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Opinion of the Scientific Committee on Food on specifications for gelatine in terms of consumer health

(adopted on 27 February 2002)

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Terms of reference

The Scientific Committee on Food (SCF) is requested to advise the Commission on the adequacy of the specifications laid down in Part V of the Annex to Commission Decision 1999/724/EC, amending Part V of Chapter 4 of Annex II to Directive 92/118/EEC, in terms of consumer health.

The Commission asks the Committee to address the general adequacy of the proposed limits by drawing on relevant previous evaluations by the SCF whenever scientifically justified, rather than undertaking a full toxicological and microbiological evaluation on each of the parameters.

Background

In its Decision of 28 October 1999 (EC, 1999) the Commission set up specific rules for gelatine production. These include requirements for finished products, specifying microbiological criteria and content of residues. They may be amended to take into account scientific and technological developments.

The Commission had submitted a first request on this matter on 21 December 1998, which was amended subsequently to take account of the latest legislative developments.

Product characteristics

Gelatine is the natural, soluble protein material, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry). The raw materials are derived from animals, which have been found fit for human consumption following ante- and post mortem inspection (Scientific Steering Committee, 2001). It is also required that the raw materials must be transported and stored chilled or frozen, unless processed within 24 hours from their departure. The use of hides and skins

submitted to tanning, as defined in Commission Decision 1999/724/EC (EC, 1999), is prohibited.

Chemical specifications

The raw material for the gelatine production can be contaminated with heavy metals. Because certain amounts of the contaminants might be present even in gelatine, limits should be set.

The limits for arsenic (1 ppm), lead (5 ppm), cadmium (0.5 ppm) and mercury (0.15 ppm) laid down in Part V of the Annex to Commission Decision 1999/724/EC (EC, 1999) are lower than or equal to the purity criteria in the Directive 98/86/EC (EC, 1998a) for food additives other than colours and sweeteners, such as alginic acid and alginates, agar-agar, carrageenan, processed eucheuma seaweed, carob bean gum, tragacanth gum, gum arabicum, xanthan gum, karaya gum, tara gum and gellan gum. In the light of these specifications for additives, the proposed specifications for arsenic, lead, cadmium and mercury in gelatine are no reason for concern.

The proposed limits for copper and zinc can not be compared with specifications set for the above mentioned food additives, because no limits for these metals were set. Although there is no indication that the proposed limits for copper (30 ppm) and zinc (50 ppm) in gelatine pose a risk to consumer health, they might lead to a total content of heavy metals exceeding the common limits for heavy metals. To the Committee it appears more logical to include an overall limit for heavy metals as for food additives (e.g. not more than 20 mg/kg), rather than a specific limit for copper and zinc.

There are no generally agreed limits in existing food additive legislation for chromium. In considering the safety aspects of chromium III (CrIII), the Committee noted that the absorption of CrIII is low, around 0.5 – 2% if given orally (SCF, 1993). In a recent comprehensive review of the toxicity of chromium the US Environmental Protection Agency (USEPA, 1998) has proposed a reference dose for CrIII of l.5 mg/kg bw/day (i.e. an estimate of a daily exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime). According to the EPA report, this was based on No Observed Effect Levels (NOELs) of around l400 mg CrIII/kg/day, taken from a 2-year oral chronic toxicity/carcinogenicity study in the rat and from a 90-day oral rat study, in both of which no adverse effects were observed from feeding CrIII, as Cr_20_3, at levels up to 5% in the diet (Ikanovic and Preussmann, 1975). The reference dose of l.5mg/kg/day was derived by application of a l000-fold safety factor to the NOEL. A factor of l000 rather than l00 was used because of uncertainties regarding potential reproductive effects of CrIII (USEPA, 1998). Neither the Committee nor the Joint FAO/WHO Expert Committee on Food Additives (JECFA) have established tolerable daily intakes for chromium.

The Committee made a rough estimate of possible maximum daily consumption of gelatine, using a «worst case» assumption that l.5 kg of food per day is consumed and that this contains 3% by weight of gelatine. If CrIII was present at the proposed limit of l0 ppm in all gelatine consumed, then the daily intake of CrIII from this source would not exceed 450 μg/person/day, equivalent to 7.5 μg/kg bw/day for a 60 kg person. The Committee was informed by some sectors of industry that they could comply with a lower limit for chromium III (e.g. l ppm).

