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Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA[1]

Opinion of the Scientific Committee

(Question No EFSA-Q-2005-293)

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SCIENTIFIC COMMITTEE MEMBERS

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SUMMARY

A wide variety of microbial species are used in food and feed production. Some have a long history of apparent safe use, while others are less well understood and their use may represent a risk for consumers. Experience has shown that there is a need for a tool for setting priorities within the risk assessment of those microorganisms used in food/feed production referred to EFSA and consequently the subject of a formal assessment of safety. To meet this need a system was proposed for a pre-market safety assessment of selected groups of microorganisms leading to a "Qualified Presumption of Safety (QPS)". In essence this proposed that a safety assessment of a defined taxonomic group (*e.g.* genus or group of related species) could be made based on four pillars (establishing identity, body of knowledge, possible pathogenicity and end use). If the taxonomic group did not raise safety concerns or, if safety concerns existed, but could be defined and excluded (the qualification) the grouping could be granted QPS status. Thereafter, any strain of microorganism the identity of which could be unambiguously established and assigned to a QPS group would be freed from the need for further safety assessment other than satisfying any qualifications specified. Microorganisms not considered suitable for QPS would remain subject to a full safety assessment.

EFSA asked its Scientific Committee to consider whether this system could be used to harmonise approaches to the safety assessment of microorganisms across the various EFSA scientific panels. If so, the Committee was requested to develop a strategy for the introduction of an assessment system based on the QPS concept.

[1] For citation purposes: Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. *The EFSA Journal* (2007) 587, 1-16

The Scientific Committee reviewed the range and numbers of microorganisms likely to be the subject of an EFSA opinion. They found that approximately 100 species of microorganisms have been or are expected to be referred to EFSA for a safety assessment; the majority being the result of notifications for market authorisation as sources of food and feed additives, food enzymes and plant protection products. A large majority of these species were found to fall within four broad groupings: i) Gram-positive non-sporulating bacteria; ii) *Bacillus* species, iii) yeasts and iv) filamentous fungi. Accordingly, bacteria, yeasts and fungi falling within these four groups were selected for an initial assessment of their suitability for QPS status. The Scientific Committee concluded that the weight of evidence available for many species falling within the first three of the four groups was sufficient to ensure that QPS status provided at least the same degree of confidence as a case-by-case safety assessment. However, the Committee found that, in the case of the filamentous fungi, the body of knowledge, particularly that relating to a history of use, was for a specific purpose and did not allow extrapolation to other uses to be made with confidence and so could not recommend QPS status for such fungi.

As the number of organisms considered suitable for QPS status is sufficiently extensive to cover a majority of the safety assessments involving microorganisms required of EFSA, the Scientific Committee concluded that the introduction of a QPS system for microorganisms would meet the objectives of providing a practical tool for setting priorities and avoiding the extensive investigations of organisms known not to cause concern. Although QPS status of metabolic products of microorganisms cannot be inferred from the QPS status of the production strain, the Committee considered that the system still had value for the assessment of strains used in the production of such products. Further work, however, would be required to extend the system to encompass those microorganisms used for biological control purposes.

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

Key words:

Safety assessment, microorganisms, qualified presumption of safety, QPS, *Bacillus*, yeast, filamentous fungi, Gram-positive non-sporulating bacteria, lactic acid bacteria

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BACKGROUND

A wide variety of bacterial and fungal species are used in food and feed production, either directly or as a source of additives or food enzymes. Some of these have a long history of apparent safe use, while others are less well understood and may represent a risk for consumers. Experience has shown that there is a need for a tool for setting priorities within the risk assessment of those microorganisms used in the production of food/feed which are captured by present legislation and consequently the subject of a formal assessment of safety. Ideally such an assessment tool would allow the identification of risk without committing resources to extensive investigations of organisms known to be safe.

In 2002/3 a working group consisting of members of the former Scientific Committees on Animal Nutrition, Food and Plants of the European Commission proposed the introduction for selected microorganisms of a Qualified Presumption of Safety (QPS)[2].

In essence this proposed that a safety assessment of a defined taxonomic group (e.g. genus or group of related species) could be made independently of any particular pre-market authorisation process. If the taxonomic group did not raise safety concerns or, if safety concerns existed but could be defined and excluded (the qualification) the grouping could be granted QPS status. Thereafter any strain of microorganism the identity of which could be unambiguously established and assigned to a QPS group would be freed from the need for further safety assessment other than satisfying any qualifications specified. Those strains failing to satisfy a qualification would be considered hazardous and, in the absence of mitigating circumstances, unfit for purpose. Microorganisms not considered suitable for QPS would remain subject to a full safety assessment.

