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SCIENTIFIC OPINION

Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update)1

EFSA Panel on Biological Hazards (BIOHAZ)2, 3

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA is requested to assess the safety of a broad range of biological agents in the context of notifications for market authorisation as sources of food and feed additives, enzymes and plant protection products. The qualified presumption of safety (QPS) assessment was developed to provide a harmonised generic pre-assessment to support safety risk assessments performed by EFSA’s scientific Panels. The safety of unambiguously defined biological agents (at the highest taxonomic unit appropriate for the purpose for which an application is intended), and the completeness of the body of knowledge are assessed. Identified safety concerns for a taxonomic unit are, where possible and reasonable in number, reflected as ‘qualifications’ in connection with a recommendation for a QPS status. The list of QPS recommended biological agents is reviewed and updated periodically. Therefore, the only valid list is the one in the most recently published scientific opinion. The 2013 update reviews previously assessed microorganisms including bacteria, yeasts, filamentous fungi, oomycetes and viruses used for plant protection purposes. All taxonomic units previously recommended for the QPS list had their status reconfirmed. The new notifications since the last QPS update were reviewed. Gluconobacter oxydans and Alphaflexiviridae were assessed for the first time and were recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list. Qualifications for the taxonomic units included in the QPS recommended list were reviewed and confirmed. Filamentous fungi and enterococci were not recommended for the QPS list following updating and reviewing of current scientific knowledge.

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KEY WORDS

safety, QPS, bacteria, yeast, fungi, virus

1 On request from EFSA, Question No EFSA-Q-2013-00019, adopted on 24 October 2013.
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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food or feed (2013 update). The question included four specific tasks in the terms of reference (ToR).

The first required a preparation of an update of the list of biological agents for intentional use in feed and/or food, or as sources of food and feed additives or enzymes and as plant protection products for safety assessment as notified to EFSA Units and/or Scientific Panels such as Pesticides, the Panels on Additives and Products or Substances used in Animal Feed (FEEDAP) and Genetically Modified Organisms (GMO). The list was updated with the notifications received where applicable by EFSA Panels and Units since the last review.

The second ToR was concerned with an annual review of the list of biological agents recommended for the QPS list. Where appropriate new taxonomic units should be assessed for their suitability for an inclusion in the QPS list, and taxonomic units previously assessed should be reviewed where new information has become available. The information provided in the previous opinion should be updated where appropriate. The BIOHAZ Panel confirmed all taxonomic units previously recommended for the QPS list following review. The notifications were assessed. *Gluconobacter oxydans* and *Alphaflexiviridae* were assessed for the first time and recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list.

The third ToR required a review of the qualifications for taxonomic units included in the QPS recommended list and in particular the qualification regarding antimicrobial resistance in taxonomic units recommended for the QPS list. The information of the previous opinion was updated and the qualifications were confirmed.

The fourth ToR concerned a review and update of the body of knowledge for notified filamentous fungi and enterococci. The knowledge of filamentous fungi notified to EFSA was updated. Although numerous data, published since the 2012 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2013 to allow a filamentous fungus to be recommended for the QPS list.

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

Summary ........................................................................................................................................... 2
Background as provided by EFSA ....................................................................................................... 6
Terms of reference as provided by EFSA ............................................................................................. 7
Assessment ........................................................................................................................................ 8
1. Introduction .................................................................................................................................... 8
   1.1. QPS an assessment approach for use within EFSA ............................................................... 8
   1.2. Experience of using the QPS assessment by EFSA’s Scientific Units and Panels ................. 9
   1.3. Reference to QPS in the scientific literature .......................................................................... 10
2. Methodology ..................................................................................................................................... 11
   2.1. Taxonomy .................................................................................................................................. 11
      2.1.1. Bacterial taxonomy ............................................................................................................. 11
      2.1.2. Filamentous fungi and yeast taxonomy .............................................................................. 12
      2.1.3. Virus taxonomy .................................................................................................................. 12
      2.1.3.1. Plant virus taxonomy ....................................................................................................... 12
      2.1.3.2. Baculovirus taxonomy ..................................................................................................... 12
   2.2. Body of knowledge .................................................................................................................... 13
      2.2.1. Review of the scientific literature ....................................................................................... 13
      2.2.1.1. External extensive literature search (EFSA-Q-2012-00969) ............................................. 13
   2.3. Review of safety concerns identified as ‘qualification’ on the QPS list ..................................... 14
      2.3.1. Other qualifications .............................................................................................................. 14
3. Gram-positive non-sporeulating bacteria ....................................................................................... 15
   3.1. Antimicrobial resistance aspects of QPS lactic acid bacteria in general ................................. 15
      3.2. *Bifidobacterium* species ...................................................................................................... 15
      3.2.1. Antimicrobial resistance aspects regarding the qualification ........................................... 15
      3.3. *Corynebacterium glutamicum* ............................................................................................. 15
      3.3.1. Antimicrobial resistance aspects regarding the qualification ........................................... 16
      3.4. *Enterococcus faecium* ........................................................................................................ 16
      3.4.1. Antibiotic resistance aspects regarding the qualification ................................................. 17
      3.5. *Lactobacillus* species .......................................................................................................... 17
      3.5.1. Antimicrobial resistance aspects regarding the qualification ........................................... 18
      3.6. *Lactococcus* species ............................................................................................................ 18
      3.6.1. Antimicrobial resistance aspects regarding the qualification ........................................... 18
      3.7. *Leuconostoc* species ........................................................................................................... 18
      3.7.1. Antimicrobial resistance aspects regarding the qualification ........................................... 19
      3.8. *Pediococcus* species ............................................................................................................ 19
      3.8.1. Antimicrobial resistance aspects regarding the qualification ........................................... 19
      3.9. *Oenococcus oeni* ................................................................................................................. 19
      3.9.1. Antimicrobial resistance aspects regarding the qualification ........................................... 19
   3.10. Dairy propionic acid bacteria.................................................................................................... 19
      3.10.1. Antimicrobial resistance aspects regarding the qualification .......................................... 19
      3.11. *Streptococcus thermophilus* ............................................................................................... 19
      3.11.1. Antimicrobial resistance aspects regarding the qualification .......................................... 20
4. Gram-positive spore forming bacteria ........................................................................................... 20
   4.1. *Bacillus* species ..................................................................................................................... 20
      4.1.1. Update of the body of knowledge on safety concerns for QPS *Bacillus* species ............... 20
      4.1.1.1. Other relevant information published on QPS *Bacillus* species ..................................... 20
      4.1.2. Antimicrobial resistance aspects regarding the qualification ........................................... 21
   5. Gram-negative bacteria ............................................................................................................... 21
   5.1. *Gluconobacter oxydans* ......................................................................................................... 21
      5.1.1. Taxonomy ............................................................................................................................ 22
      5.1.2. Body of knowledge ............................................................................................................. 22
      5.1.3. Safety assessment .............................................................................................................. 22
5.1.4. Antimicrobial resistance aspects regarding the qualification ........................................ 23
5.1.5. Other relevant information ......................................................................................... 23
5.1.6. Conclusion regarding a QPS recommendation ......................................................... 23
6. Yeast ................................................................................................................................. 23
   6.1. Update of the body of knowledge on safety concerns for yeast species on the QPS list .... 23
      6.1.1. Debaryomyces hansenii ......................................................................................... 24
      6.1.2. Saccharomyces cerevisiae .................................................................................... 24
      6.1.3. Trichosporon mycotoxinivorans ........................................................................ 24
      6.1.4. Wickerhamomyces anomalus (Pichia anomala) ....................................................... 25
      6.1.5. Xanthophyllomyces dendrorhous .......................................................................... 25
      6.2. Conclusions on yeasts ............................................................................................. 25
7. Filamentous fungi ............................................................................................................. 27
   7.1. Ampelomyces quisqualis ............................................................................................ 25
   7.2. Ashbya gossypii ......................................................................................................... 26
   7.3. Aspergillus species ..................................................................................................... 26
   7.4. Beauveria bassiana and Beauveria brongniartii ......................................................... 26
   7.5. Blakeslea trispora ........................................................................................................ 26
   7.6. Coniothyrium minitans .............................................................................................. 27
   7.7. Duddingtonia flagrans .............................................................................................. 27
   7.8. Fusarium species ....................................................................................................... 27
      7.8.1. Taxonomy ............................................................................................................. 27
      7.8.2. Biosynthetic pathways of Fusarium mycotoxins and their regulation .................. 27
      7.8.3. Emerging Fusarium toxins .................................................................................. 28
   7.9. Gliocladium catenulatum ........................................................................................... 28
   7.10. Isaria fumosorosea (syn. Paecilomyces fumosoroseus) .............................................. 28
   7.11. Lecanicillium muscarium .......................................................................................... 28
   7.12. Metarhizium anisopliae ............................................................................................. 28
   7.13. Paecilomyces lilacinus .............................................................................................. 28
   7.14. Penicillium species .................................................................................................... 29
   7.15. Phlebiopsis gigantea ................................................................................................... 29
   7.16. Pseudozyma flocculosa ............................................................................................. 29
   7.17. Trichoderma species .................................................................................................. 29
      7.17.1. Taxonomy .......................................................................................................... 29
      7.17.2. Trichoderma asperellum ..................................................................................... 29
      7.17.3. Trichoderma atroviride ....................................................................................... 30
      7.17.4. Trichoderma citrinoviride .................................................................................. 30
      7.17.5. Trichoderma koningii ......................................................................................... 30
      7.17.6. Trichoderma longibrachiatum ............................................................................. 30
      7.17.7. Trichoderma reesei ............................................................................................. 30
      7.17.8. Trichoderma viride ............................................................................................. 31
   7.18. Verticillium albo-atrum ............................................................................................. 31
   7.19. Conclusions on filamentous fungi ............................................................................ 31
8. Oomycetes ....................................................................................................................... 32
   8.1. Pythium oligandrum .................................................................................................... 32
9. Viruses used for plant protection ..................................................................................... 32
   9.1. Plant viruses ............................................................................................................... 32
      9.1.1. Alphaflexiviridae ................................................................................................. 32
      9.1.2. Potyviridae .......................................................................................................... 33
   9.2. Insect viruses .............................................................................................................. 33
      9.2.1. Baculoviridae ..................................................................................................... 33
10. The 2013 updated list of QPS Status recommended biological agents in support of EFSA risk assessments ......................................................................................................................... 35
Conclusions and recommendations ..................................................................................... 37
**BACKGROUND AS PROVIDED BY EFSA**

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

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

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

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

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

In the last QPS update in 2012\(^11\) the previously assessed microorganisms including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes were reviewed and the QPS

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

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


\(^9\) Guidance prepared by the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on the assessment of bacterial susceptibility to antimicrobials of human or veterinary importance. EFSA Journal 2012;10(6):2740, 10 pp. doi:10.2903/j.efsa.2012.2740


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

**TERMS OF REFERENCE AS PROVIDED BY EFSA**

EFSA requests the BIOHAZ Panel to provide the:

1. Preparation of an update of the list of biological agents notified to EFSA Units and/or Scientific Panels such as Pesticides, FEEDAP and GMO for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products for safety assessment.

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

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

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

1. Introduction

A wide variety of microorganisms (including viruses) are intentionally added at different stages into the food chain, either directly or as a source of 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 received by EFSA for market authorisation as sources of food and feed additives, food enzymes and plant protection products received by EFSA.

Qualified Presumption of Safety (QPS) has recently entered EU law with the publication of a new Commission Implementing Regulation (EU) No 562/2012 (Commission Implementing Regulation, 2012)\(^{12}\) amending Commission Regulation (EU) No 234/2011 (Commission Regulation, 2011)\(^{13}\) with regard to specific data required for risk assessment of food enzymes. If the microorganism used in the production of a food enzyme has a status of QPS according to the most recent list of QPS recommended biological agents adopted by the Authority (meaning EFSA), the enzyme application should not be required to include toxicological data. If residues, impurities, degradation products linked to the total enzyme production process (production, recovery and purification) could give rise for concern, the Authority, pursuant to Article 6(1) of Regulation (EC) No 1331/2008 (Regulation, 2008)\(^{14}\), may request additional data for risk assessment, including toxicological data.

The purpose of the present Opinion is to review the list of previously QPS recommended biological agents which was last established in 2012 (EFSA, 2012a). The QPS approach was developed by the Scientific Committee to provide a generic concept to prioritise and to harmonise risk assessment of microorganisms intentionally introduced into the food chain within EFSA in support of the respective Scientific Panels and Units in the frame of authorisations (EFSA, 2007). The list, first established in 2007 is to be reviewed annually (EFSA, 2007). Taxonomic units were included in the QPS list either following notifications to EFSA or following proposals made during a public consultation in 2005 by stakeholders, even if they were not yet notified to EFSA (EFSA, 2005).

1.1. QPS an assessment approach for use within EFSA

QPS as a concept provides a generic safety pre-assessment approach for use within EFSA that could be applied to all requests received by EFSA for the safety assessments of microorganisms or viruses deliberately introduced into the food chain. The assessment covers risk for human, animals and the environment. In the case of viruses used for plant protection purposes the QPS assessment does not cover the environmental impact. Its introduction would harmonise and make the risk assessment approach more transparent across the EFSA Scientific Panels and Units. It would aid the consistency of assessments and make better use of resources by focussing on those organisms, which present the greatest risks or uncertainties (EFSA, 2005, 2009a).

In the QPS concept a safety assessment of a defined taxonomic unit is considered independently of any particular specific notification in the course of an authorisation process. If the taxonomic unit


does not raise any safety concerns, or if existing safety concerns can be clearly defined as specific qualifications to ensure their absence (exclusion) in the context of a specific notification, a particular taxonomic unit could be recommended for the QPS list. Subsequently, any specific representative of a QPS proposed taxonomic unit, would not need to undergo a further safety assessment other than to satisfy any of the qualifications specified if applicable. Representatives of taxonomic units that fail to satisfy a qualification would be considered unfit for the QPS list and would remain subject to a full safety assessment, in the frame of a notification by the responsible EFSA Scientific Panel (EFSA, 2007).

The QPS concept does not address hazards linked to the formulation or processing of the products based on biological agents added into the food or feed chain. Neither safety of users handling the product nor genetic modifications are taken into account. 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 exclusion 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 included. Biological agents in this context include microorganisms and viruses used in the context of plant protection. Consequently, the QPS 2013 update will review these biological agents. Biological agents intended for uses outside the remit of EFSA, and biological agents which have not been notified to EFSA, are not considered in this Opinion.

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

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

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

1.2. Experience of using the QPS assessment by EFSA’s Scientific Units and Panels

The QPS approach has proved to be a useful tool to harmonise and prioritise safety assessment within EFSA and is appreciated by both assessors and applicants. The QPS recommended list was mainly used by EFSA’s Panel on Additives and Products of Substances used in Animal Feed (FEEDAP). If a biological agent is recommended for the QPS list it should cover the safety for the target animal species, the consumers of products derived from animals treated with the additives, and the environment. Neither safety of users handling the product nor genetic modifications are taken into account. In the respective FEEDAP Opinions dealing with QPS recommended microorganisms, a standard sentence is included that the active agent in question is considered by EFSA to be suitable for the QPS approach to safety assessment. Therefore, in such case the FEEDAP Panel considers that no assessment of safety for the target species, consumer and the environment is required.

