SCIENTIFIC OPINION

Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2012 update)[1]

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

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ABSTRACT

EFSA is requested to assess the safety of a broad range of biological agents in the context of notifications for market authorisation as sources of food and feed additives, enzymes and plant protection products. The qualified presumption of safety (QPS) assessment was developed for safety risk assessments to provide a harmonised generic pre-assessment to support 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' with a recommendation for the QPS list. The list of QPS recommended biological agents is reviewed and updated annually. Therefore, the only valid list is the one in the most recently published scientific opinion. The 2012 update reviews microorganisms previously assessed including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes. The BIOHAZ Panel confirmed all taxonomic units previously recommended for the QPS list. The notifications were reviewed. *Bacillus firmus* was re-evaluated and not recommended for the QPS list. A new recommendation was made for *Leuconostoc pseudomesenteroides*. *Carnobacterium maltaromaticum* was assessed for the first time and not recommended for the QPS list. Qualifications for the taxonomic units included in the QPS recommended list were reviewed and confirmed. Filamentous fungi and enterococci were not recommended for the QPS list following updating and reviewing of current scientific knowledge. For *Enterococcus faecium* recent data indicate a possible distinction between pathogenic and non-pathogenic strains. This is considered too recent knowledge for a QPS recommendation, considering the recent information on the evolution of the epidemiology of *Enterococcus* infections in humans.

KEY WORDS

Safety, QPS, bacteria, yeast, fungi, virus

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on the maintenance of the list of QPS biological agents intentionally added to food or feed (2012 update): Pier Sandro Cocconcelli, Florence Richard Forget, Günter Klein, Tine Licht, Peixe Luisa, Miguel Prieto Maradona, Christophe Nguyen-The, Amparo Querol, Ulf Thrane and Just M. Vlak for the preparatory work on this scientific opinion and the hearing expert: Atte von Wright, and EFSA staff: Renata Leuschner for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2012 update). EFSA Journal 2012;10(12):3020. [84 pp.] doi:10.2903/j.efsa.2012.3020. Available online: www.efsa.europa.eu/efsajournal

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 (2012 update). The question included four specific tasks in the terms of reference (ToR).

The first required the preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included. The list was updated with the notifications received where applicable by EFSA Panels and Units since the last review.

The second aspect was concerned with an annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.

The BIOHAZ Panel confirmed all taxonomic units previously recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list. The notifications were assessed. *Bacillus firmus* was re-evaluated and not recommended for the QPS list. A new recommendation for the QPS list was made for the species *Leuconostoc pseudomesenteroides*. *Carnobacterium maltaromaticum* was assessed for the first time and not recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list.

Tasks three required, for the taxonomic units included in the QPS recommended list, a review and update of knowledge concerning antimicrobial resistance and a review of the qualifications. The information of the previous opinion was updated by the BIOHAZ Panel and the qualifications were confirmed.

The final aspect included a review of the body of knowledge for filamentous fungi and enterococci. The BIOHAZ Panel updated the knowledge of filamentous fungi notified to EFSA. Although numerous data, published since the 2011 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2012 to allow a filamentous fungus to be recommended for the QPS list.

Enterococcus faecium is not recommended for the QPS list in spite of the recent scientific knowledge allowing a differentiation of pathogenic from non-pathogenic strains. This is of value for the FEEDAP Scientific Panel dealing with the strain specific notification, but it is too recent knowledge for a QPS recommendation, considering the recent information on the evolution of the epidemiology of *Enterococcus* infections in human.

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BACKGROUND AS PROVIDED BY EFSA

A wide variety of bacterial and fungal species are used in food and feed production, either directly or as a source of additives or food enzymes. Some of these have a long history of apparent safe use, while others are less well understood and may represent a risk for consumers. The Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion and published a list of microorganisms recommended for a Qualified Presumption of Safety (QPS) list[4,5].

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. In its conclusion on the value of QPS as an assessment tool, the Scientific Committee recognised that there would have to be continuing provision for reviewing and modifying the list of organism given QPS recommendation. They recommended that the EFSA via its Panel on Biological Hazards (BIOHAZ) should take prime responsibility for this and should review the existing QPS list and any additions at least annually. Reviews may occur more frequently as necessary but there should be a formal requirement that even when no changes are proposed, a statement should be made annually that QPS recommendation is being maintained for the published list.

The benefits of the introduction of QPS would be a more transparent and consistent approach across the EFSA units and/or Scientific Panels (such as Pesticides, FEEDAP, GMO) and the potential to make better use of resources by focussing on those organisms which presented the greatest risks or uncertainties.

In the first annual QPS review and update[6], the existing list of QPS microorganisms was reviewed and EFSA's initial experience in applying the QPS approach was described. In addition, following the identification of antimicrobial resistance as a universal qualification of safety in the previous Opinions on QPS, the issue was addressed in line with the opinion developed by the BIOHAZ Panel[7] on 'Foodborne antimicrobial resistance as a biological hazard', and related documents[8,9] of other EFSA Panels.

The potential application of the QPS approach to microbial plant protection products was discussed in the most recent reviews[10,11]. In 2009, viruses were assessed for the first time. Insect viruses (*Baculoviridae*) and in the case of zucchini yellow mosaic viruses the *Potyviridae* family as the highest possible taxonomic unit were added to the QPS list. Bacteriophages were considered as not appropriate for the QPS list. A potential presence of antimycotic resistance of yeasts referred to on the QPS list was considered. It was concluded that yeast strains resistant to antimycotics used for treatment of infections in humans might be of public health concern.

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4 See www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/972.html

5 See http://www.efsa.europa.eu/en/scdocs/scdoc/587.htm

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

7 Opinion of the Scientific Panel on Biological Hazards on a request from EFSA on foodborne antimicrobial resistance as a biological hazard. The EFSA Journal (2008) 765, 1-87.

8 Technical guidance prepared by the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance. The EFSA Journal (2008) 732, 1-15.

9 Guidance on the risk assessment of genetically modified microorganisms and their food and feed products. EFSA Journal 2011;9(6)2193(54pp) http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm

10 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). The EFSA Journal (2009), 7(12): 1431

11 Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on the maintenance of the list of QPS biological agents intentionally added to food or feed (2010 update). EFSA Journal 2010; 8(12):1944

In the last QPS updates in 2010[11] and 2011[12] the previously assessed microorganisms including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes were reviewed and the QPS recommendations of the previous years were confirmed. Qualifications, intended to exclude potential safety concerns, relating to the agents recommended for the QPS list were also reviewed, clarified and updated where necessary. Specific sections dealing with antibiotic resistance relevant for the qualification of QPS recommended microorganisms were included. The methodology used for carrying out the annual review of the list of QPS recommended biological agents was detailed. A list of microbial species from previous notifications and as notified to EFSA, annexed in these opinions, included information on taxonomic units which are or are not recommended for the QPS list with the rational for this decision. This list of notifications aims to summarize and maintain important information for future assessments and updates and is intended to be updated annually.

TERMS OF REFERENCE AS PROVIDED BY EFSA

EFSA requests the BIOHAZ Panel to:

1. Preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA Units and/or Scientific Panels such as Pesticides, FEEDAP and GMO for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included.

2. Annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.

3. Review of the qualifications for taxonomic units included in the QPS recommended list and in particular the qualification regarding antimicrobial resistance in taxonomic units recommended for the QPS list.

4. Review of the body of knowledge for notified filamentous fungi and enterococci.

[12] Scientific Opinion of the Panel on Biological Hazards (BIOHAZ) on the maintenance of the list of QPS biological agents intentionally added to food or feed (2011 update). EFSA Journal 2011; 9(12):2497

ASSESSMENT

1. Introduction

A wide variety of microorganisms are intentionally added at different stages into the food chain, either directly or as a source of additives or enzymes. In this context, approximately 100 species of microorganisms have been expected to be referred to EFSA for a safety assessment. The majority are the result of notifications for market authorisation as sources of food and feed additives, food enzymes and plant protection products received by EFSA.

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

The purpose of the present Opinion is to review the list of previously QPS recommended biological agents which was last established in 2011 (EFSA, 2011a). The QPS approach was developed by the Scientific Committee to provide a generic concept to prioritise and to harmonise risk assessment of microorganisms intentionally introduced into the food chain within EFSA in support of the respective Scientific Panels and Units in the frame of authorisations (EFSA, 2007). The list, first established in 2007 is to be reviewed annually (EFSA, 2007). Taxonomic units were included in the QPS list either following notifications to EFSA or following proposals made during a public consultation in 2005 by stakeholders, even if they were not yet notified to EFSA (EFSA, 2005).

1.1. QPS an assessment approach for use within EFSA

QPS as a concept provides a generic pre-assessment approach for use within EFSA that could be applied to all requests received by EFSA for the safety assessments of microorganisms or viruses deliberately introduced into the food chain. Its introduction would harmonise and make the risk assessment approach more transparent across the EFSA Scientific Panels and Units. It would aid the consistency of assessments and make better use of resources by focussing on those organisms which present the greatest risks or uncertainties (EFSA, 2005; EFSA, 2009a).

In the QPS concept a safety assessment of a defined taxonomic unit is considered independently of any particular specific notification in the course of an authorisation process. If the taxonomic unit does not raise any safety concerns, or if existing safety concerns can be clearly defined as specific qualifications to ensure their absence (exclusion) in the context of a specific notification, a particular taxonomic unit could be recommended for the QPS list. Subsequently, any specific representative of a QPS proposed taxonomic unit, would not need to undergo a further safety assessment other than to satisfy any of the qualifications specified if applicable. 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 (EFSA, 2007).

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. These aspects are assessed, where applicable, separately by the EFSA Panel responsible for assessing the notification.

Concerning microorganisms discussed 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 taxonomic units, for example to an ex- or inclusion of taxonomic units on the list. An assessment of taxonomic units, not previously considered for the QPS list, and for which representatives are notified to EFSA is also discussed. These include, beside microorganisms, viruses used in the context of plant protection and bacteriophages. Consequently, the QPS 2012 update will review these biological agents. Biological agents intended for usages outside the remit of EFSA, and biological agents which have not been notified to EFSA, are not considered in this Opinion.

In 2008 antimicrobial resistance was introduced as a possible safety concern for the assessment of the inclusion of bacterial species in the QPS list (EFSA, 2008). In the 2009, 2010 and 2011 Opinions (EFSA, 2009, 2010, 2011a) a qualification regarding absence of antimycotic resistance for yeast was introduced. The qualifications are reviewed and discussed in the present Opinion.

The list of QPS recommended biological agents is reviewed and updated annually. Therefore, the only valid list is the one from the most recent scientific opinion.

In accordance with the recommendation by the Scientific Committee that the QPS concept should be implemented within EFSA where relevant, an impact assessment of the use of the QPS pre-assessment for risk assessments by EFSA's Scientific Units or Panels in the frame of authorisations and its quotation in the scientific literature is provided.

1.2. Experience of using the QPS pre-assessment by EFSA's Scientific Units and Panels

The QPS approach has proved to be a useful tool to harmonise and prioritise safety assessment within EFSA and is appreciated by both assessors and applicants. The QPS recommended list was mainly used by the EFSA's Panel on Additives and Products of Substances used in Animal Feed (FEEDAP). If the assessment of a biological agent is recommended for the QPS list it should cover the safety for consumers, animals and the environment. Neither safety of users handling the product nor genetic modifications are taken into account. In the respective FEEDAP Opinions dealing with QPS recommended microorganisms, a standard sentence is included that the active agent in question is considered by EFSA to be suitable for the QPS approach to safety assessment. Therefore, 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 is not related to a specific purpose but has to take account of any reasonable use of the organism under consideration, and since all QPS assessments have been 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 taxonomic unit, safety is presumed at any reasonable dose (EFSA, 2012c).

Until late August 2012, the QPS approach has been applied by the FEEDAP Panel, in the assessment of 12 dossiers out of a total of 15 published opinions on the safety assessment of microorganisms used as feed additives (EFSA, 2011c; 2012d-n).

For the Pesticide Unit, the annual QPS updates provide relevant new information from the literature for biological agents currently under peer-review which, if showing more critical or adverse effects,

will be taken into account during the process of the peer-review or in the EFSA conclusion. When a microorganism is approved under Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009), a cycle of 10 to 15 years is foreseen for the revision of the dossier including new information according to the regulatory framework. This shows the usefulness of the QPS approach as a mean of regularly updating the body of knowledge on taxonomic units of importance for EFSA Panels and Units, even if they are not recommended for the QPS list. Hence, the annual update of the body of knowledge concerning fungi is appreciated by the Pesticide Unit.

Biological agents recommended for the QPS list and proposed as plant protection products (under the Council Directive 91/414/EC (Official Journal, 1991) could be 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, 2012o; p). The QPS recommendation does not address risks for the user and risks for the environment, which have to be assessed specifically for plant protection products according to the Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009). The activity of maintenance of the QPS list has also been communicated to the Pesticide Steering Committee in March 2011.

1.3. Reference to QPS in the scientific literature

The EFSA 2011 Opinion cited and discussed references to the QPS approach in the scientific literature (EFSA, 2011a). This review was continued and references are discussed below.

The list of QPS recommended biological agents is reviewed and updated annually therefore the only valid list is the one from the most recent scientific opinion. The most recent QPS Opinion is cited by Adimpong et al. (2012) and Bourdichon et al. (2012a,b). In other publications this is not always the case (Ambalam et al., 2012; Baffoni et al., 2012; Bonaterra et al., 2012; Bosch et al., 2012; Chaabouni et al., 2012; Christoffersen et al., 2012; Danilova et al., 2012; El-Sharoud et al., 2012; Gálvez et al., 2012; Gardana et al., 2012; Hill, 2012; Maldonado et al., 2012; Nikolic et al., 2012; Permpoonpattana et al., 2012; Popova et al., 2012; Salminen and van Loveren, 2012; Songisepp et al., 2012; Stahl and Barrangou, 2012; Thumu and Halami, 2012; Vogel et al., 2011; Xu et al., 2012).

Some references refer to the QPS list as if it would be static (Delavenne et al., 2012; Espeche et al., 2012; Jans et al., 2012; Jones et al., 2012; Marty et al., 2012; Sulemankhil et al., 2012), however there might well be changes with regards to the QPS recommended agents depending on the annual review and its conclusions.

Some publications refer to the QPS assessment in analogy with the Generally Recognised As Safe (GRAS) concept used in the United States (Bennama et al., 2012; Cosentino et al., 2012; Sanz-Penella et al., 2012; Tamayo-Ramos et al., 2012; van Loveren et al., 2012) and it has to be clearly emphasised that the QPS assessment has a different aim. It assesses always the highest taxonomic unit possible which is usually the species. It never assesses notified strains because this is done by the responsible Scientific Panel for the evaluation.

2. Methodology

The safety assessment of a defined taxonomic group (e.g. genus or species) could be made based on four pillars: establishing identity, body of knowledge, possible pathogenicity and end use (EFSA, 2007).

The QPS assessment is generic regarding a notified taxonomic unit intended to be intentionally added into the food chain at any stage. The QPS concept can also be applied to microorganisms that are used to produce enzymes, metabolites (e.g. amino acids), dead biomass or other specific end uses that do

not involve live microbial cells. In this case the QPS recommendation only applies to the specific end use e.g. enzyme production. A QPS assessment is triggered by receipt of an application dossier by EFSA which requires a safety assessment. It is intended to be independent of the specific application dossier which remains the responsibility of the EFSA Scientific Unit or Panel to which the risk assessment is mandated.

In this context the QPS recommended list might be useful for authorities assessing safety of microorganisms for other areas of use such as e.g. in foods for which notifications were not received by EFSA. Notifications received by EFSA are summarised in Appendix A of this opinion and are updated annually. These notifications are subject to a QPS assessment. Especially in food there are numerous microorganisms with technological beneficial use widely applied which are not notified to EFSA and are subsequently not QPS assessed (Bourdichon et al., 2012a).

