifications**[a]
Gluconobacter oxydans			QPS only applies when the species is used for vitamin production
Xanthomonas campestris[g]			QPS only applies when the species is used for the production of xanthan gum
Yeasts[e]			
Species			**Qualifications**
Candida cylindracea[f]			QPS only applies when the species is used for enzyme production
Debaryomyces hansenii			
Hanseniaspora uvarum			
Kluyveromyces lactis	*Kluyveromyces marxianus*		
Komagataella pastoris			QPS only applies when the species is used for enzyme production
Lindnera jadinii			
Ogataea angusta			
Saccharomyces bayanus	*Saccharomyces cerevisiae*[d]	*Saccharomyces pastorianus*	Absence of resistance to antimycotics used for medical treatment of yeast infections, in cases where viable cells are added to the food or feed chain. *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37°C
Schizosaccharomyces pombe			
Wickerhamomyces anomalus			QPS only applies when the species is used for enzyme production. Absence of resistance to antimycotics used for medical treatment of yeast infections, in cases where viable cells are added to the food or feed chain
Xanthophyllomyces dendrorhous			

Viruses			
Plant viruses			
Family			
Alphaflexiviridae	Potyviridae		
Insect viruses			
Family			
Baculoviridae			

A specific representative of a QPS proposed taxonomic unit, does not need to undergo a further safety assessment other than to satisfy the specified qualifications, if applicable. On the other hand, representatives of taxonomic units that fail to satisfy a qualification would be considered unfit for the QPS list and would remain subject to a full safety assessment, in the frame of a notification by the responsible EFSA Scientific Panel.

(a): Generic qualification for all QPS bacterial taxonomic units: the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antimicrobials.

(b): *Brevibacterium lactofermentum* is a synonym of Corynebac*terium glutamicum*.

(c): The previously described species '*Lactobacillus zeae'* has been included in the species *Lactobacillus casei.*

(d): *Saccharomyces cerevisiae*, subtype *boulardii* is contraindicated for persons with fragile health, as well as for patients with a central venous catheter in place.

(e): Yeast synonyms commonly used in the feed/food industry:
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*.

(f): Microorganisms recommended in the Panel Statement published in December 2014 (EFSA BIOHAZ Panel, 2014).

(g): Microorganisms recommended in the Panel Statement published in June 2015 (EFSA BIOHAZ Panel, 2015a).

(h): Microorganisms recommended in the Panel Statement published in December 2015 (EFSA BIOHAZ Panel, 2015b).

(i): Microorganisms recommended in the Panel Statement published in June 2016 (EFSA BIOHAZ Panel, 2016).

(j): Microorganisms recommended in the Panel Statement published in March 2017 (EFSA BIOHAZ Panel et al., 2017a).

(k): Microorganisms recommended in this Panel Statement published in July 2017.

Appendix C – Microbial species as notified to EFSA received (between end of September 2016 and March 2017)

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*	Technological additive	EFSA-Q-2016-00646 http://www.efsa.europa.eu/en/efsajournal/pub/4860		Yes	No
Feed additives	*Bacillus amyloliquefaciens*	Zootechnical additive	EFSA-Q-2016-00782		Yes	No
Food additives, food enzymes, flavourings	*Bacillus amyloliquefaciens* (strain DP-Czb53)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00204	GMM strain	Yes	No
Food additives, food enzymes, flavourings	*Bacillus circulans*	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00523		No	Yes
Food additives, food enzymes, flavourings	*Bacillus circulans*/ *Paenibacillus alginolyticus*	Production of food enzyme 1,4-alpha-glucan 6-alpha-glucosyltransferase	EFSA-Q-2016-00522		No	Yes
Food additives, food enzymes, flavourings	*Bacillus circulans*/ *Paenibacillus alginolyticus*	Production of food enzyme alpha-amylase	EFSA-Q-2016-00521		No	Yes
Food additives, food enzymes, flavourings	*Bacillus licheniformis* (strain DP-Dzb25)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00202	GMM strain	Yes	No
Food additives, food enzymes, flavourings	*Bacillus licheniformis* (strain DP-Dzb45)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00143	GMM strain	Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2016-00668		Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2016-00781		Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2017-00090		Yes	No
Feed additives	*Bacillus subtilis*	Zootechnical additive	EFSA-Q-2017-00287		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	*Bacillus subtilis*	Production of food enzyme bacillolysin	EFSA-Q-2016-00527		Yes	No
Food additives, food enzymes, flavourings	*Bacillus subtilis* (strain CICC10074)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00512		Yes	No
Food additives, food enzymes, flavourings	*Bacillus subtilis* (strain DP-Ezx42)	Production of food enzyme subtilisin	EFSA-Q-2016-00175	GMM strain	Yes	No
Food additives, food enzymes, flavourings	*Bacillus subtilis* (strain DP-Ezx62)	Production of food enzyme subtilisin	EFSA-Q-2016-00174	GMM strain	Yes	No
Feed additives	*Corynebacterium glutamicum*	Production of arginine	EFSA-Q-2016-00783		Yes	No
Food additives, food enzymes, flavourings	*Corynebacterium glutamicum* (strain FIS003)	Production of food enzyme D-fructose 4-epimerase	EFSA-Q-2016-00525	GMM strain	Yes	No
Feed additives	*Enterococcus faecium*	Zootechnical additive	EFSA-Q-2017-00051		No	No
Food additives, food enzymes, flavourings	*Escherichia coli* (strain W3110-TKO)	Production of food enzyme D-fructose 3-Epimerase	EFSA-Q-2016-00211	GMM strain	No	Yes
Feed additives	*Escherichia coli* CGMCC 3705	Production of lysine	EFSA-Q-2016-00824 http://www.efsa.europa.eu/en/efsajournal/pub/4714		No	Yes
Feed additives	*Escherichia coli* DSM 25084	Production of tryptophane	EFSA-Q-2016-00570 http://www.efsa.europa.eu/en/efsajournal/pub/4712		No	Yes
Feed additives	*Escherichia coli* K-12	Production of tryptophane	EFSA-Q-2017-00485 http://www.efsa.europa.eu/en/efsajournal/pub/4712		No	Yes