Following requests from applicants, the European Commission requested EFSA to provide an opinion on the implications of the deletion of the maximum dose applied to those authorised microbial products for which safety was assessed using the QPS approach and, more generally to all
microorganisms for which this approach is used. Since the QPS assessment is not related to a specific purpose but has to take account of any reasonable use of the organism under consideration, and since all QPS assessments have been made independently of the dose, the FEEDAP Panel concluded that unless a specific provision relating to dose is included in the ‘qualification’ for a given taxonomic unit, safety is presumed at any reasonable dose (EFSA, 2012c).

Until late September 2013, the QPS approach has been applied by the FEEDAP Panel, in the assessment of 14 assessments out of a total of 24 published opinions on the safety assessment of microorganisms used as feed additives (EFSA, 2012e-h, 2013a-j).

For the Pesticide Unit, the annual QPS updates provide relevant new information from the literature for biological active agents currently under peer-review, which, if showing more critical or adverse effects, can be taken into account during the process of the peer-review or in the EFSA conclusion. When a microorganism is approved under Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009)\textsuperscript{15}, a cycle of 10 to 15 years is foreseen for the revision of the dossier including new information according to the regulatory framework. This shows the usefulness of the QPS approach as a mean of regularly updating the body of knowledge on taxonomic units of importance for EFSA Panels and Units, even if they are not recommended for the QPS list. Hence, the annual update of the body of knowledge for several taxonomic units is appreciated by the Pesticide Unit.

Biological agents recommended for the QPS list and proposed as plant protection products under the Council Directive 91/414/EC (Official Journal, 1991)\textsuperscript{16} could be exempted from certain data requirements such as oral toxicity data. As an example, the QPS recommendation of the Baculoviridae family was used during the peer review of several species of baculoviruses (EFSA, 2012 i, j). In the scope of the pesticide assessment, the QPS recommendation does not address risks for the user and risks for the environment, which have to be assessed specifically for plant protection products according to the Regulation (EC) No 1107/2009 (Official Journal of the European Union, 2009). The activity of maintenance of the QPS list has also been communicated to the Pesticide Steering Committee in March 2011.

1.3. Reference to QPS in the scientific literature

The EFSA 2012 Opinion cited and discussed references to the QPS approach in the scientific literature (EFSA, 2012a). This review was continued and some references are discussed below.

The list of QPS recommended biological agents is reviewed and updated annually, therefore the only valid list is the one from the most recently published scientific opinion. However, some publications refer more to the general principle of QPS which has been outlined by Leuschner et al. (2010) in a review (Castellano et al., 2013; Castellazzi et al., 2013; Dušková and Karpišková, 2013; Elli et al., 2013; Fatma and Bennmehrene, 2013; Fontana et al., 2013; Hrnčár et al., 2013; Klein et al., 2013; Nybom, 2013; Sakar, 2013; Smitha and Bhat, 2013; Sundh and Goettel, 2013; Syal and Vohra, 2013; Toscano et al., 2013).

Some publications refer to the QPS assessment in analogy with the Generally Recognised As Safe (GRAS) concept used in the United States (Ghanban et al., 2013; Lauková et al., 2012; Szkaradkiewicz and Karpiński, 2013). It has to be clearly emphasised that the QPS assessment has a different aim. QPS is a pre-assessment intended to be considered and complemented by a safety


assessment of a specific notification. QPS assesses always the highest taxonomic unit possible, which is usually the species. It never assesses notified strains because this is within the responsibility of the Scientific Panel, which is mandated for the safety evaluation.

2. Methodology

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

The QPS assessment is generic regarding a notified taxonomic unit intended to be intentionally added into the food chain at any stage. The QPS concept can also be applied to microorganisms that are used to produce enzymes, metabolites (e.g. amino acids), dead biomass or other specific end uses that do not involve live microbial cells. In this case the QPS recommendation only applies to the specific end use e.g. enzyme production. A QPS assessment is triggered by receipt of an application dossier by EFSA which requires a safety assessment. It is intended to be independent of the specific application dossier which remains the responsibility of the EFSA Scientific Unit or Panel to which the risk assessment is mandated.

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

The QPS assessment does not address hazards linked to the formulation or processing of the products based on biological agents added into the food or feed chain. Neither safety of users handling the product nor genetic modifications are taken into account. These aspects are assessed, where applicable, separately by the EFSA Scientific Unit or Panel responsible for the risk assessment of the notification.

2.1. Taxonomy

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

2.1.1. Bacterial taxonomy

Taxonomy and nomenclature of bacteria are covered by the International Code of Nomenclature of Bacteria (International Code of Nomenclature of Bacteria, 1992). New taxonomic units or alteration to the taxonomy and nomenclature are published in the International Journal of Systematic and Evolutionary Microbiology (IJSEM). In this journal a list appears where all ‘validly published’ taxonomic units are listed in the Notification List, i.e. the Approved List of Bacterial Names. Validly published are all taxonomic units, which are published in the IJSEM. Taxonomic units that were published outside the IJSEM are called effectively published. They appear after notification by the authors in a Validation List. Also changes in nomenclature are listed separately. These can be spelling errors in the original description or decisions of the Judicial Commission. A comprehensive and up-to-date presentation of the current taxonomy and nomenclature of bacteria is given on the following website: LPSN (List of Prokaryotic names with Standing in Nomenclature, formerly List of Bacterial names with Standing in Nomenclature (LBSN)) (Euzeby, 2013).
2.1.2. Filamentous fungi and yeast taxonomy

The nomenclature and taxonomy of fungi are covered by the International Code of Nomenclature for algae, fungi, and plants (ICN) (McNeill et al., 2012). New taxa or new taxonomic opinions are published in the international scientific literature following the rules of ICN. The major change is that the dual nomenclature with separate names for individual stages in pleomorphic fungi has been terminated meaning that all legitimate fungal names are treated equally for the purposes of establishing priority, regardless of the life history stage of the type. To be validly published new taxonomic units and nomenclatural changes must be registered electronically at MycoBank (2013), Index Fungorum (2013) and Fungal Names (2013) to avoid duplication of names and, in part, a quality check of the formalities. These are also useful sources for validity of published names. There is an ongoing debate among mycologists to protect or preserve names (Geiser et al., 2013; Hibbett and Taylor, 2013; Rossman et al., 2013). For practical identification of fungi a DNA barcode initiative has been launched (Schoch et al., 2012; Blaalid et al., 2013). As of now the general opinion is that more than a single gene is needed as exemplified for Aspergillus and Penicillium (Peterson, 2012) and Fusarium (O’Donnell et al., 2013). Without any doubt there will be a rapid development in this area and combined with enhanced phylogenetic analyses it is foreseen that the species concept in mycology will improve by being more robust.

It was decided to keep the names as they are right now until such lists of ‘recommended species names’ appear in future. The presentation of the yeast taxonomy of the 2011 QPS Opinion is still valid (Kurtzmann et al., 2011; EFSA, 2012a) and maintained in this update.

2.1.3. Virus taxonomy

The taxonomy and nomenclature of viruses are the responsibility of the International Committee on Taxonomy of Viruses (ICTV, 2013). Every three years an update is made based on proposals of working groups after adoption by the Executive Committee. The most recent update is from November 2011 (King et al., 2011). Virus taxonomy is based on shared characteristics such as (i) the type of nucleic acid (RNA or DNA), (ii) the structure of the nucleic acid (single-stranded or double stranded RNA or DNA), (iii) the polarity of the nucleic acid (positive stranded = translatable into proteins; negative stranded = nontranslatable into proteins) and (iv) the form of the virus (isometric, rod-shaped, filamentous or pleomorphic). In addition to these characters, the replication strategy of the viruses is also taken into account and contributes to their taxonomic position (Baltimore, 1971, 1974). Viruses are organized in orders (-virales), families (-viridae), genera (-virus) and species (-virus) by virtue of shared characteristics as described above. Viruses do not have a common ancestor; therefore phylogenetic information is only partially useful in directing the taxonomy of viruses.

2.1.3.1. Plant virus taxonomy

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

2.1.3.2. Baculovirus taxonomy

Baculoviruses are large DNA viruses occurring in members of the insect orders Lepidoptera (moths and butterflies), Hymenoptera (sawflies) and Diptera (flies). The family Baculoviridae is subdivided into four genera, Alphabaculovirus, Betabaculovirus, Gammabaculovirus and Deltabaculovirus (Jehle et al., 2006). Fifty baculoviruses have been officially recognized as species (King et al., 2011; ICTV, 2013), but about 700 different baculoviruses have been described. Baculoviruses, unlike many other virus groups have a common ancestor assisting in the assignment of their taxonomic status.
2.2. **Body of knowledge**

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

2.2.1. **Review of the scientific literature**

A literature review was carried out for each taxonomic unit that was notified to EFSA either for the QPS Opinions in 2007, 2008, 2009b, 2010, 2011a and 2012a. QPS recommended taxonomic units (Table 1) and those which represent an important part of the notifications are annually reviewed. For the taxonomic units recommended for the QPS list the time period of this review covered is the beginning of May 2012 until 30 April 2013 for the QPS 2013 update. For new notifications the literature review was broader to cover the history of use, the potential safety concerns and the ecology.

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

2.2.1.1. **External extensive literature search (EFSA-Q-2012-00969)**

In addition to the review undertaken by the working group experts, an external extensive literature search was carried out in part using the methodology outlined above.

The extensive literature search of studies related to safety concerns for humans, animals, or the environment of microorganisms recommended for the Qualified Presumption of Safety (QPS) 2012 list (EFSA, 2012a) was carried out by an external contractor (EFSA-Q-2012-00969). The literature search involved extensive searches of the published and grey literature for selected yeasts, Gram-positive non-sporulating bacteria, and Gram-positive sporulating bacteria. The total number of citations identified by the database searches was 15,349. Following de-duplication, there were 7,499 unique citations, with one additional citation identified through a search of the reference lists of relevant case reports. Thus, the titles and abstracts of 7,500 citations were screened for relevance, and data characterization of relevant publications was undertaken. One hundred and fifty-two citations passed relevance screening, of which 22 were case reports. Of the 152 studies included, 88 (58 per cent) were identified using Science Citation Index and/or PubMed. BIOSIS Citation Index and CAB Abstracts appeared to be the highest yielding information sources for studies not found by Science Citation Index and/or PubMed. No included studies were found uniquely in Conference Proceedings Citation Index, TOXNET, OpenGREY or Science.gov. Ten eligible studies were found by ScienceResearch.com, which were not found using PubMed, Science Citation Index, BIOSIS Citation Index, or CAB Abstracts. ScienceResearch.com did not identify any relevant grey literature suggesting that its use in this context was limited.
The external extensive literature search confirmed the information obtained by the working group experts.

2.3. **Review of safety concerns identified as ‘qualification’ on the QPS list**

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

A recent EFSA review concluded that for EFSA as a whole, the use of interpretative criteria and methods to define and monitor antimicrobial resistance have been harmonised and are reflected in EFSA’s guidance documents. The use of harmonised methods and epidemiological cut-off values ensures the comparability of data over time at country level, and also facilitates the comparison of the occurrence of resistance between Member States (EFSA, 2012b).

Absence of acquired genes coding for antimicrobial resistance for QPS recommended bacterial taxonomic units is a generic qualification. Generally, it has been considered for the QPS approach that strains carrying acquired resistances should not be intentionally introduced into the food and feed chain. The scope and search for the review of antimicrobial resistance is to conduct a review of each taxonomic unit recommended for the QPS list as it was done last year. During the last QPS update (EFSA, 2012a) the quality of the studies regarding antimicrobial resistance appeared to be variable. The approach adopted has been to consider all available information and subsequently discuss any potential weak points in the available studies.

General search terms used were: ‘susceptibility’, ‘resistance’, ‘antimicrobial’ and ‘antibiotic’. Additional search terms are related to acquired resistance genes in line with the generic qualification mentioned in Table 1 ‘not harbouring any acquired antimicrobial resistance genes’ and included e.g. tet, bla\_VIM, bla\_KPC, bla\_CTX-M, vanA, vanB, vanD, vanE, vanG, vanL, vanM, aac, aph, aad, arm, rmt, erm, lnu, vat, vga, ere, mef, mre, msr, mph, lin, isa, cfr, sul, dhfr, cat, flo, flex, qep, qnR, oqxAB. This list is not exhaustive.

2.3.1. **Other qualifications**

Several *Bacillus* species are on the QPS list with the qualification ‘absence of toxigenic activity’. This is based on the observation that some rare strains among the *Bacillus* species on the QPS list have caused food borne intoxication in the past, and that these intoxications have been attributed to the production by these strains of compounds with toxic activities. A technical guidance to identify these toxic compounds among *Bacillus* species has been elaborated by EFSA (EFSA, 2011b) which is at present updated. The application of the qualification should permit to identify this safety concern among strains of the QPS *Bacillus* species. It is the purpose of the annual update of the QPS list to verify that no other relevant safety concerns have been identified for the QPS *Bacillus* species.

*Enterococcus faecium* was considered in the last QPS review (EFSA, 2012a) because members of this species are authorized in the EU as feed additives to improve growth performances of animals. In the last years the EFSA safety assessment of these microorganisms was made at strain level, assessing the absence of putative virulence factors and acquired antibiotic resistance determinants. In 2012 EFSA has issued the Guidance on the safety assessment of *Enterococcus faecium* in animal nutrition (EFSA, 2012d), based on the most recent genomic, phylogenetic and epidemiologic data. This approach introduces safety criteria such as the susceptibility to the antibiotic ampicillin and the absence of three genetic markers associated with virulence, which permits to differentiate between safe and the
potentially harmful strains belonging to the hospital associated subpopulation of this species to add practical application of this guidance on the safety assessment of *Enterococcus faecium* species (EFSA, 2012d). The purpose of the annual update of this species is to continuously assess the available scientific information on the taxonomy and safety of *Enterococcus faecium* and to consider if it suffices to give this species a QPS recommendation.

3. **Gram-positive non-sporulating bacteria**

3.1. **Antimicrobial resistance aspects of QPS lactic acid bacteria in general**

There are specific aspects mentioned in the subchapters below. Nothing substantial new concerning the genus level (EFSA, 2012a) could be identified and the following is still valid.