In April 2003, responsibility for the safety assessments of food/feed undertaken by the Scientific Committees of the Commission formally passed to the European Food Safety Authority (EFSA). Shortly after EFSA asked its own Scientific Committee to consider whether the approach to safety assessment of microorganisms proposed in the QPS document could be used to harmonise approaches to the safety assessment of microorganisms across the various EFSA scientific panels. In doing so, the Committee was requested to take into account the response of the stakeholders to the QPS approach. Their views had been sought by the three Commission Scientific Committees in 2002/3 and, subsequently, by EFSA at a Scientific Colloquium organised at the end of 2004 (EFSA 2005b).

The Scientific Committee concluded that QPS as a concept could provide a generic assessment system *for use within EFSA* that could be applied to all requests received for the safety assessments of microorganisms deliberately introduced into the food chain (EFSA 2005a). The benefits of the introduction of QPS would be a more transparent and consistent approach across the EFSA panels and the potential to make better use of resources by focussing on those organisms which presented the greatest risks or uncertainties.

[2] See http://ec.europa.eu/food/fs/sc/scf/out178_en.pdf

However, the Committee stressed that 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. Judgement as to whether the existing data are sufficient needed, in the view of the Committee, to be determined by an expert group established for this purpose and should be based on a weight-of-evidence approach.

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

EFSA accepted the recommendation of its Scientific Committee and proposed that the Committee should continue its assessment of the QPS system with a view to implementation[3]. Specifically, the Scientific Committee was asked first to establish which were the microorganisms most commonly referred to EFSA, including those used as a source of microbial products. Then, on the basis of this survey, to select relevant groups of microorganisms, examine the available data on safety and propose whether QPS status would be appropriate. If this proved possible in a significant number of cases then the Scientific Committee should consider how implementation of QPS across the various panels could be achieved.

TERMS OF REFERENCE AS PROVIDED BY EFSA

In response to its Opinion on the potential value of the QPS approach, the Scientific Committee is now requested by the European Food Safety Authority:

1. To establish which are the microorganisms most commonly referred to EFSA. This to include both organisms deliberately introduced into the food chain and those used as a source of microbial products entering the chain.

2. To select appropriate and relevant groups of microorganisms and, with the help of additional experts as necessary, to determine whether QPS status should be given.

3. Thereafter, to advise whether QPS represents a practical and robust method of safety assessment for microorganisms and, if so, to consider how the QPS could be applied across EFSA within the framework of the current and proposed legislation.

[3] See http://www.efsa.europa.eu/en/science/sc_commitee/sc_documents/1368.html

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ASSESSMENT

1. Questions to EFSA involving microorganisms

Approximately 100 species of microorganisms have been or are expected to be referred to EFSA for a safety assessment. The majority are the result of notifications for market authorisation as sources of food and feed additives, food enzymes and plant protection products. Others are the subject of the GMO and novel food/feed legislation. A few microbial species are also the subject of requests for opinions relating to consumer or animal safety not directly linked to product authorisation or to legislative requirements. Generally such requests relate to human enteropathogens or veterinary pathogens and so are beyond the scope of any consideration for QPS. Microorganisms referred to EFSA include both live organisms deliberately introduced into the food chain and those used as a source of food/feed additives and food enzymes. Individual species may be the subject of a single notification but more usually are found in several notifications. A large majority of these approximately 100 species were found to fall within four broad groupings:

1. Gram-positive non-sporulating bacteria (GPNS)
2. *Bacillus* species
3. Yeasts
4. Filamentous fungi

Accordingly, bacteria and fungi falling within these four groups were selected for an initial assessment of their suitability for QPS status. Organisms falling outside the four broad groups are infrequently notified. The Scientific Committee considers that such organisms could be considered for QPS at a later date but, in the interim, should continue to be assessed on a case-by-case basis. This would include viruses which are the occasional subject of notifications.

It should be noted that QPS status is taken to apply strictly to the microorganism and not to any traded product containing the organism or to a product of the microorganism. The Scientific Committee recognises that the final formulation may, on rare occasions, introduce additional hazards needing assessment. In addition, QPS status informs only on the safety of a microorganism and should be used without prejudice to any other requirements of legislation.

