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European Food Safety Authority

EFSA Journal 2014;12(12):3938

SCIENTIFIC OPINION

Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until October 2014[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA is requested to assess the safety of a broad range of biological agents in the context of notifications for market authorisation as sources of food and feed additives, enzymes and plant protection products. The qualified presumption of safety (QPS) assessment was developed to provide a harmonised generic pre-assessment to support safety risk assessments performed by EFSA's scientific Panels. The safety of unambiguously defined biological agents (at the highest taxonomic unit appropriate for the purpose for which an application is intended), and the completeness of the body of knowledge are assessed. Identified safety concerns for a taxonomic unit are, where possible and reasonable in number, reflected as 'qualifications' in connection with a recommendation for a QPS status. A total of 99 biological agents were notified to EFSA between May 2013 and October 2014. From those, 26 biological agents already had a QPS status and were not further evaluated, and 54 were also not included as they are filamentous fungi or enterococci, biological groups which have been excluded from the QPS activities since 2014. The remaining 19 notifications were considered for the assessment of the suitability for the QPS list. These 19 notifications referred to 13 taxonomic units which were evaluated for the QPS status, three of which were recommended for the QPS list: a) *Carnobacterium divergens,* with the qualification of absence of acquired antibiotic resistance determinants; b) *Microbacterium imperiale,* only for enzyme production, and c) *Candida cylindracea,* only for enzyme production.

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KEY WORDS

safety, QPS, bacteria, yeast, *Carnobacterium divergens*, *Microbacterium imperiale*, *Candida cylindracea*

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[1] On request from EFSA, Question No EFSA-Q-2014-00611, adopted on 4 December 2014.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on QPS: Miguel Prieto Maradona, Amparo Querol, Christophe Nguyen-the, Güenter Klein, Ingvar Sundh, Juan E. Suarez, Luisa Peixe, Pablo S. Fernandez Escamez, Pier Sandro Cocconcelli and Just Vlak for the preparatory work on this scientific opinion, and EFSA staff: Sandra Correia and Winy Messens for the support provided to this scientific opinion.

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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 QPS biological agents intentionally added to food or feed (2013 update). The question included three specific tasks in the terms of reference (ToR).

The BIOHAZ Panel decided to change the evaluation procedure: the publication of the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA, 2013) will be carried out after three years in a scientific opinion of the BIOHAZ Panel (December 2016) but in any case, that list of microorganisms will be maintained and frequently checked based on the evaluation of extensive literature reviews which will be updated regularly with new publications. 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 Feed Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition Unit and by the Pesticides Unit. Evaluations of these notifications will be compiled in a single statement for periods of around six months. The results of these assessments will also be included in the scientific opinion of the BIOHAZ Panel to be published until December of 2016. The "2013 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA scientific Panels and Units", will be appended to each Panel statement. New biological agents recommended for the QPS status will be included in that list, after the assessment of the new notifications evaluated for each Panel statement.

The first ToR required to 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 and Pesticides), for intentional use in feed and/or food 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 last review and it is appended to the current statement. Notifications considered for the current statement were received between May 2013 and October 2014. Within this period, 99 notifications were received from those four Units, of which, 47 from Feed, 44 from FIP, 3 from Nutrition and 5 from Pesticides.

The second ToR concerns the revision of the taxonomic units previously recommended for the QPS list and their qualifications (especially the qualification regarding antimicrobial resistance) when new information has become available and to update the information provided in the previous opinion (EFSA, 2013) where appropriate. The work being developed in order to reply to this ToR is not reflected in the current statement, but will be published in a scientific Opinion of the BIOHAZ Panel until December of 2016 as previously mentioned.

The third ToR required 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 focusses on this ToR by including the individual assessments of the taxonomic units not previously included in the 2013 QPS list. Of those 99 notifications received, 26 biological agents already had a QPS status and were not further evaluated in this statement. From the remaining 73 (without a QPS status), 54 were not further assessed as they are filamentous fungi or enterococci, biological groups which have been excluded from QPS activities since 2014 and 19 were considered for the assessment of the suitability of the respective taxonomic units for inclusion for the QPS list. Sixteen species were notified to the Feed Unit, 2 to the FIP Unit and one to the Nutrition Unit. The respective taxonomic units (13 in total) were assessed for their suitability for the QPS list. Of a total of 12 bacterial taxonomical units evaluated, 10 were notified to the Feed Unit (*Actinomadura roseorufa*, *Bacillus toyonensis* (previously *B. cereus* var. *toyoi*), *Carnobacterium divergens*, *Clostridium butyricum*, *Escherichia coli*, *Paenibacillus lentus*, *Streptomyces albus*, *Streptomyces aureofaciens*, *Streptomyces lasaliensis*, *Streptomyces cinnamonensis*), one to the FIP Unit (*Microbacterium imperiale*) and one to the Nutrition Unit (*Bacteroides xylanisolvens*). The only yeast taxonomic unit evaluated was notified to the FIP Unit (*Candida cylindracea*). After the assessment, which is included in the current statement, three taxonomic units were recommended for the QPS list: a) *Carnobacterium divergens,* with the

qualification of absence of acquired antibiotic resistance determinants; b) *Microbacterium imperiale,* only for enzyme production, and c) *Candida cylindracea,* only for enzyme production.

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BACKGROUND AS PROVIDED BY EFSA

A wide variety of microorganisms (including viruses) are intentionally added at different stages into the food chain, either directly or as a source of additives or food enzymes or plant protection products. EFSA is requested to assess the safety of these biological agents in the context of applications for market authorisation as sources of food and feed additives, enzymes and plant protection products received by EFSA.

The 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 Qualified Presumption of Safety (QPS list),[4,5] consisting of 48 species of Gram-positive non-sporulating bacteria, 13 *Bacillus* species and 11 yeast species. Filamentous fungi were also assessed but these were not recommended for QPS status. The Scientific Committee recommended that a QPS approach should be implemented across EFSA and applied equally to all safety considerations of microorganisms that EFSA is required to assess. The Scientific Committee recognised that there would have to be continuous provision for reviewing and modifying the QPS list. The EFSA Panel on Biological Hazards (BIOHAZ) took the prime responsibility for this and annually reviewed the existing QPS list, as recommended by the Scientific Committee.

In the first annual QPS review and update,[6] the existing QPS list was reviewed and EFSA's initial experience in applying the QPS approach was described. The potential application of the QPS approach to microbial plant protection products was discussed in the 2009 review.[7] In 2009, viruses and bacteriophages were assessed for the first time, leading to the addition of two virus families used for plant protection purposes to the QPS list. Bacteriophages were not considered appropriate for the QPS list. After consecutive years of updating the existing scientific knowledge, the filamentous fungi (2008 to 2013 update) and enterococci (2010-2013 update) were not recommended for the QPS list.

The 2013 update of the recommended QPS list includes 53 species of Gram-positive non-sporulating bacteria, 13 Gram-positive spore forming bacteria (*Bacillus* species), 1 Gram-negative bacterium (*Gluconobacter oxydans*), 13 yeast species, and 3 virus families. No QPS recommended species has been taken down from the list following six (2008-2013 update) annual reviews.

Based on the above mentioned information, the BIOHAZ Panel at their plenary meeting in January 2014, made a proposal for future QPS activities that was discussed at the Scientific Committee meeting in February 2014. The Scientific Committee agreed to exclude some biological groups (filamentous fungi, bacteriophages and enterococci) in future QPS activities, while an extensive literature review of the QPS recommended list could be done less frequently. The deadline for the assessment of the suitability of new taxonomic units notified to EFSA for inclusion in the QPS list would be tailored to the needs of the requesting EFSA Units and/or Scientific Panels.

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, and Nutrition), for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products for safety assessment.

[4] 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.

[5] 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.

[6] 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.

[7] 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. doi:10.2903/j.efsa.2009.1431.

ToR 2: Review taxonomic units previously recommended for the QPS list and their qualifications (especially the qualification regarding antimicrobial resistance) when new information has become available. Update the information provided in the previous opinion where appropriate.

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.

EVALUATION

1. Introduction

A wide variety of microorganisms (including viruses) are 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 to assess their safety.

Qualified Presumption of Safety (QPS) entered EU law with the publication of a new Commission Implementing Regulation (EU) No 562/2012[8] amending Commission Regulation (EU) No 234/2011[9] with regard to specific data required for risk assessment of food enzymes. If the microorganism used in the production of a food enzyme has a status of QPS according to the most recent list of QPS recommended biological agents adopted by the European Food Safety Authority (EFSA), the enzyme application should not be required to include toxicological data. If residues, impurities and degradation products linked to the total enzyme production process (production, recovery and purification) could give rise for concern, the Authority, pursuant to Article 6(1) of Regulation (EC) No 1331/2008,[10] may request additional data for risk assessment, including toxicological data.