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

There are several reviews and studies describing the antibiotic resistance of *Lactobacillus* species as well as other LABs (Hummel et al., 2007; Kastner et al., 2006; Klare et al., 2007; Klein, 2011; Liu et al., 2009; Zonenschain et al., 2009). Intrinsic resistance could be shown mainly for aminoglycosides, quinolones, and glycopeptides (Hummel et al., 2007; Klein, 2011). Moreover, the transfer of antibiotic resistance within LAB isolates from food has been recently studied (Nawaz et al., 2011; Toomey et al., 2010). Presence of genes coding for antibiotic resistances, such as tet (including tet(M), tet(O), tet(S), tet(W), tet(K), tet(L)) and erm (including ermA, ermB and ermC) (Ammor et al., 2008; Hummel et al., 2007; Ishihara et al., 2013) have been reported. This is a non-comprehensive list.

3.2. **Bifidobacterium species**

Bifidobacteria, as other beneficial and commensal bacteria can occasionally be associated with local infections or severe systemic infections, as has been demonstrated in previous EFSA opinions (EFSA, 2012a). Only one new case report of a septicemia with *Bifidobacterium longum* and *Bifidobacterium infantis* was identified (Jenke et al., 2012). The patient was an extremely low-birthweight infant. The patient was under probiotic therapy with a product containing *Lactobacillus acidophilus* and *Bifidobacterium infantis*. This is another typical case report, which can be found in immune compromised hosts. These reports do not change the status of bifidobacteria as safe microorganisms in general.

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

3.2.1. **Antimicrobial resistance aspects regarding the qualification**

No new antimicrobial resistance aspects were reported for bifidobacteria since the last update (EFSA, 2012a).

3.3. **Corynebacterium glutamicum**

A literature review did not reveal new information about adverse health effects or safety concerns with regards to the last update (EFSA, 2012a). The QPS recommendation has been confirmed.
3.3.1. Antimicrobial resistance aspects regarding the qualification

No new relevant information in the last year was published on the antimicrobial susceptibility or resistance of *Corynebacterium glutamicum*, therefore no modifications in the qualification of the antimicrobial resistance are proposed.

3.4. *Enterococcus faecium*

Enterococci are commensal bacteria of the gastrointestinal tract of humans and other mammals, and are frequently found as members of the bacterial communities of food fermentations. Among these, *Enterococcus faecium* is the most encountered species in food fermentations, such as cheese, fermented vegetable and sausages. This microorganism is also intentionally introduced in the food chain as a feed additive (animal probiotic), under a specific EU Regulation (Regulation (EC) No 1831/2003 (Official Journal, 2003))

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

The assessment of *Enterococcus faecium* for QPS has been performed by EFSA in 2012 (EFSA, 2012a), reaching the conclusion that although a differentiation between the clade containing strains associated to clinical infections from the clade composed by commensal strains is possible, this knowledge was too recent knowledge for a QPS recommendation, considering the past evolution of the epidemiology of *Enterococcus* infections in humans. This scientific information was used by the FEEDAP panel (Guidance on the safety assessment of *Enterococcus faecium* in animal nutrition, (EFSA, 2012d)) to issue in 2012 a scientific opinion with the aim to exclude *Enterococcus faecium* strains belonging to the hospital-associated clade from the use in animal nutrition because of the hazard they present to a vulnerable subpopulation of consumers. Strains to be used in animal nutrition shall be susceptible to ampicillin (MIC ≤ 2 mg/L) and shall not harbour the genetic elements IS16, hylEfm, and esp. This is of value for the FEEDAP Scientific Panel dealing with the strain specific notification, but it is too recent knowledge for a QPS recommendation, considering the recent information on the evolution of the epidemiology of *Enterococcus* infections in human.

In this last year, additional genomic and phylogenetic data support the view that *Enterococcus faecium* species consists of two distinct lineages or clades. One subpopulation, clade B consists predominantly of human gut commensals and is characterized by susceptibility to ampicillin. The other subpopulation, named clade A contains most of the clinical isolates (Willems and van Schaik, 2009; Galloway-Peña et al., 2011; Galloway-Peña et al., 2012, Palmer et al., 2012; de Been et al. 2013). Genomic analyses demonstrated that differences between the two clades depends on an evolutionary divergence that occurred at least 300,000 years ago (Galloway-Peña et al., 2012) and on more recent recombination events, which mainly affect the strains of clade A (de Been et al., 2013), which seem more prone to receive foreign DNA.

Clinical isolates of clade A are characterized by resistance to ampicillin (MIC > 4 mg/L), related to the presence of the allelic form *php5-R* form of the gene coding for the penicillin binding protein 5 (PBPs) and by the presence of a putative phosphotransferase system contributing to the intestinal colonisation during antibiotic treatments (Zang et al., 2013). An additional differential factor between

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the two clades is the presence in strains from human infections of the insertion sequence IS16 (Leavis et al., 2007; van Schaik et al., 2010; Werner et al., 2011), which presumably confers a level of genomic flexibility, and the esp pathogenicity island ICEEfm1 (van Schaik et al., 2010; Top et al., 2011, 2013).

3.4.1. Antibiotic resistance aspects regarding the qualification

The rise in prevalence of Enterococcus faecium in human infections has coincided with the emergence of drug or multi-drug resistant strains. The antibiotic resistances in this species may be both intrinsic or acquired. Thus, this species shows intrinsic resistance to several antibiotics, e.g. low-level resistance to streptogramin B and aminoglycosides and resistance to beta-lactams, typical of strains of clade A (Hollenbeck and Rice, 2012). Mobile genetic determinants conferring resistance to different classes of antibiotics such as aminoglycosides [aph(3')-III, aac(6') and aph(2'')] variants, beta-lactams (bla, php5), glycopeptides (vanA/B/D/E/G/L/M), phenicols (cat genes), tetracyclines (tetO/L/K/S/U), oxazolidinone, lincosamides, pleuromutilins and streptogramin A (cfr) and to macrolides, lincosamides and streptogramins group (ermA/B/C/F/T, linB, vatB/D/E, msrA/C/D, IsaA, vgaB and mefA) have been observed in enterococci from different sources, including in food producing animals and food strains. The intrinsic and acquired mechanisms of resistance to antimicrobials have been review by Hollenbeck and Rice (2012).

Conclusions on a recommendation for the QPS list

Enterococcus faecium is not recommended for the QPS list in spite of the rapidly evolving scientific knowledge allowing a differentiation of pathogenic strains from non-pathogenic strains within this species. This is however of value for the FEEDAP Scientific Panel dealing with the strain specific notification.

3.5. Lactobacillus species

There were several case reports including lactobacilli and infections of immunocompromised hosts. Especially the species Lactobacillus rhamnosus is mentioned in some reports. This confirms the observation in the previous QPS reports (EFSA, 2008, 2012a) and observations in the literature (Klein, 2011), that Lactobacillus rhamnosus is the most prevalent species in Lactobacillus associated human infections. Case reports involving immunocompromised hosts were given for Lactobacillus delbrueckii (Duprey et al., 2012), Lactobacillus iners (Murata et al., 2012), Lactobacillus acidophilus (Nishijima et al., 2012; associated with dental caries, most probably misidentified instead of Lactobacillus gasseri) and Lactobacillus spp. not further characterised (Hamadah et al., 2013).

Concerns about the use of probiotics within a clinical settlement was raised by several authors, e.g. by Vahabnezhad et al. (2013), where a 17-year-old immunocompromised boy with ulcerative colitis was treated with Lactobacillus rhamnosus GG and exhibited a bacteraemia with this strain. The authors point to the risk in applying probiotics to immunosuppressed patients with severe active ulcerative colitis. However, this use is not the normal use for QPS taxonomic species. Lactobacillus rhamnosus GG has been previously involved in similar clinical circumstances. A 95-year old woman with underlying chronic diseases exhibited an infection in a prosthetic joint with Lactobacillus casei and Lactobacillus paracasei (Orkaby et al., 2012). The identification to species level was not described. Yoghurt containing Lactobacillus casei could be confirmed in her diet, but the etiological connection could not be made. In a retrospective study Simkins et al. (2012) explored the incidence of probiotic-related bloodstream infections due to Lactobacillus acidophilus or Lactobacillus bulgaricus in a large medical centre. They stated only a minimal risk of such infections.
The reports identified in the external extensive literature search were either not related to clinical infections (Abubacker et al., 2012) or were isolated from sputum of different patient groups with underlying disease but with no etiological connection to the microbiological finding (Popoca et al., 2012). They were thus not furthermore considered.

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

### 3.5.1. Antimicrobial resistance aspects regarding the qualification

The external extensive literature search identified two reports with reference to antibiotic resistance in lactobacilli. Giri et al. (2012) did not find antibiotic resistances in a strain of *Lactobacillus plantarum* isolated from fish and intended to be used as probiotics. On the other hand, Turchi et al. (2013) found a tetracycline resistant phenotype in 6 of 42 wild *Lactobacillus plantarum* strains intended to be used as a probiotic. These findings emphasise the qualification of absence of transferable, acquired resistance genes for QPS strains.

### 3.6. *Lactococcus* species

*Lactococcus lactis* subsp. *lactis* and *Lactococcus lactis* subsp. *cremoris* are common starter organisms used worldwide in dairy industry and have been included in the QPS list, despite of isolated human and animal clinical cases involving *Lactococcus lactis* that have been reported (EFSA, 2012a). A search in PubMed revealed three new human cases, a necrotic abscess in a middle-aged patient (Hadjisymeou et al., 2013), an early postoperative infective endocarditis caused in a 75-year-old man (Rostagno et al., 2013) and an atypical necrotising pneumonia (Buchelli-Ramirez et al., 2013). In the first two studies the authors did not describe the method used for species identification, while a phenotypic approach was used for the taxonomical identification of the strain isolated from necrotising pneumonia.

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

### 3.6.1. Antimicrobial resistance aspects regarding the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria (3.1.). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

### 3.7. *Leuconostoc* species

Four species of the genus *Leuconostoc* (*Leuconostoc citreum*, *Leuconostoc mesenteroides*, *Leuconostoc lactis* and *Leuconostoc pseudomesenteroides*) were previously given a QPS recommendation.

Since 2012, a single new case of *Leuconostoc lactis* infection was reported in a patient who had undergone to liver transplantation. The identification of the infective agent was properly performed using phenotypic tests and 16S rDNA gene sequence analysis (Deng et al., 2012).

In conclusion, QPS recommendations for *Leuconostoc citreum*, *Leuconostoc lactis*, *Leuconostoc mesenteroides* and *Leuconostoc pseudomesenteroides* are given.
3.7.1. Antimicrobial resistance aspects regarding the qualification

No new relevant information in the last year was published and the genus is covered by general section on lactic acid bacteria (3.1.). There is no new information that would require a modification in the qualification of the antimicrobial resistance.

3.8. Pediococcus species

One case report involving a not further identified Pediococcus spp. isolate could be found, where a tumor patient exhibited a necrotizing infection after rupture of the tumor (Michalopoulos et al., 2013).

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

3.8.1. Antimicrobial resistance aspects regarding the qualification

No new antimicrobial resistance aspects were reported for pediococci in the external extensive literature search since the last update (EFSA, 2012a).

3.9. Oenococcus oeni

No new reports for clinical infections were found for Oenococcus oeni and also in the external extensive literature search no new reports were cited since the last update (EFSA, 2012a).

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

3.9.1. Antimicrobial resistance aspects regarding the qualification

No new antimicrobial resistance aspects were reported for oenococci in the external extensive literature search since the last update (EFSA, 2012a).

3.10. Dairy propionic acid bacteria

No new reports for clinical infections were found for dairy propionic acid bacteria and also in the external extensive literature search no new reports were cited since the last update (EFSA, 2012a).

Therefore, there is no need to change the QPS recommendation of the previously recommended dairy propionic acid bacteria species.

3.10.1. Antimicrobial resistance aspects regarding the qualification

No new antimicrobial resistance aspects were reported for dairy propionic acid bacteria in the external extensive literature search since the last update (EFSA, 2012a).

3.11. Streptococcus thermophilus

No reports of clinical infections related to Streptococcus thermophilus were identified in scientific literature since 2012. The name Streptococcus thermophilus is considered as the correct basonym for Streptococcus salivarius subspecies thermophilus. Therefore, the QPS recommendation for this species is maintained.
3.11.1. Antimicrobial resistance aspects regarding the qualification

Although little scientific information is still available on the *Streptococcus thermophilus* susceptibility to clinically relevant antibiotics, the presence of acquired resistance genes in this dairy bacterium has been reported. For example, the presence of acquired resistance genes, the erythromycin resistance determinant *ermB* and the tetracycline-resistance genes *tet(S), tet(M),* and *tet(L)* and aminoglycoside resistance determinants *ant(6) and aph(3’)-IIIa* were detected in dairy strains of *Streptococcus thermophilus* (Rizzotti et al., 2009; Zhou et al., 2012). These resistances are covered by the general qualification on antibiotic susceptibility. There is no new information that would require a modification in the qualification of the antimicrobial resistance.

4. Gram-positive spore forming bacteria

4.1. *Bacillus* species

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

In total 230 articles found by relevant search terms were screened. A bacteraemia related to a pacemaker wire infection was caused by *Bacillus licheniformis* (Idelevich et al., 2012). *Bacillus subtilis* and *Bacillus licheniformis* were identified as the cause of a bacteraemia in a patient with an oesophageal perforation (La Jeon et al., 2012). Kim et al. (2012) reported a case of bacteraemia caused by *Bacillus licheniformis* following vertebrotherapy in a patient with a lung cancer. Safety concerns for food producing animals were also considered in the search because ‘the body of knowledge about the organisms for which QPS is sought must be sufficient to provide adequate assurance that any potential to produce adverse effects in humans, livestock or the wider environment is understood and predictable’ (EFSA, 2007). A *Bacillus* sp. was isolated from abscesses in several sheep and goats, but authors could not identify the isolates to the species level by phenotypic tests and sequence of 16s rRNA gene (Mariappan et al., 2012). Gangrenous mastitis in several goats was caused by *Bacillus spp.*, one of the isolates was identified *Bacillus cereus*, but other isolates were not identified at the species level (Mavangira et al., 2013). *Bacillus subtilis* was isolated, together with *Staphylococcus*, from milk of goats with subclinical mastitis (Razi et al., 2012), but without evidence that *Bacillus subtilis* was the cause of mastitis.

These cases of infections in human are linked to specific predisposing factors and do not suggest a risk for the consumer via exposure through the food and feed chain. The abscesses reported in sheeps were not sufficiently characterized to know if *Bacillus* species from the QPS list were involved. For the mastitis in goats, the co-isolation of *Staphylococcus aureus*, a well-known agent of mastitis, raises doubt on the role of *Bacillus subtilis* in the infection.