2. Consideration for QPS status

The suitability of various taxonomic groups falling under the four broad headings for QPS status was examined by working groups of the Scientific Committee. Their preliminary proposals for suitable candidates for QPS status and the documentation supporting these conclusions were made available for public consultation. Interested parties were invited in particular to comment on whether the weight of evidence presented was sufficient to ensure that QPS status provides at least the same degree of confidence as a case-by-case safety assessment, whether this was adequately documented and whether there were issues that have not been sufficiently considered.

Responses from some thirty individuals and organisations were received, principally from trade organisations and companies, but including scientists from a number of European academic institutions, trade associations and national food safety authorities. Relatively few comments were directed to the specifics of the analyses of suitability for QPS status. Most were concerned with more general issues, some positive and others raising matters which were considered insufficiently developed. Concerns remain about the status of QPS in relation to existing and future legislation recognising that the application of QPS by EFSA could have implications for risk managers. The issue of how a QPS list would be maintained was also raised, since scientific developments might require a species to be withdrawn or allow a species to be added. There were also concerns about the continuing emphasis on the absence of acquired antibiotic resistance determinants as a qualification in bacteria and that a restriction on end-use was not more generally applied to allow additional organisms to be considered suitable for QPS, particularly amongst the filamentous fungi.

All of the comments received were taken into consideration when reviewing and revising the conclusions on suitability for QPS status. The organisms which the Scientific Committee considers suitable for QPS status is given in Table 1. For convenience this is given as a list of presently-recognised species. Where QPS status is proposed, the Scientific Committee is satisfied that the body of knowledge available is sufficient to provide adequate assurance that any potential to produce adverse effects in humans, livestock or the wider environment is understood and capable of exclusion.

A summary of some of the specific issues arising within each of the four broad groupings is highlighted below. Otherwise the scientific justifications for inclusion in this list are given in the individual reports on the four groupings (Appendices A-D). These reports take a common structure based around the four pillars of the assessment for suitability for QPS status (establishing identity, body of knowledge, possible pathogenicity and end use) following the general scheme previously published[4]. The current state of knowledge and the very different nature of the organisms involved, however, have meant that the emphasis and content within the four reports inevitably differs. Each individual report is a summary of extended considerations based on a thorough review of the available scientific literature and the knowledge and experience of the scientists involved. Where literature is cited, this is to support key conclusions or more generally to illustrate an issue.

[4]See http://www.efsa.europa.eu/etc/medialib/efsa/science/colloquium_series/no2_qps/948.Par.0015.File.dat/summary_report1.pdf , page 16

Table 1. **List of taxonomic units proposed for QPS status**

Gram-Positive Non-Sporulating Bacteria[5]			
Species			**Qualifications**
Bifidobacterium adolescentis *Bifidobacterium animalis*	*Bifidobacterium bifidum* *Bifidobacterium breve*	*Bifidobacterium longum*	
Corynebacterium glutamicum			QPS status applies only when the species is used for production purposes.
Lactobacillus acidophilus *Lactobacillus amylolyticus* *Lactobacillus amylovorus* *Lactobacillus alimentarius* *Lactobacillus aviaries* *Lactobacillus brevis* *Lactobacillus buchneri* *Lactobacillus casei* *Lactobacillus crispatus* *Lactobacillus curvatus* *Lactobacillus delbrueckii*	*Lactobacillus farciminis* *Lactobacillus fermentum* *Lactobacillus gallinarum* *Lactobacillus gasseri* *Lactobacillus helveticus* *Lactobacillus hilgardii* *Lactobacillus johnsonii* *Lactobacillus kefiranofaciens* *Lactobacillus kefiri* *Lactobacillus mucosae* *Lactobacillus panis*	*Lactobacillus paracasei* *Lactobacillus paraplantarum* *Lactobacillus pentosus* *Lactobacillus plantarum* *Lactobacillus pontis* *Lactobacillus reuteri* *Lactobacillus rhamnosus* *Lactobacillus sakei* *Lactobacillus salivarius* *Lactobacillus sanfranciscensis* *Lactobacillus zeae*	
Lactococcus lactis			
Leuconostoc citreum	*Leuconostoc lactis*	*Leuconostoc mesenteroides*	
Pediococcus acidilactici	*Pediococcus dextrinicus*	*Pediococcus pentosaceus*	
Propionibacterium. freudenreichii			
Streptococcus thermophilus			

[5] Absence of acquired antibiotic resistance should be systematically demonstrated unless cells are not present in the final product (EFSA, 2005c).