The QPS assessment does not address hazards linked to the formulation or processing of the products based on biological agents added into the food or feed chain. These aspects are assessed, where applicable, separately by the EFSA Scientific Unit or Panel responsible for the risk assessment of the notification.

2.1.1. Taxonomy

In the context of a notification received by EFSA for a safety assessment, the QPS assessment is carried out at the highest level possible of the identified taxonomic unit which is usually at the species level can also consider a family as a whole (EFSA, 2011a; Bourdichon et al., 2012b).

2.1.1.1. Bacterial taxonomy

Taxonomy and nomenclature of bacteria is covered by the International Code of Nomenclature of Bacteria (International Code of Nomenclature of Bacteria, 1992). New taxonomic units or alteration to the taxonomy and nomenclature are published in the International Journal of Systematic and Evolutionary Microbiology (IJSEM). In this journal a list appears where all 'validly published' taxonomic units are listed in the Notification List, i.e. the Approved List of Bacterial Names. Validly published are all taxonomic units, which are published in the IJSEM. Taxonomic units that were published outside the IJSEM are called 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. A comprehensive and up-to-date presentation of the current taxonomy and nomenclature of bacteria is given on the following website: LPSN (List of Prokaryotic names with Standing in Nomenclature, formerly List of Bacterial names with Standing in Nomenclature (LBSN) (Euzeby, 2012).

2.1.1.2. Filamentous fungi and yeast taxonomy

The nomenclature and taxonomy of fungi are covered by the International Code of Botanical Nomenclature (ICBN) updated in 2005 (McNeill et al., 2006). New taxa or new taxonomic opinions are published in the international scientific literature following the rules of ICBN. Due to an intensive promotion by leading mycologists and the International Mycological Association (IMA, 2012) it is now common practice to submit new taxonomic units and nomenclatural changes to MycoBank (2012) and Index Fungorum (2012) to avoid duplication of names and, in part, a quality check of the formalities. MycoBank and Index Fungorum are also useful sources for validity of published names, however information on synonyms is not complete as it is a matter of subjectivity. For a few genera lists of currently accepted names in use are available, but these have no official status. This year, there is an important change for mycological systematics. Fungi that produce asexual and sexual forms/morphs ('pleomorphic fungi') have been allowed under a special provision of the ICBN

(Article 59) to have separate names referring to the sexual ('teleomorph') and asexual ('anamorph') stages; when referring to the whole fungus ('holomorph'), the teleomorph name has taken precedence, at least until now. At the 2011 meeting of the Nomenclature Session of the Botanical Congress in Melbourne, it was decided that Article 59 will not apply as of January 1, 2013 (Hawksworth, 2011). Furthermore, all names, whether they are typified by an 'anamorph' or a 'teleomorph' stage, will be equal in terms of priority, so the opportunity exists to conserve "anamorph" names in a way that the scientific community sees fit.
It was decided to keep the names as they are right now until such lists of 'recommended species names' appear in future. The presentation of the yeast taxonomy of the 2011 QPS Opinion is still valid (Kurtzmann et al., 2011; EFSA, 2011a).

2.1.1.3. Virus taxonomy

The taxonomy and nomenclature of viruses is the responsibility of the International Committee on Taxonomy of Viruses (ICTV, 2010). Every three years an update is made based on proposals of working groups after adoption by the Executive Committee. The most recent update is from November 2011 (King et al., 2011). 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 = nontranslatable into proteins) and (iv) the form of the virus (isometric, rod-shaped, filamentous or pleiomorph). In addition to these characters, the replication strategy of the viruses is also taken into account and contributes to their taxonomic position (Baltimore, 1971; Baltimore, 1974). Viruses are organized in orders (*-virales*), families (*-viridae*), genera (*-virus*) and species (*-virus*) by virtue of shared characteristics as described above. Viruses do not have a common ancestor; therefore phylogenetic information is only partially useful in directing the taxonomy of viruses.

Plant virus taxonomy

Plant viruses cause disease in plants and many of these viruses are transmitted by vectors (insects, nematodes, fungi). The large majority of plant viruses contain positive stranded (= directly translatable) RNA as genetic information. About 1,000 plant virus species have been recognized and accommodated into two orders and 20 families (King et al., 2011; Mayo, 1999).

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). Forty-two baculoviruses have been recognized as a species (King et al., 2011), but about 700 different baculoviruses have been described. Baculoviruses, unlike other viruses have a common ancestor assisting in the assignment of their taxonomic status.

2.1.2. Body of knowledge

The body of knowledge concerning a defined taxonomic unit is assessed to conclude whether it is sufficient to reach a decision regarding its safety. The body of knowledge includes the history of use of a taxonomic unit, scientific literature, clinical aspects, industrial applications, ecology and other factors as considered appropriate. An inventory of microbial food cultures with a technological role in fermented food was published by the International Dairy Federation (Bourdichon et al., 2012 c, d). In this Opinion only scientific information was considered which can be cited in a transparent manner and includes sufficient description of the methodologies and the results obtained.

2.1.2.1. Review of the scientific literature

A literature review was carried out for each taxonomic unit that was notified to EFSA either for the QPS Opinions in 2007, 2008, 2009, 2010 and 2011. QPS recommended taxonomic units (Table 1) and those which represent an important part of the notifications are annually reviewed. For the taxonomic units recommended for the QPS list the time period of this review covered is the beginning of May 2011 until 30 April 2012 for the QPS 2012 update. For new notifications the literature review was broader to cover the history of use, the potential safety concerns and the ecology.

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

2.1.3. Review of safety concerns identified as 'qualification' on the QPS list

The assessment of antimicrobial resistance in the frame of a specific notification is within the responsibility of the EFSA Scientific Panel or Unit to which the notification was assigned. The QPS WG aims to provide general background information for their consideration and support. In particular, the generic qualification for all bacterial taxonomic units on the QPS recommended list that the strains should not harbour any acquired antimicrobial resistance genes to clinically relevant antibiotics (Table 1) is reviewed.

A recent EFSA review concluded that for EFSA as a whole, the use of interpretative criteria and methods to define and monitor antimicrobial resistance 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 Member States (EFSA, 2012a).

Absence of acquired genes coding for antimicrobial resistance for QPS recommended bacterial taxonomic units is a generic qualification. Generally, it has been considered for the QPS approach that strains carrying acquired resistances should not be intentionally introduced into the food and feed chain. The scope and search for the review of antimicrobial resistance is to conduct a review of each taxonomic unit recommended for the QPS list as it was done last year. During the last QPS update (EFSA, 2011a) the quality of the studies regarding antimicrobial resistance appeared to be variable. Because of this the approach adopted has been to consider everything that is available and subsequently discuss potential weak points in the available studies.

General search terms used were: susceptibility, resistance, antimicrobial, antibiotic. Additional search terms are related to acquired resistance genes in line with the generic qualification on 'not harbouring any acquired antimicrobial resistance genes' e.g. *tet, blaVIM, blaKPC, blaCTX-M, vanA, vanB, vanD, vanE, vanG, vanL, vanM, aac, aph, aad, arm, rmt, erm, lnu, vat, vga, ere, mef, mre, msr, mph, lin, lsa, cfr, sul, dhfr, cat, flo, flex, qep, qnR, oqxAB.* This list is not exhaustive.

2.1.3.1. Other qualifications

Several *Bacillus* species are on the QPS list with the qualification 'absence of toxigenic activity'. This is based on the observation that some rare strains among the *Bacillus* species on the QPS list have caused food borne intoxication in the past, and that these intoxications have been attributed to the

production by these strains of compounds with toxic activities. A technical guidance to identify these toxic compounds among *Bacillus* species has been elaborated by EFSA (EFSA, 2011b). The application of the qualification should permit to identify this safety concern among strains of the QPS *Bacillus* species. The purpose of the annual update of the QPS list is to verify that no other relevant safety concerns have been identified for the QPS *Bacillus* species.

Members of the species *Enterococcus faecium* are authorized in the EU as feed additives to improve growth performances of animals. In the last years the EFSA safety assessment of these microorganisms was made at strain level, assessing the absence of putative virulence factors and acquired antibiotic resistance determinants. In 2012 EFSA has issued the Guidance on the safety assessment of *Enterococcus faecium* in animal nutrition (EFSA, 2012b), based on the most recent genomic, phylogenetic and epidemiologic data. This approach introduces qualifications, the susceptibility to the antibiotic ampicillin and the absence of three genetic markers associated with virulence, which permits to differentiate between safe and the potentially harmful strains belonging to the hospital associated subpopulation of this species.

The purpose of the annual update of the QPS list is to verify the available scientific information on the safety of *Enterococcus faecium* suffice to give this species a QPS recommendation.

3. Gram-positive non-sporulating bacteria

3.1.1. Antimicrobial resistance aspects of QPS lactic acid bacteria in general

There are specific aspects mentioned in the subchapters below. Nothing substantial new concerning the genus level (EFSA, 2011a) could be identified and the following is still valid.

Antimicrobial resistance is an issue in lactobacilli and other lactic acid bacteria (LAB) and should be assessed according to international standards and guidelines (e.g. ISO/DIS 10932/IDF223, 2010) and Clinical and Laboratory Standards Institute (CLSI) guidelines (CLSI, 2007)). For the purpose of QPS the FEEDAP guidance document (EFSA, 2012a) is of further relevance.

There are several reviews and studies describing the antibiotic resistance of *Lactobacillus* species as well as other LABs (Hummel et al., 2007; Kastner et al., 2006; Klare et al., 2007; Klein, 2011; Liu et al., 2009; Zonenschain et al., 2009). Intrinsic resistance could be shown mainly for aminoglycosides, quinolones, and glycopeptides (Hummel et al., 2007; Klein, 2011). Moreover, the transfer of antibiotic resistance within LAB isolates from food has been recently studied (Nawaz et al., 2011; Toomey et al., 2010). Presence of genes coding for antibiotic resistances, such as *tet* (including *tet(*M*), tet(*O*), tet(*S*), tet(*W*), tet(*K*), tet(*L*)*) and *erm* (including *ermA*, *ermB* and *ermC*) (Ammor et al., 2008; Hummel et al., 2007) have been reported. This is a non-comprehensive list.

3.1.2. *Bifidobacterium* species

Bifidobacteria, as other beneficial and commensal bacteria can occasionally be associated with local infections or severe systemic infections, as has been demonstrated in previous EFSA opinions (EFSA, 2011a). A case report of a urinary tract infection with *Bifidobacterium scardovii* can be classified (Barberis et al., 2012). The patient was an 80-year old woman and immune compromised. This was the first report, where *Bifidobacterium scardovii* was involved, which was originally isolated from human sources. Another, previously not available report summarizes bacteriological findings in abdominal surgical emergencies (Israil et al., 2010). In about 10% of such cases bifidobacteria could be isolated. Again these cases could only be found in immune compromised hosts. These reports do not change the status of bifidobacteria as safe microorganisms in general.

In conclusion, there is no need to change the QPS recommendation of the previously recommended *Bifidobacterium* species.

3.1.2.1. Antimicrobial resistance aspects regarding the qualification

No new antimicrobial resistance aspects were reported for bifidobacteria since the last update (EFSA, 2011a).

3.1.3. *Carnobacterium* species

3.1.3.1. *Carnobacterium maltaromaticum*

The *Carnobacterium* genus belongs to the family of *Carnobacteriaceae* in the order of *Lactobacillales* (Collins et al., 1987). The most important species is *Carnobacterium maltaromaticum* due to its common occurrence in foods of animal origin.

Carnobacterium maltaromaticum is known as a fish pathogen (Loch et al., 2011; Schaffer et al., 2012). Few reports of *Carnobacterium* species have shown isolation from human pus or from human blood culture (Hoenigl et al., 2010). More specifically a recent study (Leisner et al., 2012) identified virulence factors in a *Carnobacterium maltaromaticum* strain including haemolysis and invasion. The authors concluded that despite of these factors the presence of this species in food products gives no concern for human health aspects. A specific strain of *Carnobacterium maltaromaticum* has been assessed by Health Canada and the Canadian Environmental Authority Environment Canada (Health Canada, 2010; Environment Canada, 2012). The conclusion of this assessment was that the strain is not toxic to the Canadian environment or human health according to national legislation. This relates specifically to the assessment concerning the environment and also to one specific strain of *Carnobacterium maltaromaticum*.

The body of knowledge is insufficient for an intentional use of this species in the food chain and it is a known pathogen in fish species. Therefore, a QPS recommendation can not be given based on the current knowledge.

3.1.4. *Corynebacteria*

A literature review did not reveal new information about adverse health effects or safety concerns with regards to the last update (EFSA, 2011a). The QPS recommendation has been confirmed.

3.1.4.1. Antimicrobial resistance aspects regarding the qualification

While no actual antibiotic MIC determinations for *Corynebacterium glutamicum* appear to have been done, the antibiotic sensitivity of a strain used for amino acid production, has been tested using a disc method (Costa-Riu et al., 2003). The strain was sensitive to ampicillin, kanamycin, streptomycin, tetracycline, gentamicin and resistant to norfloxacin, and chloramphenicol. The susceptibility test was not performed according to the methodology recommended by the CLSI guideline (CLSI, 2007). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.5. *Enterococcus faecium*

Enterococci are commensal bacteria of the gastrointestinal tract of humans and other mammals, and are frequently found as members of the bacterial communities of food fermentations. Among these, *Enterococcus faecium* is the most encountered species in food fermentations, such as cheese,

fermented vegetable and sausages. This microorganism is also intentionally introduced in the food chain as feed additive (animal probiotic), under a specific EU Regulation (Regulation (EC) No 1831/2003 (Official Journal, 2003)) which requires risk assessment by EFSA, or as food starter culture.

Enterococcus faecium is also an important cause of infections in hospitalized or immune compromised patients, being responsible for endocarditis, urinary tract infections, or abdominal/pelvic infections resulting from contamination by the faecal microbiota. Human infections caused by enterococci outside the healthcare setting are very uncommon (Murray, 2000).

The assessment of *Enterococcus faecium* for QPS has been performed by EFSA in 2011 (EFSA, 2011a), reaching the conclusion that a strain specific evaluation is necessary to assess the risk associated to the intentional use of enterococci in the food chain.

In this last year, new genomic and phylogenetic data support the view that *Enterococcus faecium* species consists of two distinct lineages or clades. One subpopulation consists predominantly of isolates from the faeces of healthy humans, and is characterized by susceptibility to ampicillin. The other subpopulation contains most of the ampicillin resistant clinical isolates (Galloway-Peña et al., 2011; Leavis et al., 2007; Palmer et al., 2012; Willems and van Schaik, 2009). In this second clade the insertion sequence IS*16* (Leavis et al., 2007; van Schaik et al., 2010; Werner et al., 2011), which presumably confers a level of genomic flexibility to its host, is overrepresented. An additional differential factor between the two clades is the presence in strains from human infections of the *pbp5*-R gene. This is an allelic form of the gene coding for the penicillin binding protein 5 (PBP5), which confers resistance to ampicillin (MIC > 4 mg/L).

Based on this new scientific information, EFSA has recently developed a safety assessment of *Enterococcus faecium* (Guidance on the safety assessment of *Enterococcus faecium* in animal nutrition, EFSA 2012b) with the aim to exclude *Enterococcus faecium* strains belonging to the hospital-associated clade from the use in animal nutrition because of the hazard they present to a vulnerable subpopulation of consumers. Strains to be used in animal nutrition shall be susceptible to ampicillin (MIC $\leq$ 2 mg/L) and shall not harbour the genetic elements IS*16*, hyl_{Efm}, and *esp*. Nevertheless, this is too recent knowledge for a QPS recommendation, considering the recent information on the evolution of the epidemiology of *Enterococcus* infections in humans.

