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## Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 5: suitability of taxonomic units notified to EFSA until September 2016

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### Abstract

EFSA was 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 were assessed. Safety concerns identified 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 57 biological agents were notified to EFSA between the end of April 2016 and the beginning of September 2016. From these, 34 biological agents already had a QPS status and did not require further evaluation, and 10 were not included in the evaluation as they are filamentous fungi or enterococci, biological groups which have been excluded from QPS evaluation since 2014. Three notifications for *Streptomyces violaceoruber*, one for *Streptomyces albus*, one for *Bacillus circulans* and four for *Escherichia coli* were not evaluated for QPS status because these species were recently assessed and considered not suitable for QPS status. Therefore, only four notifications related to three taxonomic units were evaluated for QPS status. Of these, *Arthrobacter ramosus* and *Pseudomonas fluorescens* are not recommended for the QPS list. *Bacillus smithii* is recommended for the QPS status.

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**Amendment:** An editorial amendment was carried out that does not materially affect the contents or outcome of this scientific output. On p. 15, the text on the qualification of the taxonomic unit *Pasteuria nishizawae* has been deleted following the decision taken by the BIOHAZ Panel at the meeting held in November-December 2016. 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.

**Erratum:** 1. (12 September 2017) Table B.1 in Appendix B was revised to delete an erroneous footnote on "*Paenibacillus lentus*", with the subsequent re-ordering of the following footnotes of Table B.1. 2. (24 January 2018) Table B.1 was revised so as to substitute "*Paenibacillus lentus*" with "*Bacillus lentus*".

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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. The request included three specific tasks as mentioned in the Terms of Reference (ToR).

In 2014, the BIOHAZ Panel decided to change the evaluation procedure: instead of publishing the overall assessment of the taxonomic units previously recommended for the QPS list annually, as prior to 2013, it is now carried out every 3 years in a scientific Opinion of the BIOHAZ Panel (the first adopted in December 2016). Meanwhile, the list of microorganisms is maintained and around every 6 months checked based on the evaluation of standardised extensive literature searches, a database that will be updated regularly with new publications. Intermediate deliverables in the form of a Panel Statement are produced and published when an assessment for a QPS classification of a microbiological agent notified to EFSA is requested by the Feed Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition Unit or the Pesticides Unit. Evaluations of these notifications are compiled in a single Statement encompassing periods of around 6 months. The main results of these assessments since 2014 are included in the scientific Opinion of the BIOHAZ Panel to be published in January 2017. The '2013 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA scientific Panels and Units' has been updated with the inclusion of new recommendations for QPS status and is appended to each Panel Statement published until 2016. The current valid version of the QPS list is the one from the scientific Opinion published in January of 2017, also appended to the current Panel Statement.

The first ToR requires ongoing updates of the list of biological agents being notified, in the context of a technical dossier to EFSA Units (such as Feed Unit, FIP Unit, Nutrition Unit, and Pesticides Unit), for intentional use in food and/or feed or as sources of food and feed additives, enzymes and plant protection products. The list was updated with the notifications received since the latest review and the new ones were included in a table appended to the current Statement (Appendix C). Notifications considered for the current Statement were received between the end of April 2016 and the beginning of September 2016. Within this period, 57 notifications were received from the four EFSA Units, of which 24 were from the Feed Unit, 28 from FIP, four from Nutrition, and one from the Pesticides Unit. The overall updated list of notifications received from the beginning of the QPS exercise in 2007 is appended to the scientific Opinion published in January of 2017.

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 became available and to update the information provided in the previous Opinion published in November 2013, where appropriate. The work being developed in order to meet this ToR is not reflected in the current Statement, but will be published in a scientific Opinion of the BIOHAZ Panel, in January of 2017.

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 this ToR by including the individual assessments of the taxonomic units not previously included in the 2013 QPS list and that were notified to EFSA between the end of April 2016 and the beginning of September 2016. Of the 57 notifications received, 34 biological agents already had QPS status and did not require further evaluation in this Statement. From the remaining 23 (without a QPS status), 10 were not further assessed as they are filamentous fungi or enterococci, biological groups that have been excluded from QPS since 2014. Three notifications for *Streptomyces violaceoruber*, one for *Streptomyces albus* and one for *Bacillus circulans* were not included because the pertinent taxonomic units have already been evaluated in the previous Statements of December of 2014 and of June of 2015 and found unsuitable for QPS. Four notifications of strains belonging to the species *Escherichia coli* were not included because the species had also been re-evaluated in the previous Statement (2015) and was considered not suitable for QPS status. There were three notifications, notified by the FIP Unit, related to two taxonomic units and one for Feed Unit that were evaluated for QPS status. *Arthrobacter ramosus* and *Pseudomonas fluorescens* are not recommended for the QPS list. *Bacillus smithii* is recommended for the QPS list.

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## 1. Introduction

In the context of applications for market authorisation of these biological agents, the European Food Safety Authority (EFSA) is requested by the EC, National competent Authorities or Applicants to assess the safety of microorganisms 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. 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 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, 2005). For the update to be started in 2014, it was decided by the Scientific Committee and BIOHAZ Panel to change the procedures. The publication of the overall assessment of the taxonomic units previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) is now carried out every 3 years through a scientific Opinion by the Panel on Biological Hazards (BIOHAZ). In any case, the recommendations provided concerning that list of microorganisms will be maintained and every 6 months 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 are produced and published whenever an assessment for a QPS classification of a microbiological agent notified to EFSA is requested by Feed, Food Ingredients and Packaging (FIP), Nutrition, or Pesticides Units. Evaluations of these notifications are compiled in single Statements for periods of around 6 months. The results of these assessments are also included in the scientific Opinion published in January of 2017. The '2013 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units' to which new recommendations of taxonomic units for the QPS was included, was also appended to each Panel Statement published until 2016.

