Appendix 1

Proposal to introduce national legislation to disapply the time limits between the number of days from slaughter to the mincing of meat.

1. The Agency considers that the requirements of paragraph 2(b), Chapter III, Section V, Annex III of Regulation (EC) 853/2004, concerning the statutory time limits after slaughter for the production of minced meat in approved establishments, are prescriptive and not based on risk. These prescriptive requirements of the legislation prevent the English tradition of ageing meat that is used to produce minced meat. Research commissioned by the UK shows that there is no scientific basis to support these requirements. Both the Agency and the European Livestock and Meat Trading Union have raised the matter with the European Commission on the basis that strict time limits appear overly prescriptive given the legal requirement for food business operators to implement risk based food safety management systems.

2. The time limits set out in the EU food hygiene legislation have been carried over from the former Council Directive 94/65 laying down requirements for the production and placing on the market of minced meat and meat preparations. It applied to meat produced for trade between Member States and took account of the preference, in some other Member States, to eat lightly cooked/raw minced meat. The new legislation, however, applies to the production of all minced meat, including that for the national market. The only cases where the time limits would not apply are for those businesses that supply the final consumer and where only Regulation (EC) 852/2004 is applicable - e.g. butcher's shops, supermarkets and restaurants producing mince on the premises, and to minced meat intended for use in foods that are heat treated prior to sale, such as cooked pies.

3. While this issue is on the Commission's list for review, it will take some time before any change to the Regulation could be made. In the meantime, the UK considers that the good hygiene practices and HACCP requirements set out in Regulation (EC) 852/2004, as well as the requirements of Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs, would suffice to ensure that food business operators produce safe food. With this in mind, and subject to the other requirements in Section V, Annex III of Regulation (EC) 853/2004, the UK is proposing national legislation that disapplies the criteria in paragraph 2(b), Chapter III, Section V, Annex III of Regulation (EC) 853/2004 regarding the number of days between the slaughter and the mincing of chilled meat. The product would be eligible to bear the oval identification mark and would be available for trade within all Member States.

4. **Please note** that this consultation is running in parallel with a similar one under the Technical Standards Directive with the European Commission and the other Member States to seek their acceptance of this proposal. **Only if the proposal is accepted by the Commission and other Member States, would the proposed amendment be made.**

5. As part of this consultation we have produced an Impact Assessment for each proposal, attached at **Annex F** to this letter. If you are able to respond to this consultation, we would particularly like to know whether you agree with the assumptions behind the sections on the costs and benefits. If you do not agree, please provide us with evidence that should be used to assess the costs and benefits.

Appendix 2

Facilities for detained meat in slaughterhouses

1. It is proposed to introduce a national measure to allow certain slaughterhouses formerly classified as low throughput slaughterhouses to be exempt from the requirement to have facilities for detained meat.

2. Under the previous meat hygiene legislation, slaughterhouses with a low throughput were not required to have refrigerated detained facilities on site. However, Regulation (EC) No. 853/2004 requires all slaughterhouses to have "*lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption"*.

3. Article 10 of Regulation (EC) No. 853/2004 allows member states to adopt national measures adapting the requirements laid down in Annex III and point 4b states that the national measures shall apply to the construction, layout and equipment of establishments.

4. It is therefore proposed, subject to certain conditions, to exempt some slaughterhouses from this current requirement, which they are unable to meet because of their location and lack of physical space or because they occupy buildings of historical significance.

5. The conditions that slaughterhouses must meet to be eligible for exemption from the need to have these facilities are that:

    - the slaughterhouse was approved as a low throughput slaughterhouse on 31 December 2005;
    - the slaughterhouse otherwise meets the requirements of Regulation (EC) No. 852/2004 and 853/2004;
    - the operator has such control over the acceptance of animals for slaughter that the establishment rarely, if ever, produces meat that requires detention for further examination by the official veterinarian (OV);
    - where further inspection is considered necessary by the OV, the meat concerned is destroyed or is detained at an alternative detention facility in the locality of the slaughterhouse;
    - no processing for human consumption of domestic bovines aged over 30 months at slaughter, or of domestic porcine animal that are required under hygiene legislation to be examined for Trichinosis, takes place at the slaughterhouse.

Facilities at slaughterhouses for cleansing and disinfection of livestock vehicles

6. It is proposed to introduce a national measure to allow certain slaughterhouses formerly classified as low throughput slaughterhouses to be exempt from the requirement to have facilities for cleansing and disinfection of livestock vehicles.

