

Comments on:

“Opinion of the Scientific Committee on a request from EFSA related to a generic approach to the safety assessment by EFSA of microorganisms used in food/feed and production of food/feed additives”

The Panel on Biological Hazards, of the Norwegian Scientific Committee for Food Safety (VKM), was invited by EFSA to submit their comments to EFSA on whether Qualified Presumption Safety (QPS) represents **a practical and robust method** of safety assessment for microorganisms, and if so, on **how this approach could be applied across EFSA**.

The Panel on Biological Hazards of VKM agrees with EFSA that the general use of QPS should be based on four principle factors: taxonomy, familiarity, pathogenicity, and end use.

Listed below are comments that VKM considers should be deliberated with respect to implementation of QPS, in particular regarding the practicality and robustness of the method and the application of the QPS approach:

Practicality and robustness of the method

1. Detailed statement required on those respects in which the QPS approach is an improvement in comparison with the present approach.
2. Detailed statement describing how limitations will be set, particularly with regard to a) fermentation mixtures; b) those microorganisms whose taxonomy is poorly defined or under revision; and c) microorganisms which may acquire, either through deliberate intervention or unintentionally, genetic elements from other microorganisms, either related or unrelated.
3. Detailed statement required regarding how interactions between microorganisms and particular target consumers/user groups will be incorporated into QPS. For example, in recent years, strains of some

microorganisms have been included in a number of probiotic products, and various manufacturers are interested in establishing probiotic products intended specifically for infants and children. Whether an “artificial” microbiota could be designed to benefit babies, who do not also consume breast milk, following the lactation period remains unresolved. Although, no immediate adverse effects of such microorganisms have been observed in healthy individuals, the long-term effects of such products on infants or small children are unknown. In particular the long-term effects of a heavy, artificial, single-species bacterial load on the infant intestine, and any consequences for the immune function (immune defence, allergy, autoimmunity), are unknown.

Application of the QPS approach across EFSA

1. Establishment of QPS by EFSA must be in advance of, and transparently independent of, applications of Notifiers.
2. The decision of whether or not award QPS status to microorganisms should remain with risk assessors, and should be subject to review at pre-determined intervals, as well as triggered by specific events, for example if a specific alteration occurs, including acquisition of new, relevant knowledge.
3. Consideration should be given to whether QPS should be applied to microorganisms with respect to particular consumer groups (or with particular, potentially-vulnerable consumer groups should excluded) (see point 3, above).
4. In incorporating QPS, an alternative, parallel system for microorganisms not eligible for QPS, should also be established. Similarly, a system should be established for evaluating microorganisms which may be of special significance for particular, potentially-vulnerable consumer groups.