The QPS approach was developed by the 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 (Butaye et al., 2003). The list, first established in 2007 has been revised and updated. Taxonomic units were included in the QPS list either following notifications to EFSA or following proposals made by stakeholders during a public consultation in 2005, even if they were not yet notified to EFSA (EFSA BIOHAZ Panel, 2013). For the 2014 update, it was decided to change the procedures. The publication of the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) will be carried out less frequently (every three years) through a scientific opinion of the BIOHAZ Panel. In any case, the recommendations provided concerning that list of microorganisms will be maintained and frequently checked based on the evaluation of extensive literature reviews which will be updated regularly with new publications. 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 Feed, Food Ingredients and Packaging (FIP), Nutrition or Pesticides Units. Evaluations of these notifications will be compiled in a single statement for periods of around six months. The results of these assessments will also be included in the scientific opinion to be published in December of 2016. The "2013 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units", will be appended to each Panel statement. New biological agents recommended for the QPS status will be included in that list, after the assessment of the new notifications by the BIOHAZ Panel.

2. Methodology

In response to ToR1, the EFSA Units (Feed, FIP, Nutrition and Pesticides Units), have been asked to update the list of biological agents being notified to EFSA. For the current statement, 99 notifications were received between May 2013 and October 2014, of which, 47 from Feed, 44 from FIP, 3 from Nutrition and 5 from Pesticides.

[8] Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes. OJ L 168, 28.6.2012, p. 21-23.

[9] Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 64, 11.3.2011, p. 15-24.

[10] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L354, 31.12.2008, p. 1-6.

In response to ToR3, from those 99 notifications, 26 biological agents already had a QPS status and were not further evaluated neither the 54 biological agents that are filamentous fungi or enterococci, biological groups which have been excluded from QPS activities (in the follow up of a recommendation of the QPS 2013 update (EFSA BIOHAZ Panel, 2013)). The remaining 19 biological agents were assessed for the suitability of the respective taxonomic units for inclusion in the QPS list. From the assessed taxonomic units, 16 species were notified to the Feed Unit, 2 to the FIP Unit and one to the Nutrition Unit. The respective taxonomic units (total of 13) were assessed for their suitability to the QPS list. Of a total of 12 bacterial taxonomical units evaluated, 10 were notified to the Feed Unit (*Actinomadura roseorufa*, *Bacillus toyonensis* (previously *B. cereus* var. *toyoi*), *Carnobacterium divergens*, *Clostridium butyricum*, *Escherichia coli*, *Paenibacillus lentus*, *Streptomyces albus*, *Streptomyces aureofaciens*, *Streptomyces lasaliensis*, *Streptomyces cinnamonensis*), one to the FIP Unit (*Microbacterium imperiale*) and one by the Nutrition Unit (*Bacteroides xylanisolvens*). The only yeast taxonomic unit evaluated was notified to the FIP Unit (*Candida cylindracea*).

The procedure followed for this assessment is the same as in the previous QPS 2013 update of the scientific opinion.

Table 1: Notifications received by EFSA Units (Feed, FIP, Nutrition and Pesticides Units) and by biological group from May 2013 until October 2014

Unit/ Panel	**Not QPS**		**Already QPS**	**Grand Total**
Biological group	Not evaluated	Evaluated		
Feed/FEEDAP	**16**	**16**	**15**	**47**
Bacteria	1	16	9	26
Filamentous fungi	15			15
Yeasts			6	6
FIP/CEF	**34**	**2**	**8**	**44**
Bacteria		1	6	7
Filamentous fungi	34		1	35
Yeasts		1	1	2
Nutrition/NDA		**1**	**2**	**3**
Bacteria		1	1	2
Yeasts			1	1
Pesticides/PPR	**4**		**1**	**5**
Filamentous fungi	4			4
Viruses			1	1
Grand Total	**54**	**19**	**26**	**99**

For the taxonomic units associated with the notifications compiled within the time period covered by this statement (from May 2013 until October 2014), the literature review was broader in order to consider the identity, the body of knowledge, history of use and the potential safety concerns.

Relevant databases such as PubMed, Web of Knowledge, CasesDatabase, GoogleScholar, CAB Abstracts or Food Science Technology Abstracts (FSTA) were searched using specific sections. Keywords used may equally be specified in the specific section. Some common keywords such as the taxonomic unit in combination with 'toxin', 'disease', 'infection', 'clinical', 'virulence', 'antimicrobial and/or antibiotic/antimycotic resistance', 'safety', 'risk', 'abortion', 'urinary', 'mastitis', 'syndrome', 'vaginitis'. In addition some animal categories such as 'poultry', 'chicken', 'hen', 'broiler', 'turkey', 'fowl', 'piglet', 'pig', 'calf', 'calves', 'cattle', 'cow', 'fish' and 'salmon' were generally applied. Relevant studies were evaluated, reported and discussed. The search terms were broad and covered synonyms or former names of taxonomic units.

3. Bacteria

3.1. *Actinomadura roseorufa*

Identity

The genus *Actinomadura* consists of Gram-positive actinobacteria belonging to the order *Actinomycetales,* (fam. *Thermomonosporaceae*) and is composed of microorganisms with cell walls containing meso-2,6-diaminopimelic acid and madurose but lacking arabinose and galactose. Actinomadurae are chemo-organotrophs that produce stable vegetative mycelia and aerial hyphae differentiating into spore chains. The genus currently contains 37 species including 2 subspecies (Euzéby and Tindall, online) and they are known to produce bioactive secondary metabolites. The taxonomy identification of this bacterium is not established as a species with a validated name in IJSEM and LPSN.[11]

Actinomadura roseorufa is notified as a producer of semduramicin, a polyether ionophor (Microbial Genomes, online), to be used as a feed supplement acting as a coccidiostat to inhibit intestinal coccidia (Rutkowski and Brzezinski, 2013). No strain belonging to this species has been fully sequenced according to NCBI (Microbial Genomes, online).

Body of knowledge

No scientific reports or articles on the safety of *A. roseorufa* have been found. A search in the Thomson Reuters Web of Science (1 October 2014) using "*Actinomadura roseorufa*" as search term in "topic" retrieved 9 hits all related to the production and properties of semduramicin. The body of knowledge is limited to the use of strains as producers of this compound. Since *A. roseorufa* produces semduramicin, its use in feed might promote bacterial resistance.

The safety of semduramicin when used as coccidiostat for fattening of chickens has been assessed by EFSA (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2011). The general conclusion from this report is that on the basis of the data provided on semduramicin sodium for use as feed additive under the proposed conditions of use, the safety of semduramicin is demonstrated for the target animal, the user, the consumer and the environment. Consequently, an additive containing semduramicin has been authorized as cocciodiostat in the EU (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2011).

Safety concerns

A. roseorufa produces semduramicin, an approved coccidiostat, with antimicrobial activity. The possible contribution of this ionophore to the development of antibiotic resistance to important human antibiotics is a matter of concern. No studies on the safety of *A. roseorufa* were found. Therefore no definitive conclusions can be attained. There is a limited number of reports from EFSA on the safety concerns of semduramicin (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2011).

Conclusions on a recommendation for the QPS list

A. roseorufa produces semduramicin, an approved coccidiostat, with antimicrobial activity and therefore cannot be considered for the QPS list. Moreover its identity is not well established.

3.2. *Bacillus toyonensis* (previously *B. cereus* var. *toyoi*)

Identity

The species *Bacillus toyonensis* was recently published in the validation list no 155 (Oren and Garrity, 2014).

[11] http://www.bacterio.net/

The phylogenetic analysis of the 16S rRNA, 23S rRNA and of the *gyrB* gene sequences and average nucleotide identity calculations, derived from the whole genome sequence indicate that the species *B. toyonensis* belongs to the *B. cereus* group or *B. cereus sensu lato* (Jimenez et al., 2013).

Body of knowledge

B. toyonensis was originally called *B. cereus* var. *toyoi*, and was represented by a single strain authorized in the past in the EU as a feed additive for various farm animal species (EFSA, 2004, 2005, 2007a, b; Williams et al., 2009). The body of knowledge concerns therefore, only one strain and not a generic taxonomic unit. Similarly, a publication (Jimenez et al., 2013) describes *B. toyonensis* on the basis of one strain.

Safety concerns

B. toyonensis was included before 2013 within the species *B. cereus* (EFSA, 2004, 2005, 2007a, 2007b; Williams et al., 2009). Therefore, the safety concerns defined for *B. cereus*, which led to the conclusion in 2007 (EFSA, 2007c) that *B. cereus* and related species (such as *B. thuringiensis*) should not be included in the QPS list, apply to *B. toyonensis*, unless specific information could relieve these concerns. Jimenez et al. (2013) do not provide any specific information for *B. toyonensis* with regards to the toxins known to be produced by the *B. cereus* group. The safety of the only described *B. toyonensis* strain intended to be used as a feed additive has recently been reassessed by EFSA (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2012; EFSA FEEDAP Panel, 2014). These assessments concluded that this strain has the capacity to produce functional *B. cereus* toxins. All the above information concerns a single strain, and cannot be extended to the *B. toyonensis* species, should more strains of the species were described.