7. Under the previous meat hygiene legislation, slaughterhouses with a low throughput were not required to have cleansing and disinfection facilities on site. However, Regulation (EC) No. 853/2004 requires that for meat of domestic ungulates slaughterhouses must have "*a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised facilities exist nearby.*" Similarly, it requires that for meat from poultry and lagomorphs slaughterhouses must have "*a separate place with appropriate facilities for cleaning, washing and disinfection of: (a) transport equipment such as crates; and (b) means of transport. These place and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby."*

8. Article 10 of Regulation (EC) No. 853/2004 allows member states to adopt national measures adapting the requirements laid down in Annex III and point 4b states that the national measures shall apply to the construction, layout and equipment of establishments.

9. It is therefore proposed, subject to certain conditions, to exempt some slaughterhouses from this current requirement, where they are unable to meet it because of their location and lack of physical space, thus requiring vehicles delivering livestock to such premises to be cleaned elsewhere. Where officially authorised facilities exist, for example at livestock markets, they may not necessarily be located nearby or be open at appropriate times

10. The conditions that slaughterhouses must meet to be eligible for exemption from the need to have these facilities are that:

    - the slaughterhouse was approved as a low throughput slaughterhouse on 31 December 2005;
    - the slaughterhouse otherwise meets the requirements of Regulation (EC) No. 852/2004 and 853/2004;
    - that the slaughterhouse only accepts animals that have been transported direct from the holding of origin or, in the case of domestic ungulates, from a market;
    - the food business operator responsible for transporting the domestic ungulates or poultry or lagomorphs undertakes to ensure that the means of transport will be cleaned and, if necessary, disinfected after emptying; and
    - the food business operator at the slaughterhouse acknowledges to the official veterinarian (OV) that he may be required under animal health rules to cease operating at the slaughterhouse in the event of an animal disease outbreak.

Introduction of a special health and identification mark for meat

11. It is proposed to provide a statutory basis in domestic legislation for the format of a special health and identification mark to be used on the

carcases of animals subject to emergency slaughter outside a slaughterhouse and on the meat derived from such carcases.

12. Annex III, Section I, Chapter VI of Regulation (EC) No. 853/2004 sets out the requirements relating to emergency slaughter of animals outside the slaughterhouse. The slaughter of an animal outside the slaughterhouse is restricted to an otherwise healthy animal which has suffered an accident that prevented its transport to the slaughterhouse for welfare reasons. A veterinarian must carry out an ante-mortem inspection of the animal prior to slaughter. The slaughtered and bled animal must then be transported hygienically to the slaughterhouse without undue delay.

13. Point 9 of Chapter VI requires that food business operators may not place meat from animals having undergone emergency slaughter on the market unless it bears a special health mark which cannot be confused with the health mark provided for in Regulation (EC) No. 854/2004 or with an identification mark provided for in Annex II, Section I to Regulation (EC) No. 853/2004. It also requires that such meat may be placed on the market only in the Member State where slaughter took place and in accordance with national law. Additionally, point 8 requires that food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.

14. The format of the health and identification mark to be used has been included in the FSA's "Guide to Food Hygiene and other Regulations for the UK Meat Industry" (MIG) issued in 2006 to food business operators (FBOs) at abattoirs and cutting plants. The Guide provides advice on what FBOs should do to comply with the requirements of the EU Regulations. The format that is required is a square mark containing in legible form the letters "UK" in the upper part, the approval number of the premises in the centre and the letter "N" in the lower part. This format is the same as a 'national' mark used under previous legislation to restrict the sale of meat to the national market.

15. As part of this consultation we have produced an Impact Assessment for each proposal described in this Appendix, attached at **Annex F** to this letter. If you are able to respond to this consultation, we would particularly like to know whether you agree with the assumptions behind the sections on the costs and benefits. If you do not agree, please provide us with evidence that should be used to assess the costs and benefits.

Appendix 3

Proposal for a pilot varying official controls at certain approved game handling establishments

1. The objective of the proposed regulations is to provide a legislative framework for carrying out a pilot project at certain low throughput approved game handling establishments (AGHEs) to determine the value of the post-mortem inspection carried out by an official veterinarian over and above operators' HACCP based controls with regard to post mortem inspection procedures.

2. The existing requirements of official controls at AGHEs contained in Regulation (EC) No 853/2004 and Regulation (EC) No 854/2004 are currently implemented in England by the Food Hygiene (England) Regulations 2006, as amended, and by similar regulations in Scotland, Wales and Northern Ireland. In Great Britain these official controls are carried out by the Meat Hygiene Service (MHS) an Executive Agency of the Food Standards Agency.

