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Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA*

EFSA Panel on Biological Hazards (BIOHAZ),

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Abstract

EFSA is requested to assess the safety of a broad range of biological agents in the context of notification for market authorisation as sources of food and feed additives, food 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. The list of QPS recommended biological agents was reviewed and updated in the current opinion and therefore becomes the valid list. The 2016 update reviews previously assessed microorganisms including bacteria, yeasts and viruses used for plant protection purposes following an Extensive Literature Search strategy. The taxonomic units related to the new notifications received since the 2013 QPS opinion, were periodically evaluated for a QPS status and the results published as Statements of the BIOHAZ Panel. *Carnobacterium divergens*, *Lactobacillus diolivorans*, *Microbacterium imperiale*, *Pasteuria nishizawae*, *Pediococcus parvulus*, *Bacillus flexus*, *Bacillus smithii*, *Xanthomonas campestris* and *Candida cylindracea* were recommended for the QPS list. All taxonomic units previously recommended for the 2013 QPS list had their status reconfirmed as well their qualifications with the exception of *Pasteuria nishizawae* for which the qualification was removed. The exclusion of filamentous fungi and enterococci from the QPS evaluations was reconsidered but monitoring will be maintained and the status will be re-evaluated in the next QPS Opinion update. Evaluation of bacteriophages should remain as a case-by-case procedure and should not be considered for QPS status.

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* The BIOHAZ Panel would like to dedicate this opinion to the memory of Günter Klein – see Obituary in the March 2017 issue of the EFSA Journal.

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Amendment: The name of one author has been corrected on page 1 and in the suggested citation paragraph; text under the additional information column has been added for *E. coli* rows on page 115. In Table A.1, p. 70, 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. These editorial corrections do not materially affect the contents or outcome of this scientific output; in Appendix A the paragraph text has been slightly re-edited; deletion of the text 'and no viable cells are found' in the Yeasts section. 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: Table A.1 in Appendix A was revised to correct an erroneous footnote on "*Paenibacillus lentus*" and to add a new footnote 'd' on *Lactobacillus animalis*; in Appendix E the reference to *Paenibacillus lentus* has been deleted on p. 98; text on *Paenibacillus lentus* under column Additional information on page 132 for EFSA-Q-2016-00181 has been revised. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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Summary

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food or feed. The request included three specific tasks as described 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 until 2013, it is now carried out every 3 years in a Scientific Opinion of the BIOHAZ Panel (December 2016). Meanwhile, that list of microorganisms has been maintained based on the evaluation of extensive literature reviews that will be updated regularly with new publications. When an assessment for a QPS recommendation 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, the respective evaluations for a QPS status have been compiled and published in Panel Statements every 6 months.

The first ToR requires 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 has been updated with the notifications received since May of 2013 until September of 2016. The notifications received within every 6-month period have been included in a table appended to each respective Panel Statement (five in total within this period). These new notifications were also included in Appendix E of this Opinion, compiling all microorganism notified to EFSA from the beginning of the QPS exercise in 2007. From the last notifications included in the previous QPS Opinion in 2013, 405 notifications were received between May 2013 and September 2016, of which, 137 were from Feed, 196 from FIP, 11 from Nutrition and 61 from Pesticides. For the type of microorganisms, 183 were bacteria, 177 filamentous fungi, 9 viruses and 36 yeasts TUs.

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 (AMR)) when new information has become 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 reflected in the current Scientific Opinion of the BIOHAZ Panel. The 2016 update reviews previously assessed microorganisms including bacteria, yeasts and viruses used for plant protection purposes following an Extensive Literature Search strategy. The list of QPS recommended biological agents was reviewed and updated in the current opinion, and therefore becomes the valid list. Information about AMR has been reviewed following recent recommendations from EFSA Opinions published in this topic.

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 taxonomic units related to the new notifications received since the 2013 QPS opinion, were periodically evaluated for a QPS status and the results published as Statements of the BIOHAZ Panel. They have also been included in this update so that all the information about QPS microorganisms is available in a single document. *Carnobacterium divergens*, *Lactobacillus diolivorans*, *Microbacterium imperiale*, *Pasteuria nishizawae*, *Pediococcus parvulus*, *Bacillus flexus*, *Bacillus smithii*, *Xanthomonas campestris* and *Candida cylindracea* were recommended for the QPS list. All taxonomic units previously recommended for the 2013 QPS list had their status reconfirmed as well their qualifications with the exception of *Pasteuria nishizawae* for which the qualification was removed.

The QPS concept as a pre-assessment approach for use within EFSA, that can be applied to the requests received for a safety assessment of microorganisms deliberately introduced into the food and feed chain, is discussed and refined in the light of the changes of the specific regulatory framework of the different areas covered by EFSA when dealing with those types of microorganisms. In that context, the recent experience while incorporating the QPS assessment into each specific EFSA's safety risk assessments area is described. The data and methodologies are further described, including the Extensive Literature Search approach, the verification of the identity of the main taxonomic units groups, the evaluation of the body of knowledge of the safety concerns and the possible influence of the end use of the microorganism. The workflow diagrams of the QPS process at different levels are presented.

All taxonomic units previously recommended for the 2013 QPS list had their status reconfirmed as well their qualifications with the exception of *Pasteuria nishizawae* for which the qualification was removed. The exclusion of filamentous fungi and enterococci from the QPS evaluations was reconsidered but monitoring will be maintained and the status will be re-evaluated in the next QPS Opinion update. Evaluation of bacteriophages should remain as a case-by-case procedure and should not be considered for QPS status.

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1. Introduction

1.1. Background and Terms of Reference 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. The European Food Safety Authority (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, food enzymes and plant protection products.

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),^{1,2} status, 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 continuing provision for reviewing and updating 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,³ 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.⁴ 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 QPS list includes 53 species of Gram-positive non-sporulating bacteria, 13 Gram-positive spore-forming bacteria (*Bacillus* species), 1 Gram-negative bacteria (*Gluconobacter oxydans*), 13 yeast species and 3 virus families. No QPS recommended species has been removed from the list following six (2008–2013 updates) 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 the 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 (TUs) notified to EFSA for inclusion in the QPS list would be tailored to the needs of the requesting EFSA Units and/or Scientific Panels.

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 Packing, 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.

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.

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

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

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

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

1.2. Interpretation of the Terms of Reference

1.2.1. Background to the QPS assessment approach

The QPS approach was developed by the Scientific Committee of EFSA to provide a generic concept to prioritise and to harmonise risk assessment of microorganisms intentionally introduced into the food chain, in support of the respective Scientific Panels and Units in the frame of market authorisations (EFSA, 2007; Leuschner et al., 2010). The list of QPS recommended biological agents, first established in 2007, has been updated annually until 2013. Taxonomic units (TUs) (usually species for bacteria and yeasts, families for viruses) were included in the QPS list either following notifications to EFSA or proposals made by stakeholders during a public consultation in 2005, even if they were not yet notified to EFSA (EFSA, 2005). Since then and currently, the QPS assessment is only triggered when a microorganism is notified to EFSA through an application for market authorisation of regulated products (such as feed additives, food ingredients as food enzymes, novel foods and plant protection products).⁵

The QPS concept was first formulated by a joint working group of a number of Scientific Advisory Committees of the European Commission and placed on the website of the European Commission – Health and Food Safety Directorate General (EC – DG SANCO) in 2003.⁶ This concept was then developed to serve within EFSA as a tool for assessing the safety of microorganisms introduced deliberately in the food chain, obviating the need of unnecessary testing. The approaches for assessing the safety of microorganisms entering the human food chain differ considerably depending on the legislation, if any, applicable. In the view of EFSA, QPS represents a route to harmonisation of risk assessment approaches within EFSA which allows additional safety concerns (e.g. transmissible antimicrobial resistance (AMR)) to be addressed. Moreover, QPS is a pragmatic approach to risk assessment that focuses on the hazards associated with a specific microbial species and could avoid redoing unnecessary testing for already demonstrated evidence data knowledge, and therefore could allow a better use of resources without compromising safety.

A wide variety of microorganisms are intentionally used at different stages in the food chain, either directly or as a source of food and feed additives, food enzymes or used as plant protection products. In the context of applications for market authorisation of these biological agents, EFSA is requested to assess their safety. In scientific publications, the QPS system has often been misinterpreted (Songisepp et al., 2012) as the European counterpart to the Generally Recognised As Safe (GRAS) system, established by the Food and Drug Administration (FDA) in the United States. There are certain important differences between the two systems. The GRAS guidelines apply to food additives in general, whereas QPS is dedicated to microorganisms only. GRAS also concerns a specific substance or organism, i.e. it is not applicable for a whole microbial TU like the QPS system. From the opposite perspective, QPS is not applicable to single products containing a specific microbial strain, but for a TU, usually species level for bacteria and yeasts, families for viruses. As an example, *Bifidobacterium longum* evaluation: in the GRAS system, approval would be granted for a specific strain like *B. longum* strain XYZ while in the QPS system it would be applicable to the whole *B. longum* species. If a TU does not get QPS status, it still can get the approval after full assessment at the strain level within the respective EFSA Panel/Unit. Further details can be found in Table 1.

Table 1: Differences between the GRAS guidelines (FDA, USA) and the QPS system (EFSA, EU) (amended from Wassenaar and Klein, 2008)

GRAS	QPS
Applies to food additives including microorganisms	Applies to microorganisms only
Performed after a specific GRAS notification to the FDA	Performed for microorganisms used as a source of/contained in products assessed for the EU market authorisation
Determination of a GRAS status by the FDA and/or external experts	Determination of a QPS status by EFSA
Open to all types of food additives	Restricted only to the microorganisms related to regulated food and feed products

⁵ See more information in <http://www.efsa.europa.eu/en/applications/regulatedproducts>

⁶ European Commission (2003). On a generic approach to the safety assessment of microorganisms used in feed/food and feed/food production. A working paper open for comment. Available online: http://europa.eu.int/comm/food/fs/sc/scf/out178_en.pdf

GRAS	QPS
Applicants request a GRAS status	EFSA requests evaluation of new taxonomic units within the scope of an internal mandate
Based on history of use, body of knowledge and the absence of adverse effects at the strain level	Based on history of use, body of knowledge and the absence of adverse effects at the TU level
Describes specific substance or microorganism at the strain level	Describes taxonomic unit (usually species level for bacteria and yeasts, families for viruses, not at strain level)
Case-by-case safety assessment at the strain level	General safety assessment at the TU level
Based on specific Guidance ^(a)	Support to the safety assessment required in the Founding EU Regulation ^(b)
Open tool to all applicants	Internal tool only under the frame of dossiers for authorisation of regulated products by EFSA

FDA: US Food and drug Administration; GRAS: Generally Recognised as Safe; QPS: Qualified Presumption of Safety;

TU: taxonomic unit.

(a): <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/>

(b): Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

QPS entered into the European Union (EU) law with the publication of a new Commission Implementing Regulation (EU) No 562/2012⁷ amending Commission Regulation (EU) No 234/2011⁸ 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 QPS status, according to the most recent list of QPS recommended biological agents adopted by the Authority (meaning EFSA), the food enzyme application could not need to provide specific toxicological test data. It should be noted that if residues, impurities, degradation products linked to the production and downstream process to obtain the food enzyme as defined in the legislation could give rise to concern, the Authority, pursuant to Article 6(1) of Regulation (EC) No 1331/2008⁹ may request additional data for risk assessment, including toxicological test data. Specifications and scientific data needed according to a case-by-case basis assessment are detailed in the 'Explanatory Note for the Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes'.¹⁰

1.2.2. New approach related to the present QPS mandate

In 2014, the BIOHAZ Panel decided to change the evaluation procedure: the publication of the overall assessment of the TUs previously recommended for the QPS list (EFSA BIOHAZ Panel, 2013) would be carried out after 3 years in a Scientific Opinion of the BIOHAZ Panel (the current opinion). In the meantime, that list of microorganisms would be maintained and frequently checked based on the evaluation of Extensive Literature Searches that would be regularly updated. Intermediate deliverables in the form of a Panel Statement would be produced and published, should an assessment for a QPS status of a microbiological agent notified to EFSA be requested by any other EFSA Unit, e.g. the Feed Unit, the Food Ingredients and Packaging (FIP) Unit, the Nutrition Unit or by the Pesticides Unit. Evaluations of these notifications are compiled in Panel Statements every 6 months. The conclusions of these Statements are included in this Scientific Opinion.

The Scientific Committee agreed to exclude some biological groups (filamentous fungi, bacteriophages and enterococci) notified to EFSA from the regular QPS assessment (66th plenary, 18–19 February 2014). The reason for this exclusion was that it was considered unlikely that any taxonomical units within these groups would be granted a QPS status in the foreseeable future. Thus,

⁷ Commission Implementing Regulation, 2012. 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.

⁸ Commission Regulation, 2011. 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.

⁹ Regulation, 2008. 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.

¹⁰ European Food Safety Authority, 2014; Explanatory Note for the Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes. EFSA supporting publication 2014:EN-689. 22 pp.

the assessment should be done at the strain level and therefore on a case-by-case basis, and should be done by the relevant EFSA Units.

EFSA asked the BIOHAZ Panel 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 ToRs.

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, FIP, Nutrition and Pesticides), for intentional use in feed and/or food or as sources of food and feed additives, food enzymes and plant protection products for safety assessment. The notifications considered for each Panel Statement (from December 2014 until December 2016) have been published in each respective appendix. The previous list (published with the QPS 2103 update Opinion) has been updated with the corresponding notifications received between May 2013 and September 2016 (see Appendix E).

The second ToR concerns the revision of the TUs previously recommended for the QPS list and their qualifications (especially the qualification regarding AMR) when new information has become available and to update the information provided in the previous opinion (EFSA BIOHAZ Panel, 2013) where appropriate. For TUs on the QPS list, this update of the literature aims at verifying if any new safety concern has arisen that could require the removal of the TU from the list, and to verify if the qualifications still efficiently exclude safety concerns. If such a situation would have happened before the publication of the current Opinion, a Panel Statement would have been published with the explanation of the reason that lead to the exclusion of a TU or the change in a qualification. At the same time, the QPS Opinion from 2013 would have been properly changed and an erratum included. The work being developed in order to reply to this ToR is reflected in the current Opinion.

The third ToR required a (re)assessment of the suitability of TUs notified to EFSA not present in the current QPS list for their inclusion in the updated list. The current Opinion takes into consideration the outcome from the several Panel Statements published from December 2014 where the evaluation of those TUs was included. The notifications received within that period and respective evaluation for a QPS status of the TU associated have been included in Appendix E together with the previous notifications and respective evaluations. The new recommendations for a QPS status have been included in the current QPS list (Appendix A).

1.3. Additional information

1.3.1. QPS: an assessment approach for use within EFSA

QPS as a concept provides a generic safety pre-assessment approach for use within EFSA that could be applied to all requests received by EFSA for the safety assessments of microorganisms deliberately introduced into the food and feed chain. The assessment covers risks for humans, animals and the environment. Its introduction harmonises and makes the risk assessment approach more transparent across the EFSA Scientific Panels and Units. It improves the consistency of assessments and makes better use of resources by focussing on those organisms that present the greatest risks or uncertainties (EFSA, 2005, 2009).

In the QPS concept, a safety assessment of a defined TU is considered independently of any particular specific notification in the course of an authorisation process, whenever possible. If the TU does not raise any safety concerns, or if existing safety concerns related to this TU can be clearly identified and excluded at a strain level (qualifications), a particular TU could be recommended for the QPS list. Subsequently, any specific representative of a QPS proposed TU, would not need to undergo a further safety assessment other than to satisfy any of the qualifications specified if applicable and if not required by a specific EU regulation framework. Representatives of TUs 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 submitted to the responsible EFSA Scientific Panel/Unit (EFSA, 2007).

The QPS concept does not address hazards linked to the formulation or other processing of the products containing the microbial agents and added into the food or feed chain. Although general human safety is part of the evaluation, specific issues connected to type and level of exposure of users handling the product (e.g. dermal, inhalation, ingestion) are not addressed. Assessment of potential allergenicity to microbial residual components is beyond the QPS remit; nevertheless, in cases where there is science-based evidence for allergenicity, it will be reported. These aspects are assessed, where applicable, separately by the EFSA Panel responsible for assessing the notification.

QPS is independent of the level of exposure. The latter is strictly related to the amount of microorganisms intentionally used in the food chain. Sometimes, a qualification 'for production purpose only' may apply to TUs used for the biosynthesis of specific products used in the food chain and under specific regulation. In this case, the QPS recommendation may only apply to this specific end use not including living organisms, e.g. certain enzymes, vitamins or amino acid production. This specific consideration of end use does not conflict with the generic applicability of QPS, because in this case the end use corresponds to different hazards (living organisms versus dead cells or their metabolites).

Concerning microorganisms evaluated for QPS status in previous Opinions, the continuously evolving body of knowledge possibly reveals new information that could lead to a modification of the list of QPS recommended TUs, for example to an ex- or inclusion of TUs on the list. Assessments of new TUs, not previously considered for the QPS list, and for which representatives are notified to EFSA are included. Microorganisms intended for usages outside the remit of EFSA, and those that have not been notified to EFSA, are not considered in this Opinion.

Acquired AMR was introduced as a possible safety concern for the assessment of the inclusion of bacterial species in the QPS list published in 2008 (EFSA, 2008). In the 2009 QPS Opinion (EFSA BIOHAZ Panel, 2009) a qualification regarding absence of antimycotic resistance for yeasts was introduced. These and other qualifications are reviewed and discussed in the present Opinion.

1.3.2. The QPS approach applied to each EFSA food and feed safety risk assessment area

The QPS approach has proved to be a useful tool to harmonise and prioritise safety assessment within EFSA. The QPS recommended list is used by EFSA's Panel on Additives and Products of Substances used in Animal Feed (FEEDAP), on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and on Dietetic Products, Nutrition and Allergies (NDA) and their respective current Units (Feed, FIP and Nutrition, respectively) as well as by the Pesticides Unit.

Feed additives safety assessment area

The EFSA Unit responsible for this area (Feed Unit) applies the QPS evaluation on the assessment of biological agents intended for use as feed additives or as a source of a feed additive, as defined in Regulation (EC) 1831/2003¹¹. When a biological agent is assessed for inclusion in the QPS list, the evaluation should cover the safety for the target animal species, the consumers of products derived from animals treated with the additives, and the environment. In the respective FEEDAP Opinions dealing with QPS recommended microorganisms, a standard sentence is included mentioning that the active agent in question is considered by EFSA to have a QPS status. Therefore, in such case, the FEEDAP Panel considers that no assessment of safety for the target species, consumer and the environment is required.

Following requests from applicants, the European Commission requested EFSA to provide an opinion on the implications of the deletion of the maximum dose applied to those authorised microbial products for which safety was assessed using the QPS approach and, more generally, to all microorganisms for which this approach is used. Since the QPS assessment has to take account of any reasonable use of the organism under consideration (sometimes restricted to certain types of application, e.g. enzyme production), and since QPS assessments are made independently of the dose, the FEEDAP Panel concluded that unless a specific provision relating to dose is included in the 'qualification' for a given TU, safety is presumed at any reasonable dose (EFSA FEEDAP Panel, 2012b).

Pesticides safety assessment area

The EFSA Unit responsible for this area (Pesticide Unit) organises the peer-review of microbial plant protection products that are submitted for approval under Regulation (EC) No 1107/2009¹². The data

¹¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.

¹² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–49.

requirements for the microorganisms (and the final product to be placed on the market) are described in the Regulations (EU) No 283/2013¹³ and 284/2013¹⁴. They request a clear identification at the strain level, information on their biological properties, on the production and uses, description of the analytical methods, investigations of effects on human health, data on residues in or on treated products, information on the fate and behaviour in the environment (persistence, multiplication and mobility in soil, water and air), and investigations of effects on non-target organisms (birds, aquatic organisms, bees, other arthropods, earthworms, soil microorganisms). Additionally, scientific peer-reviewed open literature published within the last 10 years before the date of submission of the dossier has to be provided, in accordance with the Guidance of EFSA.¹⁵

For the microbial pesticides approved under Regulation (EC) No 1107/2009, a period not exceeding 15 years is foreseen for the revision of the dossier including new information according to the regulatory framework. If new scientific or technical knowledge shows that the microbe no longer satisfies the approval criteria, a review of its approval can be triggered. This shows the usefulness of the QPS approach as a means of regularly updating the body of knowledge on taxonomic units of importance for EFSA Panels and Units.

In February 2016, it was agreed to improve the assessment of the QPS status and its applicability for the Pesticide Unit by taking into account the data provided to EFSA within the applicant's dossier (that is required to include an assessment of the scientific peer-reviewed open literature). This should bring additional experts' views on specific issues related to microorganisms being evaluated.

It is noted that, in the case of plant protection products, the QPS evaluation should be considered as addressing the safety evaluation of the risks for human consumers exposed to microorganism residues via diet. Non-dietary human exposure during or after the application of the plant protection product represents a set of situations not normally covered by the QPS assessment. In addition, environmental risk assessment as defined by the regulation cannot be considered to be always completely covered by the QPS assessment alone, since the deliberate release of organisms into agricultural or horticultural fields or protected cropping systems before harvest (s), triggers an assessment of risk for a variety of non-target organisms covering a wide range of taxonomic and functional groups. This assessment, contrary to that needed for food and feed additives, has to cover environmental distribution without prior digestion by farm animals or humans. There are specific regulatory data requirements that applicants must address and criteria for approval prescribed in Regulation (EC) No 1107/2009. These are not always covered by the QPS assessment process. Therefore, these non-dietary human risk and environmental risk assessments have to be systematically considered under the process prescribed in this Regulation.

Historically microbiological agents recommended for the QPS list and proposed as plant protection products under the Council Directive 91/414/EC (Official Journal, 1991)¹⁶ were often exempted from certain data requirements, such as oral toxicity data. As an example, the QPS recommendation of the Baculoviridae family was used during the peer review of several species of baculoviruses (EFSA, 2012a,b).

Food Ingredients and Packaging safety assessment area

The EFSA Unit responsible for this area (FIP Unit) applies the QPS evaluation of those specific microbial TUs used for the production of food enzymes in agreement with the QPS approach that entered EU law with the publication of a new Commission Implementing Regulation (EU) No 562/2012¹⁷ amending Commission Regulation (EU) No 234/2011¹⁸ 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

¹³ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009. OJ L 93, 3.4.2013, p. 1–84.

¹⁴ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009. OJ L 93, 3.4.2013, p. 1–84. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009. OJ L 93, 3.4.2013, p. 85–152.

¹⁵ EFSA, 2011: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092).

¹⁶ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC). OJ L 230, 19.8.1991, p. 1–32.

¹⁷ 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.

¹⁸ 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.

QPS status according to the most recent list of QPS recommended biological agents adopted by the Authority (meaning EFSA), the food enzyme application could not need to provide specific toxicological test data. If residues, impurities or degradation products linked to the total food enzyme production process (production, recovery and purification) could give rise to concern, the Authority, pursuant to Article 6(1) of Regulation (EC) No 1331/2008¹⁹ may request additional data for risk assessment, including toxicological data. In the same legislation frame, the QPS status will also have an important consideration on the risk assessment approach applied for enzyme products derived from genetically modified microorganisms developed from strain lineage species fulfilling the recommendations for QPS status.¹⁰

Nutrition safety assessment area

The tasks of the Panel on Dietetic Products, Nutrition and Allergies (NDA) include the safety assessment of novel foods (NF) that fall under Regulation (EU) 2015/2283²⁰. 'Novel Food' means 'any food that was not used for human consumption to a significant degree within the Union before 15 May 1997'. 'Food consisting of, isolated from or produced from microorganisms, fungi or algae' is among the categories of NF as defined by the Novel Food Regulation (EU) 2015/2283. In this case, the BIOHAZ Panel assesses whether the species would qualify for a QPS status, while the NDA Panel assesses the information provided in the novel food application on the specific strain (EFSA NDA Panel, 2016).

In the framework of Regulation (EC) No 1924/2006 on health claims made on foods (including microorganisms), the NDA Panel is also responsible for verifying the scientific substantiation (efficacy assessment) of submitted health claims. Under this framework, it should be noted that a safety assessment is not foreseen. Where relevant, the NDA Panel may recommend restrictions of use based on safety considerations.

In Table 2, the areas of assessment for the QPS approach are summarised and compared to general principles for each EFSA food and feed risk assessment area when microorganisms are considered. This table provides an overview of the principles followed for the assessment of each of the main four areas (feed, food ingredients, pesticides and nutrition). For details of the specific requirements for the safety risk assessment for each of these areas, please consult the specific EU regulations and/or guidance as described in the above specific areas under Section 1.3.2. This is not a stand-alone table and terminology used can vary between regulatory frameworks. An effort has been made to apply the same terms as much as possible in order to improve clarity in the content of the table and to identify areas that can be considered to be generally equivalent. Where specificities could not be covered in general terms, this is reflected in the text chosen. Some of the areas are not covered by the relevant regulation or guidance and are also described in the following table.

¹⁹ 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.

²⁰ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1–22.

Table 2: Table summarising the areas of assessment for the QPS approach and for each EFSA food and feed safety risk assessment area when microorganisms are considered

QPS assessment remit	Feed area assessment remit ^(a)	Food Ingredients area assessment remit ^(b)	Pesticides area assessment remit ^(c)	Nutrition area assessment remit ^(d)
1. Identity: taxonomy identification parameters	Verification of species and strain Certificate of deposit in a culture collection	Verification of species and strain Certificate of deposit in a culture collection	Verification of species and strain Certificate of deposit in a culture collection	Verification of species and strain Certificate of deposit in a culture collection <i>(for Health Claims and Novel Foods (NF))</i>
2.1. Body of Knowledge: history of safe use in the food and feed chain	Other authorisations and uses Description of the genetic modifications Confirm genetic stability	Other authorisations of the same strain lineage Description of the genetic modifications Confirm genetic stability	Proposed uses Historical background Organisms genetically modified should comply to the GMO Regulation Confirm genetic stability	History of safe use <i>(for NF)</i>
2.2 Body of Knowledge: general ecology/distribution in ecosystems	Origin to be declared Production of antimicrobial compounds	 Production of antimicrobial compounds	Origin (geographical and place in the ecosystem) and natural occurrence (if possible at strain level) Ability to colonise available niches Production of antimicrobial compounds	Out of the scope of the specific Regulation
3.1. Safety concerns: virulence/pathogenicity/toxigenicity for humans	Pathogenicity potential and virulence factors Production of toxins and toxic secondary metabolites	Pathogenicity potential and virulence factors Production of toxins and toxic secondary metabolites	Pathogenicity potential and virulence factors Possible toxicity of secondary metabolites	Pathogenicity potential and virulence factors <i>(for NF)</i>
3.2. Safety concerns: virulence/pathogenicity/toxigenicity for animals (domestic and wild)	Pathogenicity potential and virulence factors Production of toxins and toxic secondary metabolites	Out of the scope of the specific Regulation	Adverse effects of organism or metabolites on non-target animals (in the environment)	Out of the scope of the specific Regulation

QPS assessment remit	Feed area assessment remit ^(a)	Food Ingredients area assessment remit ^(b)	Pesticides area assessment remit ^(c)	Nutrition area assessment remit ^(d)
3.3. Safety concerns: virulence/pathogenicity for plants	Out of the scope of the specific Regulation	Out of the scope of the specific Regulation	Adverse effects of organism or metabolites on non-target vascular plants and algae (in the environment)	Out of the scope of the specific Regulation
3.4. Safety concerns: antimicrobial resistance	Verification of the absence of antimicrobial resistance associated with acquired genes	Verification the of absence of antimicrobial resistance associated with acquired genes	Verification of the absence of antimicrobial resistance and of possible transfer of genes coding for resistance	Verification of the absence of antimicrobial resistance associated with acquired genes (for NF)
3.5. Safety concerns: environmental safety	Genetically modified microorganisms (GMMs): deliberate release GMMs: the absence of viable cells GMMs: the absence of recombinant DNA Effect on water and soil	Not direct applicable within Food Enzymes legislation: Microorganisms used for production purposes, including GMMs: the absence of viable cells GMMs: the absence of recombinant DNA	Risk for non-target organisms (which are not vertebrate animals or plants), arising from exposure to the microorganism and its secondary metabolites remaining in or on plants or plant products, in soil water and air	Out of the scope of the specific Regulation
4.1. End use: intended exposure to viable cells of animals and consumers	Tolerance studies in target animals Toxicological studies <i>in vitro</i> and in laboratory animals	Not direct applicable within Food Enzymes legislation: Microorganisms used for production purposes, including GMMs: the absence of viable cells GMMs: the absence of recombinant DNA	End use is intended exposure of a target organism, i.e. organisms that are: 1) pathogenic to or damage/consume plants or plant commodities; or 2) unwanted plants (weeds). Efficacy investigations are required for these purposes	Intended exposure of viable cells to consumers (for NF)

QPS assessment remit	Feed area assessment remit ^(a)	Food Ingredients area assessment remit ^(b)	Pesticides area assessment remit ^(c)	Nutrition area assessment remit ^(d)
4.2. End use: enzymes/ metabolites producer: no or limited exposure to viable cells	Microorganisms used for production purposes, including GMMs: absence of viable cells GMMs: absence of recombinant DNA Tolerance studies in target animals Toxicological studies <i>in vitro</i> and in laboratory animals	Microorganisms used for production purposes, including GMMs: absence of viable cells GMMs: absence of recombinant DNA	When there are no viable cells in a plant protection product then it is regulated as a chemical (not a microorganism) even if it was produced by microbial fermentation	(for NF)

GMM: genetically modified microorganisms; NF: novel food.

(a): Based on the specific Feed Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008.

(b): Based on the specific FIP/GMMs Regulation: absence of recombinant DNA (under Reg. 1829/2003).

(c): Based on the specific Pesticides Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

(d): Based on the specific Health Claims Regulation (EU) No 1924/2006 and Novel foods Regulation (EU) 2015/2283.

1.3.3. Summary of the BIOHAZ Panel Statements adopted between December 2013 and December 2016

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. From the last notifications received for the previous QPS Opinion in 2013, 405 notifications were received between May 2013 and September 2016, of which, 137 were from Feed, 196 from FIP, 11 from Nutrition and 61 from Pesticides (see Table 3).

In response to ToR3, from those 405 notifications, 153 biological agents already had a QPS status and were not further evaluated, neither were the 188 filamentous fungi and enterococci, biological groups which have been excluded from QPS consideration (following a recommendation of the QPS 2013 update (EFSA BIOHAZ Panel, 2013)). Another 28 were not included because the corresponding TUs have already been evaluated in the previous Statements during this period. Furthermore, it was agreed not to include nine notifications from Pesticides Unit as the respective dossiers (including the literature review) were not yet received (evaluation in standby). For the type of microorganism, 183 were bacteria, 177 filamentous fungi, 9 viruses and 36 yeasts TUs. The remaining 41 biological agents were assessed for the suitability of the respective TUs for inclusion in the QPS list. The assessment of the respective TUs was published in five Panel Statements, adopted every 6 months, from December 2014 until December 2016 (see Table 3).

Table 3: Notifications received by EFSA Units (Feed, FIP, Nutrition and Pesticides) by biological group from May 2013 until September 2016 (total numbers for the five Panel Statements)

Unit/Panel	Not QPS				Already QPS	Grand Total
Biological group	Not evaluated			Evaluated		
	Excluded in QPS 2013 update	Previously evaluated	Evaluation in stand by			
Feed/FEEDAP	34	15	0	21	67	137
Bacteria	5	15	0	21	46	87
Filamentous fungi	29	0	0	0	0	29
Yeasts	0	0	0	0	21	21
FIP/CEF	125	10	0	16	59	196
Bacteria	0	10	0	14	48	68
Filamentous fungi	125	0	0	0	1	119
Yeasts	0	0	0	2	10	9
Nutrition/NDA	0	0	0	1	10	11
Bacteria	0	0	0	1	8	9
Yeasts	0	0	0	0	2	2
Pesticides	29	3	9	3	17	61
Bacteria	0	3	6	3	7	19
Filamentous fungi	29	0	0	0	0	29
Viruses	0	0	0	0	9	9
Yeasts	0	0	3	0	1	4
Grand Total	188	28	9	41	153	405

2. Data and methodologies

2.1. Data

For the TUs associated with the notifications compiled within the time period covered by the mandate (May 2013–September 2016) and assessed for a possible QPS status within the Panel Statements adopted during this period (every six months between December 2014 and December 2016), the literature review considered the identity, the body of knowledge, history of use, and the potential safety concerns found (including AMR). Relevant databases, such as PubMed, Web of Science, CasesDatabase, CAB Abstracts or Food Science Technology Abstracts (FSTA) and Scopus, were searched and details on the search strategy, search keys and approach followed are described in each Panel Statement.

For the review of the recommendations for the QPS list (as published in 2013) and specific qualifications, an Extensive Literature Search (ELS) was run as described in Section 2.2.1 and in Appendices B and C.

2.2. Methodologies

The QPS assessment is generic regarding a notified TU intended to be intentionally added into the food chain at any stage. The QPS concept applies to microorganisms either used as viable cells in the food chain, or to produce enzymes, metabolites (e.g. amino acids), dead biomass or other specific end products that are not expected to contain live microbial cells. In this last condition, the QPS recommendation may apply only to the specific end use, e.g. enzyme production. A QPS assessment is triggered by receipt of an application dossier by EFSA that requires a safety assessment. It is intended to be independent of the specific application dossier that remains the responsibility of the EFSA Scientific Unit or Panel to which the risk assessment is mandated.

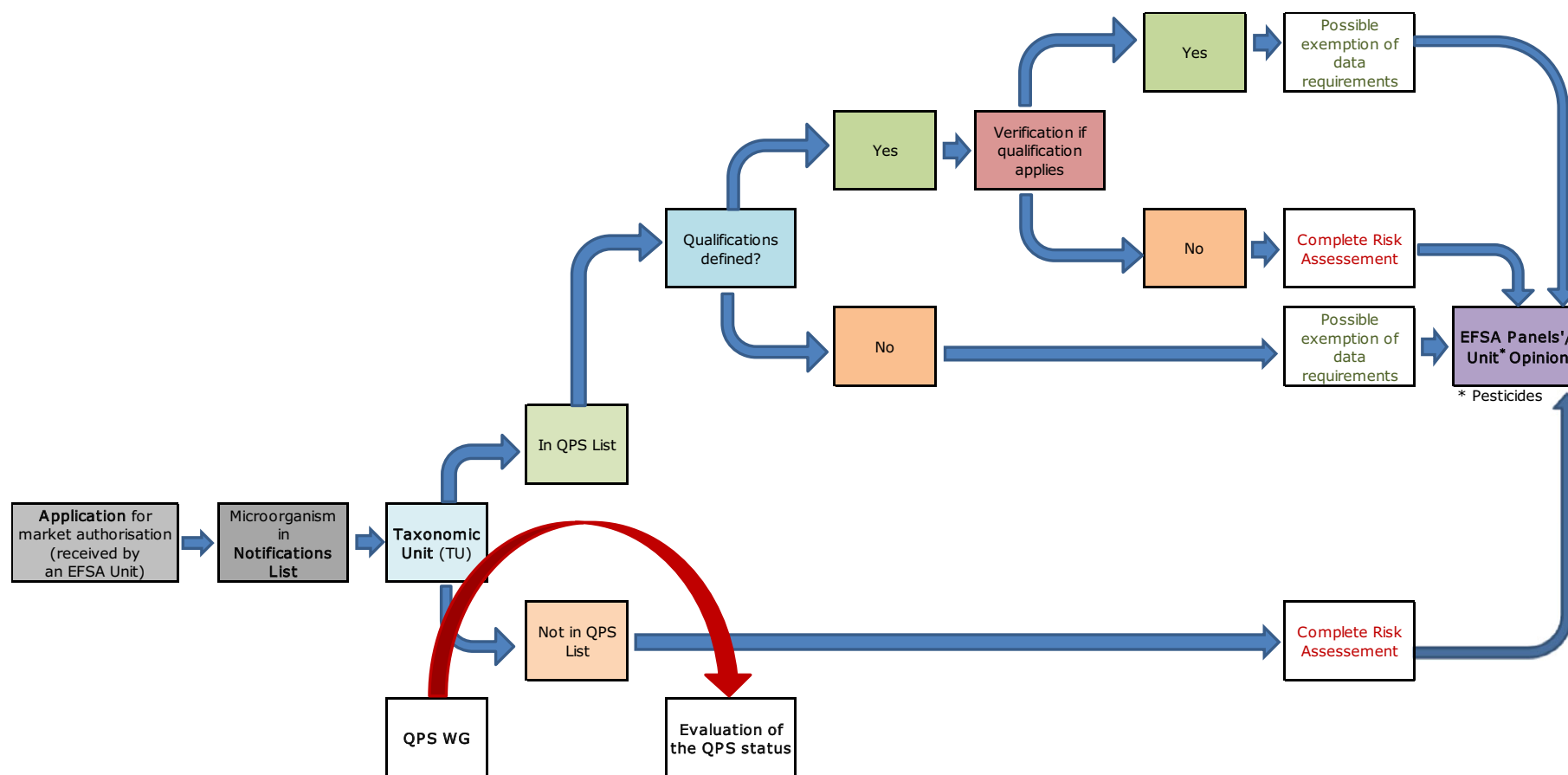
In order to illustrate how the QPS list is used or its approach considered by the four EFSA Units or by the QPS Working Group (WG), three flow charts have been prepared and included below.

The first one (Figure 1), represents how in general, EFSA Units incorporate the QPS status of a certain TU, related to a microorganism notified in an application, into their own evaluation process (risk assessment). After receiving a notification of a microorganism or their products in a new application, the relevant information is included in the 'notifications list'. EFSA screens the respective TUs and chooses which ones are to be included in the ongoing Panel Statement to be considered for the QPS list (Figure 2). The EFSA Unit initially checks if the TU is in the QPS list and if foreseen in the respective regulatory framework, applicants may be exempt from a certain part of the data requirements and the risk assessment process may be simplified. Possible qualifications of QPS microorganisms need to be evaluated by the EFSA Unit with the information provided in the respective dossier. Only when the qualification applies, the data requirements exemption can be effective. The specific risk assessment is included in the EFSA Unit's Opinion and reference to the QPS status of the TU notified and eventual qualifications are included in that Opinion. For TUs initially not included in the QPS list, but for which a new recommendation for that list is provided from the process described in Figure 2, the inclusion in the list may still be considered for the risk assessment process of that specific EFSA Unit.