QPS entered the European Union (EU) law with the publication of a new Commission Implementing Regulation (EU) No 562/2012<sup>1</sup> amending Commission Regulation (EU) No 234/2011<sup>2</sup> 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 EFSA, the enzyme application would 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<sup>3</sup>, may request additional data for risk assessment, including toxicological data.

### 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 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 received by EFSA for market authorisation as sources of food and feed additives, enzymes and plant protection products.

The Scientific Committee of EFSA 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 QPS,<sup>4,5</sup> consisting of 48 species of Gram-positive non-sporulating bacteria, 13 *Bacillus* species and 11

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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 L 354, 31.12.2008, p. 1–6.

<sup>4</sup> Opinion of the Scientific Committee on a request from EFSA related to a generic approach to the safety assessment by EFSA of microorganisms used in food/feed and the production of food/feed additives. EFSA Journal 2005, 226, 1–12.

<sup>5</sup> Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA – Opinion of the Scientific Committee. EFSA Journal 2007, 293, 1–85.

yeast species. Filamentous fungi were also assessed but none was 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,<sup>6</sup> 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.<sup>7</sup> 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 (2008–2013 updates) and enterococci (2010–2013 updates) 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), one Gram-negative bacterium (*Gluconobacter oxydans*), 13 yeast species, and three virus families. No QPS-recommended taxa have been taken down from the list following six (2008–2013 updates) annual reviews.

Based on the above 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 March 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.

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

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.

## 2. Data and methodologies

### 2.1. Data

For the taxonomic units associated with the notifications compiled within the time period covered by this Statement (from the end of April 2016 until the beginning of September 2016), the literature review considered the identity, the body of knowledge, history of use, 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 followed are described in Appendix A.

In February 2016, it was agreed to improve the assessment of the QPS status and its applicability for the Pesticides Unit by taking into account the data provided to EFSA within the applicant's dossier (that is required to include an extensive systematic literature review of the peer-reviewed scientific literature).

<sup>6</sup> Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on the maintenance of the list of QPS microorganisms intentionally added to food or feed. EFSA Journal 2008, 923, 1–48.

<sup>7</sup> 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

## 2.2. Methodologies

In response to ToR1, the EFSA Units have been asked to update the list of biological agents being notified to EFSA. Fifty-seven notifications were received between the end of April 2016 and the beginning of September 2016 of which 24 from the Feed Unit, 28 from FIP, four from the Nutrition Unit, and one from the Pesticides Unit (Table 1).

In response to ToR3, from those 57 notifications, 34 biological agents already had a QPS status and did not require further evaluation; neither did the 10 biological agents that are 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). Three notifications for *Streptomyces violaceoruber*, one for *Streptomyces albus*, and one for *Bacillus circulans* were not included because the corresponding taxonomic units have already been evaluated in the previous Statement of December of 2014 and June of 2015, respectively, and found unsuitable for QPS (EFSA BIOHAZ Panel, 2014, 2015a). Four notifications of strains belonging to *Escherichia coli* were not included as this species has been previously re-evaluated and found unsuitable for QPS (EFSA BIOHAZ Panel, 2014). Three biological agents were assessed for their suitability for inclusion in the QPS list as the species were not previously assessed. They were notified to the EFSA Food Ingredients and packaging (FIP) (*Arthrobacter ramosus* and *Pseudomonas fluorescens*) and one to the Feed Unit (*Bacillus smithii*).

The procedure followed for this assessment is the same as in the previous QPS 2013 update of the scientific Opinion (EFSA BIOHAZ Panel, 2013) and in the Panel Statements published in December 2014 and June and December 2015 and June 2016 (EFSA BIOHAZ Panel, 2014, 2015a,b, 2016).

**Table 1:** Notifications received by EFSA Units (Feed, FIP, Nutrition, and Pesticides) by biological group from April 2016 until September 2016

| Unit/Panel           | Not QPS                             |                                     |                        | Evaluated | Already QPS | Grand Total |
|----------------------|-------------------------------------|-------------------------------------|------------------------|-----------|-------------|-------------|
|                      | Not evaluated                       |                                     |                        |           |             |             |
| Biological group     | Excluded in QPS 2013 <sup>(a)</sup> | Previously evaluated <sup>(b)</sup> | Evaluation in stand by |           |             |             |
| <b>Feed/FEEDAP</b>   | <b>3</b>                            | <b>4</b>                            |                        | <b>1</b>  | <b>16</b>   | <b>24</b>   |
| Bacteria             | 2                                   | 4                                   |                        | 1         | 9           | 16          |
| Filamentous fungi    | 1                                   |                                     |                        |           |             | 1           |
| Yeasts               |                                     |                                     |                        |           | 7           | 7           |
| <b>Nutrition/NDA</b> |                                     |                                     |                        |           | <b>4</b>    | <b>4</b>    |
| Bacteria             |                                     |                                     |                        |           | 4           | 4           |
| <b>Pesticides</b>    |                                     |                                     |                        |           | <b>1</b>    | <b>1</b>    |
| Bacteria             |                                     |                                     |                        |           | 1           | 1           |
| Filamentous fungi    |                                     |                                     |                        |           |             |             |
| Viruses              |                                     |                                     |                        |           |             |             |
| Yeasts               |                                     |                                     |                        |           |             |             |
| <b>FIP/CEF</b>       | <b>7</b>                            | <b>5</b>                            |                        | <b>3</b>  | <b>13</b>   | <b>28</b>   |
| Bacteria             |                                     | 5                                   |                        | 3         | 12          | 20          |
| Filamentous fungi    | 7                                   |                                     |                        |           |             | 7           |
| Yeasts               |                                     |                                     |                        |           | 1           | 1           |
| <b>Total</b>         | <b>10</b>                           | <b>9</b>                            | <b>0</b>               | <b>4</b>  | <b>34</b>   | <b>57</b>   |

