SCIENTIFIC OPINION

Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2010 update)[1]

EFSA 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 (including microorganisms and viruses) 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) concept was developed by EFSA for its own use to provide a generic risk assessment approach applicable across EFSA's scientific Panels, for biological agents notified for intentional use in the whole food chain. The safety of unambiguously defined biological agents at the highest taxonomic unit that is appropriate for the purpose for which an application is intended are assessed, considering if the body of knowledge is sufficient. Identified safety concerns for a taxonomic unit could be reflected as 'qualifications' when considered appropriate for an inclusion on the QPS list. The list of QPS recommended biological agents is reviewed and updated annually. The 2010 update reviews the previously assessed microorganisms including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes. The recommendations of biological agents of the previous year were confirmed in the current update. Qualifications relating to the agents recommended for QPS were reviewed, clarified and updated where necessary. Specific sections dealing with antibiotic resistance relevant for QPS recommended microorganisms and yeast 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 this opinion, includes information on taxonomic units which are or are not recommended for the QPS list. This list of notifications aims to summarize and maintain important information for future assessments and updates.

KEY WORDS

Qualified presumption of safety, QPS, microorganisms, viruses

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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the list of QPS biological agents (microorganisms and viruses) intentionally added to food or feed (2010 update).

The Opinion reviews the previous assessments of biological agents in the context of a proposal for a qualified presumption of safety (QPS). The previous list of QPS biological agents that was published in 2009 was reviewed and confirmed. Qualifications of QPS recommended agents were reviewed and updated. Antibiotic resistance with regards to QPS recommended microorganisms were included in the current review and update.

The list of biological agents (microorganism and viruses) notified to EFSA remained the same as in the 2009 QPS Opinion. Since the previous Opinion, important information for each taxonomic unit was included in the notification table.

Following the annual review, there was no modification to the list of QPS recommended biological agents while changes were introduced with regards to the qualifications. A generic qualification concerning antimicrobial susceptibility was included for bacteria and yeasts. The qualification concerning *Bacillus* species was simplified and the qualification concerning production purposes for *Corynebacterium* species and the yeast species was clarified with regard to amino acid and enzyme production, respectively.

Isolation of lactobacilli and bifidobacteria in clinical cases remains a rare event, but maybe also underreported due to isolation difficulties. Especially for bifidobacteria the isolation difficulties are of importance. Within the *Lactobacillus* group, *L. rhamnosus* proved to be the most important species related to clinical cases. However, considering the circumstances and number of reports at the moment no update to the QPS recommendation for lactobacilli or bifidobacteria is necessary. Similarly, one clinical case caused by a *Bacillus* species was reported but due to the rarity of these infections and of the existence of important predisposing factors in the host, no modification of the QPS list for Gram-positive spore forming bacteria is necessary.

Resistance to therapeutic antimicrobials, some potentially transmissible, has been reported among microbial species recommended for the QPS list. These resistant isolates would have been detected by the qualification on antimicrobial resistance.

Saccharomyces cerevisiae and *Kluyveromyces* species have been isolated from infections but there are no indications that food isolates contributed to these. More information on the characteristics of the isolates involved in clinical aspects would be needed. In addition, these infections remained very rare compared to *Candida albicans* and no change in the QPS list is necessary.

Some microbial species not included on the QPS list have been notified only once to EFSA, and will no longer be assessed in the future maintenance of the list, until a new notification. This is indicated in the updated list of microbial species notified to EFSA. Some microbial species not included on the QPS list will no longer be assessed in the future maintenance of the list because increasing evidence of pathogenicity precludes any future inclusion in the QPS list. This is indicated in the updated list of microbial species notified to EFSA. Filamentous fungi and enterococci are not on the QPS list. However their regular assessment permits a yearly update of the body of knowledge on the numerous fungal and enterococcal strains notified to EFSA.

The QPS list has permitted a simplification and a harmonisation of the assessment for micro-organisms notified to the Panels and Unit of EFSA. However, many microbial species notified to EFSA are not on the QPS list and their safety may not be assessed as consistently as for QPS species.

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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. Experience has shown that there is a need for a tool for setting priorities within the risk assessment of those microorganisms used in the production of food/feed which are captured by present legislation and consequently the subject of a formal safety assessment.

In 2002/3 a working group consisting of members of the former Scientific Committees on Animal Nutrition, Food and Plants of the European Commission proposed the introduction for selected microorganisms of a Qualified Presumption of Safety (QPS)[4].

In April 2003, responsibility for the safety assessments of food/feed undertaken by the Scientific Committees of the Commission formally transferred to the European Food Safety Authority (EFSA). Shortly after EFSA asked its own Scientific Committee to consider whether the approach to safety assessment of microorganisms proposed in the QPS document could be used to harmonise approaches to the safety assessment of microorganisms across the various EFSA scientific Panels.

The Scientific Committee concluded that QPS as a concept could provide a generic approval system for use within EFSA that could be applied to all notification requests received for the safety assessments of microorganisms deliberately introduced into the food chain[5]. The benefits of the introduction of QPS would be a more transparent and consistent approach across the EFSA panels and the potential to make better use of resources by focussing on those organisms which presented the greatest risks or uncertainties.

On the basis of these conclusions the Scientific Committee recommended that EFSA should develop a strategy for the introduction of an assessment system based on the QPS concept. This should be limited to microorganisms introduced into the food chain or used as producer strains for food/feed additives until the robustness and value of such a system could be tested in practice.

EFSA accepted the recommendation of its Scientific Committee and proposed that the Committee should continue its assessment of the QPS system with a view to implementation[6].

Specifically, the Scientific Committee was asked first to establish that were the most commonly encountered microorganisms in notifications received by EFSA, including those used as a source of microbial products. Then, on the basis of this survey, to select relevant groups of microorganisms, examine the available data on safety and propose whether a QPS recommendation would be appropriate.

If this proved possible in a significant number of cases then the Scientific Committee should consider how implementation of QPS across the various Panels could be achieved.

The Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA Opinion[7]. They found that a large majority of these species were found to fall within four broad groupings: i) Gram-positive non-sporulating bacteria; ii) *Bacillus* species, iii) yeasts and iv) filamentous fungi. Accordingly, bacteria, yeasts and fungi falling within these four groups were selected for an initial assessment of their suitability for the QPS list, and the resulting list of microorganisms recommended for QPS was published[7].

In reaching 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 a QPS recommendation. They recommended that the EFSA via its Science

4 See http://ec.europa.eu/food/fs/sc/scf/out178_en.pdf
5 See www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/972.html
6 See www.efsa.europa.eu/en/science/sc_commitee/sc_documents/1368.html
7 See www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178667590178.htm

Department should take prime responsibility for this and should review the suitability for QPS recommendations of the existing 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 the QPS recommendations are being maintained for the published list.

The Scientific Committee recommended[5] that a QPS system for microorganisms should be introduced and that it should be implemented across EFSA and applied equally to all safety considerations of microorganisms intentionally added to the food chain that EFSA is required to assess.

The Biological Hazards Panel was identified as being the most appropriate to take up the task of carrying out an annual review of the QPS list. In the first annual review[8], 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[9] on 'Foodborne antimicrobial resistance as a biological hazard', and related Opinions[10] and guidance documents[11] of other EFSA Panels. The potential application of the QPS approach to microbial plant protection products was discussed in the most recent review[12].

TERMS OF REFERENCE AS PROVIDED BY EFSA

1. Preparation of an update of the list of biological agents notified to EFSA, which should be a starting point for identifying new taxonomic units for review under the QPS system. Only those taxonomic units relevant to current legal requirements from notification to EFSA for feed/food use (principally as sources of food and feed additives, food enzymes and plant protection products) shall be included.
2. Carry out an annual review of the list of biological agents recommended for QPS. Where appropriate new taxonomic units should be assessed for their suitability for inclusion on 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 the qualifications currently included for biological agents recommended for the QPS list.

8 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.

9 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.

10 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.

11 Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Microorganisms and their Derived Products Intended for Food and Feed Use. The EFSA Journal (2006) 374, 1-115. www.efsa.europa.eu/EFSA/Scientific_Document/comm_Guidance%20doc_GMM_en,0.pdf

12 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

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.

The purpose of the present Opinion is to review the list of previously Qualified Presumption of Safety (QPS) recommended biological agents which was last established in 2009 (EFSA, 2009a). 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, 2007a). The list, first established in 2007 (EFSA, 2007a) is to be reviewed annually. 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, 2005a).

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 groups 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 within the responsible EFSA Scientific Panel (EFSA, 2007a).

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 2010 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, 2008a). In the 2009 Opinion, a qualification regarding absence of antimycotic resistance for yeast was introduced. The qualifications are reviewed and discussed in the present 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 QPS system by EFSA Units in the frame of authorisations and its quotation in the scientific literature is provided.

1.1. Experience of using the QPS approach within EFSA

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 was mainly used by the EFSA's Panel on Additives and Products of Substances used in Animal Feed (FEEDAP). If a biological agent is recommended for the QPS list this covers in their assessment as well 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 the European Food Safety Authority (EFSA) to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment. Therefore, no assessment of safety for the target species, consumer and the environment is required. In 2010, the QPS recommendation has been applied by FEEDAP, in the assessment of seven dossiers out of a total of 13 dossiers dealing with microorganisms and feed additives (EFSA, 2010a; b; c; d; e; f; g).

Viruses belonging to the families Baculoviridae and Potyviridae used for plant protection purposes were recommended for the QPS list in 2009 (EFSA, 2009a). Biological agents recommended for the QPS list and proposed as plant protection products (under the Directive 91/414/EC) could be exempt from certain data requirements such as oral toxicity data. The QPS recommendation for biological agents can be used as a waiver for limited data requirements. However, the QPS recommendation does not address other risks, specifically risks for the user and risks for the environment, which will have to be assessed specifically for plant protection products according to legislation Directive (EC) No 91/414/EEC (Official Journal, 1991) or its subsequent amendment, Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009).

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 included in Annex I of Directive (EC) No 91/414/EEC (Official Journal, 1991), 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 on the QPS list. This for instance concerns several genera and species of filamentous fungi, notified to EFSA as plant protection products. However, in the meantime, the notification of new adverse information is a legal requirement on the authorization holder (i.e. applicant) and Member State's regulatory authorities responsible for the authorization of the product. For the evaluation of biological agents under the new Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009), systematic literature review will be a legal requirement for the applicant. In order to support this, guidance on literature review and reporting has been provided by EFSA and will be systematically applied for each new active substance notified as a pesticide (including biological agents). The activity of maintenance of the QPS list will also be communicated to the Pesticide Steering Committee in December 2010.