As this «worst case» estimate of intake from gelatine containing CrIII at l0 ppm is 200-fold lower than the EPA reference dose, the Committee does not consider that the proposed specification limit of l0 ppm for chromium would pose any risk to consumer health, provided that the specification was restricted to the trivalent form of chromium and provided the assumptions the Committee has made about maximum likely intakes of gelatine covers the situation for EU consumers.

Microbiological criteria

Hides, skins and bones used as raw material for gelatine production are usually heavily contaminated with micro-organisms originating from soil and faecal material. These organisms consist of potentially pathogenic and non-pathogenic vegetative cells and spores. The initial washing and degreasing step using hot water will remove a substantial number of the contaminating microbes. The subsequent treatment at low or high pH over substantial periods of time will effectively kill contaminating micro-organisms (Russell *et al.*, 1994; Russell, 1998). The level of potentially surviving micro-organisms will be further reduced due to the high-temperature-short-time processing step before drying. The combined effect of exposure to high or low pH in combination with heat treatment ensures that viable micro-organisms would not be present in the final product (Brown and Booth, 1991; Schreiber and Seybold, 1993). However, as with other food materials gelatine can be contaminated after manufacture.

The recommendations made by this Committee and the Scientific Committee on Veterinary Measures related to Public Health (SCVPH) of the European Commission on principles for the development of microbiological criteria (EC, 1998b) specify the scientific principles to be taken into account when mandatory microbiological criteria (standards) for foodstuffs are developed. Priority for such criteria should be given for microorganisms where a risk assessment has established a hazard to the consumer and a failure to comply with them can result in a rejection of the food. These mandatory criteria should not be confused with microbiological guidelines. Guidelines are used by manufacturers and food inspectors to ensure the use of good hygienic practices. The microbiological standard adopted for Community legislation on gelatine (EC, 1999) does not follow these principles. It requires that each production batch of gelatine shall meet the following microbiological limits: Total aerobic bacteria, 10^3/g; Coliforms (30 °C), 0/g; Coliforms (44.5 °C), 0/10g; Anaerobic

sulphite-reducing bacteria (no gas production), 10/g; *Clostridium perfringens*, 0/g; *Staphylococcus aureus*, 0/g; *Salmonella*, 0/25g.

Fundamental for the production of foodstuffs according to Directive 93/43/EEC, is the utilisation of Hazard Analysis and Critical Control Points (HACCP) and Good Hygienic Practice (GHP). The HACCP system includes the determination of Critical Control Points (CCP) and establishment of Critical Limits (CL). CL have to be established for pH, concentration of acid/base and treatment time and temperature/time at appropriate processing steps regarded as CCP's for a safe gelatine production. The Committee finds that GHP and HACCP can be verified and validated microbiologically. The Committee proposes that Salmonella is retained as a mandatory microbiological criterion reflecting the recontamination. Microbiological guidelines for indicator organisms can be established as process/production criteria for validation and/or verification by manufacturers and food inspectors on a safe and hygienic production of gelatine. Such guidelines have to be established in the light of relevant data.

Conclusion

The Committee is of the opinion that the limits for heavy metals set in the Annex to Commission Decision 1999/724/EC (EC, 1999) presently appear to be adequate in terms of consumer health. In the context of efforts to reduce levels of contaminants in the diet generally, the Committee emphasises the importance of good manufacturing practices and notes that some sectors of industry have stated that they could comply with a lower limit for chromium III (e.g. l ppm).

The Committee considers gelatine should be microbiologically safe if it is produced according to GHP with the application of HACCP. The technology used in gelatine production as briefly described in this document effectively ensures that the microbes present in the raw materials are destroyed.

This Committee and the SCVPH (EC, 1998b) have established principles to be followed when developing microbiological criteria. In the light of this report, the microbiological criteria in the standard for gelatine adopted by the Commission (EC, 1999) in terms of consumer health, are excessive, and the Committee considers it sufficient to apply a mandatory microbiological criterion for Salmonella only.

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