Conclusions on a recommendation for the QPS list

In conclusion, *Bacillus toyonensis* cannot be proposed for the QPS list because it is a member of the *B. cereus* group, and because of the absence of evidences at the species level that it does not present safety concerns.

3.3. *Bacteroides xylanisolvens*

Identity

The first report on *Bacteroides xylanisolvens* (Chassard et al., 2008) described the new species mainly based on 16S rRNA sequence and carbohydrate metabolism differences to other *Bacteroides*. The type strain was also designated. Presently, there are five strains that received attention, all of which were defined by their 16S rRNA sequences. One strain was isolated from human feces (Ulsemer et al., 2012a), two based on their capacity to ferment xylan (Chassard et al., 2008; Mirande et al., 2010) and the other two after growing on cellulose (Ramaraj et al., 2014). Draft genome sequences have been deposited for these last two and the type strain.

Body of knowledge

The body of knowledge of the species in mainly based on its ability to ferment carbohydrates (Chassard et al., 2008; Mirande et al., 2010; Ramaraj et al., 2014). No record of its use in food fermentation processes exists, and only a couple of pilot studies using fermented milk were performed (Ulsemer et al., 2012b). Therefore the body of knowledge on use of *B. xylanisolvens* as a food or feed ingredient is limited.

Safety concerns

Tests on the safety of *B. xylanisolvens* have been mainly performed *in vitro* (Mirande et al., 2010; Ulsemer et al., 2012a, c) although some studies on mice, mainly intraperitoneal injection of live bacteria, indicate that the pathogenic potential of the strain used may be low (Ulsemer et al., 2012c). Finally, two complementary pilot studies with healthy volunteers that received orally administered

dead bacteria have not shown changes in several immunological parameters and liver markers (Ulsemer et al., 2012b).

Although no safety concerns have been observed, the studies published are insufficient to exclude safety concerns. The human cohorts used in the pilot studies were small and used killed bacteria on healthy volunteers. This is a limitation to the use of strains of this species as probiotics, which, by definition, have to be alive.

Conclusions on a recommendation for the QPS list

Bacteroides xylanisolvens is not recommended for the QPS list, because the body of knowledge is insufficient and safety concerns cannot be totally excluded.

3.4. *Carnobacterium divergens*

Identity

The *Carnobacterium* genus belongs to the family *Carnobacteriaceae* in the order of *Lactobacillales* (Collins et al., 1987). The most important species is *Carnobacterium maltaromaticum* due to its common occurrence in foods of animal origin. *Carnobacterium divergens* (and later also *C. maltaromaticum*) has been reclassified and transferred from the genus *Lactobacillus* to the described genus nov. *Carnobacterium* in 1987 (Collins et al., 1987) based on phenotypic classification. The first description was given by Holzapfel and Gerber (1983). The original strains were isolated from raw vacuum-packaged, as well as SO_2-treated, minced beef, in the course of shelf life studies on this product (Holzapfel and Gerber, 1983). The complete genome sequence is known for some strains of *Carnobacterium* spp., but not for *C. divergens*.

Body of knowledge

The species *C. divergens* frequently dominates the microbiota of refrigerated meat and seafood, stored under vacuum or modified atmosphere (Laursen et al., 2005; Leisner et al., 2007; Rieder et al., 2012). For its ability to produce bacteriocins, this species has been used in food with the aim to reduce spoilage and pathogenic bacteria (Richard et al., 2003; Leisner et al., 2007; Rihakova et al., 2009). *C. divergens* has been also studied as probiotic for fish, such as Atlantic cod (*Gadus morhua* L.) (Lauzon et al., 2010), Atlantic salmon (*Salmo salar* L.) (Ringø et al., 2007) and rainbow trout (*Oncorhynchus mykiss*) (Kim and Austin, 2008), and as probiotic for chicken for fattening (Jozefiak et al., 2011).

Safety concerns

In a single study two strains of *C. divergens*, isolated from the blood of a newborn delivered by caesarean section and from a febrile lymphoma patient, were identified by sequencing the variable regions of the 16S rRNA gene. The two strains encode a possibly acquired new class A β-lactamase (Meziane-Cherif et al., 2008). Strains carrying these determinants for resistance can be detected following the Euzéby and Tindall (online) applying the ampicillin cut off value defined for "*Lactobacillus* heterofermentatives".

However, these infections represent extremely rare individual cases, occurring on highly vulnerable individuals, so that these microorganisms cannot be considered as pathogenic taking into account the extent of exposure.

Conclusions on a recommendation for the QPS list

The taxonomic unit is well described and the body of knowledge shows it as a common species in the food chain, especially in meat. *Carnobacterium divergens* can be recommended for the QPS list with the qualification of absence of acquired antibiotic resistance determinants.

3.5. *Clostridium butyricum*

Identity

Clostridium butyricum is a well described species and it is the type species of the genus (Collins et al., 1994).

Body of knowledge

C. butyricum was assessed as non-suitable for QPS in 2011 because some strains can produce botulinum toxin E (EFSA Panel on Biological Hazards (BIOHAZ), 2011).

Regarding the history of use, several reports on the use of *C. butyricum* as probiotic in animals and humans, were found (Yang et al. (2012); Zhang et al. (2014) on broilers; Uyeno et al. (2013) on calves; Imase et al. (2008); Sharma et al. (2008); Chen et al. (2010); Sato et al. (2012) on human subjects). UK the "Advisory Committee on Novel Foods and Processes" issued a draft opinion in 2013 on *C. butyricum* CBM588 as a novel ingredient to be added to supplements and concluded that "it did not have any unanswered safety concerns relating to this novel ingredient" (ACNFP, online). These studies concern a limited number of strains, in particular several used the same strain *C. butyricum* CBM588.

Safety concerns

A minority of strains of *C. butyricum* are able to form botulinum neurotoxin type E, harbouring BoNT/E gene on a large plasmid (Hauser et al., 1992; Peck, 2009; Ghoddusi and Sherburn, 2010). Toxigenic strains of this species were responsible for infant botulism (Fenicia et al., 1999; Abe et al., 2008) and involved in foodborne intoxications. Botulinum neurotoxins are extremely potent toxins. Methods exists to detect the genes coding for these toxins and to detect the production of the toxins by the bacteria.

New safety concerns are indicated by one report of bacteremia in a drug addict who very likely injected himself drug contaminated with *C. butyricum* (Gardner et al., 2008). *C. butyricum* was also suspected to be one of the bacterial species contributing to necrotizing enterocolitis in premature infants (Waligora-Dupriet et al., 2009; Morowitz et al., 2010). Therefore, *C. butyricum* has been a rare cause of human disease in association with very specific risk factors.

Conclusions on a recommendation for the QPS list

The information collected supports the view that the safety of *C. butyricum* is only known for a few strains, therefore *Clostridium butyricum* is not recommended for the QPS list. Thus, no additional information supports a revision of the previous conclusion attained in 2011.

3.6. *Escherichia coli*

Escherichia coli was assessed in 2009 as not suitable for the QPS list with the following conclusion: "although some *E. coli (e.g. E.coli* Nissle 1917 (EcN)) have a long history of safe use as probiotics, and in spite of the large body of knowledge acquired for this species, it cannot be recommended for the QPS list because of the large diversity of human and animal diseases caused by *E. coli* and the complexity of the virulence mechanisms (DSMZ, online)".

Identity

E. 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).

Body of knowledge

E. coli is a versatile bacterium, both retrieved in 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, the most extensively studied prokaryote, was brought 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) have been used as host organisms, namely for producing aminoacids for use in animal feed (Bachmann, 1972).

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. immune status of the host, production of virulence factors by the bacterium, portal of entry, inoculum dose, and the genetic background of the bacterium. Several virulence determinants are recognized, either involved in enteric infection (e.g. enterotoxins and pili) and/or in extra-intestinal infections (e.g. siderophores, mucinase, cytotoxins, immunomodulators, lectin-like hemagglutinin and colibactin) (Pacheco and Sperandio, 2012; Ruiz-Perez and Nataro, 2014). Recently, worrying observations about their potential implication in colon cancer were described, although apparently associated to a specific phylogenetic group (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 persist (Wijetunge et al., 2014). These facts prevent the proposal of a set of precise qualifications for QPS status.

Conclusions on a recommendation for the QPS list

Escherichia 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.

3.7. *Microbacterium imperiale*

Identity

Microbacterium imperiale, previously known as *Brevibacterium imperiale*, was included in the genus based on its close relationship to *Microbacterium lacticum* (Collins et al., 1983). The genus is phylogenetically coherent as determined by 16S rRNA gene sequencing and chemotaxonomic data (Takeuchi and Yokota, 1994; Rivas et al., 2004; Park et al., 2006; 2008). The bacteria of the genus *Microbacterium* are Gram positive organisms that belong to the Phylum Actinobacteria (G + C ≈ 66-70 %), strictly aerobic, rod shaped and usually non-motile.