1.2. Reference to QPS in the scientific literature

Since the publication of the EFSA 2009 Opinion (EFSA, 2009a) where references to the QPS approach in the scientific literature were discussed several, additional publications made reference to the concept (Heller, 2010; Leuschner et al., 2010; Zago et al., 2010; Mayrhofer et al., 2010; Cuddeford and Kabaluk, 2010; Quigley, 2010; Gaggìa et al., 2010; Aureli et al., 2010; Scarano et al., 2009; Maragkoudakis et al., 2009, Wind et al., 2010; Falentin et al., 2010; Spano et al., 2010). The taxonomy and safety of the major genera of microorganisms used in the dairy industry was reviewed (Anonymous, 2009). Although several of the genera presented in this book are not recommended for the QPS list, it starts with a presentation of the QPS approach as an illustration of the safety assessment of microorganisms used in the food chain.

A recent review outlines the potential biogenic amine formation by lactobacilli (Spano et al., 2010). This aspect was addressed in the last QPS update (EFSA, 2009a) and a published review by the QPS working group (Leuschner et al., 2010). While the QPS assessment concentrates on the characteristics of the biological agent, it is recognised that certain aspects related to safety are strongly influenced by the specific conditions of preparation, formulation and application of the final product. This is currently out of scope of the generic QPS assessment. An example would be the potential formation of biogenic amines. These aspects are assessed, where applicable, separately by the EFSA Panel responsible for assessing the notification.

The concerns raised by Member States in the context of the EFSA Network meeting on Microbiological Risk Assessment in 2009 (Spano et al., 2010) are currently addressed by a working group of the Biological Hazards Panel in response to an EFSA self-tasking mandate dealing with these Member States concerns entitled 'Risk based control of biogenic amine formation in fermented foods' (EFSA-Q-2009-00829). The resulting scientific opinion is foreseen for adoption at the end of 2011.

2. Review of the list of QPS assessed microorganisms

2.1. Methodology

A literature review was carried out for each taxonomic unit that was notified to EFSA either for the QPS Opinions in 2007a, 2008a or 2009a. QPS recommended taxonomic units (Table 1) and those which represent an important part of the notifications are annually reviewed. The time period of the review covered is the whole year of 2009 until end of May 2010 for the QPS 2010 update. Databases searched are specified in the specific sections. Keywords used are equally specified in the specific section however some common keywords such as the taxonomic unit in combination with 'toxin', 'disease', 'infection', 'clinical', 'virulence', 'antimicrobial/antibiotic/antimycotic resistance', 'safety' and 'risk' were generally applied. Relevant studies were evaluated, reported and discussed.

2.2. Gram-positive non-sporulating bacteria

Since 2009 several reports have been published concerning lactobacilli and bifidobacteria and clinical infections according to a PubMed search including 'clinical infection'.

2.2.1. *Lactobacillus* species

A case report described by Chan et al. (2010) relates to a hepatic abscess caused by *Lactobacillus rhamnosus* in an immunocompromised patient undergoing chemotherapy. This is in line with a number of case reports already discussed in the previous QPS opinions (EFSA, 2009a), where always host factors debilities are involved, which can support opportunistic infections.

Another report given by Shoji et al. (2010) describes a lung abscess also caused by *L. rhamnosus*. In this case, however, the patient is described as immunocompetent which is very uncommon. The patient was aged 79 and the lung had an impaired local immune system, due to emphysema. Therefore some predisposition factor facilitating the infection can be assumed.

A systematic review was performed by Whelan and Myers (2010) on safety of probiotics in patients receiving nutritional support. The conclusions were that many probiotics have been used safely in patients receiving nutritional support, although some probiotic products have been shown to increase the risk of complications in specific patient groups. Complications occurred specifically in patient groups with severe underlying disease and/or in immunocompromised patients. The study focused explicitly beside others on *L. rhamnosus*.

2.2.2. *Bifidobacterium* species

Concerning bifidobacteria a study looking for the association between *Bifidobacteriaceae* and the clinical severity of root caries lesions (Mantzourani et al., 2009a) revealed that a number of different species can be isolated from caries lesions, including *Bifidobacterium breve*. Therefore not only *B. dentium* is associated with caries. This is supported by a number of other studies (Mantzourani et al., 2009b; Beighton et al., 2008). However, this association is well known and contributes not to a new hazard for man.

A study by Mahlen and Clarridge (2009) showed that different bifidobacterial species (incl. *B. longum* and *B. breve*) could be isolated from different clinical specimen. It could not be demonstrated that the organisms were the causative agent, but they could be isolated as mono-cultures. The immune status of the patients was not reported or was unknown.

2.2.3. *Leuconostoc* species

Three species of leuconostocs, *Leuconostoc citreum*, *L. mesenteroides* and *L. lactis*, were previously given a QPS recommendation. A fourth species, *L. pseudomesenteroides*, was considered unsuitable because of a limited body of knowledge on food and feed application and of its (rare) implication in opportunistic infections. During 2009 and the five first months of 2010, seven reports on involvement of leuconostoc strains on human pathology were detected through a Pub-Med survey, using the key words leuconostoc and 2009 or 2010, plus one of the following terms: safety, pathology, infection, clinical. Out of these, five were caused by *Leuconostoc* species (Yossuck et al., 2009; Janow et al., 2009; Cortés et al., 2009; Yamazaki et al., 2009; Camarasa et al., 2009), while the sixth and seventh were caused by *L. pseudomesenteroides* (Tholpady et al., 2010), which is not recommended for the QPS list and *L. mesenteroides* (Ballesteros Sanz et al., 2010) which is. Six of the patients developed septicaemia and of these, two were premature babies (Yossuck et al., 2009; Janow et al., 2009) one, a severely malnourished infant (Cortés et al., 2009), two were transplant receptors (Yamazaki et al., 2009; Tholpady et al., 2009) and the sixth suffered from a colon adenocarcinoma (Ballesteros Sanz et al., 2010), the origin of the infection being a central venous catheter. In this last case, the *L. mesenteroides* isolate was identified by a combination of an automatic system and 16S rRNA sequencing. The seventh patient suffered from a chronic obstructive pulmonary disease (COPD) and developed a pulmonary abscess (Camarasa et al., 2009). It is proposed that no change in the QPS list are recommended because of the extremely low frequency of leuconostoc associated pathology and its opportunistic nature.

2.2.4. *Pediococcus* species

Only one report, dealing with a polymicrobial bacteremia caused by, among others, *Pediococcus acidilactici* and *Lactobacillus* species, was detected during the period 2009 until the first five months of 2010 (Suh, 2010). It occurred in a severely ill patient previously operated for a gall bladder adenocarcinoma, as a consequence of insertion and subsequent removal of a biliary stent. This single opportunistic infection is not considered enough to change the QPS recommendation of *P. acidilactici*.

2.2.5. *Oenococcus oeni*

Oenococcus oeni was recommended for the QPS list in the last EFSA opinion (EFSA, 2009a) based on its wide use in alcoholic beverage fermentation without a single case of association to pathology. No reports on colonization and/or pathology associated to *Oenococcus oeni* have been published since, for this reason its permanence in the list of QPS recommended organisms is proposed.

2.2.6. Antibiotic resistance of *Leuconostoc, Pediococcus* and *Oenococcus oeni*

The body of knowledge for *Leuconostoc*, *Pediococcus* and *Oenococcus* was not reviewed in the previous QPS opinions. A literature review, more comprehensive than for other taxonomic units, is therefore presented here. The search was undertaken for articles published during the last ten years (from 2001 to the end of June 2010) using antibiotic resistance plus *Leuconostoc*, *Pediococcus* or *Oenococcus oeni* as key words. Out of this search, 40, 34 and 5 references were recovered, respectively. Most of them dealt with opportunistic infections, bacteriocin production and/or susceptibility or with their probiotic use, thus being irrelevant for the purpose of this section on therapeutic antimicrobials resistance. Out of the rest, the majority of papers were devoted to the study of antibiotic susceptibilities of multiple strains of lactic acid bacteria, especially lactobacilli, but that included some leuconostocs and/or pediococci (Hummel et al., 2007; Kastner et al., 2006; Katla et al., 2001; Klare et al., 2007; Mathur and Singh, 2005; Rojo-Bezares et al., 2006; Vay et al., 2007).

The exceptions were a couple of articles specifically dealing with *Pediococcus* species antibiotic susceptibility (Danielsen et al., 2007; Haakensen et al., 2009a). Only one paper referred to a significant number of *Oenococcus oeni* isolates (Rojo-Bezares et al., 2006). The methodology used (culture media, antibiotic presentation, inoculum density, etc.) in these studies differed, being only recently proposed as a standardized methodology for some non-enterococcal lactic acid bacteria, including *Leuconostoc* (Huys et al., 2010). Besides, epidemiological cutoffs (ECOFFS) essential for the differentiation between wild-type organisms, which lack acquired and mutational resistance mechanisms, from non-wild-type members of the same species that contain one or more mechanisms conferring antimicrobial resistance are not yet defined. In fact, current epidemiological cutoffs recommended by FEEDAP do not descriminate at species level (EFSA, 2008b).

With these constrains, relevant information from available studies was included in the following discussion which is centered, albeit not exclusively, on the QPS recommended taxonomic units *Leuconostoc mesenteroides*, *Pediococcus pentosaceus*, *Pediococcus acidilactici* and *Oenococcus oeni*. Data on other QPS leuconostocs and pediococci are mostly limited to four isolates of *Leuconostoc lactis* isolated from clinical samples and identified only phenotypically (Vay et al., 2007) and to three *Pediococcus dextrinicus* isolates that appeared to be generally more susceptible than the other QPS pediococci analyzed in the same report (Danielsen et al., 2007). Reclassification of *P. dextrinicus* into the genus *Lactobacillus* has been recently proposed (Haakensen et al, 2009b).

Susceptibility to β-lactam antibiotics is general, penicillins being more effective than cephalosporins, with cases of resistance to cefotaxime and ceftriaxone (Haakensen et al., 2009a; Kastner et al., 2006), while the same isolates are susceptible to penicillin G. This is, in fact, the most effective β-lactam and is followed by ampicillin, thus excluding the presence of penicillinase determinants in the group, an impression confirmed by the lack of amplification of *bla* sequences (Hummel et al., 2007) and response to nitrocephin disks (Rojo-Bezares et al., 2006). Beta-lactamase resistant molecules such as methicillin and oxacillin are usually active, although their MICs tend to be higher than those of penicillin G. The resistance against cephalosporins and even imipenem of some clinical *Leuconostoc* isolates (Vay et al., 2007) is probably due to their lower affinity for their targets when compared to penicillins, but the existence of cephalosporinases and carbapenemases was not addressed and, consequently, cannot be excluded.