Table 1 (cont'd). **List of taxonomic units proposed for QPS status**

Bacillus[6]			
Species			**Qualifications**
Bacillus amyloliquefaciens	*Bacillus lentus*	*Bacillus pumilus*	Absence of emetic food poisoning toxins with surfactant activity.*
Bacillus atrophaeus	*Bacillus licheniformis*	*Bacillus subtilis*	Absence of enterotoxic activity.*
Bacillus clausii	*Bacillus megaterium*	*Bacillus vallismortis*	
Bacillus coagulans	*Bacillus mojavensis*	*Geobacillus stearothermophillus*	
Bacillus fusiformis			

* When strains of these QPS units are to be used as seed coating agents, testing for toxic activity is not necessary, provided that the risk of transfer to the edible part of the crop at harvest is very low (section 4.3 of Appendix B).

Yeasts			
Species			**Qualifications**
Debaryomyces hansenii			
Hanseniaspora uvarum			
Kluyveromyces lactis	*Kluyveromyces marxianus*		
Pichia angusta	*Pichia anomala*		
Saccharomyces bayanus	*Saccharomyces cerevisiae*	*Saccharomyces pastorianus (synonym of Saccharomyces carlsbergensis)*	S. cerevisiae, subtype S. boulardii is contraindicated for patients of fragile health, as well as for patients with a central venous catheter in place. A specific protocol concerning the use of probiotics should be formulated
Schizosaccharomyces pombe			
Xanthophyllomyces dendrorhous			

2.1. Gram-positive non-sporulating bacteria

Many of the referred microorganisms falling within this grouping are normal inhabitants of the digestive tract of humans and livestock or are commonly used in the preparation of foods and feed. Consequently, there has been a long history of human exposure with only very occasional reports of adverse effects and then only amongst compromised individuals. However, amongst the microorganisms referred to EFSA, two particular groups of microorganisms raised issues requiring particular attention. The most important was the consideration given to the enteroccoci. Bacteria in the genus *Enterococcus* are amongst the leading causes of community- and hospital-acquired (nosocomial) infections. Infections often result from *Enterococcus faecalis*, but there are also virulent strains found within *E. faecium*, the species of *Enterococcus* most commonly deliberately introduced into the food chain. Although a considerable amount is known about the virulence determinants in enteroccoci, given the prevalence of enteroccocal infections, the Scientific Committee verged on the side of caution and did not propose QPS status for *Enterococcus* species, as at present it is not possible readily to distinguish between virulent and non-virulent strains without resorting to the level of investigation used in a case-by-case assessment. This position could be reviewed as it becomes clearer which are the key determinants of virulence and as suitable molecular probes for such determinates are developed.

The second issue highlighted the debate about the distinction between opportunistic infections, of which almost all microorganisms that humans commonly encounter are capable, and pathogenicity. Many *Lactobacillus* species have been occasionally encountered in clinical specimens, the clinical significance of which is not always clear. Such occurrences have almost invariably been associated with immunocompromised patients, those who had suffered surgical or accidental insult or who had a serious underlying illness, and remain rare. As such, these infections can be considered opportunistic and beyond the capacity of any safety assessment to exclude. Although a number of *Lactobacillus* spp. have been reported to infect otherwise healthy individuals with a history of rheumatic endocarditis or following heart valve replacement, one species, *L. rhamnosus*, appears to predominate. This organism could be considered on the edge of being defined as pathogenic. The Scientific Committee took the view that the at-risk population is not placed at added risk by the use of *L. rhamnosus* in food/feed and so confirmed the proposed QPS status of this bacterium. The Committee considers that this is a decision which should be reviewed at regular intervals.

2.2. Bacillus species

The Scientific Committee is of the opinion that the use of strains from the *B. cereus* group should be avoided whenever there is a possibility of human exposure whether intended or incidental. The *B. cereus* group is therefore excluded from consideration for QPS status.

There is an artificial distinction held between *B. cereus* and *B. thuringiensis* (used for plant protection) which has little scientific basis. The plasmid encoding the insecticidal enterotoxin, which provides the phenotypic distinction for *B. thuringiensis*, is readily lost, particularly when grown at 37^{o}C, leaving an organism indistinguishable from *B. cereus*. Consequently it is likely

that *B. thuringiensis* has been the causative organism of some instances of food poisoning but identified as *B. cereus* because clinical investigations would have failed to recognise the distinguishing features characteristic of *B. thuringiensis*.

However, the Scientific Committee recognises that *B. thuringiensis* has value to the industry as a means of biological pest control and that its widespread use for this purpose may not lead to significant human exposure.