3. An independent study[1] was commissioned to ascertain the risks of food-borne illness from the handling and consumption of UK wild game meat, and to assess whether the consequences of additional inspections over and above operators' HACCP-based procedures, were proportional to those risks. It concluded that, in view of the level of risk, veterinary post-mortem inspections were unlikely to have any additional effect on food safety other than improved identification of *M. bovis* in deer during post-mortem inspection of the viscera.

4. The study was undertaken before the application of Regulation (EC) No. 853/2004. In accordance with that regulation, deer viscera may now be removed from each carcase and checked by a trained person to determine whether it has any abnormal characteristics that would indicate that the meat may present a risk to public health. The trained person then completes and attaches an individually numbered declaration to the carcase reporting his/her findings. The carcase may then be supplied to an AGHE. UK hunting organisations have shown strong commitment to the new requirements for training and traceability. The FSA is satisfied that tuition materials for UK trained persons include how to identify tubercular lesions in deer viscera and instructions on the action to be taken if such lesions are found.

5. As deer viscera no longer routinely accompany carcases to the AGHE, the FSA perceives no obvious advantage in having a post-mortem inspection carried out by an official veterinarian. Setting up the pilot project would enable data to be gathered to test that thesis.

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[1] '**An evaluation of the effect of EU proposals to inspect licensed premises on the marketing of wild game: a qualitative risk assessment (M01025)**' - for a copy of the report, telephone: +44 (0)20 7276 8181 or email: infocentre@foodstandards.gsi.gov.uk.
Summary by H L Coburn *et al* published in The *Veterinary Record (2005) 157, 321-32*

6. If the thesis were proved correct then continuing with the current system of inspection would be an unnecessary burden on industry and would not provide value for money for taxpayers.

7. It is proposed that, on a case by case basis, certain game handling establishments that meet the specified eligibility criteria should not be required to have official veterinary post-mortem inspection during the pilot project. We will write to all AGHEs seeking expressions of interest in due course. Please note that no expressions of interest are requested at the present time.

8. As part of this consultation we have produced an Impact Assessment for each proposal, attached at **Annex F** to this letter. If you are able to respond to this consultation, we would particularly like to know whether you agree with the assumptions behind the sections on the costs and benefits. If you do not agree, please provide us with evidence that should be used to assess the costs and benefits.

S T A T U T O R Y I N S T R U M E N T S

2008 No.

FOOD, ENGLAND

The Food Hygiene (England) (Amendment) Regulations 2008

Made - - - -	*2008*
Laid before Parliament	*2008*
Coming into force	*2008*

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**a**).

The Secretary of State has been designated for the purposes of that section in relation to measures relating to food (including drink) including the primary production of food(**b**).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(**c**) there has been open and transparent public consultation during the preparation of the following Regulations.

Title and commencement

1. These Regulations may be cited as the Food Hygiene (England) (Amendment) Regulations 2008 and come into force on [ ] 2008.

Amendments to the Food Hygiene (England) Regulations 2006

2.—(1) The Food Hygiene (England) Regulations(**d**) are amended in accordance with paragraphs (2) to (8).

(2) In paragraph (1) of regulation 2 (interpretation) for the definitions of the Community instruments appearing immediately after the definition of "the Community Regulations" there are substituted the following definitions-

> ""Directive 2004/41", "Regulation 178/2002", "Regulation 852/2004", "Regulation 853/2004", "Regulation 854/2004", "Regulation 882/2004", "Regulation 1688/2005", "Regulation 2073/2005", "Regulation 2074/2005", "Regulation 2075/2005", "Regulation 2076/2005", "Regulation 575/2006", "Regulation 1791/2006", "Regulation A",

(**a**) 1972 c.68.
(**b**) S.I. 2003/2901.
(**c**) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European food Safety Authority (OJ No. L100, 8.4.2006, p.3).
(**d**) S.I. 2006/14, amended by S.I. 2007/56.

"Regulation B", "Regulation C", "Regulation D" and "Regulation E" have the meanings respectively given to them in Schedule 1;".

(3) For Schedule 1 (definitions of Community legislation) there is substituted the Schedule set out in Schedule 1 to these Regulations.

(4) For regulation 17 (offences and penalties) there is substituted the following regulation—

"Offences and penalties

17.—(1) Subject to paragraphs (4) to (10), any person who contravenes or fails to comply with any of the specified Community provisions shall be guilty of an offence.

(2) Subject to paragraph (3), a person guilty of an offence under these Regulations shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to imprisonment for a term not exceeding two years, to a fine or to both.

(3) A person guilty of an offence under regulation 15 shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding three months or to both.