Chloramphenicol is usually effective, but there are several instances of MICs close or slightly above the EFSA breakpoint. However, it does not seem that this is due to the presence of active chloramphenicol acetyl transferases (CAT). In fact, although *cat*-like determinants have been detected by PCR, they are probably pseudogenes (Hummel et al., 2007).

Most isolates are susceptible to erythromycin (no other macrolides have been generally tested), to lincosamides and to streptogramins (Danielsen et al., 2007; Haakensen et al., 2009a; Hummel et al., 2007; Kastner et al., 2006; Katla et al., 2001; Klare et al., 2007; Mathur and Singh, 2005; Rojo-

Bezares et al., 2006; Toomey et al., 2010; Vay et al., 20071) although some inconsistencies have been noted (strains susceptible to lincomycin but resistant to clindamycin). However, the presence of the *ermB* determinant, both chromosomally and plasmid encoded, may confers resistance to some strains against these three families of antibiotics and even to the association of the streptogramins dalfopristin and quinupristin (Danielsen et al., 2007; O'Connor et al., 2007; Rojo-Bezares et al., 2006).

Linezolid, introduced as an alternative for the treatment of β-lactam and glycopeptide resistant Gram positive cocci, appears to be active on the organisms of the three genera. The MICs shown by the bacteria under scrutiny are between 0.5 and 2 µg/ml for pediococci (Klare et al., 2007; Vay et al., 2007) with some isolates of *P. acidilactici* reaching 6 µg/ml (Danielsen et al., 2007) and between 2-4 µg/ml for *Leuconostoc* (Vay et al., 2007).

Intrinsic resistance to aminoglycosides is expected for these genera, as occurs with most anaerobic bacteria. Nevertheless, epidemiological cutoffs aren´t available for aminoglycosides, except for streptomycin (EFSA, 2008b), making the detection of acquired resistance phenotypes difficult. Besides, these antibiotics are probably inactivated in susceptibility studies using MRS medium (Klare et al., 2007). Aminoglycoside resistance genes were described in few isolates, being their contribution for the observed resistance only demonstrated in one *P. acidilactici* carrying an adenylation determinant (*aadE*), which conferrs resistance to streptomycin, in a plasmid similar to the ones described in streptococci and enterococci (O'Connor et al., 2007). The resistance *aac (6')-aph(2")* gene which encodes the bifunctional aminoglycoside-modifying AAC(6′)-APH(2") associated with gentamicin and kanamycin resistances in *Staphylococcus* and *Enterococcus* (Novais et al., 2006; Culebras and Martinez, 1999) was observed in one *P. pentosaceus*, one *P. acidilactici* and two *O. oeni* strains (Rojo-Bezares et al., 2006; Tenorio et al., 2001). Moreover, in the same study conducted by Rojo-Bezares et al. (2006) the *aph(3')-IIIa* was found in one *O. oeni*, although its contribution for kanamycin resistance in this isolate was not demonstrated.

Tetracycline inhibits the growth of *O. oeni* (Rojo-Bezares et al., 2006) and most *Leuconostoc* isolates (Hummel et al., 2007; Rojo-Bezares et al., 2006; Toomey et al., 2010), the exception being a *L. mesenteroides* isolated from meat that carries a non-transmissible *tet*(S) determinant that confers resistance to >256 µg/ml of the antibiotic (Toomey et al., 2010). On the contrary, pedicocci are generally resistant to tetracycline (Danielsen et al., 2007; Haakensen et al., 2009a; Hummel et al., 2007; Kastner et al., 2006; Klare et al., 2007; Rojo-Bezares et al., 2006) and even a *tet*(K) determinant has been detected (Kastner et al., 2006). However, the three isolates of *P. dextrinicus* analyzed in the study of Danielsen et al. (2007) turned out to be susceptible, as were 2 out of 10 strains of *P. acidilactici* and *P. pentosaceus* associated to beer spoilage (Haakensen et al., 2009a) and the two *P. pentosaceus* characterized in Toomey et al. (2010).

Most strains of *P. acidilactici* and *P. pentosaceus* tested are resistant to the fluoroquinolone ciprofloxacin (Danielsen et al., 2007; Haakensen et al., 2009a; Hummel et al., 2007; Rojo-Bezares et al., 2006; Vay et al., 2007). However, *P. dextrinicus* appears to be susceptible (Danielsen et al., 2007) and the character varies with the isolate among leuconostocs (Katla et al., 2001; Rojo-Bezares et al., 2006; Vay et al., 2007) and oenococci (Rojo-Bezares et al., 2006). Other, more recent quinolones, such as trovafloxacin and gatifloxacin are active against *P. acidilactici* and the leuconostocs (Danielsen et al., 2007; Vay et al., 2007).

Rifampicin susceptibility was observed in all bacteria scrutinized exept for one isolate of *P. acidilactici* (Kastner et al., 2006) were susceptible to the antibiotic (Danielsen et al., 2007; Haakensen et al., 2009a; Kastner et al., 2006; Rojo-Bezares et al., 2006; Vay et al., 2007).

It is traditionally considered that pediococci and leuconostocs are intrinsically resistant to glycopeptides (vancomycin and teicoplanin) because their D-ala-D-ala target in the peptidoglycan is substituted by D-ala-D-lactic acid. Resistance to trimethoprim, sulfonamides and the combination of

both, known as cotrimoxazol, is generally expected as well. Most reports analyzed (Danielsen et al., 2007; Kastner et al., 2006; Katla et al., 2001; Klare et al., 2007; Rojo-Bezares et al., 2006; Vay et al., 2007) confirm this impression. However, in the already quoted survey on beer spoilage associated *Pediococcus* strains (Haakensen et al., 2009a) one isolate of *P. acidilactici*, as well as others from non QPS recommended species, were reported to be susceptible to vancomycin (Haakensen et al., 2009a). The strains were identified by 16S rRNA sequencing, thus ruling out their misclassification. In the same paper the only *P. acidilactici* and *P. pentosaceus* isolates susceptible to trimethoprim reported to date appear, while the three strains of *P. dextrinicus* included in a report (Danielsen et al., 2007) are also susceptible to this chemotherapeutical agent.

Final remark: Further improvements on susceptibility tests of these microorganisms are needed to increase data accuray. Very few acquired antibiotic resistance determinants have been detected and their contribution for the resistance was not always demonstrated, as well as potential transmissibility by conjugation.

2.2.7. *Enterococcus* species

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. Taxonomy of this genus has evolved, and currently, more than 30 species have been described. 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 which requires risk assessment by EFSA, or as food starter culture (Official Journal of the European Union, 2003).

E. faecium is also an important cause of infections in hospitalized or immunocompromised patients and the high prevalence of antimicrobial resistance in strains, limits the therapeutic treatments.

The assessment of *E. faecium* for QPS has been performed by EFSA in 2009, 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. A recent paper (van Schaik et al., 2010) describes the comparative genome analysis of seven *E. faecium* strains that were isolated from faecal and clinical samples. Four of these strains were responsible of human infections and two of them belong to Clonal Complex 17, which contains the large majority of strains isolated from nosocomial infections. This study demonstrated the extremely high plasticity of *E. faecium*, correlated to capability to efficiently acquire and incorporate exogenous DNA. The comparison of genomes of strains isolated from infections with those of commensal strains revealed group of 26 orthologous proteins are conserved in all infectious strains, while absent in commensals. Among these proteins seven are insertion sequences which may contribute to *E. faecium* genomic flexibility. Three of four infectious strains harbor large pathogenicity island which can be horizontally transferred by conjugation in other *E. faecium* strains.

This new genomic information support the view that safety of *E. faecium* is a strain-related property, and that specific qualifications cannot be applied, therefore confirming the previous view that *E. faecium* should not be recommended for the QPS list.

2.2.8. Dairy propionic acid bacteria other than *Propionibacterium freudenreichii*

Of the dairy propionic acid bacteria (DPAB; *Propionibacterium acidopropionici, P. australiense, P. cyclohexanicum, P. freudenreichii* subsp. *freudenreichii*, *P. freudenreichii* subsp. *shermanii*, *P. jensenii, P. thoenii* and *P. microaerophilum*) only *P. freudenreichii* and its subspecies and *P. acidopropionici* are included in the present QPS list.

P. freudenreichii has been extensively intentionally used in cheese making, and consequently the body of knowledge regarding its safe history of use was considered sufficient for the QPS status. '*P. globosum'* is not recognised in the official 'list of prokaryotic standing nomenclature (LPSN)' (LPSN, 2010). Currently, '*P. globosum'* maybe considered either as a subspecies of *P. freudenreichii* or even just a biovariant with a too high DNA homology to allow a subspecies status (Gautier, 2000).

The other DPAB, although commonly found in dairy products, have been considered as naturally occurring micro-organisms with more limited associated safety data regarding the human exposure. However, *P. acidipropionici* is a well known silage starter, particularly for cereal based silages (Filya et al., 2004; Bolsen et al., 1996) and its engineered mutants have been proposed for industrial propionic acid production (Suwannakham et al., 2006; Zhang and Yang, 2009). No human or animal infections associated with this bacterium have been reported.

Certain pigmented variants of *P. jensenii* have been shown to have very similar haemolytic properties as a known but totally unrelated pathogen, *Streptococcus agalactiae* (Vanberg et al., 2007). While apparently no cases of infections caused by *P. jensenii* have been reported, the presence of a potential virulence factor warrants certain prudence before making conclusions of the safety of the species.

Thus, while *P. acidipropionici* has a history of safe use and can be considered for QPS together with *P. freudenreichii*, the present gaps in the body of knowledge on other DPAB require more research on their safety aspects before this can be decided.

2.2.8.1. Antimicrobial resistance in propionic acid bacteria

The data on the antibiotic resistance patterns of the dairy Propionibacteria following a search in the PubMed database using keywords '*Propionibacterium*' and 'resistance' is very limited and no new documents appear to have been published since the 2008 EFSA guidance (EFSA, 2008b).