Conclusions on a recommendation for the QPS list

Enterococcus faecium is not recommended for the QPS list in spite of the recent scientific knowledge allowing a differentiation of pathogenic strains from non-pathogenic strains within this species. This is of value for the FEEDAP Scientific Panel dealing with the strain specific notification, but is too recent knowledge for a QPS recommendation, considering the past evolution of the epidemiology of *Enterococcus* infections in humans.

3.1.5.1. Antibiotic resistance aspects regarding the qualification

Enterococci show intrinsic resistance to several beta-lactams, low-levels of aminoglycosides, and trimethoprim-sulfamethoxazole. Additional intrinsic resistances to lincosamides and vancomycin are characteristics of specific enterococcal species (Leclerq and Courvalin, 2005; Murray, 1990). Mobile genetic determinants conferring resistance to different classes of antibiotics such as aminoglycosides [*aph(3')-III*, *aac(6')* and *aph(2'')* variants], ß-lactams (*bla*, *pbp5*), glycopeptides (*vanA/B/D/E/G/L/M*), phenicols (*cat* genes), tetracyclines (*tet*O/L/K/S/U), oxazolidinone, lincosamides, pleuromutillins and streptogramin A (*cfr*) and to macrolides, lincosamides and streptogramins group (*ermA/B/C/F/T*, *lnuB*, *vatB/D/E*, *msrA/C/D*, *lsaA*, *vgaB* and *mefA*) have been observed in enterococci from different sources, including in food producing animals and food strains

(Cocconcelli et al., 2004; Diaz *et al*., 2012; Freitas et al., 2011; Hegstad et al., 2010; Hummel et al., 2007; Rizzotti et al., 2005; Vignaroli et al., 2011).

3.1.6. *Lactobacillus* species

Complete genome sequences are being more and more available for several lactobacilli strains, e.g. *Lactobacillus plantarum* ((Zhang et al., 2012), *Lactobacillus johnsonii* (Lee et al., 2011a) and *Lactobacillus acidophilus* (Oh et al., 2011). These sequences can be used to monitor for virulence traits as well as for (transferable) antibiotic resistance genes.

As in previous opinions (EFSA, 2011a) some nosocomial infections with the involvement of lactobacilli could be observed, i.e. a catheter-related bloodstream infection with *Lactobacillus rhamnosus* (Bartalesi et al., 2012), bacteremia and endocarditis in an immune compromised host with *Lactobacillus jensenii* (Suárez-García et al., 2012) and *Lactobacillus rhamnosus* involved in sepsis (Kochan et al., 2012). The latter paper discusses the emergence of probiotic strains associated in hospital infections in immune compromised hosts. This is a well known phenomenon and has been already reported in the previous EFSA opinions (EFSA, 2011a). In the same direction goes a retrospective study of Gouriet et al. (2012) where the majority of lactobacilli isolates connected with bacteremia in immune compromised patients were identified by molecular methods as *Lactobacillus rhamnosus*.

In conclusion, there is no need to change the QPS recommendation of the previously recommended *Lactobacillus* species, but clinical infections including lactobacilli species, esp. *Lactobacillus rhamnosus*, should continue to be closely monitored.

3.1.6.1. Antimicrobial resistance aspects regarding the qualification

Several reports of transferable antibiotic resistance genes have been published, e.g. for erythromycin and chloramphenicol for *Lactobacillus acidophilus*, *Lactobacillus salivarius*, *Lactobacillus vaginalis* and *Lactobacillus reuteri* (Vieira de Souza et al., 2012), for *Lactobacillus reuteri*, *Lactobacillus acidophilus*, *Lactobacillus crispatus*, *Lactobacillus casei*, *Lactobacillus rhamnosus* and others (including mutation and decreased susceptibility after multiple exposure) (Drago et al., 2011a; b; c) and potentially for erythromycin and tetracycline in several lactobacilli species including *Lactobacillus reuteri* (Thumu and Halami, 2012). Also reports on known resistance traits in lactobacilli were given for different species, e.g. for *Lactobacillus reuteri* and others regarding tetracycline resistance and resistance genes (Chang et al., 2011). These findings emphasise the qualification of absence of transferable, acquired resistance genes for QPS strains.

3.1.7. *Lactococcus* species

Lactococcus lactis subsp. *lactis* and *Lactococcus lactis* subsp. *cremoris* are common starter organisms in dairy industry and have been included in the QPS list, despite of isolated human and animal clinical cases involving *Lactococcus lactis* that have been reported (EFSA, 2011a). A search in PubMed revealed new human cases of neonatal meningitis and septicaemia (Ushida et al., 2011a). Two reported cases of brain abscesses in children were reported whereby the details of the species identification were not described in the first (Topçu et al., 2011) and in a second case study the child was immune compromised without an individualized diet or nutrition (Feierabend et al., 2012). The authors did not describe the method of species identification. Also a fish infection involving *Lactococcus lactis* has been described (Chen et al., 2012).

The recent findings do not warrant a reconsideration of the QPS recommendation of *Lactococcus lactis* which is maintained.

3.1.7.1. Antimicrobial resistance aspects regarding the qualification

According to the survey reported by Flórez et al. (2008) the lactococcal strains are generally susceptible to ampicillin, chloramphenicol, gentamicine and vancomycin, while intrinsically resistant to streptomycin. Occasional tetracycline resistances occur, associated, among others, with *tet*(S) and *tet*(M) genes. The findings do not contradict the MIC cut-off values proposed in the latest EFSA update of the antimicrobial resistance criteria (EFSA, 2012a). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.8. *Leuconostoc* species

Three species of the genus *Leuconostoc* (*Leuconostoc citreum*, *Leuconostoc mesenteroides* and *Leuconostoc lactis*) were previously given a QPS recommendation. A fourth species, *Leuconostoc pseudomesenteroides*, classified from formerly *Leuconostoc mesenteroides* in the same study as *Leuconostoc citreum* is recommended for the QPS list based on the comprehensive body of knowledge in combination with that of *Leuconostoc mesenteroides* and history of safe use (Farrow et al., 1989; Euzeby, 2012).

Since 2011, a new case of *Leuconostoc lactis* infection was reported in a patient with coexisting rheumatoid arthritis and tuberculosis arthritis (Shin et al, 2011). A second case, a neonatal sepsis was reported by Martinez-Pajares et al. (2012). The identification of the infective agent was based on limited number of phenotypic tests, and a conclusive identification cannot be achieved.

In conclusion, QPS recommendations for *Leuconostoc citreum*, *Leuconostoc lactis*, *Leuconostoc mesenteroides* and *Leuconostoc pseudomesenteroides* are given.

3.1.8.1. Antimicrobial resistance aspects regarding the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria (3.1.1.). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.9. *Pediococcus* species

Only sporadic reports about pediococci could be found. An endocarditis due to *Pediococcus acidilactici* was reported (Iwen et al., 2011) in an immune compromised host.

Therefore, there is no need to change the QPS recommendation of the previously recommended *Pediococcus* species.

3.1.9.1. Antimicrobial resistance aspects regarding the qualification

No relevant new information concerning antimicrobial resistance aspects has been published since the last opinion (EFSA, 2011a).

3.1.10. *Oenococcus oeni*

No case reports for clinical infections were found for *Oenococcus oeni*. The state of the previous EFSA opinion is still valid (EFSA, 2011a).

3.1.10.1. Antimicrobial resistance aspects regarding the qualification

No relevant new information concerning antimicrobial resistance aspects has been published since the last opinion (EFSA, 2011a).

3.1.11. Dairy propionic acid bacteria

A review revealed no new relevant information regarding human and animal infection which would require a reconsideration of the QPS recommendation of *Propionibacterium freudenreichii* and *Propionibacterium acidipropionici*. One specific *Propionibacterium freudenreichii* strain (ET-3) has been, moreover, subjected to a safety evaluation because of its intended use as a probiotic (Uchida et al., 2011b). The studies include a 28 day toxicity study in rats with a daily dose of 6000 mg/kg/day of ET-3 culture, as well as mutagenicity (Ames test) and clastogenicity assays. No indications of adverse effects were seen in any of these studies. Since there are no data indicating any concern *Propionibacterium freudenreichii* and *Propionibacterium acidipropionici* remain on the list of microorganisms recommended for QPS.

3.1.11.1. Antimicrobial resistance aspects regarding the qualification

The data on the antibiotic resistance patterns of dairy propionic acid bacteria are scarce. One publication on the probiotic aspects of propionic acid bacteria (Suomalainen et al., 2008) and reports of MICs of ampicillin, erythromycin, virginiamycin, gentamicin, streptomycin, kanamycin, tetracycline, chloramphenicol, vancomycin, narasin, bacitracin and linezolid for four specific *Propionibacterium freudenreichii* strains were determined with the microdilution method. The values obtained are in good agreement with the proposed EFSA breakpoints (EFSA, 2012a), but the limited number of strains does not allow making general conclusions about the antimicrobial resistance patterns of dairy propionic acid bacteria. A recent search in the PubMed database using keywords '*Propionibacterium*' and 'antibiotic resistance' revealed a study of Darilmaz and Beyatli (2012) in which the resistant patterns of 15 strains of *Propionibacterium freudenreichii*, 12 strains of *Propionibacterium jensenii* and two strains of *Propionibacterium thoenii* were checked against a pool of antibiotics including penicillin, ampicillin, streptomycin, gentamycin, nalidixic acid, rifampicin, nitrofurantoin, ofloxacin, chloramphenicol and kanamycin using the agar disc diffusion method. The results indicate an intrinsic resistance to nalidixic acid. The agar diffusion method is considered not a reference method for antibiotic susceptibility evaluation (EFSA, 2011a).

There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.1.12. *Streptococcus thermophilus*

No reports of clinical infections related to *Streptococcus thermophilus* were identified in scientific literature since 2011. Therefore, the QPS recommendation for this species is maintained.

3.1.12.1. Antimicrobial resistance aspects regarding the qualification

Although few scientific information is still available on the *Streptococcus thermophilus* susceptibility to clinically relevant antibiotics, recent papers have shown the occasional presence of acquired resistance genes in this dairy bacterium. *Streptococcus thermophilus* strains which are phenotypically resistant to erythromycin, tetracycline and streptomycin have been reported by Tosi et al. (2007). The presence of acquired resistance genes, the erythromycin resistance determinant *ermB* and the tetracycline-resistance genes *tet*(S), *tet*(M), and *tet*(L) were detected in dairy strains of *Streptococcus thermophilus* (Rizzotti et al., 2009). These resistances are covered by the general qualification on antibiotic susceptibility. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

4. Gram-positive spore forming bacteria

4.1.1. *Bacillus* species

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

In total 348 articles found by relevant search terms were screened. None reported safety concerns from the *Bacillus* species of the QPS list. One cluster of bacteraemia cases among neonates in a hospital was caused by non QPS *Bacillus* species (Campbell et al., 2011).

Two cases of severe sepsis caused by *Bacillus* described as *Bacillus pumilus* in neonatal infants, one of which had no predisposing factors, were recently reported (Kimouli et al., 2012). The strains isolated from blood cultures were identified by phenotypic methods and 16S rRNA gene sequences. Evaluation of toxigenic potential of the isolates wasn't presented, it is therefore not possible to know if they would have been met the qualification for QPS *Bacillus* species "absence of toxigenic activity". The source of contamination was not identified. These results thus do not suggest a risk for the consumer via exposure through the food and feed chain.

Therefore, the QPS recommendation was confirmed.

4.1.1.2. Antimicrobial resistance aspects regarding the qualification

In the last year, most importantly it was reported in the genome of several *Bacillus* species *cfr*-like genes, including *Bacillus amyloliquefaciens*, suggesting that *Bacillales* are a natural residence of *cfr*-like genes. Although not expressed in the *Bacillus* species assayed, induced expression in *Escherichia coli* of these *cfr*-like genes was able to decrease the susceptibility of several antibiotics (Hansen et al., 2012). The *cfr* gene encodes the *cfr* methyltransferase that methylates a single adenine in the peptidyl transferase region of bacterial ribosomes. The methylation provides resistance to several classes of antibiotics that include drugs of clinical and veterinary importance, including phenicols, oxazolidinone, lincosamides, pleuromutillins and streptogramin A (Long et al., 2006; Dai et al., 2010). Plasmidic location of *cfr* gene was previously detected in a *Bacillus* species isolate from swine indicating the possibility of mobilization throughout mobile genetic elements (Dai et al., 2010). The *cfr* genes in enterococci and staphylococci from human clinical isolates presenting resistance to several antibiotics have been increasingly reported (Diaz et al., 2012; Long et al., 2006; Dai et al., 2010).

A chromosomally located *fexA* gene, encoding resistance to phenicols and associated with a defective Tn558 transposition was also identified. Remarkably, plasmidic and transposon structures associated with these genes are similar to the ones observed in staphylococci, streptococci and enterococci being worrisome the possibility of its dissemination to pathogenic human and animal isolates (Dai et al., 2010).

Tetracycline resistance genes *tet*(M) and *tet*(K) were previously described in some isolates of different environmental *Bacillus* species conferring resistance to tetracycline (Neela et al., 2009; Nikolakopoulou et al., 2008). Recently, a tetracyclin resistance gene *tet*(L) transferable to a *Bacillus subtilis* was observed in a strain of a *Bacillus* species which was isolated from a marine sponge *Haliclona simulans* (Phelan et al., 2011).

In conclusion, the available data reinforces the possibility of emergence of important resistance genes in members of the *Bacillus* genus, confirming the importance of the qualification regarding antimicrobial resistance in the QPS approach.

There is no new information that would require a modification in the qualification of the antimicrobial resistance.

4.1.1.3 *Bacillus firmus*

Bacillus firmus was assessed in 2008 for the QPS list (EFSA, 2008). It was concluded that 'knowledge on the impact on consumer safety of intentional use of *Bacillus firmus* in the food chain was not sufficient' and the species was not added to the list. Since *Bacillus firmus* was notified again to EFSA, the body of knowledge was checked, in case new information since 2008 would lead to a change of the previous assessment.

A search on the Web of Science from 2008 to end of April 2012 with the key word '*Bacillus firmus*' as 'topic' retrieved 86 articles. All were screened. Most concerned plant protection and nematicidale activities (Castillo et al., 2011; Crow, 2010; Hafez and Sundararaj 2009; Mendoza et al., 2008; Mendoza and Sikora 2009; Schrimsher et al., 2011; Terefe et al., 2009), polysaccharides and lipids biotechnology (Deepthi et al., 2011; Elayaraja et al., 2011; Jaitak et al., 2009; Jommuengbout et al., 2009; Kumar and Kannan, 2011; Mazzer et al., 2008; Pazzetto et al., 2011; Savergave et al., 2008; Sornyotha et al. 2010), production of various enzymes, water and waste water treatment (Arora et al. 2011; Sau et al., 2008; Kumar et al., 2010), use of dead bacterial cells as vaccines adjuvant (Havlíčková et al., 2011; Zanvit et al., 2010). No article concerned the presence of *Bacillus firmus* in the food or feed chain and none permitted to assess its innocuity for human and animals. Therefore, the conclusions from the 2008 assessment remain valid and *Bacillus firmus* cannot be added to the QPS list.

5. Yeast

5.1.1. Update of the body of knowledge on safety concerns for yeast species on the QPS list

The update of the literature did not identify any new safety concerns with regards to the previous QPS update (EFSA, 2011a).