4.1.1.1. Other relevant information published on QPS *Bacillus* species

A review article on foodborne illness caused by *Bacillus* species, including some QPS *Bacillus* species was published in 2012 (Logan, 2012). It is in line with previous QPS assessment (EFSA, 2008) concerning the rare implication of QPS *Bacillus* species in foodborne illnesses, and the likely implication of peptidolipides with toxic activities produced by the responsible strains. Two articles described some biological activities of peptidolipides with biosurfactants produced by *Bacillus subtilis*. A biosurfactant produced by a strain of *Bacillus subtilis* caused epithelium cells vacuolisation and microvilli damage in the mid-gut of an insect larvae (LC₅₀ around 200 ng/mg according to Ghribi et al., 2012). A *Bacillus subtilis* strain isolated from a Korean fermented soybean paste produced up to 48 mg surfactin per kg in the fermented food, and the surfactin inhibited growth of human breast cancer cells (IC₅₀ 10µg/ml, Lee et al., 2012).
The above new information does not seem to affect the *Bacillus* related QPS qualification of ‘absence of toxigenic activity’. Therefore, the QPS recommendation was confirmed.

### 4.1.2. Antimicrobial resistance aspects regarding the qualification

The MIC of 85 strains, belonging to two QPS *Bacillus* species, *Bacillus subtilis*, *Bacillus licheniformis*, and to *Bacillus sonorensis* (a very close relative of *Bacillus licheniformis* (Palmisano et al., 2001), for chloramphenicol, clindamycin, erythromycin, gentamicin, kanamycin, tetracycline and vancomycin, were obtained (Adimpong et al., 2012). The strains were isolated from starters used in traditional African bread production. No isolates with MIC higher than the breakpoint values recommended by EFSA (EFSA, 2012b) were found for gentamicin, tetracycline and vancomycin, whereas between 50 and 100% of isolates had MIC higher than the EFSA breakpoint values for chloramphenicol, clindamycin, erythromycin, kanamycin and streptomycin.

The *Bacillus licheniformis* isolates with MIC higher than EFSA breakpoints values for erythromycin presumably carried resistant genes *ermD*, *ermK* on a plasmid. Such strains would not meet the qualification ‘absence of acquired genes for antimicrobial resistance’ and would have been detected using the EFSA guidance (EFSA, 2012b) due to the MIC value higher than the breakpoint. *ErmD* and *ermK* genes were also found in one strain of *Bacillus licheniformis* strains with an MIC value equal to the EFSA break point. This strain would not be detected using EFSA guidance as carrying potentially acquired resistance genes to erythromycin. However, from the sequence of these two resistance genes, authors assumed that they are not functional.

In conclusion, the study from Adimpong et al. (2012) stresses and confirms the importance of the qualification on the 'absence of acquired genes for antimicrobial resistance' for QPS *Bacillus* species introduced in the food chain. It also demonstrates the efficacy of the EFSA guidance (EFSA, 2012b) to detect acquired genes for antimicrobial resistance.

In the course of an investigation on antimicrobial resistance among aquaculture bacteria, one *Bacillus* sp. isolate had MIC for chloramphenicol and streptomycin of 60 µg/ml and 100 µg/ml, respectively (Ozaktas et al., 2012), higher than the breakpoint of 8 µg/ml proposed for *Bacillus* spp. in the EFSA Guidance (EFSA, 2012b). Another study on aquaculture environment found *Bacillus* species (including species on the QPS list) frequently indentified among tetracycline resistant bacteria (Gao et al., 2012) but it is not possible from the results to determine the MIC of the *Bacillus* isolates.

The publication La Jeon et al. (2012) measures the antimicrobial susceptibility of six isolates of *Bacillus licheniformis* and *Bacillus subtilis* using disc diffusion assays. These do not give an indication of presence of acquired resistance genes in these isolates.

A new mechanism of antimicrobial resistance to cephalosporin in *Bacillus subtilis* was discovered (Lee et al., 2012). This resistance was due to a mutation on the chromosome and is not a transferable resistance concerned by the qualification.

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

### 5. Gram-negative bacteria

#### 5.1. *Gluconobacter oxydans*

This species is assessed this year for the first time.
5.1.1. Taxonomy

*Gluconobacter oxydans* is a Gram-negative belonging to the family *Acetobacteraceae* (acetic acid bacteria). Synonyms that have been commonly employed are *Acetobacter suboxydans* and *Gluconobacter suboxydans*. Several subspecies have been described within the species (subsp. *industrius*, melanogenes, oxydans, sphaericus, suboxydans). *Acetobacter suboxydans*, *Acetobacter oxydans* and *Gluconobacter suboxydans* have been re-classified as *Gluconobacter oxydans*, and the names can be considered as synonyms. A phylogenetic study using 16S rRNA sequence analysis has described five clusters, corresponding to the major five species of *Gluconobacter*, namely *Gluconobacter albidus*, *Gluconobacter cerinus*, *Gluconobacter frateurii*, *Gluconobacter oxydans* (type species), and *Gluconobacter thailandicus* (Takahashi et al., 2006) but since then several new species have been described and some data obtained (Yukphan et al., 2004; 2010) suggest the presence of additional new species in the genus. These results suggest that the phenotypic differences among *Gluconobacter* species are ambiguous and the species definition must be re-evaluated. At this moment according to the LSPN fourteen species and five subspecies are included in the genus *Gluconobacter* (Euzéby, 2013).

*Gluconobacter oxydans* is an obligate aerobe frequently used in classical food fermentation processes (vinegar production) as well as industrial biotechnology. It is widely used in biotechnological applications due to its capacity to incompletely oxidize a wide range of carbohydrates, alcohols and acids (D-sorbitol, glycerol, D-fructose, and D-glucose) using membrane-bound polyol dehydrogenases (De Muynck et al., 2007). *Gluconobacter* is not able to overoxidize acetic acid to CO\(_2\) and H\(_2\)O since it lacks succinate dehydrogenase and the tricarboxylic acid cycle is incomplete. Final fermentation product is mainly acetic acid but also vitamin C, (keto)gluconic acid, and dihydroxyacetone. Nowadays, new processes for the synthesis of compounds have been developed to produce l-ribulose, D-tagatose, miglitol and chiral aldehydes and acids. Membrane-bound polyol dehydrogenases are also used in biosensor technology to measure substrate concentration and for co-enzyme regeneration (De Muynck et al., 2007). It has been also used to metabolize patulin to a less-toxic compound, ascladiol (Ricelli et al., 2007). As spoilage bacteria, representatives of *Gluconobacter oxydans* are usually associated to bacterial rot of fruits and the common habitat is sugar-rich environments such as fruits and juices. The species as well as the genus are generally considered non-pathogenic to humans or animals (De Muynck et al., 2007).

5.1.2. Body of knowledge

‘*Gluconobacter oxydans*’ was searched as key word (including ‘*Gluconobacter*’) in the topic of articles on the Web of Knowledge and PubMed from 1950 until September 2013. Around 1000 references were identified in the Web of Knowledge and around 500 in PubMed. All hits were screened. No article mentioned human or animal safety concerns. There were only two articles that mentioned cases of disease caused by concomitant *Gluconobacter* spp. (Alauzet et al., 2011; Basetti et al., 2013).

*Gluconobacter oxydans* was also previously known as ‘*Acetobacter suboxydans*’. Therefore, also ‘*Acetobacter suboxydans*’ was searched as key word in the topic of articles on the Web of Knowledge and PubMed for the same period of time (including ‘*Acetobacter*’). Around 2500 were found in Web of Knowledge and about 1250 in PubMed. All hits were screened. No article mentioned human or animal safety concerns.

5.1.3. Safety assessment

Only two articles mentioned a possible pathogenic effect of *Gluconobacter* spp.. One of them described a case of endocarditis in a patient with a history of intravenous-drug abuse involving *Gluconobacter* as a concomitant bacterium (Bassetti et al., 2013). Another study described the
isolation of acetic acid bacteria (AAB) from clinical samples from three patients and the clinical and bacteriological features of these cases. It was reported for the first time (i) the isolation of a *Gluconobacter* sp. from human clinical samples; (ii) the successive isolation of different AAB, i.e., an *Asaia* sp. and two unrelated *Gluconobacter* spp., from a cystic fibrosis patient; and (iii) persistent colonization of the respiratory tract by a *Gluconobacter* sp. in this patient. The main clinical features associated with AAB isolation identified in the 10 documented reports currently available in the literature were reviewed. Albeit rare, infections as well as colonization with AAB are reported in patients with underlying chronic diseases and/or indwelling devices. Some species (however not *Gluconobacter oxydans*) in the genus have been reported as unusual opportunistic pathogens, which may be multiresistant to antimicrobial agents according to only one publication (Alauzet et al., 2011). No article mentioned human or animal safety concerns related to consumption of foods and feed.

Additionally, the Technical Rules for Biological Agents published by the Committee on Biological Agents (ABAS) in connection with occupational hazards (that complies or adapts the rules and they are announced by the Federal Ministry of Labour and Social Affairs in the German Joint Ministerial Gazette) in December 2010 (BAUA, 2013), classified all described species of *Gluconobacter* including *Gluconobacter oxydans* in risk class 1, therefore the lowest risk. Also the closely related *Acetobacter* and *Gluconacetobacter* were also placed in risk class 1.

In conclusion, the body of knowledge of this bacterium describes its extensive presence in fermented foods that have been widely consumed without any reference of safety concerns related to its presence.

5.1.4. Antimicrobial resistance aspects regarding the qualification

There was no report of resistance to antibiotics in any of the papers screened.

5.1.5. Other relevant information

In 1982, a new antibiotic, tentatively named as AB-315 (enacyloxin), was isolated from the fermentation broth of a designated *Gluconobacter* strain W-315 (Watanabe et al., 1982a; b). A strain of *Gluconobacter* sp. producing monobactam was identified from nature and it was deposited under the accession number of ATCC 31,581 (Wells et al., 1982), where it appears as producer of beta-lactam antibiotic EM5210 (ATCC online catalogue). In the same study, several ATCC strains were tested and three were identified as monobactam-producing strains of *Gluconobacter oxydans* (Wells et al., 1982). These strains are deposited in the ATCC culture collection as *Gluconobacter oxydans*, however in the current ATCC online catalogue (ATCC, 2013) antibiotic production is not mentioned. This aspect will be followed in future QPS reviews.

5.1.6. Conclusion regarding a QPS recommendation

Therefore, according to all the scientific evidence examined and evaluated, *Gluconobacter oxydans* is recommended for the QPS list subject to a qualification ‘QPS only apply when the species is used for vitamin production’ which is relevant for the intended use for which the species was notified.

6. Yeast

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

For the majority of the yeast species listed in the preceding QPS update (EFSA, 2012a), the literature update did not identify any new studies reporting potential safety concerns: *Hanseniaspora uvarum, Kluyveromyces lactis, Kluyveromyces marxianus, Komagataella pastoris, Lindnera jadinii, Ogataea*
angusta, Saccharomyces bayanus, Saccharomyces pastorianus and Schizosaccharomyces pombe. The remaining four species plus Trichosporon mycotoxinivorans are treated separately below.

6.1.1. **Debaryomyces hansenii**

Beyda et al. (2013) reported two human cases of Candida famata (the anamorph of Debaryomyces hansenii) fungemia (Houston, US). Both patients had serious underlying disease. The study indicated that Candida famata may exhibit reduced susceptibility to some common antimycotics, compared to yeasts commonly associated with opportunistic infections. Chan et al. (2013) reported isolation of Debaryomyces hansenii from a multi-fungal consortium of all untypical species isolated from a patient with persistent superficial skin infection (athlete’s foot). The results of these studies do not imply new concerns with respect to the QPS status of Debaryomyces hansenii.

6.1.2. **Saccharomyces cerevisiae**

There is currently a big interest and many publications coming out regarding the occurrence of Saccharomyces cerevisiae as an opportunistic pathogen. The main reasons for this interest can be assumed to be its wide use in food and feed and that it is considered one of the safest microorganisms known.

One study report new information on possible factors that could contribute to virulence in Saccharomyces cerevisiae. Llopis et al. (2012) present evidence that enhanced oxidative stress response is a feature in virulent clinical strains.

Among 46 yeast isolates from oral swabs from patients with head and neck cancer undergoing radiotherapy, one was a Saccharomyces cerevisiae (Bulacio et al., 2012). The isolate was sensitive to all four tested antimycotics. In oral swabs from HIV-patients, Li et al. (2013) found that one of the yeast isolates (frequency = 0.3% of isolates) was a Saccharomyces cerevisiae. The isolate was sensitive to all four tested antimycotics. Another study (Kalkanci et al., 2012) reported Saccharomyces cerevisiae in clinical samples from confirmed, or in some cases suspected, vulvovaginal candidiasis in women. They found one isolate to be Saccharomyces cerevisiae (frequency 0.5%), but did not provide specific information on antimycotic resistance in that isolate. In these three reports, Saccharomyces cerevisiae made up a very minor portion of the clinical isolates. Therefore it is highly uncertain whether it actually caused the disease.

A short case report demonstrated Saccharomyces cerevisiae fungemia, in a patient under treatment for acute myeloid leukaemia (Choi et al., 2012). They hypothesized that intestinal colonization likely preceded invasion of the intestinal wall during chemotherapy-induced enterocolitis. They concluded that symptomatic Saccharomyces cerevisiae infections are rare, but can occur in critically ill and immunocompromised patients.

These new reports of Saccharomyces cerevisiae appearing as an opportunistic pathogen add no further concern with respect to its QPS status. It has to be noted that Saccharomyces cerevisiae subtype boulardii is contraindicated for patients of fragile health, as well as for patients with a central venous catheter in place (EFSA, 2007).

6.1.3. **Trichosporon mycotoxinivorans**

Trichosporon mycotoxinivorans was first isolated from termite gut in 2004 and named according to its properties of detoxifying some mycotoxins. The promising use of some isolates in saccharification of hemicellulose or in the production of active emulsifiers from different hydrophobic substrates was also reported (Monteiro et al., 2012). Thirteen reports concerning Trichosporon mycotoxinivorans have been published since the beginning of 2012, according to a bibliographic search based on Pub-
Med and Web of Knowledge as databases. Five publications corroborate the occurrence of *Trichosporon mycotoxinivorans*-related disorder in humans and one case of a disseminated fatal infection involving this yeast species was described (Hirschi et al., 2012). Based on this, *Trichosporon mycotoxinivorans* cannot be proposed for the 2013 QPS list.

### 6.1.4. Wickerhamomyces anomalus (Pichia anomala)

Purisco et al. (2012) report that *Pichia anomala/Candida pelliculosa* was found among bloodstream isolates from patients with fungemia. The study found no antimycotic resistance of concern in the isolate. A case of fungemia due to *Candida pelliculosa/Pichia anomala* in neonatal babies (five cases) in the same intensive care unit was reported by da Silva et al. (2013). All infections were successfully treated with antimycotics. These new cases of *Pichia anomala* as an opportunistic pathogen do not give further concern for its QPS status, when used in enzyme production.

### 6.1.5. Xanthophyllomyces dendrorhous

Latha and Jeevaratanm (2012) reported that carotenoids from the yeast *Rhodotorula glutinis* (similar to carotenoids from the QPS listed *Xanthophyllomyces dendrorhous*) showed no toxicity in a mouse model. They conclude that the carotenoids can be used safely as food colourant.