(4) Provided the requirements of Schedule 3 are complied with, a person shall be considered not to have contravened or failed to comply with Article 4(2) of Regulation 852/2004 as read with paragraph 4 of Chapter IV of Annex II to that Regulation (bulk foodstuffs in liquid, granulate or powder form to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs).

(5) Provided the requirements of Schedule 3A are complied with, a person shall be considered not to have contravened or failed to comply with Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 5 of Chapter II of Section I of Annex III to that Regulation (food business operators to ensure that slaughterhouses in which domestic ungulates are slaughtered have lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption).

(6) Provided the requirements of Schedule 3B are complied with, a person shall be considered not to have contravened or failed to comply with Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 5 of Chapter II of Section II of Annex III to that Regulation (food business operators to ensure that slaughterhouses in which poultry or lagomorphs are slaughtered have lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption).

(7) Provided the requirements of Schedule 3C are complied with, a person shall be considered not to have contravened or failed to comply with Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 6 of Chapter II of Section I of Annex III to that Regulation (food business operators to ensure that slaughterhouses in which domestic ungulates are slaughtered have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock unless the competent authority permits them not to have such places and official authorised places and facilities exist nearby).

(8) Provided the requirements of Schedule 3D are complied with, a person shall be considered not to have contravened or failed to comply with Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 6(b) of Chapter II of Section II of Annex III to that Regulation (food business operators to ensure that slaughterhouses in which poultry or lagomorphs are slaughtered have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport unless officially authorised places and facilities exist nearby).

(9) Provided the requirements of Schedule 3E are complied with, a person shall be considered not to have contravened or failed to comply with—

(a) Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 7 of Chapter II of Section IV of Annex III to that Regulation (large wild game delivered to a game-handling establishment to be presented to the competent authority for inspection);

(b) Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 6 of Chapter III of Section IV of Annex III to that Regulation (small wild game delivered to a game handling establishment to be presented to the competent authority for inspection); or

(c) Article 5(1)(a) of Regulation 853/2004 as read with paragraph 2(a) of Chapter III of Section I of Annex I to Regulation 854/2004 in so far as that paragraph applies in relation to large wild game (food business operators prohibited from placing meat of large wild game on the market unless a health mark has been applied to it in accordance with Regulation 854/2004).

(10) No food business operator operating an establishment producing minced meat prepared from chilled meat shall be considered to have contravened or failed to comply with Article 3(1) or 4(1)(a) of Regulation 853/2004 as read in either case with paragraph 2(b) of Chapter III of Section V of Annex III to that Regulation (food business operators operating an establishment producing minced meat to ensure that, when prepared from chilled meat, minced meat is prepared within specified time limits).".

(5) For regulation 27 (food which has not been produced, processed or distributed in accordance with the Hygiene Regulations) there is substituted the following regulation—

"**Food which has not been produced, processed or distributed in accordance with the Hygiene Regulations**

27.—(1) On an inspection of any food, an authorised officer of an enforcement authority may certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations.

(2) Where any food is certified as mentioned in paragraph (1) it shall be treated for the purposes of section 9 of the Act as failing to comply with food safety requirements.

(3) Where any food certified as mentioned in paragraph (1) is part of a batch, lot or consignment of food of the same class or description, all the food in the batch, lot or consignment shall, until it is proved that it has been produced, processed or distributed in compliance with the Hygiene Regulations, be treated for the purposes of paragraph (2) as having been so certified.

(4) Where—

(a) meat of wild game has not been produced in accordance with Article 5(1) of Regulation 854/2004 as read with Part A of Chapter VIII of Section IV of Annex I to that Regulation (the official veterinarian to carry out post-mortem inspection in game-handling establishments in accordance with that Part);

(b) the meat is produced before 1st September 2010; and

(c) the requirements of Schedule 3E are complied with,

the meat shall be deemed to have been produced in accordance with that Article as so read.

(5) Where—

(a) meat of wild game has not been produced in accordance with Article 5(5)(a) of Regulation 854/2004 as read with paragraph 1(b) of Chapter II of Section III of Annex I to that Regulation (the competent authority to ensure that at least one official veterinarian is present in game-handling establishments throughout the post-mortem inspection);

(b) the meat is produced before 1st September 2010; and

(c) the requirements of Schedule 3E are complied with,

the meat shall be deemed to have been produced in accordance with that Article as so read."
.

(6) The following regulation is inserted immediately after regulation 32 (restrictions on the sale of raw milk intended for direct human consumption)—

"Special health mark

32A. The special health mark referred to in paragraph 9 of Chapter VI of Section I of Annex III to Regulation 853/2004 and paragraph 7 of Chapter III of Section I of Annex I to Regulation 854/2004 shall conform with Schedule 6A.".