The second flow chart (Figure 2) represents how the evaluation of newly notified TUs, not found in the QPS list, is included in each BIOHAZ Panel Statement. EFSA screens the new TU included by the EFSA Units in the 'notification list' (Figure 1), checks the respective TU and chooses which are to be included in the ongoing Panel Statement to be considered for the QPS list. As explained in the background of the mandate (Section 1.1), filamentous fungi, bacteriophages or enterococci are excluded from the QPS evaluation. If the TU has already been evaluated in one of the previous Panel Statements (from December 2014), the TU is also excluded from being re-evaluated. If a new QPS recommendation is given (and possible qualifications), the QPS list is updated. Every 6 months a new Panel Statement is published incorporating the TUs included in the 'notification list' from the last ones considered in the previously published Panel Statement. All respective notifications are included in appendix of each Panel Statement. If the TU is already in the QPS list, it is not evaluated at this stage but considered for the process represented in Figure 3.

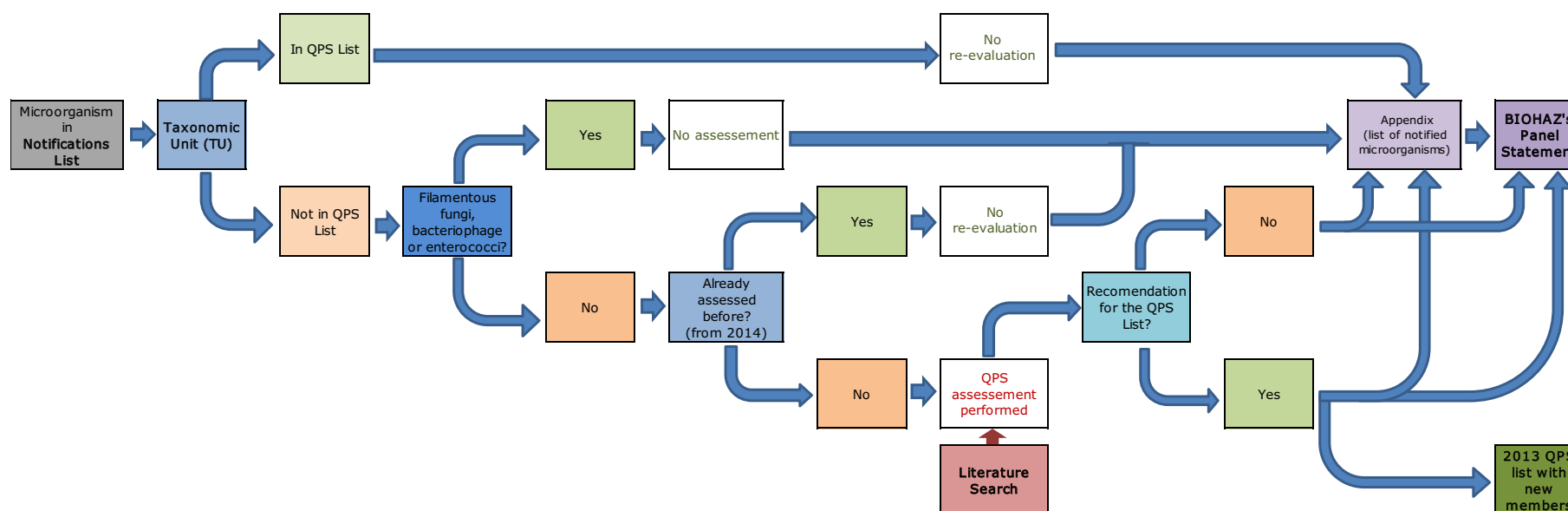
The third flow chart (Figure 3) represents how the evaluation of the TUs included in QPS list (reference to 2013 update Opinion) is performed. According to the ongoing mandate (Section 1.1), the process needs to be run and finalised every 3 years. All TUs are evaluated for possible new safety concerns that could result in excluding them from the QPS list or changing or including a possible qualification. This is done through an ELS as explained in Section 2.2.1. Any change in the QPS status or qualifications needs to be reflected in the QPS list, published in appendix to the Opinion and to each Panel Statement: if it occurs before December of 2016, the change is accomplished and the table amended within the 2013 QPS Opinion. In the current Opinion, the QPS list reflects the ELS exercise run during this period (January 2013–May 2016).

This approach to safety assessment of a defined TU (e.g. genus or, most often, species) is based on four pillars: establishing identity, body of knowledge, safety concerns (including AMR) and end use. If the TU does not raise safety concerns or, if safety concerns exist, but can be defined and excluded (the qualification), the TU can be granted QPS status. Thereafter, any strain of a microorganism, the identity of which can be unambiguously established and assigned to a QPS group, may be exempted from the need for further safety assessment, other than satisfying any qualifications specified. Microorganisms not considered suitable for QPS remain subject to a full safety assessment.



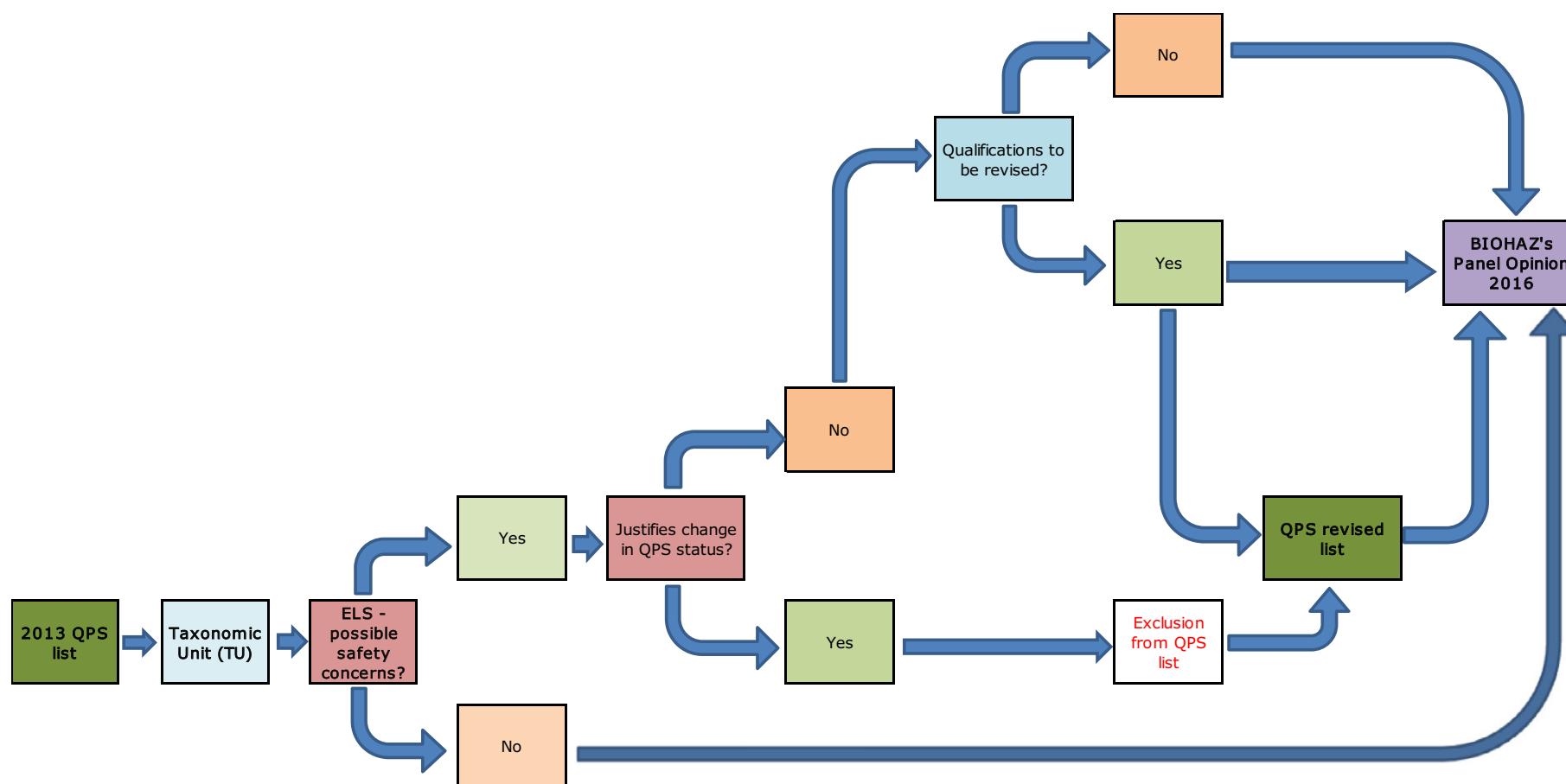
QPS: Qualified Presumption of Safety.

Figure 1: Workflow diagram describing how EFSA Units incorporate the QPS status into the safety assessment process of a microorganism notified through an application for market authorisation – overall process



BIOHAZ: Biological Hazards Panel; QPS: Qualified Presumption of Safety.

Figure 2: Workflow diagram describing how QPS status is assessed for the TU related to the microorganism notified to the EFSA Units under the frame of applications for market authorisation – elaboration of the BIOHAZ QPS Panel Statements



BIOHAZ: Biological Hazards Panel; QPS: Qualified Presumption of Safety.

Figure 3: Workflow diagram describing how QPS status is reassessed for the TU included in the latest QPS list – elaboration of the BIOHAZ QPS Opinion

2.2.1. Review of the scientific literature

An Extensive Literature Search (ELS) with relevance screening and evaluation of studies related to safety concerns for humans, animals and/or the environment, of microorganisms recommended for the QPS 2013 list was performed.

The aim was to identify any publicly available studies reporting on safety concerns for humans, animals or the environment caused by Gram-positive non-sporulating bacteria, Gram-positive sporulating bacteria, Gram-negative bacteria, viruses used for plant protection purposes and yeasts (as identified by EFSA in the ToR and Table 1 of the 2013 Scientific Opinion) since the previous QPS review (i.e. publications from January 2013 until 6 June of 2016). The results of the ELS were part of ToR 2 of the self-task mandate and were intended to inform this Scientific Opinion.

A short description of the methodology adopted is provided below, for a detailed protocol of the process – please refer to Annexes B and C. The process was performed according to the following main steps:

- ELS for potentially relevant citations;
- relevance screening to select the citations identified by the literature search, based on titles and abstract and then on full text;
- evaluation of articles according to pre-specified categories of possible safety concerns relevant to the QPS assessment.

Considering the purpose of the QPS approach, the research questions were broad in scope. The review questions were broken down into key elements using the PECO conceptual model:

- 1) Population of interest (P)
- 2) Exposure of interest (E)
- 3) Comparator (C)
- 4) Outcomes of interest (O)

The following review questions were identified:

Question 1

- Is there evidence of any safety concerns, including virulence features and toxin production, for humans, animals and/or the environment associated with microbial species currently recommended for the QPS list since the previous QPS review (i.e. published since 2013 until 6 June 2016)?

The related PECO elements are specified here below:

Population	Humans, animals and the environment
Exposure	Microbial species currently recommended for the QPS list since the previous QPS review
Comparator	Since it was expected that the prevalent study designs on this topic would lack a comparator, the latter was not included as a key element in the review question
Outcome	Any safety concerns, including virulence features and toxin production

Question 2

- Is there any evidence related to the presence or absence of antimicrobial resistance (AMR) or AMR genes for the same microbial species published during the same time period?

The related PECO elements are specified here below:

Population	Humans, animals and the environment
Exposure	Microbial species currently recommended for the QPS list since the previous QPS review
Comparator	Since it was expected that the prevalent study designs on this topic would lack a comparator, the latter was not included as a key element in the review question
Outcome	The presence or absence of AMR or AMR genes

The following outcomes of interest were identified:

Question 1	• potential harms • safety issues • virulence or infectious characteristics • intoxication
Question 2	• (acquired/intrinsic) AMR, covering phenotypic and genotypic aspects

Population, Exposure and Outcome of interest were used as eligibility criteria to select the citations identified by the literature search. In addition to them, other eligibility criteria were defined:

Language	English
Period	From January 2013 until 6 June 2016
Publication type	Primary research studies (i.e. studies generating new data)

The following bibliographic sources were searched:

Information source	Interface
Web of Science Core Collection	Web of Science, Thomson Reuters 2016
CAB Abstracts	Web of Science, Thomson Reuters 2016
BIOSIS Citation Index	Web of Science, Thomson Reuters 2016
MEDLINE	Web of Science, Thomson Reuters 2016
Food Science Technology Abstracts (FSTA)	Web of Science, Thomson Reuters 2016

It was decided to limit the search to the above-mentioned bibliographic databases, without extending to the grey literature.

The search strategy used to identify relevant studies comprised two key elements, (i) a set of strings aimed at capturing articles related to the target microbiological species (Exposure); (ii) a set of strings aimed at capturing articles related to outcomes of interest (Outcome).

A total of 16,927 records were found by the search strategy that, after duplicate removal, led to the identification of 16,025 articles. Title screening led to the exclusion of 15,040 articles. Of the 985 articles eligible for Article evaluation, 765 were found not to meet the eligibility criteria and 220 were finally evaluated at full text level.

Table 4: Flow of records by search strategy

No	Search strategy	No records identified	No duplicate records removed	No record screened	No full text article evaluated	No of articles considered relevant for QPS
Gram-positive non-sporulating bacteria						
1	<i>Bifidobacterium</i>	939	60	879	70	6
2	<i>Corynebacterium glutamicum</i>	195	7	188	33	2
3	<i>Lactobacilli</i>	2,432	171	2,261	105	21
4	<i>Lactococcus lactis</i>	881	46	835	39	17
5	<i>Leuconostoc</i>	160	21	139	26	9
6	<i>Oenococcus</i>	297	41	256	2	0
7	<i>pediococci</i>	815	125	690	11	2
8	<i>Propionibacterium</i>	228	25	203	12	0
9	<i>Streptococcus thermophilus</i>	352	17	335	12	0
Gram-positive sporulating bacteria						
10	<i>Bacillus</i>	4,176	85	4,091	264	40
Gram-negative bacteria						
11	<i>Gluconobacter oxydans</i>	199	19	180	8	0
Yeasts						
12	<i>Debaryomyces hansenii</i> ...	1,428	141	1,287	175	69
13	<i>Kluyveromyces lactis</i> ...	1,632	62	1,570	89	14
14	<i>Saccharomyces cerevisiae</i>	2,493	72	2,421	117	27

No	Search strategy	No records identified	No duplicate records removed	No record screened	No full text article evaluated	No of articles considered relevant for QPS
Viruses used for plant protection						
15	Baculoviridae	496	4	492	13	7
16	Alphaflexiviridae...	204	6	198	9	6
	TOTAL	16,927	902	16,025	985	220

The flow of records from their identification by the different search strategies (as reported in Appendix C) until their consideration as QPS potentially relevant papers is shown in Table 4 above.

The articles were evaluated according to the following categories of possible safety concerns:

- impact on human health;
- impact on animal health;
- impact on the environment;
- antimicrobial resistance;
- other not pre-specified concerns.

The overall results were presented in tabular format for each group/subgroup and species.

2.2.2. Identity

Information about the systematics (classification, identification and nomenclature) of the notified TU is considered in this section, including a general description of the TU. Attention is given to the inclusion of the TU name in the Official lists stemming from Taxonomy Commissions (for bacteria, yeasts and viruses) and to the use of appropriate methodologies for identification according to standardised molecular, phenotypic and chemotaxonomical methods. The occurrence of changes in the taxonomy or the use of synonyms in the taxonomical description is also highly relevant. Possible misidentifications and lack of precision within closely related taxa assignments (due to the use of phenotypic tests, etc.) are also taken into account.

In the context of a notification received by EFSA for a safety assessment, the QPS assessment is usually carried out considering taxonomic aspects, body of knowledge and safety concerns of the species (for bacteria and yeasts) or families (for virus) to which it belongs, which is referred to as the lowest taxonomic level for which QPS status can be granted (Bourdichon et al., 2012; EFSA BIOHAZ Panel, 2012).

Bacterial taxonomy

Taxonomy and nomenclature of bacteria are covered by the International Code of Nomenclature of Bacteria (1992). New TU or alteration to the taxonomy and nomenclature are published in the International Journal of Systematic and Evolutionary Microbiology (IJSEM) (Oren and Garrity, 2016). This journal publishes a Notification List, containing all 'validly published' TU, i.e. the Approved List of Bacterial Names. Validly published are all taxonomic units, which are published in the IJSEM. TUs that were published outside the IJSEM are referred to as 'effectively' published. They appear after notification by the authors in a Validation List. Also changes in nomenclature are listed separately. These can be spelling errors in the original description or decisions of the Judicial Commission. Moreover, a comprehensive tool and up-to-date presentation of the current taxonomy and nomenclature of bacteria is given on the LPSN website (List of Prokaryotic names with Standing in Nomenclature, formerly List of Bacterial names with Standing in Nomenclature (LBSN)) (Euzéby, 2013).

Fungal taxonomy

The nomenclature and taxonomy of fungi, including yeasts, is covered by the International Code of Nomenclature for algae, fungi, and plants (ICN) (McNeill et al., 2012). An authoritative taxonomy of yeasts was published in 2011 (Kurtzman et al., 2011). It is still valid, although proposals for taxonomical revisions are now appearing.

The introduction of the one-name system for pleomorphic fungi is ongoing and will undoubtedly have a strong impact on yeast nomenclature. In those cases where separate names are established and in use for both forms, the likely outcome is that one of them will eventually be given priority. The International Commission on the Taxonomy of Fungi (ICTF, 2014) has a special working group for yeasts and it is anticipated that lists of new and prioritised names will appear in the coming years. The ICN recently suggested that the perfect form (teleomorph form) is the name that should have priority.

Virus taxonomy

The taxonomy and nomenclature of viruses are the responsibility of the International Committee on Taxonomy of Viruses. Every 5–6 years a full report is made available, the most recent one, the 9th Report, is from 2012 (King et al., 2012). Annual updates are made based on proposals of study groups after adoption by the Executive Committee and are available through the ICTV website.²¹ The most recent update is from 2015.

Virus taxonomy is based on shared characteristics such as (i) the type of nucleic acid (RNA or DNA), (ii) the structure of the nucleic acid (single-stranded or double-stranded RNA or DNA), (iii) the polarity of the nucleic acid (positive stranded = translatable into proteins; negative stranded = non-translatable into proteins) and (iv) the form of the virus (isometric, rod-shaped, filamentous or pleomorphic). In addition to these characteristics, the replication strategy (v) of the viruses is also taken into account and could contribute to their taxonomic position (Baltimore, 1971, 1974). Viruses are organised in orders (-*virales*), families (-*viridae*), genera (-*virus*) and species (-*virus*) by virtue of shared characteristics as described above. The species is the lowest taxon considered by the ICTV. Many viruses do not have a common ancestor; therefore phylogenetic information is only useful within taxons in directing the taxonomy of viruses. The current status of e-viruses (computationally generated from next generation sequencing endeavours) is being discussed within the ICTV.

Plant virus taxonomy

Plant viruses cause diseases in plants and (sometimes) insects. Many of these viruses are transmitted via direct contact or by vectors (insects, nematodes, fungi). The large majority (> 90%) of plant viruses contain positive stranded (= directly translatable) RNA as genetic information. About 1,000 plant virus species have been recognised by the ICTV and they have been accommodated into two orders and 20 families (King et al., 2012).

Relevant for this report (notifications) are the Alphaflexiviridae (Order Tymovirales) accommodating seven genera encompassing 49 species in total, including the genus *Potexvirus* containing the species *Pepino mosaic virus*, and Potyviridae, encompassing eight genera, including the genus *Potyvirus* with 162 species including *Zucchini mosaic virus*.

Baculovirus taxonomy

Baculoviruses are large DNA viruses occurring in members of the insect orders Lepidoptera (moths and butterflies), Hymenoptera (sawflies) and Diptera (flies). The family Baculoviridae is subdivided into four genera, *Alphabaculovirus*, *Betabaculovirus*, *Gammabaculovirus* and *Deltabaculovirus* (Jehle et al., 2006). Fifty-five baculovirus species have been officially recognised as species (King et al., 2012). About 700 further baculovirus isolates have been described in literature, but not yet biologically and genetically fully analysed and therefore not accepted as species by the ICTV. Baculoviruses, unlike many other virus groups, have a common ancestor assisting in the assignment of the taxonomic status of any baculovirus.

2.2.3. Body of knowledge

The body of knowledge concerning a defined TU is assessed to determine whether there is sufficient information to reach a conclusion regarding its safety. The body of knowledge includes the history of use (Constable et al. 2007; Pariza et al., 2015) and ecology of a TU in the agro-food chain or in other sectors, the scientific literature, clinical aspects, industrial applications, and other factors as considered appropriate.

History of use in the food and feed chain

The history of use of a specific microbial species in the food chain is taken into consideration. In particular, information on the direct use of viable cells (e.g. as feed additives, food starter cultures,

²¹ www.ictvonline.org/virus.taxonomy.asp

microorganisms as food with a health claim or plant protection products) or the use for production purposes (e.g. production of amino acids, enzymes, vitamins and polysaccharides) is examined to evaluate the history of human and animal exposure to the TU under assessment.

General ecology/distribution in ecosystems

The assessment of safety for the environment of a TU proposed for the QPS list takes into account the distribution in natural environments (e.g. in the gut of wild and farmed animals, and plants association), Information about the natural habitats of the organism and the types of samples from which it can usually be isolated is considered. Likewise, information on the geographical distribution range (e.g. does the species occur worldwide?) is valuable. It is also of interest whether the species can occur as a commensal or an endophyte. Spread and prevalence in natural environments and the survival and longevity in the food chain are considered. Properties related to colonisation ability and routes for dispersal are considered. Knowledge about its interactions with other microorganisms, especially with respect to antagonism and competitive ability, is also relevant.

2.2.4. Safety concerns

Safety concerns were investigated in the course of the first assessment of a TU proposed for the QPS list, and are regularly verified for the QPS TUs. In this Opinion, only scientific information that can be cited in a transparent manner and includes a scientifically valid description of the methodologies and the results obtained is considered (i.e. the methods used are suitable for the TU and the evaluation and can be relied on).

Virulence/pathogenicity to humans

TUs assessed for the QPS list should not represent a hazard to human health when used in the food or feed chain. Relevant information includes case reports of human diseases, particularly infections or human intoxications linked to the TU under assessment. Additional important information is whether the negative impacts affected patients with severe underlying diseases, and whether transmission occurred through food or other routes (e.g. medical devices). Studies indicating the presence of virulence factors (e.g. toxins and enzymes that may contribute to the pathogenicity of the microorganism) in the TU are also relevant for identification of potential safety concerns.

Assessment of allergenicity to microbial residual components is beyond the QPS assessment remit; nevertheless, if there is science-based evidence for some microbial species related to well-defined clinical cases, this may be reported.

Virulence/pathogenicity to vertebrate animals (domesticated and wild)

Reports of infection, intoxication or other diseases caused by the assessed TU on domesticated and wild animals are also a relevant set of information for identifying potential safety concerns. As with safety concerns for humans, whether diseases occur through feed or other routes (e.g. wounds, inhalation) is also relevant information. Whenever the TU has been studied as a probiotic in animals, publications reporting failure of the probiotic to, for example, promote growth of farmed animals are not considered as indicators of a safety concern.

Antimicrobial resistance

The scope of the review is to provide general background information on AMR issues concerning the TU under assessment. In particular, a generic qualification for all bacterial TUs on the QPS recommended list is that strains should not harbour any acquired gene conferring resistance to clinically relevant antimicrobials, in order to exclude the presence of potentially transferable AMR. The ability to produce antimicrobials is also relevant because these antimicrobials could select for resistance in bacterial populations. Especially important is the ability to produce antimicrobials which are used in human and veterinary practice or which are inactivated by genes conferring cross-resistance to those. Moreover, microorganisms producing antimicrobials carry genes that confer resistance to their own compounds, which might be transferred to other bacteria and further disseminated.

In the case of yeasts, transferability of AMR determinants is not an issue, but a QPS TU should not be resistant to antimycotic compounds used in human medicine.

In this review, the bacterial TUs recommended for the 2013 QPS list were revised with regard to their potential to produce antimicrobials, and the presence of transferable or transmissible AMR genes. The fungal TUs were revised for their potential to produce antimicrobials and for resistance to antimycotic compounds.

Environmental safety

For plant protection products, as mentioned above, the QPS considerations of environmental safety do not cover all aspects of the regulatory data requirements.

The assessment of environmental safety considers information on, e.g. the capability of the species to survive, compete and proliferate in specific environments, the possibility that it may cause adverse health or environmental effects not connected to pathogenicity and infectivity to vertebrate animals and plants, and the possibility for transfer and expression of the microbial DNA in other organisms.

So far, safety of plants has not been systematically considered in the QPS assessment. In the QPS Statements and in the 2016 QPS Opinion, it was decided to consider infections and other diseases caused to plants in the QPS assessment and updates, should they appear in the literature searches.

2.2.5. End use

For a TU, the body of knowledge and the safety concerns may differ for the living organisms and for the dead biomass or specific compounds produced (e.g. long history of use for enzymes or amino acids production for food/feed purposes). For the majority of the TUs, the QPS approach assesses the deliberate introduction of viable microorganisms capable of multiplication in the food chains, with consequent exposure of humans and/or animals. The second circumstance does not involve a significant number of live microbial cells and only the products derived from microbial metabolism, such as cell extracts, enzyme preparations and amino acids are considered. In this latter case, the QPS recommendation may only apply to this specific end use not including living organisms, which is indicated as a qualification in the QPS list. This specific consideration of end use does not conflict with the generic applicability of QPS because in this case the end use corresponds to different hazards (living organisms versus dead cells or their metabolites). Other types of end use of these TUs might impact the dissemination of the taxonomic units and/or the exposure of humans or animals. This requires a specific case-by-case risk assessment.

2.2.6. Can safety concerns be excluded?

Qualifications for antimicrobial resistance

The absence of acquired genes coding for resistance to antimicrobials relevant for humans and animals in a QPS recommended bacterial TU is a generic qualification. The verification that a specific bacterial strain, notified to a certain Panel, fulfils the qualification of the absence of acquired AMR genes is conducted by the specific EFSA Unit/Panel to which the notification was assigned. Within the framework of EFSA activities, the use of interpretative criteria and methods to define and monitor AMR have been harmonised and are reflected in EFSA's guidance documents. The use of harmonised methods and epidemiological cut-off values ensures the comparability of data over time at country level, and also facilitates the comparison of the occurrence of resistance between the Member States (EFSA FEEDAP Panel, 2012a).

In the case of yeasts, acquired AMR genes are not of relevance, but susceptibility to antimycotic compounds used in human medicine should be proved.

Qualification for the absence of toxigenic potential

Several *Bacillus* species are on the QPS list with the qualification 'absence of toxigenic activity'. This is based on the observation that some strains among the *Bacillus* species on the QPS list have caused food-borne intoxication in the past, which have been attributed to the production by these strains of compounds with toxic activities. Technical guidance to identify these toxic compounds among *Bacillus* species has been elaborated and updated by EFSA (EFSA FEEDAP Panel, 2011, 2014). The application of the qualification should permit identification of this safety concern among strains of the QPS *Bacillus* species. It is the purpose of the regular update of the QPS list to verify that no other relevant safety concerns have been identified for the QPS species of *Bacillus*.

Qualification for production purposes

The qualification 'for production purpose only' applies to a TU used for the biosynthesis of specific products used in the food chain and subject to a specific authorisation (e.g. feed additives – vitamins, amino acids, polysaccharides and enzymes – and food enzymes). For most of the TUs used for production, data are lacking on direct exposure to humans and animals, while there is a long history of use of their fermentation products in the food chain. Under specific regulation (e.g. Commission Regulation (EC) No 429/2008), the absence of production organisms in the additive derived from fermentation must be demonstrated.

3. Assessment

Under this section, two types of assessments have been included: the re-evaluation of the TUs included in the QPS list published in the Opinion from 2013 (ToR2) and the assessment of the new TUs corresponding to the microorganisms notified to the EFSA Units under the frame of an application for market authorisation (ToR3). The latter have been included in the Panel Statements adopted between December 2014 and December 2016. For both types of assessments, the QPS approach has been applied in the same way and based on the four main pillars as described in Section 2.2.

For the revision of the TUs included in the QPS list and respective qualifications, the update of the body of knowledge to check for possible new safety concerns was done based on an ELS and on expert knowledge. The previous information published in 2013 (EFSA BIOHAZ Panel, 2013) was taken into consideration whenever it was recommended the monitoring of possible safety concerns.

For the evaluation of the new TUs corresponding to the microorganisms notified to the EFSA Units between May of 2013 and September of 2016, the search for information was done using the available databases and according to the expert knowledge. These TUs were not included in the ongoing ELS revision as only the ones that were already present in the 2013 Opinion were considered for this step.

3.1. Gram-positive non-sporulating bacteria

3.1.1. *Bifidobacterium* species

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Bifidobacterium* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 879; after screening at title/abstract level, 70 passed to the full text phase; of those, six were considered relevant for the QPS assessment.

Five references concerned case reports involving bifidobacteria in patients with immunosuppression and/or underlying disease. Two reports described infections with *Bifidobacterium breve*, i.e. a sepsis in a 2-year-old immunocompromised child (acute leukaemia with chemotherapy) and a 45-year-old patient with infection and a severe underlying disease (Suwantararat et al., 2014; Avcin et al., 2015). A further three reports describe infections with *Bifidobacterium longum*. The first report (Bertelli et al., 2015) includes two cases with bacteraemia in preterm infants receiving antimicrobials, identifying the infectious agent more precisely as *Bifidobacterium longum* subsp. *infantis*. Three similar cases were reported by Zbinden et al. (2015). Tena et al. (2014) describe a case of peritonitis due to *B. longum* in a patient with underlying disease.

Revision of antimicrobial resistance aspects

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), one report described for the first time the occurrence of the acquired *erm(X)* gene in *B. longum* subsp. *longum* (Luo et al., 2015).

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

The cases of infection in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection. The use of microorganisms intended to be used as 'probiotic' for humans as a health claim does not fall under the remit of the QPS assessment. In conclusion, the QPS status of the *Bifidobacterium* species previously included in the list does not change and monitoring should continue.

3.1.2. *Carnobacterium divergens* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014).

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. *C. 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 SO₂-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 (Jözefiak 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 D, β -lactamase Oxa 63 (Meziane-Cherif et al., 2008).

However, these infections represent extremely rare individual cases, occurring on highly vulnerable individuals, and do not suggest a risk for consumers or animals via exposure through the food and feed chain.

Conclusions on a recommendation for the QPS list

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

3.1.3. *Corynebacterium glutamicum*

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the *C. glutamicum* has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 188; after screening at title/abstract level, 33 passed to the full text phase; of those, two were considered relevant for the QPS assessment.

A literature review did not reveal any new information about adverse health effects or safety concerns since the last update (EFSA BIOHAZ Panel, 2013).

Revision of antimicrobial resistance aspects

The involvement of class 1 integrons in the AMR towards streptomycin/spectinomycin and tetracycline in *C. glutamicum* isolates has been confirmed and reviewed by Deng et al. (2015).

No additional relevant information was published in the last year on the antimicrobial susceptibility or resistance of *C. glutamicum*.

Update on other qualifications

This TU has the following qualification 'QPS only applies when the species is used for aminoacid production'. Due to a lack of knowledge in relation to history of use of the viable organisms and because other members of the same genus are pathogenic, the qualification is confirmed.

Other relevant information

No new relevant information was identified.

Conclusion regarding a QPS recommendation

The QPS recommendation is confirmed for *C. glutamicum* as well as the qualification.

3.1.4. *Lactobacillus* species

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Lactobacillus* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 2,261; after screening at title/abstract level, 105 passed to the full text phase; of those, 21 were considered relevant for the QPS assessment.

Two of them (Krishnan and Abraham, 2014; Encarnacion et al., 2016) did not provide any information on how the identification of the aetiological agents of the two endocarditis cases was performed, and another (Doern et al., 2014b) duplicated the information of Doern et al. (2014a). The 18 reports that remained described association or causality of infection on heavily debilitated/immunocompromised patients (premature newborns or elderly subjects suffering from cancer, vascular disease complicated diabetes, diverticulitis, etc.).

Two articles (Martinez et al., 2014; Lee et al., 2015) compiled cases that occurred in particular hospitals over prolonged periods. In both, a variety of lactobacilli (*L. fermentum*, *L. gasseri*, *L. casei*, *L. paracasei*, *L. plantarum*, *L. reuteri*, *L. rhamnosus*, *L. delbrueckii*, *L. salivarius*) were associated with disease, but in most instances to just single cases. This illustrates the ability of microorganisms, even those considered harmless, to colonise patients suffering from life-threatening illnesses. Out of the rest, single reports associated *L. paracasei* (Franko et al., 2013), *L. fermentum* (Chery et al., 2013), *L. acidophilus* (Mehta et al., 2013), *L. gasseri* (Sun et al., 2015a) and *L. casei* (Aroutcheva et al., 2016) with production of endocarditis, cholecystitis, septicæmia, surgical wound/urinary tract infection and contamination of a central catheter, respectively, in patients who have suffered from prostate cancer, coronary disease, lymphoma, simultaneous infection by a coagulase-negative *Staphylococcus* and chronic lung and renal insufficiency.

Two reports addressed infections where *L. plantarum* was isolated (Nei et al., 2013; Tena et al., 2013) as part of polymicrobial infections. The first patient suffered from an advanced laryngeal cancer while the second had uncontrolled diabetes that caused chronic arterial ischaemia.

Finally, eight reports on infection with *L. rhamnosus* were detected, one of which describes two cases. In all of them, the affected patients were immunocompromised and included five newborns, out of which, one suffered an intrauterine growth restriction (Sadowska-Krawczenko et al., 2014), two were premature children, one had suffered consecutive intestinal perforations (Brecht et al., 2016), and another had experienced respiratory distress and a previous sepsis by *Staphylococcus haemolyticus* (Dani et al., 2016). The fifth was a girl with a trisomy 18 and triple-X syndromes who had previously suffered from sepsis and pneumonia (Dani et al., 2016). All of these developed bacteraemia by *L. rhamnosus*, as did a kidney transplant recipient (Falci et al., 2015) and two patients with ulcerative colitis who were being treated with corticosteroids and mesalazine (Vahabnezhad et al., 2013; Meini et al., 2015). The last two were a man and a baby (trisomy 21) suffering from acute myeloid leukaemia and bronchiolitis, respectively, who developed a severe oral infection (Ishihara et al., 2014) and pneumonia (Doern et al., 2014a,b). It is noticeable that at least eight of the nine patients were ingesting or have recently taken *L. rhamnosus*-based probiotic preparations despite their general compromising situation and that in several cases genetic identity between pathogenic and probiotic strains was confirmed.

Revision of antimicrobial resistance aspects

A report (Jaimee and Halami, 2016) described the presence of aminoglycoside resistance determinants in a few *L. plantarum* isolates from meat. No evidence of transmissibility was provided. In addition, lactobacilli, as any other anaerobic organisms, tend to be intrinsically resistant to aminoglycosides which weakens the claim on causality of the observed lack of susceptibility.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

There is no requirement to change the QPS recommendation of the previously recommended *Lactobacillus* species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed. As already noted in the 2013 Opinion, *L. rhamnosus* produced most of the clinical cases reported, probably due to frequent inclusion of isolates of this species into human 'probiotic' preparations. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection. The use of microorganisms intended to be used as 'probiotic' for humans as a health claim does not fall under the remit of the QPS assessment.

3.1.4.1. *Lactobacillus diolivorans* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a).

Identity

The species *L. diolivorans*, first described in Krooneman et al. (2002) (belongs to the group of obligate heterofermentative lactobacilli. The phylogenetic analysis of the 16S rRNA, indicates that this species belong to the *Lactobacillus buchneri* group.

Body of knowledge

A search for the body of knowledge on *L. diolivorans* was done considering all years available in the literature databases, using the species name as search terms. A limited number of papers (32) were retrieved. This species was originally isolated from maize silage and it has been found in several foods of plant origin, such as apple juice, sourdough, pickles and tofu. The organism has been isolated also from kefir grains.

Safety concerns

No reports were found on safety concerns related to this *Lactobacillus* species in the literature database searches. Since members of this species were in the past probably assigned to *L. buchneri*, a species granted the QPS status, additional safety concerns related to misidentification are not expected.

Antimicrobial resistance

No information related to the presence of AMR determinants has been identified in *L. diolivorans*.

Conclusions on a recommendation for the QPS list

The species *L. diolivorans* is a natural component of bacterial communities of fermented vegetables and plant derived products. It has never been implicated in human or animal diseases and therefore can be recommended for the QPS list.

3.1.5. *Lactococcus lactis*

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Lactococcus* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 835; after screening at title/abstract level, 39 passed to the full text phase; of those, 18 were considered relevant for the QPS assessment.

Eight of them describe non-reliable phenotypical identification methods, do not give enough indication on which methodology was used, or/and provide data strongly suggestive of environmental contamination (Buchelli-Ramirez et al., 2013; Feierabend et al., 2013; Hadjisymeou et al., 2013; Rostagno et al., 2013; Inoue et al., 2014; Karanth et al., 2014; Lee et al., 2014a; Taniguchi et al., 2016). All of these describe single cases of patients suffering from very debilitating illnesses, such as necrotising pneumonia, heart or renal failure, peritonitis, uncontrolled diabetes, etc.

Of the remaining articles, three papers describe *L. lactis* isolates from cases of bovine mastitis (Plumed-Ferrer et al., 2013, 2015; Werner et al., 2014) while another links strains of *L. lactis* to aquaculture fish problems (Ucko and Colorni, 2014). However, a definite link between these animal pathologies with *L. lactis* as the aetiological agent is lacking. The other communications describe association or causality of infection with *L. lactis* in seriously debilitated/immunocompromised patients, such as premature newborns or elderly subjects suffering from cancer, uncontrolled diabetes, heart problems, etc. These include bacteraemia (Karaaslan et al., 2015, 2016) and uncomplicated urinary infection (Newby and Ramesh, 2014).