Studies on the antimicrobial resistance on propionic acid bacteria have been focused on cutanoeus species with clinical importance. Accordingly, MIC values for *Propionibacterium acnes* have been determined for benzylpenicillin, vancomycin, erythromycin, clindamycin, tetracycline and linezolid (Oprica et al., 2007). In other studies MICs for chloramphenicol, thrimethoprim (Ross et al., 2001) and clindamycin/dalfopristin (Mory et al., 2005) have also been determined.

In an agar diffusion based screening study with dairy strains and a range of antibiotics, including β-lactams, aminoglycosides, macrolides, tetracyclines, quinolones and glycopeptides, indication of resistance to nalidixic acid, quinolones and to gentamicin was observed however the accuracy of the method does not permit a determination of resistance with regards to the QPS qualification (Roland et al., 2007).

The present FEEDAP guidance (EFSA, 2008b) on antimicrobial breakpoints for strains used as feed additives is mainly based on the available studies cited above. When new relevant information will become available, specifically on dairy propionic acid bacteria this will be taken in consideration.

2.2.9. *Streptococcus thermophilus*

No reports of clinical infections related to *Streptococcus thermophilus* were identified in scientific literature since 2009. Although few scientific information is still available on the *S. thermophilus* susceptibility to clinically relevant antibiotics, recent papers have shown the occasional presence of acquired resistance genes in this dairy bacterium. *S. 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 *S.*

thermophilus (Rizzotti et al., 2009). These resistances are covered by the general qualification on antibiotic susceptibility.

2.3. Gram-positive spore forming bacteria

2.3.1. *Bacillus* species

A search on the Web of Science from 2009 to end of May 2010 with the key words *Bacillus* (excluding species from the *B. cereus* Group which are not QPS) combined with disease*, infection*, toxin*, lipopeptide* (produced by several Bacillus isolates and potentially toxic), retrieved 132 publications. Several *Bacillus* species are on the QPS list because of an important history of safe use in the food and feed chain production (EFSA 2007a), and a sufficient body of knowledge. However, some of these *Bacillus* species have been implicated in foodborne poisoning, and the production of several toxins, were associated with the diseases (EFSA, 2008a). *Bacillus* species on the QPS list therefore must meet a qualification to ensure the absence of toxin production.

Update of the qualification:

The footnote attached previously to the qualification for Gram-positive sporulating bacteria in the QPS list 'when strains of these QPS units are to be used as seed coating agents, testing for toxic activity is not necessary, provided that the risk of transfer to the edible part of the crop is very low' was removed as it does not concern the QPS approach but was rather a comment intended to future assessment of specific representative of QPS Gram-positive sporulating bacteria for market authorisation as plant protection products.

The qualification for Gram-positive sporulating bacteria in the QPS list is updated as "absence of toxigenic potential". This includes both toxins which could be produced in the food and enterotoxins produced in the enteral tract. The reference to "surfactant activity" was introduced in the qualification of the first QPS list (EFSA, 2007a) because it was at that time a possible indication of the production of food poisoning toxins. Since then, new information on the toxins from *Bacillus* species involved in food poisoning and methods to detect them have been published and reviewed by EFSA (EFSA, 2008a).

Update of the body of knowledge:

QPS *Bacillus* sppecies also cause rare local or systemic infections, mostly in immunocompromised patient. The possibility that such infection could be transmitted *via* food should remain a topic for surveillance.

A search on the Web of Science retrieved 132 publications. Most described activities of *Bacillus* species to fight against plant or farm animals infections by other pathogens (probiotic and plant protection activities). None described toxins from QPS *Bacillus* species, active on human or animals. Only one publication since the previous review of the QPS list (EFSA, 2009a) concerned a human infection by a *Bacillus* species (Aoyagi et al., 2009). The *Bacillus* isolate was not identified at species level, it is therefore not possible to know if it belonged to a species of the QPS list. The infection with the *Bacillus* species was associated with a rupture of the spleen. The patient had an aortic prosthetic valve, which was, according to the authors the likely cause of the infection and the associated anticoagulant therapy is presented as a contributing factor to the spleen rupture. According to authors such symptoms are extremely rarely caused by *Bacillus*. This report is in line with the previous cases of *Bacillus* clinical infections in human discussed in the QPS Opinions (EFSA, 2007a; 2008a; 2009a) and would not lead to a revision of the QPS list, if the isolate belonged to a *Bacillus* species recommended for the QPS list.

2.3.2. Gram-positive spore forming bacteria previously assessed and not on the QPS list

Paenibacillus macerans, *Bacillus brevis* (now *Aneurinibacillus* spp or *Brevibacillus* spp), *Bacillus firmus*, *Bacillus circulans* were assessed previously (EFSA, 2008a; EFSA, 2009a) and not recommended for the QPS list because some safety concerns were identified for some representatives of these species (production of antibiotics, report of human infection, production of potential toxins) and because the body of knowledge on their use in the food and feed chain was not sufficient. They have been rarely notified to EFSA and these species will no longer be assessed for the QPS list unless in case of a new notification.

Species from the *Bacillus cereus* Group were not considered suitable for the QPS list (EFSA, 2007a) because most strains from these groups are toxigenic. Since then, there is increasing evidence of pathogenicity (EFSA, 2008a), and species from this group will not longer be assessed unless new scientific information becomes available.

2.3.3. Antimicrobial resistance among QPS *Bacillus* species

Information published since January 2009 on antimicrobial resistance among QPS gram positive spore forming bacteria was searched on the Web of Sciences (key words *Bacillus* combined with resistance, antimicrobial*, antibiotic*, or with a list of antibiotic names). Out of the 164 articles retrieved, most did not concern the occurrence of resistance to therapeutic antimicrobials among Gram positive spore forming bacteria from the QPS list, or did not give sufficiently detailed information. Nine articles were eventually selected which gave information on antibiotic resistance of *Bacillus* species on the QPS list.

Resistance to some of the antibiotics used in the criteria to assess antimicrobial resistance of bacteria introduced in the food or feed chain (EFSA, 2008a,b) was reported (Adewumi et al., 2009; Ahmad et al., 2010). Nevertheless some inconsistencies have been noted in the methodology and interpretation of the results precluding the validation of the results (Adewumi et al., 2009; Ahmad et al., 2010).

Susceptibility studies were performed in 110 isolates belonging to QPS *Bacillus* species (*Bacillus subtilis* cluster and *B. licheniformis*) recovered from commercial probiotic formulations used for food animals in Thailand (Wanaprasat et al., 2009). The MICs breakpoints defined by the Scientific Committee on Animal Nutrition (SCAN, 2003) were used for the interpretation of results. Resistance was more frequent for tetracycline and resistance to ampicillin, chloramphenicol, erythromycin, rifampicin, streptomycin, trimethoprim and vancomycin was observed in some isolates The reported detection of *tetW* and *vanA* resistance genes in a *B. subtilis* isolate from a probiotic formulation (Wanaprasat et al., 2009) should be taken with caution as controls for these genes were not included neither the corresponding amplicons sequencing.

Tetracyclin resistance gene *tet*(M) was detected in 3 isolates of *Bacillus* species from marine sediments and several isolates form other genera (Neela et al., 2009). The *tet*(M) from the *Bacillus* isolates could not be transferred to recipient strains (*E. coli* and *E. faecalis*), whereas transfer was obtained from isolates from other genera. Presence of *tet*(K) or both *tet*(K) and *tet*(M) genes was observed in two *B. megaterium* isolates from the environment (Nikolakopoulou et al., 2008). Both isolates had an MIC values higher than the breakpoint defined in EFSA (2008b) and would not have met the QPS qualification on antimicrobial resistance.

Resistance to Chloramphenicol (MIC equivalent to or >above 16 µg/ml) in *B. clausii* strains used in probiotic preparations in Europe was linked to a chloramphenicol acyltransferase gene, cat_{bcl} very likely on the chromosome (Galopin et al., 2009).

A new mechanism responsible for multridrug resistance in *B. subtilis* was discovered (Kim et al., 2009). It results from a mutation in the repressor of a multidrug transporter and is presumably not transferable.

In conclusion, resistance level above the breakpoints defined for *Bacillus* species (EFSA, 2008b) for relevant antibiotics was found among several QPS *Bacillus* species, including in probiotic formulations. This confirms the importance of the qualification regarding antimicrobial resistance in the QPS approach. No new transferable antibiotic resistance mechanism was reported in *Bacillus*.

2.4. Yeast

The yeast species recommended for the QPS list are *Debaryomyces hansenii*, *Hanseniaspora uvarum*, *Kluyveromyces lactis* and *Kluyveromyces marxianus, Saccharomyces bayanus*, *Saccharomyces cerevisiae*, *Saccharomyces pastorianus*, *Schizosaccharomyces pombe* and *Xanthophyllomyces dendrorhous*, and for enzyme production purposes, *Pichia angusta*, *Pichia jadinii*, *Komagataella pastoris* (*Pichia pastoris*) and *Wickerhamomyces anomalus* (*Pichia anomala*). During the review period, only few studies concerning safety aspects of these yeasts, including infections, disease, clinical significance, virulence and toxins were published. In addition, *Pichia anomala* has been reassigned as *Wickerhamomyces anomalus* and *Pichia pastoris* as *Komagataella pastoris (*Kurtzman et al., 2008).

Fungal infections have substantially increased in number and severity for the past 2 decades, especially in immunocompromised patients and those hospitalized with serious underlying diseases. Fungal infections are mainly caused by *Candida* species. Anamorphic species of *Candida* are the most frequent pathogenic yeasts. More than 90% of the infections due to *Candida* species are attributed to five species (*Candida albicans*, *Candida glabrata*, *Candida parapsilosis*, *Candida tropicalis*, and *Candida krusei*), although the list of reported species continues to grow. *Candida kefyr* (teleomorph *Kluyveromyces marxianus*) and *C. sphaerica* (teleomorph *Kluyveromyces lactis*) have been recently reported as a possible emerging pathogen (Gomez-Lopez et al., 2010). Nevertheless, infections caused by these yeasts are rare despite the very wide and frequent application of *Kluyveromyces lactis* in food. The recommendation of *K. marxianus* and *K. lactis* for the QPS list remains as previously. In the future the review will focus on publications dealing with the teleomorphic forms of *Candida* species.