Body of knowledge

Their habitat is the soil where they thrive on plant decaying material thanks to their enzymatic potential to degrade complex polysaccharides. Xylanolytic, amilolytic and β-glucosidase activities have been detected in different isolates of the genus (Rivas et al., 2004; Park et al., 2006; 2008; Wu et al., 2014). Endophytic and gut of caterpillar associated strains have been isolated as well (Zinniel et al., 2002; Huang et al., 2012; Gan et al., 2014), with no signs of pathology perceived in the colonized plant or animal tissues.

No records of intended use of *M. imperiale* cells in foods manufacturing exist. However, the enzymes produced by organisms of the genus are used in food processing. Of special interest to this evaluation is the use of the 1,4-α-maltotriohydrolase for the production of maltotriose, an oligosaccharide used for the production of desserts and baked pastries (Anonymous, 2000, 2011; Wu et al., 2014) .

Safety concerns

In literature, no association of *M. imperiale* to pathology has been reported. In fact, out of the 84 species of the genus *Microbacterium* only four have been described as involved in human pathological processes, the cases being extremely rare, occurring in patients with predisposing conditions and, in some cases, being part of a polymicrobial infection (Alonso-Echanove et al., 2001; Giammanco et al., 2006; Adames et al., 2010; Enoch et al., 2011; Buss et al., 2014). The frequent need of a previous life-threatening or immunodeficiency condition for successful *Microbacterium* spp. infection may indicate that no significant virulence factors are produced by the species of this genus. Finally, resistance to chemotherapy appears to be scarce, with an almost universal susceptibility to β-lactam and glycopeptide antibiotics (Adames et al., 2010; Buss et al., 2014).

Conclusions on a recommendation for the QPS list

No record exists of intended use of any *Microbacterium* in food processing and/or ingestion of viable cells. However, there is a history of use in food processing of enzymes produced by *Microbacterium imperiale*, therefore it can only be recommended for QPS for enzyme production.

3.8. *Paenibacillus lentus*

Identity

Paenibacillus lentus was described recently as a new species by Li et al. (2014), as a β-mannanolytic bacterium isolated from soil.

Body of knowledge

No information was found on *P. lentus* apart from its description as a new species.

Safety concerns

No experimental information has yet been developed and/or available.

Conclusions on a recommendation for the QPS list

Due to the absence of a body of knowledge apart from the description of the species, *Paenibacillus lentus* cannot be proposed for the QPS list.

3.9. *Streptomyces albus*

Identity

Streptomyces albus is the type species of the genus *Streptomyces* and appears to be a coherent taxonomic entity, as judged by 16S rRNA gene sequence and multilocus sequence analysis (Labeda et al., 2014). The only strain that has been completely sequenced is *S. albus* J1074 (Olano et al., 2014; Zaburannyi et al., 2014). This strain does not carry the gene cluster encoding for salinomycin biosynthesis, thus suggesting a high intraspecies variability.

Body of knowledge

There is a long record of use of salinomycin as an anticoccidial additive, especially with chicken (Yvoré et al., 1980; Lee et al., 2013). However, cases of accidental salinomycin intoxication to turkeys, horses, calves and other farm animals that involve internal organ compromise (cardiac and muscular lesions) and even death have been reported (Potter et al., 1986; Aleman et al., 2007;

Holliman et al., 2011). It is not clear in these cases whether salinomycin is being administered as a pure compound or as a crude extract.

The bacteria of this species are virtually avirulent, although a report exists in which an actinomycetoma developed in the forearm of a person that had previously been treated with corticosteroids. The identity of the infection was determined through 16S rRNA gene sequencing (Martin et al., 2004).

Safety concerns

Apart from the toxicity referred to in the previous paragraph, there are two other reasons for concern:

- Salinomycin is demonstrating a potential as an anticancer agent, especially for stem cell and prostate tumors (Zhou et al., 2013). Its use in feed might promote resistance development as a consequence of its ingestion with the meat of treated animals.

- The sequenced strain *S. albus* J1074, in spite of not harbouring the cluster for salinomycin production, has the potential to synthesize 27 secondary metabolites, the majority of which have antimicrobial properties (Olano et al., 2014; Zaburannyi et al., 2014). The capacity to produce multiple antimicrobials is general among the streptomycetes that have been completely sequenced and it can be assumed that this can be the case also for the salinomycin producer. The potential production of this kind of compounds by *S. albus* represents a risk of toxicity and generation of resistance in the intestinal microbiota that might become subsequently transferred to pathogens.

S. albus appears to be a complex species that includes strains harbouring different sets of gene clusters that encode a wide variety of metabolites with biological activity. This means that the lack of toxicity and of antibiotic activity has to be tested on a strain basis.

Conclusions on a recommendation for the QPS list

Streptomyces albus is not recommended for the QPS list, because safety concerns cannot be excluded.

3.10. *Streptomyces aureofaciens*

Identity

Streptomyces aureofaciens was initially described in 1948 as a narasin producer although, depending on the strain, it also produces tetracyclines and other biologically active compounds. Its taxonomy was settled on the basis of extensive phenotypic properties (Groth et al., 2003).

However, no strain belonging to the species has been fully sequenced according to NCBI (Microbial Genomes, online).

Body of knowledge

There is a long record of using narasin as an anticoccidial additive (Peeters et al., 1981; Jeffers et al., 1988; Brennan et al., 2001) although the extent of usage is not comparable to that of other polyether ionophores such as salinomycin and monensin. Accidental narasin intoxication of rabbits and of some laboratory animal species may involve diarrhea and internal organ compromise, including respiratory stress, skeletal muscle degeneration and even death (Novilla et al., 1994; Salles et al., 1994; Oehme and Pickrell, 1999). This toxicity appears to be, however, less pronounced than that of salinomycin and monensin (Dorne et al., 2013). There are no clinical reports involving *S. aureofaciens* in human disease.

Safety concerns

Apart from the toxicity referred to in the previous paragraph, there are two other reasons for concern:

- Narasin belongs to the same family as that of salinomycin and monensin. These two drugs are being tested as possible anticancer agents (Zhou et al., 2013; Tumova et al., 2014). The possibility exists that use of narasin as an additive in feed might promote cross-resistance development as a consequence of its ingestion with the meat of treated animals.

- The biosynthetic capacity of *S. aureofaciens* cannot be assessed due to lack of information on its genome. However, the common occurrence of multiple pathways encoding secondary metabolites among the streptomycetes whose genomes are known, allow hypothesizing that this might also be the case for this QPS candidate. Many of these secondary metabolites act as antimicrobials. The potential production of this kind of compounds by *S. aureofaciens* represents a risk of toxicity and generation of resistance in the intestinal microbiota that might become subsequently transferred to pathogens.

Knowledge of the strain and, by extension, of the species it belongs to, is not enough to ensure a safe application. Especially important is the fact that the ability to produce secondary metabolites appears to be strain-specific. Finally, narasin seems to have moderate toxicity to man and animals. Under these circumstances, toxicity and co-production of antibiotics has to be excluded on a strain basis.

Conclusions on a recommendation for the QPS list

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

3.11. *Streptomyces cinnamonensis*

Identity

A search in Pub-Med using the key word *Streptomyces cinnamonensis*, retrieved 69 articles, the vast majority of which dealt with different aspects of monensin production. No paper on *S. cinnamonensis* taxonomic characteristics was found, apart from some that justified classification of *S. cinnamonensis* 16S rRNA-related strains into new species. Furthermore, no strain belonging to the species has been fully sequenced according to NCBI (Microbial Genomes, online). All this indicates absence of coherence of the taxonomic unit.

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). However, cases of accidental monensin intoxication of chicken, 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.

Safety concerns

Apart from the toxicity referred to in the previous paragraph, 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). Its use in feed might promote resistance development as a consequence of its ingestion with the meat of treated animals.

- The biosynthetic capacity of *S. cinnamonensis* cannot be assessed due to lack of information on its genome. However, 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 this QPS candidate. Many of these secondary metabolites act as antimicrobials. The potential production of this kind of compounds by *S. cinnamonensis*

represents a risk of toxicity and generation of resistance in the intestinal microbiota that might become subsequently transferred to pathogens.

Knowledge of the strain and, by extension, of the species it belongs to, is not enough to ensure a safe application. Especially important is the fact that the ability to produce secondary metabolites appears to be strain-specific. Finally, monensin seems to have moderate toxicity to man and animals. Under these circumstances, toxicity and co-production of antibiotics has to be excluded on a strain basis.

Conclusions on a recommendation for the QPS list

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

3.12. *Streptomyces lasaliensis*

Identity

The majority of the 13 articles retrieved with the use of the *Streptomyces lasaliensis* key words were devoted to the study of the lasalocid genetic cluster and to the production of terpenoids. No paper on the taxonomy of the species was retrieved. Its identity may be more dependent on production of lasalocid than on biological characteristics in general. Moreover, no strain belonging to the species has been fully sequenced according to Microbial Genomes (online).

