Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Articles 4(4) and 12 thereof,

Whereas:

(1) A high level of protection of public health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(2)]. Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.

(2) Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.

(3) Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

(5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria are set.

(6) According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority. It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, it is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.

(7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(3)] requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.

(8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs[(4)] describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.

(9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.

(10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.

(11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.

(12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.

(13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC[(5)] in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.

(14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.

(15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.

(16) The SCVPH adopted an opinion on salmonellae in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.

(17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution

permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard. Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.

(18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.

(19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC[(6)] should be revised and certain new criteria set in the light of the scientific advice.

(20) The microbiological criteria laid down in Commission Decision 93/51 EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish[(7)] are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat[(8)] is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcases in this Regulation.

(21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(9)], the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.

(22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.

(23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.

(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus.*

(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[10] is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.

(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.