Revision of antimicrobial resistance aspects

Three papers addressed the susceptibility resistance to antimicrobials of *L. lactis* isolates (Plumed-Ferrer et al., 2015; Zycka-Krzesinska et al., 2015; Li et al., 2016). In two of these, *terR* and *bla*CMY-2 determinants were detected; whether these genes encoded relevant phenotypes or/and if any of them were plasmid-encoded was not determined. In the third report, general resistance to rifampin, presumably a chromosomally encoded trait, was found among *L. lactis* isolates from cases of bovine mastitis.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

There is no need to change the QPS recommendation of *L. lactis*, as the infections reported were extremely scarce, and the affected patients already suffered from highly debilitating illnesses and/or were significantly immunodepressed. The possibility that *L. lactis* might be involved in bovine mastitis, albeit limited for the moment, should be monitored.

3.1.6. *Leuconostoc* species

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Leuconostoc* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 139; after screening at title/abstract level, 26 passed to the full text phase; of those, nine were considered relevant for the QPS assessment.

Three reports describe cases of infection in humans associated with *Leuconostoc* spp. All of them used unreliable phenotypical identification methods or did not give enough data on the methodology.

They refer to a case of cholecystolithiasis in an 83-year-old Asian woman due to *Lc. lactis* (Yang et al., 2015), a case with pleural empyema due to *Leuconostoc mesenteroides* in a healthy person handling pickled vegetables (Usta-Atmaca et al., 2015), and a case of an endophthalmitis by vancomycin-resistant *Lc. mesenteroides* after intravitreal injection of ranibizumab in an 89-year-old patient with cancer (Damasceno et al., 2016).

These articles mostly describe cases of infection in patients with predisposing or risks factors, with unreliable identification methods, and do not suggest a risk for the consumer via exposure through the

food and feed chain. The above new information does not modify the QPS recommendation of *Leuconostoc* species.

Revision of antimicrobial resistance aspects

Six articles have reported the AMR and minimal inhibitory concentration (MIC) values of strains belonging to *Leuconostoc* isolated from different food sources. The AMR of *Leuconostoc pseudomesenteroides* (n = 13) isolated from Alorena green table olives to 15 antimicrobials was evaluated. No genes encoding possible transferable AMR determinants for the observed phenotypic resistance were detected by polymerase chain reaction (PCR). The AMR of 14 *Lc. mesenteroides* isolates from Turkish dairy products to six antimicrobials was studied (Başbülül et al., 2015). No AMR genes were detected by PCR in the *Leuconostoc* isolates. Selected *Leuconostoc* isolates from traditional cheeses made from raw milk were tested for AMR (Alegria et al., 2013). From the 14 isolates tested, 13 were susceptible or intrinsically resistant to a set of 16 antimicrobials while one *Leuconostoc citreum* strain showed an atypical resistance to ciprofloxacin. Flórez et al. (2016) determined the MIC for 16 antimicrobials in 34 isolates of dairy origin. Atypical resistances were found for several antimicrobials. Evidence of the genetic basis of atypical resistances, and interspecies transfer of erythromycin resistance were shown. In another article, the genome sequence of three *Lc. mesenteroides* isolates from Italian soft cheese samples were published (Campedelli et al., 2015). The isolates displayed atypical resistance to several antimicrobials. Preliminary analysis of the sequences revealed the presence of *erm*(B) and *tet*(S) in two isolates. The AMR of one *Lc. citreum* strain, isolated from Korean kimchi, was studied (Ji et al., 2013) and found susceptible to all antimicrobials tested.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

The cases of infections in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. The above new information does not modify the QPS recommendation of *Leuconostoc* species. Therefore, the QPS recommendation for *Lc. mesenteroides*, *Lc. lactis*, *Lc. pseudomesenteroides* and *Lc. citreum* was confirmed.

3.1.7. *Microbacterium imperiale* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014).

Identity

Microbacterium imperiale, previously known as *Brevibacterium imperiale*, was included in the genus based on its close relationship with *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 colonised 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* spp. in food processing and/or ingestion of viable cells. There is a history of use in food processing of enzymes produced by *M. imperiale*, therefore it can only be recommended for QPS for enzyme production.

3.1.8. *Oenococcus oeni*

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *O. oeni* has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 265; after screening at title/abstract level, two passed to the full text phase; of those, none were considered relevant for the QPS assessment.

Revision of antimicrobial resistance aspects

No new information regarding AMR issues was retrieved during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified for *O. oeni*. Therefore, its QPS status does not change and monitoring should continue.

3.1.9. *Pasteuria nishizawae* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015b).

Identity

The genus *Pasteuria* comprises endospore-forming, Gram-positive bacteria of the phylum Firmicutes, phylogenetically mostly related to members of the family Alicyclobacillaceae, as judged by the sequence similarity of their 16S rRNA genes (Preston et al., 2003; Noel et al., 2005). Sequencing of sporulation genes and multilocus sequence typing also place these organisms as members of the order Bacillales (Preston et al., 2003; Trotter and Bishop, 2003; Charles et al., 2005). All *Pasteuria* species described so far are obligate parasites of invertebrates, including plant parasitic nematodes and planktonic freshwater crustaceans of the genus *Daphnia*, and none have been grown *in vitro*. Five species have been recognised: *P. ramosa* (which parasitises cladoceran water-fleas), *P. hartismeri*, *P. penetrans*, *P. thornei* and *P. nishizawae* (parasitising plant pathogenic nematodes) based on their host range, morphology and 16S rRNA signatures (Bishop et al., 2007, 2011). Since vegetative forms of *P. nishizawae* (and of any other nematode-parasitic *Pasteuria* spp.) have so far only been found in the pseudocoelom of female worms once they have infected the roots of the susceptible plant, it has

been extremely difficult to obtain pure DNA. Thus, endospores have been the only possible source for DNA to the point that this has prevented genome sequence determination.

P. nishizawae parasitises *Heterodera glycines*, the causal agent of soybean cyst formation, and it has been proposed as a biocontrol agent for that disease. Its endospores also attach to larvae of *Heterodera schachtii*, the cyst eelworm of sugarbeet, possibly indicating that its host range is wider than described (Sayre et al., 1991; Noel et al., 2005). In addition to its host specificity, *P. nishizawae* presents a morphologically distinctive vegetative cycle and endospores and, most important, a 16S rRNA gene sequence that is less than 96% identical to that of any other *Pasteuria* spp. investigated (Preston et al., 2003; Atibalentja et al., 2004; Noel et al., 2005).

Body of knowledge

The *Pasteuria* species show a high host specificity that is commonly restricted to one or a few related species of nematodes. Since the plant host range of their host helminths is also very narrow, each *Pasteuria* species can be ascribed to particular plants. The relation between the bacterium and the plant is mutualistic, because the bacterium kills an important plant parasite. This has given rise to expectations of using *Pasteuria* in control of pest nematodes.

In soil, endospores of *Pasteuria* (morphologically similar to those of bacilli) present peripheral fibres that attach to the tegument of recently hatched, free-living juvenile worms. Upon infestation of the root by the larvae (which may be mechanically prevented in case that a high number of spores have attached to them), spore germination takes place, followed by formation of a pseudomycelium (reason why *Pasteuria* was proposed to belong to the phylum Actinomycetales) that becomes fragmented and expands throughout the body of the helminth, leading to formation of new microcolonies. Sporulation takes place only in the adult female worm (possibly because males abandon the plant before complete maturation) thus interfering with the externalisation of its caudal end, which, in the absence of the bacterium, will swell to form a cyst full of eggs. Up to 10^6 endospores can be produced per infected worm, which may amount to 10^7 – 10^8 shed into the soil per infected plant.

Safety concerns

A search in the Web of Science retrieved information from the Environmental Protection Agency (EPA) of the United States on 'Exemption from the Requirement of a Tolerance' for residues of *P. nishizawae*-Pn1 in all food commodities, including drinking water (US EPA, 2012) registered as an active ingredient in products for controlling the soybean cyst nematode. The exemption was based on the absence of any signs of toxicity/pathogenicity/hypersensitivity in tests performed on laboratory animals. Other databases looked at, such as the CasesDatabase, GoogleScholar, CAB Abstracts or Food Science Technology Abstracts, provided no additional information.

QPS evaluation is not equivalent to the one performed by EPA, therefore a separate evaluation was conducted. As already stated, members of the genus *Pasteuria* have a narrow nematode host range and their spores only become vegetative cells after infestation of a plant root by the helminth. Thus, it seems unlikely that *P. nishizawae* can develop in, or harm any other organisms. Moreover, endospores resembling those of *Pasteuria* have been detected attached to almost all nematode species investigated and, in many cases, infection has been proven (Chen and Dickson, 1998; Tian et al., 2007). This indicates the ubiquitous nature of these bacteria and of their frequent contact with higher organisms, including humans. Nevertheless, there are no reports on pathogenicity or hypersensitivity even in farmers or crops handlers known to use *Pasteuria*-based helminth control.

Antimicrobial resistance

No data on antimicrobial susceptibility/resistance are available for *Pasteuria* spp.

Conclusions on a recommendation for the QPS list

In December 2015, *P. nishizawae* was recommended for the QPS status for use as a plant protection product to combat cyst nematodiasis (EFSA BIOHAZ Panel, 2015b). This conclusion was based on the following: (i) it is an obligate parasite, unable to grow independently of its host species, *H. glycines* and possibly *H. schachtii*. In addition, available evidence indicates that this species of bacteria requires entry of the nematode into the root of a plant for vegetative growth; (ii) the ubiquity and abundance of *Pasteuria* spp. endospores in soils and the lack of any reports on harmful effects of these bacteria on organisms other than their hosts.

The qualification linked to this taxonomic unit was re-evaluated and the QPS recommendation is now ascribed without the previous qualification ('QPS only applies when used in pesticides to combat cyst nematodiasis').

3.1.10. *Pediococcus* species

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Pediococcus* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 690, after screening at title/abstract level, 11 passed to the full text phase; of those, one was considered relevant for the QPS assessment, (Al-Badah et al., 2015), describing an incidental colonisation by pediococci of endodontic roots infected with a variety of pathogens. However, unreliable phenotypic identification was used in this article.

Revision of antimicrobial resistance aspects

Yüceer and Özden Tuncer (2015) report isolation of *Pediococcus acidilactici* and *Pediococcus pentosaceus* from almost 50% of uninoculated sucuk samples (a dry, spicy sausage, also named sucuk, sujux, suxhuk, etc.), suggestive of their technological role, and determined their AMR profiles. A lack of susceptibility to vancomycin, aminoglycosides and quinolones, all of which may be considered as intrinsic/ chromosomally encoded. No attempt to relate these traits to specific genes associated to mobile elements is reported.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

There is no need to change the recommendation of the QPS-granted pediococci species because no causality of infection has been reported during the scrutinised period.

3.1.10.1. *Pediococcus parvulus* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a).

Identity

Pediococcus parvulus appears to be a well-defined species by 16S rRNA gene sequencing (Collins et al., 1990). It clusters with other species of the genus, such as *P. acidilactici*, *P. pentosaceus* and *Pediococcus damnosus* (Collins et al., 1990) which has been confirmed after comparison of the *P. parvulus* DSM20332 draft sequence (accession number: NZ_JQBE01000001) with those of representative strains of the other species (Sun et al., 2015b). Phylogenetically, the whole genus has been proposed to be allocated into the *Lactobacillus* genus complex together with genera *Weissella*, *Leuconostoc*, *Oenococcus* and *Fructobacillus* because in phylogenetic trees their species appear intermixed with those of *Lactobacillus* (Sun et al., 2015b).

Body of knowledge

P. parvulus is commonly associated to spoilage of alcoholic beverages because it commonly produces EPS and diacetaldehyde upon fermentation of the must sugars (Renouf et al., 2007; Petri et al., 2013; Delsart et al., 2016). The former confers an oily appearance to the liquid known as ropiness, while the latter generates a butter-like flavour. In addition, some strains are histamine producers (Landete et al., 2005). The EPS synthesising strains have been proposed as suitable for production of ropy dairy products (Elizaquível et al., 2011) but they have not been included in any commercial products. Similarly, it appears that EPS-producing strains are less susceptible to simulated and mice digestive conditions, while lowering the cholesterol levels (Immerstrand et al., 2010; Lindström et al., 2013) reason why they have been proposed as potential probiotics but never used as such or intentionally added to any food. *P. parvulus* is, however, frequently found in fermented foods (Mesas et al., 2011; Abriouel et al., 2012; Bağder Elmaci et al., 2015) and feed, such as silage (Tohno

et al., 2012), and thus there is frequent exposure to it without any signs of pathogenicity for humans or animals.

Safety concerns

No communications on pathogenicity of *P. parvulus* were detected.

Antimicrobial resistance

Two reports on *P. parvulus* antibiotic resistance (Rojo-Bezares et al., 2006; Danielsen et al., 2007) provide similar data. The strains examined are highly susceptible to the β -lactams tested, but resistant to vancomycin, tetracycline, aminoglycosides, ciprofloxacin and trimethoprim. Genes conferring resistance to aminoglycosides (*ant(6)*, *aac(6')*-*aph(2'')*) and tetracyclines (*tet(L)*) have been detected but their expression or transmissibility was not tested.

Conclusions on a recommendation for the QPS list

P. parvulus can be granted the QPS status, being a species commonly found in fermented food and beverages and based on lack of pathogenicity as determined by the absence of any significant virulence determinants in its genome and of any reports on its role on human or animal infection.

3.1.11. Dairy propionic acid bacteria – *Propionibacterium* species

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *Propionibacterium* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 203, after screening at title/abstract level, 12 passed to the full text phase; of those, none was considered relevant for the QPS assessment.

Revision of antimicrobial resistance aspects

No new information regarding AMR issues was identified during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, the QPS status of the *Propionibacterium* species does not change.

3.1.12. *Streptococcus thermophilus*

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *S. thermophilus* has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 335; after screening at title/abstract level, 12 passed to the full text phase; of those, none was considered relevant for the QPS assessment.

Revision of antimicrobial resistance aspects

No new information regarding AMR issues was identified during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change.

3.2. Gram-positive spore-forming bacteria

3.2.1. *Bacillus* species

Taxonomy

Bacillus paralicheniformis, a recently described species, comprises former group 2 *Bacillus licheniformis* strains. Among relevant features of these new species members is the absence of ability to produce lichenicidin. Nevertheless, a putative new lantipeptide and gene clusters encoding bacitracin and fengycin are common features identified in *B. paralicheniformis* isolates (Dunlap et al., 2015)

The often-incorrect assignment of *Bacillus pumilus* isolates was recently reported (Espariz et al., 2016; Branquinho et al., 2014). Classifying strains of this species using 16S rRNA gene sequence analysis can lead to incorrect species assignment, as it demonstrates over 99.5% identity with other species in the *B. pumilus* group.

Update of the body of knowledge on safety concerns for QPS *Bacillus* species

The total number of references found through the ELS was 4,091; after screening at title/abstract level, 264 passed to the full text phase; of those, 41 were considered relevant for the QPS assessment.

The following papers were not considered for further QPS assessment because of methodological shortcomings in the method used to identify the *Bacillus* strains to the species level (Jaber et al., 2013; Li et al., 2013b; Kıvanç et al., 2014; Garcia Hejl et al., 2015; Guo et al., 2015; Shivamurthy et al., 2015; Grass et al., 2016). *Bacillus thuringiensis* is not considered for QPS, and therefore papers on this species (e.g. Fagerlund et al., 2014) were not further considered. A paper considering *Lysinibacillus sphaericus*, *Lysinibacillus fusiformis* and *Paenibacillus amylolyticus* was not considered in the context of the QPS evaluation on *Bacillus* spp. (Wenzler et al., 2015). The paper on a transovarial transmission of a *Bacillus subtilis* isolate that was made from a silkworm was not considered relevant for the QPS evaluation (Rai et al., 2013). Northern Ireland disease surveillance reports (Anonymous 2013a,b,c, 2014a,b,c) mentioned the involvement of *B. licheniformis* in bovine and ovine abortion cases. As these cases were linked with haematogenous spread of the bacteria (Agerholm et al., 1999), they were not further considered in the QPS evaluation.

Yoo et al. (2014) investigated a set of isolates, collected over several years, for possible production of cereulides and found producing isolates of *B. subtilis*, *B. pumilus* and *Bacillus megaterium*. Due to the lack of information on the identification methodology used for these isolates and the unreliability of several bacterial identification methodologies, there is uncertainty associated with the identity of these isolates.

The enterotoxic potential of *B. megaterium* isolates has been investigated by their adherence and invading potential in enterocyte-like Caco-2 cells (López et al., 2013). The cytotoxic activity reported, would be detected by current methodologies for assessing toxigenic activity in *Bacillus* species (EFSA BIOHAZ Panel, 2014).

The *B. subtilis* ATCC6051 showed a weak virulence in a virulence assay on brine shrimps (Lee et al., 2014b). Because this non-standard virulence test is not yet validated, this result was not further taken considered the QPS evaluation.

Lichenysin production by all *B. licheniformis* isolates tested by Madslien et al. (2013) was reported, with cytotoxic levels associated with levels above 10 µg mL⁻¹ corroborating previous findings (Madslien et al., 2013). Moreover, the cytotoxic activity reported, would be detected by the mandatory assessment of toxin production in isolates of QPS *Bacillus* species intended for food use (EFSA BIOHAZ Panel, 2014).

Idelevich et al. (2013) reported a bacteraemia case of small colony variants of *B. licheniformis* related to a pacemaker. The infection was cured by removal of the infected pacemaker.

A *B. subtilis* strain producing gamma-glutamyltranspeptidase (GGT) as a bone-resorbing virulence factor has also been described (Kim et al., 2016).

The cases of infections in humans and animals that were reported were not taken into account because of uncertainty on the identification methodology used and/or because the cases were linked to specific predisposing factors and do not suggest a risk for the consumer or the animal via exposure through the food and feed chain.

A recently published opinion of the EFSA BIOHAZ Panel addressed the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *B. thuringiensis* in foodstuffs did not report any additional concerns about *Bacillus* spp. included in the QPS list (EFSA BIOHAZ Panel, 2016b).

Revision of antimicrobial resistance aspects

Several papers reporting on AMR *Bacillus* strains were not taken into account because of uncertainty on the identification methodology (Kıvanç et al., 2014), or on the methodology used to confirm the AMR (Shweta and Joseph, 2013; Fernández-Fuentes et al., 2014; Mohammadou et al., 2014; Sadashiv and Kaliwal, 2014).

Update on other qualifications

The above new information does not affect the *Bacillus*-related QPS qualification ('absence of toxigenic activity').

Other relevant information

A review article on new diagnostic identification methods of *Bacillus* stressed the evolution from detection towards subtyping and risk-related strain profiling (Ehling-Schulz and Messelhäusser 2013).

The whole genome of an isolate reported as *Bacillus amyloliquefaciens* subsp. *plantarum* (UCMB5033) has been published (Niazi et al., 2014). The whole genome of an isolate from the gut of an organically reared broiler reported as *B. subtilis* has been published (Schyns et al., 2013). The whole genome sequences of 20 isolates reported to belong to *B. anthracis*, *B. atrophaeus*, *B. cereus*, *B. licheniformis*, *B. macerans*, *B. megaterium*, *B. mycoides* and *B. subtilis* have been published (Daligault et al., 2014).

Conclusion regarding a QPS recommendation

There is no requirement to change the QPS recommendation of the previously recommended *Bacillus* species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain.

3.2.1.1. *Bacillus flexus* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a).

Identity

B. flexus was originally described by Batchelor in 1919, and validated as revived species name (sp. nov., nom. rev.) by Priest et al. (1988). *B. flexus* is most closely related to *Bacillus paraflexus* (16S rRNA gene sequence similarity 98.1%), although also phylogenetically closely related to *B. nealsonii* (95%), *B. niabensis* (95%) and *B. azotoformans* (94%) (Chandna et al., 2013). *B. flexus* can be identified through 16S rRNA gene sequencing and differentiated from its closest phylogenetic neighbour *B. paraflexus* with standard phenotypic tests.

Body of knowledge

B. flexus has been used for production of enzymes, e.g. β -amylase in food production and of alkaline amylase, lipase and protease for detergent formulations (Niyonzima and More, 2014). It has also been used for the production of exopolysaccharides (EPS) (Singh et al., 2013), and for bioremediation (Sivaprakasam et al., 2008; Pal et al., 2014; Das et al., 2016). Zhang et al. (2014) sequenced the whole genome of *B. flexus* strain T6186-2, isolated from deep-subsurface oil reservoirs.

Safety concerns

A recent outbreak of wound infections in burned patients was reported (Uçar et al., 2016). The outbreak was associated with contaminated swabs for wound sampling. Isolate identification procedures and virulence features characterisation were not presented in the study, neither was the relation between the infection and the *B. flexus* strain. To our knowledge, there are no reports of any virulence feature or disease associated with *B. flexus*, further supporting the absence of pathogenicity potential in a non-compromised host.

Antimicrobial resistance

Genes encoding resistance to vancomycin (*vanB*), fosfomycin (*fosB*) and tetracycline (*tetA*) were described in a *B. flexus* strain (Zhang et al., 2014). Nevertheless, it was not possible from the data

presented to assess if these genes are part of the chromosomal core genome and therefore present in all members of this species or associated with mobile resistance elements. Moreover, it is not possible to infer if they confer resistance to the mentioned antimicrobials.

Conclusions on a recommendation for the QPS list

B. flexus can be recommended for the QPS list with a qualification of the absence of toxigenic activity (as applied to all strains of *Bacillus* species recommended to the QPS list).

3.2.1.2. *Bacillus smithii* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2017).

Identity

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

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).

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.

Antimicrobial resistance

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

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).

3.2.2. *Geobacillus stearothermophilus*

Taxonomy

The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 4,091 together with *Bacillus* search; after screening at title/abstract level, 264 passed to the full text phase; of those and specifically for this TU, none was considered relevant for the QPS assessment.

Revision of antimicrobial resistance aspects

No new information regarding AMR was retrieved during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change.

3.3. Gram-negative bacteria

3.3.1. *Gluconobacter oxydans*

Taxonomy

Since the last update on the QPS status (EFSA BIOHAZ Panel, 2013), no new information on the taxonomy of the considered *G. oxydans* species has been published.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 180; after screening at title/abstract level, eight passed to the full text phase; of those, none was considered relevant for the QPS assessment.

Revision of antimicrobial resistance aspects

No new information regarding AMR issues was identified during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified that justifies changing the qualification that the QPS only applies when the species is used for vitamin production.

Other relevant information

The presence of strains of *G. oxydans* with putative production of antimicrobials was followed in the ATCC Online Catalogue²² as indicated in the 2013 QPS Opinion. Antimicrobial production is not mentioned in any of the isolates, apart from one described as *Gluconobacter* spp.

Conclusion regarding a QPS recommendation

A total of 188 references were screened for relevant information related to *G. oxydans*. No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, the QPS status of *G. oxydans* does not change.

3.3.2. *Xanthomonas campestris* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015a).

Identity

X. campestris is a valid name species (Skerman et al., 1980; Vauterin et al., 1995) from the genus *Xanthomonas*. It is a Gram-negative, strictly aerobic, motile rod. *X. campestris* is a plant pathogen originally described as causing a vascular disease of *Brassica* spp. The species has been subdivided into pathovars, grouping strains having the same host plants (Bradbury, 1984).

Body of knowledge

On *Brassica* spp., *X. campestris* pathovar *campestris* is a seed-borne pathogen, causing a systemic vascular disease of the plant (Vicente and Holub, 2013). Different pathovars do not produce the same symptoms, some causing non systemic spots on the host's leaves (Bradbury, 1984). *X. campestris* have been extensively studied in relation to interactions with the plant hosts in the field, but a literature search similar to that described for the body of knowledge of *B. circulans* failed to find studies on its presence in the harvested plants used as food or feed.

Some strains of *X. campestris* produce capsular polysaccharides, giving a slimy appearance of colonies on agar media containing utilisable carbon sources. Xanthan gum is one of them and it is composed of repetitive units of D-glucose, D-mannose, D-glucuronic acid with terminal groups of pyruvic and acetic acids (Bradbury, 1984). Xanthan gum is industrially produced from *X. campestris* grown on adequate

²² See ATCC website at: https://www.lgcstandards-atcc.org/Products/Cells_and_Microorganisms.aspx?geo_country=it

carbon sources for a very wide range of food and non-food applications (Palaniraj and Jayaraman, 2011). Xanthan gum is used worldwide as an additive in many processed foods (Codex Alimentarius, 2014).

The genome of a strain of *X. campestris* used for industrial production of xanthan gum has been sequenced (Tao et al., 2012).

Safety concerns

X. campestris is a pathogen of many plant species. A search on safety concerns similar to that done for *B. circulans* retrieved articles on the virulence of *X. campestris* on plants (search strings in Appendix A). An additional search was done on its association with animals and humans, combining search terms relating to human and some animal species with *X. campestris*. Only one publication was found, mentioning its isolation from a human blood sample in China (Li et al., 1990).

Antimicrobial resistance

X. campestris pv. *campestris* expresses a chromosomally encoded class A β -lactamase which confers resistance to penicillin and carboxypenicillins (Yang et al., 2011, 2014). No evidence of the acquisition of an antibiotic resistance gene was retrieved in the literature search performed.

Conclusions on a recommendation for the QPS list

Xanthan gum produced by *X. campestris* has a long and broad history of safe use in the food industry. *X. campestris* is a plant pathogen. Apart from one record (Li et al., 1990), *X. campestris* has never been implicated in human or animal disease. However, human consumers are presumably very rarely exposed to high levels of *X. campestris* through food, indicating a lack of knowledge on the effect of high levels of live cells of *X. campestris* on animals and humans.

In all papers screened, none of them mentioned acquisition of resistance to antimicrobials. *X. campestris* can be recommended for the QPS list for the production of xanthan gum.

3.4. Yeasts

Fungi are unique among living organisms because they may have two valid names. The primary name is based on the sexual state or teleomorph, but a second valid name may be based on the asexual state or anamorph. This redundancy of names developed because teleomorphs have not been found for many fungi, or it has not been clear that a particular teleomorph is the same species as a particular anamorph (Kurtzman et al., 2011).

In the screened scientific reports on yeasts, alternatively the teleomorph or anamorph names (and sometimes both) are used. However, in the following evaluations of the yeast species, in general, the teleomorph name is preferentially used, but for clarity the anamorph (when known) and synonyms are also mentioned.

3.4.1. *Candida cylindracea* (TU included after the 2013 QPS update)

Evaluation published in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014).

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 *Candida tropicalis*, *Candida glabrata*, *Candida 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 *C. 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 the QPS status. However, since there were no reports on its use in applications involving direct consumption of *C. cylindracea* viable cells by humans or animals, the QPS should apply only for the production of enzymes.

3.4.2. *Debaryomyces hansenii*

Taxonomy

The anamorph form of *D. hansenii* is *Candida famata*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment.

However, from these, only 37 were linked to *D. hansenii* and considered relevant for the QPS assessment. In the majority of the publications identified, the authors used the name of the anamorphic form, *C. famata*.

Only in very few of the reports, the yeast was identified by molecular techniques like PCR using specific primers (Pisa et al., 2015) or PCR-restriction fragment length polymorphism (PCR-RFLP) (Muadcheingka and Tantivitayakul, 2015) or other techniques like specific antibody detection (Pisa et al., 2015) or by matrix-assisted laser desorption/ionisation time-of-flight mass spectrometry (MALDI-TOF MS) (Riat et al., 2015). In the majority of the publications, physiological criteria were used or the methodologies used were not specified. Using this approach, the presence of *D. hansenii* has been described in patients infected by HIV (Nidhi et al., 2015; Ribeiro et al., 2015; Minea et al., 2016), with cancer (Li et al., 2013a; Nidhi et al., 2015), with post-operational acute respiratory distress syndrome (Mun et al., 2015), with invasive candidiasis (Ghahri et al., 2013; Wang et al., 2014; Jung et al., 2015; Nieto et al., 2015), in pregnant women in Malaysia hospital (Masri et al., 2015) or vulvovaginal candidiasis (Liu et al., 2014), in patients with fungal eye infections (Ghodasra et al., 2014), with psoriasis (Sarvtin et al., 2014), with chronic diarrhoea (Banerjee et al., 2013), athlete's foot (Chan et al., 2013) and in children with neutropenia (Haddadi et al., 2014). The value of these reports is often limited considering the limitations of the identification method.

In the big majority of cases, *D. hansenii* was isolated from patients with various serious underlying diseases or other immunosuppressed states, and there is no connection between the disease and consumption of the yeast. Additionally, in all the cases, the presence of *D. hansenii* among other species involved in the yeast infections is very low, seldom above 5%.

Revision of antimicrobial resistance aspects

Beyda et al. (2013) described a strain of *D. hansenii* from bloodstream infections which exhibited a reduced susceptibility to echinocandins and azoles.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

The new information regarding potential concerns for human or animal safety, or other related aspects do not imply new concerns with respect to the QPS status of *D. hansenii*. Therefore, its QPS status does not change.

3.4.3. *Hanseniaspora uvarum*

Taxonomy

The anamorph form of *H. uvarum* is *Kloeckera apiculata*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. Specifically for this TU, no further information concerning safety concerns was found.

Revision of antimicrobial resistance aspects

No new information regarding AMR issues was retrieved during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not suffer any change.

3.4.4. *Kluyveromyces* species

Taxonomy

Two species of the genus *Kluyveromyces* are included in QPS list, *Kluyveromyces lactis* (anamorph *Candida spherica*) and *Kluyveromyces marxianus* (anamorph *Candida kefir*). The species names have not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. From these, only 43 were linked to *Kluyveromyces* species.

The ELS search retrieved no new studies with relevance for the QPS evaluation of *K. lactis* (or its anamorphic name *C. spherica*). For *K. marxianus* (including the anamorph *C. kefir*), a total number of 43 references were selected after full text phase. The great majority of studies (33) deemed relevant for the QPS used the anamorph name *C. kefir*. The new information on *K. marxianus/C. kefir* is evaluated below.

Quite a few of the reports deemed relevant in the ELS (43) presented information demonstrating a low or very low prevalence (seldom above 5%) of *K. marxianus* among fungi (mainly *Candida* spp.) isolated from patients with various serious underlying diseases, like cancer or HIV, or other immunosuppressed states, and patients with catheters (de Freitas et al., 2013; Ghahri et al., 2013; Parmeland et al., 2013; Abrantes et al., 2014; Dufresne et al., 2014; Haddadi et al., 2014; Taj-Aldeen et al., 2014; Youngster et al., 2014; Leuck et al., 2015; Menezes et al., 2015; Nidhi et al., 2015; Nieto et al., 2015; Sahin et al., 2015).

Sarbu et al. (2013) studied virulence factors in isolates from vulvovaginal infections. A single case included a *K. marxianus* isolate, but it was positive only for haemolysins and siderophore-like compounds and negative for the other factors studied.

Muadcheingka and Tantivitayakul (2015) found *K. marxianus* at a low prevalence (3.6%) in *Candida* isolates from patients with oral candidiasis (no underlying diseases reported) in a dental clinic in Thailand.

A *K. marxianus* bloodstream infection in a patient with brainstem dysfunction and a case of cardiac arrest was reported by Khan et al. (2015).

Alfouzan et al. (2015) reported very low prevalence of *K. marxianus* among yeast isolates from patients with vaginitis (no other underlying disease reported) in Kuwait, and Madhumati et al. (2014) reported similar observations in India.

Swarajyalakshmi and Jyothilakshmi (2014) reported a case of sinusitis caused by *K. marxianus* (solely biochemical identification) in a woman with diabetes.

K. marxianus was moderately prevalent (5.8%) among 855 yeast isolates from various clinical specimens (mainly nail and vulva-vagina) from different regions in Iran (Mohammadi et al., 2013). The association with disease in the subjects is not described and the significance of the study for the QPS is therefore unclear.

Khosravi et al. (2013) reported that *K. marxianus* constituted 6.2% of yeast species obtained from patients with nail infections.

Revision of antimicrobial resistance aspects

Some studies demonstrate antimycotic susceptibility in *K. marxianus*. Montagna et al. (2014) found no amphotericin resistance in the tested clinical isolates, and Yigit and Aktas (2014) similarly found no resistance against amphotericin B and azoles.

Other studies reported antimycotic resistance in *K. marxianus* clinical isolates. For instance, in India, Shyamala and Parandekar (2014) reported azole resistance in isolates from HIV patients, and Deorukhkar and Santosh (2013) and Sasikala et al. (2013) in isolates from patients with suspected or confirmed vulvovaginal candidiasis.

Dufresne et al. (2014) provided indications that under treatment with antimycotics, some *K. marxianus* isolates could develop resistance to the provided substance. Similarly, Fekkar et al. (2013) showed that a *K. marxianus* isolate acquired echinocandin resistance after initiation of caspofungin treatment for candidemia.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

There is no doubt that *K. marxianus*/*C. kefir* should be considered a significant opportunistic fungus, and it has received increased attention in recent years. However, reports where it has been unambiguously shown to be causative agent of infectious disease in otherwise healthy individuals are very rare. Therefore, its QPS status does not change. There is reason to be alert regarding whether there is a tendency for *K. marxianus* to become more common in this kind of infection.

3.4.5. *Komagataella pastoris*

Taxonomy

The anamorph of *K. pastoris* is not described. The previous name of this species is *Pichia pastoris*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. Specifically for this TU, no further information concerning safety concerns was found.

Revision of antimicrobial resistance aspects

No new information regarding AMR was identified during the period covered by the ELS.

Update on other qualifications

For *K. pastoris*, the QPS only applies when the species is used for enzyme production and no viable cells are found.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change. The qualification is unchanged.

3.4.6. *Lindnera jadinii*

Taxonomy

The anamorph form of *L. jadinii* is *Candida utilis*. Synonyms of this species are *Pichia jadinii*, *Hansenula jadinii* and *Torulopsis utilis*. The species name has not been changed since the 2013 QPS Opinion.

All studies relevant for the evaluation of this species were retrieved when using the anamorph name *C. utilis*, and there were no hits when using the teleomorph name *L. jadinii*.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. From these, only six were linked to *L. jadinii*.

Svobodova et al. (2016) compared biochemical identification of clinical yeast isolates to *Wickerhamomyces anomalus*/*Candida pelliculosa* and *L. jadinii*/*C. utilis*, with MALDI-TOF MS identification of the same isolates. The MALDI-TOF identified the majority of the isolates as *Candida fabianii*, a non-QPS species. This indicates that the prevalence of *L. jadinii* (and *W. anomalus*) in clinical samples may have been overestimated in previous studies employing biochemical identification.

Another study (Fadda et al., 2013) compared identification methods for yeast isolates from cows with mastitis. API kits for assimilation tests generally agreed well with a PCR-RFLP method for the *Candida* species investigated, including *L. jadinii*/*C. utilis*.

Update of the body of knowledge on safety concerns

Minea et al. (2016) found *L. jadinii* in low prevalence from HIV or diabetes patients in Romania, but it the identification methods used in the study were not described. Hammad et al. (2013) reported a very low prevalence (0.6%) of *L. jadinii* in oral yeast flora of type II diabetics with periodontitis in Jordan. Luzzati et al. (2013) found very low prevalence (0.7%) of *L. jadinii* in yeast isolates from elderly, candidemia patients in Italy. Eddouzi et al. (2013) reported very low prevalence (0.25%) of *L. jadinii* among isolates from patients with fungal infections in Tunisian hospitals.

Scoppettuolo et al. (2014) reported a rare case of catheter-related blood stream infection with *L. jadinii* in a cancer patient with a long-term implanted venous catheter.

Revision of antimicrobial resistance aspects

Minea et al. (2016) reported antimicrobial susceptibility of clinical isolates, largely confirming previous data. A Tunisian study (Eddouzi et al., 2013) reported high antimycotic susceptibility in clinical isolates of *L. jadinii*.

Update on other qualifications

For *L. jadinii*, the QPS only applies when the species is used for enzyme production and no viable cells are found.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

Few studies reported isolation of *L. jadinii*/*C. utilis* in clinical samples. Human isolates were only recovered from people with underlying disease, and prevalence was generally low compared to other infectious yeast isolated from collections of clinical samples. No studies reported increased prevalence of antimycotic resistance. In conclusion, no information was retrieved to indicate a change in the QPS status.

3.4.7. *Ogataea angusta*

Taxonomy

The anamorph form of *O. angusta* is not described. A synonym of this species is *Pichia angusta*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. Specifically for this TU, no further information concerning safety concerns was found.

Revision of antimicrobial resistance aspects

No new information regarding AMR was retrieved during the period covered by the ELS.

Update on other qualifications

For *Ogataea angusta*, the QPS only applies when the species is used for enzyme production and no viable cells are found.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change.

3.4.8. *Saccharomyces cerevisiae*/species

Taxonomy

The anamorph form of *S. cerevisiae* is not described. A synonym of this species is *Saccharomyces boulardii*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 2,421, after screening at title/abstract level, 117 passed to the full text phase; of those, 27 were considered relevant for the QPS assessment and linked to *S. cerevisiae*. From the searches done, for the other two searches for yeasts groups as described in Appendix C, 7 references were also found. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. Therefore, a total of 34 references were identified for this TU.

During this period, new cases of fungaemia caused by *S. cerevisiae* were described. In the majority of these reports, the authors used molecular techniques like RFLP of the ribosomal region that included the 58S and ITS region. The reports where the authors used only physiological methods for identification or the methodology was not described, were not considered. Popiel et al. (2015) report fungaemia in a 60-year-old man whose orthotopic liver transplant was complicated by *S. cerevisiae* (Popiel et al., 2015). Pillai et al. (2014) report fungaemia caused by *S. cerevisiae* in a woman with chronic kidney disease and *S. cerevisiae* was isolated from blood, urine and stool, as well as vaginal swabs (Pillai et al., 2014).

Some other reports are associated with the synonymous *S. boulardii*. Santino et al. (2014) reported fungaemia caused by *S. cerevisiae/boulardii* in an 86-year-old man with gastrointestinal disorders (*Clostridium difficile* infection). Cohen et al. (2013) reported a case of a young drug user that injected *S. cerevisiae/boulardii* intravenously. She developed a transient fever but spontaneously recovered after 2 days.

S. cerevisiae also has been described in fungaemias with very low incidence levels associated with other yeast species of the genus *Candida* (Martos et al., 2014), including other QPS species like *D. hansenii* and the anamorph form *C. famata*, *C. kefir* (anamorph form of *K. marxianus*), *C. utilis* (anamorph form of *L. jadinii*), also appearing at low incidence (Eddouzi et al., 2013; Fadda et al., 2013; Fekkar et al., 2013; Li et al., 2013c; Arancia et al., 2014).