(7) Immediately after Schedule 3 (bulk transport in sea-going vessels of liquid oils or fats and the bulk transport of raw sugar) there are inserted the Schedules set out in Schedule 2 to these Regulations.

(8) Immediately after Schedule 6 (restrictions on the sale of raw milk intended for direct human consumption) there is inserted the Schedule set out in Schedule 3 to these Regulations.

Signed by authority of the Secretary of State for Health

Name
Minister of State,
Department of Health

2008

SCHEDULE 1

Regulation 2(3)

SCHEDULE SUBSTITUTED FOR SCHEDULE 1 TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

"SCHEDULE 1

DEFINITIONS OF COMMUNITY LEGISLATION

"Directive 2004/41" means Directive 2004/41/EC of the European Parliament and of the Council 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(**a**);

"Regulation 178/2002" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(**b**) as last amended by Regulation 575/2006;

"Regulation 852/2004" means Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs(**c**) as read with Regulation 2073/2005;

"Regulation 853/2004" means Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(**d**) as last amended by Regulation A and as read with Directive 2004/41, Regulation 1688/2005, Regulation 2074/2005 and Regulation 2076/2005;

"Regulation 854/2004" means Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption(**e**) as last amended by Regulation 1791/2006 and as read with Directive 2004/41, Regulation 2074/2005, Regulation 2075/2005 and Regulation 2076/2005;

"Regulation 882/2004" means Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(**f**) as last amended by Regulation 1791/2006 and as read with Regulation 2074/2005 and Regulation 2076/2005;

"Regulation 1688/2005" means Commission Regulation (EC) No. 1688/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs(**g**);

"Regulation 2073/2005" means Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs(**h**) as amended by Regulation B;

(**a**) OJ No. L157, 30.4.2004, p.33. The revised text of Directive 2004/41/EC is now set out in a Corrigendum (OJ No. L195, 2.6.2004, p.12).

(**b**) OJ No. L31, 1.2.2002, p.1.

(**c**) OJ No. L139, 30.4.2004, p.1. The revised text of Regulation (EC) No. 852/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.3) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).

(**d**) OJ No. L139, 30.4.2004, p.55. The revised text of Regulation (EC) No. 853/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.22) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).

(**e**) OJ No. L139, 30.4.2004, p.206. The revised text of Regulation (EC) No. 854/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.83) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26).

(**f**) OJ No. L165, 30.4.2004, p.1. The revised text of Regulation (EC) No. 882/2004 is now set out in a Corrigendum (OJ No. L191, 28.5.2004, p.1) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.29).

(**g**) OJ No. L271, 15.10.2005, p.17.

(**h**) OJ No. L338, 22.12.2005, p.1, as read with the corrigenda at OJ No. L278, 10.10.2006, p.32 and OJ No. L283, 14.10.2006, p.62.

"Regulation 2074/2005" means Commission Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No. 854/2004 of the European Parliament and of the Council and Regulation (EC) No. 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No. 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004(**a**) as last amended by Regulation C;

"Regulation 2075/2005" means Commission Regulation (EC) No. 2075/2005 laying down specific rules on official controls for *Trichinella* in meat(**b**) as last amended by Regulation D;

"Regulation 2076/2005" means Commission Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004(**c**) as last amended by Regulation E;

"Regulation 575/2006" means Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority(**d**);

"Regulation 1791/2006" means Council Regulation (EC) No. 1791/2006 adapting certain Regulations and Decisions in the fields of free movement of goods, freedom of movement of persons, company law, competition policy, agriculture (including veterinary and phytosanitary legislation), transport policy, taxation, statistics, energy, environment, cooperation in the fields of justice and home affairs, customs union, external relations, common foreign and security policy and institutions, by reason of the accession of Bulgaria and Romania(**e**);

"Regulation A" means Commission Regulation (EC) No. [ ]/2007 amending Annex III to Regulation (EC) No. 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin(**f**);

"Regulation B" means Commission Regulation (EC) No. [ ]/2007 amending Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs(**g**);

"Regulation C" means Commission Regulation (EC) No. [ ]/2007 amending Regulation (EC) No. 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat(**h**);

"Regulation D" means Commission Regulation (EC) No. [ ]/2007 amending Annex I to Regulation (EC) No. 2075/2005, as regards the use of liquid pepsin for the detection of *Trichinella* in meat(**i**); and

"Regulation E" means Commission Regulation (EC) No. [ ]/2007 amending Regulation (EC) No. 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption(**j**).".