Several yeast species are currently included in the QPS list (Table 1). The inclusion is mainly based on the apparent history of safety. The specific virulence factors that differentiate pathogenic yeasts like infectious *Candida* and *Cryptococcus* species from innocuous ones are not conclusively known. There are some experimental models that can be used to assess the pathogenic potential of a yeast species or strain (EFSA, 2011a).

Recently, Pérez-Torrado et al. (2012) studied *Saccharomyces cerevisiae* clinical isolates in an *in vitro* intestinal epithelial barrier model, comparing their behaviour with that of several strains of the related pathogens *Candida glabrata* and *Candida albicans*. The results showed that, in contrast to *Candida glabrata* and *Candida albicans*, *Saccharomyces cerevisiae* was not able to cross the intestinal barrier. The authors concluded that *Saccharomyces cerevisiae* can only perform opportunistic or passive crossings when epithelial barrier integrity is previously compromised. This information supports that *Saccharomyces cerevisiae* is not virulent like *Candida* species.

The QPS recommendations and the related qualifications are confirmed.

5.1.2. *Trichosporon mycotoxinivorans*

A literature search within Pubmed and Web of Science, restricted to the last 16 months, revealed five publications concerning *Trichosporon mycotoxinivorans*. Among these, one report highlights the biotechnological potential of *Trichosporon mycotoxinivorans* for use in saccharification of hemicellulose (Matos et al., 2012) and another study documents its potential usefulness as a mycotoxin deactivator (Hanif et al., 2012). In their work aiming at evaluating the impact of *Trichosporon mycotoxinivorans* on liver function in mice, Khalel et al. (2012) did not report any negative effects on liver enzymes. The report of Tintelnot et al. (2011) corroborates the occurrence of

Trichosporon mycotoxinivorans related disorder in humans, as previously described (EFSA, 2011a). Based on this, *Trichosporon mycotoxinivorans* cannot be recommended for the QPS list.

6. Filamentous fungi

6.1.1. *Ampelomyces quisqualis*

Ten publications, referred in the Web of Science database between April 2011 and May 2012, have been devoted to *Ampelomyces quisqualis*. Two main topics are considered in these papers: the genetic diversity occurring between *Ampelomyces quisqualis* strains and the efficiency of using *Ampelomyces*-based preparations as biofungicides against powdery mildew.

No new data certifying the lack of biological active secondary metabolites produced by this species has been retrieved and *Ampelomyces quisqualis* remains ineligible for a QPS recommendation.

6.1.2. *Ashbya gossypii*

First isolated as a cotton pathogen (1926 by Ashby and Novell), *Ashbya gossypii* is also a riboflavin-overproducing filamentous fungus that is closely related to unicellular yeasts such as *Saccharomyces cerevisiae*. *Ashbya gossypii*, that can be easily genetically manipulated, is also frequently used as a relevant model for fungal development investigations. These characteristics explain the high number of publications devoted to this filamentous fungus. According to a literature survey using PubMed and Web of Science as databases, 40 publications dealing with *Ashbya gossypii* have been retrieved. Many of these publications report basic results on fungal physiology and five of them are devoted to riboflavin production. Among these, the review published by Kato and Park (2012) summarized the recent progress in isolating overproducing mutants strains and optimizing the highest inducing environmental conditions for riboflavin production. The knowledge concerning the capacity of *Ashbya gossypii* to produce biological active secondary metabolites remains insufficient and this species cannot be recommended for the QPS list.

6.1.3. *Aspergillus* species

For the *Aspergillus* species listed in the QPS 2011 update (EFSA, 2011a), *Aspergillus aculeatus*, *Aspergillus candidus*, *Aspergillus niger* and *Aspergillus oryzae*, no new information on the lack of toxicity or toxins have been retrieved. The reports of 2011 to 2012 retrieved by a search in ISI Web of Science deal with production of the specific products, often enzymes, or food spoilage problems. *Aspergillus* species are not recommended for the QPS list.

6.1.4. *Beauveria bassiana* and *Beauveria brongniartii*

During 2011 and the five first months of 2012, three hundred twenty reports dealing with *Beauveria* have been identified through a PubMed and Web of Science survey. Three hundred seven were retrieved using *Beauveria bassiania* as keyword and fourteen using *Beauveria brongniartii*. *Beauveria bassiania* and *Beauveria brongniartii* are the two species notified to EFSA for plant protection use and the major part of the recent publications focuses on their efficiency as entomopathogenic fungi. Production of secondary metabolites such as the mycotoxins beauvericin, tenellin, bassianin, beauveriolide, oosporein and bassiacridin has been reported for strains belonging to these two fungal species. The report of Valencia et al. (2011) corroborates the production of beauvericin by *Beauveria bassiania* strains and illustrates the high level of variation in beauvericin potential. This last publication also clarifies the compared cytotoxicity of beauvericin, oosporein, tenellin and bassianin on different insect cell lines. Like many microorganisms, *Beauveria* species have the potential to act as opportunistic pathogens, but as this updated literature study confirms, these infections are extremely rare events: a *Beauveria bassiania* strain was isolated from clinical

samples (Pagiotti et al., 2011) and a case of *Beauveria bassiania* keratitis documented (Figuiera et al., 2012). Due to the limited but recognized risk of human infection and its ability to produce toxic secondary metabolites, *Beauveria* remains ineligible for the QPS list.

6.1.5. *Blakeslea trispora*

The reports retrieved from a search in ISI Web of Science did not disclose any information on their potential to produce toxins or toxicity. In light of this limited information *Blakeslea trispora* is not recommended for the QPS list.

6.1.6. *Coniothyrium minitans*

The twenty three reports published since the beginning of 2011, according to a PubMed and Web of Science search, were on the ability of *Coniothyrium* for reducing *Sclerotinia sclerotiorum*. No new relevant data on bioactive metabolites (including macrosphelide A production) or safety were retrieved. In light of this limited information, *Coniothyrium minitans* is still ineligible for a QPS recommendation.

6.1.7. *Duddingtonia flagrans*

During 2011 and the five first months of 2012, twenty nine reports dealing with *Duddingtonia flagrans* have been identified through a PubMed and Web of Science survey. The majority of these investigate the use of this nematode-trapping fungus as an agent for biological control against infective larvae of gastrointestinal nematode parasites of production animals and therefore as an alternative to anthelmintic treatments. No new data have been published concerning the potential of flagranones production by *Duddingtonia flagrans* neither the toxicity of these cyclohexenoxide antibiotics. No new data certifying the lack of toxins or toxicity against animals have been retrieved and *Duddingtonia flagrans* remains ineligible for QPS status.

6.1.8. *Fusarium* species

With more than 2000 references retrieved when the keyword *Fusarium* was used to search Web of Science, the *Fusarium* genus is still one of the most extensively studied. This high publishing activity directly results from the significant economic impact on cereals and crops induced by several species of this genus together with their ability to produce mycotoxins. In the recently published 'top 10' plant fungal pathogens list established according to scientific and economic criteria (Dean et al., 2012), *Fusarium graminearum* and *Fusarium oxysporum* rank at the fourth and fifth place, respectively. *Fusarium* species are not recommended for the QPS list.

6.1.8.1. Taxonomy

Since the beginning of 2011, the development of strategies for molecular identification or quantification of *Fusarium* isolates has been the subject of numerous publications (close to 150). Main of these strategies was PCR-based assay with species-specific regions of genes. For instance, a galactose oxidase was the targeted gene used by Faria et al. (2012) to successfully discriminate *Fusarium* species of the *Giberrella fujikoroi* complex. An aminoadipate reductase gene (*lys*2) was also reported as a promising genetic marker with high resolution for discriminating and identifying *Fusarium* isolates (Watanabe et al., 2011a). Using the *lys2*, β-tubuline and elongation factor 1α genes for their phylogenic analyses, the last authors identified the occurrence of seven clades within the *Fusarium* genus (Watanabe et al., 2011b). The review of Summerell and Leslie (2011) gathered the major advances in the knowledge of the phylogeny of the *Fusarium* genus achieved over the past 50 years and one of their conclusions was that many new species remain to circumscribe. Three new

species were actually discovered and described since 2011, including *Fusarium temperatum* isolated from maize (Scauflaire et al., 2011), *Fusarium burgessi* from Austrian soil (Laurence et al., 2011) and Fsp-1 from *Florida torreya* (Smith et al., 2011).

6.1.8.2. Biosynthetic pathways of *Fusarium* mycotoxins and their regulation

Only few publications among the nearly 500 reports retrieved by a search in Web of Science when the key words *Fusarium* and mycotoxins were combined deal with the processes involved in the biosynthesis of mycotoxins by *Fusarium* species. The most significant advances have been made in the understanding of deoxynivalenol production by *Fusarium graminearum*. In their review (Kazan et al., 2012; Merhej et al., 2011) gathered the most recent discoveries concerning the factors able to induce or repress trichothecenes biosynthesis together with the mechanisms involved in these regulatory events. Up to now, four *Fusarium* genomes have been sequenced. The sequencing of additional genomes including new *Fusarium graminearum* strains that differ in their toxigenic potential or chemotype will allow uncovering new insights in trichothecenes production and regulation. These new insights will also result from the recent construction of a *Fusarium graminearum* deletion mutant library that comprises mutant strains for nearly 700 putative transcription factors (Son et al., 2011). Concerning fumonisins, the most relevant and new result concern the report of the occurrence of an epigenetic regulation attained through the modulation of histone acetylation at the level of the promoter regions of key biosynthetic *FUM* genes (Visentin et al., 2012). Lastly, although nearly twenty recent papers were devoted to zearalenone, its biosynthesis remains the least well understood of the three major classes of mycotoxins produced by *Fusarium* species. A significant progress was achieved with the report of a putative *ABC* transported gene, *ZRA1*, required for zearalenone production (Lee et al., 2011b).

6.1.8.3. Emerging *Fusarium* toxins

Nearly hundred recent publications were retrieved by a search in Web of Science when the key words *Fusarium* and enniatin, *Fusarium* and beauvericin, *Fusarium* and moniliformin, *Fusarium* and fusaproliferin were combined. This high number illustrates the increasing interest raised by these mycotoxins designed as emerging ones. These hundred publications were mainly reports on their occurrence in several matrices (Santini et al., 2012) and the knowledge concerning their biosynthetic pathway remains less documented. The availability of *Fusarium* sequenced genomes (*Fusarium graminearum*, *Fusarium oxysporum*, *Fusarium solani* and *Fusarium verticillioides*) that allowed Hansen et al. (2012) to establish an update and accurate list of *PKS* and *NRPS* genes occurring in the former *Fusarium* species, provides a useful resource for identifying the biosynthetic genes cluster of some of these emerging toxins.

6.1.9. *Gliocladium catenulatum*

The current name in use for *Gliocladium catenulatum* is *Clonostachys rosea* f. *catenulata* and the taxonomic relationship as well as nomenclature is described in detail (EFSA, 2009b). No information on lack of toxins or toxicity against mammals is reported, therefore this species cannot be proposed for the QPS list.

6.1.10. *Lecanicillium muscarium*

Reports from a Web of Science search did not reveal any new data on toxins or safety, therefore this species cannot be proposed for the QPS list.

6.1.11. *Metarhizum anisopliae*

The reports on *Metarhizum anisopliae* retrieved by a search in Web of Science deal with toxicity towards insects and the genetic and physiological regulation of the metabolism. There have not been retrieved any reports on lack of toxins or toxicity, therefore *Metarhizum anisopliae* cannot be proposed for the QPS list.

6.1.12. *Paecilomyces lilacinus*

A bibliographic survey using PubMed and Web of Science as databases indicates that more than forty five reports dealing with *Paecilomyces lilacinus* have been published since the beginning of 2011. While few of these reports investigate the use of this entomopathogen fungus as biocontrol agent, most of them illustrate invasive human infection cases linked to this opportunistic fungal pathogen. Ocular infections, cutaneous and subcutaneous infections and sinusitis are the most commonly encountered *Paecilomyces lilacinus* related disorders. In their review, Antas et al. (2012) summarized the most recent scientific literature on *Paecilomyces lilacinus* hyalohyphomycosis including human manifestations, in vitro antifungal susceptibility and management. Several cases of cutaneous infections have been recently documented (Ezzedine et al., 2012; Huang et al., 2011; Innocenti et al., 2011; Lopes et al., 2011), in addition to a keratitis disorder (Maier et al., 2011) and two sinusitis ones (Permi et al., 2011; Wong et al., 2012). Due to recognised human infection disorders, *Paecilomyces lilacinus* cannot be recommended for the 2012 QPS list.

6.1.13. *Penicillium* species

Penicillium species of relevance for cheese production have been reviewed by Ropars et al. (2012). In general no new information on the lack of toxicity or toxins has been retrieved through a search in ISI Web of Science. For the *Penicillium* species listed in QPS 2011 update (EFSA, 2011a), *Penicillium camemberti*, *Penicillium chrysogenum*, *Penicillium funiculosum*, *Penicillium nalgiovense* and *Penicillium roqueforti* the reports deal with production of the specific products or food spoilage problems, therefore these species still are ineligible for a QPS recommendation.

6.1.14. *Phlebiopsis gigantea*

The recent search in Web of Science did not reveal any new information of the general lack of toxicity of *Phlebiopsis gigantea*. The knowledge concerning the capacity of *Phlebiopsis gigantea* to produce biological active secondary metabolites remains therefore insufficient and this species cannot be proposed for the QPS list.

6.1.15. *Pseudozyma flocculosa*

The recent search for new information on metabolites or lack of toxicity did not retrieve any new relevant data for this organism. The body of knowledge is insufficient to recommend *Pseudozyma flocculosa* for the QPS list.

6.1.16. *Pythium oligandrum*

Pythium oligandrum is recognized as an effective mycoparasite of economically important soil-borne pathogens including *Alternaria*, *Botrytis*, *Fusarium* and *Phytophtora*. *Pythium oligandrum* is also capable of colonizing the root rhizosphere of many crop plants and by this association, of inducing plant defence responses. Lastly, *via* the production of tryptamine, *Pythium oligandrum* may promote plant growth. The eighteen reports devoted to this oomycete that have been published since the beginning of 2011 (according to a PubMed and Web of Science search) illustrate the usefulness of

Pythium oligandrum as a biocontrol agent and investigate the involved mechanisms. For instance, two new elicitin-like proteins (in addition to oligandrin) essential for stimulating defence responses in tomato were partially characterized by Takenaka et al. (2011). With pythiosis as key word, twenty-four reports were retrieved; all associated with the *Pythium insidiosum* species.

The literature survey did not reveal any new information on a general lack of toxicity of *Pythium oligandrum* and this species remains ineligible for a QPS recommendation.

6.1.17. *Trichoderma* species

More than 1650 papers dealing with the genus *Trichoderma* have been retrieved in the time frame of search 2011 to 2012, using the Web of Knowledge database. This substantial publishing activity mainly results from the promising use of several *Trichoderma* species as biocontrol agents (540 reports) and the capacity of some species to produce large amounts of cellulolytic enzymes (680 reports). A special issue of the Journal Microbiology gathering the most recent advances obtained by the *Trichoderma* research community was published in January 2012. In this special issue, an interesting review aims at highlighting the diversity of secondary metabolites including both useful for plant-interactions and toxic compounds some species of the genus *Trichoderma* (*Trichoderma reesei*, *Trichoderma virens* and *Trichoderma atroviride*) are potentially able to produce (Mukherjee et al., 2012).

6.1.17.1. Taxonomy

The taxonomy of *Trichoderma* is constantly being improved by frequent publications on enhanced species deliminations based on phylogenetic analyses. These endeavours do not have any impact on taxonomic designations of species notified to EFSA.