CEF: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; FEEDAP: EFSA Panel on Additives and products or Substances used in Animal Feed; FIP: EFSA Food ingredients and packaging Unit; NDA: EFSA Panel on Dietetic Products, Nutrition and Allergy; QPS: Qualified Presumption of Safety.

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

(b): The number includes biological agents that have been recently evaluated. Three notifications for *Streptomyces violaceoruber* and one for *Streptomyces albus* were not included because they have already been evaluated in the previous Statement of December of 2014 and found unsuitable for QPS (EFSA BIOHAZ Panel, 2014). Four notifications corresponding to four strains of *E. coli* were not included as the species has been previously evaluated and found unsuitable for QPS (EFSA BIOHAZ Panel, 2014). One notification corresponding to *Bacillus circulans* was not included because it was already evaluated in June 2015.

### 3. Bacteria

#### 3.1. *Arthrobacter ramosus*

##### 3.1.1. Identity

*Arthrobacter ramosus* is a Gram-positive, aerobic and rod-shaped species belonging to *Micrococcaceae*, firstly described by Jensen (1960). This species has the highest 16S rRNA gene sequence similarity with *A. gyeryongensis* (98.2% between both type strains), being, namely, differentiated by metabolic reactions.

##### 3.1.2. Body of knowledge

*A. ramosus* produces trehalose from maltooligosaccharide and it can also produce an extracellular protease (Yamamoto et al., 2001).

There is a very limited body of knowledge, with a total of 15 scientific papers retrieved and screened. Soil is considered the main habitat for arthrobacters in general (Crocker et al., 2000), although strains have been isolated from clinical specimens and may have been previously identified as CDC coryneform group B-1 and B-3 (Funke et al., 1996). Thus, several other *Arthrobacter* species have now been reported to be associated with human diseases such as peritonitis, erythema or endocarditis (*A. sanguinis* (Yap et al., 2015), *A. mysorens* (Imirzalioglu et al., 2010), *A. woluwensis* (Bernasconi et al., 2004)) and even some unnamed species (Busse et al., 2012). Although *Arthrobacter* spp. are widely present in nature and it is expected that *A. ramosus* is also present in soil and, therefore, in the food chain, there are no reports indicating the isolation of *A. ramosus* in food as contaminant, and there is no indication of the intentional use of the microorganism in foods or food ingredients to date.

##### 3.1.3. Safety concerns

No information indicating any safety concern related to this specific taxonomic unit was found.

##### 3.1.4. Antimicrobial resistance

No information about antimicrobial resistance aspects was found.

##### 3.1.5. Conclusions on a recommendation for the QPS list

Due to a very limited body of knowledge and the association of some *Arthrobacter* spp. with human disease (although not food-borne), QPS status cannot be granted to *A. ramosus*.

#### 3.2. *Bacillus smithii*

##### 3.2.1. Identity

*B. smithii* is a rod-shaped, motile, spore-forming, facultatively anaerobic and facultatively thermophilic bacterium. This species is most closely related to *B. coagulans*, which is also a facultatively thermophilic species. The complete genome of *B. smithii* type strain (*B. smithii* DSM 4216<sup>T</sup>) is available (Bosma et al., 2016).

##### 3.2.2. Body of knowledge

There is a limited body of knowledge (48 references were found). As most spore-forming bacteria, it is ubiquitous in nature, and therefore it is also present in many raw materials and dry ingredients of processed food such as milk products (Lücking et al., 2013). It also has potential for the production of enzymes and other compounds, e.g. nitrile hydratases (Takashima et al., 2000) and a thermophilic inulinase (Gao et al., 2009). *B. smithii* possesses a possible protective effect against *Salmonella* and *Clostridium difficile* (Suitso et al., 2007; Jögi et al., 2008). It has been considered a relevant microorganism for biotechnological purposes, namely for conversion of biomass to fuel or chemicals, (Bosma et al., 2015).



### 3.2.3. Safety concerns

Cytotoxicity assays using Vero and HEp-2 cells in several *Bacillus* spp. strains, including *B. smithii*, did not identify any cytotoxic components, indicating that the risk of food-borne disease is most likely low if at all (Lücking et al., 2013). Since members of this species were in the past probably assigned to *B. coagulans*, a species with QPS status, additional safety concerns related to misidentification are not expected.

### 3.2.4. Antimicrobial resistance

No information related to the presence of antimicrobial resistance determinants in members of this taxon has been identified.

### 3.2.5. Conclusions on a recommendation for the QPS list

The species *B. smithii* is a natural component of bacterial communities of fermented vegetables and plant-derived products. Considering the lack of evidence of pathogenicity, it can be recommended for the QPS list with a qualification of absence of toxigenic activity (as applied to all strains of *Bacillus* species recommended to the QPS list).