Body of knowledge

There is a long record of using lasalocid as an anticoccidial additive, with some emphasis on the treatment of calves (Reid et al., 1975; Stromberg et al., 1982; Fuller et al., 2008) although the extent of usage is not comparable to that of other polyether ionophores. Intoxication of cattle and horses with lasalocid may result in myocardial and neurological damage and even death (Galitzer et al., 1986; Oehme and Pickrell, 1999; Decloedt et al., 2012). This toxicity appears to be, however, less pronounced than that of salinomycin and monensin (Dorne et al., 2013). There are no clinical reports involving *S. lasaliensis* in human disease.

Safety concerns

Apart from the toxicity referred to in the previous paragraph, there are two other reasons for concern:

- Lasalocid belongs to the same family of compounds as salinomycin and monensin. These two drugs are being tested as possible anticancer agents (Zhou et al., 2013; Tumova et al., 2014). The possibility exists that the use of lasalocid in feed might promote cross-resistance development as a consequence of its ingestion with the meat of treated animals.

- The biosynthetic capacity of *S. lasaliensis* cannot be assessed due to lack of information on its genome. However, the common occurrence of multiple pathways encoding secondary metabolites among the streptomycetes whose genomes are known, allow hypothesizing that this might also be the case for this QPS candidate. Many of these secondary metabolites act as antimicrobials. The potential production of this kind of compounds by *S. lasaliensis* represents a risk of toxicity and generation of resistance in the intestinal microbiota that might become subsequently transferred to pathogens.

Knowledge of the strain and, by extension, of the species it belongs to, is not enough to ensure a safe application. Especially important is the fact that the ability to produce secondary metabolites appears to be strain-specific. Finally, lasalocid seems to have moderate toxicity to man and animals. Under these circumstances, toxicity and co-production of antibiotics has to be excluded on a strain basis.

Conclusions on a recommendation for the QPS list

Streptomyces lasaliensis is not recommended for the QPS list, because its identity is not well established, the body of knowledge is limited and safety concerns cannot be excluded.

3.13. General conclusion for the genus *Streptomyces* on a recommendation for the QPS list

Streptomycetes are essentially non-virulent, with the exception of some plant pathogens such a *S. scabies*. However, they produce antibiotics and may thus select 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 revealed 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 the consideration of any species of the genus as a QPS organism.

4. Yeast

4.1. *Candida cylindracea*

Identity

C. cylindracea belongs to the *Ogataea* clade of the Ascomycetous yeasts (Kurtzman et al., 2011; Daniel et al., 2014). The species was described by Yamada and Machida (1962), and validated by Meyer and Yarrow (1998). No synonym names have been used. Only the anamorphic form is known and described. The type strain for *C. cylindracea* – CBS 6330 – is also marketed under other designations, e.g. DSMZ 2031 (online) and ATCC 14930 (online). Unfortunately, in the literature on lipase-producing yeasts, the *C. cylindracea* type strain has at times been referred to as *Candida rugosa* (e.g. Benjamin and Pandey (1998); Takaç et al. (2010)). This has caused some confusion since *C. cylindracea* and *C. rugosa* are two well defined species, not closely related phylogenetically (Kurtzman et al., 2011). It is also unfortunate since *C. rugosa* is considered an emerging, opportunistic yeast (Miceli et al., 2011). However, identification according to molecular methods can easily separate between the two species. It is therefore recommended that the species identity of lipase-producing strains of *Candida* is confirmed by using such methods.

Body of knowledge

C. cylindracea has been used for a long time in industry as a lipase producer (Tomizuka et al., 1966; Brozzoli et al., 2009). The *Ogataea* clade to which it belongs does not include the pathogenic yeast *Candida albicans* (which belongs to the *Lodderomyces-Spathaspora* clade) or other *Candida* species associated with human infections, like *C. tropicalis*, *C. glabrata*, *C. parasilopsis* or *C. rugosa*.

Safety concerns

A literature search for "*Candida cylindracea*" on Thomson Reuters Web of Science (7 July 2014) gave 797 hits. The vast majority of the retrieved studies treated different aspects of enzyme production by this species. None of the studies implied a potential safety issue for *C. cylindracea*. No clinical reports for *C. cylindracea* were recovered in the search and the species is not mentioned in reviews on emerging opportunistic yeasts (e.g. Miceli et al. (2011)). *C. cylindracea* does not grow at 37 °C (Kurtzman et al., 2011).

Conclusions on a recommendation for the QPS list

In the *Candida cylindracea* bibliography, the species was only reported for use as an enzyme producer and no safety concerns were identified. Therefore it was concluded that it can be recommended for QPS status. However, since there were no reports on its use in applications involving direct consumption of *Candida cylindracea* viable cells by humans or animals, QPS should apply only for the production of enzymes.

CONCLUSIONS AND RECOMMENDATIONS

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 and Pesticides), 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 May 2013 and October 2014, 99 notifications were received from those four Units, of which 44 from FIP, 47 from Feed, 3 from Nutrition and 5 from Pesticides.

ToR 2: Review taxonomic units previously recommended for the QPS list and their qualifications (especially the qualification regarding antimicrobial resistance) when new information has become available:

- The work being developed in order to reply to this ToR is not reflected in the current Panel statement.
- This ToR is being dealt with by the QPS working group and the ongoing revision of the overall assessment of the biological agents included in the 2013 QPS update opinion will be published through a scientific opinion of the BIOHAZ Panel in December of 2016.

ToR 3: (Re)assess the suitability of taxonomic units notified to EFSA not present in the current QPS list for their inclusion in that list:

- Of those 99 notifications received, 26 biological agents already had a QPS status and were not further evaluated.
- From the remaining 73 (without a QPS status), 54 biological agents were not further assessed as they are filamentous fungi or enterococci, biological groups which have been excluded from QPS activities, and 19 were further assessed for the suitability of the respective taxonomic units for inclusion in the QPS list.
- From the assessed taxonomic units, 16 species were notified to the Feed Unit, 2 to the FIP Unit and one to the Nutrition Unit. The respective taxonomic units (total of 13) were assessed for their suitability to the QPS list.
- Of a total of 12 bacterial taxonomical units evaluated, 10 were notified to the Feed Unit (*Actinomadura roseorufa*, *Bacillus toyonensis* (previously *B. cereus* var. *toyoi*), *Carnobacterium divergens*, *Clostridium butyricum*, *Escherichia coli*, *Paenibacillus lentus*, *Streptomyces albus*, *Streptomyces aureofaciens*, *Streptomyces lasaliensis*, *Streptomyces cinnamonensis*), one to the FIP Unit (*Microbacterium imperiale*) and one to the Nutrition Unit (*Bacteroides xylanisolvens*). The only yeast taxonomic unit evaluated was notified to the FIP Unit (*Candida cylindracea*).
- For 3 of the 13 taxonomic units assessed, no safety concerns were found than a specific qualification or an indication for a specific use (food enzyme production), therefore a recommendation for a QPS status was included and the 2013 updated QPS list.

RECOMMENDATIONS

Three taxonomic units were recommended for the QPS list:

a) *Carnobacterium divergens* with the qualification of absence of acquired antibiotic resistance determinants;

b) *Microbacterium imperiale* only for enzyme production;

c) *Candida cylindracea* only for enzyme production.

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APPENDICES

Appendix A. The 2013 updated list of QPS Status recommended biological agents in support of EFSA risk assessments – 1st revision (new additions)

The 2013 update list of QPS Status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units, as shown in Table 1 below, is undergoing a revision process in accordance with a self-task mandate of the BIOHAZ Panel. The revisions will be published as an Appendix to a Statement of the BIOHAZ Panel around every six months, with the first revision in December 2014 and the last revision as an Appendix to a Scientific Opinion of the BIOHAZ Panel in December 2016. The most up-to-date QPS list will be published on the web as an Appendix of the corresponding revision and also as a separate file associated with the respective revision.