An allergic reaction and positive skin test was reported in a patient who took *S. cerevisiae/boulardii* as an antidiarrhoeal therapy (Kartal et al., 2014).

Llopis et al. (2014) used virulence-associated phenotypic traits and an *in vivo* study in a murine model, to analyse the potential virulence of viable isolates contained in dietary supplements. One of the *S. cerevisiae* isolates caused death in murine models. The authors suggest a strong relationship between some of the virulence-associated phenotypic traits (ability to grow at 39°C and pseudohyphal growth) and the *in vivo* virulence in a mouse model of intravenous inoculation. These data confirm previous QPS qualifications for *S. cerevisiae*.

Revision of antimicrobial resistance aspects

Santino et al. (2014) described an isolate of *S. boulardii* (synonym of *S. cerevisiae*) from an 86-year-old man that presented susceptibility to caspofungin and voriconazole but resistance to fluconazole, intraconazole and amphotericin B. According to these data, the recommendation (qualification) is to maintain the 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.

Update on other qualifications

In the case of *S. cerevisiae* the qualification that applies for yeast strains able to grow above 37°C is maintained.

Other relevant information

Other papers are related to the virulence and pathogenicity characterisation of *S. cerevisiae*. Anoop et al. (2015) and Pérez-Torrado and Querol (2015) overview the infection mechanisms and virulence factors in opportunistic isolates of *S. cerevisiae*. Pérez-Torrado et al. (2015) performed a genomic characterisation of *S. cerevisiae* isolates including clinical and food isolates. The results showed increased copy numbers of immune deficiency-like genes in opportunistic isolates, which are implicated in the *de novo* biosynthesis of the purine nucleotides pathway. These results demonstrated a specific mechanism present in virulent isolates of *S. cerevisiae* that opportunistic yeasts may use (enhanced *de novo* biosynthesis of the purine nucleotides pathway) to increase survival and favour infections in the host. Roig et al. (2013) reports a genetic determinant that seems to contribute to virulence in clinical isolates of *S. cerevisiae*, the *FLO11* gene. Strobe et al. (2015) performed whole genome sequencing of 93 isolates of *S. cerevisiae* including clinical isolates. The authors found changes in the genome sequence of the gene *PDR5* (a multidrug transporter), present exclusively in clinical isolates.

Conclusion regarding the maintenance of the QPS recommendation

These new reports of *S. cerevisiae* appearing as an opportunistic pathogen add no further concern regarding its QPS status. Consumption of *S. boulardii* (synonym of *S. cerevisiae*) by patients with fragile health may be considered as the origin of the infection, although the use of microorganisms intended to be used as 'probiotic' for humans as a health claim does not fall under the remit of the QPS assessment. These new reports also confirm the previous QPS qualifications, the 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 and inability to grow above 37°C. Therefore, its QPS status does not change.

3.4.9. *Schizosaccharomyces pombe*

Taxonomy

There are no synonym names in common use for this species and the name has not been changed since 2013.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS

assessment. Specifically for this TU, one reference was identified but no further information concerning safety concerns was found.

Revision of antimicrobial resistance aspects

No new information regarding AMR was retrieved during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change.

3.4.10. *Wickerhamomyces anomalus* (*Pichia anomala*)

Taxonomy

The anamorph form of *W. anomalus* is *Candida pelliculosa*. Synonyms of this species are *Hansenula anomala*, *Pichia anomala* and *Saccharomyces anomalus*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. From these, 16 references were related to *W. anomalus*.

Some of the reports deemed relevant in the ELS (16) reported *W. anomalus*/*C. pelliculosa* among fungi (mainly *Candida* spp.) isolated from patients with various serious underlying diseases and suffering infections by opportunistic microbes (Kuiper et al., 2013; Oliveira et al., 2014; Taj-Aldeen et al., 2014; Lin et al., 2015; Nidhi et al., 2015; Tzar et al., 2015). Additionally, *W. anomalus* was always a minor fraction (less than 10%) of the isolates.

Svobodova et al. (2016) compared biochemical identification of clinical yeast isolates to *W. anomalus* and *C. utilis*, with MALDI-TOF MS identification of the same isolates. MALDI-TOF identified the majority of the isolates as *Candida fabianii*, a non-QPS species. This indicates that the prevalence of *W. anomalus* in clinical samples may have been overestimated in previous studies employing biochemical identification.

Deepak et al. (2015) reported that yeasts (e.g. *W. anomalus*) can have detoxifying activity on aflatoxin.

One study presented the MALDI-TOF MS method that conveniently and reliably identified many yeasts that may cause opportunistic infections, including *W. anomalus* (Ghosh et al., 2015).

Kamoshita et al. (2015) reported a case where a 91-year-old woman suffered from fungal keratitis caused by *W. anomalus* after corneal transplantation. Similarly, Esgin et al. (2014) reported post-operational infection by *W. anomalus* in the eye of an adult man in Turkey.

One study reported an outbreak of *W. anomalus* fungaemia, where one strain was retrieved from the bloodstream of six infants, in a neonatal intensive care unit in Taiwan (Lin et al., 2013).

Revision of antimicrobial resistance aspects

Some studies demonstrate antimycotic susceptibility in *W. anomalus*. Montagna et al. (2014) found no amphotericin resistance in the sole, tested clinical isolate. Shyamala and Parandekar (2014) reported that the sole tested clinical isolate of *W. anomalus* was susceptible to three of the tested azoles and non-susceptible to one (itraconazole).

Update on other qualifications

For *W. anomalus*, the QPS only applies when the species is used for enzyme production and no viable cells are found. The 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.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

Comparatively few studies reported isolation of *W. anomalus*/*C. pelliculosa* in clinical samples. Human clinical isolates were mainly recovered from people with underlying disease and in these cases *W. anomalus* was always a minor fraction of the isolates, and there were no indications it may be food-borne. No studies reported infection in healthy, non-hospitalised subjects or signs of increased prevalence of antimycotic resistance. Therefore, its QPS status does not change.

3.4.11. *Xanthophyllomyces dendrorhous*

Taxonomy

The anamorph form of *X. dendrorhous* is *Phaffia rhodozyma*. The species name has not been changed since the 2013 QPS Opinion.

Update of the body of knowledge on safety concerns

This TU was included in a search for several TUs as described in Appendix C. The total number of references found through the ELS for these groups of TUs was 2,857; after screening at title/abstract level, 264 passed to the full text phase; of those, 143 were considered relevant for the QPS assessment. Specifically for this TU, no further information concerning safety concerns was found.

Revision of antimicrobial resistance aspects

No new information regarding AMR was retrieved during the period covered by the ELS.

Update on other qualifications

No new relevant information was identified.

Other relevant information

No new relevant information was identified.

Conclusion regarding the maintenance of the QPS recommendation

No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change.

3.5. Viruses used for plant protection

A number of viruses has been recommended for use to control plant pests. The first category encompasses 'mild strains' of plant viruses to mitigate the effects of 'severe strains' of the same virus species, the latter causing severe disease for example in tomato and squash. The viruses notified to EFSA are members of two well-characterised plant virus families, the Alphaflexiviridae (Order Tymovirales) and Potyviridae. The second category consists of baculoviruses (family Baculoviridae) that kill specific species of pest insects.

Taxonomy

In order for viruses to be considered for QPS, the taxonomy of these pathogens should be unequivocal. The taxonomy and nomenclature of viruses are the responsibility of the International Committee on Taxonomy of Viruses. The most recent report (9th) is from November 2011 (King et al., 2012), but regular updates are published on the ICTV website, the most recent one being from 2015. The status of e-viruses (computationally identified viruses) is being discussed. The taxonomy of the viruses relevant for QPS assessment is outlined in a previous QPS report (2013) and has not changed since.

3.5.1. Plant viruses

Viruses belonging to certain plant virus families (Alphaflexiviridae and Potyviridae) are sometimes used for cross protection purposes, i.e. the application of mild strains of a plant virus giving mild symptoms is used to protect the food or feed crop against strains of the virus giving severe symptoms and yield losses. This strategy was also previously known as premunition. The mechanistic explanation for the protective effect has not been unequivocally determined. One theory holds that the innate

immunity (RNAi) response is triggered throughout the plant by mild strains and quickly controls virus attack by virus strains that would otherwise provoke a severe response. Sequence similarity between two such viruses is a prerequisite for this. Another theory postulates that the mild strains produce considerable amounts of virion coat protein. Upon uncoating of virions of a severe strain of the virus, there is a surplus of coat protein present from virions of the mild strain, hence promoting the repackaging of the uncoated virus RNA of the severe strain and thus blocking it from expression of its virulent genes.

Plant viruses do not replicate in organisms other than plants. The parts exposed to animal and/or humans are the coat protein(s) and the nucleic acid, which are, in all but a few cases, RNA. The potential effects of such viruses on animals and/or humans, when applied to food or feed, were reviewed and assessed, and the results were published in the EFSA Opinions on QPS in 2009 (EFSA, 2009, 2012b), 2010 (EFSA BIOHAZ Panel, 2010), 2011 (EFSA BIOHAZ Panel, 2011), 2012 (EFSA BIOHAZ Panel, 2012) and 2013 (EFSA BIOHAZ Panel, 2013).

3.5.1.1. Alphaflexiviridae

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 198; after screening at title/abstract level, nine passed to the full text phase; of those, six were considered relevant for the QPS assessment.

From these, four 'alphaflexiviridae' papers were either related to a human vaccine using an alphaflexivirus as a carrier (not related to agronomic application) or reported some hypothetical effect on the environment (EFSA BIOHAZ Panel, 2013; Yusibov et al., 2013; Duff-Farrier et al., 2015; Minicka et al., 2015).

There was no scientific evidence that alphaflexiviruses or members of the genus *Potexvirus* have any negative effects on animals and humans. Viruses of this family have been reported from a wide range of herbaceous and woody plants, both monocotyledons and dicotyledons. Species of this virus family are mostly plant-specific and are transmitted from plant to plant either mechanically or through insect vectors. So, they are widely present in the environment and deliberate release will not cause additional environmental effects. In terms of safety, the viruses neither carry nor encode toxic compounds to vertebrates including humans (EFSA BIOHAZ Panel, 2013) and the familiarity principle was taken into account as well, in that, these viruses have been part of the food and feed of animals and humans via plant material.

A pathogenicity determinant of the alphaflexivirus, Pepino mosaic virus (mild strain vs severe strain) in plants was mapped to the N-terminus of viral coat protein (Duff-Farrier et al., 2015), but there is no evidence it can affect vertebrates. The major component of an alphaflexivirus (e.g. Pepino mosaic virus), the coat protein, was tested computationally in 2013 against a plant database (UniRef100 plant database (UniProt NREF, 2013) and did not show any homology to known toxins. None of the hits were related to the search terms 'disease' or 'toxins'. No other negative impacts of alphaflexiviruses, more specifically potexviruses such as Pepino mosaic virus (genus *Potexvirus*) on humans or animals have been reported to date (EFSA BIOHAZ Panel, 2013).

Update on other qualifications

Not applicable.

Other relevant information

No safety concerns, including environmental effects, have been reported for members of the Alphaflexiviridae.

Conclusion regarding the maintenance of the QPS recommendation

On the basis of the scientific information identified through the ELS, the QPS recommendation on members of the Alphaflexiviridae family can be maintained.

3.5.1.2. Potyviridae

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 198; after screening at title/abstract level, nine passed to the full text phase; of those, six were considered relevant for the QPS assessment.

From the relevant reports, it was concluded that the four papers were either related to a functional, fundamental aspect of the pertinent virus or reported some ecological effect (EFSA BIOHAZ Panel, 2013; Yusibov et al., 2013; Hillung et al., 2014; Hasiow-Jaroszewska et al., 2015).

For the potyviruses, no scientific evidence indicated that these viruses have any negative effects on animals and humans to date. In addition, the familiarity principle was taken into consideration, since these viruses have been part of the food and feed of animals and humans since they are widely present in edible plants.

Computational analysis demonstrated that the major component of a *Potyvirus* (Zucchini yellow mosaic virus), the coat protein, did not show any homology to known toxins (Health Canada, 1999; Kuiper et al., 2001). Such an analysis was repeated in 2012 against a plant database (UniRef100 plant database (UniProt NREF, 2013) and a general database (GenBank nt database, 2013) and none of the hits were related to 'disease' or 'toxins'. Since the last major review by Kuiper et al. (2001), no new information has appeared that would compromise the conclusion drawn in 2013 (EFSA BIOHAZ Panel, 2013).

Update on other qualifications

Not applicable.

Other relevant information

No safety concerns, including environmental effects, have been reported for members of the Potyviridae.

Conclusion regarding the maintenance of the QPS recommendation

On the basis of the scientific information found, including the one retrieved from the ELS, the QPS recommendation on members of the Potyviridae family can be maintained.

3.5.2. Insect viruses

Most, but not all, insect viruses are pathogenic to insects, but only baculoviruses (family Baculoviridae) have been fully developed as bioinsecticides. The latter viruses act by killing larvae of target insects in a few days and disseminating new viruses that can affect new target insect larvae. These baculoviruses are usually species-specific and are natural biocontrol agents, as through their lethal action on insect larvae they regulate the size of insect populations in agroecosystems. As they are sprayed on crops, the plants or fruits for consumption can be contaminated with the relevant baculovirus.

3.5.2.1. Baculoviridae

Update of the body of knowledge on safety concerns

The total number of references found through the ELS was 492; after screening at title/abstract level, 13 passed to the full text phase; of those, seven were considered relevant for the QPS assessment.

From the relevant reports, it was concluded that they either concerned fundamental and mechanistic aspects of baculoviruses or medical and/or pharmaceutical applications of baculovirus vector-derived products, stating their safety to humans (OECD, 2002; Lapointe et al., 2012; Airenne et al., 2013; Chen et al., 2013; O'Flynn et al., 2013; Swift et al., 2013; Fujihira et al., 2014; Felberbaum, 2015; Fujita et al., 2015).

No scientific evidence indicated that these viruses have any negative effects on animals and humans to date. In addition, the familiarity principle was taken into consideration. Baculoviruses have been extensively used for over seven decades as biocontrol agents of insect pests without any report of a negative effect on humans or animals. The Organisation for Economic Cooperation and Development (OECD) already concluded in 2002 that baculoviruses were safe to use for products meant for human consumption (OECD, 2002). This opinion was supported in a more recent review by Lapointe et al. (2012).

A matter of concern has been the observation that the budded virus phenotype of baculoviruses is able to enter vertebrate cells, including mammalian cells and tissues (Hofmann et al., 1995). This baculovirus phenotype is responsible for the systemic infection of insect larvae and has been developed into an effective gene delivery vehicle (vector) for gene therapy. So far, there is no evidence that such a baculovirus-derived vectors can transform vertebrate cells or induce malignancies in test animals or humans (Fleming and Hunt, 2000; Kost and Condreay, 2001; Chen et al., 2011; EFSA

BIOHAZ Panel, 2013). In addition, this phenotype is not present in the occlusion bodies that are sprayed to control insects.

Update on other qualifications

Not applicable.

Other relevant information

The impact of using baculoviruses as insect biocontrol agents on the environment has been assessed in an OECD report in 2002 and again in a FAO report in 2007 (McWilliam, 2007). From both assessments was apparent clear that there is no major impact on the environment, beyond what is expected from an intervention, other than the elimination of pest insects. There is, for example, no effect on non-target insects and no long-term effects on the ecosystem. Short-term effects may be the depletion of food (insects) for birds and reptiles, but the ecological balance is expected to be restored in the long-term.

Conclusion regarding the maintenance of the QPS recommendation

On the basis of the scientific information found including the one retrieved through the ELS, the QPS recommendation on members of the Baculoviridae family does not change and that the family Baculoviridae is the lowest TU with QPS.

3.6. Taxonomic groups excluded from the QPS exercise

3.6.1. Bacteriophages

In the 2009 Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed, “phages were not considered appropriate for consideration as QPS organisms because: (i) no rational classification could be established to the species level and (ii) discarding temperate phages, which promote bacterial survival through superinfection immunity and confer new, potentially harming, properties to their hosts (lysogenic conversion) and elimination of bacterial DNA transfecting phages, had to be done on a case-by-case basis.

After a 5-year period without considering phages for QPS, the working group again raised the question, based on two premises: (i) the TU to be taken into consideration may not be the species (for instance, families are being considered for insect and plant specific viruses) and (ii) the impediments associated with phage biology might be converted into qualifications.

The outcome of the discussion was, against changing the bacteriophage consideration with respect to QPS. The reasons were: (i) the lowest level phylogenetic TU should be the order Caudovirales (which includes 95% of all known phages) and which was considered to be too wide; (ii) qualifications are perceived as traits whose presence/absence in an otherwise safe organism, can be tested with procedures that provide unequivocal answers, are limited in number, and are easy to apply. Testing for virulence vs temperate, for the absence of genes that promote lysogenic conversion and deciphering the DNA packaging mechanisms as a means to distinguish between transducing and non-transducing phages would involve thorough analysis of the genomes.

These reservations indicated that phage application on foods should remain as a case-by-case procedure and, consequently, that these biological entities should not be considered for the QPS status.

3.6.2. Clades of *Enterococcus faecium*

The QPS approach relies on the basis of the evaluation of TU, where the species/subspecies level is the lowest level of evaluation. Therefore, clades within the *E. faecium* species cannot be considered as a TU and cannot be evaluated separately. The specific guidance document on *E. faecium* produced by the FEEDAP Panel in 2012 is a valuable tool that enables a simplified evaluation without unnecessary animal experiments outside the QPS approach (EFSA FEEDAP Panel, 2012c). This approach considers that strain of *E. faecium* that do not contain marker genes typical of hospital-associated isolates responsible for clinical infections or show resistance to clinically relevant antibiotics are considered safe for use as feed additives.

Thus, the conclusions of the last update on the QPS (EFSA BIOHAZ Panel, 2013) are still valid and *E. faecium* should be monitored and re-evaluated in the next QPS Opinion update.

3.6.3. Filamentous fungi

Although fungal taxonomy is in a rapid development, still these studies seldom provide information about the ecological properties and the function of the TUs. The discontinuation of dual nomenclature for pleomorphic fungi has resulted in nomenclatural changes to well-established fungal species. The increasing availability of fungal genome sequences is facilitating the discovery and characterisation of numerous novel secondary metabolites by genome mining. While knowledge of fungal secondary metabolites has grown to a big extent, information on their toxic effects in humans and animals is still evolving at a much slower rate.

Therefore, it was decided that until further notice, filamentous fungi are excluded from the QPS evaluations. Their status should be monitored and re-evaluated in the next QPS Opinion update.

4. Conclusions

Answer to the terms of reference (ToR):

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, FIP 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."

The list of biological agents notified in the context of technical dossiers was updated. From the last notifications received for the previous QPS Opinion in 2013, 405 notifications were received between May 2013 and September 2016; of which, 137 were from Feed, 196 from FIP, 11 from Nutrition and 61 from Pesticides. For the type of microorganisms, 183 were bacteria, 177 filamentous fungi, 9 viruses and 36 yeasts TUs.

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."

All TUs that had been previously recommended for the QPS list in the 2013 Opinion were reviewed and confirmed. The information of the previous opinion was updated and the qualifications were also confirmed. An ELS was included, which has allowed a better harmonisation and transparency of the assessment process, identifying the criteria to exclude possible safety concerns described in the articles identified within the search and screened as relevant. A more structured description of the evaluation process for the revision of TUs included in the QPS list, as well as for those evaluated for a possible QPS recommendation from new notifications (ToR3) has been applied. Information about antimicrobial resistance has been reviewed following recent recommendations from EFSA Opinions published in this topic.

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."

Five Panel Statements have been published periodically (approximately every 6 months) in order to assess the suitability of new TU notified to EFSA and to update the list with those biological agents that were recommended for the QPS list. From a total of 405 notifications, 153 biological agents already had a QPS status and were not further evaluated, neither were the 188 filamentous fungi and enterococci, biological groups which have been excluded from QPS consideration (following a recommendation of the QPS 2013 update, 28 were not included because the corresponding TUs have already been evaluated in the previous Statements during this period. Furthermore, it was agreed not to include nine notifications from Pesticides Unit as the respective dossiers (including the literature review) were not yet received. The remaining 41 biological agents were assessed for the suitability of the respective TUs for inclusion in the QPS list.

As a result of the evaluation, *C. divergens*, *L. diolivorans*, *M. imperiale*, *P. nishizawae*, *P. parvulus*, *B. flexus*, *B. smithii*, *X. campestris* and *C. cylindracea* are included in this Opinion as new members since the 2013 update. This increased periodicity (instead of once per year before 2014) has allowed faster support to the EFSA Risk Assessment of regulated products, before the finalisation of the evaluation of the application for market authorisation of those products. Some changes in the evaluation done in the previous Panel Statements have been made in relation to *P. nishizawae* and *C. divergens*.

Enterococcus faecium is not recommended for the QPS list in spite of advances in recent scientific knowledge allowing a differentiation of pathogenic from non-pathogenic strains at the clade level. The QPS approach relies on the basis of the evaluation of TU, where the species/subspecies level is the

lowest level of evaluation. Therefore, clades within the *E. faecium* species cannot be considered as a TU and cannot be evaluated separately.

The exclusion of filamentous fungi from the QPS evaluations was reconsidered but it was recommended to keep the monitoring and to re-evaluate it in the next QPS Opinion update.

Evaluation of bacteriophages should remain as a case-by-case procedure and should not be considered for QPS status.

5. Recommendations

An ELS was incorporated in the process (related to ToR2) improving the level of harmonisation and transparency of the assessment. The lessons learned during this exercise will allow identifying ways to improve and refine the searches and include further exclusion criteria during future exercises. The criteria to judge the information provided by the selected studies, as the possible safety concerns related to a certain TU, such as the identification methodologies used or the presence of microorganisms in immune-compromised/suppressed patients, should be carefully monitored and updated in future evaluations.

While recent findings screened since 2013 do not warrant any reconsideration of the QPS status of lactic acid bacteria (LAB) and *Bacillus* species, further studies on both human and veterinary clinical isolates particularly from cases where there have been no predisposing factors, should be considered to find out any specific factors that might contribute to the pathogenicity.

Regarding LAB, in particular for *Lactococcus lactis*, further studies on both human and veterinary clinical isolates could be considered to find out any possible strain specific factors that might contribute to the pathogenicity.

Consumption of microorganisms such as *Bifidobacterium* species, *Lactobacillus* and *S. boulardi* (*cerevisiae*) by patients with immunosuppression and/or underlying disease can be the origin of the infection described in some articles. Although the use of microorganisms intended to be used as 'probiotic' for humans as a health claim does not fall under the remit of the QPS assessment, attention should be paid to this aspect.

The possible inclusion of *E. faecium* and filamentous fungi TUs in the QPS list should be monitored and re-evaluated in the next QPS Opinion update. Bacteriophages are not foreseen to be eligible for QPS status.

Advances in AMR of microorganisms are rapidly evolving and should keep being closely monitored and taken into consideration for revision of QPS microorganisms and for the evaluation of new TUs.

More information on the 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 is needed.

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Abbreviations

AMR	antimicrobial resistance
BIOHAZ Panel	EFSA Panel on Biological Hazards
CEF Panel	EFSA Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids
DG SANCO	Health and Food Safety Directorate General
ELS	Extensive Literature Search
EPS	exopolysaccharides
FDA	Food and Drug Administration
FEEDAP Panel	EFSA Panel on Additives and Products of Substances used in Animal Feed
FIP	Food Ingredients and Packaging
FSTA	Food Science Technology Abstracts
GGT	gamma-glutamyltranspeptidase
GMM	Genetically modified microorganisms
GRAS	Generally Recognised As Safe
ICN	International Code of Nomenclature
ICTF	International Commission on the Taxonomy of Fungi
ICTV	International Commission on the Taxonomy of Viruses
IJSEM	International Journal of Systematic and Evolutionary Microbiology
LAB	lactic acid bacteria
LBSN	List of Bacterial names with Standing in Nomenclature
LPSN	List of Prokaryotic names with Standing in Nomenclature

MALDI-TOF MS	Matrix-Assisted Laser Desorption/ionisation Time-of-Flight Mass Spectrometry
MIC	minimal inhibitory concentration values
NDA Panel	EFSA Panel on Dietetic Products, Nutrition and Allergies
NF	Novel Food
OECD	Organisation for Economic Cooperation and Development
QPS	Qualified Presumption of Safety
PCR	polymerase chain reaction
PCR-RFLP	polymerase chain reaction-restriction fragment length polymorphism
PECO	Population Exposure Comparator Outcome
ToR	Term of reference
TU	taxonomic unit
WG	Working Group

Appendix A – 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 A.1 below, was revised in accordance with a self-task mandate of the BIOHAZ Panel. Additions to the QPS list (EFSA BIOHAZ Panel, 2017) are published as an Appendix to the BIOHAZ Panel Statements published around every 6 months, with the first revision in the Panel Statement adopted in June 2017 and the last revision in the Scientific Opinion of the BIOHAZ Panel planned for adoption in December 2019. The most up-to-date QPS list is published on the web as an Appendix included in the document and also as a separate file associated with the respective revision.

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

Bacteria			
Gram-positive non-sporulating bacteria			
Species			Qualifications ^(a)
<i>Bifidobacterium adolescentis</i>	<i>Bifidobacterium bifidum</i>	<i>Bifidobacterium longum</i>	
<i>Bifidobacterium animalis</i>	<i>Bifidobacterium breve</i>		
<i>Carnobacterium divergens</i> ^(b)			
<i>Corynebacterium glutamicum</i> ^(c)			QPS only applies when the species is used for amino acid production.
<i>Lactobacillus acidophilus</i>	<i>Lactobacillus delbrueckii</i>	<i>Lactobacillus paracasei</i>	
<i>Lactobacillus amylolyticus</i>	<i>Lactobacillus diolivorans</i> ^(f)	<i>Lactobacillus paraplantarum</i>	
<i>Lactobacillus amylovorus</i>	<i>Lactobacillus farciminis</i>	<i>Lactobacillus pentosus</i>	
<i>Lactobacillus animalis</i> ^(d)	<i>Lactobacillus fermentum</i>	<i>Lactobacillus plantarum</i>	
<i>Lactobacillus alimentarius</i>	<i>Lactobacillus gallinarum</i>	<i>Lactobacillus pontis</i>	
<i>Lactobacillus aviaries</i>	<i>Lactobacillus gasseri</i>	<i>Lactobacillus reuteri</i>	
<i>Lactobacillus brevis</i>	<i>Lactobacillus helveticus</i>	<i>Lactobacillus rhamnosus</i>	
<i>Lactobacillus buchneri</i>	<i>Lactobacillus hilgardii</i>	<i>Lactobacillus sakei</i>	
<i>Lactobacillus casei</i> ^(e)	<i>Lactobacillus johnsonii</i>	<i>Lactobacillus salivarius</i>	
<i>Lactobacillus cellobiosus</i>	<i>Lactobacillus kefir</i>	<i>Lactobacillus sanfranciscensis</i>	
<i>Lactobacillus collinoides</i>	<i>Lactobacillus kefir</i>		
<i>Lactobacillus coryniformis</i>	<i>Lactobacillus mucosae</i>		
<i>Lactobacillus crispatus</i>	<i>Lactobacillus panis</i>		
<i>Lactobacillus curvatus</i>			
<i>Lactococcus lactis</i>			
<i>Leuconostoc citreum</i>	<i>Leuconostoc mesenteroides</i>	<i>Leuconostoc pseudomesenteroides</i>	
<i>Leuconostoc lactis</i>			
<i>Microbacterium imperiale</i> ^(b)			QPS only applies when the species is used for enzyme production.
<i>Oenococcus oeni</i>			
<i>Pasteuria nishizawae</i> ^(g)			
<i>Pediococcus acidilactici</i>	<i>Pediococcus parvulus</i> ^(f)	<i>Pediococcus pentosaceus</i>	
<i>Pediococcus dextrinicus</i>			
<i>Propionibacterium acidipropionici</i>	<i>Propionibacterium freudenreichii</i>		
<i>Streptococcus thermophilus</i>			

Gram-positive spore-forming bacteria			
<i>Bacillus</i>			
Species			Qualifications ^(a)
<i>Bacillus amyloliquefaciens</i>	<i>Bacillus fusiformis</i>	<i>Bacillus mojavensis</i>	Absence of toxigenic activity.
<i>Bacillus atrophaeus</i>	<i>Paenibacillus lentus</i>	<i>Bacillus pumilus</i>	
<i>Bacillus clausii</i>	<i>Bacillus licheniformis</i>	<i>Bacillus smithii</i> ^(h)	
<i>Bacillus coagulans</i>	<i>Bacillus megaterium</i>	<i>Bacillus subtilis</i>	
<i>Bacillus flexus</i> ^(f)		<i>Bacillus vallismortis</i>	
<i>Geobacillus stearothermophilus</i>			Absence of toxigenic activity.
Gram-negative bacteria			
Species			Qualifications ^(a)
<i>Gluconobacter oxydans</i>			QPS only applies when the species is used for vitamin production.
<i>Xanthomonas campestris</i> ⁽ⁱ⁾			QPS only applies when the species is used for the production of xanthan gum.
Yeasts ^(j)			
Species			Qualifications
<i>Candida cylindracea</i> ^(b)			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>			QPS only applies when the species is used for enzyme production.
<i>Lindnera jadinii</i>			
<i>Ogataea angusta</i>			
<i>Saccharomyces bayanus</i>	<i>Saccharomyces cerevisiae</i> ^(k)	<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. In the case of <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. 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			

QPS: Qualified Presumption of Safety.

A specific representative of a QPS proposed taxonomic unit, does not need to undergo a further safety assessment other than to satisfy any of the qualifications specified 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): Microorganisms recommended in the Panel Statement published in July 2017.

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

(f): Microorganisms recommended in this Panel Statement published in June 2016.

(g): Microorganisms recommended in the Panel Statement published in December 2015.

(h): Microorganisms recommended in the Panel Statement published in January 2017.

(i): Microorganisms recommended in the Panel Statement published in June 2015.

(j): 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 kefir*;
- *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*.

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

Appendix B – Extensive Literature Search, relevance screening, and article evaluation for the maintenance and update of list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA

This Extensive Literature Search (ELS) protocol will be used in the context of the EFSA self-task mandate on the update of the list of QPS-recommended biological agents intentionally added to the food or feed (EFSA-Q-2014-00189).

B.1. Objective of the Extensive Literature Search

An ELS of studies related to safety concerns for humans, animals, plants and/or the environment of microorganisms recommended for the Qualified Presumption of Safety (QPS) 2016 list was performed. The aim was to identify any publicly available studies reporting on safety concerns for humans, animals or the environment caused by Gram-positive non-sporulating bacteria, Gram-positive sporulating bacteria, Gram-negative bacteria, viruses (used for plant protection purposes) and yeasts on the QPS recommended list (as identified by EFSA in the terms of reference and on Table 1 from the 2013 update QPS Scientific Opinion) since the previous QPS review (i.e. publications from 2013 until the date of the search). The results of the ELS are part of ToR 2 of the self-task mandate and are intended to inform the BIOHAZ Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA.

The task included the following steps:

- ELS for potentially relevant citations;
- Relevance screening to be used to select the citations identified by the literature search, based on titles and full-text;
- Evaluation of articles according to pre-specified categories of possible safety concerns.

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

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

B.1.1. Target population

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

B.1.2. Exposure

Citations must report on at least one species included in one of the five groups of named species specified in the EFSA QPS recommended list (Table 1) of the QPS 2013 update:

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

Namely:

- a) Gram-positive non-sporulating bacteria:

Bifidobacterium adolescentis, *Bifidobacterium animalis*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium longum*, *Corynebacterium glutamicum*, *Lactobacillus acidophilus*, *Lactobacillus amylolyticus*, *Lactobacillus amylovorus*, *Lactobacillus alimentarius*, *Lactobacillus aviaries*, *Lactobacillus brevis*, *Lactobacillus buchneri*, *Lactobacillus casei*, *Lactobacillus cellobiosus*, *Lactobacillus collinoides*, *Lactobacillus coryniformis*, *Lactobacillus crispatus*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii*, *Lactobacillus farciminis*, *Lactobacillus fermentum*, *Lactobacillus gallinarum*, *Lactobacillus gasseri*, *Lactobacillus helveticus*, *Lactobacillus hilgardii*, *Lactobacillus johnsonii*, *Lactobacillus kefiranoferiens*, *Lactobacillus kefir*, *Lactobacillus mucosae*, *Lactobacillus panis*, *Lactobacillus paracasei*, *Lactobacillus*

paraplantarum, Lactobacillus pentosus, Lactobacillus plantarum, Lactobacillus pontis, Lactobacillus reuteri, Lactobacillus rhamnosus, Lactobacillus sakei, Lactobacillus salivarius, Lactobacillus sanfranciscensis, Lactococcus lactis, Leuconostoc citreum, Leuconostoc lactis, Leuconostoc mesenteroides, Leuconostoc pseudomesenteroides, Oenococcus oeni, Pediococcus acidilactici, Pediococcus dextrinicus, Pediococcus pentosaceus, Propionibacterium freudenreichii, Propionibacterium acidopropionici, Streptococcus thermophilus;

b) Gram-positive sporulating bacteria:

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

c) Gram-negative bacteria:

Gluconobacter oxydans;

d) Viruses used for plant protection:

Plant viruses (Family): Alphaflexiviridae, Potyviridae;

Insect viruses (Family): Baculoviridae;

e) Yeasts:

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

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

B.1.3. Comparator

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

The comparator was not included as a key element in the search strategy; it would be difficult to express using free text or index terms and may not be explicitly described in the title or abstract.

B.1.4. Outcomes of interest

Outcomes of interest to this ELS are:

Question 1:

- potential harms
- safety issues
- virulence or infectious characteristics
- intoxication

Question 2:

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

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

B.1.5. Identification of the review questions

As this task involves an ELS, followed by screening for relevance and article evaluation, the research questions were broad in scope rather than focussed as appropriate to a systematic review:

- Is there evidence of any safety concerns, including virulence features and toxin production, for humans, animals, plants and/or the environment associated with microbial species currently recommended for the QPS list since the previous QPS review (2013 QPS update)?
- Is there evidence related to the presence or absence of antimicrobial resistance or antimicrobial resistance genes for the same microbial species published during the same time period?

B.2. Eligibility criteria for study selection

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

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

	Criteria
Study design	No specific type of study design will be used to include/exclude relevant studies, although it is expected that the prevalent study designs will be case reports or case series and studies based on surveys or isolate collections
Study characteristics:	No exclusion will be based on study characteristics but 3 criteria for reliability of studies are proposed at the stage of article evaluation (see Section B.4 'Study selection and article evaluation' below) (i) taxonomical identification carried out and well described (including method applied); (ii) clear statement on the relationship between the microorganism and the host in case of infection/disease; (iii) rationale about exposure to the microorganism is well reported and is consistent
Population	Humans, animals, plants and the environment
Exposure	Studies must report on at least one TU as identified in Section B.1.2
Outcome of interest	Outcomes as listed in Section B.1.4
Language	English
Time	2013 until 6 June 2016
Publication type	Primary research studies (i.e. studies generating new data)

B.3. Literature searches

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

Scoping searches were run to test the key terms and strategies identified, as well as the information sources selected.

Considering the results of the scoping search to handle the high number of studies identified in each group, 16 search strategies were prepared: three for yeasts, one for insect viruses, one for plant viruses, ten for Gram-positive bacteria and one for Gram-negative bacteria according to named species specified by EFSA in the QPS recommended list (Table A.1) of the QPS 2013 update (see Appendix A).

The 16 subgroups of target microbial species will be searched separately.

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

B.3.1. Search terms

The search strategies used to identify studies are given in Appendix C.

Each strategy will comprise two key elements:

- Target microbial species as described in Section B.1.2 ('Exposure')
- Safety issues as described in Section B.1.4 ('Outcomes')

Scoping exercises were carried out to check whether the search strategy can be run without including outcome related terms; this has the purpose of maximising the search sensitivity and should be feasible for those selected species for which the number of overall publications in the relevant time period is expected to be low.

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

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

The 16 subgroups of target microbial species were entered on separate search lines. The search line for each group will be combined with the safety terms individually. This allowed the number of results returned for each of the subgroups to be identified.

The searches were not limited by language or study design. The review period was 2013 until 6 June 2016.

B.3.2. Information sources searched

A range of information sources indexing published research were searched for studies reporting safety concerns regarding the target microbial species.

Searches to identify studies for the 2013 Qualified Presumption of Safety (QPS) list were run in the following information sources: PubMed, Web of Knowledge, CasesDatabase, Google Scholar, CAB Abstracts and Food Technology Science Abstracts. The evaluation of the results obtained revealed that CAB Abstracts and BIOSIS Citation Index appeared to be the information sources that provided the greatest added value in this topic area.

Information sources with coverage of grey literature such as Science.gov, ScienceResearch.com, OpenGREY and conference websites were not included.

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

Information source	Interface
Web of Science Core Collection	Web of Science, Thomson Reuters 2016
CAB Abstracts	Web of Science, Thomson Reuters 2016
BIOSIS Citation Index	Web of Science, Thomson Reuters 2016
MEDLINE	Web of Science, Thomson Reuters 2016
Food Science Technology Abstracts (FSTA)	Web of Science, Thomson Reuters 2016

Search results were downloaded from the information sources and imported into EndNote® X7 bibliographic management software. For each of the 16 species groups, within-group removal of duplicate entries was done in EndNote® X7. Following uploading of the species groups into the DistillerSR online software, removal of duplicates was again undertaken, using the Duplicate Detection feature.

B.4. Study selection and article evaluation

Studies to be included in the review were selected by a two-step selection procedure.

B.4.1. Screening for potential relevance

To identify potentially relevant studies that will be included for article evaluation.

It will be carried out at title level.

If the information contained in the title is not relevant for the research objectives, the article is not selected for 'Article evaluation'. Articles that will be excluded during screening this step will be stored in DistillerSR.

This step will be conducted in duplicate by experts and, if needed, EFSA staff. In case of doubts or divergences between the reviewers, the paper will proceed to step 2.

B.4.2. Article evaluation

To confirm that the article is relevant for the QPS project and, in case it is, to evaluate it.

It will be carried out at full text level.

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

This step will be conducted in duplicate by the experts. In case of divergences between the reviewers an agreement will be reached between the two experts reviewing the study.