Saccharomyces cerevisiae which is recommended for the QPS list based on a long history of safe use has also been implicated in human infections (EFSA, 2007a, EFSA, 2008a). A literature review for the preceeding year has not revealed any information that affected the recommendation for the QPS list (EFSA, 2009a). During the last year, some manuscripts have been published concerning *Saccharomyces cerevisiae* isolates from hospitals. Clemons et al. (2010) recovered, between 1997 and 2002, 97 (95 from multiple body sites of 23 patients and 2 from the hospital kitchen) *S. cerevisiae* isolates. The majority of patients were immunocompromised. Molecular typing analyses suggest a common source of colonizing organisms, possibly from the hospital food preparation area (in-house baking and for preparing a local beverage). The route of infection is not clarified and there is no indication that the infections are foodborne. Previous studies show that clinical isolates of *S. cerevisiae* display certain phenotypic characteristics, like the ability to grow at 42ºC and pseudohyphal growth in minimum medium and nitrogen starvation not always associated with food isolates (QPS, 2008a).

Cordeiro et al. (2010) reported that isolates of *Saccharomyces* species from air samples in a hospital environment in Fortaleza, Brazil were related with infections. Unal et al. (2010) analysed the fungal infections in patients undergoing peritoneal dialysis for a total of 21 fungal species, one of which was identify as *Saccharomyces*. In all the new reports *S. cerevisiae* can cause clinically relevant infections

in immunocompromised patients. Nevertheless, infections caused by *S. cerevisiae* remain rare despite the very wide and frequent application in food and in the population.

Considering the recently published available information, the recommendation of *Saccharomyces cerevisiae* and *Kluyveromyces lactis* for the QPS list was confirmed. Monitoring of new information as it becomes available should be conducted and more studies being required to understand the infection mechanisms and the differences between pathogenic and nonpathogenic strains.

2.5. Filamentous fungi

Filamentous fungi are important agents for intentional addition and use along the food chain. Therefore, even though no recommendation for the QPS list is anticipated in the near future, an updated knowledge on developments in this field and of the body of knowledge is considered essential in support of risk assessment that are carried out by EFSA. The body of knowledge on fungi in fields relevant for assessment of strains notified to EFSA is rapidly moving (e.g. methods for identification of strains, safety concerns for humans, nature and diversity of toxic compounds produced, conditions leading to toxin productions). The yearly update done in the QPS Opinions provides regular, useful and consistent information on fungal species of importance for EFSA (see section 1.1. of this opinion).

The general body of knowledge on filamentous fungi has been updated in the present Opinion, considering in particular the progress and limitation in the taxonomy, in the knowledge of metabolic pathways and in the identification of the production of toxic compounds. New issues were considered, such as the resistance of fungi to therapeutic antifungal agents and the risks linked to the use of fungi as plant protection products. Where a species or genus is not mentioned in the specific sections in the text of the body of this opinion, a remark on the outcome of the 2010 review was included in the notification table (Appendix A).

2.5.1. *Aspergillus* species

Among the quite many new papers on *Aspergillus* species there are no relevant reports on the lack of toxicity or toxin production. Most reports on *Aspergillus niger* and *Aspergillus oryzae* deal with the genetic regulation of enzyme production or the industrial production of metabolites. One paper reports production of aflatoxins by *Aspergillus candidus* (Fraga et al., 2008). This could be white mutants of other aspergilli which are often mis-identified as *Aspergillus candidus* (Varga et al., 2007). Based on this *Aspergillus candidus* cannot be proposed for the QPS list.

2.5.2. *Beauveria brongniartii*

Use of *Beauveria brongniartii* as a biological agent to suppress several pathogens and particularly the European cockchafer is well documented. In the 2009 EFSA opinion (EFSA, 2009a), *Beauveria brongniartii* has not been proposed on the QPS list based on its potential to produce oosporein. During 2009 and the five first months of 2010, about 20 reports dealing with *Beauveria brongniartii* have been detected through a Pub-Med and Web of Science survey. The major part of these reports describes the efficacy of *Beauveria brongniartii* in suppressing pathogen insects. Two of them (Schwarzenbach et al., 2009; Scheepmaker and Butt, 2010) illustrate the lack of persistence of *Beauveria brongniartii* in soil after application and its relatively small effect on indigenous soil fungal communities. One report describes the chemical synthesis of oosporein (Love et al., 2009). No new data demonstrate the lack of toxicity associated with *Beauveria brongniartii* or clarify the toxicity of oosporein. Therefore, *Beauveria brongniartii* is still ineligible for the QPS list.

2.5.3. *Blakeslea*

The search for new information on *Blakeslea* did not retrieve any new relevant data on toxicity or toxins. All papers were on production of lycopene from *Blakeslea* species.

2.5.4. *Coniothyrium minitans*

The use of *Coniothyrium minitans* as a biocontrol agent of diseases caused by sclerotium-forming pathogens has been extensively investigated. This species was not recommended for the 2009 QPS list (EFSA, 2009a) due to the lack of data confirming a general absence of toxic biological active secondary metabolites.

A bibliographic survey using Pub-Med and Web of Science as databases indicates that 25 reports have been recently devoted to *Coniothyrium minitans* and to macrosphelide A. The main data delivered by these reports illustrate the potential of *Coniothyrium minitans* to be involved in biocontrol strategy and concern the key role associated to macrosphelide A in the antimicrobial activity of *Coniothyrium minitans* (Tomprefa et al., 2009). The apoptosis activity of macrosphelide A and its potential use as an anti-tumor drug is also largely discussed. However no new data have been published that allow to guarantee the safety of *Coniothyrium minitans* use and this species remains ineligible for the QPS list.

2.5.5. *Duddingtonia flagrans*

A PubMed and Web of Science search revealed that more than 30 reports devoted to *Duddingtonia flagrans* have been published since the beginning of 2009. The major part of these publications supports the predatory activity of this nematophagous fungus and its efficacy in controlling larvae infecting horses, sheep, and dogs. Several reports describe also some useful methods to identify and quantify nematophagous fungi such as *Duddingtonia flagrans*. However, no new data certifying the lack of biological active secondary metabolites produced by this species has been found and *Duddingtonia flagrans* cannot be proposed for QPS status.

2.5.6. *Fusarium*

2.5.6.1. Taxonomy

Since the beginning of 2009, the panel of molecular methods to identify *Fusarium* strains and their ability to produce mycotoxins has been significantly expanded. Most assays that have been recently developed included PCR-based methods that exploited DNA conserved regions (LSU rDNA, IGS, beta-tubulin and TEF1-alpha gene) for the design of species-specific primers (Schroers et al., 2009; Sampietro et al., 2010) as well as generic PCR detection or quantification assay (QPCR) developed for genes involved in the biosynthetic pathway of *Fusarium* mycotoxins (Meng et al., 2010; Sampietro et al., 2010). Several studies aim at improving a "DNA Barcode" for identification of *Fusarium* species (Galvez et al., 2009); the first identification database for *Fusarium*, called *Fusarium* ID (Geiser et al., 2004) and based on translation elongation factor 1-alpha will be improved by including an additional identification marker, the ribosomal polymerase B2 (Seifert, 2009).

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

One of the key challenges that research on *Fusarium* has to answer is the elucidation of the effects of environmental factors on initiation or repression of toxins biosynthesis. Actually, the development of new strategies aiming at reducing toxin accumulation in cereals requires a profound knowledge of the mechanisms underlying the biosynthesis of *Fusarium* mycotoxins. According to a PubMed and Web of Science search, the main consistent data published since the beginning of 2009 concern the

regulation of trichothecenes biosynthesis. Specific amines such as agmatin and putrescine that naturally occur in kernels have been reported as potent inducers of trichothecenes B biosynthesis (Gardiner et al., 2009a); phenolic acids were demonstrated as potent inhibitors (Boutigny et al., 2009). The impact of environmental factors such as pH (Merhej et al., 2010) or oxidative stress has been clarified. According to a recent review (Reverberi et al., 2010), oxidative stress by promoting differentiation process and secondary metabolism in fungi was considered as a common and pivotal key involved in the regulation of trichothecenes, fumonisins but also aflatoxin and patulin. However, even if the recent publication of Gardiner et al. (2009b) reveals the occurrence of a suite of genes that are co-regulated with TRI-genes, the molecular mechanisms underlying the regulation of trichothecenes biosynthesis remain to be elucidated.

2.5.6.3. Emerging *Fusarium* toxins

The PubMed and Web of Science search mentioned above, exploiting *Fusarium* and mycotoxins as keywords, has also revealed an increased interest in the study of mycotoxins designed as emerging ones. More than 50 publications have been devoted to the enniatin, moniliformin, fusaproliferin and beauvericin toxins. They mainly report the optimisation of analytical methods, the results of food and feed monitoring surveys, the identification and characterisation of *Fusarium*-producing species.

2.5.7. *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, 2009a). No new relevant information was retrieved since.

2.5.8. *Metarhizum anisopliae*

Most reports on *Metarhizum anisopliae* deal with the production of metabolites and genetic and physiological regulation of the metabolism, as well as the toxicity towards insects. However, Toriello et al. (2009) report that one specific strain of *Metarhizum anisopliae* var. *acridum* appears to be non-toxic to mice. This is contradictory to most other reports on this species (including the variety acridum) that have shown toxic effects on animals and/or animal cells. It should be mentioned that there is a great variability among strains and how they respond to different growth conditions as discussed by Toriello et al. (2009). Despite this single report *Metarhizum anisopliae* cannot be proposed for the QPS list as there is no evidence of a general lack of toxicity.

2.5.9. *Paecilomyces lilacinus*

Paecilomyces lilacinus is an entomopathogenic fungus, which successful use as a nematode pathogen is related by numerous reports. Since the beginning of 2009, according to a PubMed and Web of Science search, more than 50 publications dealing with *Paecilomyces lilacinus* have been published. Among these, several papers indicated some cases of human infections caused by *Paecilomyces lilacinus* such as endophtalmitis, keratitis, chronic sinusitis and skin infection. For instance, a case of eumycetoma caused by *Paecilomyces lilacinus* has been reported by Mostwaledi et al. (2009).

According to these authors, this was the first report of *Paecilomyces lilacinus* causing eumycetoma of the foot in the English literature. In a recent report, *Paecilomyces lilacinus* is also described as an emerging fungal pathogen that infects corneal tissue by filamentous invasion with occasional intrastromal sporulation (Yuan et al., 2009). Concerning the biological active peptaibols produced by *Paecilomyces lilacinus*, no new information related to their nature and toxicity has been published since the beginning of 2009. In the recent classification proposed by Brase et al. (2009), peptaibols are reported as less abundant mycotoxins. In agreement with the 2009 QPS update (EFSA, 200a) and the recent published papers, *Paecilomyces lilacinus* is ineligible for the 2010 QPS list.