Table 1: The 2013 updated list of QPS Status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units – 1st revision (new additions)

Gram-Positive Non-Sporulating Bacteria			
Species			**Qualifications ***
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
Carnobacterium divergens †††			
*Corynebacterium glutamicum***			QPS only applies when the species is used for amino acid production
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei* *** *Lactobacillus cellobiosus* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus curvatus* *Lactobacillus delbrueckii*	*Lactobacillus farciminis* *Lactobacillus fermentum* *Lactobacillus gallinarum* *Lactobacillus gasseri* *Lactobacillus helveticus* *Lactobacillus hilgardii* *Lactobacillus johnsonii* *Lactobacillus kefiranofaciens* *Lactobacillus kefiri* *Lactobacillus mucosae* *Lactobacillus panis* *Lactobacillus collinoides*	*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 pseudomesenteroides*	*Leuconostoc lactis*	*Leuconostoc mesenteroides*	
Microbacterium imperiale †††			QPS only applies when the species is used for enzyme production
Oenococcus oeni			
Pediococcus acidilactici	*Pediococcus dextrinicus*	*Pediococcus pentosaceus*	
Propionibacterium freudenreichii	*Propionibacterium acidipropionici*		
Streptococcus thermophilus			

Bacillus			
Species			**Qualifications***
Bacillus amyloliquefaciens *Bacillus atrophaeus* *Bacillus clausii* *Bacillus coagulans*	*Bacillus fusiformis* *Bacillus lentus* *Bacillus licheniformis* *Bacillus megaterium*	*Bacillus mojavensis* *Bacillus pumilus* *Bacillus subtilis* *Bacillus vallismortis*	Absence of toxigenic activity.
Geobacillus stearothermophilus			Absence of toxigenic activity.
Gram-Negative Bacteria			
Species			**Qualifications***
Gluconobacter oxydans			QPS only applies when the species is used for vitamin production
Yeasts††			
Species			**Qualifications**
Candida cylindracea †††			QPS only applies when the species is used for enzyme production
Debaryomyces hansenii			
Hanseniaspora uvarum			
Kluyveromyces lactis	*Kluyveromyces marxianus*		
Komagataella pastoris *Lindnera jadinii* *Ogataea angusta*			QPS only applies when the species is used for enzyme production
*Saccharomyces bayanus*****	*Saccharomyces cerevisiae*†,****	*Saccharomyces pastorianus*****	
Schizosaccharomyces pombe			
*Wickerhamomyces anomalus*****			QPS only applies when the species is used for enzyme production
Xanthophyllomyces dendrorhous (imperfect form *Phaffia rhodozyma)*			
Virus			
Plant viruses			
Family			
Alphaflexiviridae	*Potyviridae*		
Insect viruses			
Family			
Baculoviridae			

* Generic qualification for all QPS bacterial taxonomic units: the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antibiotics.

** *Brevibacterium lactofermentum* is a synonym of *Corynebacterium glutamicum*

*** The previously described species '*Lactobacillus zeae'* has been included in the species *Lactobacillus casei*

**** 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. In the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C.

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

†† Yeast synonyms commonly used in the feed/food industry:
Wickerhamomyces anomalus: synonym *Hansenula anomala*, *Pichia anomola, Saccharomyces anomalus*
Lindnera jadinii: synonyms *Pichia jadinii*, *Hansenula jadinii*, *Torulopsis utilis*
Saccharomyces cerevisiae synonym: *Saccharomyces boulardii*
Saccharomyces pastorianus: synonym *Saccharomyces carlsbergensis*
Komagataella pastoris: synonym *Pichia pastoris*
Ogataea angusta: synonym *Pichia angusta*
Debaromyces hansenii: synonym *Candida famata*

††† new microorganisms recommended in this Panel Statement published in December 2014

Appendix B. Microbial species as notified to EFSA received (May 2013 and October 2014)

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
Bacteria						
Feed/ FEEDAP	*Actinomadura roseorufa* ATCC 53664	Production of semduramicin (coccidiostat)	EFSA-Q-2014-00219 FAD-2014-0009		No	Yes
Feed/ FEEDAP	*Bacillus licheniformis* (ATCC 53757)	Zootechnical feed additive	EFSA-Q-2013-00630 FAD-2013-0017		Yes	No
Feed/ FEEDAP	*Bacillus toyonensis* (previously *B. cereus* var. *toyoi)*	Zootechnical feed additive	EFSA-Q-2014-00043 EFSA Journal 2014;12(7):3766, 17 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3766.htm	Already assessed in several occasions but now it has been reassigned to this novel taxonomical unit	No	Yes
Feed/ FEEDAP	*Bifidobacterium animalis* ssp. *animalis* DSM 16284	Zootechnical feed additive	EFSA-Q-2014-00224 FAD-2014-0011	Already assessed in EFSA-Q-2009-00823	Yes	No
Feed/ FEEDAP	*Carnobacterium divergens* S1	Zootechnical feed additive	EFSA-Q-2013-00996 FAD-2013-0048	Very first notification of this species	No	Yes
Feed/ FEEDAP	*Clostriduim butyricum* CBM 588	Zootechnical feed additive	EFSA-Q-2013-00594 EFSA Journal 2014;12(3):3603, 10 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3603.htm	Already assessed in several occasions	No	Yes
Feed/ FEEDAP	*Corynebacterium glutamicum* KCTC 10423BP	Nutritional additives (amino acid)	EFSA-Q-2014-00296 FAD-2014-0012		Yes	No
Feed/ FEEDAP	*Enterococcus faecium* DSM 21913	Zootechnical feed additive	EFSA-Q-2014-00224 FAD-2014-0011	Already assessed in EFSA-Q-2009-00823	No	No
Feed/ FEEDAP	*Escherichia coli*/DC231	Nutritional/Production of L-lysine sulphate	EFSA-Q-2014-00003 FAD-2013-0045		No	Yes
Feed/ FEEDAP	*Escherichia coli* FERM BP-10941	Nutritional/Production of copper chelate of L-	EFSA-Q-2013-00407	GMM Production strain of L-Lysine-HCl used in	No	Yes

[12] Not present in the QPS list as published in the 2013 QPS update scientific opinion (version before the publication of this Panel statement)