## 3.3. *Pseudomonas fluorescens*

### 3.3.1. Identity

*Pseudomonas fluorescens* is a Gram-negative rod, motile, unable to ferment glucose, and oxidase and pyoverdinin producer. The taxonomy of *Pseudomonas* genus has evolved, with the multi locus sequence analysis (MLSA) of four housekeeping genes (16S rRNA, *gyrB*, *rpoB* and *rpoD* genes) (Mulet et al., 2012). In fact, MLSA has demonstrated that a significant number of *Pseudomonas* strains are not correctly assigned at the species level, with errors also including *P. fluorescens* strain assignments (Mulet et al., 2012). Several complete genomes of *P. fluorescens* strains are available (Gomila et al., 2015).

### 3.3.2. Body of knowledge

*P. fluorescens* is a ubiquitous bacterium commonly encountered in aquatic, aerial and soil matrices, and more specifically in spoiled food, rhizospheres and surfaces of plants, as well as a coloniser of mammalian hosts (Bergsma-Vlami et al., 2005; Dickson et al., 2014).

This metabolically versatile species produces a large number of secondary metabolites enabling it to succeed in competing with other microorganisms, and also making it of interest for biotechnology applications. Examples include hydrogen cyanide, suppressing plant disease, which may be produced in rhizosphere-inhabiting *P. fluorescens*, and phenazine compounds with antitumour, antiparasitic and antimicrobial activities (Ramette et al., 2003; Mavrodi et al., 2006). Of note is the production of pyrrolnitrin, an antifungal compound formulated for clinical and agricultural use, and the production of pseudomonic acids, with mupirocin used for prevention of methicillin-resistant *Staphylococcus aureus* infections (Sutherland et al., 1985; Villiger et al., 1986; Umio et al., 1987; Ligon et al., 2000).

### 3.3.3. Safety concerns

*P. fluorescens* has been considered to be an opportunistic pathogen, involved in acute nosocomial infections, and with a rapid increase in cases over the last few years (CDC, 2005, 2006).

Production of bioactive secondary metabolites, haemolysins, siderophores, type III secretion system, the ability to form biofilms and to adapt to growth at higher temperatures are functional features that have been associated with the ability to cause disease in humans (Scales et al., 2014; Mazurier et al., 2015).

A new possible clinically important issue of this bacterium is the "association" between *P. fluorescens* and Crohn's disease in humans, as revealed by the detection of a highly specific antigen of *P. fluorescens* (designated as I2) in the serum of 54% of Crohn's patients (Sutton et al., 2000; Dalwadi et al., 2001). Moreover, the possibility that *P. fluorescens* may be as common as *Helicobacter pylori* in the human gastrointestinal tract was recently described (Patel et al., 2013).

### 3.3.4. Antimicrobial resistance

Intrinsic antimicrobial resistance mechanisms, namely efflux pumps belonging to the resistance-nodulation-division (RND) superfamily, have been described in *P. fluorescens* (Adebusuyi and Foght, 2011). Moreover, different acquired resistance genes have also been associated with this opportunistic bacterial species (e.g. *bla*<sub>VIM-2</sub>, *bla*<sub>IMP-1</sub>, and *bla*<sub>IMP-22</sub> conferring resistance to carbapenems) (Koh et al., 2004; Pellegrini et al., 2009; Abigail et al., 2011; Rubin et al., 2014).

### 3.3.5. Conclusions on a recommendation for the QPS list

The pathogenic potential of *P. fluorescens* demonstrated by its implication in human infections and virulence features is an important safety concern, preventing its recommendation for the QPS list. Moreover, the possibility of mupirocin-resistant *S. aureus* strains selection, as a result of *P. fluorescens* ability to produce mupirocin, further supports the rejection of the QPS status.

## 4. Conclusions

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

- Between the end of April 2016 and the beginning of September 2016, 57 notifications were received from those four Units, of which 24 were from the Feed Unit, 28 from FIP, four from Nutrition, and one from the Pesticides Unit.

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 January of 2017.

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

- Of the 57 notifications received, 34 biological agents already had a QPS status and did not require further evaluation.
- From the remaining 23 notifications (without a QPS status), 10 were not further assessed as they are filamentous fungi or enterococci, biological groups which have been excluded from QPS activities since 2014. Four notifications of strains belonging to *E. coli* were also not evaluated because the species has not been recommended for the QPS approach in the previous Statement of December of 2014. Three notifications for *Streptomyces violaceoruber* and one for *Streptomyces albus*, were not included because several species of the genus had already been evaluated in the previous Statement of December of 2014 and found unsuitable for QPS. One notification corresponding to *Bacillus circulans* was not included because it had already been evaluated in the Statement of June 2015 and found unsuitable for QPS. Four notifications were considered for the assessment of the suitability of the respective taxonomic units for inclusion in the QPS list.
- From the three taxonomic units assessed, two were notified by the FIP Unit (*Arthrobacter ramosus* and *Pseudomonas fluorescens*) and one to the Feed Unit (*Bacillus smithii*).

## 5. Recommendations

- *Arthrobacter ramosus* and *Pseudomonas fluorescens* are not recommended for the QPS list.
- *Bacillus smithii* is recommended for the QPS status.

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## Abbreviations and Glossary

|                            |  |
|----------------------------|--|
| antimicrobial (substances) | antibiotics, bacteriocins and/or small peptides                                |
| BIOHAZ                     | EFSA Panel on Biological Hazards   |
| CEF                        | EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids |

|        |  |
|--------|--|
| FEEDAP | EFSA Panel on Additives and Products or Substances used in Animal Feed |
| FIP    | EFSA Food ingredients and packaging Unit                               |
| FSTA   | Food Science Technology Abstracts                                      |
| GMM    | genetically modified microorganism                                     |
| MLSA   | multi locus sequence analysis  |
| NDA    | EFSA Panel on Dietetic Products, Nutrition and Allergies               |
| QPS    | Qualified Presumption of Safety  |
| RND    | resistance-nodulation-division   |
| ToR    | Term of Reference  |

## Appendix A – Search strategy for the evaluated microorganisms

### *Arthrobacter ramosus*

A literature search was performed in Web of Science Core collection, using the search terms "Arthrobacter ramosus", considering all years available: a total of 15 hits, plus the Bergey's Manual of Systematic Bacteriology, section "Arthrobacter", were identified and screened.