2.5.10. *Penicillium* species

For the *Penicillium* species, *Penicillium camemberti*, *Penicillium chrysogenum*, *Penicillium funiculosum* and *Penicillium roqueforti*, no new information on the lack of toxicity or toxins have been retrieved. The reports deal with production of the specific products or food spoilage problems. Strains of *Penicillium nalgiovense* intended for use as starter cultures in dry fermented sausages were tested for toxicity on brine shrimp larvae and the human cell line MCF7, for mutagenicity in the Ames test and for antibacterial activity against gram-positive and gram-negative bacteria by (Ludemann et al. 2009). They concluded that there is a great variability in toxicity among they strains but low toxic and a few non-toxic strains in all analyses exists. Despite this *Penicillium nalgiovense* cannot be proposed for the QPS list, as there is no evidence of a general lack of toxicity.

2.5.11. *Phlebiopsis gigantea*

Less than 10 reports concerning *Phlebiopsis gigantea* have been published since the beginning of 2009, according to a bibliographic survey based on Pub-Med and Web of Science as databases. The major part of these reports describes data that support the efficacy of *Phlebiopsis gigantea* as a biocontrol agent against *Heterobasideon* species on spruce stumps. One interesting publication reports the identification of molecular markers (microsatellite ones) that could be used to monitor the impact of a treatment using *P. gigantea* on natural *P. gigantea* populations and more largely on the environment (Liu et al., 2009). The knowledge concerning the capacity of *Phlebiopsis gigantea* to produce biological active secondary metabolites remains therefore insufficient and this species can not be proposed for the QPS list.

2.5.12. *Pseudozyma flocculosa*

Pseudozyma flocculosa is a yeast-like fungus in the family *Ustilaginaceae* and has morphological features that resemble filamentous fungi. For this reason *Pseudozyma flocculosa* will be covered in this section and not in the yeast section as previously. The recent search did not retrieve any new relevant data on the toxicity of metabolites from this organism.

2.5.13. *Pythium oligandrum*

A bibliographic survey using Pub-Med and Web of Science as databases indicates that 16 reports have been recently devoted to *Pythium oligandrum* (since the beginning of 2009). All these reports concern the use of *Pythium oligandrum* as a biocontrol agent and its ability to produce elicitin and auxin-like protein, leading to an enhancement of plant defences. It is also notified that introduction of *Pythium oligandrum* in the rizosphere of plants (such as tomato plants) do not induce any significant impact of fungal and oomycetes communities (Vallance et al., 2009). No new data has been published since the beginning of 2009 demonstrating the occurrence of biological active secondary metabolites produced by *Pythium oligandrum*. The body of knowledge remains therefore very limited, restricted to the use of *Pythium oligandrum* as a biocontrol agent and this species can not be proposed for the QPS list.

2.5.14. *Trichoderma*

The taxonomy of *Trichoderma* has been improved by a handful of papers and monographs that clarifies the species delimitation in some sections of this genus. The new taxonomic schemes do not have any impact on taxonomic designations of species notified to EFSA.

Since the beginning of 2009 (according to a Web of Science search), thousand reports dealing with *Trichoderma* have been published, illustrating the idea that *Trichoderma* is one of the best studied fungi. Half of these publications report the efficient use of *Trichoderma* species for industrial applications (production of plant cell wall-degrading enzymes, production of food additives, and

production of heterologous proteins). More than 150 papers describe the development of efficient biocontrol strains of this genus as promising biological fungicides. Production of secondary metabolites by *Trichoderma* species has received closer attention in two papers, leading to potential relevant information for QPS assessments. The study of Stoppacher et al. (2010) describes a new approach, based on HS-SPME-GC-MS, for the direct profiling of living fungal cultures of filamentous fungi. Its application to the biocontrol fungus *T. atroviride* has led to the identification of 25 volatile organic compounds; according to the authors, 13 of them have never been reported to be produced by *Trichoderma* spp before. Several sesquiterpenes were characterized, the toxicity of which remains to be clarified. New and significant insights into the impact of environmental factors on the peptaibols production by *Trichoderma* species have been reviewed by Tisch and Schmoll (2010).

In 2010, a review which aims to cover the knowledge on *Trichoderma* species, to shed light on intriguing findings and on the promising applications linked with this genus has been published by Schuster and Schmoll (2010). This review concludes on the future challenges that research on *Trichoderma* will have to answer the increased requirement for biocontrol agents according to the development of a sustainable agriculture, the development of green and white biotechnologies.

2.5.15. *Verticillium alboatrum*

Since 2009, four reports have been published concerning *Verticillium alboatrum* according to a PubMed and Web of Science search. Two of them concern the secondary biological active metabolite, alboatrin, that *Verticillium alboatrum* is able to produce. Alboatrin has been registered as a less abundant mycotoxin by Brase et al. (2009) in a recent review aiming at updating the knowledge of chemistry and biology of mycotoxins and fungal metabolites. A protocol to chemically synthesise alboatrin has also been proposed by Sarkar et al. (2009). This protocol offers the opportunity to a better characterisation of its toxicity. Considering the capacity of this species to produce biological active compounds, each strain should be investigated in detail, which makes *Verticillium alboatrum* ineligible for the QPS list.

2.5.16. Conclusions on filamentous fungi

Filamentous fungi cannot be proposed for inclusion on the QPS list. The first rationale for this is that the methods for identification of fungal cultures to genus/species level remain very difficult and often need in depth mycological expertise. There is still an ongoing debate on species concepts in the mycological society, which result in a lack of a universally accepted fungal taxonomy. This makes identification of fungal cultures intended for commercial use a difficult issue and should be verified by one or more independent specialists. For the time being there is no universally accepted method for fungal identification, but international collaborative initiatives are working on universal DNA based barcode for identification at species level.

The second rationale is insufficient knowledge concerning the factors and regulation mechanisms underlying the production of fungal metabolites. In several cases it has been demonstrated that toxic compounds can be produced under conditions of usage, but often this information is not available. We can however reasonably assume that the recent availability of fungal genomic data will allow tremendous progress in the next future. In addition, there are only few validated and certified analytical methods for the detection of a limited number of fungal metabolites.

The third and last rationale is that the body of knowledge concerning the toxicology of fungal secondary metabolites remains insufficient. In general, mycotoxins, i.e. fungal secondary metabolites that in small concentrations are toxic to vertebrates when introduced via a natural route (ingestion, inhalation and skin penetration), have a non-acute effect which makes very difficult the assessment of their toxicological potential in real cases. The knowledge on long-term effects is insufficient. Bioassays are developed to address specific needs but are not validated. Moreover the toxicological

knowledge is of little or no relevance to real life situations, e.g. lack of information on synergistic effects.

In conclusion, all notified fungal species and strains should be evaluated on a case-by-case basis.

2.6. Bacteriophages

In the previous EFSA opinion on QPS microorganisms (EFSA, 2009a) bacteriophages were extensively analyzed and it was concluded that they should be subjected to case-by-case scrutiny for the following reasons: i) Impossibility to allocate them to precise taxonomic units, ii) Need to sequence the genome to exclude those that were temperate and/or carried undesirable genes and iii) Absence of an *a priori* indication of their ability to transduce bacterial DNA.

It seems that these constraints are not going to be relieved in the near future and, given the ease with which experiments to test their innocuousness can be performed, it is agreed that bacteriophages are not appropriate to be subjected to QPS evaluation.

On the other hand, the intentional addition of phages to food and feed may be hindered in the European Union by the impossibility to define them as processing aids or as additives (EFSA, 2009b).

2.7. Viruses used for plant protection

2.7.1. Potyviridae

The Potyviridae and their potential effects on animals and humans, when applied to food or feed, were reviewed and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009a). 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. Hence it was agreed that the family Potyviridae is the highest taxonomic unit should receive a QPS recommendation. Since this last major review, no new information which would compromise the conclusion drawn in 2009 has appeared. In fact, further literature was retrieved to support the QPS statement of plant viruses at large (Fuchs and Gonsalves, 2007).

2.7.2. Baculoviridae

The 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 in 2009 (EFSA, 2009a). It was concluded that there was no scientific or other evidence that baculoviruses 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 extensively used for over five decades as biocontrol agents of insect pests without any report about a negative effect on humans or animals. Hence it was agreed that the family Baculoviridae is the highest taxonomic unit should receive a QPS recommendation.

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

Apart from the intrinsic biological features of baculoviruses and their inherent safety for humans and other vertebrates, a point of attention to note is the fact that these viruses have to be produced in animals (insects) and have to be formulated to stick to plant material and to protect the virus against UV damage. Microbial contaminants, allergenicity and toxicity of additives are among the agents, which could affect human and animal health. This concerns the formulation and does not contradict the recommendation to include the Baculoviridae on the QPS list. Regulation on the microbiological contaminants in baculovirus preparations is in place as part of the registration requirements (Rochon et al., 2009).

THE 2010 UPDATED LIST OF QPS RECOMMENDED BIOLOGICAL AGENTS

Table 1: The 2010 updated list of QPS recommended biological agents

Gram-Positive Non-Sporulating Bacteria			
Species			**Qualifications ***
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
*Corynebacterium glutamicum***			QPS recommendation only when the species is used for amino acid production.
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei* *** *Lactobacillus cellobiosus* *Lactobacillus coryniformis* *Lactobacillus crispatus* *Lactobacillus curvatus* *Lactobacillus delbrueckii*	*Lactobacillus farciminis* *Lactobacillus fermentum* *Lactobacillus gallinarum* *Lactobacillus gasseri* *Lactobacillus helveticus* *Lactobacillus hilgardii* *Lactobacillus johnsonii* *Lactobacillus kefiranofaciens* *Lactobacillus kefiri* *Lactobacillus mucosae* *Lactobacillus panis* *Lactobacillus collinoides*	*Lactobacillus paracasei* *Lactobacillus paraplantarum* *Lactobacillus pentosus* *Lactobacillus plantarum* *Lactobacillus pontis* *Lactobacillus reuteri* *Lactobacillus rhamnosus* *Lactobacillus sakei* *Lactobacillus salivarius* *Lactobacillus sanfranciscensis*	
Lactococcus lactis			
Leuconostoc citreum	*Leuconostoc lactis*	*Leuconostoc mesenteroides*	
	Oenococcus oeni		
Pediococcus acidilactici	*Pediococcus dextrinicus*	*Pediococcus pentosaceus*	
Propionibacterium freudenreichii	*Propiobacterium acidopropionici*		
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 2010 updated list of biological agents recommended for QPS

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

****Absence of resistance to antimycotics used for medical treatment of yeast infections

† *S. cerevisiae*, subtype *boulardii* is contraindicated for patients of 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*
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*

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Answer to the terms of reference (ToR):

The list of biological agents (microorganism and viruses) notified to EFSA (Annex A) remained the same as in the last Opinion (EFSA, 2009a). Since the previous Opinion, important information for each taxonomic unit was included in the notification table.