Screeners will be trained using written documentation on study eligibility. Eligibility criteria will be pilot tested on a subset of records, and refined if prone to misinterpretation. The results of the different phases of the study selection process will be reported in a flowchart as recommended in the PRISMA statement on preferred reporting items for systematic reviews and meta-analyses (Moher et al., 2009).

The studies and related form will be inserted in the DistillerSR software.

B.4.2.1. Questions for study selection and article evaluation

STEP 1 (Screening for potential relevance):

Question 1: Can this article be relevant for QPS project?

- Yes or Unclear: Include and continue to Article evaluation form
- No: Exclude

STEP 2 (Article evaluation):

Question 2: Is the full text available?

- Yes: Include and continue to the Article evaluation form
- No: Exclude

Question 3: Is the full text in English?

- Yes: Include and continue to the Article evaluation form
- No: Exclude

Question 4: Is the article relevant for QPS project?

- Yes: Include and continue to the Article evaluation form
- No: Exclude

Question 5: Identification of the microorganisms

- The article will be characterised in terms of the microorganisms involved (multiple choice question: the expert can identify the microorganism/s described in the article)

Question 6: Safety concerns with an impact on human health

- Free text

Question 7: Safety concerns with an impact on animal health

- Free text

Question 8: Safety concerns with an impact on the environment

- Free text

Question 9: Safety concerns related to AMR (antimicrobial resistance factors)

- Free text

Question 10: Other concerns (please specify)

- Free text

B.5. Presentation of the results

The overall results of the searches and evaluations of individual articles will be presented in tabular format for each group/subgroup and species.

B.6. Evidence becoming available after the first deadline for retrieving evidence

The literature search (Annexes B and C) will be repeated every 6 months.

B.7. Human resources, software and timelines for performing the ELS

Tasks for performing ELS were allocated among EFSA staff members and WG experts as shown in the table below. Provisional deadlines were agreed in advance and were subject to changes depending on the volume of data retrieved.

Table B.3: Task allocation for performing the ELS

WHAT	WHO	SOFTWARE	WHEN (PROVISIONAL)
Search process	EFSA staff	Endnote	Nov 2015
Screening title	WG experts (with EFSA staff)	DistillerSR	Dec 2015–Jan 2016
Evaluation of articles	WG experts	DistillerSR	Dec 2015–Feb 2016
Presentation of the results	EFSA staff	DistillerSR	March 2016

References

- EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). EFSA Journal 2013;11(11):3449, 108 pp. doi:10.2903/j.efsa.2013.3449
- Moher D, Liberati A, Tetzlaff J and Altman DG for the PRISMA Group, 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. British Medical Journal, 338, b2535. doi:10.1136/bmj.b2535

Appendix C – Search strategies

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium

String for species	
' <i>Bifidobacterium adolescentis</i> ' OR ' <i>Bifidobacterium animalis</i> ' OR ' <i>Bifidobacterium bifidum</i> ' OR ' <i>Bifidobacterium breve</i> ' OR ' <i>Bifidobacterium longum</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistanc*' OR 'antibiotic resistanc*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* OR septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Corynebacterium glutamicum

String for species	
' <i>Corynebacterium glutamicum</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistanc*' OR 'antibiotic resistanc*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* OR septic* OR bacteremia OR bacteraemia OR toxin* OR 'pathogen*'
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Lactobacilli

String for species	
' <i>Lactobacillus acidophilus</i> ' OR ' <i>Lactobacillus amylolyticus</i> ' OR ' <i>Lactobacillus amylovorus</i> ' OR ' <i>Lactobacillus alimentarius</i> ' OR ' <i>Lactobacillus aviaries</i> ' OR ' <i>Lactobacillus brevis</i> ' OR ' <i>Lactobacillus buchneri</i> ' OR ' <i>Lactobacillus casei</i> ' OR ' <i>Lactobacillus zeae</i> ' OR ' <i>Lactobacillus cellobiosus</i> ' OR ' <i>Lactobacillus coryniformis</i> ' OR ' <i>Lactobacillus crispatus</i> ' OR ' <i>Lactobacillus curvatus</i> ' OR ' <i>Lactobacillus delbrueckii</i> ' OR ' <i>Lactobacillus farciminis</i> ' OR ' <i>Lactobacillus fermentum</i> ' OR ' <i>Lactobacillus gallinarum</i> ' OR ' <i>Lactobacillus gasseri</i> ' OR ' <i>Lactobacillus helveticus</i> ' OR ' <i>Lactobacillus hilgardii</i> ' OR ' <i>Lactobacillus johnsonii</i> ' OR ' <i>Lactobacillus kefirifaciens</i> ' OR ' <i>Lactobacillus kefir</i> ' OR ' <i>Lactobacillus mucosae</i> ' OR ' <i>Lactobacillus panis</i> ' OR ' <i>Lactobacillus collinoides</i> ' OR ' <i>Lactobacillus paracasei</i> ' OR ' <i>Lactobacillus paraplantarum</i> ' OR ' <i>Lactobacillus pentosus</i> ' OR ' <i>Lactobacillus plantarum</i> ' OR ' <i>Lactobacillus pontis</i> ' OR ' <i>Lactobacillus reuteri</i> ' OR ' <i>Lactobacillus rhamnosus</i> ' OR ' <i>Lactobacillus sakei</i> ' OR ' <i>Lactobacillus salivarius</i> ' OR ' <i>Lactobacillus sanfranciscensis</i> '	

OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistan*' OR 'antibiotic resistan*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	<i>Not applied</i>
5. Disease Risk	opportunistic OR virulen*

Lactococcus lactis

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

Oenococcus

String for species	
' <i>Oenococcus oeni</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	<i>Not applied</i>
2. Infection/Bacteraemia/Fungaemia/Sepsis	<i>Not applied</i>
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	<i>Not applied</i>
5. Disease Risk	<i>Not applied</i>

Leuconostoc

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

Pediococci

String for species	
' <i>Pediococcus pentosaceus</i> ' OR ' <i>Pediococcus dextrinicus</i> ' OR ' <i>Pediococcus acidilactici</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	<i>Not applied</i>
2. Infection/Bacteraemia/Fungaemia/Sepsis	<i>Not applied</i>
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	<i>Not applied</i>
5. Disease Risk	<i>Not applied</i>

Propionibacterium

String for species	
' <i>Propionibacterium acidipropionici</i> ' OR ' <i>Propionibacterium freudenreichii</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	<i>Not applied</i>
2. Infection/Bacteraemia/Fungaemia/Sepsis	<i>Not applied</i>
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	<i>Not applied</i>
5. Disease Risk	<i>Not applied</i>

Streptococcus thermophilus

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

Gram-Positive Sporulating Bacteria***Bacillus***

String for species	
' <i>Bacillus amyloliquefaciens</i> ' OR ' <i>Bacillus coagulans</i> ' OR ' <i>Bacillus clausii</i> ' OR ' <i>Bacillus atrophaeus</i> ' OR ' <i>Bacillus fusiformis</i> ' OR ' <i>Lysinibacillus fusiformis</i> ' OR ' <i>Bacillus licheniformis</i> ' OR ' <i>Bacillus lentus</i> ' OR ' <i>Bacillus mojavensis</i> ' OR ' <i>Bacillus megaterium</i> ' OR ' <i>Bacillus vallismortis</i> ' OR ' <i>Bacillus subtilis</i> ' OR ' <i>Bacillus pumilus</i> ' OR ' <i>Geobacillus stearothermophilus</i> '	

OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistanc*' OR 'antibiotic resistanc*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* OR septic* OR bacteremia OR bacteraemia OR toxin*
3. Type of disease	endocarditis OR abscess OR meningitis
4. Mortality/Morbidity	Not applied
5. Disease Risk	opportunistic OR virulen*

Gram-negative bacteria

Gluconobacter oxydans

String for species	
' <i>Gluconobacter oxydans</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	Not applied
2. Infection/Bacteraemia/Fungaemia/Sepsis	Not applied
3. Type of disease	Not applied
4. Mortality/Morbidity	Not applied
5. Disease Risk	Not applied

Yeasts

Debaryomyces hansenii ...

String for species	
' <i>debaryomyces hansenii</i> ' OR ' <i>candida famata</i> ' OR ' <i>hanseniaspora uvarum</i> ' OR ' <i>kloeckera apiculata</i> ' OR ' <i>candida spherica</i> ' OR ' <i>candida kefir</i> ' OR ' <i>lindnera jadinii</i> ' OR ' <i>pichia jadinii</i> ' OR ' <i>hansenula jadinii</i> ' OR ' <i>torulopsis utilis</i> ' OR ' <i>ogataea angusta</i> ' OR ' <i>pichia angusta</i> ' OR ' <i>saccharomyces bayanus</i> ' OR ' <i>saccharomyces pastorianus</i> ' OR ' <i>saccharomyces carlsbergensis</i> ' OR ' <i>wickerhamomyces anomalus</i> ' OR ' <i>hansenula anomala</i> ' OR ' <i>pichia anomala</i> ' OR ' <i>candida pelliculosa</i> ' OR ' <i>xanthophyllomyces dendrorhous</i> ' OR ' <i>phaffia rhodozyma</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	Not applied
2. Infection/Bacteraemia/Fungaemia/Sepsis	Not applied
3. Type of disease	Not applied
4. Mortality/Morbidity	Not applied
5. Disease Risk	Not applied

Kluyveromyces lactis ...

String for species	
' <i>Kluyveromyces lactis</i> ' OR ' <i>Kluyveromyces marxianus</i> ' OR ' <i>Komagataella pastoris</i> ' OR ' <i>Pichia pastoris</i> ' OR ' <i>Candida utilis</i> ' OR ' <i>Saccharomyces boulardii</i> ' OR ' <i>Schizosaccharomyces pombe</i> '	

OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistan*' OR 'antimycotic resistan*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR fungemia OR fungaemia OR mycos*
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	clinical* OR death* OR morbidit* OR mortalit* OR disease* OR illness*
5. Disease Risk	opportunistic OR virulen*

Saccharomyces cerevisiae

String for species	
' <i>Saccharomyces cerevisiae</i> '	
OUTCOME	String
1. Antimicrobial/Antibiotic/Antimycotic	'antimicrobial resistan*' OR 'antimycotic resistan*' OR 'antimicrobial susceptibil*'
2. Infection/Bacteraemia/Fungaemia/Sepsis	infection* OR abscess* OR sepsis* or septic* OR fungemia OR fungaemia OR mycos*
3. Type of disease	<i>Not applied</i>
4. Mortality/Morbidity	<i>Not applied</i>
5. Disease Risk	opportunistic or virulen*

Viruses used for plant protection

Baculoviridae

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

Alphaflexiviridae

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

Appendix D – References selected from the ELS exercise as relevant for the QPS

Gram-Positive Non-Sporulating Bacteria

Bifidobacterium

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Lactococcus lactis

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Viruses used for plant protection

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Appendix E – Microbial species as notified to EFSA until September 2016

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Bacteria				
Feed/FEEDAP	<i>Actinomadura roseorufa</i> ATCC 53664	Production of semduramicin (coccidiostat)	EFSA-Q-2014-00219	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion ' <i>A. roseorufa</i> produces semduramicin, an approved coccidiostat, with antimicrobial activity and therefore cannot be considered for the QPS list. Moreover its identity is not well established'. Please refer to the complete assessment. Also notified for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a).
Feed/FEEDAP	<i>Actinomadura roseorufa</i> ATCC 53664	Production of semduramicin sodium	EFSA-Q-2015-00714	
Feed/FEEDAP	<i>Actinomadura yumaensis</i>	Production of maduramicin ammonium	EFSA-Q-2008-757 http://www.efsa.europa.eu/en/efsajournal/pub/1954 EFSA-Q-2011-00059 http://www.efsa.europa.eu/en/efsajournal/pub/4013	<i>Actinomadura yumaensis</i> produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008).
Feed/FEEDAP	<i>Actinoplanes utahensis</i>	Production of acarbose	EFSA-Q-2007-172 http://www.efsa.europa.eu/en/efsajournal/pub/839	No body of knowledge, therefore it is not appropriate for QPS (EFSA, 2008).
Feed/FEEDAP	<i>Alcaligenes acidovorans</i> = <i>Ralstonia</i> sp.	Biomass for animal feed	EFSA-Q-2004-171 http://www.efsa.europa.eu/en/efsajournal/pub/230	No body of knowledge, therefore it is not appropriate for QPS (EFSA, 2008).
FIP/CEF	<i>Arthrobacter ramosus</i>	Production of food enzyme 4- α -D- $\{(1\rightarrow4)\alpha$ -D-glucano} trehalose trehalohydrolase	EFSA-Q-2016-00135	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel et al., 2017) with the conclusion 'Due to a very limited body of knowledge and the association of some <i>Arthrobacter</i> spp. to human disease (although not food-borne), QPS status cannot be granted to <i>A. ramosus</i> '. Please refer to the complete assessment.
FIP/CEF	<i>Arthrobacter ramosus</i>	Production of food enzyme (1 $\rightarrow$ 4)- α -D-glucan 1- α -D-glucosylmutase	EFSA-Q-2016-00136	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus amyloliquefaciens</i>	Feed additive	EFSA-Q-2007-190 http://www.efsa.europa.eu/en/efsajournal/pub/773 EFSA-Q-2009-00825 http://www.efsa.europa.eu/en/efsajournal/pub/1918 EFSA-Q-2011-00389 http://www.efsa.europa.eu/en/efsajournal/pub/3042 EFSA-Q-2011-00965	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus amyloliquefaciens</i> , GMM strain	Production of enzyme	EFSA-Q-2007-0020 http://www.efsa.europa.eu/en/efsajournal/pub/1156 and related opinions: EFSA-Q-2007-112 http://www.efsa.europa.eu/en/efsajournal/pub/1154 EFSA-Q-2009-00470 http://www.efsa.europa.eu/en/efsajournal/pub/1949 Other applications: EFSA-Q-2010-01295 EFSA-Q-2010-01297 EFSA-Q-2012-00411	
Feed/FEEDAP	<i>Bacillus amyloliquefaciens</i>	Technological additive	EFSA-Q-2016-00646	
FIP/CEF	<i>Bacillus amyloliquefaciens</i>	Production of food enzyme α -amylase	EFSA-Q-2015-00846	
FIP/CEF	<i>Bacillus amyloliquefaciens</i> /AE-GT	Production of food enzyme	EFSA-Q-2015-00289	
Pesticides	<i>Bacillus amyloliquefaciens</i> AH2	Plant protection product	EFSA-Q-2015-00614 Application for approval	
Feed/FEEDAP	<i>Bacillus amyloliquefaciens</i> BS 15A-P4, LSSA01, BS2084	Zootechnical additive	EFSA-Q-2015-00179 http://www.efsa.europa.eu/en/efsajournal/pub/4505	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Bacillus amyloliquefaciens</i> strain FZB240	Plant protection product	EFSA-Q-2014-00322 http://www.efsa.europa.eu/en/efsajournal/pub/4494 Application for approval	
Pesticides	<i>Bacillus amyloliquefaciens</i> strain MBI600	Plant protection product	EFSA-Q-2014-00323 http://www.efsa.europa.eu/en/efsajournal/pub/4359 Application for approval	
Pesticides	<i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747	Plant protection product	EFSA-Q-2013-00038 http://www.efsa.europa.eu/en/efsajournal/pub/3624 Application for approval EFSA-Q-2015-00081 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	
FIP/CEF	<i>Bacillus amyloliquefaciens</i> (strain BANSC)	Production of enzyme amylase	EFSA-Q-2014-00730	
Feed/FEEDAP	<i>Bacillus brevis</i> = <i>Aneurinibacillus</i> and <i>Brevibacillus</i> species Strains from <i>B. brevis</i> are now mostly <i>Brevibacillus</i> species and some are <i>Aneurinibacillus</i> species	Biomass for animal feed	EFSA-Q-2004-171 http://www.efsa.europa.eu/en/efsajournal/pub/230	No sufficient body of knowledge and safety concern because of antibiotic production. Therefore not appropriate for QPS (EFSA, 2008). It will no longer be assessed for the QPS list unless new notification to EFSA (EFSA BIOHAZ Panel, 2010).

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus cereus</i> var. <i>toyoi</i> = <i>B. cereus</i> *	Feed additive	EFSA-Q-2003-086 http://www.efsa.europa.eu/en/efsajournal/pub/62 EFSA-Q-2005-021 http://www.efsa.europa.eu/en/efsajournal/pub/288 EFSA-Q-2006-037 http://www.efsa.europa.eu/en/efsajournal/pub/458 EFSA-Q-2007-090 http://www.efsa.europa.eu/en/efsajournal/pub/549 EFSA-Q-2008-287 http://www.efsa.europa.eu/en/efsajournal/pub/913 EFSA-Q-2010-01095 and EFSA-Q-2011-00832 http://www.efsa.europa.eu/en/efsajournal/pub/3042	QPS status inapplicable for the group of <i>B. cereus</i> strains (see EFSA, 2007, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion ' <i>Bacillus toyonensis</i> cannot be proposed for the QPS list because it is a member of the <i>B. cereus</i> group, and because of the absence of evidences at the species level that it does not present safety concerns'. Please refer to the complete assessment. *The species <i>Bacillus toyonensis</i> (previously <i>B. cereus</i> var. <i>toyoi</i>) was recently published in the validation list no 155 (Oren and Garrity, 2014).
FIP/CEF	<i>Bacillus circulans</i> (AE-LT)	Production of food enzyme β -galactosidase	EFSA-Q-2014-00670	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015a) with the conclusion ' <i>Bacillus circulans</i> is not recommended for the QPS list due to the lack of sufficient body of knowledge on a safe history of use or presence in foods and feeds'. Please refer to the complete assessment.
FIP/CEF	<i>Bacillus circulans</i> (strain M3-1)	Production of food enzyme β -galactosidase	EFSA-Q-2016-00210	
Feed/FEEDAP	<i>Bacillus coagulans</i>	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus coagulans</i>	Production of lactic acid	EFSA-Q-2016-00645	
Feed/FEEDAP	<i>Bacillus coagulans</i>	Zootechnical additive	EFSA-Q-2014-00832	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus firmus</i> = <i>Brevibacillus agri</i>	Biomass for animal feed	EFSA-Q-2004-171 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008). It will no longer be assessed for the QPS list unless new notification to EFSA (EFSA BIOHAZ Panel, 2010).
Pesticides	<i>Bacillus firmus</i> I-1582	Plant protection product	EFSA-Q-2011-00999 http://www.efsa.europa.eu/en/efsajournal/pub/2868 Application for approval EFSA-Q-2013-00346 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residues Limits)	A reassessment of this species was carried out in the QPS 2012 review and it was not recommended for the QPS list Included in the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) but it was agreed not to evaluate it until the respective dossier (including the literature review) is received.
FIP/CEF	<i>Bacillus flexus</i>	Production of food enzyme β -amylase	EFSA-Q-2015-00691	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion ' <i>Bacillus flexus</i> can be recommended for the QPS list with a qualification of absence of toxigenic activity (as applied to all strains of <i>Bacillus</i> species recommended to the QPS list)'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus lentus</i>	Feed additive	EFSA-Q-2006-004 http://www.efsa.europa.eu/en/efsajournal/pub/412 and related question: EFSA-Q-2012-00244	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus lentus</i>	Production of enzyme		

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
European Commission SCF Opinion 2000	<i>Bacillus licheniformis</i>	Production of β -cyclodextrin (food additive carrier and stabiliser of food flavours, food colours and some vitamins)	Scientific Committee on Food SCF/CS/ADD/AMI 52 Final (13 July) Opinion of the Scientific Committee on Food on β -cyclodextrin produced using cycloglycosyl-transferase from a recombinant <i>Bacillus licheniformis</i> (adopted on 22 June 2000) https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out58_en.pdf	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus licheniformis</i>	Production of enzyme	EFSA-Q-2005-090 http://www.efsa.europa.eu/en/efsajournal/pub/351 EFSA-Q-2006-181 http://www.efsa.europa.eu/en/efsajournal/pub/451 EFSA-Q-2010-00139 http://www.efsa.europa.eu/en/efsajournal/pub/2777 EFSA-Q-2008-431 http://www.efsa.europa.eu/en/efsajournal/pub/2777	
Feed/FEEDAP	<i>Bacillus licheniformis</i>	Feed additive	EFSA-Q-2006-136 http://www.efsa.europa.eu/en/efsajournal/pub/2356 EFSA-Q-2007-166 (withdrawn) EFSA-Q-2009-00970 (withdrawn) EFSA-Q-2009-00680 http://www.efsa.europa.eu/en/efsajournal/pub/4558	
Feed/FEEDAP	<i>Bacillus licheniformis</i>	Production of enzyme	EFSA-Q-2014-00575	
FIP/CEF	<i>Bacillus licheniformis</i>	Production of food enzyme α -amylase	EFSA-Q-2014-00911	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Bacillus licheniformis</i> , GMM strain	Production of food enzyme β -galactosidase	EFSA-Q-2015-00093	
FIP/CEF	<i>Bacillus licheniformis</i>	Production of food enzyme subtilisin	EFSA-Q-2015-00232	
FIP/CEF	<i>Bacillus licheniformis</i> , GMM strain	Production of food enzyme glucan 1,4- α -maltotetrahydrolase	EFSA-Q-2015-00448	
FIP/CEF	<i>Bacillus licheniformis</i> , GMM strain	Production of food enzyme α -amylase	EFSA-Q-2015-00666	
FIP/CEF	<i>Bacillus licheniformis</i> , GMM strain	Production of food enzyme pullulanase	EFSA-Q-2015-00667	
FIP/CEF	<i>Bacillus licheniformis</i> , GMM strain	Production of food enzyme acetolactate decarboxylase	EFSA-Q-2016-00031	
Feed/FEEDAP	<i>Bacillus licheniformis</i> (ATCC 53757), GMM strain	Zootechnical additive	EFSA-Q-2013-00630	
FIP/CEF	<i>Bacillus licheniformis</i> (DP-Dzb44), GMM strain	Production of food enzyme α -amylase	EFSA-Q-2015-00836	
FIP/CEF	<i>Bacillus licheniformis</i> /DP-Dzr46, GMM strain	Production of food enzyme glucan 1,4- α -maltotetrahydrolase	EFSA-Q-2016-00095	
FIP/CEF	<i>Bacillus licheniformis</i> /DP-Dzr50, GMM strain	Production of food enzyme glucan 1,4- α -maltotetrahydrolase	EFSA-Q-2016-00096	
FIP/CEF	<i>Bacillus licheniformis</i> /DP-Dzr52, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2016-00093	
Feed/FEEDAP	<i>Bacillus licheniformis</i> DSM 28710	Zootechnical additive	EFSA-Q-2015-00346 http://www.efsa.europa.eu/en/efsajournal/pub/4615	
FIP/CEF	<i>Bacillus licheniformis</i> NZYM-AC, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2013-00586	
FIP/CEF	<i>Bacillus licheniformis</i> (NZYM-AN), GMM strain	Production of food enzyme α -amylase	EFSA-Q-2015-00084	
FIP/CEF	<i>Bacillus licheniformis</i> (NZYM-AV), GMM strain	Production of food enzyme α -amylase	EFSA-Q-2014-00794	
FIP/CEF	<i>Bacillus licheniformis</i> NZYM-BC, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2013-00685	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Bacillus licheniformis</i> (NZYM-BT), GMM strain	Production of food enzyme β -galactosidase	EFSA-Q-2014-00093 (withdrawn)	
FIP/CEF	<i>Bacillus licheniformis</i> (NZYM-CE), GMM strain	Production of food enzyme xylanase	EFSA-Q-2015-00064	
FIP/CEF	<i>Bacillus licheniformis</i> /NZYM-JA	Production of food enzyme	EFSA-Q-2015-00275	
FIP/CEF	<i>Bacillus licheniformis</i> NZYM-KE, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2012-00898	
FIP/CEF	<i>Bacillus licheniformis</i> NZYM-RH, GMM strain	Production of food enzyme serine protease	EFSA-Q-2014-00292	
Feed/FEEDAP	<i>Bacillus megaterium</i>	Production of vitamin C	EFSA-Q-2010-01290 amended to EFSA-Q-2011-00250 http://www.efsa.europa.eu/en/efsajournal/pub/3103	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bacillus pumilus</i>	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.
FIP/CEF	<i>Bacillus pumilus</i> (BLXSC)	Production of food enzyme xylanase	EFSA-Q-2014-00844	
Pesticides	<i>Bacillus pumilus</i> strain QST 2808	Plant protection product	EFSA-Q-2012-00776 http://www.efsa.europa.eu/en/efsajournal/pub/3346 Application for approval EFSA-Q-2014-00359 Review of MRLs (Maximum Residue Limits)	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	' <i>Bacillus smithii</i> '	Production of lactic acid	EFSA-Q-2016-00645	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2017) with the conclusion 'The species <i>Bacillus smithii</i> 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 <i>Bacillus</i> species recommended to the QPS list)'. Please refer to the complete assessment.
Pesticides	<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> (strains ABTS 1857 and GC-91) = <i>Bacillus thuringiensis</i> serovar <i>aizawai</i>	Plant protection product	EFSA-Q-2009-00121 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00247 http://www.efsa.europa.eu/en/efsajournal/pub/3063 Application for approval	Already considered as not appropriate for QPS (see EFSA, 2007. Considered for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a). In agreement with the Pesticides Unit, this notification was kept in standby until the respective dossiers (including the literature review) are received.
Pesticides	<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> (serotype H-14), strain AM 6552 = <i>Bacillus thuringiensis</i> serovar <i>israelensis</i>	Plant protection product	EFSA-Q-2009-00122 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00248 http://www.efsa.europa.eu/it/efsajournal/pub/3054 Application for approval	Mentioned in the current Scientific Opinion (refer to Section 3.2.1) ' <i>B. thuringiensis</i> is not considered for QPS, and therefore papers on this species (e.g. Fagerlund et al., 2014) were not further considered'. A recently published Opinion of the EFSA BIOHAZ Panel addressed the risks for public health related to the presence of <i>Bacillus cereus</i> and other <i>Bacillus</i> spp. including <i>Bacillus thuringiensis</i> in foodstuffs did not report any additional concerns about <i>Bacillus</i> spp. included in the QPS list (EFSA BIOHAZ Panel, 2016b)'. Please refer to the complete assessment.
Pesticides	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> (strains ABTS 351, PB 54, SA11, SA 12, EG 2348) = <i>Bacillus thuringiensis</i> serovar <i>kurstaki</i>	Plant protection product	EFSA-Q-2009-00123 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00249 http://www.efsa.europa.eu/en/efsajournal/pub/2540 Application for approval	
Pesticides	<i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> (strain NB176 (TM 141)) = <i>Bacillus thuringiensis</i> serovar <i>tenebrionis</i>	Plant protection product	EFSA-Q-2009-00124 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00250 http://www.efsa.europa.eu/en/efsajournal/pub/3024 Application for approval	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus subtilis</i>	Feed additive	EFSA-Q-2003-008 http://www.efsa.europa.eu/en/efsajournal/pub/6 EFSA-Q-2004-174 http://www.efsa.europa.eu/en/efsajournal/pub/272 EFSA-Q-2005-150 http://www.efsa.europa.eu/en/efsajournal/pub/336 EFSA-Q-2005-237 http://www.efsa.europa.eu/en/efsajournal/pub/406 EFSA-Q-2006-136 http://www.efsa.europa.eu/en/efsajournal/pub/2356 EFSA-Q-2007-166 (withdrawn) EFSA-Q-2007-040 http://www.efsa.europa.eu/en/efsajournal/pub/543 EFSA-Q-2008-473 www.efsa.europa.eu/en/scdocs/scdoc/1314.htm EFSA-Q-2008-771 http://www.efsa.europa.eu/en/efsajournal/pub/2375 EFSA-Q-2009-00533 http://www.efsa.europa.eu/en/efsajournal/pub/1426	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Evaluated in the current Scientific Opinion (refer to Section 3.2.1) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Bacillus</i> species, as the few infections associated with members of the genus were linked to specific predisposing factors and do not suggest a risk for consumers or animals via exposure through the food and feed chain'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus subtilis</i>	Production of enzyme	EFSA-Q-2007-0020 http://www.efsa.europa.eu/en/efsajournal/pub/1156 EFSA-Q-2012-00411 and related opinions: EFSA-Q-2007-112 http://www.efsa.europa.eu/en/efsajournal/pub/1154 EFSA-Q-2009-00470 http://www.efsa.europa.eu/en/efsajournal/pub/1949 Other applications: EFSA-Q-2010-01298 http://www.efsa.europa.eu/en/efsajournal/pub/4562	
Feed/FEEDAP	<i>Bacillus subtilis</i>	Feed additive	EFSA-Q-2009-00680 http://www.efsa.europa.eu/en/efsajournal/pub/4558 EFSA-Q-2009-00525 http://www.efsa.europa.eu/en/efsajournal/pub/4230 EFSA-Q-2010-00814 http://www.efsa.europa.eu/en/efsajournal/pub/1867 EFSA-Q-2010-01150 http://www.efsa.europa.eu/en/efsajournal/pub/2114 EFSA-Q-2010-01151 http://www.efsa.europa.eu/en/efsajournal/pub/2112 EFSA-Q-2011-01151 http://www.efsa.europa.eu/en/efsajournal/pub/3176 EFSA-Q-2012-00246 http://www.efsa.europa.eu/en/efsajournal/pub/2671	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus subtilis</i>	Production of vitamin B2	EFSA-Q-2010-00991 http://www.efsa.europa.eu/en/efsajournal/pub/3531 EFSA-Q-2010-01319 http://www.efsa.europa.eu/en/efsajournal/pub/4349 EFSA-Q-2012-00954 (withdrawn)	
Feed/FEEDAP	<i>Bacillus subtilis</i>	Zotechnical additive	EFSA-Q-2014-00587	
Feed/FEEDAP	<i>Bacillus subtilis</i>	Zotechnical additive	EFSA-Q-2014-00832	
Feed/FEEDAP	<i>Bacillus subtilis</i>	Technological additive	EFSA-Q-2016-00220	
Feed/FEEDAP	<i>Bacillus subtilis</i>	Production of lactic acid	EFSA-Q-2016-00645	
FIP/CEF	<i>Bacillus subtilis</i>	Production of food enzyme α -amylase	EFSA-Q-2016-00133	
FIP/CEF	<i>Bacillus subtilis</i> (strain 11096)	Production of food enzyme pectate lyase	EFSA-Q-2016-00207	
Feed/FEEDAP	<i>Bacillus subtilis</i> C-3102 (DSM 15544)	Zotechnical additive	EFSA-Q-2015-00004	
Feed/FEEDAP	<i>Bacillus subtilis</i> C-3102 (DSM 15544)	Zotechnical additive	EFSA-Q-2015-00005 http://www.efsa.europa.eu/en/efsajournal/pub/4231	
Feed/FEEDAP	<i>Bacillus subtilis</i> C-3102 DSM 15544	Zotechnical additive	EFSA-Q-2015-00239 http://www.efsa.europa.eu/en/efsajournal/pub/4274	
Feed/FEEDAP	<i>Bacillus subtilis</i> C-3102 DSM 15544	Zotechnical additive	EFSA-Q-2015-00296	
Feed/FEEDAP	<i>Bacillus subtilis</i> CJKB0001	Production of vitamin B2	EFSA-Q-2016-00505	
FIP/CEF	<i>Bacillus subtilis</i> (DP-Ezd31), GMM strain	Production of food enzyme endo-1, 4- β -xylanase	EFSA-Q-2015-00839	
FIP/CEF	<i>Bacillus subtilis</i> (DP-Ezg29), GMM strain	Production of food enzyme β -galactosidase	EFSA-Q-2015-00838	
FIP/CEF	<i>Bacillus subtilis</i> (DP-Ezm28), GMM strain	Production of food enzyme endo-1, 3(4)- β -glucanase	EFSA-Q-2015-00828	
Feed/FEEDAP	<i>Bacillus subtilis</i> DSM 15544	Zotechnical additives	EFSA-Q-2016-00197	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bacillus subtilis</i> (DSM 27273)	Zootechnical additive	EFSA-Q-2014-00729 http://www.efsa.europa.eu/en/efsajournal/pub/4269	
Feed/FEEDAP	<i>Bacillus subtilis</i> DSM 28343	Zootechnical additive	EFSA-Q-2015-00164	
Feed/FEEDAP	<i>Bacillus subtilis</i> DSM 29784	Zootechnical additive	EFSA-Q-2016-00448	
Pesticides	<i>Bacillus subtilis</i> strain IAB/BS03	Plant protection product	EFSA-Q-2015-00389 Application for approval	
FIP/CEF	<i>Bacillus subtilis</i> (LMG S-24584)	Production of food enzyme xylanase	EFSA-Q-2015-00065	
FIP/CEF	<i>Bacillus subtilis</i> (LMGS 25520), GMM strain	Production of food enzyme aqualysin 1	EFSA-Q-2014-00920	
FIP/CEF	<i>Bacillus subtilis</i> /LMG-S-27588	Production of food enzyme	EFSA-Q-2015-00408	
Feed/FEEDAP	<i>Bacillus subtilis</i> LMG S 27588	Production of endo-1,4- β -xylanase	EFSA-Q-2016-00179	
FIP/CEF	<i>Bacillus subtilis</i> strain MAM	Production of enzyme glucan 1,4- α - maltohydrolase	EFSA-Q-2013-00790	
FIP/CEF	<i>Bacillus subtilis</i> MAM, GMM strain	Production of food enzyme glucans 1,4-alpha glucosidase	EFSA-Q-2013-00790	
FIP/CEF	<i>Bacillus subtilis</i> (NBA), GMM strain	Production of food enzyme α -amylase	EFSA-Q-2014-00912	
FIP/CEF	<i>Bacillus subtilis</i> (NZYM-CK), GMM strain	Production of food enzyme asparaginase	EFSA-Q-2014-00845	
FIP/CEF	<i>Bacillus subtilis</i> /NZYM-DB	Production of food enzyme	EFSA-Q-2015-00127	
FIP/CEF	<i>Bacillus subtilis</i> (NZYM-OC), GMM strain	Production of food enzyme maltogenic amylase	EFSA-Q-2014-00922	
FIP/CEF	<i>Bacillus subtilis</i> (NZYM-SM), GMM strain	Production of food enzyme maltogenic Amylase (glucan 1,4- α -maltohydrolase)	EFSA-Q-2015-00096	
FIP/CEF	<i>Bacillus subtilis</i> (NZYM-SO)	Production of food enzyme maltogenic amylase (glucan 1,4- α -maltohydrolase)	EFSA-Q-2015-00046	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Bacillus subtilis</i> strain QST 713	Plant protection product	EFSA-Q-2008-492 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) Review report for the active substance <i>Bacillus subtilis</i> QST 713, SANCO/10184/2003-rev. final, July 2006	
Pesticides	<i>Bacillus subtilis</i> strain QST 713	Plant protection product	EFSA-Q-2016-00172 Application for renewal of approval (AIR III)	
FIP/CEF	<i>Bacillus subtilis</i> TD160(229), GMM strain	Production of food enzyme xylanase	EFSA-Q-2014-00733	
FIP/CEF	<i>Bacillus subtilis</i> XAS, GMM strain	Production of food enzyme endo 1,4-beta xylanase	EFSA-Q-2014-00293 http://www.efsa.europa.eu/en/efsajournal/pub/3766	
Feed/FEEDAP	<i>Bacillus toyonensis</i> (previously <i>B. cereus</i> var. <i>toyo</i>)	Zootechnical additive	EFSA-Q-2014-00043 http://www.efsa.europa.eu/en/efsajournal/pub/3766	Already assessed in several occasions as <i>Bacillus cereus</i> var. <i>toyo</i> but in 2014 has been reassigned to this novel taxonomical unit. Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion ' <i>Bacillus toyonensis</i> cannot be proposed for the QPS list because it is a member of the <i>B. cereus</i> group, and because of the absence of evidences at the species level that it does not present safety concerns'. Please refer to the complete assessment.
Nutrition/NDA	Pasteurised milk products fermented with <i>Bacteroides xylanisolvens</i>	As a novel food ingredient	EFSA-Q-2014-00301 http://www.efsa.europa.eu/en/efsajournal/pub/3955 As a Novel food ingredient in the context of Regulation (EC) No 258/97	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: ' <i>Bacteroides xylanisolvens</i> is not recommended for the QPS list, because the body of knowledge is insufficient and safety concerns cannot be totally excluded'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Bifidobacterium animalis</i>	Feed additive	EFSA-Q-2006-169 (withdrawn) EFSA-Q-2009-00823 http://www.efsa.europa.eu/en/efsajournal/pub/2965 EFSA-Q-2009-00817 http://www.efsa.europa.eu/en/efsajournal/pub/2964	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Evaluated in the current Scientific Opinion (refer to Section 3.1.1) with the conclusion: 'The cases of infection in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection. The use of microorganisms intended to be used as "probiotic" for humans as a health claim does not fall under the remit of the QPS assessment. In conclusion, the QPS status of the <i>Bifidobacterium</i> species previously included in the list does not change and monitoring should continue'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Bifidobacterium animalis</i> AHC7 (NCIMB 41617)	Zootechnical additive	EFSA-Q-2014-00573 (withdrawn)	
Feed/FEEDAP	<i>Bifidobacterium animalis</i> subsp. <i>animalis</i> DSM 16284	Zootechnical additive	EFSA-Q-2014-00224 http://www.efsa.europa.eu/en/efsajournal/pub/3966	
Nutrition/NDA	<i>Bifidobacterium bifidum</i> CNCM I-3426	Food targeted for health claims: 'increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such a moderate stress'	EFSA-Q-2014-00673 http://www.efsa.europa.eu/en/efsajournal/pub/4094	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.
Feed/FEEDAP	<i>Bifidobacterium longum</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Evaluated in the current Scientific Opinion (refer to Section 3.1.1) conclusion: 'The cases of infection in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection. The use of microorganisms intended to be used as "probiotic" for humans as a health claim does not fall under the remit of the QPS assessment. In conclusion, the QPS status of the <i>Bifidobacterium</i> species previously included in the list does not change and monitoring should continue'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Nutrition/NDA	A combination of four bacterial strains: <i>Bifidobacterium longum</i> LA 101, <i>Lactobacillus helveticus</i> LA 102, <i>Lactococcus lactis</i> LA 103 and <i>Streptococcus thermophilus</i> LA 104	Food targeted for health claims: 'improvement of bowel function by increasing stool frequency'	EFSA-Q-2013-00893 http://www.efsa.europa.eu/en/efsajournal/pub/3659.htm	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.
Feed/FEEDAP	BIOMIN [®] BBSH 797 – DSM 11798 Genus nov. (formerly <i>Eubacterium</i>) species nov.	Feed additive	EFSA-Q-2012-00719 http://www.efsa.europa.eu/en/efsajournal/pub/3203.htm	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015b): First studies revealed that the strain belongs to an undescribed new genus within the family Coriobacteriaceae. The conclusion says that 'As the taxonomic unit of strain BBSH 797 is not identified so far, it does not qualify for QPS inclusion. A strain-specific evaluation is therefore necessary'. Please refer to the complete assessment.
Feed/FEEDAP	BIOMIN [®] BBSH 797 – gen. nov., sp. nov. DSM 11798	Technological additive	EFSA-Q-2015-00145	
GMO	<i>Brevibacterium lactofermentum</i> = <i>Corynebacterium glutamicum</i>	Dried killed biomass for feed	EFSA-Q-2007-157 (withdrawn)	The recipient species is QPS for production purposes only, but not for this application, therefore not appropriate for QPS (EFSA, 2008) Re-evaluated in the current Scientific Opinion (refer to Section 3.1.3): 'This TU has the following qualification 'QPS only applies when the species is used for aminoacid production'. Due to a lack of knowledge in relation to history of use of the viable organisms and because other members of the same genus are pathogenic, the qualification is confirmed', with the conclusion: 'The QPS recommendation is confirmed for <i>Corynebacterium glutamicum</i> as well as the qualification'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Carnobacterium divergens</i> S1	Zotechnical additive	EFSA-Q-2013-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4555	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion 'The TU is well described and the body of knowledge shows it as a common species in the food chain, especially in meat. <i>Carnobacterium divergens</i> can be recommended for the QPS list with the qualification of absence of acquired AMR determinants'. Please refer to the complete assessment.
FIP/CEF	<i>Carnobacterium maltaromaticum</i> CNCM I-3298	Microbiological time temperature integrators used as 'active and intelligent' food contact materials	EFSA-Q-2011-00120 http://www.efsa.europa.eu/en/efsajournal/pub/3307	No QPS recommendation given because the species represents fish pathogens (EFSA BIOHAZ Panel, 2012).