6.1.17.2. *Trichoderma asperellum*

During 2011 and the five first months of 2012, twenty-one reports dealing with *Trichoderma asperellum* have been retrieved through a PubMed and Web of Science survey. Among these new papers, there were no relevant publications on the lack of toxicity or toxin production. Most reports investigate the diversity of promising industrial use which this species offers. The potential of *Trichoderma asperellum* as a biocontrol agent was the subject of several publications, with for instance, a report investigating the development of a formulation to control black rot disease on pineapple (Wijesinghe et al., 2011). The others publications were devoted to *Trichoderma asperellum* cell wall degrading enzymes and the soil bioremediation perspectives associated with the use of this fungal species.

The knowledge concerning the capacity of *Trichoderma asperellum* to produce biological active secondary metabolites remains therefore insufficient and this species can still not be recommended for the QPS list.

6.1.17.3. *Trichoderma longibrachiatum*

The search for new information on the species *Trichoderma longibrachiatum* led to the identification of twenty-four papers (using the Web of Knowledge database, since the beginning of 2011). The main part of the paper was on plant cell wall degrading enzymes (xylanase, cellulase, etc.). One interesting paper aimed at characterizing the molecular phylogeny in the section *Longibrachiatum* and clarifies the *Trichoderma longibrachiatum* species delimitation (Druzhinina et al., 2012). In an attempt to develop a chemotaxonomy approach to differentiate *Trichoderma* species, Kang et al. (2011) have established a partial secondary metabolite profile of *Trichoderma longibrachiatum*. Their results did not allow concluding on the occurrence or lack of toxic secondary metabolites. A new

report of post-operative *Trichoderma longibrachiatum* infection was published in 2011 (Santillan et al., 2011). According to the insufficient information on the production of biological active secondary metabolites and the occurrence of clinical infection events, *Trichoderma longibrachiatum* cannot be given a QPS recommendation.

6.1.17.4. *Trichoderma viride*

Since the beginning of 2011, a significant number of reports (more than 110) have been published concerning Trichoderma *viride* according to a PubMed and Web of Science search. Among these new reports, more than fifty were devoted to its utilization in cellulose degradation and more than thirty to its efficiency as a biocontrol agent. When the keyword alamethicin, a peptaibol produced by *Trichoderma viride* characterized for its ability to permeabilize biological membranes, was used, forty reports were retrieved. The main part of these reports focuses on the mechanisms of membrane pore formation (such as the publication of Ye et al., (2012)) and none provides new information on its animal or human toxicity. No new data were retrieved concerning the production of another class of biological active metabolites. The body of knowledge remains limited and this species cannot be proposed for the QPS list.

6.1.18. *Verticillium albo-atrum*

Verticillium albo-atrum, a soil-borne fungus, is one of the main causal agents of wilt disease that affects several hundred species of trees, shrubs, vines, flowers, house plants, vegetables, fruits, field crops and weeds. Mutant strains, devoid of pathogenic properties and able to induce natural defense mechanisms against Dutch Elm disease in treated trees have been notified to EFSA. Since the beginning of 2011, forty publications dealing with *Verticillium albo-atrum* have been identified through a PubMed and Web of Science search. The majority of these focuses on wilt diseases and several reports investigate the mechanisms that confer pathogenicity to *Verticillium albo-atrum* and enable this fungus to specifically colonize xylem vessels. To gain insight into these mechanisms, the genome of a *Verticillium albo-atrum* strain was sequenced and compared to that of a *Verticillium dahlia* strain (Klosterman et al., 2011). Despite this high number of recent publications, it has not been possible to verify a general absence of biological active secondary metabolites. In the future, availability of *Verticillium albo-atrum* sequenced genome should help in identifying genes cluster involved in secondary metabolites biosynthesis.

In conclusion, the body of knowledge remains too restricted to allow recommendation of *Verticillium albo-atrum* for the QPS list.

6.1.19. Conclusions on filamentous fungi

In the 2011 QPS opinion, it was concluded that filamentous fungi cannot be proposed for inclusion on the QPS list owing to three main rationales: the frequent occurrence of inaccuracies and inconsistencies in fungal species identification, the insufficient knowledge concerning the regulation mechanisms underlying the production of fungal metabolites and the poor knowledge concerning the toxic impact of fungal secondary metabolites (EFSA, 2011a). Although numerous data, published since the 2011 QPS opinion, have contributed to partially fulfil these gaps of knowledge, too many unknowns remain in 2012 to allow a filamentous fungus to be qualified as QPS.

The extensive literature search that has been performed to establish this 2012 QPS opinion has actually underlined:

(i) the fungal taxonomy is in a rapid development as many phylogenetic studies are conducted and disclose new taxonomic units (i.e. phylogenetic species) leaving long-term recognized species with more narrow and clear boundaries. It has to be stressed that these studies seldom provides new

information about the ecological properties and function of the taxonomic units, which will be a major task in the future. The discontinuation of dual nomenclature for pleomorphic fungi will without any doubt require close attention in the years to come. The expected lists of recommended names to be used may result in nomenclatural changes to well-established fungal species. This may be a hurdle for a logic and clear-cut link to already published information in scientific literature, patents, guidelines and legal regulations.

(ii) the increasing availability of fungal genome sequences that could facilitate the discovery and characterization of numerous novel secondary metabolites by genome mining. If we could reasonably imagine that the biosynthetic potential of numerous fungal strains will be successfully elucidated in a close future, this extensive literature search has also highlighted the fact that while knowledge of fungal secondary metabolites accumulates exponentially, knowledge on their toxic impact improves much slower.

6.2. Viruses used for plant protection

6.2.1. *Potyviridae*

Viruses belonging to the family *Potyviridae* are used for cross protection purposes, i.e. the application of mild strains of a virus is used to protect the crop against strains of the virus giving severe symptoms. Their potential effects on animals and/or humans, when applied to food or feed, were reviewed and assessed, and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009b), 2010 (EFSA, 2010) and 2011 (EFSA, 2011a). It was concluded that there was no scientific or other evidence that potyviruses have any negative effect on animals and humans to date. In addition, the familiarity principle was taken into consideration as well in that these viruses have been part of the food and feed for animals and humans since plant material was part of the food package. Finally, by computational analysis it was found that the major component of a potyvirus (Zucchini mosaic virus), the coat protein, did not show any homology to known toxins (Kuiper et al., 2001; Health Canada, 1999). Such an analysis was repeated in 2012 against a plant database (UniRef100 plant database (UniProt NREF, 2012)) and a general database (GenBank nt database (GenBank nt, 2012) and none of the hits were related to 'disease' or 'toxic'. Hence it was agreed that the family *Potyviridae* as the highest taxonomic unit is recommended for the QPS list. Since this last major review by Kuiper et al. (2001), no new information has appeared which would compromise the conclusion drawn in 2011. Hence it was agreed that the family *Potyviridae* as the highest taxonomic unit is recommended for the QPS list.

6.2.2. *Baculoviridae*

Viruses belonging to the family *Baculoviridae* and their potential effects on animals and humans, when applied to food or feed, were extensively reviewed and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009b), 2010 (EFSA 2010) and 2011 (EFSA 2011a). It was concluded that there was no scientific or other evidence that baculoviruses have any negative effect on animals and humans to date when used appropriately. In addition the familiarity principle was taken into consideration as well in that these viruses have been extensively used for over five decades as biocontrol agents of insect pests without any report describing a negative effect on humans or animals. The OECD already concluded that baculoviruses were safe to use for products meant for human consumption (OECD, 2002). Baculoviruses were also classified as Risk Group 1 (RG1) agents, as they were not related to any disease of humans (Flemming and Hunt, 2000; Kost and Condreay, 2001). Hence it was agreed that the family *Baculoviridae* is the highest taxonomic unit and should receive a QPS recommendation in the registration process (EFSA 2009b; EFSA 2010; EFSA, 2011a).

Since the last major review, no new information which would compromise the conclusion drawn in 2009, 2010 and 2011 has appeared. Further support for the safety of baculoviruses is taken from the fact that a number of baculovirus-derived products (recombinant proteins) have been registered and reached the market, such as vaccines against cervical cancer of humans (Szarewski, 2010; Harper, 2009), porcine circovirus for animals (Fort et al., 2009) and immunotherapeutics for prostate cancer of humans (Kantoff et al., 2010).

A matter of contention could be the observation that the budded virus (BV) phenotype of baculoviruses, that is responsible for the systemic infection of insect larvae, is able to infect vertebrate including mammalian cells and tissues (Hofmann et al., 1995) to serve as a gene delivery vehicle for recombinant protein production and gene therapy. The safety issues related to this particular application are discussed in detail in the 2011 QPS report and elsewhere (EFSA, 2011a; Kost and Condreay, 2001).

The QPS recommendation for the family *Baculoviridae* as the highest taxonomic unit was confirmed.

7. THE 2012 UPDATED LIST OF QPS RECOMMENDED BIOLOGICAL AGENTS IN SUPPORT OF EFSA RISK ASSESSMENTS

Table 1: The 2012 updated list of QPS recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units

Gram-Positive Non-Sporulating Bacteria			
Species			**Qualifications ***
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
*Corynebacterium glutamicum*** (only for amino acid production)			
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei* *** *Lactobacillus cellobiosus* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus curvatus* *Lactobacillus delbrueckii*	*Lactobacillus farciminis* *Lactobacillus fermentum* *Lactobacillus gallinarum* *Lactobacillus gasseri* *Lactobacillus helveticus* *Lactobacillus hilgardii* *Lactobacillus johnsonii* *Lactobacillus kefiranofaciens* *Lactobacillus kefiri* *Lactobacillus mucosae* *Lactobacillus panis* *Lactobacillus collinoides*	*Lactobacillus paracasei* *Lactobacillus paraplantarum* *Lactobacillus pentosus* *Lactobacillus plantarum* *Lactobacillus pontis* *Lactobacillus reuteri* *Lactobacillus rhamnosus* *Lactobacillus sakei* *Lactobacillus salivarius* *Lactobacillus sanfranciscensis*	
Lactococcus lactis			
Leuconostoc citreum *Leuconostoc pseudomesenteroides*	*Leuconostoc lactis*	*Leuconostoc mesenteroides*	
	Oenococcus oeni		
Pediococcus acidilactici	*Pediococcus dextrinicus*	*Pediococcus pentosaceus*	
Propionibacterium freudenreichii	*Propiobacterium acidipropionici*		
Streptococcus thermophilus			
Bacillus			
Species			**Qualifications***
Bacillus amyloliquefaciens *Bacillus atrophaeus* *Bacillus clausii* *Bacillus coagulans* *Bacillus fusiformis*	*Bacillus lentus* *Bacillus licheniformis* *Bacillus megaterium* *Bacillus mojavensis*	*Bacillus pumilus* *Bacillus subtilis* *Bacillus vallismortis* *Geobacillus stearothermophilus*	Absence of toxigenic activity.

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

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

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

Table 1 Continued: The 2012 updated list of QPS recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units

Yeasts[13]			
Species			**Qualifications**
Debaryomyces hansenii			
Hanseniaspora uvarum			
Kluyveromyces lactis	*Kluyveromyces marxianus*		
Komagataella pastoris *Lindnera jadinii* *Ogataea angusta*			QPS applies only when the species is used for enzyme production
*Saccharomyces bayanus*****	*Saccharomyces cerevisiae*†****	*Saccharomyces pastorianus*****	
Schizosaccharomyces pombe			
*Wickerhamomyces anomalus*****			QPS applies only when the species is used for enzyme production
Xanthophyllomyces dendrorhous (imperfect form *Phaffia rhodozyma)*			
Virus			
Family			
Potyviridae	*Baculoviridae*		

****Absence of resistance to antimycotics used for medical treatment of yeast infections in cases where viable cells are added to the food or feed chain. In the case of *Saccharomyces cerevisiae* this qualification applies for yeast strains able to grow above 37 °C.

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

[13] Yeast synonyms commonly used in the feed/food industry
Wickerhamomyces anomalus: synonym *Hansenula anomala, Pichia anomola, Saccharomyces anomalus*
Lindnera jadinii: anamorph *Candida utilis*; synonyms *Pichia jadinii, Hansenula jadinii, Torulopsis utilis*
Saccharomyces cerevisiae synonym *Saccharomyces boulardii*
Saccharomyces pastorianus: synonym of Saccharomyces carlsbergensis
Komagataella pastoris: synonym *Pichia pastori*
Ogataea angusta: previously *Pichia angusta*

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Answer to the terms of reference (ToR):

ToR1: *Preparation of an update of the list of biological agents notified to EFSA for safety assessment. This should be a starting point for identifying new taxonomic units for review under the QPS assessment. Only those taxonomic units relevant to current legal requirements in the context of notification to EFSA Units and/or Scientific Panels such as Pesticides, FEEDAP and GMO for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products shall be included.*

- The list was completed with the notifications received where applicable by EFSA Panels and Units since the last review.

ToR2*: Annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate.*

- All taxonomic units previously recommended for the QPS list were reviewed and confirmed. The notifications were assessed. *Bacillus firmus* was re-evaluated and not recommended for the QPS list. A new recommendation for the QPS list was made for the species *Leuconostoc pseudomesenteroides*. *Carnobacterium maltaromaticum* was assessed for the first time and not recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list.

ToR3: *Review of the qualifications for taxonomic units included in the QPS recommended list and in particular the qualification regarding antimicrobial resistance in taxonomic units recommended for the QPS list.*

- The information of the previous opinion was updated and the qualifications were confirmed.

ToR4: *Review of the body of knowledge for notified filamentous fungi and enterococci.*

- The knowledge of filamentous fungi notified to EFSA was updated. Although numerous data, published since the 2011 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2012 to allow a filamentous fungus to be recommended for the QPS list.

- *Enterococcus faecium* is not recommended for the QPS list in spite of the recent scientific knowledge allowing a differentiation of pathogenic from non-pathogenic strains. This is of value for the FEEDAP Scientific Panel dealing with the strain specific notification, but it is too recent knowledge for a QPS recommendation, considering the recent information on the evolution of the epidemiology of *Enterococcus* infections in human.

RECOMMENDATIONS

While recent findings 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.

Increased information on the structure of the *Enterococcus faecium* population, mainly derived from genomic analyses, indicates that a distinction between pathogenic and non-pathogenic strains may be possible. Therefore, additional population analyses and infection studies addressing a comprehensive collection of isolates are recommended.

More data on minimum inhibitory concentrations (MIC) for therapeutic antimicrobials and guidelines for the interpretation are needed for some bacteria (e.g. propionic acid bacteria, *Corynebacterium*) used for food and feed purposes.

More information on the 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.

Concerning filamentous fungi, the same recommendations as those issued from the 2011 QPS opinion remain valid. Progresses have to be achieved to attain three main objectives:

(i) the definition and use of standardized methods to allow a correct identification of fungal species

(ii) an accurate establishment of the metabolic profile for each considered species and an increased knowledge of the factors controlling the production of fungal toxic metabolites

(iii) an increased knowledge of the toxicological impact of fungal secondary metabolites.