### *Pseudomonas fluorescens*

A literature search was performed in Web of Science Core collection, considering all years available: using the search terms "Pseudomonas fluorescens phylogeny" a total of 52 hits were identified and screened; "Pseudomonas fluorescens" AND "antibiotic resistance" AND "mechanisms" a total of 85 hits were identified and screened; and "Pseudomonas fluorescens" AND "safety" AND ("infection", OR "hospitalisation" OR "outbreak" OR "disease" OR "immunocompromised" OR "Crohn's disease" OR "opportunistic") a total of 20 hits were identified and screened.

### *Bacillus smithii*

A literature search was performed in Web of Science Core collection using the search terms "Bacillus smithii", considering all years available: a total of 48 hits were identified and screened.

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

The previous list of QPS status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units, as shown in Table B.1 below, was revised in accordance with a self-task mandate of the BIOHAZ Panel. The previous QPS list (EFSA BIOHAZ Panel, 2013) has been revised so as to include new additions and has been published as an Appendix to the Statements of the BIOHAZ Panel published around every 6 months until July 2016. This is the most up-to-date QPS list, including also the new additions, and is also published on the web as a separate file.

**Table B.1:** The 2016 updated list of QPS status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units

| <b>Bacteria</b>                                 |  |  |  |
|---|--|--|--|
| <b>Gram-positive non-sporulating bacteria</b>   |  |  |  |
| <b>Species</b>                                  |  |  | <b>Qualifications<sup>(a)</sup></b>                                  |
| <i>Bifidobacterium adolescentis</i>             | <i>Bifidobacterium bifidum</i>                 | <i>Bifidobacterium longum</i>          |  |
| <i>Bifidobacterium animalis</i>                 | <i>Bifidobacterium breve</i>                   |  |  |
| <i>Carnobacterium divergens<sup>(b)</sup></i>   |  |  |  |
| <i>Corynebacterium glutamicum<sup>(c)</sup></i> |  |  | QPS only applies when the species is used for amino acid production. |
| <i>Lactobacillus acidophilus</i>                | <i>Lactobacillus delbrueckii</i>               | <i>Lactobacillus panis</i>             |  |
| <i>Lactobacillus amylolyticus</i>               | <i>Lactobacillus diolivorans<sup>(e)</sup></i> | <i>Lactobacillus paracasei</i>         |  |
| <i>Lactobacillus amylovorus</i>                 | <i>Lactobacillus farciminis</i>                | <i>Lactobacillus paraplantarum</i>     |  |
| <i>Lactobacillus alimentarius</i>               | <i>Lactobacillus fermentum</i>                 | <i>Lactobacillus pentosus</i>          |  |
| <i>Lactobacillus aviaries</i>                   | <i>Lactobacillus gallinarum</i>                | <i>Lactobacillus plantarum</i>         |  |
| <i>Lactobacillus brevis</i>                     | <i>Lactobacillus gasseri</i>                   | <i>Lactobacillus pontis</i>            |  |
| <i>Lactobacillus buchneri</i>                   | <i>Lactobacillus helveticus</i>                | <i>Lactobacillus reuteri</i>           |  |
| <i>Lactobacillus casei<sup>(d)</sup></i>        | <i>Lactobacillus hilgardii</i>                 | <i>Lactobacillus rhamnosus</i>         |  |
| <i>Lactobacillus cellobiosus</i>                | <i>Lactobacillus johnsonii</i>                 | <i>Lactobacillus sakei</i>             |  |
| <i>Lactobacillus collinoides</i>                | <i>Lactobacillus kefiranoferiens</i>           | <i>Lactobacillus salivarius</i>        |  |
| <i>Lactobacillus coryniformis</i>               | <i>Lactobacillus kefir</i>                     | <i>Lactobacillus sanfranciscensis</i>  |  |
| <i>Lactobacillus crispatus</i>                  | <i>Lactobacillus mucosae</i>                   |  |  |
| <i>Lactococcus lactis</i>                       |  |  |  |
| <i>Leuconostoc citreum</i>                      | <i>Leuconostoc mesenteroides</i>               | <i>Leuconostoc pseudomesenteroides</i> |  |
| <i>Leuconostoc lactis</i>                       |  |  |  |
| <i>Microbacterium imperiale<sup>(b)</sup></i>   |  |  | QPS only applies when the species is used for enzyme production.     |
| <i>Oenococcus oeni</i>                          |  |  |  |
| <i>Pasteuria nishizawae<sup>(f)</sup></i>       |  |  |  |
| <i>Pediococcus acidilactici</i>                 | <i>Pediococcus parvulus<sup>(e)</sup></i>      | <i>Pediococcus pentosaceus</i>         |  |
| <i>Pediococcus dextrinicus</i>                  |  |  |  |
| <i>Propionibacterium freudenreichii</i>         | <i>Propionibacterium acidipropionici</i>       |  |  |
| <i>Streptococcus thermophilus</i>               |  |  |  |
| <b>Gram-positive spore-forming bacteria</b>     |  |  |  |
| <b>Bacillus</b>                                 |  |  |  |
| <b>Species</b>                                  |  |  | <b>Qualifications<sup>(a)</sup></b>                                  |
| <i>Bacillus amyloliquefaciens</i>               | <i>Bacillus fusiformis</i>                     | <i>Bacillus mojavensis</i>             | Absence of toxigenic activity.                                       |
| <i>Bacillus atrophaeus</i>                      | <i>Bacillus lentus</i>                         | <i>Bacillus pumilus</i>                |  |
| <i>Bacillus clausii</i>                         | <i>Bacillus licheniformis</i>                  | <i>Bacillus smithii<sup>(g)</sup></i>  |  |
| <i>Bacillus coagulans</i>                       | <i>Bacillus megaterium</i>                     | <i>Bacillus subtilis</i>               |  |
| <i>Bacillus flexus<sup>(e)</sup></i>            |  | <i>Bacillus vallismortis</i>           |  |

