

Opinion on the scientific background of the Spanish notification on a regulation on broths, consommés, soups and creams (expressed on 10 December 98)

Terms of Reference

To assess whether the information provided by the notification of the Spanish Decree on soups and broths form a scientific basis for risk assessment of the organisms enlisted and to consider the risk to consumer's health from the soups and broths covered by the document.

Background

The Spanish authorities notified to the Commission their intention to amend national legislation on microbiological limits for certain organisms in soups, broths, consommés etc. under article 7 of Directive 93/43/EEC on the hygiene of foodstuffs. The Commission subsequently requested from the Spanish authorities information concerning the scientific basis for these microbiological limits and the assessment of risk to consumers that had led the Spanish authorities to propose these. A response from the Spanish authorities has been made available.

An evaluation of the information provided

The discussed commodity covers a spectrum of different recipes, thus leaving a broad spectrum of bacteriological associations. The document does not unambiguously state whether the microbiological criteria suggested concerns finished products or ready to be consumed products or both.

a) Limits:

Scientific information as well as available data from the industry and national guidelines and limits for certain organisms in soups, broths, consommés etc. was assessed by the Committee. The Committee took into account also data from AIIBP (Association Internationale de l'Industrie des Bouillons et Potages) guidelines, which reflect Good Manufacturing Practice.

The information provided indicated that these limits updated existing limits in Spanish legislation, additionally *B. cereus* has been included. However there were certain constraints placed upon the Committee in this assessment relating to:

- lack of epidemiological information provided concerning the risk to consumer from the consumption of these foodstuffs.
- lack of clarity in the information about the exact point in the preparation of these foods to which the limits apply.

The Committee considered national limits and guidelines as well as industrial data. The Spanish limits and data of the AIIBP are shown in Table 1.

Table 1: Comparison of the Spanish Limits with data from AIIBP

| Spanish Decree 2180 (1975*) | | Spanish Proposal | | | | | Guidelines of AIIBP (**) | | | |
|--------------------------------|-------|------------------|---|---|---|---|--------------------------|---|---|--|
| | limit | n | c | m | M | n | c | m | M | |

| | | | | | | | | | |
|-----------------------|-----------------|---|---|-----------------|-----------------|---|---|-----------------|-----------------|
| <i>Salmonella</i> | - /25 g | 5 | 0 | - /25 g | - | 5 | 0 | - / 25 g | - |
| <i>C. perfringens</i> | 10 ¹ | 5 | 2 | 10 ² | 10 ³ | 5 | 3 | 10 ² | 10 ⁴ |
| <i>S.aureus</i> | 10 ² | 5 | 2 | 10 ² | 10 ³ | 5 | 2 | 10 ² | 10 ³ |
| <i>B.cereus</i> | not set | 5 | 2 | 10 ² | 10 ³ | 5 | 3 | 10 ³ | 10 ⁵ |

*: quoted from N.N. (1992), EUR 17638 (1998); **: quoted from N.N. (1992)

n = number of sample units examined from a lot

c = number of samples being accepted between m and M

m = microbial limit separating good quality from marginally acceptable quality

M = microbial limit separating marginally acceptable quality from defective (to be rejected) quality

Salmonella and Staphylococcus aureus

According to the information provided the proposed limits meet results of recently performed analyses of Spanish soups and broths.

Clostridium perfringens

The new limits refer to surveys, which were performed by the national Centro Nacional de Alimentación (CNA) analysing 115 samples, the results of which (highest count: 10²/g) were accepted as "m". On the basis of results from the literature (Arnold, 1991, in notification 97/406/E), the limit for M was set as 10³ per g. The sampling plan was taken from ICMSF, classifying *C. perfringens* into category "moderate, direct risk; limited diffusion", meaning category 7: "m" is in accordance with guidelines of AIIBP. The limit for M is 1 log lower than the proposed M by AIIBP. Other national limits are set between m = 10⁴ and M = 10⁵.

Bacillus cereus

With respect to soups and broths, this bacterium has been introduced as a criterion with this proposal for the first time in Spain. The Spanish limits have been set lower than AIIBP guidelines (Table 1).

Analysis of foodborne disease outbreaks caused by *S. aureus*, *C. perfringens* and *B. cereus* show that the numbers of organisms present varied from 10⁵ - 10⁷ per g of product respectively.

From report EUR 17638 (1998) a list of Spanish publication on food borne diseases for the years 1970-1995 has been quoted. From these documents as well as from the sources quoted in the notification 97/406/E (AIIBP 1992; results of analysis of CNA; ICMSF) no evidence has been provided to support the notion that commodities subjected to the Decree are a major source of food borne infections or intoxications recently.

b) Use of Risk Assessment in the establishment of the microbiological limits

The Spanish authorities indicated that risk assessment techniques are currently not sufficiently advanced in the development of the microbiological limits contained in the notification. The information presented by them therefore was not relevant for this purpose.

However, the Committee in its report "Principles for the Development of Microbiological Criteria for Foodstuffs as Covered by the hygiene of Foodstuffs Directive 93/43/EEC", expressed on 7 June 1996, recommended detailed guidelines for the risk assessment of microbiological hazards in foodstuffs. While recognising that all the information

required to undertake a precise quantitative risk assessment is not always available, the Committee recommends the use of these guidelines to the fullest extent possible when developing microbiological criteria, and in the setting of microbiological limits. Regarding the new limit *B. cereus*, which has been newly introduced by the Spanish authorities, the committee recommends to follow the whole procedure of Risk Analysis.

Conclusion

The criteria proposed by the Spanish authorities are based on testing samples, some data from the literature and data from other countries. The Committee is of the opinion, that the data that have been provided, are insufficient to form a scientific basis for Microbiological Risk Assessment.

The risks of food borne disease from soups have not been shown to be any greater than the risk of other general food groups and relates primarily to the mishandling of these types of food. The Committee is of the opinion, that it is unlikely, that the introduction of specific criteria at this stage will change the effects of mishandling food.

References

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- - ARNOLD (1991) in Notification 97/406/E