### 6.2. Conclusions on yeasts

The inclusion of several yeast species in the QPS list (Table 1) is mainly based on the apparent history of safety. Overall, the annual update of the literature gave no reason to modify the QPS status, including the related qualifications.

The specific virulence factors that differentiate pathogenic yeasts from innocuous ones are not conclusively known. However, in the current update, a study came up pointing to an additional factor that could contribute to virulence in opportunistic variants of e.g. *Saccharomyces cerevisiae* (ability to cope with oxidative stress (Llopis et al., 2012). More comparative studies of virulence factors in opportunistic yeasts are needed before a general picture can evolve.

Reduced sensitivity to antimycotics used for medical treatment of yeast infections is occasionally reported. But there were no indications in the reviewed studies that the prevalence of resistance is increasing in the reviewed species or that resistance is becoming a problem in the treatment of infections by opportunistic yeasts.

The introduction of the one-name system for pleomorphic fungi will undoubtedly have a strong impact on yeast nomenclature. In those cases where there are established, separate names for both forms in use, the likely outcome is that one of them will eventually be given priority, according to the rules of the ICN (McNeill et al., 2012). The ICTF (International Commission on the Taxonomy of Fungi) (ICTF, 2013) has a special working group for yeasts and it is anticipated that lists of new and prioritised names will appear in the coming years.

### 7. Filamentous fungi

#### 7.1. Ampelomyces quisqualis

*Ampelomyces quisqualis*, a natural occurring mycoparasite, is considered as one of the best alternatives to chemicals against Erysiphales, the casual agents of powdery mildews. During 2012 and the five first months of 2013, seventeen reports dealing with *Ampelomyces quisqualis* have been identified through a literature search. These 17 publications were all devoted to the evaluation of
Ampelomyces quisqualis mycoparasitic activity with new insights in the mycoparasitism process such as the key role played by cell wall degrading enzymes (Angeli et al., 2012). No new data certifying the lack of toxins or toxicity against animals have been retrieved and therefore Ampelomyces quisqualis remains ineligible for QPS status.

7.2. Ashbya gossypii
During 2012 and the five first months of 2013, more than 80 reports dealing with Ashbya gossypii have been identified through a literature search. Two main topics were discussed in these reports: fungal developmental biology with the use of Ashbya gossypii as an organism model and riboflavin production. Ashbya gossypii is a natural overproducer of riboflavin and several of the recently published works aimed at identifying strategies to improve this production. The overproduction induced by environmental stresses, nutritional or oxidative ones, reported by Walther and Wendland (2012) could be one of this strategy. No new data certifying the lack of toxins or toxicity against animals has been retrieved and in light of this limited information, Ashbya gossypii is still ineligible for a QPS recommendation.

7.3. Aspergillus species
For the Aspergillus species listed in the QPS 2012 update (EFSA, 2012a), Aspergillus aculeatus, Aspergillus candidus, Aspergillus niger and Aspergillus oryzae, no new information on the lack of toxicity or toxins have been retrieved. The reports of mid-2012 to mid-2013 retrieved by a search in Thomson Reuters Web of Knowledge deal with production of the specific products, often enzymes, or food spoilage problems. Aspergillus species are not recommended for the QPS list.

7.4. Beauveria bassiana and Beauveria brongniartii
More than 540 references published between 2012 and 2013 were retrieved when the keyword Beauveria was used in a literature search. 512 papers were devoted to Beauveria bassiana and 26 to Beauveria brongniartii. This high publishing activity directly results from the use of these two entomopathogen fungi as bioinsecticides. Few papers (close to 20) focus on the bioactive and toxic metabolites, beauvericin, oosporein, destruxin and pyridovericin these fungal species are able to produce. A first metabolomic approach, using nuclear magnetic resonance spectroscopy, was applied to Cordyceps bassiana (the sexual form of Beauveria bassiana) allowing the establishment of metabolic profiles for both mycelia and fruiting bodies (Park et al., 2013). No case of human infection linked to Beauveria bassiana or Beauveria brongniartii was retrieved but the potential involvement of these species in keratitis was corroborated by the review of Karsten et al. (2013). Conclusion on the peer review of the pesticide risk assessment of the active substances Beauveria bassiana strains ATCC-74040 and GHA was published in 2013 in the EFSA Journal (EFSA, 2013k). This conclusion highlights several data gaps that require to be filled, among which the potential of secondary metabolites/toxins production and the risk to non-target organisms.

Due to the limited but recognized risk of human infection and its ability to produce toxic secondary metabolites, Beauveria remains ineligible for the 2013 QPS list.

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

Eighteen papers dealing with *Coniothyrium minitans* have been retrieved in the time frame of the literature search. *Coniothyrium minitans* can parasitize the sclerotia and mycelia of *Sclerotinia sclerotiorum* and most of the former papers investigate the potential of *Coniothyrium minitans* as a bio-control agent. No information on lack of toxins or toxicity against mammals was retrieved, therefore this species cannot be proposed for the QPS list.

7.7. **Duddingtonia flagrans**

*Duddingtonia flagrans* is recognized as a nematophagous fungus and its potential for biological control of nematode parasites of different livestock was the main subject of the 34 publications retrieved through the literature search in the time frame April 2012 to May 2013. Among these 34 papers, the review of Benyon (2012) highlights the necessity to further investigate the potential environmental impact of this biocontrol agent that, for instance, is indiscriminate in its nematode infection and could reduce beneficial soil populations. No new data have been published concerning the potential of flagranones production by *Duddingtonia flagrans* neither the toxicity of these cyclohexenoxide antibiotics. No new data certifying the lack of toxins or toxicity against animals has been retrieved and *Duddingtonia flagrans* remains ineligible for QPS status.

7.8. **Fusarium species**

With more than 7000 references retrieved when the keyword *Fusarium* was used in the literature search in the time frame May 2012 to April 2013, the *Fusarium* genus is still one of the most extensively studied. Publications involving *Fusarium* deal with numerous research fields including plant pathology, mycology, mycotoxicology, biotechnology and medicine. Three significant points have to be highlighted: (i) the first published reaction of the *Fusarium* scientific community to the recent changes in the international code of nomenclature for algae, fungi and plant, (ii) the first attempts to develop integrated system approaches applied to *Fusarium* mycotoxin production and (iii) numerous studies illustrating the frequent occurrence of ‘Fusarium emerging mycotoxins’. *Fusarium* species are not recommended for the QPS list.

7.8.1. **Taxonomy**

In the QPS 2012 update, a special paragraph was devoted to recent important changes for mycological systematics. The desire of mycologists to adopt one name for each fungal species was recognized by the Amsterdam Declaration of Fungal Nomenclature (Hawksworth, 2011). If such an approach will reduce confusion arising from dual nomenclature system relating to pleomorphism in fungi (Wingfield et al., 2012), it raises the issue of ‘one fungus, which name?’. In recent publications (Geiser et al., 2013; Rossman et al., 2013), the impact of these new systematic rules for the *Fusarium* genus is discussed.

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

The significant progress on *Fusarium* mycotoxin regulation achieved during the last decade of research (as described in the QPS 2012 update (EFSA, 2012a)) has led to the early foundations required for developing system biology approaches. Disentangling and modelling the biological networks involved in the biosynthesis of *Fusarium* mycotoxins could significantly improve prevention strategies to control mycotoxins contamination of food and feed. These promising developments are the subject of a recent review published by Subramaniam and Rampitsch (2013) and a first study restricted to the impact of some environmental factors on fumonisin production (Medina et al., 2013).
7.8.3. Emerging Fusarium toxins

More than 150 recent publications were retrieved by a literature search when the key words *Fusarium* and enniatin, *Fusarium* and beauvericin, *Fusarium* and moniliformin, *Fusarium* and fusaproliferin were combined. These publications were mainly reports on their occurrence in several matrices, cereals but also dried fruits (Tolosa et al., 2013) or on the improvement of analytical methods (mainly multi-toxins analysis).

7.9. Gliocladium catenulatum

The current name in use for *Gliocladium catenulatum* is *Clonostachys rosea* f. *catenulata* and the taxonomic relationship as well as nomenclature is described in detail (EFSA, 2009b). In light of the recent change in nomenclatural rules the genus *Clonostachys* is proposed to be protected against *Gliocladium* and *Bionectria* (Rossman et al., 2013). No information on lack of toxins or toxicity against mammals is reported, therefore this species cannot be proposed for the QPS list.

7.10. Isaria fumosorosea (syn. Paecilomyces fumosoroseus)

Since the most recent QPS opinion update in 2009, more than 250 reports dealing with *Isaria fumosoroea* (formerly *Paecilomyces fumosoroseus*) have been identified through an intensive literature search. These publications were identified using *Isaria fumosorosea* or *Paecilomyces fumosoroseus* as key words. The major part of these publications concerns the potential use of strains belonging to this species as biocontrol agents. *Isaria fumosorosea* which is an entomopathogenic fungus with a relatively wide host range is described as one of the most promising fungal species for control of diamondback moth, whiteflies and other insect pests. A recent conclusion on pesticide peer review was published by EFSA (EFSA, 2012k). This review concerns the pesticide risk assessment of the use of a *Paecilomyces fumosoroseus* strain as an insecticide in glasshouses on tomatoes. The literature search performed for this QPS review in the time frame 2009-2013 did not retrieve case report of human mycotic infection ascribed to *Isaria fumosoropea*.

The potential of several isolates of *Isaria fumosoropea* to produce the beauvericin mycotoxin, which is toxic for humans, was however corroborated by the report of Luangsa-Ard et al. (2009). *Isaria fumosoropea* cannot be proposed for the 2013 QPS list.

7.11. Lecanicillium muscarium

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

7.12. Metarhizium anisopliae

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

7.13. Paecilomyces lilacinus

The egg-parasitic fungus *Paecilomyces lilacinus*, a common soil hyphomycete, is a recognized efficient fungus for the control of root-knot nematodes *Meloidogyne* spp.. The majority of the 109 reports devoted to *Paecilomyces lilacinus* that have been published since the beginning of 2012 investigate its usefulness as a biocontrol agent. When the key words ‘human and infection’ were used,
12 papers reporting invasive human infection cases involving this opportunistic fungal pathogen were retrieved. Cutaneous infections were the most frequently reported cases (Keshtkar-Jahromi et al., 2012; Lavergne et al., 2012, Rimawi et al., 2013). Due to recognised human infection disorders, *Paecilomyces lilacinus* cannot be proposed for the 2013 QPS list.

### 7.14. *Penicillium* species

No new information on the lack of toxicity or toxins has been retrieved through a search in Thomson Reuters Web of Knowledge. For the *Penicillium* species listed in QPS 2011 update (EFSA, 2011a), *Penicillium camemberti*, *Penicillium chrysogenum*, *Penicillium funiculosum*, *Penicillium nalgiovense* and *Penicillium roqueforti* the reports deal with production of the specific products or food spoilage problems, therefore these species still are ineligible for a QPS recommendation.

### 7.15. *Phlebiopsis gigantea*

The recent search in Thomson Reuters Web of Knowledge did not reveal any new information of the general lack of toxicity of *Phlebiopsis gigantea*. Conclusion on the peer review of the pesticide risk assessment of the active substances *Phlebiopsis gigantea* strains was published in 2013 in the EFSA Journal (EFSA, 2013). This review highlights several data gaps to be filled, such as the potential of secondary metabolites/toxins production and the risk to non-target organisms. The knowledge concerning the capacity of *Phlebiopsis gigantea* to produce biological active secondary metabolites remains therefore insufficient and this species cannot be proposed for the QPS list.

### 7.16. *Pseudozyma flocculosa*

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

### 7.17. *Trichoderma* species

Nearly 1000 papers dealing with the genus *Trichoderma* have been retrieved in the time frame of the search. This substantial publishing activity mainly results from capacity of some species to produce large amounts of cellulolytic enzymes (440 reports) and the promising use of several *Trichoderma* species as biocontrol agents (90 reports).

#### 7.17.1. Taxonomy

The taxonomy of *Trichoderma* is constantly being improved by frequent publications on enhanced species descriptions based on phylogenetic analyses. These endeavours do not have any impact on taxonomic designations of species notified to EFSA. In light of the one name nomenclature for fungi it is proposed to protect the use of *Trichoderma* against *Hypocrea* (Rossman et al., 2013).

#### 7.17.2. *Trichoderma asperellum*

A literature search retrieved twenty-nine reports dealing with *Trichoderma asperellum*. Among these new papers, there were no relevant publications on the lack of toxicity or toxin production; in contrast production of peptaibols and the pyranone volatiles have been reported (Chen et al., 2013; Wickel et al., 2013). Most reports investigate the diversity of promising industrial use, which this species offers. The potential of *Trichoderma asperellum* as a biocontrol agent was the subject of several publications and patents, with for instance, an evaluation of control of potato wilt (Ommati and Zaker 2012).
Conclusion on the peer review of the pesticide risk assessment of the active substances *Trichoderma asperellum* strains was published in 2013 in the EFSA Journal (EFSA, 2013m). This review highlights several data gaps to be filled, such as the potential of secondary metabolites/toxins production and the risk to non-target organisms.

Based on the reports that *Trichoderma asperellum* is able to produce biological active secondary metabolites this species cannot be recommended for the QPS list.

### 7.17.3. *Trichoderma atroviride*

More than 500 papers were retrieved by a literature search with about half of them published within the last five years. Many scientific papers and patents published within recent years describe the potential of *Trichoderma atroviride* as an efficient biological control agent. Due to taxonomic confusion in the past this species has not been recommended for the QPS list (EFSA, 2009b); recently production of biological active peptaibols have been demonstrated (Degenkolb et al., 2012; Carroux et al., 2013), whereas none reports lack of toxicity or toxin production.

In conclusion, *Trichoderma atroviride* cannot be recommended for the QPS list.

### 7.17.4. *Trichoderma citrinoviride*

Due to taxonomic confusion isolates of *Trichoderma citrinoviride* may have been mis-identified in the past, which may explain that only 62 reports were retrieved by the literature search. Recently, the taxonomic delimitation of this species has been updated by Samuels et al. (2012) elaboration on previous work (Samuels et al., 1998). Several reports exploit the extra-cellular enzymes of *T. citrinoviride* for bioconversion and bioenergy production (e.g. Chandra et al., 2013; Toth et al., 2013), but as production of biological active peptaibols have been reported (Maddau et al., 2009), this species cannot be recommended for the QPS list.

### 7.17.5. *Trichoderma koningii*

*Trichoderma koningii* is a very well known species reported in nearly 900 references retrieved by a literature search. The taxonomic clarification of this and related species was published some years ago (Samuels et al., 2006) and is still used today. This species is reported to be useful to biological control of insects and other pathogens but also exploited for its production of enzymes. *Trichoderma koningii* has been reported to produce biological active peptaibols (Song et al., 2006), therefore this species cannot be recommended for the QPS list.