| Gram-positive spore-forming bacteria  |  |                                  |   |
|---|--|----------------------------------|---|
| Species   |  |                                  | Qualifications <sup>(a)</sup>   |
| <i>Geobacillus stearothermophilus</i>   |  |                                  | Absence of toxigenic activity.  |
| Gram-negative bacteria  |  |                                  |   |
| Species   |  |                                  | Qualifications <sup>(a)</sup>   |
| <i>Gluconobacter oxydans</i>  |  |                                  | QPS only applies when the species is used for vitamin production.   |
| <i>Xanthomonas campestris</i> <sup>(h)</sup>                                      |  |                                  | QPS only applies when the species is used for the production of xanthan gum.  |
| Yeasts <sup>(i)</sup>   |  |                                  |   |
| Species   |  |                                  | Qualifications  |
| <i>Candida cylindracea</i> <sup>(b)</sup>   |  |                                  | QPS only applies when the species is used for enzyme production.  |
| <i>Debaryomyces hansenii</i>  |  |                                  |   |
| <i>Hanseniaspora uvarum</i>   |  |                                  |   |
| <i>Kluyveromyces lactis</i>   | <i>Kluyveromyces marxianus</i>                 |                                  |   |
| <i>Komagataella pastoris</i><br><i>Lindnera jadinii</i><br><i>Ogataea angusta</i> |  |                                  | QPS only applies when the species is used for enzyme production.  |
| <i>Saccharomyces bayanus</i>  | <i>Saccharomyces cerevisiae</i> <sup>(j)</sup> | <i>Saccharomyces pastorianus</i> | 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<br><i>Saccharomyces cerevisiae</i> this qualification applies for yeast strains able to grow above 37°C. |
| <i>Schizosaccharomyces pombe</i>  |  |                                  |   |
| <i>Wickerhamomyces anomalus</i>   |  |                                  | QPS only applies when the species is used for enzyme production.<br>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.                                     |
| <i>Xanthophyllomyces dendrorhous</i>  |  |                                  |   |
| 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): Microorganisms recommended in the Panel Statement published in December 2014.
- (c): *Brevibacterium lactofermentum* is a synonym of *Corynebacterium glutamicum*.
- (d): The previously described species '*Lactobacillus zeae*' has been included in the species *Lactobacillus casei*.
- (e): Microorganisms recommended in the Panel Statement published in June 2016.
- (f): Microorganisms recommended in the Panel Statement published in December 2015.
- (g): Microorganisms recommended in this Panel Statement published in January 2017.
- (h): Microorganisms recommended in the Panel Statement published in June 2015.
- (i): 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 kefyri*;
  - *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*.
- (j): *Saccharomyces cerevisiae*, subtype *boulardii* is contraindicated for persons with fragile health, as well as for patients with a central venous catheter in place.

**Appendix C – Microbial species as notified to EFSA received between the end of April 2016 and the beginning of September 2016**