Following the annual review, there was no modification to the list of QPS recommended biological agents while changes were introduced with regards to the qualifications. A generic qualification concerning antimicrobial susceptibility was included for bacteria and yeasts. The qualification concerning *Bacillus* species was simplified and the qualification concerning production purposes for *Corynebacterium* species and the yeast species was clarified regarding amino acid and enzyme production, respectively.

Additional conclusions:

Isolation of lactobacilli and bifidobacteria in clinical cases remains a rare event, but maybe also underreported due to isolation difficulties. Especially for bifidobacteria the isolation difficulties are of importance. Within the *Lactobacillus* group, *L. rhamnosus* proved to be the most important species related to clinical cases. However, considering the circumstances and number of reports at the moment no update to the QPS recommendation for lactobacilli or bifidobacteria is necessary.

Similarly, one clinical case caused by a *Bacillus* species was reported but due to the rarity of these infections and of the existence of important predisposing factors in the host, no modification of the QPS list for Gram-positive spore forming bacteria is necessary.

Resistance to therapeutic antimicrobials, some potentially transmissible, has been reported among microbial species recommended for the QPS list. These resistant isolates would have been detected by the qualification on antimicrobial resistance.

Saccharomyces cerevisiae and *Kluyveromyces* species have been isolated from infections but there are no indications that food isolates contributed to these. More information on the characteristics of the isolates involved in clinical aspects would be needed. In addition, these infections remained very rare compared to *Candida albicans* and no change in the QPS list is necessary.

Some microbial species not included on the QPS list have been notified only once to EFSA, and will no longer be assessed in the future maintenance of the list, until new notification. This is indicated in the updated list of microbial species notified to EFSA.

Some microbial species not included on the QPS list will no longer be assessed in the future maintenance of the list because increasing evidence of pathogenicity precludes any future inclusion in the QPS list. This is indicated in the updated list of microbial species notified to EFSA.

Filamentous fungi and enterococci are not on the QPS list. However their regular assessment permits a yearly update of the body of knowledge on the numerous fungal and enterococcal strains notified to EFSA.

The QPS list has permitted a simplification and a harmonisation of the assessment for micro-organisms notified to the Panels and Unit of EFSA. However, many microbial species notified to EFSA are not on the QPS list and their safety may not be assessed as consistently as for QPS species.

RECOMMENDATIONS

A harmonised safety assessment applicable for microorganisms and viruses also including those not recommended for the QPS list might be advisable for EFSA evaluation purposes.

Studies are needed to better define the breakpoints characterising resistance in non-enterococcal lactic acid bacteria strains. Therefore, antimicrobial susceptibility surveys, using standardised methods, of a representative sample of strains are recommended.

The maintenance of the QPS list is recommended. For non-QPS microbial species notified to EFSA, the body of knowledge should be updated whenever information is brought in supporting the work of EFSA panels and units (e.g. some species of filamentous fungi and enterococci).

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APPENDIX

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

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [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	*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 (under consideration) EFSA-Q-2009-00470 (under consideration, GMM)	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 brevis* = *Aneurini bacillus 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 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	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
(70/524/EEC) 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	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.
1831/2003	*Bacillus coagulans*	Feed additive		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 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).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*Bacillus lentus*	Feed additive		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).
SCF Opinion 22 June 2000	*Bacillus licheniformis*	Production of b-cyclodextrin (food additive carrier and stabiliser of food flavours, food colours and some vitamins)		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).
Reg(EC)1831/ 2003	*Bacillus licheniformis*	Feed additive	EFSA-Q-2009-00970 (Under consideration) EFSA-Q-2009-00680 (Under consideration)	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).
Reg(EC)1831/ 2003	*Bacillus pumilus*	Feed additive		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	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*Bacillus subtilis*	Feed additive	EFSA-Q-2008-473 EFSA Journal 2009; 7(9):1314 www.efsa.europa.eu/en/scdocs/scdoc/1314.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-2007-040 The EFSA Journal (2007) 543, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/543.htm EFSA-Q-2009-00533 EFSA Journal 2010; 8(1):1426 www.efsa.europa.eu/en/scdocs/scdoc/1426.htm EFSA-Q-2009-00680 (Under consideration) EFSA-Q-2009-00803 (In progress) EFSA-Q-2009-00525 (In progress) EFSA-Q-2009-00470 (under consideration, GMM) EFSA-Q-2010-00814 EFSA Journal 2010;8(10):1867 www.efsa.europa.eu/en/scdocs/scdoc/1867.htm	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	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
PRAPeR	*Bacillus subtilis* Strain QST 713	Plant protection product	EFSA-Q-2008-492 (In progress)	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).
PRAPeR	*Bacillus* subsp. *thuringiensis aizawai* (strains ABTS 1857 and GC-91) = *Bacillus thuringiensis* serovar aizawai	Plant protection product	EFSA-Q-2009-00121 (In progress) EFSA-Q-2009-00247 (In progress) [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.
PRAPeR	*Bacillus* subsp. *thuringiensis israelensis* (serotype H-14), strain AM 6552 = *Bacillus thuringiensis* serovar israelensis	Plant protection product	EFSA-Q-2009-00122 (in progress) EFSA-Q-2009-00248 (In progress) [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.
PRAPeR	*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 (in progress) EFSA-Q-2009-00249 (In progress) [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.
PRAPeR	*Bacillus* subsp. *thuringiensis tenebrionis* (strain NB176 (TM 141)) = *Bacillus thuringiensis* serovar tenebrionis	Plant protection product	EFSA-Q-2009-00124 (in progress) EFSA-Q-2009-00250 (In progress)	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.

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Bifidobacterium animalis subsp. animalis*	Feed additive	EFSA-Q-2006-00169 (In progress) EFSA-Q-2009-00823 (In progress) EFSA-Q-2009-00817 (In progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Bifidobacterium animalis subsp. Lactis*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*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 (Additional data requested)	The recipient species is QPS for production purposes only, but not for this application, therefore not appropriate for QPS (EFSA, 2008 opinion)
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	No history of use, 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)
Reg(EC)1831/ 2003	*Enterococcus faecium*	Feed additive	EFSA-Q-2008-289 The EFSA Journal (2009) 990, 1-12 www.efsa.europa.eu/en/scdocs/scdoc/990.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-2007-033 The EFSA Journal (2007) 521, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/521.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	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			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 EFSA-Q-2004-001 The EFSA Journal (2004) 51, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/51.htm EFSA-Q-2004-027 The EFSA Journal (2004) 120, 1-4 www.efsa.europa.eu/en/scdocs/scdoc/120.htm EFSA-Q-2003-087 The EFSA Journal (2005) 207, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/207.htm EFSA-Q-2004-096 The EFSA Journal (2005) 206, 1-6 www.efsa.europa.eu/en/scdocs/scdoc/206.htm EFSA-Q- 2009-00679 (Under consideration) EFSA-Q-2009-00969 (Under consideration) EFSA-Q-2009-00823 (In progress) EFSA-Q-2009-00202 (In progress)	
Reg(EC)1831/ 2003	*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)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
GMO	*Escherichia coli*	Dried killed biomasses for feed	EFSA-Q-2008-412a and EFSA-Q-2008-669a (Additional data requested)	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 (Additional data requested)	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-cystein production		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 (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)
Reg(EC)1831/ 2003	*Lactobacillus acidophilus*	Feed additive	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-2003-115 The EFSA Journal (2004) 119, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/119.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus amylolyticus*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*Lactobacillus amylovorans*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus brevis*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacilllus buchneri*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*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	Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus casei* (note: this species is very rare and its identity might need to be verified)	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus casei rhamnosus* = *Lactobacillus rhamnosus*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus cellobiosus*	Feed additive		Not initially considered for QPS (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010
Reg(EC)1831/ 2003	*Lactobacillus collinoides*	Feed additive		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)
Reg(EC)1831/ 2003	*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)
Reg(EC)1831/ 2003	*Lactobacillus fermentum*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus helveticus*	Feed additive	EFSA-Q-2006-135 The EFSA Journal (2008) 912, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/912.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*Lactobacillus mucosae*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus paracasei*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus pentosus*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus plantarum*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus reuteri*	Feed additive	EFSA-Q-2003-010 The EFSA Journal (2005) 229, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/229.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus rhamnosus*	Feed additive	EFSA-Q-2006-062 The EFSA Journal (2008) 771, 1-13 www.efsa.europa.eu/en/scdocs/scdoc/771.htm	Already QPS (EFSA, 2007, 2008, 2009, 2010) *Lactobacillus rhamnosus* is recommended for the QPS list, and remains a topic for surveillance.
Reg(EC)1831/ 2003	*Lactobacillus sakei*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactobacillus salivarius*	Feed additive	EFSA-Q-2009-00823 (In progress)	Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*Lactococcus lactis*	Feed additive		Already QPS (EFSA, 2007, 2008, 2009, 2010)
2001/122/EC	*Leuconostoc mesenteroides*	Production of dextran as NF ingredient for bakery industrial and food fermentations		Already QPS (EFSA, 2007, 2008, 2009, 2010)
Reg(EC)1831/ 2003	*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)
Reg(EC)1831/ 2003	*Leuconostoc pseudomesenteroides*	Feed additive		Not recommended for QPS (see EFSA opinions 2007, Appendix A; 2009; 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
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	No body of knowledge, therefore not considered for QPS (EFSA, 2008)
Reg(EC)1831/2003	*Pediococcus acidilactici*	Feed additive	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-2007-205 www.efsa.europa.eu/en/scdocs/scdoc/1037.htm EFSA-Q-2008-421 www.efsa.europa.eu/en/scdocs/scdoc/1038.htm	Already QPS
Reg(EC)1831/2003	*Pediococcus pentosaceus*	Feed additive	EFSA-Q-2009-00717 EFSA Journal 2010; 8(2):1502 www.efsa.europa.eu/en/scdocs/scdoc/1502.htm	Already QPS
Reg(EC)1831/2003	*Propionibacterium acidipropionici*	Feed additive		Not proposed for QPS status (see EFSA opinion 2007, Appendix A). In 2009, 2010 recommended for the QPS list (EFSA, 2009; 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*Propionibacterium freudenreichii shermanii*	Feed additive		Already QPS
Reg(EC)1831/ 2003	*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)
PRAPeR	*Pseudomonas sp.* DSMZ 13134	Plant Protection Product	Draft Assessment Report: no further info on the species. It is considered as a new species within the RNA-group I-pseudomonads. No EFSA question number yet.	Not assessed because species to be clarified (EFSA, 2009)
PRAPeR	*Pseudomonas chlororaphis*	Plant Protection Product	EFSA-Q-2008-618 [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.
Reg(EC)1831/ 2003	*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.
Reg(EC)1831/ 2003	*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.
Reg(EC)1831/ 2003	*Streptococcus cremoris = L. lactis subsp. cremoris*	Feed additive		Already QPS