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	*Escherichia coli* K12 (WCM105 x pCM6420)	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00531	GMM strain	No	Yes
Food additives, food enzymes, flavourings	*Escherichia coli* K12 (WCM105 x pCM703)	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00530	GMM strain	No	Yes
Feed additives	*Escherichia coli* KCCM 11132P	Production of tryptophane	EFSA-Q-2016-00570		No	Yes
Food additives, food enzymes, flavourings	*Geobacillus stearothermophilus*	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00863		Yes	No
Food additives, food enzymes, flavourings	*Geobacillus stearothermophilus* (strain DP-Gzb47)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00145		Yes	No
Novel foods area	*Hyphomicrobium denitrificans* CK-275	As a novel food ingredient	EFSA-Q-2016-00659	Pyrroloquinoline Quinone produced by fermentation with *Hyphomicrobium denitrificans* CK-275, non – GMM, Gram-negative, non-spore forming and not present (neither viable bacteria nor detectable genomic DNA) in the final product.	No	Yes
Feed additives	*Lactobacillus acidophilus*	Zootechnical additive	EFSA-Q-2017-00051		Yes	No
Feed additives	*Lactobacillus animalis*	Technological additive	EFSA-Q-2016-00713		No	Yes
Feed additives	*Lactobacillus buchneri*	Technological additive	EFSA-Q-2016-00669		Yes	No
Feed additives	*Lactobacillus delbrueckii* ssp. Bulgaricus	Zootechnical additive	EFSA-Q-2017-00051		Yes	No
Feed additives	*Lactobacillus delbrueckii* ssp. lactis	Zootechnical additive	EFSA-Q-2017-00051		Yes	No
Feed additives	*Lactobacillus farciminis*	Zootechnical additive	EFSA-Q-2016-00711		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]
Feed additives	*Lactobacillus farciminis*	Zootechnical additive	EFSA-Q-2016-00712		Yes	No
Feed additives	*Lactobacillus helveticus*	Zootechnical additive	EFSA-Q-2017-00051		Yes	No
Feed additives	*Lactobacillus plantarum*	Zootechnical and technological additive	EFSA-Q-2017-00023		Yes	No
Feed additives	*Lactobacillus reuteri*	Zootechnical additive	EFSA-Q-2017-00049	New additive	Yes	No
Feed additives	*Lactobacillus reuteri*	Zootechnical additive	EFSA-Q-2017-00050	New additive	Yes	No
Feed additives	*Leuconostoc mesenteroides*	Nutritional additive	EFSA-Q-2014-00592	New additive	Yes	No
Food additives, food enzymes, flavourings	*Pseudomonas amyloderamosa*	Production of food enzyme isoamylase	EFSA-Q-2016-00524		No	Yes
Feed additives	*Streptococcus thermophiles*	Zootechnical additive	EFSA-Q-2017-00051		Yes	No
Feed additives	*Streptomyces cinnamonensis*	Production of coccidostat	EFSA-Q-2016-00643		No	Yes
Food additives, food enzymes, flavourings	*Streptomyces mobaraensis* (strain DSM40587)	Production of food enzyme transglutaminase	EFSA-Q-2016-00657		No	Yes
Food additives, food enzymes, flavourings	*Streptomyces netropsis* (strain DSM 40093)	Production of food enzyme phospholipase D	EFSA-Q-2016-00536		No	Yes
Food additives, food enzymes, flavourings	*Streptomyces rubiginosus* (strain DP-Pzn37)	Production of food enzyme xylose isomerase	EFSA-Q-2016-00203	GMM strain	No	Yes
Food additives, food enzymes, flavourings	*Streptomyces violaceoruber* (strain pPDN)	Production of food enzyme phospholipase D	EFSA-Q-2016-00206	GMM strain	No	Yes
Filamentous fungi						
Feed additives	*Aspergillus niger*	Production of xylanase	EFSA-Q-2017-00025		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain AGS614)	Production of food enzyme alpha-galactosidase	EFSA-Q-2016-00578		No	No