### 7.17.6. *Trichoderma longibrachiatum*

The majority of the twenty-nine papers that were retrieved by the literature search is concerning plant cell wall degrading enzymes (xylanase, cellulase, etc.). Among the retrieved information there were no concluding reports on the occurrence or lack of toxic secondary metabolites; however there was one report on *Trichoderma longibrachiatum* infection (Rodriguez Peralta et al., 2013). According to the insufficient information on the production of biological active secondary metabolites and the occurrence of clinical infection events, *Trichoderma longibrachiatum* cannot be given a QPS recommendation.

### 7.17.7. *Trichoderma reesei*

*Trichoderma reesei* is widely used for enzyme production and the need for toxicological evaluations was long time reported (Blumenthal, 2004). Since the QPS update in 2009 more than 1200 scientific
papers on *Trichoderma reesei* (syn. *Hypocrea jecorina*) have been published. Following publication of the *Trichoderma reesei* genome paper (Martinez et al., 2008), numerous gene clusters encoding biosynthetic pathways for secondary metabolites have been identified (Mukherjee et al., 2011). Among these gene clusters, the genes for non-ribosomal peptide synthetases (NRPSs) are the most important. These enzymes produce peptaibol compounds, which are known to disintegrate cell membranes causing apoptosis (Brückner and Graf, 1983). Degenkolb et al. (2012) demonstrated the production of more peptaibol families by *Trichoderma reesei* strains. At least eleven polyketide synthase gene clusters have been predicted in *Trichoderma reesei*; however, the products of these remain unknown (Baker et al., 2012).

The capacity of *Trichoderma reesei* to produce peptaibols and additional compounds with unknown biological activity makes *Trichoderma reesei* ineligible for QPS.

### 7.17.8. *Trichoderma viride*

*Trichoderma viride* is widely known for its production of cellulases and the beneficial use as a biological control agent. This is also reflected in the 165 papers and patents that were retrieved by the literature search. The production of peptaibols reported in the Opinion of 2012 (EFSA 2012a) has been substantiated by another report in 2013 (Röhrich et al., 2013) in addition to a report on biological active volatile compounds (Wickel et al., 2013). No new data were retrieved concerning the production of other classes of biological active metabolites or lack of such production. The body of knowledge remains limited and this species cannot be proposed for the QPS list.

### 7.18. *Verticillium albo-atrum*

Non-pathogenic strains of *Verticillium albo-atrum* are used as biocontrol agent to prevent Dutch elm disease by inducing the treated tree’s natural defence mechanisms. Using *Verticillium albo-atrum* as keyword leads to the identification of 38 publications published during 2012 and the five first months of 2013, identified through a literature search. Pathogenicity of this fungal species in relation to Wilt diseases of vegetable crops was the focus of main part of these 38 reports. In 2013, EFSA published the ‘conclusion on the peer review of the pesticide risk assessment of the active substance *Verticillium albo-atrum* (strain WCS850)’ (EFSA, 2013n).

Despite the apparent safe use as biocontrol agents of non-pathogenic isolates of *Verticillium albo-atrum*, it has not been possible through extensive literature searches to verify a general absence of biological active secondary metabolites from this species. *Verticillium albo-atrum* remains ineligible for QPS status in 2013.

### 7.19. Conclusions on filamentous fungi

The literature search that has been performed to establish this 2013 QPS opinion supports the conclusion of the previous review (EFSA, 2012a):

(i) the fungal taxonomy is in a rapid development as many phylogenetic studies are conducted and disclose new taxonomic units (i.e. phylogenetic species) leaving long-term recognized species with more narrow and clear boundaries. It has to be stressed that these studies seldom provides new information about the ecological properties and the function of the taxonomic units, which will be a major task in the future. The discontinuation of dual nomenclature for pleomorphic fungi will without any doubt require close attention in the years to come. The expected lists of recommended names to be used may result in nomenclatural changes to well-established fungal species. This issue needs to be dealt with in future QPS updates.
the increasing availability of fungal genome sequences could facilitate the discovery and characterization of numerous novel secondary metabolites by genome mining. Biosynthetic potential of numerous fungal strains will be successfully elucidated in a near future. While knowledge of fungal secondary metabolites accumulates exponentially, information on their toxic effects in humans and animals evolve at a much slower rate.

8. Oomycetes

8.1. *Pythium oligandrum*

*Pythium oligandrum* is a non-pathogenic soil oomycete that colonizes the root ecosystem of many crops and has the ability to protect plants from biotic stress in addition to promoting plant growth. This promising biocontrol agent was the subject of 25 publications published during 2012 and the five first months of 2013, identified through a PubMed and Web of knowledge search. The most recent advances concerning the mechanisms by which *Pythium oligandrum* can exert its efficient mycoparasitic activity were gathered in the review of Benhamou et al. (2012). In 2013, EFSA published the conclusion on the peer review of the pesticide risk assessment of the active substance *Pythium oligandrum* strain M1 (EFSA, 2013o). To determine whether *Pythium oligandrum* produces toxic secondary metabolites was one of the data gaps identified in this last report.

The literature review did not reveal any new information and because of a lacking body of knowledge this species remains ineligible for QPS status.

9. Viruses used for plant protection

9.1. Plant viruses

Viruses belonging to certain plant virus families are sometimes used for cross protection purposes, i.e. the application of mild strains of a plant virus is used to protect the food or feed crop against strains of the virus giving severe symptoms. The potential effects of such viruses on animals and/or humans, when applied to food or feed, were reviewed and assessed, and the results were published in the EFSA Opinions on QPS in 2009 (EFSA, 2009b), 2010 (EFSA, 2010), 2011 (EFSA, 2011a) and 2012 (EFSA, 2012a). Plant viruses do not replicate in organisms other than plants. The parts exposed to animal and/or humans are the coat protein(s) and the nucleic acid, in all but a few cases RNA.

9.1.1. *Alphaflexiviridae*

No scientific or other evidence was found that alphaflexiviruses (Family *Alphaflexiviridae*) or members thereof such as from the genus *Potexvirus* (Adams et al., 2011) have any negative effect on animals and humans to date. Viruses of this family have been reported from a wide range of herbaceous and woody plants, both mono- and dicotyledons. Species of this virus family are mostly plant-specific and are transmitted either mechanically or through insect vectors from plant to plant. In terms of safety, the familiarity principle was taken into account as well, in that these viruses have been part of the food and feed of animals since plant material was part of the food package. The major component of an alphaflex virus (e.g. Pepino mosaic virus), the coat protein, is tested computationally in 2013 against a plant database (UniRef100 plant database (UniProt NREF, 2013) and did not show any homology to known toxins. None of the hits were related to the search terms ‘disease’ or ‘toxins’. No other negative impacts of alphaflexiviruses, more specifically potexviruses such as Pepino Mosaic Virus (Genus *Potexvirus*) on humans or animals have been reported to date. Hence it was agreed that the family *Alphaflexiviridae*, as the highest taxonomic unit, is recommended for the QPS list.
Other relevant information

For other plant virus families interactions of some viruses with humans have been reported (Colson et al., 2010; Liu et al., 2013). For example, pepper mild mottle virus (PMMoV), a member of the *Tobamoviridae* family, is present in stools from healthy individuals, but it is found associated with higher frequency in individuals with clinical symptoms (Colson et al., 2010). Such patients appear to have a higher specific immune response to PMMoV (seropositivity). Recently, Liu et al. (2013) argued that antibodies against Tobacco Mosaic Virus (TMV, *Virgaviridae*) in humans, e.g. as a long-term consequence of smoking, interact with the human TOMM40L protein through a conserved amino acid stretch between TMV and TOMM40L. Such TMV antibodies are implied in the emergence of autoimmune diseases. However, a direct causal relationship between a plant virus and disease in humans, such as virus replication in cells or pathology has not been demonstrated.

9.1.2. *Potyviridae*

There was no scientific or other evidence that potyviruses (Family *Potyviridae*) or members thereof 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 of animals and humans since plant material was part of the food package. By computational analysis it was further found that the major component of a potyvirus (Zucchini yellow mosaic virus), the coat protein, did not show any homology to known toxins (Kuiper et al., 2001; Health Canada, 1999). Such an analysis was repeated in 2012 against a plant database (UniRef100 plant database (UniProt NREF, 2013)) and a general database (GenBank nt database, 2013) and none of the hits were related to ‘disease’ or ‘toxic’. Since the last major review by Kuiper et al. (2001), no new information has appeared which would compromise the conclusion drawn in 2012. No other negative impacts of potyviruses on humans or animals have been reported to date. Hence it was agreed that the family *Potyviridae*, as the highest taxonomic unit, is recommended for the QPS list.

9.2. Insect viruses

9.2.1. *Baculoviridae*

Viruses belonging to the family *Baculoviridae* and their potential effects on animals and humans, when applied to food or feed, were extensively reviewed and the results were published in the EFSA Opinion on QPS 2009 (EFSA, 2009b), 2010 (EFSA 2010), 2011 (EFSA 2011a) and 2012 (EFSA 2012a). It was concluded that there was no scientific or other evidence that baculoviruses to date have any negative effect on animals and humans when used appropriately. In addition the familiarity principle was taken into consideration as well, in that these viruses have been extensively used for over six decades as biocontrol agents of insect pests without any report describing a negative effect on humans or animals. The OECD already concluded in 2002 that baculoviruses were safe to use for products meant for human consumption (OECD, 2002). Baculoviruses were also classified as Risk Group 1 (RG1) agents, as they were not related to any disease of humans (Flemming and Hunt, 2000; Kost and Condrey, 2001). Hence it was agreed that the family *Baculoviridae* is the highest taxonomic unit that should receive a QPS recommendation in the registration process (EFSA 2009b, 2010, 2011a, 2012a).

Since the last major review, no new information, which would compromise the conclusion drawn in 2009, 2010, 2011 and 2012 has appeared. Further support for the safety of baculoviruses is taken from the fact that a number of baculovirus-derived products (recombinant proteins) have been registered including a vaccine against flu in 2012 or reached the market, such as vaccines against cervical cancer of humans (Harper, 2009; Szarewski, 2010), porcine circovirus for animals (Fort et al., 2009) and immunotherapeutics for human prostate cancer (Kantoff et al., 2010).
A matter of contention could be the observation that the budded virus (BV) phenotype of baculoviruses, that is responsible for the systemic infection of insect larvae, is able to infect vertebrate including mammalian cells and tissues (Hofmann et al., 1995) to serve as a gene delivery vehicle for recombinant protein production and gene therapy. The safety issues related to this particular application are discussed in detail in the 2011 QPS report and elsewhere (EFSA, 2011a; Kost and Condreay, 2001).

The QPS recommendation for the family *Baculoviridae* as the highest taxonomic unit was confirmed.
10. The 2013 updated list of QPS Status recommended biological agents in support of EFSA risk assessments

Table 1: The 2013 updated list of QPS Status recommended biological agents for safety risk assessments carried out by EFSA Scientific Panels and Units

<table>
<thead>
<tr>
<th>Gram-Positive Non-Sporulating Bacteria</th>
<th>Qualifications *</th>
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<tbody>
<tr>
<td><strong>Species</strong></td>
<td><strong>Qualifications</strong></td>
</tr>
<tr>
<td><em>Bifidobacterium</em></td>
<td></td>
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<tr>
<td>Bifidobacterium adolescentis</td>
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<tr>
<td>Bifidobacterium animalis</td>
<td></td>
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<tr>
<td><em>Corynebacterium glutamicum</em>**</td>
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<tr>
<td><em>Lactobacillus</em></td>
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<tr>
<td>Lactobacillus acidophilus</td>
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<tr>
<td>Lactobacillus amyloyticus</td>
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<tr>
<td>Lactobacillus amylovorus</td>
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<td>Lactobacillus alimentarius</td>
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<td>Lactobacillus aviaries</td>
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<td>Lactobacillus brevis</td>
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<tr>
<td>Lactobacillus buchneri</td>
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<tr>
<td>Lactobacillus casei ***</td>
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<tr>
<td>Lactobacillus cebloidiosus</td>
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<tr>
<td>Lactobacillus coryniformis</td>
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<td>Lactobacillus crispyatus</td>
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<td>Lactobacillus curvatus</td>
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<td>Lactobacillus delbrueckii</td>
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<tr>
<td>Lactococcus lactis</td>
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<tr>
<td>Leuconostoc citreum</td>
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<tr>
<td>Leuconostoc pseudomesenteroides</td>
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<tr>
<td>Oenococcus oeni</td>
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<tr>
<td>Pediococcus acidilactici</td>
<td></td>
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<tr>
<td>Propionibacterium freudenreichii</td>
<td></td>
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<tr>
<td>Streptococcus thermophilus</td>
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<tr>
<td><strong>Bacillus</strong></td>
<td></td>
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<tr>
<td>Bacillus amyloliquefaciens</td>
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<tr>
<td>Bacillus atrophaeus</td>
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<tr>
<td>Bacillus clausii</td>
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<tr>
<td>Bacillus coagulans</td>
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<tr>
<td>Geobacillus stearotherophilus</td>
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<tr>
<td><strong>Gram-Negative Bacteria</strong></td>
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<tr>
<td><strong>Species</strong></td>
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<tr>
<td><em>Gluconobacter</em></td>
<td></td>
</tr>
<tr>
<td><em>Qualifications</em></td>
<td></td>
</tr>
<tr>
<td>QPS only apply when the species is used for amino acid production</td>
<td></td>
</tr>
</tbody>
</table>

| QPS only apply when the species is used for amino acid production |

Absence of toxigenic activity.

Absence of toxigenic activity.
### Yeasts

<table>
<thead>
<tr>
<th>Species</th>
<th>Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Debaryomyces hansenii</strong></td>
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<tr>
<td><strong>Hanseniaspora uvarum</strong></td>
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</tr>
<tr>
<td><strong>Kluveromyces lactis</strong></td>
<td><strong>Kluveromyces marxianus</strong></td>
</tr>
<tr>
<td><strong>Komagataella pastoris</strong></td>
<td></td>
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<tr>
<td><strong>Lindnera jadinii</strong></td>
<td></td>
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<tr>
<td><strong>Ogataea angusta</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Saccharomyces bayanus</strong>**</td>
<td><strong>Saccharomyces cerevisiae†</strong>**</td>
</tr>
<tr>
<td><strong>Saccharomyces pastorianus</strong>**</td>
<td></td>
</tr>
<tr>
<td><strong>Schizosaccharomyces pombe</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Wickerhamomyces anomalus</strong>**</td>
<td></td>
</tr>
<tr>
<td><strong>Xanthophyllomyces dendrorhous</strong></td>
<td>(imperfect form <em>Phaffia rhodozyma)</em></td>
</tr>
</tbody>
</table>

### Virus

#### Plant viruses

#### Family

- **Alphaflexiviridae**
- **Potyviridae**

#### Insect viruses

#### Family

- **Baculoviridae**

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

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

***The previously described species ‘*Lactobacillus zeae*’ has been included in the species *Lactobacillus casei*.*

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

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

†† Yeast synonyms commonly used in the feed/food industry:

- **Wickerhamomyces anomalus**: synonym *Hansenula anomala*, *Pichia anomola*, *Saccharomyces anomalus*
- **Lindnera jadinii**: synonyms *Pichia jadinii*, *Hansenula jadinii*, *Tordopsis utilis*
- **Saccharomyces cerevisiae** synonym: *Saccharomyces boulardii*
- **Saccharomyces pastorianus**: synonym *Saccharomyces carlsbergensis*
- **Komagataella pastoris**: synonym *Pichia pastori*
- **Ogataea angusta**: synonym *Pichia angusta*
- **Debaromyces hansenii**: synonym *Candida famata*
CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Answer to the terms of reference (ToR):

ToR1.: Preparation of an update of the list of biological agents notified to EFSA Units and/or Scientific Panels such as Pesticides, FEEDAP and GMO for intentional use in feed and/or food or as sources of food and feed additives, enzymes and plant protection products for safety assessment.

