European Food Safety Authority

SCIENTIFIC COMMITTEE

The proposed replacement of a case-by-case safety assessment by a Qualified Presumption of Safety (QPS) approach for selected microorganisms notified to EFSA.

A request for comments by interested parties

Background

A wide variety of bacterial and fungal species are used in food and feed production, either directly or as a source of additives. Some of these have a long history of apparent safe use, while others are less well understood and may represent a possible risk for consumers. To capture important risk aspects without committing resources to thorough investigations of organisms known to be safe, there is a need for a tool for setting priorities within the risk assessment of microorganisms in the production of food and feed.

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)[1], a concept which shared some of the elements and purpose of the USA GRAS (Generally Recognised As Safe) system. *In essence this proposed that a safety assessment of a defined taxonomic group (e.g. genus or group of related species) would 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 would be granted QPS status. Thereafter a strain of microorganism whose identity could be unambiguously established and assigned to a QPS group would be freed from the need for further safety assessment other than meeting any qualifications specified. Microorganisms not considered suitable for QPS status 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

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

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[2].

The Scientific Committee concluded that QPS as a concept could provide a generic approval system *for use within EFSA* that could be applied to all requests received for the safety assessments of microorganisms deliberately introduced into the food chain[3]. 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.

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

The present position

Strains representing approximately 100 species of microorganisms have been or are expected to be referred to EFSA for a safety assessment (see Annex 1 for those already notified to EFSA). Individual species may be the subject of a single notification but more usually are found in several notifications. This list includes both live organisms deliberately introduced into the food chain and those used as a source of food/feed additives. A large majority of these ~100 species fall within four broad groupings:

[2] See http://www.efsa.europa.eu/en/science/colloquium_series/no2_qps.html
[3] See http://www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/972.html
[4] See http://www.efsa.europa.eu/en/science/sc_commitee/sc_documents/1368.html

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

The suitability of various taxonomic groups falling under these broad headings for QPS status has now been examined by working groups of the Scientific Committee and their preliminary proposals for suitable candidates for QPS status (including any qualifications) are listed in Annex 2. For convenience, Annex 2 is given as a list of presently-recognised species. The scientific justifications for inclusion in or exclusion from this list are given in the individual reports on the four broad groups (Annexes 3-6). Where QPS status is proposed, the working group was satisfied that the body of knowledge available was 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. It should also be noted that QPS status applies to the microorganism and not to the product containing the organism. The formulation may, on occasion, introduce additional hazards needing assessment. Neither does it extend to the product of a microorganism.

An invitation to comment

The Scientific Committee are minded to recommend the introduction of QPS for the list of species shown in Annex 2. Before doing so, they would like to invite detailed and general comments from all interested parties. The Committee would be particularly interested in knowing whether the weight-of-evidence presented is considered sufficient to ensure that QPS status provides at least the same degree of confidence as a case-by-case safety assessment, whether this has been sufficiently documented and whether there are issues that have not been sufficiently considered. Attention is drawn to the proposal to include *Lactobacillus rhamnosus* amongst the species proposed as suitable for QPS and the decision to exclude all members of the *Bacillus cereus* group including *B. thuringiensis*.

Interested parties are invited to submit their comments by means of the dedicated email address "qps@efsa.europa.eu". The commenting period ends on Monday 5 March 2007. Comments will be taken into account when preparing the opinion on whether QPS represents a practical and robust method of safety assessment for microorganisms and, if so, on how the QPS approach could be applied across EFSA within the framework of the current and proposed legislation.