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Position paper
of the Scientific Committee on Animal Nutrition on

Safety Assessment and Regulatory Aspects of Micro-organisms in Feed and Food Applications

Today, in the European Union, Novel foods are defined by Article 1 d) of Council and Parliament Regulation 258/97/EC as "foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae". As such, they are subject to a specific approval procedure and a safety assessment. However, this definition applies only to products that have not previously been used in or as a human food to a significant degree within the Community. Micro-organisms entering the food chain in association with animal feeds are subject to different legislation. Those defined as a feed additive are considered for approval under 70/524/EEC, while those used as silage additives at present escape regulatory scrutiny. Micro-organisms used as plant protection products are governed by a further regulation (91/414/EEC).

In fact a wide variety of bacterial and fungal species and strains have been and are used to produce fermented foods both in Europe and in other parts of the world. The bacterial genera involved include *Lactobacillus*, *Lactococcus*, *Pediococcus*, *Leuconostoc*, *Carnobacterium*, *Enterococcus*, *Micrococcus, Streptococcus*, *Staphylococcus*, *Propionibacterium*, *Acetobacter* to mention just the most obvious and well known. In addition to *Saccharomyces* also other fungal genera such as *Kluyveromyces, Pichia, Kloeckera, Candida*, *Penicillium*, *Aspergillus*, *Mucor* etc. are used in food fermentations. The typical products (such as alcoholic drinks, fermented milks, butter, cheeses, leavened and sourdough bread, pickled vegetables and fruit, cured meats, chocolate, tea and coffee) are parts of a normal everyday diet. Some of these foods are manufactured using defined starter cultures, but many, even in the developed world, are produced either by spontaneous fermentation or by back-slopping.

The very large number of strains and the range of products may cause difficulties in defining whether a species, strain or application is novel or not. This situation may, in turn, lead to discrepancies in regulatory measures, if relatively minor modifications of the traditional applications are introduced to the market via the procedures defined in Regulation 258/97/EC.

Recently the Scientific Committee on Animal Nutrition (SCAN) published its recommendations as guidelines for assessment of enzymes and micro-organisms used as feed additives. After careful consideration it was concluded that history of safe human use of a micro-organism cannot be accepted as an exemption of toxicological testing requirements to ensure the consumer safety. The reason for this was the lack of clearly defined criteria for a micro-organism to be considered as safe for human food applications. SCAN, however, recognised that this situation would lead to cases where the safety requirements for a feed additive are considerably more stringent than those considered necessary in human food applications.

In the United States of America, the Food and Drug Administration (FDA) classifies certain micro-organisms and other products as Generally Recognised As Safe (GRAS). An organism or a product with a GRAS status is exempt from the statutory premarket approval requirements. An organism can be in the GRAS list either on the basis of a history of safe use or after an appropriate safety assessment.

SCAN suggests that also in EU a list of micro-organisms with a known and well documented history of safe use would improve and clarify the present approval procedures on food and feed products based on such micro-organisms. However, it is recognised that such a listing should not seek to reproduce the US FDA GRAS system but should take account of the different social and regulatory climate present in Europe. This is necessary since issues of importance to Europe would not necessary influence a GRAS listing. A clear example of this would be the presence of acquired antibiotic resistance factors, considered highly undesirable in Europe but of lesser issue in the USA.

Consequently it is proposed that any listing should be **qualified**, allowing the general safety of the organism/group of organisms to be concluded provided that certain specifics are met. In the case of many of the live organisms currently used in the manufacture of, or added to, dairy products, this may simply be a requirement to demonstrate the absence of acquired resistance factors.

This would be intended to lead to a system which would allow a:

"**Qualified presumption of safety (QPS)"**, presumption being defined as "a belief or assumption based on reasonable evidence" and qualified to allow certain restriction to apply.

A QPS system could have many advantages:

- It would provide an urgently needed mechanism to harmonise the safety assessment of micro-organisms throughout the food chain. This could be done without either compromising the standards set for micro-organisms used in animal feedingstuffs or requiring all organisms with a long history of use to be subjected to a full and unnecessary safety review. Thereafter it would aid the consistency of assessment and make better use of assessment resources.
- It could, in the future allow the introduction of a qualified generic approval system, reducing the need for unnecessary and repetitive testing and thereby encouraging the commercial development of novel products without compromising safety.
- Safety assessment could be limited only on those aspects that are relevant for the organism in question (i.e. the presence of transmissible antibiotic resistance markers in a lactic acid bacterium or known virulence factors in a species known to have pathogenic strains).
- Although it is proposed that the possibility of a QPS system should be first explored using micro-organisms and microbial products, in principle it would applicable to all forms of food/feed and food/feed products.

Recommendation

SCAN proposes that, together with the other Scientific Committees (SCP, SCF) dealing with the assessment of micro-organisms, a cross-committee discussion on whether a system leading to a Qualified Presumption of Safety of some food and feed-related micro-organisms is viable should be initiated. The results of this consideration would be provided to the Management of the European Food Safety Authority and could be brought to the attention of the European Commission for a possible legislative action.