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

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

All taxonomic units previously recommended for the QPS list were reviewed and confirmed. The notifications were assessed. *Gluconobacter oxydans* and *Alphaflexiviridae* were assessed for the first time and recommended for the QPS list. The information of the previous opinion was updated for the taxonomic units on the QPS list.

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

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

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

The knowledge of filamentous fungi notified to EFSA was updated. Although numerous data, published since the 2012 QPS opinion, have contributed to partially fulfil gaps of knowledge, too many unknowns remain in 2013 to allow a filamentous fungus to be recommended for the QPS list.

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

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

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

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

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

More information on the absence of resistance to antimycotics used for medical treatment of yeast infections in cases where viable cells are added to the food or feed chain is needed.

Concerning filamentous fungi, the same recommendations as those issued from the 2012 QPS opinion remain valid. Progresses have to be achieved to attain three main objectives:

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

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

(iii) an increased knowledge of the toxicological impact of fungal secondary metabolites.
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EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2013d. Scientific Opinion on the safety and efficacy of Lactobacillus brevis (DSM 23231), Lactobacillus buchneri (DSM 22501), Lactobacillus buchneri (NCIMB 40788—CNCM I-4323), Lactobacillus buchneri (ATCC PTA-6138) and Lactobacillus buchneri (ATCC PTA-2494) as silage additives for all species. EFSA Journal 2013;11(4):3168, 16 pp. doi:10.2903/j.efsa.2013.3168


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### APPENDIX

Appendix A. Microbial species from previous notifications and as notified to EFSA

<table>
<thead>
<tr>
<th>EFSA Panel/Unit</th>
<th>Microorganism species/strain</th>
<th>Intended use</th>
<th>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFront/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFront/ questionsList.jsf</a>)</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td><strong>Bacteria</strong></td>
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<tr>
<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
<td>Intended use</td>
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<td>Comments</td>
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<tr>
<td></td>
<td>subspecies plantarum strain D747</td>
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<tr>
<td>FEEDAP</td>
<td><em>Bacillus brevis</em> (= <em>Aneurinibacillus</em> and <em>Brevibacillus</em> species) Strains from <em>B. brevis</em> are now mostly <em>Brevibacillus</em> species and some are <em>Aneurinibacillus</em> species</td>
<td>Biomass for animal feed</td>
<td>EFSA-Q-2004-171 The EFSA Journal (2005) 230, 1-6 <a href="http://www.efsa.europa.eu/EFSA/efsalocale-1178620753812_1178620784006.htm">www.efsa.europa.eu/EFSA/efsalocale-1178620753812_1178620784006.htm</a></td>
<td>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).</td>
</tr>
<tr>
<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
<td>Intended use</td>
<td>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf</a>)</td>
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http://www.efsa.europa.eu/en/efsajournal/pub/3042.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.  
Publication by Jiménez et al. (2013) on the description of *Bacillus toyonensis* sp. nov., as a novel species of *Bacillus cereus* (Syst. Appl. Microbiol., 36, 383-391) |
<table>
<thead>
<tr>
<th>EFSA Panel/Unit</th>
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<th>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFrontend/QuestionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFrontend/QuestionsList.jsf</a>)</th>
<th>Comments</th>
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<td>FEEDAP</td>
<td><em>Bacillus firmus</em> = <em>Brevibacillus agri</em></td>
<td>Biomass for animal feed</td>
<td>No body of knowledge, therefore not appropriate for QPS (EFSA 2008). It will no longer be assessed for the QPS list unless new notification to EFSA (EFSA, 2010).</td>
<td></td>
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<tr>
<td>Pesticides</td>
<td><em>Bacillus firmus</em> I-1582</td>
<td>Plant protection product</td>
<td>A reassessed of this species was carried out in the QPS 2012 review and it was not recommended for the QPS list.</td>
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EFSA Journal 2013;11(11):3449 56
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<th>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFront/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFront/questionsList.jsf</a>)</th>
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| FIP             | *Bacillus licheniformis*    | Production of food enzyme | EFSA-Q-2012-00898  
The food enzyme is an alpha-amylase | Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010, 2011, 2012, 2013). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention. |
| FIP             | *Bacillus licheniformis*    | Production of enzyme | EFSA-Q-2013-00586  
| FIP             | *Bacillus licheniformis*    | Production of enzyme | EFSA-Q-2013-00685  
| FEEDAP          | *Bacillus megaterium*       | Production of vitamin C | EFSA-Q-2010-01290 amended EFSA-Q-number: EFSA-Q-2011-00250  
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EFSA-Q-2007-166 (withdrawn)  
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<th>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf</a>)</th>
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<tr>
<td><strong>FIP</strong></td>
<td><em>Bacillus subtilis</em> Strain MAM</td>
<td>Production of enzyme</td>
<td>EFSA-Q-2013-00790&lt;br&gt;The food enzyme is a glucan 1,4-α-maltohydrolase</td>
<td>Already QPS (EFSA, 2007). Qualification: Absence of toxigenic potential (see EFSA opinions, 2008, 2009, 2010, 2011, 2012, 2013). The possibility that new virulence factors, with activities different from those described previously could be discovered should be kept under attention.</td>
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<td>Pesticides</td>
<td>Bacillus subsp. thuringiensis israelensis (serotype H-14), strain AM 6552 = Bacillus thuringiensis serovar israelensis</td>
<td>Plant protection product</td>
<td>EFSA-Q-2009-00122 EFSA-Q-2009-00248 EFSA Journal 2013;11(1):3054 <a href="http://www.efsa.europa.eu/en/efsajournal/pub/3054.htm">www.efsa.europa.eu/en/efsajournal/pub/3054.htm</a></td>
<td>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.</td>
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<tr>
<td>Pesticides</td>
<td>Bacillus subsp. thuringiensis kurstaki (strains ABTS 351, PB 54, SA11, SA 12, EG 2348) = Bacillus thuringiensis serovar kurstaki</td>
<td>Plant protection product</td>
<td>EFSA-Q-2009-00123 EFSA-Q-2009-00249 EFSA Journal 2012;10(2):2540. [66 pp.] <a href="http://www.efsa.europa.eu/en/efsajournal/pub/2540.htm">www.efsa.europa.eu/en/efsajournal/pub/2540.htm</a></td>
<td>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.</td>
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<tr>
<td>FEEDAP</td>
<td>Bifidobacterium longum</td>
<td>Feed additive</td>
<td></td>
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<tr>
<td>GMO</td>
<td>Brevibacterium lactofermentum = Corynebacterium glutamicum</td>
<td>Dried killed biomass for feed</td>
<td>EFSA-Q-2007-157 (Applicant is going to withdraw application)</td>
<td></td>
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<tr>
<td>FIP (CEF Panel)</td>
<td>Carnobacterium maltaromaticum CNCM I-3298</td>
<td>Microbiological time temperature integrators used as ‘active and intelligent’ food contact materials</td>
<td>EFSA-Q-2011-00120</td>
<td>No QPS recommendation given because the species represents fish pathogens (EFSA, 2012)</td>
</tr>
<tr>
<td>FEEDAP</td>
<td>Corynebacterium glutamicum</td>
<td>Production of L-lysine sulphate</td>
<td>EFSA-Q-2011-00996</td>
<td>QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)</td>
</tr>
<tr>
<td>FEEDAP</td>
<td>Corynebacterium glutamicum (Brevibacterium flavum)</td>
<td>Production of L-lysine HCl or sulphate</td>
<td>EFSA-Q-2011-00991</td>
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<tr>
<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
<td>Intended use</td>
<td>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf</a>)</td>
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<tr>
<td>FEEDAP</td>
<td><em>Corynebacterium pekinese</em> = <em>Corynebacterium glutamicum</em></td>
<td>Production of L-lysine sulphate</td>
<td>EFSA-Q-2011-00995</td>
<td><em>Corynebacterium pekinese</em> is not a valid species name however used in the literature [<a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=corynebacterium+pekinense">www.ncbi.nlm.nih.gov/pubmed/?term=corynebacterium+pekinense</a> e.g. Ma W, Zhao Z, Wang Y, Zhang Y, Ding J. Wei Sheng Wu Xue Bao. 2012 Nov 4;52(11):1344-51. Chinese]</td>
</tr>
<tr>
<td>FEEDAP</td>
<td><em>Corynebacterium glutamicum</em></td>
<td>Production of L-tryptophan</td>
<td>EFSA-Q-2011-00946</td>
<td>QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)</td>
</tr>
<tr>
<td>FEEDAP</td>
<td><em>Corynebacterium glutamicum</em></td>
<td>Production of L-valine</td>
<td>EFSA-Q-2012-00377</td>
<td>QPS status applies only when the species is used for production purposes (EFSA opinion, 2007)</td>
</tr>
<tr>
<td>FEEDAP</td>
<td><em>Ensifer adhaerens</em></td>
<td>Production of vitamin B12</td>
<td>EFSA-Q-2012-00455, EFSA-Q-2012-00456</td>
<td>Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge</td>
</tr>
<tr>
<td>FEEDAP</td>
<td><em>Ensifer fredii</em></td>
<td>Production of vitamin B12</td>
<td>EFSA-Q-2012-00456</td>
<td>Not recommended for the QPS list, QPS 2011 update due to insufficient body of knowledge</td>
</tr>
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<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
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<td>EFSA-Q-2006-169 (withdrawn)</td>
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<td>EFSA-Q-2008-471 (withdrawn)</td>
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<td>EFSA-Q-2009-00202 (withdrawn)</td>
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<td>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFrontend/questions1_list.jsf">http://registerofquestions.efsa.europa.eu/roqFrontend/questions1_list.jsf</a>)</td>
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<td>EFSA-Q-2011-00965&lt;br&gt;EFSA-Q-2012-00245</td>
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<tr>
<td>FEEDAP</td>
<td>Enterococcus mundtii</td>
<td>Feed additive</td>
<td>EFSA-Q-2012-00454 EFSA-Q-2012-00419 EFSA-Q-2012-00422</td>
<td>No taxonomical unit within <em>Enterococcus</em> can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinion, 2007)</td>
</tr>
<tr>
<td>GMO</td>
<td>Escherichia coli</td>
<td>Dried killed biomasses for feed</td>
<td>EFSA-Q-2008-412a and EFSA-Q-2008-669a</td>
<td>QPS 2009, 2010 update. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.</td>
</tr>
<tr>
<td>FEEDAP</td>
<td>Escherichia coli</td>
<td>Dried killed biomasses for feed</td>
<td>EFSA-Q-2008-412b and EFSA-Q-2008-669b</td>
<td>QPS 2009, 2010 updates. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.</td>
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| FEEDAP          | *Escherichia coli*          | Feed additive L-threonine production | EFSA-Q-2012-00113  
EFSA-Q-2012-00114  
EFSA-Q-2012-00115  
EFSA-Q-2012-00116  
EFSA-Q-2012-00117  
EFSA-Q-2012-00118 | QPS 2009, 2010 updates. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available. |
| FEEDAP          | *Escherichia coli*          | Feed additive L-threonine production | EFSA-Q-2012-00113 | Is not recommended for the QPS list in the past. There is increasing evidence of pathogenicity (QPS 2009, 2010). |
| FEEDAP          | *Escherichia coli*          | Feed additive L-tryptophan production | EFSA-Q-2011-00946  
EFSA-Q-2011-00947  
EFSA Journal 2013;11(10):3368 [2 pp.].  
EFSA-Q-2011-00948  
EFSA-Q-2011-00949 | QPS 2009, 2010 updates. 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/efsajournal/pub/1178620753812_1211902391773.htm | QPS 2009, 2010 updates. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available. |
| FIP             | *Escherichia coli*          | To produce polyhydroxyalkanoate (PHA) = from the reaction of dextrose and 1,4 butanediol | EFSA-Q-2011-01080 | Additional data requested, expected in June 2013  
QPS 2009, 2010 updates. There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available. |
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<th>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFront/questionsList.jsf">http://registerofquestions.efsa.europa.eu/roqFront/questionsList.jsf</a>)</th>
<th>Comments</th>
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</table>
| FEEDAP          | *Eubacterium* sp.             | Reduce toxicity of mycotoxins | EFSA-Q-2003-052  
The EFSA Journal (2005) 169, 1-14  
www.efsa.europa.eu/efsajournal/11786/1178620753812_1178620782757.htm  
| FEEDAP          | BIOMIN® BBSH 797 - DSM 11798  
*Genus nov.* (formerly *Eubacterium*)  
*species nov* | Feed additive | EFSA-Q-2012-00719  
EFSA Journal 2013;11(5):3203 [18 pp.]  
| FEEDAP          | *Gluconobacter oxydans*      | Production of vitamin C | EFSA-Q-2011-00250  
EFSA Journal 2013;11(2):3102  
| FEEDAP          | *Ketogulonicigenium vulgare* | Production of vitamin C | EFSA-Q-2011-00250  
EFSA Journal 2013;11(2):3102  
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| FEEDAP          | *Lactobacillus acidophilus*      | Feed additive    | EFSA-Q-2003-115  
EFSA-Q-2003-055  
EFSA-Q-2006-135  
EFSA-Q-2008-377 (withdrawn)  
EFSA-Q-2010-00071  
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| FEEDAP         | *Lactobacillus brevis*       | Feed additive| EFSA-Q-2010-01304  
EFSA-Q-2011-00382  
EFSA Journal 2013;11(4):3168 [16 pp.].  
EFSA-Q-2011-00385  
EFSA Journal 2011;9(9):2368  
| FEEDAP         | *Lactobacillus buchneri*     | Feed additive| EFSA-Q-2010-01276  
EFSA Journal 2011;9(4):2138  
EFSA-Q-2011-00375  
EFSA Journal 2011;9(9):2359  
EFSA-Q-2011-00376  
EFSA Journal 2011;9(9):2361  
EFSA-Q-2011-00382  
EFSA Journal 2013;11(4):3168 [16 pp.].  
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<tr>
<td>FEEDAP</td>
<td><em>Lactobacillus cellobiosus</em></td>
<td>Feed additive</td>
<td></td>
<td>Not initially considered for QPS (see EFSA opinions 2007, 2008). QPS recommended 2009, 2010</td>
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<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
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<tr>
<td>FEEDAP</td>
<td><em>Leuconostoc oeno</em> = <em>Oenococcus oeni</em></td>
<td>Feed additive</td>
<td></td>
<td>Not initially considered for QPS (see EFSA opinion 2007, 2008) and recommended for the QPS list in 2009, 2010, 2011, 2012, 2013</td>
</tr>
<tr>
<td>EFSA Panel/Unit</td>
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<td>Intended use</td>
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| FEEDAP          | *Methylococcus capsulatus* | Biomass for animal feed | EFSA-Q-2004-171  
The EFSA Journal (2005) 230, 1-6  
www.efsa.europa.eu/EFSA/efsalocale-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  
www.efsa.europa.eu/EFSA/efsalocale-1178620753812_1178650355146.htm  
EFSA-Q-2009-00629  
EFSA Journal 2010; 8(1):1428 [8 pp.].  
EFSA-Q-2012-00064 | No body of knowledge, therefore not considered for QPS (EFSA, 2008) |
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<tr>
<td>FEEDAP</td>
<td><em>Propionibacterium freudenreichii shermanii</em></td>
<td>Feed additive</td>
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<td>Already QPS</td>
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<td>FEEDAP</td>
<td><em>Propionibacterium freudenreichii shermanii</em></td>
<td>Production of vitamin B12</td>
<td>EFSA-Q-2012-00456 EFSA-Q-2012-00457</td>
<td>Already QPS</td>
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<td>FEEDAP</td>
<td><em>Propionibacterium globosum</em> (=subspecies of <em>Propionibacterium freudenreichii</em>)</td>
<td>Feed additive</td>
<td></td>
<td>Not recommended for QPS (see EFSA opinion 2007, Appendix A). Identical with <em>P. freudenreichii</em> therefore included on QPS (EFSA, 2010)</td>
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<tr>
<td>Pesticides</td>
<td><em>Pseudomonas chlororaphis</em> strain MA342</td>
<td>Plant Protection Product</td>
<td>EFSA-Q-2008-618 Review report for the active substance <em>Pseudomonas chlororaphis</em>, EU-SANCO, 4204/VI/98-Final, March 2004</td>
<td>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.</td>
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<td>FEEDAP</td>
<td><em>Rhodopseudomonas palustris</em></td>
<td>Feed additive</td>
<td></td>
<td>Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.</td>
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<td>FEEDAP</td>
<td><em>Serratia rubidaea</em></td>
<td>Feed additive</td>
<td></td>
<td>Insufficient body of knowledge (EFSA 2009). It will no longer be assessed for the QPS list unless new notification to EFSA.</td>
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<td>FEEDAP</td>
<td><em>Streptococcus cremoris</em> = <em>L. lactis</em> subsp. cremoris</td>
<td>Feed additive</td>
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<td>Already QPS</td>
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<td>EFSA Panel/Unit</td>
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<td>FEEDAP</td>
<td><em>Streptococcus faecium</em> = <em>Enterococcus faecium</em></td>
<td>Feed additive</td>
<td>No taxonomical unit within <em>Enterococcus</em> can be considered as free of infectious strains. Therefore no recommendation for QPS status (EFSA opinions 2007, 2008, 2009, 2010). There is increasing evidence of pathogenicity, and this species will not longer be assessed unless new scientific information becomes available.</td>
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<td>FEEDAP</td>
<td><em>Streptococcus thermophilus</em></td>
<td>Feed additive</td>
<td>Already QPS</td>
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<td>FEEDAP</td>
<td><em>Streptomyces albus</em></td>
<td>Production of salinomycin sodium</td>
<td><em>Streptomyces</em> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)</td>
<td></td>
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<tr>
<td>FEEDAP</td>
<td><em>Streptomyces aureofaciens</em></td>
<td>Production of polyether monocarboxylic acid</td>
<td><em>Streptomyces</em> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)</td>
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<tr>
<td>FEEDAP</td>
<td><em>Streptomyces cinnamomensis</em></td>
<td>Production of monensin sodium</td>
<td><em>Streptomyces</em> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion 2008)</td>
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<td>Microorganism species/strain</td>
<td>Intended use</td>
<td>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: <a href="http://registerofquestions.efsa.europa.eu/roqFr">http://registerofquestions.efsa.europa.eu/roqFr</a> ontend/questionsL1_list.jsf)</td>
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<tr>
<td>Pesticides</td>
<td><em>Streptomyc es lydicus</em> strain WYEC 108 (ATCC 55445)</td>
<td>Plant protection product</td>
<td>EFSA-Q-2012-00775</td>
<td><em>Streptomyc es</em> spp. produce antibiotics, are therefore inappropriate for QPS (EFSA opinion, 2008).</td>
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<td>Yeasts</td>
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<td>FEEDAP</td>
<td><em>Hansenula polymorpha</em> = <em>Pichia angusta</em></td>
<td>Production of enzymes</td>
<td></td>
<td>Already QPS status applies only when species is used for production purposes (EFSA opinion, 2008, 2010)</td>
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<tr>
<td>EFSA Panel/Unit</td>
<td>Microorganism species/strain</td>
<td>Intended use</td>
<td>Additional information provided by the EFSA Scientific Unit (see also EFSA register of questions: [<a href="http://registerofquestions.efsa.europa.eu/roqFr">http://registerofquestions.efsa.europa.eu/roqFr</a> ontend/questionsList.jsf](<a href="http://registerofquestions.efsa.europa.eu/roqFr">http://registerofquestions.efsa.europa.eu/roqFr</a> ontend/questionsList.jsf))</td>
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<td>2148/2004/EC</td>
<td><em>Kluyveromyces marxianus var. lactis</em> K1</td>
<td>Feed additive</td>
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<tr>
<td>Reg(EC)773/2006</td>
<td><em>Kluyveromyces marxianus-fragilis</em></td>
<td>Feed additive</td>
<td></td>
<td>Already QPS</td>
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</tbody>
</table>
| FEEDAP          | Astaxanthin rich *Phaffia rhodozyma* = *Xanthophyllomyces dendrorhous* | Production of astaxanthin | EFSA-Q-2004-148  
www.efsa.europa.eu/EFSA/efsALocale-1178620753812_1178620783707.htm  
EFSA-Q-2003-112  
www.efsa.europa.eu/EFSA/efsALocale-1178620753812_1178620783707.htm | *Phaffia rhodozyma* was assessed not appropriate for QPS (EFSA opinion 2008) because of insufficient body of knowledge. Later recommended for the QPS list (EFSA, 2011) as it is the imperfect form of *Xanthophyllomyces dendrorhous* according to the 2011 revision of the yeast taxonomy. |
| FEEDAP          | *Komagella pastoris* = *Pichia pastoris*    | Production of enzyme | EFSA-Q_2006-025 (GMM)  
and related opinions:  
EFSA-Q-2009-00804:  
EFSA-Q-2011-00148  
Other applications:  
EFSA-Q-2010-00152 (GMM)  
EFSA-Q-2013-00022 (GMM) | FEEDAP          | *Saccharomyces cerevisiae* | Organic selenium source | EFSA-Q-2005-071  
EFSA-Q-2005-117 |
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|                |                            | Production of enzyme | The EFSA Journal (2006) 348, 1-40  
EFSA-Q-2008-381  
EFSA-Q-2009-00524  
EFSA Journal 2011;9(6):2279  
EFSA-Q-2009-00752  
EFSA Journal 2011;9(4):2110  
EFSA-Q-2010-01029  
EFSA Journal 2012;10(7):2778 [17 pp.]  
EFSA-Q-2005-224 (withdraw)  
EFSA-Q-2009-00534 (GMM)  
EFSA Journal 2011;9(12):2451 [19 pp.]  
and related application:  
EFSA-Q-2012-00909  
EFSA Journal 2013;11(7):3286 [8 pp.]  
| FEEDAP        | Saccharomyces cerevisiae    |                          |  | |