(**a**) OJ No. L338, 22.12.2005, p.27.
(**b**) OJ No. L338, 22.12.2005, p.60.
(**c**) OJ No. L338, 22.12.2005, p.83.
(**d**) OJ No. L100, 8.4.2006, p.3.
(**e**) OJ No. L363, 20.12.2006, p.1.
(**f**) OJ No. [ ].
(**g**) OJ No. [ ].
(**h**) OJ No. [ ].
(**i**) OJ No. [ ].
(**j**) OJ No. [ ].

SCHEDULE 2

Regulation 2(7)

SCHEDULES INSERTED IMMEDIATELY AFTER SCHEDULE 3 TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

"SCHEDULE 3A

Regulation 17(5)

REQUIREMENTS REFERRED TO IN REGULATION 17(5)

The requirements are that —

(a) on 31st December 2005 the slaughterhouse was licensed as a low throughput slaughterhouse under the Fresh Meat (Hygiene and Inspection) Regulations 1995(**a**);

(b) the condition of meat derived from domestic ungulates slaughtered at the slaughterhouse is only rarely such that it is necessary to detain such meat after post-mortem inspection for further inspection by the official veterinarian;

(c) where such further inspection is considered necessary by the official veterinarian, the meat concerned is destroyed or is detained at an alternative detention facility in the locality of the slaughterhouse; and

(d) no processing for human consumption of domestic bovine animals aged over 30 months at slaughter or of domestic porcine animals that, under Article 5 of Regulation 854/2004 as read with paragraph 1 of Part C of Chapter IX of Section IV of Annex I to that Regulation, require examination for Trichinosis takes place at the slaughterhouse.

(**a**) S.I. 1995/539, revoked by S.I. 2005/2059.

SCHEDULE 3B

Regulation 17(6)

REQUIREMENTS REFERRED TO IN REGULATION 17(6)

The requirements are that—

(a) on 31st December 2005 the slaughterhouse was licensed as a low throughput slaughterhouse under the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995(**a**);

(b) the condition of meat derived from poultry or lagomorphs slaughtered at the slaughterhouse is only rarely such that it is necessary to detain such meat after post-mortem inspection for further inspection by the official veterinarian; and

(c) where such further inspection is considered necessary by the official veterinarian, the meat concerned is destroyed or is detained at an alternative detention facility in the locality of the slaughterhouse.

(**a**) S.I. 1995/540, revoked by S.I. 2005/2059.

SCHEDULE 3C

Regulation 17(7)

REQUIREMENTS REFERRED TO IN REGULATION 17(7)

The requirements are that—

(a) on 31st December 2005 the slaughterhouse was licensed as a low throughput slaughterhouse under the Fresh Meat (Hygiene and Inspection) Regulations 1995;

(b) the food business operator at the slaughterhouse only accepts domestic ungulates that have been transported direct from the holding of origin or from a market;

(c) the food business operator responsible for transporting the domestic ungulates undertakes to the food business operator at the slaughterhouse that he will ensure that the means of transport are cleaned and, if necessary, disinfected after emptying; and

(d) the food business operator at the slaughterhouse acknowledges to the official veterinarian that he may be required under animal health rules to cease operating at the slaughterhouse in the event of an animal disease outbreak.

SCHEDULE 3D

Regulation 17(8)

REQUIREMENTS REFERRED TO IN REGULATION 17(8)

The requirements are that—

(a) on 31st December 2005 the slaughterhouse was licensed as a low throughput slaughterhouse under the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995;

(b) the food business operator at the holding of origin of the poultry or lagomorphs transports them from that holding direct to the slaughterhouse and undertakes to the food business operator at the slaughterhouse that he will ensure that the means of transport are cleaned and, if necessary, disinfected after emptying; and

(c) the food business operator at the slaughterhouse acknowledges to the official veterinarian that he may be required under animal health rules to cease operating at the slaughterhouse in the event of an animal disease outbreak.

SCHEDULE 3E

Regulations 17(9) and 27(4)(c) and (5)(c)

REQUIREMENTS REFERRED TO IN REGULATIONS 17(9) AND 27(4)(c) AND (5)(c)

The requirements are that—

(a) the game-handling establishment has a throughput not exceeding 500kg of game meat per week;

(b) the food business operator at the game-handling establishment—

(i) has completed suitable preparatory training arranged by the Agency,

(ii) does not accept wild game carcases for preparation at the game-handling establishment for the purpose of placing them on the market unless—

(aa) they have been subject to an initial examination by a trained person and display no characteristics indicating a health risk, and

(bb) they have been supplied direct to the game handling establishment by a local hunter,

(iii) does not accept for such preparation carcases of feral wild boar,

(iv) undertakes checks on wild game carcases accepted for such preparation,

(vi) records the results of those checks and retains those records until 1st September 2011,

(vii) applies to all game meat prepared at the game-handling establishment for the purpose of placing it on the market the special health mark described in Schedule 6A, which must additionally include the first section of the establishment's post code, and

(viii) does not supply meat of wild game prepared at the game-handling establishment for the purpose of placing it on the market other than to the final consumer or to local retail establishments.".