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
		Lysinate-HCl	EFSA Journal 2014;12(7):3796, 20 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3796.htm EFSA-Q-2014-00496 FAD-2014-0021	the manufacturing of the additive		
Feed/ FEEDAP	*Escherichia coli* K-12/ AG7056X	Nutritional/Production of threonine	EFSA-Q-2013-00676 EFSA Journal 2014;12(10):3825, 14 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3825.htm		No	Yes
Feed/ FEEDAP	*Escherichia coli* K-12/ AG8012X	Nutritional/Production of tryptophan	EFSA-Q-2013-00677 EFSA Journal 2014;12(10):3826, 13 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3826.htm		No	Yes
Feed/ FEEDAP	*Escherichia coli* K-12/ INTK-01X	Nutritional/Production of lysine	EFSA-Q-2013-00823 EFSA Journal 2014;12(11):3895, 20 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3895.htm		No	Yes
Feed/ FEEDAP	*Escherichia coli* VA-05	Nutritional additives (amino acid)	EFSA-Q-2014-00299 FAD-2014-0015	GMM	No	Yes
Feed/ FEEDAP	*Lactobacillus casei* LOCK 0915	Zootechnical feed additive	EFSA-Q-2013-00996 FAD-2013-0048		Yes	No
Feed/ FEEDAP	*Lactobacillus lactis* IBB500 *Lactobacillus delbrueckii*	Zootechnical feed additive	EFSA-Q-2013-00996 FAD-2013-0048	WG Comment: should be moved to QPS *Lactobacillus delbrueckii*	Yes	No
Feed/ FEEDAP	*Lactobacillus plantarum* LOCK 0862	Zootechnical feed additive	EFSA-Q-2013-00996 FAD-2013-0048		Yes	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
Feed/ FEEDAP	*Lactobacillus salivarius* ssp. *salivarius* DSM 16351	Zootechnical feed additive	EFSA-Q-2014-00224 FAD-2014-0011	Already assessed in EFSA-Q-2009-00823	Yes	No
Feed/ FEEDAP	*Paenibacillus lentus* DSM 28088	Zootechnical feed additive Production of enzyme	EFSA-Q-2014-00115 FAD-2014-0001		No	Yes
Feed/ FEEDAP	*Pediococcus acidilactici* (CNCM) MA 18/5M	Zootechnical feed additive	EFSA-Q-2014-00091 FAD-2010-0122	Already assessed in several occasions	Yes	No
Feed/ FEEDAP	*Pediococcus acidilactici* (CNCM) MA 18/5M	Zootechnical feed additive	EFSA-Q-2013-00704 FAD-2013-0031	Already assessed in several occasions	Yes	No
Feed/ FEEDAP	*Streptomyces albus* ATCC 21838	Production of salinomycin sodium (coccidiostat)	EFSA-Q-2013-00706 FAD-2013-0029 EFSA-Q-2013-00998 FAD-2013-0053 EFSA-Q-2014-00350 FAD-2014-0016	It will be validated end of 2014. The full registration number is ATCC21838/US 9401-06	No	Yes
Feed/ FEEDAP	*Streptomyces albus* NCIMB 30321	Production of salinomycin sodium (coccidiostat)	EFSA-Q-2014-00350 FAD-2014-0016	It will be validated end of 2014. The applicant is presenting two production strains in the same application. Accordingly, one mandate has been sent by the EC.	No	Yes
Feed/ FEEDAP	*Streptomyces aureofaciens* NRRL 8092	Production of narasin (coccidiostat)	EFSA-Q-2013-00767 FAD-2013-0041		No	Yes
Feed/ FEEDAP	*Streptomyces cinnamonensis* ATCC 15413	Production of monensin sodium (coccidiostat)	EFSA-Q-2013-00752 FAD-2013-0037		No	Yes
Feed/ FEEDAP	*Streptomyces lasaliensis* ATCC 31180	Production of lasalocid A sodium (coccidiostat)	EFSA-Q-2013-00813 FAD-2013-0040		No	Yes
FIP/CEF	*Bacillus subtilis* MAM	Production of Food Enzyme	EFSA-Q-2013-00790 FIP-2013-0071	The food enzyme is a glucans 1,4-alpha glucosidase and produced by a GMM strain	Yes	No
FIP/CEF	*Bacillus subtilis* XAS	Production of Food Enzyme	EFSA-Q-2014-00293 FIP-2014-0029	The food enzyme is a endo 1,4-beta xylanase and produced by a GMM strain	Yes	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
FIP/CEF	*Bacillus licheniformis* NZYM-AC	Production of Food Enzyme	EFSA-Q-2013-00586 FIP-2013-0043	The food enzyme is an alpha-amylase produced by a GMM strain	Yes	No
FIP/CEF	*Bacillus licheniformis* NZYM-BC	Production of Food Enzyme	EFSA-Q-2013-00685 FIP-2013-0066	The food enzyme is an alpha-amylase produced by a GMM strain	Yes	No
FIP/CEF	*Bacillus licheniformis* NZYM-KE	Production of Food Enzyme	EFSA-Q-2012-00898 FIP-2012-0051	The food enzyme is an alpha-amylase produced by a GMM strain	Yes	No
FIP/CEF	*Bacillus licheniformis* NZYM-RH	Production of Food Enzyme	EFSA-Q-2014-00292 FIP-2014-0028	The food enzyme is a Serine protease produced by a GMM strain	Yes	No
FIP/CEF	*Microbacterium imperiale AE-AMT*	Production of Food Enzyme	EFSA-Q-2014-00544 FIP-2014-0063	The food enzyme is an alpha-amylase	No	Yes
Nutrition/ NDA	Pasteurised milk products fermented with *Bacteroides xylanisolvens*	As a Novel Food ingredient	EFSA-Q-2014-00301 Under validation	A safety assessment under the framework of Novel Foods	No	Yes
Nutrition/ NDA	A combination of four bacterial strains: *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104	Food targeted for health claims: "improvement of bowel function by increasing stool frequency"	EFSA-Q-2013-00893 EFSA Journal 2014;12(5):3659, 10 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3659.htm	An intake of one sachet (2.5 g) per day for 28 days. The concentration of the bacterial strains in colony forming units (CFU) is of 10^{10} CFU/per sachet (2.9×10^{9} CFU *B. longum* LA 101; 2.9×10^{9} CFU *L. helveticus* LA 102; 2.9×10^{9} CFU L. lactis LA 103; 1.3×10^{9} CFU *S. thermophilus* LA 104) In the framework of the EU Regulation 1924/2006 on health claims made on foods, EFSA is only requested to perform efficacy assessment (i.e. relationship between the food consumption and the claimed beneficial effect). Safety assessment is not foreseen.	NA	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
Nutrition/ NDA	Combination of four bacterial strains: *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104	Food targeted for health claims: "reducing intestinal discomfort"	EFSA-Q-2013-00892 EFSA Journal 2014;12(5):3658, 10 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3658.htm	The concentration of the bacterial strains in colony forming units (CFU) is of 1010 CFU/per sachet (2.9×10^9 CFU *B. longum* LA 101; 2.9×10^9 CFU *L. helveticus* LA 102; 2.9×10^9 CFU *L. lactis* LA 103; 1.3×10^9 *CFU S. thermophilus* LA 104) Safety assessment is not foreseen.	NA	No
Nutrition/ NDA	Synbio, a combination of *Lactobacillus rhamnosus* IMC 501® and *Lactobacillus paracasei* IMC 502®		EFSA-Q-2014-00567 0425_IT	Notes: In the framework of the EU Regulation 1924/2006 on health claims made on foods, EFSA is only requested to perform efficacy assessment (i.e. relationship between the food consumption and the claimed beneficial effect). Safety assessment is not foreseen.	Yes	No
Filamentous fungi						
Feed/ FEEDAP	*Aspergillus niger* (CBS 18404)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00886 EFSA Journal 2014;12(6):3723, 9 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3723.htm EFSA-Q-2014-00291 FAD-2014-0007	Already assessed in EFSA-Q-2008-013a	No	No
Feed/ FEEDAP	*Aspergillus niger* (CBS 109.713)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00886 EFSA Journal 2014;12(6):3723, 9 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3723.htm EFSA-Q-2014-00291 FAD-2014-0007	Already assessed in EFSA-Q-2008-013a	No	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
Feed/ FEEDAP	*Aspergillus niger* MUCL 39199	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00229 FAD-2010-0227		No	No
Feed/ FEEDAP	*Aspergillus niger* NRRL 25541	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00503 FAD-2014-0019 EFSA-Q-2014-00504 FAD-2014-0018	Already assessed in EFSA-Q2010-01519 and EFSA-Q-2010-00585	No	No
Feed/ FEEDAP	*Aspergillus niger* Strains: ZLCA0323 Van Tieghem ZS9 TN-A09	Production of Citric Acid	EFSA-Q-2013-00612 FAD-2012-0048		No	No
Feed/ FEEDAP	*Aspergillus oryzae* DSM 17594	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00450 FAD-2014-0017	GMM already assessed in EFSA-Q-2007-133	No	No
Feed/ FEEDAP	*Aspergillus oryzae* DSM 22594	Zootechnical feed additive (production of enzyme)	EFSA-Q-2014-00289 FAD-2014-0008	Already assessed in EFSA-Q-2010-00769	No	No
Feed/ FEEDAP	*Aspergillus oryzae* DSM 26372	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00447 FAD-2013-0047	GMM already assessed in EFSA-Q-2008-419	No	No
Feed/ FEEDAP	*Aspergillus oryzae* NRRL 66222	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00503 FAD-2014-0019	Already assessed in EFSA-Q2010-01519	No	No
Feed/ FEEDAP	*Penicillium funiculosum* (*Talaromyces versatilis* sp.nov. DSM 26702)	Zootechnical feed additive	EFSA-Q-2013-00750 EFSA Journal 2014;12(7):3793, 20 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3793.htm EFSA-Q-2014-00463 FAD-2014-0020	GMM	No	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
Feed/ FEEDAP	*Penicillium funiculosum* (*Talaromyces versatilis* IMI 378536)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00750 EFSA Journal 2014;12(7):3793, 20 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3793.htm EFSA-Q-2014-00463 FAD-2014-0020	Already assessed in EFSA-Q-2010-01287	No	No
Feed/ FEEDAP	*Trichoderma citroviridae* (IMI SD 135)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00809 FAD-2013-0046	Already assessed in EFSA-Q-2010-00036	No	No
Feed/ FEEDAP	*Trichoderma citroviridae* (IMI SD 142)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2014-00297 FAD-2014-0013	Already assessed in EFSA-Q-2010-01025	No	No
Feed/ FEEDAP	*Trichoderma longibrachiatum* MUCL 39203	Zootechnical feed additive (product of enzyme)	EFSA-Q-2014-00228 FAD-2010-0213	Already assessed in EFSA-Q-2008-288	No	No
Feed/ FEEDAP	*Trichoderma reesei* (ATCC SD-6528)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00997 FAD-2013-0049	GMM strain	No	No
FIP/CEF	*Aspergillus acidus*/ RF7398	Production of Food Enzyme	EFSA-Q-2014-00163 FIP-2014-0020	The food enzyme is a endo 1,4-betaxylanase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus aculeatus*/ NZYM-RE CBS 589.94	Production of Food Enzyme	EFSA-Q-2014-00200 FIP-2014-0024 EFSA-Q-2014-00201 FIP-2014-0025	The food enzyme is a polygalacturonase The food enzyme is a betaglucanase	No	No
FIP/CEF	*Aspergillus melleus*/AE-DN	Production of Food Enzyme	EFSA-Q-2014-00326 FIP-2014-0037	The food enzyme is an AMP deaminase	No	No
FIP/CEF	*Aspergillus niger*	Production of Food Enzyme	EFSA-Q-2013-01018 FIP-2013-0082	The food enzyme is a glucose oxidase and catalase	No	No
FIP/CEF	*Aspergillus niger*/AGN	Production of Food Enzyme	EFSA-Q-2014-00401 FIP-2014-0059	The food enzyme is an asparaginase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/DS 53180	Production of Food Enzyme	EFSA-Q-2013-00895 FIP-2013-0077	The food enzyme is an asparaginase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/EPG	Production of Food Enzyme	EFSA-Q-2014-00402 FIP-2014-0060	The food enzyme is a polygalacturonase produced by a GMM strain	No	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
FIP/CEF	*Aspergillus niger*/NZYM-BE	Production of Food Enzyme	EFSA-Q-2013-00896 FIP-2013-0078	The food enzyme is a glucoamylase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/NZYM-BF	Production of Food Enzyme	EFSA-Q-2014-00307 FIP-2014-0032	The food enzyme is a glucoamylase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/NZYM-BR	Production of Food Enzyme	EFSA-Q-2013-00686 FIP-2013-0067	The food enzyme is an amyloglucosidase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/NZYM-BX	Production of Food Enzyme	EFSA-Q-2013-00877 FIP-2013-0073	The food enzyme is a glucan 1,4-alpha-glucosidase with activity also of an alpha amylase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/NZYM-MC	Production of Food Enzyme	EFSA-Q-2014-00306 FIP-2014-0031	The food enzyme is an alpha amylase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/NZYM-SB	Production of Food Enzyme	EFSA-Q-2014-00413 FIP-2014-0053	The food enzyme is an alpha-amylase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/LFS	Production of Food Enzyme	EFSA-Q-2014-00325 FIP-2014-0036	The food enzyme is a tryacylglycerol lipase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/XYL	Production of Food Enzyme	EFSA-Q-2014-00305 FIP-2014-0030	The food enzyme is a Endo-1,4-beta-xylanase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus niger*/ZGL	Production of Food Enzyme	EFSA-Q-2013-01005 FIP-2013-0080	The food enzyme is a glucose oxidase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/AE-TL	Production of Food Enzyme	EFSA-Q-2014-00112 FIP-2014-0014	The food enzymes are triacylglycerol lipase and transesterase	No	No
FIP/CEF	*Aspergillus oryzae*/NZYM-AL	Production of Food Enzyme	EFSA-Q-2013-00198 EFSA Journal 2014;12(7):3778, 2 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3778.htm	The food enzyme is a lipase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/NZYM-FA	Production of Food Enzyme	EFSA-Q-2013-00789 FIP-2013-0070	The food enzyme is a xylanase produced by a GMM strain	No	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
FIP/CEF	*Aspergillus oryzae*/NZYM-FL	Production of Food Enzyme	EFSA-Q-2013-00197 EFSA Journal 2014;12(7):3762, 15 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3762.htm	The food enzyme is a lipase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/NZYM-KE	Production of Food Enzyme	EFSA-Q-2012-00897 EFSA Journal 2014;12(5):3645, 17 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3645.htm	The food enzyme is a xylanase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/NZYM-KP	Production of Food Enzyme	EFSA-Q-2013-00687 FIP-2013-0065	The food enzyme is a glucose oxidase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/ NZYM-LH	Production of Food Enzyme	EFSA-Q-2012-01009 EFSA Journal 2014;12(7):3763, 15 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3763.htm	The food enzyme is a lipase produced by a GMM strain	No	No
FIP/CEF	*Aspergillus oryzae*/ NZYM-NA	Production of Food Enzyme	EFSA-Q-2012-01010 FIP-2013-0007	The food enzyme is an alpha-amylase	No	No
FIP/CEF	*Aspergillus oryzae*/ NZYM-SP	Production of Food Enzyme	EFSA-Q-2013-00587 FIP-2013-0044	The food enzyme is an asparaginase produced by a GMM strain	No	No
FIP/CEF	*Disporotrichum dimorphosporum*/DXL	Production of Food Enzyme	EFSA-Q-2014-00355 FIP-2014-0040 EFSA-Q-2014-00356 FIP-2014-0041	The food enzymes is a Endo-1,4-beta-xylanase & beta-glucanase	No	No
FIP/CEF	*Fusarium venenatum*	Production of Food Enzyme	EFSA-Q-2014-00412 FIP-2014-0052	The food enzyme is a trypsin produced by a GMM strain	No	No
FIP/CEF	*Leptographium procerum*	Production of Food Enzyme	EFSA-Q-2013-01006 FIP-2013-0081	The food enzyme is a phosphodiesterase produced	No	No
FIP/CEF	*Penicillium roqueforti AE-*	Production of Food Enzyme	EFSA-Q-2014-00545	The food enzymes is a triacylglycerol	No	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
	LRF		FIP-2014-0064	lipase		
FIP/CEF	*Rhyzopus oryzae*/AE-MB	Production of Food Enzyme	EFSA-Q-2014-00114 FIP-2014-0016	The food enzymes are leucyl aminopeptidase, protease and amylase	No	No
FIP/CEF	*Rhyzopus oryzae*/AE-PER	Production of Food Enzyme	EFSA-Q-2014-00354 FIP-2014-0038	The food enzymes is a leucyl aminopeptidase	No	No
FIP/CEF	*Trichoderma citrinoviride/ TCLSC*	Production of Food Enzyme	EFSA-Q-2014-00543 FIP-2014-0062	The food enzyme is an endo-1,4-β-xylanase	No	No
FIP/CEF	*Trichoderma reesei*/RF5703	Production of Food Enzyme	EFSA-Q-2014-00410 FIP-2014-0050	The food enzyme is a endo 1,4-betaxylanase produced by a GMM strain	No	No
FIP/CEF	*Trichoderma reesei*/RF6199	Production of Food Enzyme	EFSA-Q-2014-00164 FIP-2014-0021	The food enzyme is a pectine lyase	No	No
FIP/CEF	*Trichoderma reesei*/RF8793	Production of Food Enzyme	EFSA-Q-2014-00411 FIP-2014-0051	The food enzyme is a phospholipase A2 produced by a GMM strain	No	No
Pesticides/ PPR	*Beauveria bassiana* strain NPP111B005	Plant protection product	EFSA-Q-2014-00327		No	No
Pesticides/ PPR	*Beauveria bassiana* strain 147	Plant protection product	EFSA-Q-2014-00324		No	No
Pesticides/ PPR	*Isaria fumosorosea* strain Apopka 97	Plant protection product	EFSA-Q-2013-00833 EFSA Journal 2014;12(5):3679, 23 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3679.htm	It has been formerly evaluated as *Paecilomyces fumosoroseus* (DG SANCO, 4203/VI/98-final) and approved in 2001, now resubmitted for renewal of the approval.	No	No
Pesticides/ PPR	*Trichoderma atroviride* SC1	Plant protection product	EFSA-Q-2014-00334		No	No
Yeasts						
Feed/ FEEDAP	*Komagataella pastoris* (DSMZ 25376)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00528 FAD-2013-0013	GMM	Yes	No
Feed/ FEEDAP	*Komagataella pastoris* (DSMZ 26469)	Zootechnical feed additive (production of enzyme)	EFSA-Q-2013-00528 FAD-2013-0013	GMM	Yes	No
Feed/ FEEDAP	*Komagataella pastoris* (DSM 26643)	Technological/ Production of fumonisine esterase	EFSA-Q-2013-00090 EFSA Journal 2014;12(5):3667, 19 pp.	GMM Synonym used: *Pichia pastoris*	Yes	No