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| FEEDAP         | *Saccharomyces cerevisiae*  | Feed additive | EFSA-Q-2005-025  
EFSA-Q-2005-234  
EFSA-Q-2005-149  
EFSA-Q-2005-176  
EFSA-Q-2006-003  
EFSA-Q-2006-067  
EFSA-Q-2007-104  
EFSA-Q-2007-139  
EFSA-Q-2007-165  
EFSA Journal 2009;7(10):1353  
EFSA-Q-2008-009  
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| GMO             | *Saccharomyces cerevisiae*   | Dried killed biomass for feed | EFSA-Q-2007-156b (withdrawn)  
EFSA-Q-2009-00866 (withdrawn) |           |
| FEEDAP          | *Schizosaccharomyces pombe*  | Production of enzymes | EFSA-Q-2005-063  
and related questions:  
EFSA-Q-2005-080  
The EFSA Journal (2006) 404, 1-20  
EFSA-Q-2008-272  
EFSA-Q-2011-00835  
The EFSA Journal 2012;10(3):2619 [9 pp.].  
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<td>FEEDAP</td>
<td><em>Trichosporon mycotoxinivorans</em></td>
<td>Feed additive</td>
<td>EFSA-Q-2010-01030 (withdrawn)</td>
<td>Not recommended for the QPS list, assessed in the 2011 update (EFSA, 2011)</td>
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<td><strong>Filamentous fungi</strong></td>
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| FEEDAP          | *Aspergillus niger*         | Production of Enzyme | EFSA-Q-2008-013  
The EFSA Journal (2008) 914, 1-19  
and related Questions:  
EFSA-Q-2010-00937  
EFSA Journal 2011;9(5):2172  
EFSA-Q-2011-00061  
EFSA Journal 2013;11(7):3285 [10 pp.].  
EFSA-Q-2010-01519  
| FIP             | *Aspergillus niger* strain NZYM-BR | Production of enzyme | EFSA-Q-2013-00686  
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| 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/efsalocal2178620753812_1178620764493.htm  
EFSA-Q-2007-001  
The EFSA Journal (2008) 674, 1-66  
| FEEDAP | *Blakeslea trispora* | Production strain for beta-carotene | EFSA-Q-2009-00884  
EFSA Journal 2012;10(6):2737 [33 pp.].  
| NDA | *Blakeslea trispora* | Food ingredient | EFSA-Q-2004-169  
The EFSA Journal (2005) 212, 1-29  
www.efsa.europa.eu/EFSA/efsalocal21178620753812_1178620765774.htm  
EFSA-Q-2008-697  
| Pesticides | *Coniothyrium minitans* | Plant protection product | EFSA-Q-2008-515  
| FEEDAP | *Duddingtonia flagrans* | Feed additive | EFSA-Q-2004-115  
www.efsa.europa.eu/EFSA/efsalocal21178620753812_1178620783270.htm  
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<td><strong>FEEDAP</strong></td>
<td><em>Trichoderma citrinoviride</em></td>
<td>Production of enzyme</td>
<td>EFSA-Q-2010-00036 EFSA Journal 2013;11(2):3105 <a href="http://www.efsa.europa.eu/en/efsajournal/pub/3105.htm">www.efsa.europa.eu/en/efsajournal/pub/3105.htm</a></td>
<td>This was submitted as <em>Trichoderma longibrachiatum</em> but the assessment revealed that should be classified differently. New assessment for QPS 2013 update</td>
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<td><strong>FEEDAP</strong></td>
<td><em>Trichoderma koningii</em></td>
<td>Production of enzyme</td>
<td>EFSA-Q-2008-288 EFSA Journal 2012;10(7):2843 [13 pp.]. <a href="http://www.efsa.europa.eu/en/efsajournal/pub/2843.htm">www.efsa.europa.eu/en/efsajournal/pub/2843.htm</a></td>
<td>This was submitted as <em>Trichoderma longibrachiatum</em> but the assessment revealed that should be classified as koningii. New assessment for QPS 2013 update</td>
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| FEEDAP         | *Trichoderma reesei*        | Production of enzyme | EFSA-Q-2006-137  
and related opinions:  
EFSA-Q-2007-0020  
The EFSA Journal (2009) 1156, 1-25  
EFSA-Q-2007-109  
The EFSA Journal (2007) 586, 1-12  
EFSA-Q-2007-112  
EFSA-Q-2007-185  
EFSA-Q-2009-00470  
EFSA-Q-2010-00141  
EFSA Journal 2010;8(12):1916 [22 pp.]  
EFSA-Q-2009-00802  
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<td>EFSA-Q-2010-00142</td>
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<td>EFSA Journal 2011;9(6):2277</td>
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<td>EFSA-Q-2012-00693 and EFSA-Q-2012-00905</td>
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| FEEDAP          | *Trichoderma reesei*        | Production of enzyme | EFSA-Q-2008-308  
The EFSA Journal (2009) 1094, 1-17  
and related questions:  
EFSA-Q-2010-00018  
EFSA-Q-2008-432  
The EFSA Journal (2009) 1186, 1-17  
EFSA-Q-2008-748  
EFSA Journal 2009;7(11):1380 [27 pp.].  
and related opinion:  
EFSA-Q-2010-0069  
EFSA Journal 2010; 8(3):1553 [4 pp.]  
EFSA-Q-2010-00141  
EFSA Journal 2010;8(12):1916 [22 pp.]  
EFSA-Q-2011-00112  
EFSA Journal 2011;9(3):2111 [5 pp.]  
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<td>FEEDAP</td>
<td><em>Trichoderma viride</em></td>
<td>Production of enzyme</td>
<td>EFSA-Q-2010-01295 EFSA-Q-2010-01297</td>
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<td><strong>Oomycetes</strong></td>
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<td>FEEDAP</td>
<td><em>Haematococcus pluvialis</em></td>
<td>Production of astaxanthin</td>
<td>No body of knowledge except for this strain. Therefore not considered for QPS (EFSA opinion 2008)</td>
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<td><strong>Bacteriophages</strong></td>
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<td>FEEDAP</td>
<td><em>Clostridium sporogenes</em> phage</td>
<td>Feed additive</td>
<td>QPS 2009, 2010 updates, no recommendation to the QPS list because phages are subject to a case-by-case assessment</td>
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<td>FEEDAP</td>
<td><em>Clostridium tyrobutyricum</em> phage</td>
<td>Feed additive</td>
<td>QPS 2009, 2010 updates, no recommendation to the QPS list because phages are subject to a case-by-case assessment</td>
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<td>BIOHAZ</td>
<td><em>Listeria monocytogenes</em> phage</td>
<td>Food surface decontamination</td>
<td>Phages were already assessed in QPS 2009, 2010 updates and they are subject to a case-by-case assessment</td>
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<td><strong>Viruses</strong></td>
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<td>Pesticides</td>
<td><em>Pepino Mosaic Virus</em></td>
<td>Plant protection product</td>
<td>EFSA question number not yet attributed Dossier not yet provided to EFSA</td>
<td>New assessment for QPS 2013 update</td>
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Yeast Synonyms commonly used in the feed/food industry:
- *Wickerhamomyces anomalus*; synonym *Hansenula anomala, Pichia anomala, 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*