Although occasional strains of *Bacillus* not falling within the *B. cereus* group also produce human enterotoxins, experience gained with *B. cereus* has provided the tools for their exclusion. This is recognised as a qualification in recommending QPS status for other *Bacillus* species.

2.3. Yeasts

Yeasts used in food production, particularly brewers/bakers yeast, are considered amongst the safest of microorganisms. However, even amongst this group there are reports of very occasional invasive infections. A sub-type of *Saccharomyces cerevisiae*, commonly referred to as *Saccharomyces boulardii* has been used as an adjunct to the antibiotic treatment of persistent diarrhoea often arising from *Clostridium difficile* infections, to reduce the likelihood of reoccurrence. This subtype has been isolated from the blood in approximately half of the reported invasive infections involving *Saccharomyces*. The majority of these cases occurred in compromised individuals. However this has to be placed in context. Despite the continuous and universal exposure to this yeast there have been less than a hundred documented cases of invasive infection by *Saccharomyces* spp., half of which occurred amongst those undergoing aggressive antibiotic treatment. As the at-risk group results from a strictly medical application without implication for the healthy population, the Scientific Committee did not see a reason to exclude *Saccharomyces* and so confirmed the proposed QPS status of this genus.

2.4. Filamentous fungi

The filamentous fungi could not be included within the QPS system. Although in many cases there has been a history of use, this has been for specific purposes such as the production of citric acid or processing enzymes. The body of knowledge that has developed has, in consequence, centred on these uses. However, many of the filamentous fungi used for production purposes are known to produce substances of potential concern (mycotoxins, *etc*).

The strength of the QPS lies in the ability to provide a generic system of safety assessment. This can be extended in scope by introducing a limited number of qualifications, allowing the majority of a taxonomic group to be assumed safe while excluding a minority of problematic strains. On examination, while it was possible to identify specific metabolites of filamentous fungi which should be excluded, it was not possible to be sure that these represented the totality of substances of concern capable of being produced by the taxonomic unit. Introducing restricted use as a qualification did not offer a solution since purpose does not offer any reassurance on overall metabolic capacity. The absence of undesirable compounds in one or

more selected production strains does not allow extrapolation to all strains within the selected taxonomic unit.

3. QPS as a tool for the assessment of the safety of microorganisms

3.1. Value to EFSA of QPS as an assessment tool

The list of organisms in Table 1 is sufficiently extensive to cover a large majority of the safety assessments involving microorganisms required of EFSA. Consequently, the Scientific Committee considers the introduction of a QPS system for microorganisms would meet the original objectives of providing a practical tool for setting priorities and avoiding the extensive investigations of organisms already known to be safe.

Although QPS status of metabolic products of microorganisms cannot be inferred from the QPS status of the production strain, the system still has considerable value for the assessment. Microbial products (*e.g.* enzymes, organic acids, amino acids) used in food/feed are rarely the primary source of possible concerns. Most case-by-case assessments focus on the presence of other metabolites which might be carried through to the final product. The QPS status of the production strain would provide the assurance that any metabolites other than that intended which are found in the final product would not be hazardous. This would simplify and greatly assist the assessment process.

Genetically modified microorganisms (GMMs) are the subject of specific legislation, whether used directly and released into the environment (Regulation 1829/2003[6], Directive 2001/18/EC[7]) or used under containment as a source of specific products (Directive 98/81/EC[8]). In the simplest case, that of self-cloning, the QPS status of the parent strain should be accepted and extrapolated to the modified strain without further need for assessment (EFSA 2006). Whenever foreign genetic material is introduced in a GMM, QPS is most likely to be of relevance to the recipient strain and only rarely to the source of the introduced trait. When the recipient strain has QPS status, then the assessment is free to focus on the introduced trait(s), relying on the reviewed body of knowledge to exclude potential hazards arising from the recipient strain.

QPS in its present form does not offer a generic approach to the safety assessment of microorganisms used as biological control agents. Most are based on filamentous fungi or bacteria hazardous to humans when they are directly exposed. Indeed the protection offered to plants by such organisms may depend, in part at least, on these toxic principles. However, the Scientific Committee considers that it may be possible to devise robust use qualifications which would allow a QPS approach in the future. Such qualifications would have to include a consideration of effects on non-target species.