| 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? <sup>(a)</sup> | To be evaluated? Yes or no <sup>(b)</sup> |
|-----------------|---|---------------------------|---|---|-------------------------------------|---|
| <b>Bacteria</b> |   |                           |   |   |                                     |   |
| FIP/CEP         | <i>Arthrobacter ramosus</i>                 | Production of food enzyme | EFSA-Q-2016-00135                           | The food enzyme is a 4-alpha-D- $\{(1\rightarrow4)\alpha\text{-D-glucano}\}$ trehalose trehalohydrolase | No                                  | Yes                                       |
| FIP/CEP         | <i>Arthrobacter ramosus</i>                 | Production of food enzyme | EFSA-Q-2016-00136                           | The food enzyme is a (1 $\rightarrow$ 4)-alpha-D-glucan 1-alpha-D-glucosylmutase                        | No                                  | Yes                                       |
| FIP/CEP         | <i>Bacillus amyloliquefaciens</i>           | Production of food enzyme | EFSA-Q-2015-00846                           | The food enzyme is an alpha-amylase   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus circulans</i> (strain M3-1)     | Production of food enzyme | EFSA-Q-2016-00210                           | The food enzyme is a beta-galactosidase   | No                                  | No  |
| Feed/FEEDAP     | <i>Bacillus coagulans</i>                   | Production of lactic acid | EFSA-Q-2016-00645                           |   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus licheniformis</i> (DP-Dzb44)    | Production of food enzyme | EFSA-Q-2015-00836                           | The food enzyme is an alpha-amylase by a GMM strain   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus licheniformis</i> /DP-Dzr46     | Production of food enzyme | EFSA-Q-2016-00095                           | The food enzyme is a glucan 1,4-alpha-maltohydrolase produced by a GMM strain                           | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus licheniformis</i> /DP-Dzr50     | Production of food enzyme | EFSA-Q-2016-00096                           | The food enzyme is a glucan 1,4-alpha-maltohydrolase produced by a GMM strain                           | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus licheniformis</i> /DP-Dzr52     | Production of food enzyme | EFSA-Q-2016-00093                           | The food enzyme is an alpha-amylase produced by a GMM strain  | Yes                                 | No  |
| Feed/FEEDAP     | " <i>Bacillus smithii</i> "                 | Production of lactic acid | EFSA-Q-2016-00645                           |   | No                                  | Yes                                       |
| Feed/FEEDAP     | <i>Bacillus subtilis</i>                    | Production of lactic acid | EFSA-Q-2016-00645                           |   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus subtilis</i>                    | Production of food enzyme | EFSA-Q-2016-00133                           | The food enzyme is an alpha-amylase   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus subtilis</i> (strain 11096)     | Production of food enzyme | EFSA-Q-2016-00207                           | The food enzyme is a pectate lyase  | Yes                                 | No  |
| Feed/FEEDAP     | <i>Bacillus subtilis</i> CJKB0001           | Production of vitamin B2  | EFSA-Q-2016-00505                           |   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus subtilis</i> (DP-Ezd31)         | Production of food enzyme | EFSA-Q-2015-00839                           | The food enzyme is an endo-1,4-beta-xylanase by a GMM strain  | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus subtilis</i> (DP-Ezg29)         | Production of food enzyme | EFSA-Q-2015-00838                           | The food enzyme is a beta-galactosidase by a GMM strain   | Yes                                 | No  |
| FIP/CEP         | <i>Bacillus subtilis</i> (DP-Ezm28)         | Production of food enzyme | EFSA-Q-2015-00828                           | The food enzyme is an endo-1,3(4)-beta-glucanase by a GMM strain  | Yes                                 | No  |
| Feed/FEEDAP     | <i>Bacillus subtilis</i> DSM 29784          | Zotechnical additive      | EFSA-Q-2016-00448                           |   | Yes                                 | No  |
| Pesticides      | <i>Bacillus subtilis</i> strain QST 713     | Plant protection product  | EFSA-Q-2016-00172                           | Application for renewal of approval (AIR III)   | Yes                                 | No  |
| Feed/FEEDAP     | <i>Corynebacterium glutamicum</i>           | Production of lysine      | EFSA-Q-2016-00574                           |   | Yes                                 | No  |
| Feed/FEEDAP     | <i>Corynebacterium glutamicum</i> KCCM80099 | Production of L-arginine  | EFSA-Q-2016-00405                           |   | Yes                                 | No  |
| Feed/FEEDAP     | <i>Enterococcus faecium</i> DSM 7134        | Zotechnical additive      | EFSA-Q-2016-00450                           |   | No                                  | No  |

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|-----------------|--|---|---|--|-------------------------------------|---|
| Feed/FEEDAP     | <i>Enterococcus faecium</i> DSM 7134   | Zotechnical additive  | EFSA-Q-2016-00452                           |  | No                                  | No  |
| Feed/FEEDAP     | <i>Escherichia coli</i> CGMCC 3667   | Production of tryptophane   | EFSA-Q-2016-00551                           |  | No                                  | No  |
| Feed/FEEDAP     | <i>Escherichia coli</i> (ATCC 9637)  | Production of histidine   | EFSA-Q-2016-00304                           |  | No                                  | No  |
| Feed/FEEDAP     | <i>Escherichia coli</i> (ATCC 9637)  | Production of histidine   | EFSA-Q-2016-00305                           |  | No                                  | No  |
| FIP/CEP         | <i>Escherichia coli</i> (BglA MCB3)  | Production of food enzyme   | EFSA-Q-2015-00622                           | The food enzyme is a beta-galactosidase by a GMM strain  | No                                  | No  |
| Feed/FEEDAP     | <i>Lactobacillus farciminis</i> CNMA67/4R  | Zotechnical additive  | EFSA-Q-2016-00712                           |  | Yes                                 | No  |
| NDA/Nutrition   | <i>Lactobacillus fermentum</i> CECT5716  | Food targeted for health claims   | EFSA-Q-2016-00318                           | 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  |
| Feed/FEEDAP     | <i>Lactobacillus hilgardii</i> CNMC I-4785   | Technological additive  | EFSA-Q-2016-00580                           |  | Yes                                 | No  |
| NDA/Nutrition   | "Nutrimune (a heat-treated fermented milk, fermented with <i>Lactobacillus paracasei</i> CBA L74)" | Food targeted for health claims   | EFSA-Q-2015-00755                           | 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  |
| NDA/Nutrition   | <i>Lactobacillus plantarum</i> 299v  | Food targeted for health claims: "increase of non-haem iron absorption"   | EFSA-Q-2015-00696                           | 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  |
| NDA/Nutrition   | <i>Lactobacillus rhamnosus</i> GG (ATCC 53103) and fructooligosaccharides (FOS)                    | Food targeted for health claims: "helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" | EFSA-Q-2015-00488                           | 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  |
| FIP/CEP         | <i>Lactococcus lactis</i> (strain DGCC5920)  | Production of food enzyme   | EFSA-Q-2016-00208                           | The food enzyme is a membrane alanyl aminopeptidase  | Yes                                 | No  |
| Feed/FEEDAP     | <i>Lactococcus lactis</i> NCIMB 30160  | Technological additive  | EFSA-Q-2016-00568                           |  | Yes                                 | No  |
| FIP/CEP         | <i>Leuconostoc citreum</i> (strain NRRL B-30894)   | Production of food enzyme   | EFSA-Q-2016-00209                           | The food enzyme is an alternansucrase  | Yes                                 | No  |
| FIP/CEP         | <i>Pseudomonas fluorescens</i> (BD15754)   | Production of food enzyme   | EFSA-Q-2016-00200                           | The food enzyme is an alpha-amylase by a GMM strain  | No                                  | Yes                                       |
| Feed/FEEDAP     | <i>Streptomyces albus</i>  | Production of coccidostat   | FAD-2016-0044                               |  | No                                  | No  |