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APPENDIX

A. MICROBIAL SPECIES FROM PREVIOUS NOTIFICATIONS AND AS NOTIFIED TO EFSA

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
	Bacteria			
FEEDAP	*Actinoplanes utahensis*	Production of acarbose	EFSA-Q-2007-172 The EFSA Journal (2008) 839, 1-40 www.efsa.europa.eu/en/scdocs/scdoc/839.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008). Full safety assessment was performed in FEEDAP Opinion.
FEEDAP	*Actinomadura yumaensis*	Production of maduramicin ammonium	EFSA-Q-2008-757 The EFSA Journal (2011) 9(1):1954 www.efsa.europa.eu/en/efsajournal/doc/1954.pdf	*Actinomadura yumaensis* produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
FEEDAP	*Alcaligenes acidovorans* = *Ralstonia* sp.	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008). Full safety assessment was performed in FEEDAP Opinion.
FEEDAP	*Bacillus amyloliquefaciens*	Feed additive	EFSA-Q-2007-190 The EFSA Journal (2008) 773, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902039267.htm EFSA-Q-2009-00825 EFSA Journal 2010;8(12):1918 [2 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1918.htm EFSA-Q-2011-00389 EFSA-Q-2011-00965	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus amyloliquefaciens*	Production of Enzyme	EFSA-Q-2007-0020 (GMM) www.efsa.europa.eu/en/efsajournal/pub/1156.htm and related opinions: EFSA-Q-2007-112 www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2009-00470 www.efsa.europa.eu/en/efsajournal/pub/1949.htm Other applications EFSA-Q-2010-01295 EFSA-Q-2010-01297 FAD-2010-0367 (formal mandate to arrive)	
Pesticides	*Bacillus amyloliquefaciens* subspecies plantarum strain D747	Plant protection product	No Draft Assessment Report received No EFSA Question yet	
FEEDAP	*Bacillus brevis* = *Aneurinibacillus* and *Brevibacillus species* Strains from *B. brevis* are now mostly *Brevibacillus* species and some are *Aneurinibacillus* species	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	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 (2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus cereus var. toyoi* *= B. cereus*	Feed additive	EFSA-Q-2003-086 The EFSA Journal (2004) 62, 1-5 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783486.htm EFSA-Q-2005-021 The EFSA Journal (2005) 288, 1-7 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783657.htm EFSA-Q-2006-037 The EFSA Journal (2007) 458, 1-9 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620781828.htm EFSA-Q-2007-090 The EFSA Journal (2008) 549, 1-11 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178647331659.htm EFSA-Q-2008-287 The EFSA Journal (2008) 913, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902299515.htm EFSA-Q-2010-01095 EFSA-Q-2011-00832	QPS status inapplicable for the group of *B. cereus* strains (see EFSA opinion 2007, Appendix B, EFSA, 2008). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Bacillus coagulans*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus firmus = Brevibacillus agri*	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 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 (2010).
Pesticides	*Bacillus firmus I-1582*	Plant protection product	EFSA-Q-2011-00999	A reassessed of this species will be carried in the QPS 2012 review.
FEEDAP	*Bacillus lentus*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus lentus*	Production of Enzyme	EFSA-Q-2006-004: www.efsa.europa.eu/en/efsajournal/doc/412.pdf	
SCF Opinion 22 June 2000	*Bacillus licheniformis*	Production of b-cyclodextrin (food additive carrier and stabiliser of food flavours, food colours and some vitamins)		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus licheniformis*	Production of Enzyme	EFSA-Q-2005-090: www.efsa.europa.eu/en/efsajournal/pub/351.htm EFSA-Q_2006-0181: www.efsa.europa.eu/en/efsajournal/pub/451.htm EFSA-Q-2010-00139 EFSA-Q-2008-431 www.efsa.europa.eu/en/efsajournal/pub/1185.htm	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus licheniformis*	Feed additive	EFSA-Q-2006-136 EFSA Journal 2011;9(9):2356 [10 pp.]. www.efsa.europa.eu/en/efsajournal/pub/2356.htm EFSA-Q-2007-166 (withdrawn) EFSA-Q-2009-00970 EFSA-Q-2009-00680	Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus megaterium*	Production of vitamin C	EFSA-Q-2010-01290	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
FEEDAP	*Bacillus pumilus*	Feed additive		Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
Pesticides	*Bacillus pumilus* strain QST 2808	Plant protection product	No Draft Assessment Report received and no EFSA Question yet.	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus subtilis*	Feed additive	EFSA-2003-008 www.efsa.europa.eu/en/efsajournal/pub/6.htm EFSA-Q-2004-174 www.efsa.europa.eu/en/efsajournal/pub/272.htm EFSA-Q-2005-150 www.efsa.europa.eu/en/scdocs/scdoc/336.htm EFSA-Q-2005-237 The EFSA Journal (2006) 336, 1-15 www.efsa.europa.eu/en/scdocs/scdoc/406.htm EFSA-Q-2006-136 EFSA Journal 2011;9(9):2356 [10 pp.]. www.efsa.europa.eu/en/efsajournal/pub/2356.htm EFSA-Q-2007-166 (withdrawn) EFSA-Q-2007-040 The EFSA Journal (2007) 543, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/543.htm EFSA-Q-2008-473 EFSA Journal 2009; 7(9):1314 www.efsa.europa.eu/en/scdocs/scdoc/1314.htm EFSA-2008-771 www.efsa.europa.eu/en/efsajournal/pub/2375.htm EFSA-Q-2009-00533 EFSA Journal 2010; 8(1):1426 www.efsa.europa.eu/en/scdocs/scdoc/1426.htm	Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Bacillus subtilis*	Feed additive	EFSA-Q-2009-00680 EFSA-Q-2009-00525 EFSA-Q-2010-00814 EFSA Journal 2010;8(10):1867 www.efsa.europa.eu/en/scdocs/scdoc/1867.htm EFSA-Q-2010-001151 EFSA Journal 2011;9(3):2112 www.efsa.europa.eu/en/efsajournal/pub/2112.htm EFSA-Q-2010-01150 EFSA Journal 2011;9(3):2114 www.efsa.europa.eu/en/efsajournal/pub/2114.htm EFSA-Q-2011-01151 EFSA-Q-2012-00246	
FEEDAP	*Bacillus subtilis*	Production of vitamin B2	EFSA-Q-2010-00991 EFSA-Q-2010-01319	
FEEDAP	*Bacillus subtilis*	Production of enzyme	FAD-2010-0367 (formal mandate to arrive) EFSA-Q-2007-0020: www.efsa.europa.eu/en/efsajournal/pub/1156.htm and related opinions: EFSA-Q-2007-112: www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2009-00470: www.efsa.europa.eu/en/efsajournal/pub/1949.htm Other applications: EFSA-2010-01298	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	*Bacillus subtilis* Strain QST 713	Plant protection product	EFSA-Q-2008-492 Review report for the active substance *Bacillus subtilis* QST 713, SANCO/10184/2003-final, July 2006	Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention (2008, 2009, 2010).
Pesticides	*Bacillus* subsp. *thuringiensis aizawai* (strains ABTS 1857 and GC-91) = *Bacillus thuringiensis* serovar aizawai	Plant protection product	EFSA-Q-2009-00121 EFSA-Q-2009-00247 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_006494.htm	Already considered as not appropriate for QPS (see EFSA opinion, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis israelensis* (serotype H-14), strain AM 6552 = *Bacillus thuringiensis* serovar israelensis	Plant protection product	EFSA-Q-2009-00122 EFSA-Q-2009-00248 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_006476.htm	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis kurstaki* (strains ABTS 351, PB 54, SA11, SA 12, EG 2348) = *Bacillus thuringiensis* serovar kurstaki	Plant protection product	EFSA-Q-2009-00123 EFSA-Q-2009-00249 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_006452.htm	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
Pesticides	*Bacillus* subsp. *thuringiensis tenebrionis* (strain NB176 (TM 141)) = *Bacillus thuringiensis* serovar tenebrionis	Plant protection product	EFSA-Q-2009-00124 EFSA-Q-2009-00250	Already considered as not appropriate for QPS (see EFSA, 2007). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Bifidobacterium animalis*	Feed additive	EFSA-Q-2006-169 EFSA-Q-2009-00823 EFSA-Q-2009-00817	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Bifidobacterium longum*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
GMO	*Brevibacterium lactofermentum* *=Corynebacterium glutamicum*	Dried killed biomass for feed	EFSA-Q-2007-157 (Applicant is going to withdraw application)	The recipient species is QPS for production purposes only, but not for this application, therefore not appropriate for QPS (EFSA, 2008 opinion)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FIP (CEF Panel)	*Carnobacterium maltaromaticum* CNCM I-3298	Microbiological time temperature integrators used as "active and intelligent" food contact materials	EFSA-Q-2011-00120	
FEEDAP	*Clostridium butyricum*	Feed additive	EFSA-Q-2008-303 The EFSA Journal (2009) 1039, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902496474.htm EFSA-Q-2010-00140 EFSA Journal 2011;9(1):1951 [15 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1951.htm	No history of use, possible production of botulinum toxins, therefore not appropriate for QPS (EFSA, 2008)
FEEDAP	*Corynebacterium glutamicum*	Production of L-arginin	EFSA-Q-2006-031 The EFSA Journal (2007) 473, 1-19 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620781637.htm	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEEDAP	*Corynebacterium glutamicum*	Production of L-lysine	EFSA-Q-2011-00991 EFSA-Q-2011-00995 EFSA-Q-2011-00996	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEEDAP	*Corynebacterium glutamicum*	Production of L-tryptophan	EFSA-Q-2011-00946	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEEDAP	*Corynebacterium glutamicum*	Production of L-valine	FAD-2011-0053 (Formal mandate still to arrive)	QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)
FEDDAP	*Ensifer adhaerens*	Production of vitamin B12	Formal mandate still to arrive	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge
FEEDAP	*Ensifer fredii*	Production of vitamin B12	Formal mandate still to arrive	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Enterococcus faecium*	Feed additive	EFSA-Q-2003-087 The EFSA Journal (2005) 207, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/207.htm EFSA-Q-2004-001 The EFSA Journal (2004) 51, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/51.htm EFSA-Q-2004-006 The EFSA Journal (2004) 138, 1-7 www.efsa.europa.eu/en/efsajournal/pub/138.htm EFSA-Q-2004-027 The EFSA Journal (2004) 120, 1-4 www.efsa.europa.eu/en/scdocs/scdoc/120.htm EFSA-Q-2004-096 The EFSA Journal (2005) 206, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/206.htm EFSA-Q-2005-020 The EFSA Journal (2006) 335, 1-10 www.efsa.europa.eu/en/scdocs/scdoc/335.htm EFSA-Q-2006-061 The EFSA Journal (2007) 440, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/440.htm EFSA-Q-2006-318 EFSA Journal 2009; 7(11):1379 www.efsa.europa.eu/en/scdocs/scdoc/1379.htm EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm	No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA, 2007, 2008, 2009, 2010). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available (2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
			EFSA-Q-2006-169 (withdrawn) EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/efsajournal/pub/912.htm EFSA-Q-2007-033 The EFSA Journal (2007) 521, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/521.htm EFSA-Q-2008-289 The EFSA Journal (2009) 990, 1-12 www.efsa.europa.eu/en/scdocs/scdoc/990.htm EFSA-Q-2008-471 EFSA-Q-2008-422 EFSA Journal 2010; 8(7):1661 [13 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1661.htm EFSA-Q-2009-00679 EFSA Journal 2012;10(2):2574 [15 pp.] EFSA-Q-2009-00969 EFSA Journal 2011;9(3):2118 www.efsa.europa.eu/en/efsajournal/pub/2118.htm EFSA-Q-2009-00823 EFSA Journal 2012;10(12):2965 http://www.efsa.europa.eu/en/efsajournal/doc/2965.pdf EFSA-Q-2009-00202 (withdrawn) EFSA-Q-2010-00070 EFSA Journal 2010; 8(6): 1636 [5 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1636.htm	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
			EFSA-Q-2010-00009 EFSA-Q-2010-00071 EFSA-Q-2011-00203 EFSA-Q-2011-00965 EFSA-Q-2012-00093 EFSA-Q-2012-00245 EFSA-Q-2012-00080	
FEEDAP	*Enterococcus mundtii*	Feed additive		No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinion, 2007)
GMO	*Escherichia coli*	Dried killed biomasses for feed	EFSA-Q-2008-412a and EFSA-Q-2008-669a	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Dried killed biomasses for feed	EFSA-Q-2008-412b and EFSA-Q-2008-669b	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Feed additive L-lysine production	EFSA-Q-2011-00992 EFSA-Q-2011-00993 EFSA-Q-2011-00994 EFSA-Q-2011-00995 EFSA-Q-2011-00996	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available
FEEDAP	*Escherichia coli*	Feed additive L-threonine production	EFSA-Q-2012-00113 EFSA-Q-2012-00114 EFSA-Q-2012-00115 EFSA-Q-2012-00116 EFSA-Q-2012-00117 EFSA-Q-2012-00118	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Escherichia coli*	Feed additive L-tryptophan production	EFSA-Q-2011-00946 EFSA-Q-2011-00947 EFSA-Q-2011-00948 EFSA-Q-2011-00949	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Escherichia coli*	Feed additive (horses)	EFSA-Q-2005-167 The EFSA Journal (2009) 989, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902391773.htm	QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Eubacterium* sp. DSM 11798	Reduce toxicity of mycotoxins	EFSA-Q-2003-052 The EFSA Journal (2005) 169, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782757.htm	No body of knowledge. Already given a negative assessment by FEEDAP. Not appropriate for QPS (EFSA opinion 2008)
FEEDAP	*Ketogulonicigenium vulgare*	Production of vitamin C	EFSA-Q-2011-00250	Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge
FEEDAP	*Lactobacillus acidophilus*	Feed additive	EFSA-Q-2003-115 The EFSA Journal (2004) 119, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/119.htm EFSA-Q-2003-055 The EFSA Journal (2004) 52, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/52.htm EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2008-377 EFSA-Q-2010-00071	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus amylolyticus*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus amylovorans*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus brevis*	Feed additive	EFSA-Q-2010-01304 EFSA-Q-2011-00382 EFSA-Q-2011-00385 EFSA Journal 2011;9(9):2368 www.efsa.europa.eu/en/efsajournal/pub/2368.htm EFSA-Q-2012-00086	Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Lactobacilllus buchneri*	Feed additive	EFSA-Q-2010-01276 EFSA Journal 2011;9(4):2138 www.efsa.europa.eu/en/efsajournal/pub/2138.htm EFSA-Q-2011-00375 EFSA Journal 2011;9(9):2359 www.efsa.europa.eu/en/efsajournal/pub/2359.htm EFSA-Q-2011-00376 EFSA Journal 2011;9(9):2361 www.efsa.europa.eu/en/efsajournal/pub/2361.htm EFSA-Q-2011-00382	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus bulgaricus* = *L. delbrueckii* subsp. *bulgaricus*	Feed additive	EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus casei* (note: this species is very rare and its identity might need to be verified)	Feed additive	EFSA-Q-2011-00381 EFSA-Q-2011-00390	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus casei rhamnosus* = *Lactobacillus rhamnosus*	Feed additive	EFSA-Q-2011-00380 EFSA Journal 2011;9(9):2365 http://www.efsa.europa.eu/en/efsajournal/pub/2365.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus cellobiosus*	Feed additive		Not initially considered for QPS (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010
FEEDAP	*Lactobacillus collinoides*	Feed additive	EFSA-Q-2012-00086	Not initially considered for QPS status (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010
FEEDAP	*Lactobacillus delbrueckii subsp. lactis*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Lactobacillus farciminis*	Feed additive	EFSA-Q-2006-062 The EFSA Journal (2008) 771, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/771.htm EFSA-Q-2004-177 The EFSA Journal (2006) 377, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/377.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus fermentum*	Feed additive	EFSA-Q-2012-00085	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus helveticus*	Feed additive	EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus mucosae*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus paracasei*	Feed additive	EFSA-Q-2011-00378 EFSA Journal 2011;9(9):2363 www.efsa.europa.eu/en/efsajournal/pub/2363.htm EFSA-Q-2011-00387 (in progress) EFSA Journal 2011;9(9):2370 http://www.efsa.europa.eu/en/efsajournal/pub/2370.htm EFSA-Q-2012-00082	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus pentosus*	Feed additive	EFSA-Q-2011-00388 EFSA Journal 2011;9(11):24 www.efsa.europa.eu/en/efsajournal/pub/2449.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Lactobacillus plantarum*	Feed additive	EFSA-Q-2010-01164 EFSA Journal 2011;9(3):2113 www.efsa.europa.eu/en/efsajournal/pub/2113.htm EFSA-Q-2011-00062 EFSA Journal 2011;9(6):2275 www.efsa.europa.eu/en/efsajournal/pub/2275.htm EFSA-Q-2011-00186 EFSA Journal 2011;9(11):2408 www.efsa.europa.eu/en/efsajournal/pub/2408.htm EFSA-Q-2011-00377 EFSA Journal 2011;9(9):2362 www.efsa.europa.eu/en/efsajournal/pub/2362.htm EFSA-Q-2011-00384 EFSA Journal 2011;9(9):2367 www.efsa.europa.eu/en/efsajournal/pub/2367.htm EFSA-Q-2011-00943 EFSA Journal 2012;10(1):2529 www.efsa.europa.eu/en/efsajournal/pub/2529.htm EFSA-Q-2011-00944 EFSA-Q-2011-00125 EFSA-Q-2011-00374 EFSA-Q-2011-00390 EFSA-Q-2012-00083 EFSA-Q-2012-00089 EFSA-Q-2012-00090 EFSA-Q-2012-00092 EFSA-Q-2012-00094	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus reuteri*	Feed additive	EFSA-Q-2003-010 The EFSA Journal (2005) 229, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/229.htm EFSA-Q-2006-169	Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Lactobacillus rhamnosus*	Feed additive	EFSA-Q-2006-062 The EFSA Journal (2008) 771, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/771.htm EFSA-Q-2011-00380 EFSA Journal 2011;9(9):2365 www.efsa.europa.eu/en/efsajournal/pub/2365.htm EFSA-Q-2011-00125	Already QPS (EFSA, 2007, 2008, 2009, 2010) *Lactobacillus rhamnosus* is recommended for the QPS list, and remains a topic for surveillance.
FEEDAP	*Lactobacillus sakei*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactobacillus salivarius*	Feed additive	EFSA-Q-2006-169 EFSA-Q-2009-00823 EFSA-Q-2011-00381	Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Lactococcus lactis*	Feed additive	EFSA-Q-2006-135 www.efsa.europa.eu/en/efsajournal/pub/912.htm EFSA-Q-2010-00901 EFSA Journal 2011;9(9):2374 www.efsa.europa.eu/en/efsajournal/pub/2374.htm EFSA-Q-2011-00373 EFSA Journal 2011;9(12):2448 www.efsa.europa.eu/en/efsajournal/pub/2448.htm EFSA-Q-2011-00383 EFSA Journal 2011;9(9):2366 www.efsa.europa.eu/en/efsajournal/pub/2366.htm EFSA-Q-2010-00071 EFSA-Q-2012-00087	Already QPS (EFSA, 2007, 2008, 2009, 2010) Attention should be focused on human clinical cases without underlying predisposing factors (EFSA, 2011).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
2001/122/EC	*Leuconostoc mesenteroides*	Production of dextran as NF ingredient for bakery industrial and food fermentations		Already QPS (EFSA, 2007, 2008, 2009, 2010)
FEEDAP	*Leuconostoc oeno = Oenococcus oeni*	Feed additive		Not initially considered for QPS (see EFSA opinion 2007, 2008) and recommended for the QPS list in 2009, 2010 (EFSA, 2009; 2010)
FEEDAP	*Leuconostoc pseudomesenteroides*	Feed additive		Not initially considered for QPS (see EFSA opinion 2007, 2008, 2009, 2010, 2011) and recommended for the QPS list in 2012 (EFSA opinion, 2012)
FEEDAP	*Methylococcus capsulatus*	Biomass for animal feed	EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620784006.htm	No body of knowledge, therefore not appropriate for QPS (EFSA, 2008)
Opinion SCF adopted on 22/06/2000	*Paenibacillus macerans*	b-cyclodextrin production (food additive)		QPS 2009 update not recommended for QPS because of insufficient body of knowledge. It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	Astaxanthin-rich *Paracoccus carotinifaciens*	Production of red carotenoids	EFSA-Q-2006-173 The EFSA Journal (2007) 546, 1-30 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178650355146.htm EFSA-Q-2009-00629 EFSA Journal 2010; 8(1):1428 [8 pp.]. www.efsa.europa.eu/en/efsajournal/pub/1428.htm	No body of knowledge, therefore not considered for QPS (EFSA, 2008)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Pediococcus acidilactici*	Feed additive	EFSA-Q-2006-169 EFSA-Q-2007-205 www.efsa.europa.eu/en/scdocs/scdoc/1037.htm EFSA-Q-2008-421 www.efsa.europa.eu/en/scdocs/scdoc/1038.htm EFSA-2009-00719 EFSA Journal 2010;8(7):1660 www.efsa.europa.eu/en/scdocs/scdoc/1660.htm EFSA-2009-00716 EFSA Journal 2010;8(10):1865 www.efsa.europa.eu/en/scdocs/scdoc/1865.htm EFSA-2009-00719 EFSA Journal 2010;8(7):1660 www.efsa.europa.eu/en/scdocs/scdoc/1660.htm EFSA-2009-00716 EFSA Journal 2010;8(10):1865 www.efsa.europa.eu/en/scdocs/scdoc/1865.htm EFSA-Q-2011-00379 EFSA Journal 2011;9(9):2364 www.efsa.europa.eu/en/efsajournal/pub/2364.htm EFSA-Q-2011-00940 EFSA-Q-2011-00941 EFSA-Q-2012-00084 EFSA-Q-2012-00253	Already QPS