[6] See http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_268/l_26820031018en00010023.pdf
[7] See http://eur-lex.europa.eu/LexUriServ/site/en/oj/2001/l_106/l_10620010417en00010038.pdf
[8] See http://eur-lex.europa.eu/LexUriServ/site/en/oj/1998/l_330/l_33019981205en00130031.pdf

3.2. Exclusion from the QPS list

Only a positive list of microorganisms judged suitable for QPS status is given in Table 1. Exclusion from this list was for a variety of reasons. Many microorganisms commonly encountered in food production were not considered because they are not presently the subject of pre-market authorisations and so would not be notified to EFSA. Other microorganisms were considered (*e.g*. the enterococci), but the potential risks associated with their use could not be fully defined or, where recognised, the tools necessary for the exclusion of hazardous strains were considered insufficient. Often the body of knowledge, particularly that relating to a history of use, was for a specific purpose and did not allow extrapolation to other uses to be made with confidence.

It should be stressed that the absence of a particular organism from the list of microorganisms judged suitable for QPS does not necessarily imply any risk associated with its use. Individual strains may be safe but this cannot be judged from the existing knowledge of the taxonomic unit to which it belongs. Consequently, all microorganisms not considered for QPS or not considered as suitable would remain subject to a full safety assessment.

3.3. Maintenance of QPS list

In reaching its conclusion on the value of QPS as an assessment tool, the Scientific Committee recognises that there would have to be continuing provision for reviewing and modifying the list of organism given QPS status. EFSA must be able to respond to any new information such as epidemiological data which might suggest that an inclusion on the list should be reconsidered. Similarly, there must be provision for additions. It is likely that the rapid developments in microbial genomics, the full annotation of genomes and the ability to predict metabolic pathways accurately from such annotation will allow inclusion of organisms not presently listed. Proposals for additions could arise from a variety of source including actual notifications to EFSA or at the request of interested parties. However, whatever the route and source of information on which on a judgement of suitability for QPS status is made, the assessment itself and the final judgement on whether to include or exclude must remain within EFSA's purlieu.

The Scientific Committee is of the opinion that responsibility for the maintenance and development of the QPS system should be the responsibility of EFSA via its Science Directorate. This would ensure that the system has the continuing necessary support and that there would be a continuity of approach. The Scientific Committee suggests that the EFSA should review at least annually the received notifications involving microorganisms and the suitability for QPS status of any new additions. The review should also consider suggestions arising from elsewhere (*e.g.* industry, Member States) for possible additions to or deletions from the QPS list. Reviews may occur more frequently but there should be a formal requirement that even where no changes are proposed a statement should be made annually that QPS status is being maintained for the published list.

3.4. Implementation of QPS within EFSA

For QPS to be effective it must be implemented across EFSA for all safety considerations of microorganisms intentionally added to the food chain, regardless of purpose. There should be full harmonisation and implementation of QPS in all EFSA Panels wherever applicable.

For those panels concerned with risk assessments leading to market authorisations there will be an interim period after the introduction of the QPS system during which Dossiers will reflect previous requirements and contain data made unnecessary for those organisms listed in Table 1. The Scientific Committee suggests that this should be managed and a consistent response adopted in which QPS status is given priority but accompanied by an acknowledgement that data has been provided which is consistent with the QPS status of the organism(s). During this initial period it is suggested that the Scientific Committee should monitor the introduction of QPS and act as a forum in which any difficulties could be resolved.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The Scientific Committee is of the view that the weight of evidence available for the bacterial and fungal species listed in Table 1 is sufficient to ensure that QPS status provides at least the same degree of confidence as a case-by-case safety assessment,

As the number of organisms considered suitable for QPS status is sufficiently extensive to cover a majority of the safety assessments involving microorganisms required of EFSA, the Scientific Committee considers the introduction of a QPS system for microorganisms would meet the objectives of providing a practical tool for setting priorities and avoiding the commitment of resources to extensive investigations of organisms known not to cause concern.

In reaching its conclusion on the value of QPS as an assessment tool, the Scientific Committee recognises that there would have to be continuing provision for reviewing and modifying the list of organism given QPS status.

RECOMMENDATIONS

The Scientific Committee recommends that a QPS system for microorganisms should be introduced initially covering the organisms listed in Table 1 and that should be implemented across EFSA for all safety considerations of microorganisms intentionally added to the food chain, regardless of purpose. Thereafter, and based on the experience gained from its use in practice, the extension of the QPS system to microbial products could be explored.

EFSA should take prime responsibility for the maintenance and development of QPS and should review at least annually the suitability for QPS status of the existing list and/or of any additions. Reviews may occur more frequently as necessary but there should be a formal requirement that even where no changes are proposed a statement should be made annually that QPS status is being maintained for the published list.

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