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
Reg(EC)1831/ 2003	*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.
Reg(EC)1831	*Streptococcus thermophilus*	Feed additive	EFSA-Q-2006-135 www.efsa.europa.eu/en/scdocs/scdoc/912.htm	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)
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)
PRAPeR	*S. griseoviridis* = *Streptomyces* strain K 61	Plant protection product	EFSA-Q-2009-00134 (In progress) EFSA-Q-2009-00295 (in progress) [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)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
	Yeasts			
PRAPeR	*Aureobasidium pullulans* strains DSM 14940 and DSM 14941	Plant Protection Product	New active substance Draft Assessment Report received. No EFSA question number yet.	Body of knowledge insufficient (QPS 2009 update)
Reg(EC)1831/2003	*Candida glabrata*	Feed additive		Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
FEEDAP	*Candida guilliermondi*	Fermentation product	EFSA-Q-2003-082	Unsuitable for QPS (see EFSA opinion 2007, Appendix C)
PRAPeR	*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)
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 dendrorphous*	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	No body of knowledge, therefore not appropriate for QPS (EFSA opinion 2008)
FEEDAP	*Saccharomyces cerevisiae*	Feed additive	EFSA-Q-2008-302 The EFSA Journal (2009) 970, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/970.htm	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			EFSA-Q-2008-472 The EFSA Journal (2009) 1040, 1-7 www.efsa.europa.eu/en/scdocs/scdoc/1040.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-2007-165 EFSA Journal 2009; 7(10):1353 www.efsa.europa.eu/en/scdocs/scdoc/1353.htm EFSA-Q-2005-234 The EFSA Journal (2006) 385, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/385.htm EFSA-Q-2005-025 The EFSA Journal (2006) 384, 1-9 www.efsa.europa.eu/en/scdocs/scdoc/384.htm EFSA-Q-2007-139 The EFSA Journal (2008) 772, 1-11 www.efsa.europa.eu/en/scdocs/scdoc/772.htm EFSA-Q-2005-149 The EFSA Journal (2006) 321, 1-8 www.efsa.europa.eu/en/scdocs/scdoc/321.htm EFSA-Q-2009-00824 EFSA Journal 2010;8(7):1662	

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
			www.efsa.europa.eu/en/scdocs/scdoc/1662.htm EFSA-Q-2009-00818 (In progress) 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-2009-00534 (under consideration, GMM)	
GMO	*Saccharomyces cerevisiae*	Dried killed biomass for feed	EFSA-Q-2007-156 (Waiting for full dossier)	
FEEDAP	*Schizosaccharomyces pombe*	Production of enzymes	EFSA-Q-2008-272 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-2005-063 The EFSA Journal (2006) 350, 1-14 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769568.htm	Already QPS (EFSA Opinions 2007, 2008, 2009, 2010).

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
	Fungi			
Reg(EC)1831/ 2003	*Aspergillus niger*	Feed additive	EFSA-Q-2009-00585 (under consideration) EFSA-Q-2009-00603 (GMM, adopted opinion, www.efsa.europa.eu/en/scdocs/scdoc/1427.htm) EFSA-Q-2009-00534 (under consideration)	Potential for mycotoxin production, therefore not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
Reg(EC)1831/ 2003	*Aspergillus oryzae*	Feed additive	EFSA-Q-2009-00525 (in progress) EFSA-Q-2009-00536 (in progress, GMM) EFSA-Q-2009-00535 (in progress, GMM)	Not suitable for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
PRAPeR	*Beauveria bassiana*	Plant protection product	EFSA-Q-2009-00125 (in progress) EFSA-Q-2009-00251 (in progress) [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)
PRAPeR	*Beauveria brongniartii*	Plant protection product	EFSA-Q-2009-00017 (in progress)	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)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
FEEDAP	*Blakeslea trispora*	Production strain for beta-carotene	EFSA-Q-2009-00884 (in progress)	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
PRAPeR	*Coniothyrium minitans*	Plant protection product	EFSA-Q-2008-515 (in progress) [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 under consideration	Insufficient body of knowledge (EFSA, 2009; EFSA, 2010)
PRAPeR	*Gliocladium catenulatum* = *Clonostachys rosea* forma *catenulata*	Plant protection product	EFSA-Q-2008-559 (in progress) [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.
PRAPeR	*Lecanicillium muscarium* *formerly* *Verticillium lecanii*	Plant protection product	EFSA-Q-2009-00130 (in progress) EFSA-Q-2009-00255 (finalized on 18/12/2009) Conclusion on the peer review (2009): 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)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
PRAPeR	*Metarhizium anisopliae* var. Anisopliae formerly *M. anisopliae*	Plant protection product	EFSA-Q-2009-00131 (in progress) EFSA-Q-2009-00253 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Paecilomyces fumosoroseus*	Plant protection product	EFSA-Q-2008-599 (in progress) EFSA-Q-2009-00323 (in progress) [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)
PRAPeR	*Paecilomyces lilacinus*	Plant protection product	EFSA-Q-2008-600 (finalized on 13/06/2007) Conclusion on the peer review (2007): 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)
PRAPeR	*Phlebiopsis gigantea*	Plant protection product	EFSA-Q-2009-00132 (in progress) EFSA-Q-2009-00285 (in progress)	Mycelial fungi: already considered as not appropriate for QPS. Insufficient body of knowledge (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Pseudozyma flocculosa*	Plant protection product	EFSA-Q-2009-00315 (in progress) [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)
PRAPeR	*Pythium oligandrum*	Plant protection product	EFSA-Q-2009-00133 (in progress) EFSA-Q-2009-00287 (in progress) [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)
PRAPeR	*Trichoderma harzianum* = *Trichoderma atroviride* I-1237	Plant protection product	No Draft Assessment Report received – no EFSA Question yet	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [additional information]	Comments
PRAPeR	*Trichoderma harzianum* =*Trichoderma asperellum*	Plant protection product	EFSA-Q-2009-00136 (in progress) EFSA-Q-2009-00300 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Trichoderma harzianum* = *Trichoderma atroviride IMI 206040*	Plant protection product	EFSA-Q-2009-00137 (in progress) EFSA-Q-2009-00297 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Trichoderma harzianum Rifai*	Plant protection product	EFSA-Q-2009-00139 (in progress) EFSA-Q-2009-00298 (in progress) [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)
Reg(EC)1831/2003	*Trichoderma longibrachiatum*	Feed additive		Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
PRAPeR	*Trichoderma polysporum*	Plant protection product	EFSA-Q-2009-00140 (in progress) EFSA-Q-2009-00299 (in progress) [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)
Reg(EC)1831/2003	*Trichoderma reesei*	Feed additive	EFSA-Q-2009-00802 (under consideration, GMM) EFSA-Q-2009-00470 (under consideration, GMM)	Ineligible for QPS status (see EFSA opinion 2007, Appendix D; EFSA, 2009; EFSA, 2010)
PRAPeR	*Trichoderma viride* =*Trichoderma gamsii*	Plant protection product	EFSA-Q-2009-00138 (in progress) EFSA-Q-2009-00300 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Trichoderma viride* = *Trichoderma asperellum*	Plant protection product	EFSA-Q-2009-00136 (in progress) EFSA-Q-2009-00300 (in progress)	Mycelial fungi: already considered as not appropriate for QPS (see EFSA, 2007; EFSA, 2009; EFSA, 2010)
PRAPeR	*Verticillium albo-atrum* formerly *Verticillium dahliae*	Plant protection product	EFSA-Q-2009-00141 (in progress) EFSA-Q-2009-00303 (in progress)	Mycelial fungi: already considered as not appropriate for QPS. Potential production of alboatrin (see EFSA, 2007; EFSA, 2009; EFSA, 2010)

EFSA Panel/Unit	Genus and species of microorganism as notified (current taxonomy where different)	Intended use	EFSA question number and published opinion [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			
1831/2003	*Clostridium sporogenes* phage	Feed additive		QPS 2009 update
1831/2003	*Clostridium tyrobutyricum* phage	Feed additive		QPS 2009 update
	Viruses			
PRAPeR	*Adoxophyes orana Granulovirus* strain BV-0001	Plant protection product	EFSA-Q-2009-00324 (in progress)	QPS 2009 update
PRAPeR	*Cydia pomonella granulovirus* Mexican isolate	Plant protection product	EFSA-Q-2009-00126 (in progress) EFSA-Q-2009-00254 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_107300.htm]	QPS 2009 update
PRAPeR	*Helicoverpa armigera nucleopolyhedrovirus*	Plant protection product	EFSA-Q-2009-00341 (in progress)	QPS 2009 update
PRAPeR	Spodoptera littoralis nucleopolyhedrovirus	Plant protection product	EFSA-Q-2008-630 (in progress)	
PRAPeR	Zucchini yellow mosaic virus, weak strain	Plant protection product	EFSA-Q-2009-00346 (in progress) [www.epa.gov/opp00001/biopesticides/ingredients/factsheets/factsheet_244201.htm]	QPS 2009 update

Glossary

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 2007 Opinion: Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA - Opinion of the Scientific Committee). The EFSA Journal, 2007, 587, 1–16 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178667590178.htm

EFSA 2008 Opinion: The maintenance of the list of QPS microorganisms intentionally added to food or feed - Scientific Opinion of the Panel on Biological Hazards (Question number: EFSA-Q-2008-006).The EFSA Journal, 2008, 923, 1 – 48 www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902221481.htm

EFSA 2009 Opinion: Scientific Opinion on the maintenance of the list of QPS microorganisms intentionally added to food or feed (2009 update) (Question number: EFSA-Q-2009-00459) EFSA Journal 2009, 7, 12, 1431 www.efsa.europa.eu/en/scdocs/scdoc/1431.htm