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Pediococcus pentosaceus*	Feed additive	EFSA-Q-2009-00717 EFSA Journal 2010; 8(2):1502 www.efsa.europa.eu/en/scdocs/scdoc/1502.htm EFSA-Q-2011-00386 EFSA Journal 2011;9(9):2369 www.efsa.europa.eu/en/efsajournal/pub/2369.htm EFSA-Q-2011-00940 EFSA-Q-2012-00081 EFSA-Q-2012-00087 EFSA-Q-2012-00091	Already QPS
FEEDAP	*Propionibacterium acidipropionici*	Feed additive	EFSA-Q-2011-00953	Not proposed for QPS status (see EFSA opinion 2007, Appendix A). In 2009, 2010 recommended for the QPS list (EFSA, 2009; 2010).
FEEDAP	*Propionibacterium freudenreichii shermanii*	Feed additive		Already QPS
FEEDAP	*Propionibacterium freudenreichii shermanii*	Production of vitamin B12	Formal mandate still to arrive	Already QPS
FEEDAP	*Propionibacterium globosum* [=subspecies of *Propionibacterium freudenreichii*]	Feed additive		Not recommended for QPS (see EFSA opinion 2007, Appendix A). Identical with *P. freudenreichii* therefore included on QPS (EFSA, 2010)
Pesticides	*Pseudomonas sp.* DSMZ 13134	Plant Protection Product	EFSA-Q-2011-01198 Draft Assessment Report: no further info on the species. It is considered as a new species within the RNA-group I-pseudomonads.	Not assessed because species to be clarified (EFSA, 2009)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	*Pseudomonas chlororaphis* strain MA342	Plant Protection Product	EFSA-Q-2008-618 Review report for the active substance Pseudomonas chlororaphis, EU-SANCO, 4204/VI/98-Final, March 2004 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_006478.htm	Not recommended for QPS in QPS 2009 update because of insufficient body of knowledge and a potential risk linked to production of secondary metabolites. It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Rhodopseudomonas palustris*	Feed additive		Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Serratia rubidaea*	Feed additive		Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.
FEEDAP	*Streptococcus cremoris = L. lactis subsp. cremoris*	Feed additive		Already QPS
FEEDAP	*Streptococcus faecium = Enterococcus faecium*	Feed additive		No taxonomical unit within *Enterococcus* can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinion, 2007, 2008, 2009, 2010). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.
FEEDAP	*Streptococcus thermophilus*	Feed additive	EFSA-Q-2006-135 www.efsa.europa.eu/en/scdocs/scdoc/912.htm EFSA-Q-2010-00071	Already QPS
FEEDAP	*Streptomyces albus*	Production of salinomycin sodium	EFSA-Q-2003-009 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783414.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Streptomyces aureofaciens*	Production of polyether monocarboxylic acid	EFSA-Q-2003-046 The EFSA Journal (2004), 90, 1-44 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783396.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
FEEDAP	*Streptomyces cinnamonensis*	Production of monensin sodium	EFSA-Q-2005-024 The EFSA Journal (2004), 42, 1-61 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783743.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
Pesticides	Now unspecified *Streptomyces* species *:* '*Streptomyces* strain K 61' Formerly : *Streptomyces griseoviridis*	Plant protection product	EFSA-Q-2009-00134 EFSA-Q-2009-00295 www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_129069.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion, 2008)
FEEDAP	*Streptomyces lasaliensis*	Production of lasalocid sodium	EFSA-Q-2004-076 The EFSA Journal (2004) 77, 1-45 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783432.htm	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)
Pesticides	*Streptomyces lydicus* strain WYEC 108 (ATCC 55445)	Plant protection product	No Draft Assessment Report received No EFSA Question yet.	*Streptomyces* spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008).
	Yeasts			
Pesticides	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Plant Protection Product	EFSA-Q-2010-01499 EFSA-Q-2011-01200	Body of knowledge insufficient (QPS 2009 update)
FEEDAP	*Candida glabrata*	Feed additive		Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
FEEDAP	*Candida guilliermondi*	Fermentation product	EFSA-Q-2003-082 www.efsa.europa.eu/en/efsajournal/pub/68.htm	Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
Pesticides	*Candida oleophila* strain O	Plant protection product	EFSA-Q-2009-00338 (in progress) www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_021008.htm	Body of knowledge insufficient, therefore not appropriate for QPS (EFSA opinion 2008)
FEEDAP	*Hansenula polymorpha = Pichia angusta*	Production of enzymes	EFSA-Q-2005-030 The EFSA Journal (2006) 333, 1-27 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769671.htm	Already QPS status applies only when species is used for production purposes (EFSA opinion 2008, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
2148/2004/EC	*Kluyveromyces marxianus var. lactisK1*	Feed additive		Already QPS
Reg(EC)773/2006 Corrigendum CS	*Kluyveromyces marxianus-fragilis*	Feed additive		Already QPS
FEEDAP	Astaxanthin rich *Phaffia rhodozyma* = *Xanthophyllomyces dendrorhous*	Production of astaxanthin	EFSA-Q-2004-148 The EFSA Journal (2004) 43, 1-4 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783707.htm EFSA-Q-2003-112 The EFSA Journal (2004) 43, 1-4 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783707.htm	*Phaffia rhodozyma* was assessed not appropriate for QPS (EFSA opinion 2008) because of insufficient body of knowledge. Later recommended for the QPS list (EFSA, 2011) as it is the imperfect form of *Xanthophyllomyces dendrorhous* according to the 2011 revision of the yeast taxonomy.
FEEDAP	*Komagaella pastoris* = *Pichia pastoris*	Production of enzyme	EFSA-Q_2006-025 (GMM) www.efsa.europa.eu/en/efsajournal/pub/627.htm and related opinions: EFSA-Q-2009-00804: www.efsa.europa.eu/en/efsajournal/pub/1550.htm EFSA-Q-2011-00148 www.efsa.europa.eu/en/efsajournal/pub/2533.htm Other applications: EFSA-Q-2010-00152 (GMM) www.efsa.europa.eu/en/efsajournal/pub/2414.htm	
FEEDAP	*Saccharomyces cerevisiae*	Organic selenium source	EFSA-Q-2005-071 www.efsa.europa.eu/en/efsajournal/pub/348.htm EFSA-Q-2005-117 www.efsa.europa.eu/en/efsajournal/pub/430.htm EFSA-Q-2008-381 www.efsa.europa.eu/en/efsajournal/pub/992.htm	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
			EFSA-Q-2009-00524 EFSA Journal 2011;9(6):2279 www.efsa.europa.eu/en/efsajournal/pub/2279.htm EFSA-Q-2009-00752 EFSA Journal 2011;9(4):2110 www.efsa.europa.eu/en/efsajournal/pub/2110.htm EFSA-Q-2010-01029 (in progress)	
FEEDAP	*Saccharomyces cerevisiae*	Production of enzyme	EFSA-Q-2005-224 (applicant is going to withdraw application) EFSA-Q-2009-00534 (GMM) www.efsa.europa.eu/en/efsajournal/pub/2451.htm	
FEEDAP	*Saccharomyces cerevisiae*	Feed additive	EFSA-Q-2005-025 www.efsa.europa.eu/en/efsajournal/pub/384.htm EFSA-Q-2005-234 The EFSA Journal (2006) 385, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/385.htm EFSA-Q-2005-149 The EFSA Journal (2006) 321, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/321.htm EFSA-Q-2005-176 www.efsa.europa.eu/en/efsajournal/pub/370.htm EFSA-Q-2006-003 www.efsa.europa.eu/en/efsajournal/pub/379.htm EFSA-Q-2006-067 www.efsa.europa.eu/en/efsajournal/pub/459.htm EFSA-Q-2007-104 www.efsa.europa.eu/en/efsajournal/pub/585.htm	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
			EFSA-Q-2007-139 The EFSA Journal (2008) 772, 1-11 www.efsa.europa.eu/en/scdocs/scdoc/772.htm EFSA-Q-2007-165 EFSA Journal 2009; 7(10):1353 www.efsa.europa.eu/en/scdocs/scdoc/1353.htm EFSA-Q-2008-009 The EFSA Journal (2009) 991, 1-14 www.efsa.europa.eu/en/scdocs/scdoc/991.htm EFSA-Q-2008-010 The EFSA Journal (2008) 837, 1-10 www.efsa.europa.eu/en/scdocs/scdoc/837.htm EFSA-Q-2008-302 The EFSA Journal (2009) 970, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/970.htm EFSA-Q-2008-472 The EFSA Journal (2009) 1040, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/1040.htm EFSA-Q-2009-00720 EFSA Journal 2010;8(10):1864 www.efsa.europa.eu/en/scdocs/scdoc/1864.htm EFSA-Q-2009-00753 EFSA Journal 2010;8(7):1659 www.efsa.europa.eu/en/scdocs/scdoc/1662.htm EFSA-Q-2009-00818 EFSA Journal 2011;9(11):2439 www.efsa.europa.eu/en/efsajournal/pub/2439.htm	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
			EFSA-Q-2009-00824 EFSA Journal 2010;8(7):1662 www.efsa.europa.eu/en/scdocs/scdoc/1662.htm EFSA-Q-2010-00936 EFSA Journal 2012;10(1):2531 www.efsa.europa.eu/en/efsajournal/pub/2531.htm EFSA-Q-2010-00938 EFSA-Q-2010-00992 www.efsa.europa.eu/en/efsajournal/pub/2173.htm EFSA-Q-2011-00390	
GMO	*Saccharomyces cerevisiae*	Dried killed biomass for feed	EFSA-Q-2007-156b (withdrawn) EFSA-Q-2009-00866 (withdrawn)	
FEEDAP	*Schizosaccharomyces pombe*	Production of enzymes	EFSA-Q-2005-063 The EFSA Journal (2006) 350, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769568.htm EFSA-Q-2005-080 The EFSA Journal (2006) 404, 1-20 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782208.htm EFSA-Q-2008-272 The EFSA Journal (2006) 350, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769568.htm EFSA-Q-2011-00835 (in progress)	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).
FEEDAP	*Trichosporon mycotoxinivorans*	Feed additive	EFSA-Q-2010-01030 (The application has been withdrawn)	Not recommended for the QPS list, assessed in the current 2011 update