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Cellulosimicrobium cellulans</i>	Production of food enzyme β -glucanase	EFSA-Q-2015-00693	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'Safety concerns regarding <i>Cellulosimicrobium cellulans</i> have not excluded the possibility of ill effects developing during its manipulation for enzyme production. Therefore, the organism cannot be awarded QPS status'. Please refer to the complete assessment.
Pesticides	<i>Chromobacterium subtsugae</i> strain PRAA4-1T	Plant protection product	EFSA-Q-2015-00478 Application for approval	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'Due to an insufficient body of knowledge, <i>Chromobacterium subtsugae</i> cannot be proposed for the QPS list'. Please refer to the complete assessment.
FIP/CEF	<i>Chryseobacterium proteolyticum</i>	Production of food enzyme protein glutaminase	EFSA-Q-2015-00695	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015b) with the conclusion "' <i>Chryseobacterium proteolyticum</i> " it is not a valid species name and all the studies refer to a single strain. Consequently, this taxonomical unit cannot be considered for the QPS list'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Clostridium butyricum</i>	Feed additive	EFSA-Q-2008-303 http://www.efsa.europa.eu/en/efsajournal/pub/1039 EFSA-Q-2010-00140 http://www.efsa.europa.eu/en/efsajournal/pub/1951	No history of use, possible production of botulinum toxins, therefore not appropriate for QPS (EFSA, 2008; EFSA BIOHAZ Panel, 2011). Re-evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'The information collected supports the view that the safety of <i>C. butyricum</i> is only known for a few strains, therefore <i>Clostridium butyricum</i> is not recommended for the QPS list. Thus, no additional information supports a revision of the previous conclusion attained in 2011'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Clostridium butyricum</i> CBM 588	Zootechnical additive	EFSA-Q-2013-00594 http://www.efsa.europa.eu/en/efsajournal/pub/3603	
Nutrition/NDA	Combination of four bacterial strains: <i>Bifidobacterium longum</i> LA 101, <i>Lactobacillus helveticus</i> LA 102, <i>Lactococcus lactis</i> LA 103 and <i>Streptococcus thermophilus</i> LA 104	Food targeted for health claims: 'reducing intestinal discomfort'	EFSA-Q-2013-00892 http://www.efsa.europa.eu/en/efsajournal/pub/3658	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.

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Production of L-arginine	EFSA-Q-2006-031 http://www.efsa.europa.eu/en/efsajournal/pub/473	This TU has the following qualification 'QPS only applies when the species is used for aminoacid production'. Evaluated in the current Scientific Opinion (refer to Section 3.1.3) with the conclusion: 'The QPS recommendation is confirmed for <i>Corynebacterium glutamicum</i> as well as the qualification'. Please refer to the complete assessment. * <i>Corynebacterium pekinese</i> is not a valid species name however used in the literature ^(c) .
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Production of L-tryptophan	EFSA-Q-2011-00946 http://www.efsa.europa.eu/en/efsajournal/pub/4238	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i> (<i>Brevibacterium flavum</i>)	Production of L-lysine HCl or sulfate	EFSA-Q-2011-00991 http://www.efsa.europa.eu/en/efsajournal/pub/4346	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Production of L-lysine sulfate	EFSA-Q-2011-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4156	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Production of L-valine	EFSA-Q-2012-00377 http://www.efsa.europa.eu/en/efsajournal/pub/3795	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Nutritional additives (amino acid)	EFSA-Q-2014-00635 (withdrawn)	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i>	Production of lysine	EFSA-Q-2016-00574	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i> KCCM80099	Production L-arginine	EFSA-Q-2016-00405	
Feed/FEEDAP	<i>Corynebacterium glutamicum</i> KCTC 10423BP	Nutritional additives (amino acid)	EFSA-Q-2014-00296 http://www.efsa.europa.eu/en/efsajournal/pub/4345	
Feed/FEEDAP	<i>Corynebacterium pekinese</i> * = <i>Corynebacterium glutamicum</i>	Production of L-lysine sulfate	EFSA-Q-2011-00995 http://www.efsa.europa.eu/en/efsajournal/pub/4052	
Feed/FEEDAP	<i>Ensifer adhaerens</i>	Production of vitamin B12	EFSA-Q-2012-00455 http://www.efsa.europa.eu/en/efsajournal/pub/4112 EFSA-Q-2012-00456	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge.
Feed/FEEDAP	<i>Ensifer fredii</i>	Production of vitamin B12	EFSA-Q-2012-00456	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge.
Feed/FEEDAP	<i>Enterococcus faecium</i>	Feed additive	EFSA-Q-2003-087 http://www.efsa.europa.eu/en/efsajournal/pub/207	No recommendation for QPS status (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) Considered in the current Scientific Opinion (refer to

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			EFSA-Q-2004-001 http://www.efsa.europa.eu/en/efsajournal/pub/51 EFSA-Q-2004-006 http://www.efsa.europa.eu/en/efsajournal/pub/138 EFSA-Q-2004-027 http://www.efsa.europa.eu/en/efsajournal/pub/120 EFSA-Q-2004-096 http://www.efsa.europa.eu/en/efsajournal/pub/206 EFSA-Q-2005-020 http://www.efsa.europa.eu/en/efsajournal/pub/335 EFSA-Q-2006-061 http://www.efsa.europa.eu/en/efsajournal/pub/440 EFSA-Q-2006-318 http://www.efsa.europa.eu/en/efsajournal/pub/1379 EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2006-169 (withdrawn) EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2007-033 http://www.efsa.europa.eu/en/efsajournal/pub/521 EFSA-Q-2008-289 http://www.efsa.europa.eu/en/efsajournal/pub/990 EFSA-Q-2008-471 (withdrawn) EFSA-Q-2008-422	Section 3.6.2) where it is mentioned that the conclusions of 'the last update on QPS (EFSA BIOHAZ Panel, 2013) are still valid and <i>E. faecium</i> should be monitored and re-evaluated in the next QPS Opinion update' and in the Conclusions chapter that ' <i>Enterococcus faecium</i> is not recommended for the QPS list in spite of advances in recent scientific knowledge allowing a differentiation of pathogenic from non-pathogenic strains at the clade level. The QPS approach relies on the basis of the evaluation of TU, where the species/subspecies level is the lowest level of evaluation. Therefore, clades within the <i>E. faecium</i> species cannot be considered as a TU and cannot be evaluated separately.' Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			http://www.efsa.europa.eu/en/efsajournal/pub/1661 EFSA-Q-2009-00679 http://www.efsa.europa.eu/en/efsajournal/pub/2574 EFSA-Q-2009-00969 http://www.efsa.europa.eu/en/efsajournal/pub/2118 EFSA-Q-2009-00823 http://www.efsa.europa.eu/en/efsajournal/pub/2965 EFSA-Q-2009-00202 (withdrawn) EFSA-Q-2010-00070 http://www.efsa.europa.eu/en/efsajournal/pub/1636 EFSA-Q-2012-00093 http://www.efsa.europa.eu/en/efsajournal/pub/3044 EFSA-Q-2010-00009 http://www.efsa.europa.eu/en/efsajournal/pub/3097 EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170 EFSA-Q-2011-00203 http://www.efsa.europa.eu/en/efsajournal/pub/3167 EFSA-Q-2012-00093 http://www.efsa.europa.eu/en/efsajournal/pub/3044 EFSA-Q-2012-00421 http://www.efsa.europa.eu/en/efsajournal/pub/3175 EFSA-Q-2012-00420 http://www.efsa.europa.eu/en/efsajournal/pub/3098	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			EFSA-Q-2012-00080 http://www.efsa.europa.eu/en/efsajournal/pub/3363 EFSA-Q-2011-00965 (withdrawn) EFSA-Q-2012-00245 http://www.efsa.europa.eu/en/efsajournal/pub/3602 EFSA-Q-2012-00454 http://www.efsa.europa.eu/en/efsajournal/pub/3727 EFSA-Q-2012-00419 http://www.efsa.europa.eu/en/efsajournal/pub/4158 EFSA-Q-2012-00422 http://www.efsa.europa.eu/en/efsajournal/pub/3672	
Feed/FEEDAP	<i>Enterococcus faecium</i> (CECT 4515)	Zootechnical additive	EFSA-Q-2014-00827 http://www.efsa.europa.eu/en/efsajournal/pub/4232	
Feed/FEEDAP	<i>Enterococcus faecium</i> CECT 4515	Zootechnical additive	EFSA-Q-2015-00055 http://www.efsa.europa.eu/en/efsajournal/pub/4111	
Feed/FEEDAP	<i>Enterococcus faecium</i> DSM 7134	Zootechnical additive	EFSA-Q-2016-00450	
Feed/FEEDAP	<i>Enterococcus faecium</i> DSM 7134	Zootechnical additive	EFSA-Q-2016-00452	
Feed/FEEDAP	<i>Enterococcus faecium</i> DSM 21913	Zootechnical feed additive	EFSA-Q-2014-00224 http://www.efsa.europa.eu/en/efsajournal/pub/3966	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Enterococcus mundtii</i>	Feed additive		No taxonomical unit within <i>Enterococcus</i> can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA, 2007).
Feed/FEEDAP	<i>Escherichia coli</i>	Feed additive (horses)	EFSA-Q-2005-167 http://www.efsa.europa.eu/en/efsajournal/pub/989	Is not recommended for the QPS list in the past. There is increasing evidence of pathogenicity (QPS 2009, 2010). Re-evaluated for the BIOHAZ Panel statement (published December 2014) with the conclusion ' <i>Escherichia coli</i> 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'.
Feed/FEEDAP	<i>Escherichia coli</i>	Feed additive L-lysine production	EFSA-Q-2011-00992 http://www.efsa.europa.eu/en/efsajournal/pub/3365 EFSA-Q-2011-00993 http://www.efsa.europa.eu/en/efsajournal/pub/3365 EFSA-Q-2011-00994 http://www.efsa.europa.eu/en/efsajournal/pub/3365 EFSA-Q-2011-00995 http://www.efsa.europa.eu/en/efsajournal/pub/4052 EFSA-Q-2011-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4156	
GMO	<i>Escherichia coli</i>	Dried killed biomasses for feed	EFSA-Q-2008-412a EFSA-Q-2008-669a	
Feed/FEEDAP	<i>Escherichia coli</i>	Dried killed biomasses for feed	EFSA-Q-2008-412b EFSA-Q-2008-669b	
FIP/CEF	<i>Escherichia coli</i>	Production of food enzyme maltogenic amylase	EFSA-Q-2015-00446	
FIP/CEF	<i>Escherichia coli</i>	Production of polyhydroxyalkanoate (PHA) = from the reaction of dextrose and 1,4 butanediol	EFSA-Q-2011-01080 (withdrawn)	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Escherichia coli</i>	Feed additive L-threonine production	EFSA-Q-2012-00113 http://www.efsa.europa.eu/en/efsajournal/pub/4236 EFSA-Q-2012-00114 http://www.efsa.europa.eu/en/efsajournal/pub/3319 EFSA-Q-2012-00115 http://www.efsa.europa.eu/en/efsajournal/pub/3726 EFSA-Q-2012-00116 http://www.efsa.europa.eu/en/efsajournal/pub/3674 EFSA-Q-2012-00117 http://www.efsa.europa.eu/en/efsajournal/pub/4051 EFSA-Q-2012-00118 http://www.efsa.europa.eu/en/efsajournal/pub/3564	
Feed/FEEDAP	<i>Escherichia coli</i>	Production of L-threonine	EFSA-Q-2015-00555 EFSA Journal 2016;14(5):4470 [11 pp.] http://www.efsa.europa.eu/en/efsajournal/pub/4470	
Feed/FEEDAP	<i>Escherichia coli</i>	Feed additive L-tryptophan production	EFSA-Q-2011-00946 http://www.efsa.europa.eu/en/efsajournal/pub/4238 EFSA-Q-2011-00947 http://www.efsa.europa.eu/en/efsajournal/pub/3368 EFSA-Q-2011-00948 http://www.efsa.europa.eu/en/efsajournal/pub/4015 EFSA-Q-2011-00949 http://www.efsa.europa.eu/en/efsajournal/pub/3673	
Feed/FEEDAP	<i>Escherichia coli</i> (ATCC 9637)	Production of histidine	EFSA-Q-2016-00304	
Feed/FEEDAP	<i>Escherichia coli</i> (ATCC 9637)	Production of histidine	EFSA-Q-2016-00305	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Escherichia coli</i> (BgIA MCB3), GMM strain	Production of food enzyme β -galactosidase	EFSA-Q-2015-00622	
Feed/FEEDAP	<i>Escherichia coli</i> CGMCC 3667	Technological additive (production of L-tryptophan)	EFSA-Q-2015-00251 http://www.efsa.europa.eu/en/efsajournal/pub/4343	
Feed/FEEDAP	<i>Escherichia coli</i> CGMCC 3667	Production of tryptophan	EFSA-Q-2016-00551	
Feed/FEEDAP	<i>Escherichia coli</i> CGMCC 7.57	Production of L-lysine monohydrochloride	EFSA-Q-2015-00556 http://www.efsa.europa.eu/en/efsajournal/pub/4471	
Feed/FEEDAP	<i>Escherichia coli</i> CGMCC 7.59	Production of L-tryptophan	EFSA-Q-2015-00557 http://www.efsa.europa.eu/en/efsajournal/pub/4444	
Feed/FEEDAP	<i>Escherichia coli</i> / DC231	Nutritional/ Production of L-lysine sulfate	EFSA-Q-2014-00003 http://www.efsa.europa.eu/en/efsajournal/pub/4155	
Feed/FEEDAP	<i>Escherichia coli</i> FERM BP-10941, GMM strain	Nutritional/ Production of copper chelate of L-lysinate-HCl	EFSA-Q-2013-00407 http://www.efsa.europa.eu/en/efsajournal/pub/3796 EFSA-Q-2014-00496 http://www.efsa.europa.eu/en/efsajournal/pub/4267	
Feed/FEEDAP	<i>Escherichia coli</i> K-12	Technological additive (production of L-threonine)	EFSA-Q-2015-00252	
Feed/FEEDAP	<i>Escherichia coli</i> K-12/ AG7056X	Nutritional/Production of threonine	EFSA-Q-2013-00676 http://www.efsa.europa.eu/en/efsajournal/pub/3825	
Feed/FEEDAP	<i>Escherichia coli</i> K-12/ AG8012X	Nutritional/Production of tryptophan	EFSA-Q-2013-00677 http://www.efsa.europa.eu/en/efsajournal/pub/3826	
Feed/FEEDAP	<i>Escherichia coli</i> K-12/INTK-01X	Nutritional/Production of lysine	EFSA-Q-2013-00823 http://www.efsa.europa.eu/en/efsajournal/pub/3895	
Feed/FEEDAP	<i>Escherichia coli</i> VA-05, GMM strain	Nutritional additives (amino acid)	EFSA-Q-2014-00299 http://www.efsa.europa.eu/en/efsajournal/pub/4110	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Eubacterium</i> sp.	Reduce toxicity of mycotoxins	EFSA-Q-2003-052 http://www.efsa.europa.eu/en/efsajournal/pub/169 EFSA-Q-2012-00719 http://www.efsa.europa.eu/en/efsajournal/pub/3203	No body of knowledge. Not appropriate for QPS (EFSA, 2008).
FIP/CEF	<i>Geobacillus caldoproteolyticus</i>	Production of food enzyme thermolysin	EFSA-Q-2015-00682	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'Due to the lack of sufficient body of knowledge on a safe history of use or presence in foods and feeds, <i>Geobacillus caldoproteolyticus</i> (<i>Anoxybacillus caldiproteolyticus</i> sp. nov.) is not recommended for the QPS list'. Please refer to the complete assessment.
FIP/CEF	<i>Geobacillus pallidus</i>	Production of food enzyme 4- α -glucanotransferase	EFSA-Q-2016-00033	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'Due to the lack of sufficient body of knowledge on a safe history of use or presence in foods and feeds, <i>Aeribacillus pallidus</i> (ex- <i>Geobacillus pallidus</i>) is not recommended for the QPS list'. Please refer to the complete assessment.
FIP/CEF	<i>Geobacillus stearothermophilus</i>	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2015-00230	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore its QPS status does not change'. Please refer to the complete assessment.
FIP/CEF	<i>Geobacillus stearothermophilus</i>	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00081	
FIP/CEF	<i>Geobacillus stearothermophilus</i>	Production of food enzyme thermolysin	EFSA-Q-2016-00083	
FIP/CEF	<i>Geobacillus stearothermophilus</i>	Production of food enzyme 1,4- α -glucan branching	EFSA-Q-2016-00100	
Feed/FEEDAP	<i>Gluconobacter oxydans</i>	Production of vitamin C	EFSA-Q-2011-00250 http://www.efsa.europa.eu/en/efsajournal/pub/3103	<i>Gluconobacter oxydans</i> was assessed for the first time in 2013 (EFSA BIOHAZ Panel, 2013) and was recommended for the QPS list with a qualification 'QPS only apply when the species is used for vitamin production' which is relevant for the intended use for which the species was notified'. Re-evaluated in the current Scientific Opinion (refer to Section 3.3.1) and 'no references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore the QPS status of <i>Gluconobacter oxydans</i> does not change'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Ketogulonicigenium vulgare</i>	Production of vitamin C	EFSA-Q-2011-00250 http://www.efsa.europa.eu/en/efsajournal/pub/3103.htm	Not recommended for the QPS list (EFSA BIOHAZ Panel, 2011) update due to insufficient body of knowledge.
FIP/CEF	<i>Klebsiella pneumoniae</i>	Production of food enzyme pullulanase	EFSA-Q-2015-00450	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion ' <i>Klebsiella pneumoniae</i> has been implicated in human infections and can be considered a source of antibiotic resistance determinants. Therefore, this species cannot be recommended for the QPS list'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus buchneri</i>	Feed additive	EFSA-Q-2010-01276 http://www.efsa.europa.eu/en/efsajournal/pub/213 EFSA-Q-2011-00375 http://www.efsa.europa.eu/en/efsajournal/pub/2359 EFSA-Q-2011-00376 http://www.efsa.europa.eu/en/efsajournal/pub/2361 EFSA-Q-2011-00382 http://www.efsa.europa.eu/en/efsajournal/pub/3168	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus acidophilus</i>	Feed additive	EFSA-Q-2003-115 http://www.efsa.europa.eu/en/efsajournal/pub/119 EFSA-Q-2003-055 http://www.efsa.europa.eu/en/efsajournal/pub/52 EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2008-377 (withdrawn) EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus acidophilus</i>	Zotechnical additive	EFSA-Q-2015-00429	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus amylolyticus</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus amylovorans</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus brevis</i>	Feed additive	EFSA-Q-2010-01304 http://www.efsa.europa.eu/en/efsajournal/pub/4156 EFSA-Q-2011-00382 http://www.efsa.europa.eu/en/efsajournal/pub/3168 EFSA-Q-2011-00385 http://www.efsa.europa.eu/en/efsajournal/pub/2368 EFSA-Q-2012-00086 http://www.efsa.europa.eu/en/efsajournal/pub/3534	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus brevis</i> TAK 124-1 NCIMB 42149	Technological additive	EFSA-Q-2015-00280 http://www.efsa.europa.eu/en/efsajournal/pub/4616	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus bulgaricus</i> = <i>L. delbrueckii</i> subsp. <i>bulgaricus</i>	Feed additive	EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus casei</i>	Feed additive	EFSA-Q-2011-00381 http://www.efsa.europa.eu/en/efsajournal/pub/2884 EFSA-Q-2011-00390 http://www.efsa.europa.eu/en/efsajournal/pub/3362	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus casei</i> DSM 28872	Technological additive	EFSA-Q-2016-00237	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus casei</i> LOCK 0915	Zootechnical additive	EFSA-Q-2013-00996	
Feed/FEEDAP	<i>Lactobacillus casei rhamnosus</i> = <i>Lactobacillus rhamnosus</i>	Feed additive	EFSA-Q-2011-00380 http://www.efsa.europa.eu/en/efsajournal/pub/2365	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'; 'As already noted in the 2013 Opinion, <i>L. rhamnosus</i> produced most of the clinical cases reported, probably due to frequent inclusion of isolates of this species into human probiotic preparations. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus cellobiosus</i>	Feed additive	EFSA-Q-2012-00085 www.efsa.europa.eu/en/efsajournal/pub/3533	Not initially considered for QPS (see EFSA 2007, 2008). QPS recommended (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus collinoides</i>	Feed additive	EFSA-Q-2012-00086 http://www.efsa.europa.eu/en/efsajournal/pub/3534	Not initially considered for QPS status (see EFSA 2007, 2008). QPS recommended (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus delbrueckii</i> subsp. <i>lactis</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus diolivorans</i> DSM 32074	Technological additive	EFSA-Q-2015-00616	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion 'The species <i>Lactobacillus diolivorans</i> is a natural component of bacterial communities of fermented vegetables and plant derived products. It has never been implicated in human or animal diseases and therefore can be recommended for the QPS list'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus farciminis</i>	Feed additive	EFSA-Q-2006-062 http://www.efsa.europa.eu/en/efsajournal/pub/771 EFSA-Q-2004-177 http://www.efsa.europa.eu/en/efsajournal/pub/377	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus farciminis</i> CNMA67/4R	Zootechnical additive	EFSA-Q-2016-00712	
Feed/FEEDAP	<i>Lactobacillus fermentum</i>	Feed additive	EFSA-Q-2012-00085 http://www.efsa.europa.eu/en/efsajournal/pub/3533	
FIP/CEF	<i>Lactobacillus fermentum</i>	Production of food enzyme urease	EFSA-Q-2016-00102	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus fermentum</i> (NCIMB 41636)	Technological additive	EFSA-Q-2014-00588	
Nutrition/NDA	<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.
Feed/FEEDAP	<i>Lactobacillus helveticus</i>	Feed additive	EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus hilgardii</i> CNMC I-4785	Technological additive	EFSA-Q-2016-00580	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus lactis</i> * IBB50	Zootechnical additive	EFSA-Q-2013-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4555	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment. *Should be moved to QPS <i>Lactobacillus delbrueckii</i>
Feed/FEEDAP	<i>Lactobacillus mucosae</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus paracasei</i>	Feed additive	EFSA-Q-2011-00378 http://www.efsa.europa.eu/en/efsajournal/pub/2363 EFSA-Q-2011-00387 http://www.efsa.europa.eu/en/efsajournal/pub/2370 EFSA-Q-2012-00082 http://www.efsa.europa.eu/en/efsajournal/pub/3611	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immuno-depressed'. Please refer to the complete assessment.
Nutrition/NDA	'Nutrimune (a heat-treated fermented milk, fermented with <i>Lactobacillus paracasei</i> CBA L74)'	Food targeted for health claims	EFSA-Q-2015-00755 http://www.efsa.europa.eu/en/efsajournal/pub/4540	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.
Feed/FEEDAP	<i>Lactobacillus pentosus</i>	Feed additive	EFSA-Q-2011-00388 http://www.efsa.europa.eu/en/efsajournal/pub/2449	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus plantarum</i>	Feed additive	EFSA-Q-2010-01164 http://www.efsa.europa.eu/en/efsajournal/pub/2113 EFSA-Q-2011-00062 http://www.efsa.europa.eu/en/efsajournal/pub/2275 EFSA-Q-2011-00186 http://www.efsa.europa.eu/en/efsajournal/pub/2408 EFSA-Q-2011-00377 http://www.efsa.europa.eu/en/efsajournal/pub/2362 EFSA-Q-2011-00384 http://www.efsa.europa.eu/en/efsajournal/pub/2367 EFSA-Q-2011-00943 http://www.efsa.europa.eu/en/efsajournal/pub/2529 EFSA-Q-2011-00374 http://www.efsa.europa.eu/en/efsajournal/pub/2732 EFSA-Q-2012-00089 http://www.efsa.europa.eu/en/efsajournal/pub/2780 EFSA-Q-2011-00390 http://www.efsa.europa.eu/en/efsajournal/pub/3362 EFSA-Q-2011-00944 http://www.efsa.europa.eu/en/efsajournal/pub/3205 EFSA-Q-2011-00125 http://www.efsa.europa.eu/en/efsajournal/pub/4397 EFSA-Q-2012-00083 http://www.efsa.europa.eu/en/efsajournal/pub/3612 EFSA-Q-2012-00090	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			http://www.efsa.europa.eu/en/efsajournal/pub/3041 EFSA-Q-2012-00092 http://www.efsa.europa.eu/en/efsajournal/pub/3535 EFSA-Q-2012-00094 http://www.efsa.europa.eu/en/efsajournal/pub/3529	
Nutrition/NDA	<i>Lactobacillus plantarum</i> 299v	Food targeted for health claims: ' <i>Lactobacillus plantarum</i> 299v and increase of non-haem iron absorption'	EFSA-Q-2015-00696 http://www.efsa.europa.eu/en/efsajournal/pub/4550	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.
Nutrition/NDA	<i>Lactobacillus plantarum</i> TENSIA [®] (DSM 21380) in the semihard Edam-type 'heart cheese' of Harmony [™]	Food targeted for health claims: 'maintenance of cardiovascular health through reduction of blood pressure'	EFSA-Q-2014-00097 http://www.efsa.europa.eu/en/efsajournal/pub/3842	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.
Feed/FEEDAP	<i>Lactobacillus plantarum</i> DSM 29024	Technological additive	EFSA-Q-2015-00627	
Feed/FEEDAP	<i>Lactobacillus plantarum</i> DSM 29025	Technological additive	EFSA-Q-2015-00652 http://www.efsa.europa.eu/en/efsajournal/pub/4479	
Feed/FEEDAP	<i>Lactobacillus plantarum</i> LOCK 0862	Zootechnical additive	EFSA-Q-2013-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4555	
Feed/FEEDAP	<i>Lactobacillus plantarum</i> (NCIMB 41638)	Technological additive	EFSA-Q-2014-00588 http://www.efsa.europa.eu/en/efsajournal/pub/4340	
Feed/FEEDAP	<i>Lactobacillus plantarum</i> TAK 59 NCIMB 42150	Technological additive	EFSA-Q-2015-00278 http://www.efsa.europa.eu/en/efsajournal/pub/4506	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus reuteri</i>	Feed additive	EFSA-Q-2003-010 http://www.efsa.europa.eu/en/efsajournal/pub/229 EFSA-Q-2006-169 (withdrawn)	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus rhamnosus</i>	Feed additive	EFSA-Q-2006-062 http://www.efsa.europa.eu/en/efsajournal/pub/771 EFSA-Q-2011-00380 http://www.efsa.europa.eu/en/efsajournal/pub/2365 EFSA-Q-2011-00125 http://www.efsa.europa.eu/en/efsajournal/pub/4397	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'; 'As already noted in the 2013 Opinion, <i>L. rhamnosus</i> produced most of the clinical cases reported, probably due to frequent inclusion of isolates of this species into human probiotic preparations. Consumption of microorganisms by patients with immunosuppression and/or underlying disease may be considered as the origin of the infection'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus rhamnosus</i> DSM 29226	Technological additive	EFSA-Q-2015-00626	
Nutrition/ NDA	<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 http://www.efsa.europa.eu/en/efsajournal/pub/4538	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.
Nutrition/NDA	Synbio, a combination of <i>Lactobacillus rhamnosus</i> IMC 501 [®] and <i>Lactobacillus paracasei</i> IMC 502 [®]	Food targeted for health claims	EFSA-Q-2014-00567 http://www.efsa.europa.eu/en/efsajournal/pub/4095	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.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactobacillus rhamnosus</i> (NCIMB 41640)	Technological additive	EFSA-Q-2014-00588 http://www.efsa.europa.eu/en/efsajournal/pub/4340	
Feed/FEEDAP	<i>Lactobacillus sakei</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus salivarius</i>	Feed additive	EFSA-Q-2006-169 (withdrawn) EFSA-Q-2009-00823 http://www.efsa.europa.eu/en/efsajournal/pub/2965 EFSA-Q-2011-00381 http://www.efsa.europa.eu/en/efsajournal/pub/2884	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Lactobacillus salivarius</i> spp. <i>salivarius</i> DSM 16351	Zootechnical additive	EFSA-Q-2014-00224 http://www.efsa.europa.eu/en/efsajournal/pub/3966	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.4) with the conclusion: 'There is no requirement to change the QPS recommendation of the previously recommended <i>Lactobacillus</i> species, as the infections reported to be due to members of the genus were extremely scarce and affected patients that already suffered from highly debilitating illnesses and/or were significantly immunodepressed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Lactococcus lactis</i>	Feed additive	EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2010-00901 http://www.efsa.europa.eu/en/efsajournal/pub/2374 EFSA-Q-2011-00373 http://www.efsa.europa.eu/en/efsajournal/pub/2448 EFSA-Q-2011-00383 http://www.efsa.europa.eu/en/efsajournal/pub/2366 EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170 EFSA-Q-2012-00087 http://www.efsa.europa.eu/en/efsajournal/pub/3610	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.5) with the conclusion: 'There is no need to change the QPS recommendation of <i>Lactococcus lactis</i> , as the infections reported were extremely scarce, and the affected patients already suffered from highly debilitating illnesses and/or were significantly immunodepressed. The possibility that <i>L. lactis</i> might be involved in bovine mastitis, albeit limited for the moment, should be monitored'. Please refer to the complete assessment.
FIP/CEF	<i>Lactococcus lactis</i> (strain DGCC5920)	Production of food enzyme membrane alanyl aminopeptidase	EFSA-Q-2016-00208	
Feed/FEEDAP	<i>Lactococcus lactis</i> NCIMB 30160	Technological additive	EFSA-Q-2016-00568	
FIP/CEF	<i>Leuconostoc citreum</i> (strain NRRL B-30894)	Production of food enzyme alternansucrase	EFSA-Q-2016-00209	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.6) with the conclusion: 'The cases of infections in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. The above new information does not modify the QPS recommendation of <i>Leuconostoc</i> species. Therefore, the QPS recommendation for <i>Lc. mesenteroides</i> , <i>Lc. lactis</i> , <i>Lc. pseudomesenteroides</i> and <i>Lc. citreum</i> was confirmed'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
2001/122/EC	<i>Leuconostoc mesenteroides</i>	Production of dextran as NF ingredient for bakery industrial and food fermentations		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.6) with the conclusion: 'The cases of infections in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. The above new information does not modify the QPS recommendation of <i>Leuconostoc</i> species. Therefore, the QPS recommendation for <i>Lc. mesenteroides</i> , <i>Lc. lactis</i> , <i>Lc. pseudomesenteroides</i> and <i>Lc. citreum</i> was confirmed'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Leuconostoc oeno</i> = <i>Oenococcus oeni</i>	Feed additive		Not initially considered for QPS (see EFSA, 2007, 2008) and recommended for the QPS list (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.8) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified for <i>Oenococcus oeni</i> . Therefore its QPS status does not change and monitoring should continue'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Leuconostoc pseudomesenteroides</i>	Feed additive		Not initially considered for QPS (see EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011) and recommended for the QPS list in 2012 (EFSA BIOHAZ Panel, 2012) and confirmed in 2013 and 2016. (EFSA BIOHAZ Panel, 2013, 2016a) Re-evaluated in the current Scientific Opinion (refer to Section 3.1.8) with the conclusion: 'The cases of infections in humans are mostly linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. The above new information does not modify the QPS recommendation of <i>Leuconostoc</i> species. Therefore, the QPS recommendation for <i>Lc. mesenteroides</i> , <i>Lc. lactis</i> , <i>Lc. pseudomesenteroides</i> and <i>Lc. citreum</i> was confirmed. Please refer to the complete assessment.
Feed/FEEDAP	<i>Methylococcus capsulatus</i>	Biomass for animal feed	EFSA-Q-2004-171 http://www.efsa.europa.eu/en/efsajournal/pub/230	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008).

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Microbacterium imperiale</i> AE-AMT	Production of food enzyme α -amylase	EFSA-Q-2014-00544	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion 'No record exists of intended use of any <i>Microbacterium</i> in food processing and/or ingestion of viable cells. However, there is a history of use in food processing of enzymes produced by <i>Microbacterium imperiale</i> , therefore it can only be recommended for QPS for enzyme production'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Paenibacillus lentus</i> DSM 28088	Zotechnical additive (production of enzyme)	EFSA-Q-2014-00115	Due to the absence of a body of knowledge apart from the description of the species, <i>Paenibacillus lentus</i> cannot be proposed for the QPS list (EFSA BIOHAZ Panel, 2014).
Feed/FEEDAP	<i>Paenibacillus lentus</i> DSM 28088	Production of endo-1,4- β -mannanase	EFSA-Q-2016-00181	
Opinion SCF adopted on 22/06/2000	<i>Paenibacillus macerans</i>	β -cyclodextrin production (food additive)		QPS 2009 update not recommended for QPS because of insufficient body of knowledge. Re-evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion: 'Due to the lack of sufficient body of knowledge on a safe history of use or presence in foods and feeds, <i>Paenibacillus macerans</i> is not recommended for the QPS list'. Please refer to the complete assessment.
FIP/CEF	<i>Paenibacillus macerans</i>	Production of food enzyme cyclomaltodextrin glucanotransferase	EFSA-Q-2016-00082	
Feed/FEEDAP	<i>Paracoccus carotinifaciens</i> Astaxanthin-rich	Production of red carotenoids	EFSA-Q-2006-173 http://www.efsa.europa.eu/en/efsajournal/pub/546 EFSA-Q-2009-00629 http://www.efsa.europa.eu/en/efsajournal/pub/1428 EFSA-Q-2012-00064	No body of knowledge, therefore not considered for QPS (EFSA, 2008).