SCHEDULE 3

Regulation 2(8)

SCHEDULE TO BE INSERTED IMMEDIATELY AFTER SCHEDULE 6 TO THE FOOD HYGIENE (ENGLAND) REGULATIONS 2006

"SCHEDULE 6A

Regulation 32A and Schedule 3E

THE SPECIAL HEALTH MARK

1. The special health mark shall consist of a square mark containing in legible form the following characters:

— on the upper part, the letters "UK";

— in the centre, the approval number of the premises; and

— on the lower part, the letter "N".

2. When applied to carcases, the special health mark shall measure 5.5 cm by 5.5 cm and contain letters 0.8 cm high and figures 1 cm high, except in the case of fresh meat from lambs, kids or piglets, when the dimensions and characters of the mark may be reduced.".

Impact assessments associated with the consultation on

The Food Hygiene (England) (Amendment) Regulations 2008

The titles of the individual impact assessments below are links that will open new pdf files of the relevant assessment

Proposed Commission Regulation amending Annex III of Regulation (EC) 853/2004

Proposed Commission Regulation amending Regulation (EC) 2073/2005

Proposed Commission Regulation amending Regulation (EC) 2074/2005

Proposed Commission Regulation amending Regulation (EC) 2075/2005

Proposed Commission Regulation amending Regulation (EC) 2076/2005

An exemption for cleansing and disinfection facilities for livestock vehicles

Exempting requirement for detained facilities in Low Throughput Slaughterhouses

Pilot project aimed at varying official controls at certain Approved Game Handling Establishments

A proposal to enable the continuation of traditional methods of production of minced meat

A special health and identification mark for meat slaughtered outside of a slaughterhouse

ANNEX A

DESCRIPTION OF THE DRAFT COMMISSION REGULATIONS

Proposal A (SANCO/140/2007 Rev 9)

Commission Regulation (EC) No…/… of […] amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin.

1. Adds to Annex III, Section VIII, paragraph 3 of Regulation 853/2004 to provide for a derogation from Annex I, Part A, point 7 of Regulation 852/2004 (record keeping for primary production) for certain small scale fishing vessels.

2. Replaces certain elements of Annex III, Section XIV to Regulation 853/2004 concerning gelatine.

Proposal B (SANCO/1797/2006 Rev 6)

Commission Regulation (EC) No…/… of […] amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

3. Replaces in its entirety Annex I of Regulation 2073/2005.

4. It amends the requirements for dried infant formulae and dried dietary foods, amends the reference to the analytical reference method for staphylococcal enterotoxins in certain cheeses, milk powder and whey powder and clarifies the requirements for sampling certain carcases for *Salmonella* analyses.

Proposal C (SANCO/2696/2006 Rev 10)

Commission Regulation (EC) No…/… of […] amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat.

5. Replaces Annex III, Chapter II of Regulation 2074/2005 to permit an alternative method of ASP detection in live bivalve molluscs for screening purposes.

6. Adds an Annex VIb to Regulation 2074/2005 specifying requirements applicable to official controls for the inspection of meat. It describes the circumstances under which the Competent Authority may decide whether the Official Veterinarian need be present throughout post mortem inspection.

Proposal D (SANCO/99/2007 Rev 3)

Commission Regulation (EC) No…/… of […] amending Annex I to Regulation (EC) No 2075/2005, as regards the use of liquid pepsin for the detection of *Trichinella* in meat

7. Amends Annex I to Regulation 2075/2005 to provide for the use of liquid pepsin in the *Trichinella* detection method.

Proposal E (SANCO/2162/2007 Rev 1)

Commission Regulation (EC) No…/… of […] amending Regulation (EC) No 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption.

8. Extends until 31 October 2008 the periods of derogation for imports of fish oil to comply with the new requirements.

SANCO/140/2007 Rev 9

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.07.2007

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin

(Text with EEA relevance)

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[1], and in particular Article 10(1) thereof,

Whereas:

(1) Reducing the administrative burden imposed on enterprises by existing Community legislation is a crucial element for improving their competitiveness and for achieving the objectives of the Lisbon agenda.

