WORKING DOCUMENT
Interpretation question: NL USE OF MICROBIOLOGICAL CULTURES

Criteria for determining status of culture use

NL would like to continue the discussion on microbiological cultures to work towards clear and harmonized criteria for determining the status of culture use. We believe that clear criteria for determining status of culture use and endorsement of these criteria by the Standing Committee is needed to provide clarity to the industry, but also to the national control authorities in order to carry out their work properly.

Already in 2006 draft criteria on regulatory classification of cultures were elaborated but not been completed. The draft criteria suggests that cultures used principally for a technological purpose are food additives.

On **14 December 2006**, the matter was on the agenda of **the Standing Committee meeting** under the item 6. The following is in the minutes of the Standing Committee meeting:

Draft Criteria for determining status of culture use

Cultures are used for a variety of purposes from traditional use in food production to more novel and targeted applications for food preservation. Such uses can be divided between ingredient/processing aid and food additive uses. To aid in this interpretation the following draft criteria have been developed.

- Cultures which are added at the beginning or early stages of manufacture and which contribute to the characteristic nature of the food would not be considered as food additives. Examples would be starter cultures used in cheese, yoghurt or dried sausage production.

- Cultures which are used during the manufacture of foodstuffs and which contribute to the characteristic nature of the food would not be considered as food additives. An example would be cultures applied to the surface of a ripening cheese which contributes to the development of the characteristic nature of the cheese (production of cheese rind).

- Cultures which are added for a specific technological effect (such as preservation) would be considered as food additives. Examples could be the use of cultures on cooked or raw meat/shellfish etc. Also included in this example would be the addition of cultures to prepared foodstuffs whereby the culture is intended to act as a preservative.

- Cultures which are added to food but which are not added for a technological function would not be considered as food additives. An example would be the addition of cultures to a yoghurt or dairy drink whereby the cultures are added for a probiotic effect in the consumer.

Later, the topic has been discussed in several working groups. The discussions show that most MS find the 2006 draft criteria valid, but that some refinement is required.

So far, the criteria have never been refined and endorsed. Therefore, NL would like to take the initiative to propose a revised version of the draft criteria for determining status of culture use.

Please find below the NL proposal for revised criteria. The following considerations have been included in this proposal:

- Consequent and clear use of terminology;
- An explanation of what is meant with ‘fermented food’ is added;
- The moment at which the culture is added is indicated for every option;
- The use of cultures for a technical purpose is further defined;
- Thoughts has been given how to deal with ‘mixtures’ where several uses of cultures are combined;
- There is an uncertainty regarding surface treatment with cultures – does this result in a fermented food or just a partly fermented food?
- For point 4 (cultures considered as food additives), two different options are proposed.

Draft Criteria for determining status of food cultures use

Microbiological cultures are used for a variety of purposes from traditional use in food production to more novel and targeted applications for food preservation. Such uses can be divided between ingredient (other than food additive) and food additive uses. Because there seemed to be ambiguity in interpreting the regulatory status of the use of cultures, it seemed necessary to establish criteria for determining the status of culture use. These criteria should provide clarity to the industry, but also to the national control authorities in order to carry out their work properly.

To aid in the interpretation of the status of microbiological cultures the following criteria have been developed:

1. Cultures which are added at the beginning or early stages of the manufacture of foodstuffs and which result in a fermented food, i.e. a food in which the characteristic nature of the food has been significantly changed*, would not be considered as food additives. Examples would be starter cultures used in cheese, yoghurt or dried sausage production.
2. Cultures which are added on the surface of a food at any stage of the manufacture of foodstuffs and which result in a fermented (part of a) food would not be considered as food additives. An example would be cultures applied to the surface of a ripening cheese which contributes to the development of the characteristic nature of the cheese (production of cheese rind).
3. Cultures which are added at any stage of the manufacture of foodstuffs for reasons other than production of fermented foods and which result in a functional food (i.e. a food with specific nutritional characteristics) would not be considered as food additives. An example would be addition of cultures to a yoghurt or a diary drink whereby the cultures are added for an alleged probiotic effect.
4. Cultures which are added at any stage of the manufacture of foodstuffs and have been specially selected in order to have a specific technological effect, for example to exhibit antimicrobial activity (such as bactericidal, bacteriostatic, or competitive behaviour against harmful microbes), analogous to food additive use (such as e.g. preservation) would be considered as food additives. Examples would be the use of cultures on cooked or raw meat/ shellfish, boiled sausages, smoked salmon, ready-to-eat salads etc. Also the addition of cultures (such as e.g. micro-algae) to foodstuffs whereby the cultures are intended to act as a colourant, are considered as food additives.

   Mixtures of cultures which are added at the beginning or early stages of the manufacture of foodstuffs, consisting of cultures which result in a fermented food combined with cultures which are added for a specific technological effect, have to be considered separately, according to their main function.

   If cultures are considered novel food they have to be approved through the novel food legislation before used as an ingredient.

*Significantly changed would mean that the produced fermented product has intrinsically different organoleptic or textural characteristics through the entire food compared with the food before fermentation.