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Pasteuria nishizawae</i> strain Pn1	Plant protection product	EFSA-Q-2015-00405 Application for approval	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015b) and re-evaluated in the current Scientific Opinion (refer to Section 3.1.3) with the conclusion: ' <i>Pasteuria nishizawae</i> was recommended for the QPS status for use as a plant protection product to combat cyst nematodiasis (EFSA EFSA BIOHAZ Panel, 2015b). This conclusion was based on the following: (i) it is an obligate parasite, unable to grow independently of its host species, <i>H. glycines</i> and possibly <i>H. schachtii</i> . In addition, available evidence indicates that this species of bacteria requires entry of the nematode into the root of a plant for vegetative growth; (ii) the ubiquity and abundance of <i>Pasteuria</i> spp. endospores in soils and the lack of any reports on harmful effects of these bacteria on organisms other than their hosts. The qualification linked to this taxonomic unit was re-evaluated and the QPS recommendation is now ascribed without the previous qualification ("QPS only applies when used in pesticides to combat cyst nematodiasis"). Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Pediococcus acidilactici</i>	Feed additive	EFSA-Q-2006-169 (withdrawn) EFSA-Q-2007-205 http://www.efsa.europa.eu/en/efsajournal/pub/1037 EFSA-Q-2008-421 http://www.efsa.europa.eu/en/efsajournal/pub/1038 EFSA-2009-00719 http://www.efsa.europa.eu/en/efsajournal/pub/1660 EFSA-2009-00716 http://www.efsa.europa.eu/en/efsajournal/pub/1865 EFSA-2009-00719 http://www.efsa.europa.eu/en/efsajournal/pub/1660 EFSA-2009-00716 http://www.efsa.europa.eu/en/efsajournal/pub/1865 EFSA-Q-2011-00379 http://www.efsa.europa.eu/en/efsajournal/pub/2364 EFSA-Q-2011-00940 http://www.efsa.europa.eu/en/efsajournal/pub/2733 EFSA-Q-2011-00941 (withdrawn) EFSA-Q-2012-00084 http://www.efsa.europa.eu/en/efsajournal/pub/3613 EFSA-Q-2012-00253 http://www.efsa.europa.eu/en/efsajournal/pub/2776	Already QPS (EFSA, 2007, 2008, 2009; EFSA BIOHAZ Panel, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.10) with the conclusion: 'There is no need to change the recommendation of the QPS-granted pediococci species because no causality of infection has been reported during the scrutinized period'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Pediococcus acidilactici</i> (CNCM) MA 18/5M	Zootechnical additive	EFSA-Q-2013-00704 http://www.efsa.europa.eu/en/efsajournal/pub/4483	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion; ' <i>Pediococcus parvulus</i> can be granted the QPS status, being a species commonly found in fermented food and beverages and based on lack of pathogenicity as determined by the absence of any significant virulence determinants in its genome and of any reports on its role on human or animal infection'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Pediococcus acidilactici</i> (CNCM) MA 18/5M	Zootechnical additive	EFSA-Q-2014-00091 http://www.efsa.europa.eu/en/efsajournal/pub/4483	
Feed/FEEDAP	<i>Pediococcus parvulus</i> DSM 28875	Technological additive	EFSA-Q-2016-00236	
Feed/FEEDAP	<i>Pediococcus pentosaceus</i>	Feed additive	EFSA-Q-2009-00717 http://www.efsa.europa.eu/en/efsajournal/pub/1502 EFSA-Q-2011-00386 http://www.efsa.europa.eu/en/efsajournal/pub/2369 EFSA-Q-2011-00940 http://www.efsa.europa.eu/en/efsajournal/pub/2733 EFSA-Q-2012-00091 http://www.efsa.europa.eu/en/efsajournal/pub/3284 EFSA-Q-2012-00081 http://www.efsa.europa.eu/en/efsajournal/pub/3609 EFSA-Q-2012-00087 http://www.efsa.europa.eu/en/efsajournal/pub/3610	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.10) with the conclusion: 'There is no need to change the recommendation of the QPS-granted pediococci species because no causality of infection has been reported during the scrutinized period'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Propionibacterium acidipropionici</i>	Feed additive	EFSA-Q-2011-00953 http://www.efsa.europa.eu/en/efsajournal/pub/2673	Not proposed for QPS status (see EFSA, 2007). In 2009 recommended for the QPS list (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.11) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, its QPS status does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Propionibacterium freudenreichii shermanii</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.11) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, the QPS status of the <i>Propionibacterium</i> species does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Propionibacterium freudenreichii shermanii</i>	Production of vitamin B12	EFSA-Q-2012-00456 EFSA-Q-2012-00457 (withdrawn)	
Feed/FEEDAP	<i>Propionibacterium globosum</i> [=subspecies of <i>Propionibacterium freudenreichii</i>]	Feed additive		Initially not recommended for QPS (see EFSA, 2007, Appendix A). Identical with <i>P. freudenreichii</i> therefore included on QPS (EFSA BIOHAZ Panel, 2010). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.11) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore, the QPS status of the <i>Propionibacterium</i> species does not change'. Please refer to the complete assessment.
FIP/CEF	<i>Protaminobacter rubrum</i>	Production of food enzyme isomaltulose synthase	EFSA-Q-2015-00620	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion: '" <i>Protaminobacter rubrum</i> " it is not a valid species name. Consequently, this taxonomical unit cannot be considered for the QPS list.' Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Pseudomonas chlororaphis</i> strain MA342	Plant protection product	EFSA-Q-2008-618 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) Review report for the active substance <i>Pseudomonas chlororaphis</i> , DG SANCO/4024/VI/98-Final, March 2004	Not recommended for QPS in 2009 update (EFSA BIOHAZ Panel, 2009) because of insufficient body of knowledge and a potential risk linked to production of secondary metabolites. Re-evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015b) with the conclusion: 'The safe use of some strains of <i>P. chlororaphis</i> in plant protection products relies on the absence of colonisation of the edible part of plants. No information exists to enable assessment of the risk whether or not <i>P. chlororaphis</i> was used in a situation where it could produce secondary metabolites in food or feed. Because of the insufficient body of knowledge and a potential risk linked to production of secondary metabolites (EFSA BIOHAZ Panel, 2009) and to antimicrobial resistance determinants, <i>Pseudomonas chlororaphis</i> should not be recommended for QPS'. Please refer to the complete assessment.
Pesticides	<i>Pseudomonas chlororaphis</i> strain MA342	Plant protection product	EFSA-Q-2015-00814 Application for renewal of approval	
FIP/CEF	<i>Pseudomonas fluorescens</i> (BD15754), GMM strain	Production of food enzyme α -amylase	EFSA-Q-2016-00200	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2017) with the conclusion: 'The pathogenic potential of <i>P. fluorescens</i> 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 <i>Staphylococcus aureus</i> strains selection, as a result of <i>P. fluorescens</i> ability to produce mupirocin, further supports the rejection of the QPS status'. Please refer to the complete assessment.
Pesticides	<i>Pseudomonas</i> sp. strain DSMZ 13134	Plant protection product	EFSA-Q-2011-01198 http://www.efsa.europa.eu/en/efsajournal/pub/2954 Application for approval	Not assessed because species to be clarified (EFSA BIOHAZ Panel, 2009).
Pesticides	<i>Pseudomonas</i> sp. strain DSMZ 13134	Plant protection product	EFSA-Q-2014-00370 Review of MRLs (Maximum Residue Limits)	Considered for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a). In agreement with the Pesticides Unit, this notification was kept in standby until the respective dossiers (including the literature review) are received.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Pullulanibacillus naganoensis</i>	Production of food enzyme pullulanase	EFSA-Q-2015-00451	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion: 'The body of knowledge on <i>Pullulanibacillus naganoensis</i> is too limited to exclude the possibility of ill effects developing during its manipulation for enzyme production. Therefore, it cannot be awarded QPS status'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Rhodopseudomonas palustris</i>	Feed additive		Insufficient body of knowledge (EFSA BIOHAZ Panel, 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
Feed/FEEDAP	<i>Serratia rubidaea</i>	Feed additive		Insufficient body of knowledge (EFSA BIOHAZ Panel, 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
Feed/FEEDAP	<i>Streptococcus cremoris</i> = <i>L. lactis</i> subsp. <i>cremoris</i>	Feed additive		Already QPS (EFSA, 2007).
Feed/FEEDAP	<i>Streptococcus faecium</i> = <i>Enterococcus faecium</i>	Feed additive		No recommendation for QPS status (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013). Considered in the current Scientific Opinion (refer to Section 3.6.2) where it is mentioned that the conclusions of 'the last update on QPS (EFSA BIOHAZ Panel, 2013) are still valid and <i>E. faecium</i> should be monitored and re-evaluated in the next QPS Opinion update' and in the Conclusions chapter that ' <i>Enterococcus faecium</i> is not recommended for the QPS list in spite of advances in recent scientific knowledge allowing a differentiation of pathogenic from non-pathogenic strains at the clade level. The QPS approach relies on the basis of the evaluation of TU, where the species/subspecies level is the lowest level of evaluation. Therefore, clades within the <i>E. faecium</i> species cannot be considered as a TU and cannot be evaluated separately'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Streptococcus thermophilus</i>	Feed additive	EFSA-Q-2006-135 http://www.efsa.europa.eu/en/efsajournal/pub/912 EFSA-Q-2010-00071 http://www.efsa.europa.eu/en/efsajournal/pub/3170	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.1.11) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore its QPS status does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Streptomyces albus</i>	Production of salinomycin sodium	EFSA-Q-2003-009 http://www.efsa.europa.eu/en/efsajournal/pub/75 EFSA-Q-2012-00994	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: ' <i>Streptomyces albus</i> is not recommended for the QPS list, because safety concerns cannot be excluded'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Streptomyces albus</i> ATCC 21838	Production of salinomycin sodium (coccidiostat)	EFSA-Q-2013-00706 EFSA-Q-2013-00998 EFSA-Q-2014-00350 (withdrawn)	
Feed/FEEDAP	<i>Streptomyces albus</i> NCIMB 30321	Production of salinomycin sodium (coccidiostat)	EFSA-Q-2014-00350 (withdrawn)	
Feed/FEEDAP	<i>Streptomyces aureofaciens</i>	Production of polyether monocarboxylic acid	EFSA-Q-2003-046 http://www.efsa.europa.eu/en/efsajournal/pub/90	
Feed/FEEDAP	<i>Streptomyces aureofaciens</i>	Production of salinomycin	EFSA-Q-2014-00666 http://www.efsa.europa.eu/en/efsajournal/pub/4614	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: ' <i>Streptomyces aureofaciens</i> is not recommended for the QPS list, because the body of knowledge is limited and safety concerns cannot be excluded'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Streptomyces aureofaciens</i> NRRL 8092	Production of narasin (coccidiostat)	EFSA-Q-2013-00767	
Feed/FEEDAP	<i>Streptomyces aureofaciens</i> NRRL 8092	Production of narasin (coccidiostat)	EFSA-Q-2015-00032	
Feed/FEEDAP	<i>Streptomyces aureofaciens</i> NRRL 8092	Production of narasin (coccidiostat)	EFSA-Q-2015-00033	
Feed/FEEDAP	<i>Streptomyces cinnamonensis</i>	Production of monensin sodium	EFSA-Q-2005-024 http://www.efsa.europa.eu/en/efsajournal/pub/283 EFSA-Q-2012-00906 EFSA-Q-2012-00791	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: ' <i>Streptomyces cinnamonensis</i> is not recommended for the QPS list, because the body of

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Streptomyces cinnamonensis</i> ATCC 15413	Production of monensin sodium (coccidiostat)	EFSA-Q-2013-00752	knowledge is limited and safety concerns cannot be excluded'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Streptomyces cinnamonensis</i> NBIMCC 3419	Production of monensin sodium	EFSA-Q-2015-00167 (withdrawn)	
Feed/FEEDAP	<i>Streptomyces lasaliensis</i>	Production of lasalocid sodium	EFSA-Q-2004-076 http://www.efsa.europa.eu/en/efsajournal/pub/77	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: ' <i>Streptomyces lasaliensis</i> 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'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Streptomyces lasaliensis</i> ATCC 31180	Production of lasalocid A sodium (coccidiostat)	EFSA-Q-2013-00813	
Pesticides	<i>Streptomyces lydicus</i> strain WYEC 108 (ATCC 55445)	Plant protection product	EFSA-Q-2012-00775 http://www.efsa.europa.eu/en/efsajournal/pub/3425 Application for approval EFSA-Q-2014-00595 Review of MRLs (Maximum Residue Limits)	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'Streptomycetes are essentially non-virulent, with the exception of some plant pathogens such as <i>S. scabies</i> . 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'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Streptomyces mobaraensis</i> S-8112	Production of food enzyme transglutaminase	EFSA-Q-2015-00095	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'Streptomyces are essentially non-virulent, with the exception of some plant pathogens such as <i>S. scabies</i> . 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 streptomyces 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'. Please refer to the complete assessment.
FIP/CEF	<i>Streptomyces murinus</i>	Production of food enzyme AMP deaminase	EFSA-Q-2015-00683	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'Streptomyces are essentially non-virulent, with the exception of some plant pathogens such as <i>S. scabies</i> . 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 streptomyces 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'. Please refer to the complete assessment.
FIP/CEF	<i>Streptomyces murinus</i>	Production of food enzyme glucose isomerase	EFSA-Q-2016-00032	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Streptomyces violaceoruber</i> (strain AS-10), GMM strain	Production of food enzyme phospholipase A2	EFSA-Q-2016-00132	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'Streptomyces are essentially non-virulent, with the exception of some plant pathogens such as <i>S. scabies</i>. 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 streptomyces 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'. Please refer to the complete assessment.
FIP/CEF	<i>Streptomyces violaceoruber</i> (pChi), GMM strain	Production of food enzyme chitinase	EFSA-Q-2015-00621	
FIP/CEF	<i>Streptomyces violaceoruber</i> (strain pCol), GMM strain	Production of food enzyme microbial collagenase	EFSA-Q-2015-00826	
FIP/CEF	<i>Streptomyces violaceoruber</i> pGlu	Production of food enzyme glucanase	EFSA-Q-2015-00097	
Pesticides	Now unspecified <i>Streptomyces</i> species: ' <i>Streptomyces</i> strain K 61', formerly: <i>Streptomyces griseoviridis</i>	Plant protection product	EFSA-Q-2009-00134 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00295 http://www.efsa.europa.eu/en/efsajournal/pub/3061 Application for approval	<i>Streptomyces</i> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA, 2008). Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'Streptomyces are essentially non-virulent, with the exception of some plant pathogens such as <i>S. scabies</i>. 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 streptomyces 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'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Xanthomonas campestris</i>	Technological additive (production of xanthan gum)	EFSA-Q-2013-01021	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2015a) with the conclusion: 'Xanthan gum produced by <i>X. campestris</i> has a long and broad history of safe use in the food industry. <i>X. campestris</i> is a plant pathogen. Apart from one record (Li et al., 1990), <i>X. campestris</i> has never been implicated in human or animal disease. However, human consumers are presumably very rarely exposed to high levels of <i>X. campestris</i> through food, indicating a lack of knowledge on the effect of high levels of live cells of <i>X. campestris</i> on animals and humans. In all papers screened, none of them mentioned acquisition of resistance to antimicrobials. <i>Xanthomonas campestris</i> can be recommended for the QPS list for the production of xanthan gum'. Please refer to the complete assessment.
Yeasts				
Feed/FEEDAP	Astaxanthin rich <i>Phaffia rhodozyma</i> = <i>Xanthophyllomyces dendrorhous</i>	Production of astaxanthin	EFSA-Q-2004-148 http://www.efsa.europa.eu/en/efsajournal/pub/320 EFSA-Q-2003-112 http://www.efsa.europa.eu/en/efsajournal/pub/43	<i>Phaffia rhodozyma</i> was assessed not appropriate for QPS (EFSA, 2008) because of insufficient body of knowledge. Later recommended for the QPS list (EFSA BIOHAZ Panel, 2011) as it is the imperfect form of <i>Xanthophyllomyces dendrorhous</i> according to the 2011 revision of the yeast taxonomy.
Pesticides	<i>Aureobasidium pullulans</i> strains DSM 14940 and DSM 14941	Plant protection product	EFSA-Q-2010-01499 http://www.efsa.europa.eu/en/efsajournal/pub/2435 EFSA-Q-2011-01200 www.efsa.europa.eu/en/efsajournal/pub/3183.htm Applications for approval EFSA-Q-2014-00369 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	Body of knowledge insufficient (QPS 2009 update). Considered for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a). In agreement with the Pesticides Unit, this notification was kept in standby until the respective dossiers (including the literature review) are received.
FIP/CEF	<i>Candida cylindracea</i>	Production of food enzyme	EFSA-Q-2015-00339	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2014) with the conclusion: 'In the <i>Candida</i>

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Candida cylindracea</i> AE-LAYH, GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2014-00113	<i>cylindracea</i> 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 <i>Candida cylindracea</i> viable cells by humans or animals, QPS should apply only for the production of enzymes'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Candida glabrata</i>	Feed additive		Unsuitable for QPS (see EFSA, 2007).
Feed/FEEDAP	<i>Candida guilliermondii</i>	Fermentation product	EFSA-Q-2003-082 http://www.efsa.europa.eu/en/efsajournal/pub/68	Unsuitable for QPS (see EFSA, 2007).
Pesticides	<i>Candida oleophila</i> strain O	Plant protection product	EFSA-Q-2009-00338 http://www.efsa.europa.eu/en/efsajournal/pub/2944 Application for approval EFSA-Q-2013-00039 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	Body of knowledge insufficient, therefore not appropriate for QPS (EFSA, 2008). Considered for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a). In agreement with the Pesticides Unit, this notification was kept in standby until the respective dossiers (including the literature review) are received.
FIP/CEF	<i>Candida rugosa</i>	Production of food enzyme triacylglycerol lipase	EFSA-Q-2015-00291	Evaluated for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a) with the conclusion: 'Although <i>Candida rugosa</i> has sometimes been reported to occur in food fermentations, due to a unclear taxonomy it may have been misidentified in several of those cases. Moreover, it has recently been described as an "emerging" human fungal pathogen and is well-known for causing mastitis. For these reasons <i>C. rugosa</i> is not recommended for QPS status'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Hansenula polymorpha</i> = <i>Pichia angusta</i> *	Production of enzymes	EFSA-Q-2005-030 http://www.efsa.europa.eu/en/efsajournal/pub/333	Already QPS status applies only when species is used for enzyme production purposes (EFSA, 2008; EFSA BIOHAZ Panel, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.7) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore its QPS status does not change. The qualification is unchanged'. Please refer to the complete assessment. * <i>Ogataea angusta</i> : synonym <i>Pichia angusta</i> .
FIP/CEF	<i>Hansenula polymorpha</i> , GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2015-00374	
FIP/CEF	<i>Hansenula polymorpha</i> , GMM strain	Production of food enzyme hexose oxidase	EFSA-Q-2015-00406	
FIP/CEF	<i>Kluyveromyces lactis</i>	Production of food enzyme β -galactosidase	EFSA-Q-2015-00409	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.4). The ELS search retrieved no new studies with relevance for the QPS evaluation of <i>Kluyveromyces lactis</i> (or its anamorphic name <i>Candida spherica</i>). Therefore its QPS status does not change. Please refer to the complete assessment.
FIP/CEF	<i>Kluyveromyces lactis</i> (AE-KL)	Production of food enzyme β -galactosidase	EFSA-Q-2014-00669	
FIP/CEF	<i>Kluyveromyces lactis</i> (CIN), GMM strain	Production of food enzyme chymosin	EFSA-Q-2015-00085	
FIP/CEF	<i>Kluyveromyces lactis</i> /CHY	Production of food enzyme	EFSA-Q-2015-00129	
2148/2004/EC	<i>Kluyveromyces marxianus</i> var. <i>lactisK1</i>	Feed additive		Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.4) with the conclusion: 'There is no doubt that <i>K. marxianus</i> /C. <i>kefyr</i> should be considered a significant opportunistic fungus, and it has received increased attention in recent years. However, reports where it has been unambiguously shown to be causative agent of infectious disease in otherwise healthy individuals are very rare. Therefore, its QPS status does not change. There is reason to be alert regarding whether there is a tendency for <i>K. marxianus</i> to become more common in this kind of infection'. Please refer to the complete assessment.
Reg(EC)773/ 2006 Corrigendum CS	<i>Kluyveromyces marxianus</i> - <i>fragilis</i>	Feed additive		

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Komagataella pastoris</i> = <i>Pichia pastoris</i> , GMM strain	Production of enzyme	EFSA-Q-2006-025 http://www.efsa.europa.eu/en/efsajournal/pub/627 and related opinions: EFSA-Q-2009-00804: http://www.efsa.europa.eu/en/efsajournal/pub/1550 EFSA-Q-2011-00148 http://www.efsa.europa.eu/en/efsajournal/pub/2533 Other applications: EFSA-Q-2010-00152 http://www.efsa.europa.eu/en/efsajournal/pub/2414 EFSA-Q-2013-00022 http://www.efsa.europa.eu/en/efsajournal/pub/4159	Already QPS (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.5) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore its QPS status does not change. The qualification is unchanged'. 'QPS only applies when the species is used for enzyme production and no viable cells are found'. Please refer to the complete assessment. * <i>Komagataella pastoris</i> (formerly named as <i>Pichia pastoris</i>).
Feed/FEEDAP	<i>Komagataella pastoris</i> * (DSMZ 25376), GMM strain	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00528	
Feed/FEEDAP	<i>Komagataella pastoris</i> * (DSMZ 26643), GMM strain	Technological/production of fumonisin esterase	EFSA-Q-2013-00090 http://www.efsa.europa.eu/en/efsajournal/pub/3667	
Feed/FEEDAP	<i>Komagataella pastoris</i> * (DSMZ 26469), GMM strain	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00528	
Feed/FEEDAP	<i>Pichia pastoris</i> *	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00829 http://www.efsa.europa.eu/en/efsajournal/pub/4200	
Feed/FEEDAP	<i>Pichia pastoris</i> *	Technological additive (production of enzyme for reduction of mycotoxin contamination of feed)	EFSA-Q-2014-00900 http://www.efsa.europa.eu/en/efsajournal/pub/4617	
Feed/FEEDAP	<i>Pichia pastoris</i> * ATCC 76273/CBS 7435/ CECT 11047	Zootechnical additive (production of enzyme 3-phytase)	EFSA-Q-2015-00482 http://www.efsa.europa.eu/en/efsajournal/pub/4622	
Feed/FEEDAP	<i>Pichia pastoris</i> * (DSMZ 23036)	Production of 6-phytase	EFSA-Q-2016-00291	
FIP/CEF	<i>Pichia pastoris</i> * (PRF), GMM strain	Production of food enzyme phospholipase C	EFSA-Q-2016-00201	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Metschnikowia fructicola</i>	Plant protection product	EFSA-Q-2015-00546 Application for approval	Considered for the BIOHAZ Panel Statement (EFSA BIOHAZ Panel, 2016a). In agreement with the Pesticides Unit, this notification was kept in standby until the respective dossiers (including the literature review) are received.
GMO/GMO	<i>Saccharomyces cerevisiae</i>	Dried killed biomass for feed	EFSA-Q-2007-156b (withdrawn) EFSA-Q-2009-00866 (withdrawn)	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.8) with the conclusion: 'These new reports of <i>Saccharomyces cerevisiae</i> appearing as an opportunistic pathogen add no further concern regarding its QPS status. Consumption of <i>Saccharomyces boulardii</i> (synonym of <i>S. cerevisiae</i>) by patients with fragile health may be considered as the origin of the infection, although the use of microorganisms intended to be used as "probiotic" for humans as a health claim does not fall under the remit of the QPS assessment. These new reports also confirm the previous QPS qualifications, 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 and inability to grow above 37°C. Therefore its QPS status does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Feed additive	EFSA-Q-2005-025 http://www.efsa.europa.eu/en/efsajournal/pub/384 EFSA-Q-2005-234 http://www.efsa.europa.eu/en/efsajournal/pub/385 EFSA-Q-2005-149 http://www.efsa.europa.eu/en/efsajournal/pub/321 EFSA-Q-2005-176 http://www.efsa.europa.eu/en/efsajournal/pub/370 EFSA-Q-2006-003 http://www.efsa.europa.eu/en/efsajournal/pub/379 EFSA-Q-2006-067 http://www.efsa.europa.eu/en/efsajournal/pub/459 EFSA-Q-2007-104 http://www.efsa.europa.eu/en/efsajournal/pub/585 EFSA-Q-2007-139 http://www.efsa.europa.eu/en/efsajournal/pub/772 EFSA-Q-2007-165 http://www.efsa.europa.eu/en/efsajournal/pub/1353 EFSA-Q-2008-009 http://www.efsa.europa.eu/en/efsajournal/pub/991 EFSA-Q-2008-010	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			http://www.efsa.europa.eu/en/efsajournal/pub/837 EFSA-Q-2008-302 http://www.efsa.europa.eu/en/efsajournal/pub/970 EFSA-Q-2008-472 http://www.efsa.europa.eu/en/efsajournal/pub/1040 EFSA-Q-2009-00720 http://www.efsa.europa.eu/en/efsajournal/pub/1864 EFSA-Q-2009-00753 http://www.efsa.europa.eu/en/efsajournal/pub/1662 EFSA-Q-2009-00818 http://www.efsa.europa.eu/en/efsajournal/pub/2439 EFSA-Q-2009-00824 http://www.efsa.europa.eu/en/efsajournal/pub/1662 EFSA-Q-2010-00936 http://www.efsa.europa.eu/en/efsajournal/pub/2531 EFSA-Q-2010-00938 http://www.efsa.europa.eu/en/efsajournal/pub/3666 EFSA-Q-2010-00992 http://www.efsa.europa.eu/en/efsajournal/pub/2173 EFSA-Q-2011-00390 http://www.efsa.europa.eu/en/efsajournal/pub/3362	
Nutrition/NDA	<i>Saccharomyces cerevisiae</i>	Food targeted for health claims	EFSA-Q-2012-00271 http://www.efsa.europa.eu/en/efsajournal/pub/2801	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.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Organic selenium source	EFSA-Q-2005-071 http://www.efsa.europa.eu/en/efsa-journal/pub/348 EFSA-Q-2005-117 http://www.efsa.europa.eu/en/efsa-journal/pub/430 EFSA-Q-2008-381 http://www.efsa.europa.eu/en/efsa-journal/pub/992 EFSA-Q-2009-00524 http://www.efsa.europa.eu/en/efsa-journal/pub/2279 EFSA-Q-2009-00752 http://www.efsa.europa.eu/en/efsa-journal/pub/2110 EFSA-Q-2010-01029 http://www.efsa.europa.eu/en/efsa-journal/pub/2778	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.8) with the conclusion: 'These new reports of <i>Saccharomyces cerevisiae</i> appearing as an opportunistic pathogen add no further concern regarding its QPS status. Consumption of <i>Saccharomyces boulardii</i> (synonym of <i>S. cerevisiae</i>) by patients with fragile health may be considered as the origin of the infection, although the use of microorganisms intended to be used as "probiotic" for humans as a health claim does not fall under the remit of the QPS assessment. These new reports also confirm the previous QPS qualifications, 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 and inability to grow above 37°C. Therefore its QPS status does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> , GMM strain	Production of enzyme	EFSA-Q-2005-224 (withdraw) EFSA-Q-2009-00534 http://www.efsa.europa.eu/en/efsa-journal/pub/2451 and related application: EFSA-Q-2012-00909 http://www.efsa.europa.eu/en/efsa-journal/pub/3286	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Zootechnical additive	EFSA-Q-2016-00292	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Zootechnical additive	EFSA-Q-2016-00297	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Zootechnical additive	EFSA-Q-2016-00298	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i>	Zootechnical additive	EFSA-Q-2016-00090	
FIP/CEF	<i>Saccharomyces cerevisiae</i> CBS615-94, GMM strain	Production of food enzyme α -galactosidase	EFSA-Q-2013-00119 http://www.efsa.europa.eu/en/efsa-journal/pub/3304	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> CNCM I-1077	Zootechnical additive	EFSA-Q-2014-00029	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> CNCM I-1077	Zotechnical additive	EFSA-Q-2014-00375	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> <i>boulardii</i> CNCM I-1079	Zotechnical additive	EFSA-Q-2015-00287	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> CNCM I-1079	Zotechnical additive	EFSA-Q-2016-00449	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> CNCM I-3060	Production of organic selenium	EFSA-Q-2016-00138	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> CNCM I-3399	Production of histidine	EFSA-Q-2016-00346	
Pesticides	<i>Saccharomyces cerevisiae</i> strain LA02	Plant protection product	EFSA-Q-2014-00333 http://www.efsa.europa.eu/en/efsajournal/pub/4322 Application for approval	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> LOCK 0141	Zotechnical additive	EFSA-Q-2013-00996 http://www.efsa.europa.eu/en/efsajournal/pub/4555	
Feed/FEEDAP	<i>Saccharomyces cerevisiae</i> (MUCL 39885)	Zotechnical additive	EFSA-Q-2014-00792 http://www.efsa.europa.eu/en/efsajournal/pub/4199	
FIP/CEF	<i>Saccharomyces cerevisiae</i> /NA	Production of food enzyme	EFSA-Q-2015-00323	
Nutrition/NDA	<i>Saccharomyces cerevisiae</i> (vitamin D-enriched UV- treated)	As a novel food ingredient	EFSA-Q-2013-00335 http://www.efsa.europa.eu/en/efsajournal/pub/3520 As a Novel food ingredient in the context of Regulation (EC) No 258/97	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Schizosaccharomyces pombe</i>	Production of enzymes	EFSA-Q-2005-063 http://www.efsa.europa.eu/en/efsajournal/pub/350 and related questions: EFSA-Q-2005-080 http://www.efsa.europa.eu/en/efsajournal/pub/404 EFSA-Q-2008-272 http://www.efsa.europa.eu/en/efsajournal/pub/915 EFSA-Q-2011-00835 http://www.efsa.europa.eu/en/efsajournal/pub/2619	Already QPS (EFSA, 2007, 2008; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a). Re-evaluated in the current Scientific Opinion (refer to Section 3.4.9) with the conclusion: 'No references related to possible concerns for human or animal safety, AMR or other related aspects were identified. Therefore its QPS status does not change'. Please refer to the complete assessment.
Feed/FEEDAP	<i>Schizosaccharomyces pombe</i>	Production of phytase	EFSA-Q-2016-00559	
Feed/FEEDAP	<i>Trichosporon mycotoxinivorans</i>	Feed additive	EFSA-Q-2010-01030 (withdrawn)	
Not recommended for the QPS list, assessed in the 2011 update (EFSA BIOHAZ Panel, 2011).				
Filamentous fungi ^(d)				
Pesticides	<i>Ampelomyces quisqualis</i> strain Q10	Plant protection product	EFSA-Q-2008-489 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) Review Report for the active substance Review Report for the active substance <i>Ampelomyces quisqualis</i> , SANCO/4205/VI/98-rev.final, October 2004	Not recommended for the QPS list (EFSA BIOHAZ Panel, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Ampelomyces quisqualis</i> strain AQ10	Plant protection product	EFSA-Q-2015-00021 Application for renewal of approval	
Feed/FEEDAP	<i>Ashbya gossypii</i>	Production of vitamin B2	EFSA-Q-2012-00953	Not recommended for the QPS list (EFSA BIOHAZ Panel, 2011, 2012, 2013).
FIP/CEF	<i>Aspergillus acidus</i> / RF7398, GMM strain	Production of food enzyme is a endo 1,4-β-xylanase	EFSA-Q-2014-00163	Not recommended for the QPS list ^(d) .

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Aspergillus aculeatus</i>	Production of enzyme	EFSA-Q-2008-432 http://www.efsa.europa.eu/en/efsajournal/pub/1186 EFSA-Q-2011-00035 http://www.efsa.europa.eu/en/efsajournal/pub/2010 EFSA-Q-2010-01297 http://www.efsa.europa.eu/en/efsajournal/pub/4234 EFSA-Q-2010-01295 http://www.efsa.europa.eu/en/efsajournal/pub/4235	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
FIP/CEF	<i>Aspergillus aculeatus</i> / NZYM-RE CBS 589.94	Production of food enzyme polygalacturonase and β -glucanase	EFSA-Q-2014-00200 EFSA-Q-2014-00201	
FIP/CEF	<i>Aspergillus fijiensis</i>	Production of food enzyme β -fructofuranosidase	EFSA-Q-2015-00840	
FIP/CEF	<i>Aspergillus melleus</i> /AE-DN	Production of food enzyme AMP deaminase	EFSA-Q-2014-00326	Not recommended for the QPS list ^(d) .
Feed/FEEDAP	<i>Aspergillus niger</i> , GMM strain	Production of enzyme	EFSA-Q-2004-068 http://www.efsa.europa.eu/en/efsajournal/pub/198 and related opinions: EFSA-Q-2006-119 http://www.efsa.europa.eu/en/efsajournal/pub/474 EFSA-Q-2008-418 http://www.efsa.europa.eu/en/efsajournal/pub/1155 EFSA-Q-2011-00147 http://www.efsa.europa.eu/en/efsajournal/pub/2575 EFSA-Q-2005-116 http://www.efsa.europa.eu/en/efsajournal/pub/369 and related opinions: EFSA-Q-2007-049	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			http://www.efsa.europa.eu/en/efsajournal/pub/472 EFSA-Q-2007-041 http://www.efsa.europa.eu/en/efsajournal/pub/544 EFSA-Q-2007-189 http://www.efsa.europa.eu/en/efsajournal/pub/614 EFSA-Q-2008-692 http://www.efsa.europa.eu/en/efsajournal/pub/1184 EFSA-Q-2009-00603 http://www.efsa.europa.eu/en/efsajournal/pub/1427 EFSA-Q-2009-00534 http://www.efsa.europa.eu/en/efsajournal/pub/2451 and related application: EFSA-Q-2012-00909 EFSA-Q-2009-00585 http://www.efsa.europa.eu/en/efsajournal/pub/3322 EFSA-Q-2008-013 http://www.efsa.europa.eu/en/efsajournal/pub/914 and related Questions: EFSA-Q-2010-00937 http://www.efsa.europa.eu/en/efsajournal/pub/2172 EFSA-Q-2011-00061 http://www.efsa.europa.eu/en/efsajournal/pub/3285 EFSA-Q-2010-01519 http://www.efsa.europa.eu/en/efsajournal/pub/3430 EFSA-Q-2012-00411	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Aspergillus niger</i>	Production of enzyme	EFSA-Q-2008-013a http://www.efsa.europa.eu/en/efsajournal/pub/914 and related Questions: EFSA-Q-2010-00937 http://www.efsa.europa.eu/en/efsajournal/pub/2172 EFSA-Q-2011-00061 http://www.efsa.europa.eu/en/efsajournal/pub/3285 EFSA-Q-2010-01519 http://www.efsa.europa.eu/en/efsajournal/pub/3430 EFSA-Q-2012-00411	
Feed/FEEDAP	<i>Aspergillus niger</i>	Production of enzyme	EFSA-Q-2014-00503	
Feed/FEEDAP	<i>Aspergillus niger</i>	Production of enzyme	EFSA-Q-2014-0057	
FIP/CEF	<i>Aspergillus niger</i> , GMM strain	Production of food enzyme carboxypeptidase C	EFSA-Q-2015-00445	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme catalase	EFSA-Q-2015-00449	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme cellulase, glucanase and hemicellulase covering xylanase and mannanase	EFSA-Q-2015-00340	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme glucoamylase	EFSA-Q-2015-00292	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme glucose oxidase and catalase	EFSA-Q-2013-01018	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme inulinase	EFSA-Q-2015-00827	
FIP/CEF	<i>Aspergillus niger</i> , GMM strain	Production of food enzyme lipase	EFSA-Q-2015-00561	
FIP/CEF	<i>Aspergillus niger</i> , GMM strain	Production of food enzyme pectin lyase	EFSA-Q-2015-00407	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme pectinase (polygalacturonase, pectinesterase, pectin lyase, arabanase)	EFSA-Q-2015-00038/ EFSA-Q-2015-00039/ EFSA-Q-2015-00040/ EFSA-Q-2015-00041/ EFSA-Q-2015-00042	
FIP/CEF	<i>Aspergillus niger</i> , GMM strain	Production of food enzyme peroxidase	EFSA-Q-2015-00274	
FIP/CEF	<i>Aspergillus niger</i>	Production of food enzyme tannase	EFSA-Q-2016-00034	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Aspergillus niger</i> GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2016-00099	
FIP/CEF	<i>Aspergillus niger</i> GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2015-00276	
Feed/FEEDAP	<i>Aspergillus niger</i>	Feed additive		
Feed/FEEDAP	<i>Aspergillus niger</i>	Zootechnical additive (production of enzymes)	EFSA-Q-2015-00054	
FIP/CEF	<i>Aspergillus niger</i> agg., GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2015-00447	
FIP/CEF	<i>Aspergillus niger</i> , (AE-TGU)	Production of food enzyme α -glucosidase	EFSA-Q-2014-00800	
FIP/CEF	<i>Aspergillus niger</i> /AGN, GMM strain	Production of food enzyme asparaginase	EFSA-Q-2014-00401	
FIP/CEF	<i>Aspergillus niger</i> (ARF)	Production of food enzyme α -L-arabinofuranosidase	EFSA-Q-2014-00671	
FIP/CEF	<i>Aspergillus niger</i> (ASNSC)	Production of food enzyme pectinase	EFSA-Q-2014-00839	
FIP/CEF	<i>Aspergillus niger</i> (ASNSC)	Production of food enzyme polygalacturonase	EFSA-Q-2014-00840	
FIP/CEF	<i>Aspergillus niger</i> (ASNSC)	Production of food enzyme pectinesterase	EFSA-Q-2014-00841	
FIP/CEF	<i>Aspergillus niger</i> (ASNSC)	Production of food enzyme pectin lyase	EFSA-Q-2014-00842	
FIP/CEF	<i>Aspergillus niger</i> (ASNSC)	Production of food enzyme arabanase	EFSA-Q-2014-00843	
Feed/FEEDAP	<i>Aspergillus niger</i> (CBS 18404)	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00886 http://www.efsa.europa.eu/en/efsajournal/pub/3723 EFSA-Q-2014-00291 http://www.efsa.europa.eu/en/efsajournal/pub/4347	
Feed/FEEDAP	<i>Aspergillus niger</i> CBS 101.672)	Preparation of 6-phytase	EFSA-Q-2015-00732	
Feed/FEEDAP	<i>Aspergillus niger</i> (CBS 109.713)	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00886 http://www.efsa.europa.eu/en/efsajournal/pub/3723 EFSA-Q-2014-00291 http://www.efsa.europa.eu/en/efsajournal/pub/4347	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Aspergillus niger</i> (CBS 109.713)	Preparation of endo-1,4- β -xylanase and endo-1,4- β -glucanase	EFSA-Q-2016-00302 http://www.efsa.europa.eu/en/efsajournal/pub/4626	
FIP/CEF	<i>Aspergillus niger</i> /DS53180, GMM strain	Production of food enzyme asparaginase	EFSA-Q-2013-00895	
FIP/CEF	<i>Aspergillus niger</i> /EPG, GMM strain	Production of food enzyme polygalacturonase	EFSA-Q-2014-00402	
FIP/CEF	<i>Aspergillus niger</i> /EPG	Production of food enzyme	EFSA-Q-2015-00178	
FIP/CEF	<i>Aspergillus niger</i> /FLOSC	Production of food enzyme	EFSA-Q-2015-00130	
FIP/CEF	<i>Aspergillus niger</i> (FLYSC), GMM strain	Production of food enzyme polygalactunase	EFSA-Q-2015-00086	
FIP/CEF	<i>Aspergillus niger</i> (FLZSC), GMM strain	Production of food enzyme polygalactunase	EFSA-Q-2015-00087	
FIP/CEF	<i>Aspergillus niger</i> (GEP), GMM strain	Production of food enzyme acid prolyl endopeptidase	EFSA-Q-2014-00852	
FIP/CEF	<i>Aspergillus niger</i> / LFS, GMM strain	Production of food enzyme triacylglycerol lipase	EFSA-Q-2014-00325	
FIP/CEF	<i>Aspergillus niger</i> var. <i>Macrosporus</i>	Production of food enzyme aspergillolisin I and II	EFSA-Q-2015-00623	
Feed/FEEDAP	<i>Aspergillus niger</i> MUCL 39199	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00229 http://www.efsa.europa.eu/en/efsajournal/pub/4620	
FIP/CEF	<i>Aspergillus niger</i> (PLA), GMM strain	Production of food enzyme phospholipase A2	EFSA-Q-2015-00043	
FIP/CEF	<i>Aspergillus niger</i> (PME), GMM strain	Production of food enzyme pectinesterase	EFSA-Q-2015-00044	
Feed/FEEDAP	<i>Aspergillus niger</i> NRRL 25541	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00503 EFSA-Q-2014-00504	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-AK	Production of food enzyme	EFSA-Q-2015-00128	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-BE, GMM strain	Production of food enzyme glucoamylase	EFSA-Q-2013-00896	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-BF, GMM strain	Production of food enzyme glucoamylase	EFSA-Q-2014-00307	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Aspergillus niger</i> /NZYM-BR, GMM strain	Production of food enzyme amyloglucosidase	EFSA-Q-2013-00686	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-BX, GMM strain	Production of food enzyme glucan 1,4- α - glucosidase with activity also of an α - amylase	EFSA-Q-2013-00877	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-DB	Production of food enzyme	EFSA-Q-2015-00234	
FIP/CEF	<i>Aspergillus niger</i> (strain NZYM- KA)	Production of food enzyme glucose oxidase	EFSA-Q-2016-00134	
FIP/CEF	<i>Aspergillus niger</i> (NZYM-LP), GMM strain	Production of food enzyme lysophospholipase	EFSA-Q-2014-00919	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-MC, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2014-00306	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-PN	Production of food enzyme	EFSA-Q-2015-00407	
FIP/CEF	<i>Aspergillus niger</i> /NZYM-SB, GMM strain	Production of food enzyme α -amylase	EFSA-Q-2014-00413	
FIP/CEF	<i>Aspergillus niger</i> (TOL), GMM strain	Production of food enzyme β -galactosidase	EFSA-Q-2014-00853	
FIP/CEF	<i>Aspergillus niger</i> (XEA), GMM strain	Production of food enzyme endo-1,4- β -xylanase	EFSA-Q-2015-00045	
FIP/CEF	<i>Aspergillus niger</i> /XYL, GMM strain	Production of food enzyme endo-1,4- β -xylanase	EFSA-Q-2014-00305	
FIP/CEF	<i>Aspergillus niger</i> /ZGL	Production of food enzyme glucose oxidase	EFSA-Q-2013-01005	
Feed/FEEDAP	<i>Aspergillus niger</i> Strains: ZLCA0323 Van Tieghem ZS9 TN-A09	Production of citric acid	EFSA-Q-2013-00612	