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Food additives, food enzymes, flavourings	*Aspergillus niger* (strain AP 233)	Production of food enzyme aspergillopepsin I	EFSA-Q-2016-00655		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain AS 29-286)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00576		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain CICC2208.5)	Production of food enzyme glucan 1,4-glucosidase	EFSA-Q-2016-00514		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain CICC2377)	Production of food enzyme aspergillopepsin I	EFSA-Q-2016-00511		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain CTS 2093)	Production of food enzyme catalase	EFSA-Q-2016-00532		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain DP-Azb60)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00273		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain DP-Aze23)	Production of food enzyme glucose oxidase	EFSA-Q-2016-00144	GMM strain	No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain DP-Azw58)	Production of food enzyme catalase	EFSA-Q-2016-00274	GMM strain	No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain IN 319)	Production of food enzyme invertase and exo-beta-glucosidase	EFSA-Q-2016-00577		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain NL 151)	Production of food enzyme triacylglycerol lipase	EFSA-Q-2016-00654		No	No
Food additives, food enzymes, flavourings	*Aspergillus niger* (strain PHY93-08)	Production of food enzyme 3-phytase	EFSA-Q-2016-00575		No	No

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Feed additives	*Aspergillus oryzae*	Production of glucanase and amylase	EFSA-Q-2016-00833		No	No
Feed additives	*Aspergillus oryzae*	Production of xylanase	EFSA-Q-2016-00842		No	No
Food additives, food enzymes, flavourings	*Aspergillus oryzae* (strain CICC2336)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00513		No	No
Food additives, food enzymes, flavourings	*Aspergillus oryzae* (strain DP-Bzb41)	Production of food enzyme alpha-amylase	EFSA-Q-2016-00176		No	No
Food additives, food enzymes, flavourings	*Aspergillus oryzae* (strain DP-Bzg59)	Production of food enzyme beta-galactosidase	EFSA-Q-2016-00141	GMM strain	No	No
Food additives, food enzymes, flavourings	*Aspergillus oryzae* (strain GL 470)	Production of food enzyme lactase	EFSA-Q-2016-00579		No	No
Food additives, food enzymes, flavourings	*Aspergillus oryzae* (strain TAN 206)	Production of food enzyme tannase	EFSA-Q-2016-00534		No	No
Plant protection products	*Beauveria bassiana* ATCC-74040	Plant protection product	EFSA-Q-2017-00134	Application for renewal of approval	No	No
Plant protection products	*Beauveria bassiana* GHA	Plant protection product	EFSA-Q-2017-00135	Application for renewal of approval	No	No
Feed additives	*Duddingtonia flagrans*	Zootechnical additive	EFSA-Q-2016-00868	New additive	No	No
Food additives, food enzymes, flavourings	*Penicillium chrysogenum* (strain PGO 19-162)	Production of food enzyme glucose oxidase	EFSA-Q-2016-00533		No	No
Food additives, food enzymes, flavourings	*Rhizopus oryzae* (strain MC3-3-9)	Production of food enzyme pectinase	EFSA-Q-2016-00656		No	No
Food additives, food enzymes, flavourings	*Rhyzopus oryzae* (strain CU634-1775)	Production of food enzyme glucoamylase	EFSA-Q-2016-00535		No	No

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Food additives, food enzymes, flavourings	*Sporobolomyces singularis* (strain YIT 10047)	Production of food enzyme beta-galactosidase	EFSA-Q-2016-00529		No	No
Food additives, food enzymes, flavourings	*Talaromyces cellulolyticus*/ *Talaromyces pinophilus*	Production of food enzyme polygalacturonase	EFSA-Q-2016-00528		No	No
Feed additives	*Trichoderma citrinoviride*	Production of xylanase	EFSA-Q-2017-00127		No	No
Feed additives	*Trichoderma reesei*	Production of xylanase	EFSA-Q-2016-00648		No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain DP-Nzh38)	Production of food enzyme glucan 1,4-alpha-glucosidase	EFSA-Q-2016-00177	GMM strain	No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain DP-Nzh63)	Production of food enzyme glucan 1,4-alpha-glucosidase	EFSA-Q-2016-00173	GMM strain	No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain DP-Nzs51)	Production of food enzyme alpha-trehalase	EFSA-Q-2016-00142	GMM strain	No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain MUCL 49754)	Production of food enzyme endo-1,3(4)-beta-glucanase	EFSA-Q-2017-00084		No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain MUCL 49755)	Production of food enzyme endo-1,4-beta-xylanase	EFSA-Q-2017-00085		No	No
Food additives, food enzymes, flavourings	*Trichoderma reesei* (strain RF10625)	Production of food enzyme triacylglycerol lipase	EFSA-Q-2016-00212	GMM strain	No	No

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Yeasts						
Feed additives	*Pichia pastoris*	Production of fumonisin esterase	EFSA-Q-2017-00073		Yes	No
Feed additives	*Pichia pastoris*	Production of phytase	EFSA-Q-2017-00387		Yes	No
Feed additives	*Saccharomyces cerevisiae*	Zootechnical additive	EFSA-Q-2017-00286		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): Not present in the QPS list as adopted in December of 2016 (EFSA BIOHAZ Panel, 2017b).
(d): In the current Panel Statement.