EFSA Unit/Panel	Microorganism species/strain	Intended use	EFSA Register of Questions and EFSA Journal	Additional information provided by the EFSA Scientific Unit	Previous QPS status? [12]	To be evaluated/ not evaluated
			http://www.efsa.europa.eu/en/efsajournal/pub/3667.htm			
Feed/ FEEDAP	*Saccharomyces cerevisiae LOCK 0141*	Zootechnical feed additive	EFSA-Q-2013-00996 FAD-2013-0048	Not validated yet	Yes	No
Feed/ FEEDAP	*Saccharomyces cerevisiae CNCM I-1077*	Zootechnical feed additive	EFSA-Q-2014-00029 FAD-2013-0054	Already assessed in several occasions	Yes	No
Feed/ FEEDAP	*Saccharomyces cerevisiae CNCM I-1077*	Zootechnical feed additive	EFSA-Q-2014-00375 FAD-2010-0120	Not validated yet Already assessed in several cases	Yes	No
FIP/CEF	*Candida cylindracea AE-LAYH*	Production of Food Enzyme	EFSA-Q-2014-00113 FIP-2014-0015	The food enzyme is a tryacilglycerol lipase by a GMM strain Enzymes for this microorganisms has been used in bakery products	No	Yes
FIP/CEF	*Saccharomyces cerevisiae CBS615-94*	Production of Food Enzyme	EFSA-Q-2013-00119 EFSA Journal 2013;11(7):3304, 28 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3304.htm	The food enzyme is an alpha-galactosidase produced by a GMM strain	Yes	No
Nutrition/ NDA	*Saccharomyces cerevisiae* (vitamin D-enriched UV-treated)	Scientific Opinion on the safety of vitamin D-enriched UV-treated baker's yeast The source for the production of the novel food ingredient is *Saccharomyces cerevisiae*	EFSA-Q-2013-00335 EFSA Journal 2014;12(1):3520, 19 pp. http://www.efsa.europa.eu/en/efsajournal/pub/3520.htm	Safety assessment As a novel food ingredient in the context of Regulation (EC) No 258/97	Yes	No
Virus						
Pesticides/ PPR	*Pepino mosaic* virus, strain CH2, isolate 1906	Plant protection product	EFSA-Q-2014-00054		Yes	No

ABBREVIATIONS

CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
FEED	EFSA Feed Unit
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FIP	EFSA Food ingredients and packaging Unit
IJSEM	International Journal of Systematic and Evolutionary Microbiology
LPSN	List of prokariotic names with standing in nomenclature
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
NUTRI	EFSA Nutrition Unit
PPR	Panel on Plant Protection Products and their Residues
PRAS	EFSA Pesticides Unit
QPS	Qualified Presumption of Safety
ToR	Term of Reference