Unit EFSA/ Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Aspergillus oryzae</i>	Production of enzymes	EFSA-Q-2003-012 http://www.efsa.europa.eu/en/efsajournal/pub/66 and related opinions: EFSA-Q-2004-070 http://www.efsa.europa.eu/en/efsajournal/pub/88 EFSA-Q-2004-118 http://www.efsa.europa.eu/en/efsajournal/pub/132 EFSA-Q-2006-060 http://www.efsa.europa.eu/en/efsajournal/pub/519 EFSA-Q-2007-132 http://www.efsa.europa.eu/en/efsajournal/pub/1862 EFSA-Q-2009-00535 http://www.efsa.europa.eu/en/efsajournal/pub/1915 EFSA-Q-2007-133 http://www.efsa.europa.eu/en/efsajournal/pub/871 and related opinions: EFSA-Q-2008-430 www.efsa.europa.eu/en/efsajournal/pub/1097.htm EFSA-Q-2009-00536 http://www.efsa.europa.eu/en/efsajournal/pub/1634 EFSA-Q-2008-419 http://www.efsa.europa.eu/en/efsajournal/pub/2790 EFSA-Q-2010-00769 http://www.efsa.europa.eu/en/efsajournal/pub/2527 and related opinion: EFSA-Q-2011-01172 http://www.efsa.europa.eu/en/efsajournal/pub/2730	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			EFSA-Q-2010-01519 http://www.efsa.europa.eu/en/efsajournal/pub/2527	Not recommended for the QPS list ^(d) .
Feed/FEEDAP	<i>Aspergillus oryzae</i>	Feed additive	EFSA-Q-2009-00525 http://www.efsa.europa.eu/en/efsajournal/pub/4230	
FIP/CEF	<i>Aspergillus oryzae</i> / AE-MB	Production of food enzymes leucyl aminopeptidase, protease and amylase	EFSA-Q-2014-00114	
Feed/FEEDAP	<i>Aspergillus oryzae</i>	Production of enzyme	EFSA-Q-2014-00503	
Feed/FEEDAP	<i>Aspergillus oryzae</i>	Technological additive	EFSA-Q-2016-00220	
FIP/CEF	<i>Aspergillus oryzae</i> , GMM strain	Production of food enzyme inulinase	EFSA-Q-2015-00337	
FIP/CEF	<i>Aspergillus oryzae</i> , GMM strain	Production of food enzyme lipase	EFSA-Q-2015-00664	
FIP/CEF	<i>Aspergillus oryzae</i>	Production of food enzyme β -galactosidase	EFSA-Q-2015-00684	
FIP/CEF	<i>Aspergillus oryzae</i>	Production of food enzyme AMP deaminase	EFSA-Q-2015-00847	
FIP/CEF	<i>Aspergillus oryzae</i> (AE-AA)	Production of food enzyme α -amylase	EFSA-Q-2014-00913	
FIP/CEF	<i>Aspergillus oryzae</i> / AE-MB	Production of food enzymes leucyl aminopeptidase, protease and amylase	EFSA-Q-2014-00114	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Aspergillus oryzae</i> / AE-TL	Production of food enzymes triacylglycerol lipase and transesterase	EFSA-Q-2014-00112	
Feed/FEEDAP	<i>Aspergillus oryzae</i> DSM 17594, GMM strain	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00450 http://www.efsa.europa.eu/en/efsajournal/pub/4392	
Feed/FEEDAP	<i>Aspergillus oryzae</i> DSM 22594	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00289 http://www.efsa.europa.eu/en/efsajournal/pub/4393	
Feed/FEEDAP	<i>Aspergillus oryzae</i> DSM 23104	Zootechnical additives	EFSA-Q-2016-00215	
Feed/FEEDAP	<i>Aspergillus oryzae</i> DSM 26372, GMM strain	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00447 http://www.efsa.europa.eu/en/efsajournal/pub/4564	
FIP/CEF	<i>Aspergillus oryzae</i> (strain L729-48)	Production of food enzyme α -amylase	EFSA-Q-2016-00205	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Aspergillus oryzae</i> (strains NBRC 110971 and 11-5)	Production of food enzyme tannase	EFSA-Q-2016-00272	
Feed/FEEDAP	<i>Aspergillus oryzae</i> NRRL 66222	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00503	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-AL, GMM strain	Production of food enzyme lipase	EFSA-Q-2013-00198 http://www.efsa.europa.eu/en/efsajournal/pub/3778	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-EX	Production of food enzyme	EFSA-Q-2015-00373	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-FA, GMM strain	Production of food enzyme xylanase	EFSA-Q-2013-00789	
FIP/CEF	<i>Aspergillus oryzae</i> strain NZYM-FB	Production of food enzyme xylanase	EFSA-Q-2012-00897 http://www.efsa.europa.eu/en/efsajournal/pub/3645	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-FL, GMM strain	Production of food enzyme lipase	EFSA-Q-2013-00197 http://www.efsa.europa.eu/en/efsajournal/pub/3762	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-KE, GMM strain	Production of food enzyme xylanase	EFSA-Q-2012-00897 http://www.efsa.europa.eu/en/efsajournal/pub/3645	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-KP, GMM strain	Production of food enzyme glucose oxidase	EFSA-Q-2013-00687	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-LH, GMM strain	Production of food enzyme lipase	EFSA-Q-2012-01009 http://www.efsa.europa.eu/en/efsajournal/pub/3763	
FIP/CEF	<i>Aspergillus oryzae</i> / NZYM-NA	Production of food enzyme α -amylase	EFSA-Q-2012-01010	
FIP/CEF	<i>Aspergillus oryzae</i> (NZYM-OA), GMM strain	Production of food enzyme phospholipase A1	EFSA-Q-2015-00063	
FIP/CEF	<i>Aspergillus oryzae</i> (NZYM-PP), GMM strain	Production of food enzyme phospholipase	EFSA-Q-2014-00921	
FIP/CEF	<i>Aspergillus oryzae</i> (strains NBRC 110971 and 11-5)	Production of food enzyme tannase	EFSA-Q-2016-00272	
Feed/FEEDAP	<i>Aspergillus oryzae</i> DSM 23104	Zootechnical additives	EFSA-Q-2016-00215	
FIP/CEF	<i>Aspergillus oryzae</i> /NZYM-SP, GMM strain	Production of food enzyme asparaginase	EFSA-Q-2013-00587	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Beauveria bassiana</i> strain 147	Plant protection product	EFSA-Q-2014-00324 http://www.efsa.europa.eu/en/efsajournal/pub/4261 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Beauveria bassiana</i> (ATCC-74040 and GHA)	Plant protection product	EFSA-Q-2009-00125 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00251 and EFSA-Q-2009-00252 http://www.efsa.europa.eu/en/efsajournal/pub/3031 Application for approval	
Pesticides	<i>Beauveria bassiana</i> strain IMI389521	Plant protection product	EFSA-Q-2015-00362 Application for approval	
Pesticides	<i>Beauveria bassiana</i> strain NPP111B005	Plant protection product	EFSA-Q-2014-00327 http://www.efsa.europa.eu/en/efsajournal/pub/4264 Application for approval	
Pesticides	<i>Beauveria bassiana</i> strain PPRI5339	Plant protection product	EFSA-Q-2015-00361 Application for approval	
Pesticides	<i>Beauveria brongniartii</i>	Plant protection product	EFSA-Q-2009-00017 Review of MRLs (Maximum Residue Limits)	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge, potential oosporein formation (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
AFC (as mentioned in EFSA register of questions)	<i>Blakeslea trispora</i>	Production of lycopene (food colourant) Production of b-carotene (food colourant)	EFSA-Q-2004-102 http://www.efsa.europa.eu/en/efsajournal/pub/275 EFSA-Q-2007-001 http://www.efsa.europa.eu/en/efsajournal/pub/674	Cannot be proposed for QPS status (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
NDA	<i>Blakeslea trispora</i>	Food ingredient	EFSA-Q-2004-169 http://www.efsa.europa.eu/en/efsajournal/pub/212 EFSA-Q-2008-697 http://www.efsa.europa.eu/en/efsajournal/pub/893	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Blakeslea trispora</i>	Production strain for β -carotene	EFSA-Q-2009-00884 http://www.efsa.europa.eu/en/efsajournal/pub/2737	
FIP/CEF	<i>Chaetomium erraticum</i>	Production of food enzyme dextranase	EFSA-Q-2015-00685	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Chaetomium gracile</i>	Production of food enzyme dextranase	EFSA-Q-2015-00231	Not recommended for the QPS list ^(d) .
Pesticides	<i>Coniothyrium minitans</i>	Plant protection product	EFSA-Q-2008-515 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) <i>Coniothyrium minitans</i> , SANCO/1400/ 2001-final, July 2003	The body of knowledge is insufficient. Potential acropellic formation (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Coniothyrium minitans</i> CON/M/91-08	Plant protection product	EFSA-Q-2014-00656 http://www.efsa.europa.eu/en/efsajournal/pub/4517 Application for renewal of the approval	
FIP/CEF	<i>Disporotrichum dimorphosporum</i> / DXL	Production of food enzymes endo-1, 4- β -xylanase and β -glucanase	EFSA-Q-2014-00355 EFSA-Q-2014-00356	Not recommended for the QPS list ^(d) .
Feed/FEEDAP	<i>Duddingtonia flagrans</i> Alternative name: <i>Trichothecium flagrans</i>	Feed additive	EFSA-Q-2004-115 http://www.efsa.europa.eu/en/efsajournal/pub/334 EFSA-Q-2005-051 (withdrawn)	Insufficient body of knowledge (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Fusarium</i> spp., strain L 13	Plant protection product	EFSA-Q-2015-00345 Application for approval	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Fusarium venenatum</i> , GMM strain	Production of food enzyme trypsin	EFSA-Q-2014-00412	Not recommended for the QPS list ^(d) .
Pesticides	<i>Gliocladium catenulatum</i> = <i>Clonostachys rosea</i> forma <i>catenulata</i> , strain J1446	Plant protection product	EFSA-Q-2008-559 Review of MRLs (Maximum Residue Limits) <i>Gliocladium catenulatum</i> , SANCO/10383/2004-rev.4, October 2004	No recommendation for QPS in 2009 (EFSA BIOHAZ Panel, 2009). No new relevant information in the 2010 and 2013 updates ^(d) .
Pesticides	<i>Gliocladium catenulatum</i> , strain J1446	Plant protection product	EFSA-Q-2015-00582 Application for renewal of approval	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Humicola isolens</i> (NZYM-ST)	Production of food enzyme β -glucanase	EFSA-Q-2014-00795	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Humicola isolens</i> (NZYM-ST)	Production of food enzyme xylanase	EFSA-Q-2014-00796	
FIP/CEF	<i>Humicola isolens</i> (NZYM-ST)	Production of food enzyme cellulose	EFSA-Q-2014-00797	
Pesticides	<i>Isaria fumosorosea</i> , strain Apopka 97	Plant protection product	EFSA-Q-2013-00833 http://www.efsa.europa.eu/en/efsajournal/pub/3679 Application for renewal of the approval.	It has been formerly evaluated as <i>Paecilomyces fumosoroseus</i> (DG SANCO, 4203/VI/98-final) and approved in 2001. Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2013) ^(d) .
Pesticides	<i>Lecanicillium muscarium</i> formerly <i>Verticillium lecanii</i> , strain Ve6	Plant protection product	EFSA-Q-2009-00130 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00255 http://www.efsa.europa.eu/en/efsajournal/pub/1446 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
FIP/CEF	<i>Leptographium procerum</i>	Production of food enzyme phosphodiesterase	EFSA-Q-2013-01006	Not recommended for the QPS list ^(d) .
Pesticides	<i>Metarhizium anisopliae</i> var. <i>Anisopliae</i> (BIPESCO 5/F52) formerly <i>M. anisopliae</i>	Plant protection product	EFSA-Q-2009-00131 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00253 http://www.efsa.europa.eu/en/efsajournal/pub/2498 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
FIP/CEF	<i>Mucor javanicus</i>	Production of food enzyme triacylglycerol lipase	EFSA-Q-2015-00692	Not recommended for the QPS list ^(d) .
Pesticides	<i>Paecilomyces fumosoroseus</i> , strain Apopka 97, PFR 97 or CG170, ATCC20874 Current name: <i>Isaria fumosorosea</i>	Plant protection product	EFSA-Q-2008-599 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2013-00833 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3679/full Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2013) ^(d) .

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Paecilomyces fumosoroseus</i> , strain FE 9901 (ARSEF 4490) Current name: <i>Isaria fumosorosea</i>	Plant protection product	EFSA-Q-2013-00352 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00323 http://www.efsa.europa.eu/en/efsajournal/pub/2869 Application for approval	
Pesticides	<i>Paecilomyces lilacinus</i> , strain 251	Plant protection product	EFSA-Q-2008-600 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2010-01337 http://www.efsa.europa.eu/en/efsajournal/pub/103r Application for approval	Mycelial fungi: already considered as not appropriate for QPS. Potential for production of peptaibols (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Paecilomyces lilacinus</i> , strain 251	Plant protection product	EFSA-Q-2015-00520 Application for renewal of approval (AIR III)	
FIP/CEF	<i>Penicillium camemberti</i> (AE-LG)	Production of food enzyme acylglycerol lipase	EFSA-Q-2014-00668	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Penicillium citrinum</i> /AE-RP	Production of food enzyme ribonuclease P	EFSA-Q-2015-00288	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Penicillium citrinum</i>	Production of food enzyme aspergillus nuclease S1	EFSA-Q-2015-00845	
FIP/CEF	<i>Penicillium decumbes</i>	Production of food enzyme α -L-rhamnosidase	EFSA-Q-2015-00756	Not recommended for the QPS list ^(d) .

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Penicillium funiculosum</i>	Production of enzyme	EFSA-Q-2005-281 http://www.efsa.europa.eu/en/efsajournal/pub/471 EFSA-Q-2010-01287 http://www.efsa.europa.eu/en/efsajournal/pub/3321 EFSA-Q-2011-00881 http://www.efsa.europa.eu/en/efsajournal/pub/3722	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
FIP/CEF	<i>Penicillium funiculosum</i> (DP-Lzc35)	Production of food enzyme cellulase	EFSA-Q-2016-00098	
Feed/FEEDAP	<i>Penicillium funiculosum</i> (<i>Talaromyces versatilis</i> sp. nov. DSM 26702), GMM strain	Zotechnical additive	EFSA-Q-2013-00750 http://www.efsa.europa.eu/en/efsajournal/pub/3793 EFSA-Q-2014-00463 http://www.efsa.europa.eu/en/efsajournal/pub/4106	
Feed/FEEDAP	<i>Penicillium funiculosum</i> (<i>Talaromyces versatilis</i> IMI 378536)	Zotechnical additive (production of enzyme)	EFSA-Q-2013-00750 http://www.efsa.europa.eu/en/efsajournal/pub/3793 EFSA-Q-2014-00463 http://www.efsa.europa.eu/en/efsajournal/pub/4106	
Feed/FEEDAP	<i>Penicillium funiculosum</i> (<i>Talaromyces versatilis</i> sp. nov.)	Preparation of endo-1,4- β -xylanase (EC 3.2.1.8) and endo-1,3(4)- β -glucanase (EC 3.2.1.6)	EFSA-Q-2015-00615 http://www.efsa.europa.eu/en/efsajournal/pub/4510	
FIP/CEF	<i>Penicillium multicolour</i>	Production of food enzyme β -glucosidase	EFSA-Q-2015-00273	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Penicillium roqueforti</i> AE-LRF	Production of food enzymes triacylglycerol lipase	EFSA-Q-2014-00545	Not recommended for the QPS list ^(d) .

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Phlebiopsis gigantea</i> (14 different strains)	Plant protection product	EFSA-Q-2009-00132 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00285 http://www.efsa.europa.eu/en/efsajournal/pub/3033 Application for approval	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Pseudozyma flocculosa</i> , strain ATCC 64874	Plant protection product	EFSA-Q-2009-00315 http://www.efsa.europa.eu/en/efsajournal/pub/4250 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Purpureocillium lilacinum</i> , strain PL 11	Plant protection product	EFSA-Q-2015-00176 Application for approval	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizomucor miehei</i>	Production of food enzyme mucorpepsin	EFSA-Q-2015-00233	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizomucor miehei</i>	Production of food enzyme mucorpepsin	EFSA-Q-2016-00030	
FIP/CEF	<i>Rhizomucor miehei</i> (strain 29547)	Production of food enzyme mucorpepsin	EFSA-Q-2015-00761	
FIP/CEF	<i>Rhizomucor oryze</i>	Production of food enzyme glucoamylase	EFSA-Q-2015-00272	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizopus miehei</i>	Production of food enzyme microbial rennet	EFSA-Q-2014-00851	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizopus niveus</i> (strain AE-N)	Production of food enzyme triacylglycerol lipase	EFSA-Q-2014-00732	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizopus niveus</i> / AE-N	Production of food enzyme rishopuspepsin	EFSA-Q-2015-00452	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Rhizopus oryzae</i> / AE-PER	Production of food enzymes leucyl aminopeptidase	EFSA-Q-2014-00354	
FIP/CEF	<i>Talaromyces cellulosyticus</i>	Production of food enzyme cellulase	EFSA-Q-2015-00370	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Talaromyces emersonii</i>	Production of food enzyme is endo-1, 3(4)- β -glucanase	EFSA-Q-2014-00801	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Talaromyces emersonii</i>	Production of food enzyme endo-1,4- β -xylanase	EFSA-Q-2014-00802	
FIP/CEF	<i>Talaromyces emersonii</i>	Production of food enzyme cellulase	EFSA-Q-2014-00803	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Talaromyces versatilis</i>	Production of food enzyme endo-1,4- β -glucanase	EFSA-Q-2015-00663	Not recommended for the QPS list ^(d) .
FIP/CEF	<i>Trametes hirsuta</i>	Production of food enzyme laccase	EFSA-Q-2015-00694	Not recommended for the QPS list ^(d) .
Pesticides	<i>Trichoderma asperellum</i> , strains ICC 012, T25 and TV1 Formerly <i>Trichoderma viride</i> T25 and TV1	Plant protection product	EFSA-Q-2009-00136 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00300 http://www.efsa.europa.eu/en/efsajournal/pub/3036 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Trichoderma asperellum</i> , strain T-34	Plant protection product	EFSA-Q-2011-00899 http://www.efsa.europa.eu/en/efsajournal/pub/2666 Application for approval EFSA-Q-2013-00013 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Trichoderma atroviride</i> I-1237	Plant protection product	EFSA-Q-2011-00900 http://www.efsa.europa.eu/en/efsajournal/pub/2706 Application for approval EFSA-Q-2013-00039 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Trichoderma atroviride</i> IMI 206040 and T11	Plant protection product	EFSA-Q-2009-00137 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00297 http://www.efsa.europa.eu/en/efsajournal/pub/3056 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Pesticides	<i>Trichoderma atroviride</i> SC1	Plant protection product	EFSA-Q-2014-00334 http://www.efsa.europa.eu/en/efsajournal/pub/4092 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Feed/FEEDAP	<i>Trichoderma citrinoviride</i>	Production of enzyme	EFSA-Q-2010-00036 http://www.efsa.europa.eu/en/efsajournal/pub/3105	This was submitted as <i>Trichoderma longibrachiatum</i> but the assessment revealed that should be classified differently. Not recommended for the QPS list ^(d) .
Feed/FEEDAP	<i>Trichoderma citrinoviride</i>	Production of enzyme	EFSA-Q-2014-00575	
Feed/FEEDAP	<i>Trichoderma citrinoviride</i> (IMI SD 135)	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00809 http://www.efsa.europa.eu/en/efsajournal/pub/3969	
Feed/FEEDAP	<i>Trichoderma citrinoviride</i> (IMI SD 142)	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00297 http://www.efsa.europa.eu/en/efsajournal/pub/4054	
FIP/CEF	<i>Trichoderma citrinoviride</i> /TCLSC	Production of food enzyme endo-1,4- β -xylanase	EFSA-Q-2014-00543	
Pesticides	<i>Trichoderma gamsii</i> , strain ICC 080, formerly <i>Trichoderma viride</i> ICC080	Plant protection product	EFSA-Q-2009-00138 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2012-00424 http://www.efsa.europa.eu/en/efsajournal/pub/3062 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Trichoderma harzianum</i> , Rifai strains T22 and ITEM 908	Plant protection product	EFSA-Q-2009-00139 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00298 http://www.efsa.europa.eu/en/efsajournal/pub/3055 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Feed/FEEDAP	<i>Trichoderma koningii</i>	Production of enzyme	EFSA-Q-2008-288 http://www.efsa.europa.eu/en/efsajournal/pub/2843	This was submitted as <i>Trichoderma longibrachiatum</i> but the assessment revealed that should be classified as <i>koningii</i> . New assessment for QPS 2013 update ^(d) .
Feed/FEEDAP	<i>Trichoderma longibrachiatum</i>	Feed additive		Ineligible for QPS status (see EFSA 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Feed/FEEDAP	<i>Trichoderma longibrachiatum</i>	Production of enzyme	EFSA-Q-2005-276 http://www.efsa.europa.eu/en/efsajournal/pub/405 and related opinion: EFSA-Q-2006-320 http://www.efsa.europa.eu/en/efsajournal/pub/520 EFSA-Q-2010-01532 http://www.efsa.europa.eu/en/efsajournal/pub/3528 EFSA-Q-2008-288 http://www.efsa.europa.eu/en/efsajournal/pub/2843 EFSA-Q-2010-00036 http://www.efsa.europa.eu/en/efsajournal/pub/3105 EFSA-Q-2010-01025 http://www.efsa.europa.eu/en/efsajournal/pub/3207 EFSA-Q-2010-01295 http://www.efsa.europa.eu/en/efsajournal/pub/4235 EFSA-Q-2010-01297 http://www.efsa.europa.eu/en/efsajournal/pub/4234 EFSA-Q-2012-00411	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Feed/FEEDAP	<i>Trichoderma longibrachiatum</i> MUCL 39203	Zootechnical additive (production of enzyme)	EFSA-Q-2014-00228 http://www.efsa.europa.eu/en/efsajournal/pub/4621	
Feed/FEEDAP	<i>Trichoderma longibrachiatum</i> SD 135	Preparation of endo-1,4-beta xylanase	EFSA-Q-2015-00834	
Pesticides	<i>Trichoderma polysporum</i> , strain IMI 206039	Plant protection product	EFSA-Q-2009-00140 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00299 http://www.efsa.europa.eu/en/efsajournal/pub/3035 Application for approval	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Feed/FEEDAP	<i>Trichoderma reesei</i>	Production of enzyme	EFSA-Q-2006-137 http://www.efsa.europa.eu/en/efsajournal/pub/548 and related opinions: EFSA-Q-2007-0020 http://www.efsa.europa.eu/en/efsajournal/pub/1156 EFSA-Q-2007-109 http://www.efsa.europa.eu/en/efsajournal/pub/586 EFSA-Q-2007-112 http://www.efsa.europa.eu/en/efsajournal/pub/1154 EFSA-Q-2007-185 http://www.efsa.europa.eu/en/efsajournal/pub/2930 EFSA-Q-2009-00470 http://www.efsa.europa.eu/en/efsajournal/pub/1949 EFSA-Q-2010-00141 http://www.efsa.europa.eu/en/efsajournal/pub/1916	Ineligible for QPS status (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d)

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			EFSA-Q-2009-00802 http://www.efsa.europa.eu/en/efsajournal/pub/2008 EFSA-Q-2011-01171 http://www.efsa.europa.eu/en/efsajournal/pub/2739 EFSA-Q-2007-120 http://www.efsa.europa.eu/en/efsajournal/pub/712 and related question: EFSA-Q-2010-00142 http://www.efsa.europa.eu/en/efsajournal/pub/2277 EFSA-Q-2012-00065 http://www.efsa.europa.eu/en/efsajournal/pub/3432 EFSA-Q-2012-00693 http://www.efsa.europa.eu/en/efsajournal/pub/3364 EFSA-Q-2012-00905 http://www.efsa.europa.eu/en/efsajournal/pub/3433	
Feed/FEEDAP	<i>Trichoderma reesei</i>	Production of enzyme	EFSA-Q-2008-308 http://www.efsa.europa.eu/en/efsajournal/pub/1094 and related questions: EFSA-Q-2010-00018 http://www.efsa.europa.eu/en/efsajournal/pub/2278 EFSA-Q-2008-432 http://www.efsa.europa.eu/en/efsajournal/pub/1186 EFSA-Q-2008-748 http://www.efsa.europa.eu/en/efsajournal/pub/1380 and related opinion: EFSA-Q-2010-0069	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
			http://www.efsa.europa.eu/en/efsajournal/pub/1553 EFSA-Q-2010-00141 http://www.efsa.europa.eu/en/efsajournal/pub/1916 EFSA-Q-2011-00112 http://www.efsa.europa.eu/en/efsajournal/pub/2111 EFSA-Q-2010-00700 http://www.efsa.europa.eu/en/efsajournal/pub/1919 EFSA-Q-2011-00035 http://www.efsa.europa.eu/en/efsajournal/pub/2010 EFSA-Q-2011-00804 http://www.efsa.europa.eu/en/efsajournal/pub/2728 EFSA-Q-2012-00668 http://www.efsa.europa.eu/en/efsajournal/pub/3172 EFSA-Q-2012-00727 http://www.efsa.europa.eu/en/efsajournal/pub/3171 EFSA-Q-2012-00085 http://www.efsa.europa.eu/en/efsajournal/pub/3533	
Feed/FEEDAP	<i>Trichoderma reesei</i>	Production of enzyme	EFSA-Q-2014-00574 http://www.efsa.europa.eu/en/efsajournal/pub/4350	
Feed/FEEDAP	<i>Trichoderma reesei</i>	Production of enzyme	EFSA-Q-2014-00575	
Feed/FEEDAP	<i>Trichoderma reesei</i>	Production of enzyme	EFSA-Q-2014-00586	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme 4-phytase	EFSA-Q-2015-00665	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme α -amylase	EFSA-Q-2015-00681	

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme aspergillopepsin I	EFSA-Q-2015-00371	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme cellulase	EFSA-Q-2015-00454	
FIP/CEF	<i>Trichoderma reesei</i>	Production of food enzyme cellulose	EFSA-Q-2014-00804	
FIP/CEF	<i>Trichoderma reesei</i>	Production of food enzyme endo-1,3(4)- β -glucanase	EFSA-Q-2014-00805	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme endo-1,4- β -glucanase	EFSA-Q-2015-00563	
FIP/CEF	<i>Trichoderma reesei</i>	Production of food enzyme endo-1,4- β -xylanase	EFSA-Q-2014-00806	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme lysophospholipase C	EFSA-Q-2015-00410	
FIP/CEF	<i>Trichoderma reesei</i> , GMM strain	Production of food enzyme xylanase	EFSA-Q-2015-00094	
Feed/FEEDAP	<i>Trichoderma reesei</i> (ATCC SD-6528), GMM strain	Zootechnical additive (production of enzyme)	EFSA-Q-2013-00997 http://www.efsa.europa.eu/en/efsajournal/pub/4275	
FIP/CEF	<i>Trichoderma reesei</i> /DP-Dzh34, GMM strain	Production of food enzyme glucan 1,4- α -glucosidase	EFSA-Q-2016-00097	
FIP/CEF	<i>Trichoderma reesei</i> (DP-Nzd22, GMM strain	Production of food enzyme endo-1,4- β -xylanase from <i>A. niger</i>	EFSA-Q-2014-00667	
FIP/CEF	<i>Trichoderma reesei</i> /DP-Nzh49, GMM strain	Production of food enzyme glucan 1,4- α -glucosidase	EFSA-Q-2016-00094	
FIP/CEF	<i>Trichoderma reesei</i> (RF5427), GMM strain	Production of food enzyme is a xylanase	EFSA-Q-2013-00876	
FIP/CEF	<i>Trichoderma reesei</i> (strain RF5427), GMM strain	Production of food enzyme xylanase	EFSA-Q-2014-00735	
FIP/CEF	<i>Trichoderma reesei</i> / RF5703, GMM strain	Production of food enzyme endo 1,4- β -xylanase	EFSA-Q-2014-00410	
FIP/CEF	<i>Trichoderma reesei</i> (RF6197), GMM strain	Production of food enzyme polygalacturonase	EFSA-Q-2014-00798	
FIP/CEF	<i>Trichoderma reesei</i> / RF6199	Production of food enzyme pectine lyase	EFSA-Q-2014-00164	
FIP/CEF	<i>Trichoderma reesei</i> (RF6201), GMM strain	Production of food enzyme pectin esterase	EFSA-Q-2014-00799	

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
FIP/CEF	<i>Trichoderma reesei</i> (RF6232), GMM strain	Production of food enzyme Mannan endo-1,4- β -mannosidase (β -mannanase)	EFSA-Q-2014-00094 (withdrawn)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
FIP/CEF	<i>Trichoderma reesei</i> /RF8793, GMM strain	Production of food enzyme phospholipase A2	EFSA-Q-2014-00411	
Feed/FEEDAP	<i>Trichoderma viride</i>	Production of enzyme	EFSA-Q-2010-01295 http://www.efsa.europa.eu/en/efsajournal/pub/4235 EFSA-Q-2010-01297 http://www.efsa.europa.eu/en/efsajournal/pub/4234	
FIP/CEF	<i>Trichoderma viride</i> (AE-CT), GMM strain	Production of food enzyme cellulase	EFSA-Q-2015-00067	
Pesticides	<i>Verticillium albo-atrum</i> formerly <i>Verticillium dahliae</i>	Plant protection product	EFSA-Q-2009-00141 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00303 http://www.efsa.europa.eu/en/efsajournal/pub/3059 Application for approval	Mycelial fungi: already considered as not appropriate for QPS. Potential production of alboatrin (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Oomycetes³⁸				
Pesticides	<i>Pythium oligandrum</i> M1	Plant protection product	EFSA-Q-2009-00133 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00287 http://www.efsa.europa.eu/en/efsajournal/pub/3034 Application for approval	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) ^(d) .
Algae				
Feed/FEEDAP	<i>Haematococcus pluvialis</i>	Production of astaxanthin		No body of knowledge except for this strain. Therefore not considered for QPS (EFSA, 2008).

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Bacteriophages				
Feed/FEEDAP	<i>Clostridium sporogenes</i> phage	Feed additive		QPS updates (EFSA BIOHAZ Panel, 2009, 2010), no recommendation to the QPS list because phages are subject to a case-by-case assessment. Considered in the current Scientific Opinion (refer to Section 3.6.1) where it is mentioned that the 'phage application on foods should remain as a case-by-case procedure and, consequently, that these biological entities should not be considered for QPS status'. Please refer to all section.
Feed/FEEDAP	<i>Clostridium tyrobutyricum</i> phage	Feed additive		
BIOHAZ	<i>Listeria monocytogenes</i> phage	Food surface decontamination	EFSA-Q-2011-00959 http://www.efsa.europa.eu/en/efsajournal/pub/2615	
Viruses				
Pesticides	<i>Adoxophyes orana granulovirus</i> , strain BV-0001	Plant protection product	EFSA-Q-2009-00324 http://www.efsa.europa.eu/en/efsajournal/pub/2654 Application for approval EFSA-Q-2012-00894 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.2) where it is mentioned that 'On the basis of the scientific information including the ELS analysis, the QPS recommendation on members of the Baculoviridae family does not change and that the family Baculoviridae is the lowest taxonomic unit with QPS'. Please refer to the complete assessment.
Pesticides	<i>Cydia pomonella granulovirus</i> Mexican isolate	Plant protection product	EFSA-Q-2009-00126 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) EFSA-Q-2009-00254 http://www.efsa.europa.eu/it/efsajournal/pub/2655 Application for approval	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.2) where it is mentioned that 'On the basis of the scientific information including the ELS analysis, the QPS recommendation on members of the Baculoviridae family does not change and that the family Baculoviridae is the lowest taxonomic unit with QPS'. Please refer to the complete assessment.
Pesticides	<i>Helicoverpa armigera nucleopolyhedrovirus</i>	Plant protection product	EFSA-Q-2009-00341 http://www.efsa.europa.eu/en/efsajournal/pub/2865 Application for approval EFSA-Q-2013-00348 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013, 2016a) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.2) where it is mentioned that 'On the basis of the scientific information including the ELS analysis, the QPS recommendation on members of the Baculoviridae family does not change and that the family Baculoviridae is the lowest taxonomic unit with QPS'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/ strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	<i>Pepino Mosaic Virus</i>	Plant protection product		New assessment for QPS 2013 update (EFSA BIOHAZ Panel, 2013). Re-evaluated in the current Scientific Opinion (refer to Section 3.5.1) where it is mentioned that 'On the basis of the scientific information identified through the ELS, the QPS recommendation on members of the Alphaflexiviridae family can be maintained'. Please refer to the complete assessment.
Pesticides	<i>Pepino mosaic virus</i> , strain CH2, isolate 1906	Plant protection product	EFSA-Q-2014-00054 http://www.efsa.europa.eu/en/efsajournal/pub/3977 Application for approval	
Pesticides	<i>Pepino mosaic virus</i> , strain CH2, isolate 1906	Plant protection product	EFSA-Q-2015-00483 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	
Pesticides	<i>Pepino mosaic virus</i> , isolate VC1	Plant protection product	EFSA-Q-2014-00474 Application for approval	
Pesticides	<i>Pepino mosaic virus</i> , strain isolate VX1	Plant protection product	EFSA-Q-2014-00472 Application for approval	
Pesticides	<i>Spodoptera exigua nuclear polyhedrosis virus</i> Current name: <i>nucleopolyhedrovirus</i>	Plant protection product	EFSA-Q-2008-630 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits) Review Report for the active substance <i>Spodoptera exigua</i> nuclear polyhedrosis virus, SANCO/T14/2007-rev.final, March 2007	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.1) where it is mentioned that 'On the basis of the scientific information identified through the ELS, the QPS recommendation on members of the Alphaflexiviridae family can be maintained'. Please refer to the complete assessment.
Pesticides	<i>Spodoptera littoralis nucleopolyhedrovirus</i>	Plant protection product	EFSA-Q-2009-00507 http://www.efsa.europa.eu/en/efsajournal/pub/2864 Application for approval EFSA-Q-2013-00347 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.1) where it is mentioned that 'On the basis of the scientific information identified through the ELS, the QPS recommendation on members of the Alphaflexiviridae family can be maintained'. Please refer to the complete assessment.

Unit EFSA/Panel	Microorganism species/strain	Intended use	EFSA Question number ^(a) and EFSA webpage link ^(b)	Additional information and QPS evaluation/comments
Pesticides	Zucchini yellow mosaic virus, weak strain	Plant protection product	EFSA-Q-2009-00346 http://www.efsa.europa.eu/en/efsajournal/pub/2754 Application for approval EFSA-Q-2013-00012 http://www.efsa.europa.eu/en/efsajournal/pub/4458 Review of MRLs (Maximum Residue Limits)	QPS updates (EFSA BIOHAZ Panel, 2009, 2010, 2011, 2012, 2013) recommended for the QPS list. Re-evaluated in the current Scientific Opinion (refer to Section 3.5.1) where it is mentioned that 'On the basis of the scientific information identified through the ELS, the QPS recommendation on members of the Potyviridae family can be maintained'. Please refer to the complete assessment.

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

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

(c): [www.ncbi.nlm.nih.gov/pubmed/?term=corynebacterium+pekinense e.g. Ma W, Zhao Z, Wang Y, Zhang Y, Ding J. Wei Sheng Wu Xue Bao. 2012 Nov 4;52(11):1344–51. Chinese]

(d): Filamentous fungi were considered in the current Scientific Opinion (refer to Section 3.4.5) with the conclusion: 'Although fungal taxonomy is in a rapid development, still these studies seldom provide information about the ecological properties and the function of the taxonomic units. The discontinuation of dual nomenclature for pleomorphic fungi has resulted in nomenclatural changes to well-established fungal species. The increasing availability of fungal genome sequences is facilitating the discovery and characterization of numerous novel secondary metabolites by genome mining. While knowledge of fungal secondary metabolites has grown to a big extent, information on their toxic effects in humans and animals is still evolving at a much slower rate. Therefore it was decided that, until further notice, filamentous fungi are excluded from QPS evaluations. Their status should be monitored and re-evaluated in the next QPS Opinion update'.