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|--------------------------|--|---------------------------|---|--|-------------------------------------|---|
| FIP/CEP                  | <i>Streptomyces violaceoruber</i> (strain AS-10)         | Production of food enzyme | EFSA-Q-2016-00132                           | The food enzymes is a phospholipase A2 by a GMM strain                     | No                                  | No  |
| FIP/CEP                  | <i>Streptomyces violaceoruber</i> (pChi)                 | Production of food enzyme | EFSA-Q-2015-00621                           | The food enzyme is a chitinase by a GMM strain                             | No                                  | No  |
| FIP/CEP                  | <i>Streptomyces violaceoruber</i> (strain pCol)          | Production of food enzyme | EFSA-Q-2015-00826                           | The food enzyme is a microbial collagenase by a GMM strain                 | No                                  | No  |
| <b>Filamentous fungi</b> |  |                           |   |  |                                     |   |
| Feed/FEEDAP              | <i>Aspergillus niger</i> CBS 109.713                     | Production of feed enzyme | EFSA-Q-2016-00302                           | The feed enzyme is endo-1,4-beta-xylanase and endo-1,4-beta-glucanase      | No                                  | No  |
| FIP/CEP                  | <i>Aspergillus oryzae</i> (strain L729-48)               | Production of food enzyme | EFSA-Q-2016-00205                           | The food enzyme is an alpha-amylase  | No                                  | No  |
| FIP/CEP                  | <i>Aspergillus oryzae</i> (strains NBRC 110971 and 11-5) | Production of food enzyme | EFSA-Q-2016-00272                           | The food enzyme is a tannase   | No                                  | No  |
| FIP/CEP                  | <i>Aspergillus niger</i> (strain NZYM-KA)                | Production of food enzyme | EFSA-Q-2016-00134                           | The food enzyme is a glucose oxidase                                       | No                                  | No  |
| FIP/CEP                  | <i>Penicillium funiculosum</i> (DP-Lzc35)                | Production of food enzyme | EFSA-Q-2016-00098                           | The food enzyme is a cellulase   | No                                  | No  |
| FIP/CEP                  | <i>Rhizomucor miehei</i> (strain 29547)                  | Production of food enzyme | EFSA-Q-2015-00761                           | The food enzyme is a mucorpepsin   | No                                  | No  |
| FIP/CEP                  | <i>Trichoderma reesei</i> /DP-Dzh34                      | Production of food enzyme | EFSA-Q-2016-00097                           | The food enzyme is a glucan 1,4-alpha-glucosidase produced by a GMM strain | No                                  | No  |
| FIP/CEP                  | <i>Trichoderma reesei</i> /DP-Nzh49                      | Production of food enzyme | EFSA-Q-2016-00094                           | The food enzyme is a glucan 1,4-alpha-glucosidase produced by a GMM strain | No                                  | No  |
| <b>Yeasts</b>            |  |                           |   |  |                                     |   |
| Feed/FEEDAP              | <i>Pichia pastoris</i> (DSM 23036)                       | Production of feed enzyme | EFSA-Q-2016-00291                           | The feed anzyme is 6-phytase   | Yes                                 | No  |
| FIP/CEP                  | <i>Pichia pastoris</i> (PRF)                             | Production of food enzyme | EFSA-Q-2016-00201                           | The food enzyme is a phospholipase C by a GMM strain                       | Yes                                 | No  |
| Feed/FEEDAP              | <i>Saccharomyces cerevisiae</i>                          | Zotechnical additive      | EFSA-Q-2016-00292                           |  | Yes                                 | No  |
| Feed/FEEDAP              | <i>Saccharomyces cerevisiae</i>                          | Zotechnical additive      | EFSA-Q-2016-00297                           |  | Yes                                 | No  |
| Feed/FEEDAP              | <i>Saccharomyces cerevisiae</i>                          | Zotechnical additive      | EFSA-Q-2016-00298                           |  | Yes                                 | No  |
| Feed/FEEDAP              | <i>Saccharomyces cerevisiae</i> CNCM I-1079              | Zotechnical additive      | EFSA-Q-2016-00449                           |  | Yes                                 | No  |
| Feed/FEEDAP              | <i>Saccharomyces cerevisiae</i> CNCM I-3399              | Production of histidine   | EFSA-Q-2016-00346                           |  | Yes                                 | No  |
| Feed/FEEDAP              | <i>Schizosaccharomyces pombe</i>                         | Production of phytase     | EFSA-Q-2016-00559                           |  | Yes                                 | No  |

CEF: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; FEEDAP: EFSA Panel on Additives and products or Substances used in Animal Feed; FIP: EFSA Food ingredients and packaging Unit; GMM: genetically modified microorganism; NDA: EFSA Panel on Dietetic Products, Nutrition and Allergy; QPS: Qualified Presumption of Safety.

(a): Not present in the QPS list as published in the 2013 QPS update scientific opinion (version before the publication of this Panel statement).

(b): In the current statement.