



FEFANA input on DG SANCO guideline document (426/2005 rev. 2): QPS Concept

Scope

The present input relates to the following sections of the guideline document

- Section II

Point 2.2.2.2

For micro-organisms for which is *no history of apparent safe use*.....

- Annex III

Point 1.3.2.1.2

Toxicity test are not requested for micro-organisms.....for those with a *history of apparent safe use*

Point 4.2 Zootechnical additives: Enzymes and Micro-organisms

Sub point 4.2.3.2

Most viable bacteriaare selected from groups of micro-organisms with a *history of apparent safe use*

From such microbial.....with a *history of apparent safe use*

Background

FEFANA, the EU Association of feed additives and premixtures, has actively followed the initiation and subsequent discussions concerning Qualified Presumption of Safety (QPS).

It has also followed through the concept in the light of the recent public consultation by the Scientific Committee published on the European Food Safety Authority website in January 2007 and has the following general comments.

FEFANA supports the use of Qualified Presumption of Safety (QPS) for the evaluation of micro-organism intended for fermentation and or as feed additives, as a replacement to individual case-by-case evaluations. FEFANA agrees that micro-organism, for which a large body of evidence already exists on their safety, should not be subject to additional and unnecessary extensive evaluations. FEFANA however considers that application of QPS should be consistent and the subject should not be isolated from the legislative, and thus risk management frameworks, and calls for the immediate integration of QPS in the various assessment tools with which EFSA undertakes risk assessments, and in particular within the guidelines for the evaluation of feed additives currently under negotiations.

Comments

FEFANA has repeatedly strived to obtain that the Commission includes the QPS concept into the draft feed additive guidelines.

The present draft guidelines mention in several sections the following sentence: "history with apparent safe of use".

In fact this sentence corresponds to the definition of the "Qualified Presumption of Safety" or "QPS".

The EFSA Scientific Committee concludes that QPS concept could provide a generic approval system that could be applied to all requests received by EFSA for the assessments of micro-organisms deliberately introduced in the food chain.

QPS represents a practical and robust method of safety assessment for micro-organisms.

In the same draft the Scientific Committee recommends that EFSA should develop a strategy for the introduction of an assessment system based on the QPS system.

Again in the same draft EFSA has accepted the recommendation of the Scientific Committee and has proposed to continue in its assessment of the QPS system with the view to implement it.

The QPS as a concept is already recognized as valid by the Scientific Committee and EFSA recommend the introduction of QPS for some lists of micro-organisms. This is the object of the last EFSA public consultation. This consultation has been set up to have comments from all interested parties and finalised the decision on the final application of the concept.

In the draft of guidelines it is mentioned "History of apparent safe use".

In fact this definition corresponds to the "Body of Knowledge" or familiarity which concern History of use, Industrial application, Ecology, Clinical aspect, Scientific literature and data base.

This body of knowledge of the group of organisms seeking QPS must be sufficient to provide assurance that any potential to produce adverse effect in humans, livestock or the wider environment is understood and predictable.

All this information corresponds to the QPS.

FEFANA proposes to have the concept of the QPS already mentioned in the feed additive guidelines for the following reasons:

-The sentence several time mentioned in the draft “History of apparent safe use” correspond exactly to the QPS definition.

-If the QPS concept is definitively agreed by EFSA only after the guidelines are published, it will take time to introduce this concept in the guidelines (Commission Regulation). This will entail a lot of penalties and non justified investment for companies. It is the reason why FEFANA requests to have a clear reference to QPS in the guidelines by now.

-FEFANA strongly proposes to have the QPS concept included in the draft guidelines as follows :

“History of apparent safe use, corresponding to QPS concept”.