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
	Fungi			
Pesticides	*Ampelomyces quisqualis* strain Q10	Plant protection product	EFSA-Q-2008-489 (in progress) Review Report for the active substance *Ampelomyces quisqualis*, EU-SANCO, 4205/VI/98-Final, October 2004	Not recommended for the QPS list, QPS 2011 update
FEEDAP	*Ashbya gossypii*	Production of vitamin B2	Formal mandate still to arrive (GMM)	Not recommended for the QPS list, QPS 2011 update
FEEDAP	*Aspergillus aculeatus*	Production of Enzyme	EFSA-Q-2008-432: www.efsa.europa.eu/en/efsajournal/pub/1186.htm EFSA-Q-2011-00035: www.efsa.europa.eu/en/efsajournal/pub/2010.htm EFSA-Q-2010-01297 EFSA-Q-2010-01295	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Aspergillus niger*	Feed additive		Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Aspergillus niger*	Production of Enzyme	EFSA-Q-2004-068 (GMM) www.efsa.europa.eu/en/efsajournal/pub/198.htm and related opinions: EFSA-Q-2006-119 www.efsa.europa.eu/en/efsajournal/pub/474.htm EFSA-Q-2008-418 www.efsa.europa.eu/en/efsajournal/pub/1155.htm EFSA-Q-2011-00147 (in progress) EFSA-Q-2005-116 The EFSA Journal (2006) 369, 1-19 www.efsa.europa.eu/en/efsajournal/doc/369.pdf and related opinions: EFSA-Q-2007-049: www.efsa.europa.eu/en/efsajournal/pub/472.htm EFSA-Q-2007-041: www.efsa.europa.eu/en/efsajournal/pub/544.htm EFSA-Q-2007-189: www.efsa.europa.eu/en/efsajournal/pub/614.htm EFSA-Q-2008-692: www.efsa.europa.eu/en/efsajournal/pub/1184.htm EFSA-Q-2009-00603: www.efsa.europa.eu/en/efsajournal/pub/1427.htm EFSA-Q-2009-00534 (in progress) EFSA-Q-2009-00585 (in progress) EFSA-Q-2008-013 www.efsa.europa.eu/en/efsajournal/pub/914.htm and related Questions: EFSA-Q-2010-00937 EFSA Journal 2011;9(5):2172 www.efsa.europa.eu/en/efsajournal/pub/2172.htm EFSA-Q-2011-00061 EFSA-Q-2010-01519 FAD-2010-0367 (formal mandate to arrive)	

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Aspergillus oryzae*	Production of enzymes	EFSA-Q-2003-012: www.efsa.europa.eu/en/efsajournal/pub/66.htm and related opinions: EFSA-Q-2004-070: www.efsa.europa.eu/en/efsajournal/pub/88.htm EFSA-Q-2006-060: www.efsa.europa.eu/en/efsajournal/pub/519.htm EFSA-Q-2007-132: www.efsa.europa.eu/en/efsajournal/pub/132.htm EFSA-Q-2009-00535: www.efsa.europa.eu/en/efsajournal/pub/535.htm EFSA-Q-2007-133: www.efsa.europa.eu/en/efsajournal/pub/871.htm and related opinions: EFSA-Q-2008-430: www.efsa.europa.eu/en/efsajournal/pub/1097.htm EFSA-Q-2009-00536: www.efsa.europa.eu/en/efsajournal/pub/1634.htm EFSA-Q-2008-419 EFSA-Q-2010-00769 EFSA-Q-2010-01519 www.efsa.europa.eu/en/efsajournal/pub/2527.htm and related opinion: EFSA-Q-2011-01172	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Aspergillus oryzae*	Feed additive	EFSA-Q-2009-00525	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	*Beauveria bassiana* (ATCC-74040 and GHA)	Plant protection product	EFSA-Q-2009-00125 EFSA-Q-2009-00251 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128818.htm www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128924.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Beauveria brongniartii*	Plant protection product	EFSA-Q-2009-00017 No dossier received, notification withdrawn.	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge, potential oosporein formation (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
ACF (as mentioned in the register of questions)	*Blakeslea trispora*	Production of lycopene (food colorant) Production of b-carotene (food colorant)	EFSA-Q-2004-102 The EFSA Journal (2005) 275, 1-17 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620764493.htm EFSA-Q-2007-001 The EFSA Journal (2008) 674, 1-66 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178700117557.htm	Can not be proposed for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Blakeslea trispora*	Production strain for beta-carotene	EFSA-Q-2009-00884	QPS 2009, 2010 update
NDA	*Blakeslea trispora*	Food ingredient	EFSA-Q-2004-169 The EFSA Journal (2005) 212, 1-29 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620765774.htm EFSA-Q-2008-697 The EFSA Journal (2008) 893, 1-15 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902228574.htm	QPS 2009, 2010 update

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	*Coniothyrium minitans*	Plant protection product	EFSA-Q-2008-515 Review report for the active substance *Coniotyrium minitans*, SANCO/1400/2001-final, July 2003 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028836.htm	The body of knowledge is insufficient. Potential acrosphelide formation (EFSA, 2009; EFSA, 2010)
FEEDAP	*Duddingtonia flagrans* Alternative name: *Trichothecium flagrans*	Feed additive	EFSA-Q-2004-115 The EFSA Journal (2006) 334, 1-8 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783270.htm EFSA-Q-2005-051	Insufficient body of knowledge (EFSA, 2009; EFSA, 2010)
Pesticides	*Gliocladium catenulatum* = *Clonostachys rosea* forma *catenulata* strain J1446	Plant protection product	EFSA-Q-2008-559 Review report for the active substance *Gliocladium catenulatum*, SANCO/10383/2004-rev.4, October 2004 www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_021009.htm	No recommendation for QPS in 2009 (EFSA, 2009). No new relevant information in the 2010 update.
Pesticides	*Lecanicillium muscarium* *Formerly Verticillium lecanii* strain Ve6	Plant protection product	EFSA-Q-2009-00130 EFSA-Q-2009-00255 Conclusion on the peer review: www.efsa.europa.eu/en/scdocs/scdoc/1446.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Metarhizium anisopliae* var. Anisopliae formerly *M. anisopliae*	Plant protection product	EFSA-Q-2009-00131 EFSA-Q-2009-00253 Conclusion on the peer review: www.efsa.europa.eu/en/scdocs/scdoc/2498.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Paecilomyces fumosoroseus* strain FE 9901 (ARSEF 4490)	Plant protection product	EFSA-Q-2008-599 EFSA-Q-2009-00323 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_115002.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Penicillium funiculosum*	Production of Enzyme	EFSA-Q-2005-281 www.efsa.europa.eu/en/efsajournal/pub/471.htm EFSA-Q-2010-01287 EFSA-Q-2011-00881	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Paecilomyces lilacinus* strain 251	Plant protection product	EFSA-Q-2008-600 Conclusion on the peer review: www.efsa.europa.eu/en/scdocs/scdoc/103r.htm www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028826.htm	Mycelial fungi: already considered as not appropriate for QPS. Potential for production of peptaibols (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Phlebiopsis gigantea* 14 different strains	Plant protection product	EFSA-Q-2009-00132 EFSA-Q-2009-00285	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Pseudozyma flocculosa* strain ATCC 64874	Plant protection product	EFSA-Q-2009-00315 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_119196.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Pythium oligandrum* M1	Plant protection product	EFSA-Q-2009-00133 EFSA-Q-2009-00287 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_028816.htm	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma asperellum* strain T-34	Plant protection product	EFSA-Q-2011-00899	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma asperellum* strains ICC 012, T25 and TV1 (formerly *Trichoderma viride* T25 and TV1)	Plant protection product	EFSA-Q-2009-00136	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma atroviride* I-1237	Plant protection product	EFSA-Q-2011-00900	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	*Trichoderma atroviride IMI 206040* and T11	Plant protection product	EFSA-Q-2009-00137 EFSA-Q-2009-00297	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma gamsii* strain ICC 080 (formerly *Trichoderma viride* ICC080)	Plant protection product	EFSA-Q-2009-00138 EFSA-Q-2009-00300	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma harzianum Rifai* (strains T22 and ITEM 908)	Plant protection product	EFSA-Q-2009-00139 EFSA-Q-2009-00298 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128902.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichoderma longibrachiatum*	Feed additive		Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichoderma longibrachiatum*	Production of Enzyme	EFSA-Q-2005-276 www.efsa.europa.eu/en/efsajournal/pub/405.htm and related opinion: EFSA-Q-2006-320: www.efsa.europa.eu/en/efsajournal/pub/520.htm EFSA-Q-2011-01532 EFSA-Q-2008-288 EFSA-Q-2010-00036 EFSA-Q-2010-01025 EFSA-Q-2010-01295 EFSA-Q-2010-01297 FAD-2010-0367 (formal mandate to arrive)	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
Pesticides	*Trichoderma polysporum* strain IMI 206039	Plant protection product	EFSA-Q-2009-00140 EFSA-Q-2009-00299 www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_128902.htm	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Trichoderma reesei*	Production of enzyme	EFSA-Q-2006-137 www.efsa.europa.eu/en/efsajournal/pub/548.htm and related opinions: EFSA-Q-2007-0020: www.efsa.europa.eu/en/efsajournal/pub/1156.htm EFSA-Q-2007-109: www.efsa.europa.eu/en/efsajournal/pub/586.htm EFSA-Q-2007-112: www.efsa.europa.eu/en/efsajournal/pub/1154.htm EFSA-Q-2007-185 EFSA-Q-2009-00470: www.efsa.europa.eu/en/efsajournal/pub/1949.htm EFSA-Q-2010-00141: www.efsa.europa.eu/en/efsajournal/pub/1916.htm EFSA-Q-2009-00802: EFSA Journal 2011;9(2):2008 www.efsa.europa.eu/en/efsajournal/pub/2008.htm EFSA-Q-2011-01171 EFSA-Q-2007-120 www.efsa.europa.eu/en/efsajournal/pub/712.htm and related question: EFSA-Q-2010-00142 EFSA Journal 2011;9(6):2277 www.efsa.europa.eu/en/efsajournal/pub/2277.htm	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
FEEDAP	*Trichoderma reesei*	Production of enzyme	EFSA-Q-2008-308: www.efsa.europa.eu/en/efsajournal/pub/1094.htm and related questions: EFSA-Q-2010-00018 EFSA-Q-2008-432: www.efsa.europa.eu/en/efsajournal/pub/1186.htm EFSA-Q-2008-748 (GMM): www.efsa.europa.eu/en/efsajournal/pub/1380.htm and related opinon: EFSA-Q-2010-0069 www.efsa.europa.eu/en/efsajournal/pub/1553.htm EFSA-Q-2011-00112 www.efsa.europa.eu/en/efsajournal/pub/2111.htm EFSA-Q-2010-00141: www.efsa.europa.eu/en/efsajournal/pub/1916.htm EFSA-Q-2010-00700: www.efsa.europa.eu/en/efsajournal/pub/1919.htm EFSA-Q_2011-00035: www.efsa.europa.eu/en/efsajournal/pub/2010.htm EFSA-Q-2011-00804 EFSA-Q-2012-00085	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
FEEDAP	*Trichoderma viride*	Production of enzyme	EFSA-Q-2010-01295 EFSA-Q-2010-01297	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
Pesticides	*Verticillium albo-atrum* formerly *Verticillium dahliae*	Plant protection product	EFSA-Q-2009-00141 EFSA-Q-2009-00303	Mycelial fungi: already considered as not appropriate for QPS. Potential production of alboatrin (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
	Algae			
FEEDAP	*Haematococcus pluvialis*	Production of astaxanthin		No body of knowledge except for this strain. Therefore not considered for QPS (EFSA opinion 2008)
	Bacteriophages			
FEEDAP	*Clostridium sporogenes* phage	Feed additive		QPS 2009, 2010 updates, no recommendation to the QPS list because phages are subject to a case-by-case assesment
FEEDAP	*Clostridium tyrobutyricum* phage	Feed additive		QPS 2009, 2010 updates, no recommendation to the QPS list because phages are subject to a case-by-case assesment
BIOHAZ	*Listeria moncytogenes* phage	Food surface decontamination	EFSA-Q-2011-00959 EFSA Journal 2012,10(3):2615. [43pp.]. www.efsa.europa.eu/en/efsajournal/pub/2615.htm	Phages were already assessed in QPS 2009, 2010 updates and they are subject to a case-by-case assessment
	Viruses			
Pesticides	*Adoxophyes orana Granulovirus* strain BV-0001	Plant protection product	EFSA-Q-2009-00324 EFSA Journal 2012;10(4):2654. [32pp.] www.efsa.europa.eu/en/efsajournal/pub/2654.htm	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list
Pesticides	*Cydia pomonella granulovirus* Mexican isolate	Plant protection product	EFSA-Q-2009-00126 EFSA-Q-2009-00254 EFSA Journal 2012;10(4):2655. [40 pp.] www.efsa.europa.eu/it/efsajournal/pub/2655.htm www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_107300.htm	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list
Pesticides	*Helicoverpa armigera nucleopolyhedrovirus*	Plant protection product	EFSA-Q-2009-00341 EFSA Journal 2012;10(9):2865 [31 pp.] www.efsa.europa.eu/en/efsajournal/pub/2865.htm	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list
Pesticides	*Spodoptera exigua nuclear polyhedrosis virus*	Plant protection product	EFSA-Q-2008-630 Review Report for the active substance *Spodoptera exigua* nuclear polyhedrosis virus, SANCO/T14/2007-rev.final, March 2007	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list
Pesticides	*Spodoptera littoralis nucleopolyhedrovirus*	Plant protection product	EFSA-Q-2009-00507 EFSA Journal 2012;10(9):2864 [33 pp.] www.efsa.europa.eu/en/efsajournal/pub/2864.htm	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list

EFSA Panel/Unit	Microorganism species/strain (current taxonomy where different)	Intended use	EFSA question number, reference and additional information	Comments
Pesticides	Zucchini yellow mosaic virus, weak strain	Plant protection product	EFSA-Q-2009-00346 www.epa.gov/opp00001/biopesticides/ ingredients/factsheets/factsheet_244201.htm	QPS 2009, 2010, 2011, 2012 updates recommended for the QPS list

Yeast Synonyms commonly used in the feed/food industry

Wickerhamomyces anomalus: synonym *Hansenula anomala*, *Pichia anomola*, *Saccharomyces anomalus*
Pichia jadinii: anamorph *Candida utilis*; synonyms *Hansenula jadinii*, *Torulopsis utilis*
Saccharomyces cerevisiae synonym *S. boulardii*
Saccharomyces pastorianus: synonym of Saccharomyces carlsbergensis
Komagataella pastoris: synonym *Pichia pastoris*

EFSA (European Food Safety Authority), 2007. Scientific Opinion of the Scientific Committee on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal, 578, 1-16. www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178667590178.htm

EFSA (European Food Safety Authority), 2008. Scientific Opinion of the Panel on Biological Hazards on the maintenance of the list of QPS microorganisms intentionally added to food or feed. The EFSA Journal, 923, 1-48. www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902221481.htm

EFSA Panel on Biological Hazards (BIOHAZ), 2009. Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update). EFSA Journal, 7(12):1431, 92 pp. www.efsa.europa.eu/en/scdocs/scdoc/1431.htm

EFSA Panel on Biological Hazards (BIOHAZ), 2010. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2010 update). EFSA Journal, 8(12): 1944, 56 pp. www.efsa.europa.eu/en/efsajournal/pub/1944.htm

EFSA Panel on Biological Hazards (BIOHAZ), 2011a. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2011 update). EFSA Journal, 9(12):2497, 82 pp. www.efsa.europa.eu/en/efsajournal/pub/2497.htm