(2) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. That Regulation provides that food business operators are to comply with the relevant provisions of Annex III thereto.

(3) The requirements of Section VIII of Annex III to Regulation (EC) No 853/2004 as regards vessels engaged in primary production and associated operations supplement those laid down in Annex I to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[2]. In particular, those vessels are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period.

(4) Experience has shown that for food business operators involved in small-scale coastal fishing within the meaning of Article 26 of Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund[3], that requirement may create an additional administrative burden. It is therefore appropriate to provide for a derogation from that requirement for such operators.

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1 OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

2 OJ L 139, 30.4.2004, p. 1; corrected version (OJ L 226, 25.6.2004, p. 3).

3 OJ L 223, 15.8.2006, p. 1.

(5) Section XIV of Annex III to Regulation (EC) No 853/2004 sets out the requirements for the production of gelatine intended for human consumption. It specifies that when manufactured from ruminant bone material, gelatine must be produced using a unique process that ensures that all bone material is subjected to an alkaline treatment of saturated lime solution (pH>12,5) for a period of at least 20 days with a heat treatment step of 138°C minimum during at least four seconds, after having been finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days.

(6) The Scientific Panel on Biological Hazards of the European Food Safety Authority adopted on 18 January 2006 an opinion on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE risk". On 18 May 2006, it adopted another opinion on the "Quantitative assessment of the human BSE risk posed by bovine vertebral column including dorsal root ganglia with respect to residual BSE risk". According to both opinions, the production processes involving an acid process or a heat and pressure process ensure respectively equivalent and higher BSE infectivity reduction compared to the safety level achieved by applying the alkaline process currently required by Section XIV of Annex III to Regulation (EC) No 853/2004. The conditions for the production of gelatine should therefore be amended accordingly.

(7) There have been difficulties in interpreting provisions on possible other use of gelatine and collagen produced in accordance with the provisions laid down in Sections XIV and XV of Annex III to Regulation (EC) No 853/2004 in some Member States. It is therefore appropriate to clarify those provisions in order to harmonise their implementation.

(8) Regulation (EC) No 853/2004 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 853/2004 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

Annex III to Regulation (EC) No 853/2004 is amended as follows:

(1) In point 3 of Section VIII, the following paragraph is added:

"By way of derogation from point (a), point 7 of Part A of Annex I to Regulation (EC) No 852/2004 may not apply to operators engaged in small-scale coastal fishing within the meaning of Article 26(1) of Council Regulation (EC) No 1198/2006*, and carrying out their activities only for short periods of less than 24 hours.

* OJ L 223, 15.8.2006, p. 1"

(2) In Section XIV, Chapters III, IV and V are replaced by the following:

"CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:

(a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days. This treatment is followed either by:

- an alkaline treatment of saturated lime solution (pH>12,5) for a period of at least 20 days with a heat treatment step of 138°C minimum during at least four seconds, or

- an acid treatment (pH < 3,5) during 10 hours minimum with a heat treatment step of 138°C minimum during at least four seconds, or

- a heat-and-pressure process for at least 20 minutes with saturated steam of 133°C at more than 3 bars, or

- any approved equivalent process;

(b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or more times in succession, followed by purification by means of filtration and heat treatment.

2. A food business operator may produce and store both gelatine intended for human consumption and gelatine not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to gelatine intended for human consumption.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table:

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (European Pharmacopoeia 2005)	50 ppm
H_2O_2 (European Pharmacopoeia 2005)	10 ppm

CHAPTER V: LABELLING

Wrapping and packaging containing gelatine must bear the words "gelatine fit for human consumption" and must indicate the date of minimum durability.”

(3) In Section XV, Chapter III, point 3 is replaced by the following:

"3. A food business operator may produce and store both collagen intended for human consumption and collagen not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to collagen intended for human consumption."

(4) The Appendix is replaced by the following:

"Appendix to ANNEX III

MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN INTENDED FOR HUMAN CONSUMPTION

Number of the commercial document: ……

I. Identification of raw material

Nature of the raw material: ……

Animal species: …….

Type of packaging: …….

Number of packages: ……

Net weight (kg): ……

II. Origin of raw material

Type, name, address and approval/registration/special authorisation number of the establishment of origin:

……

III. Destination of raw material

Name and address of the consignor [(1)]: ……

Name and address of the consignee [(2)]: ……

Type, name, address and approval/registration/special authorisation number of the production establishment of destination:

……

Means of transport: ……

Done at ……., on ……..

……..

(Signature of the owner of the establishment of origin or its representatives)

[(1)] Only if different from the establishment of origin

[(2)] Only if different from the establishment of destination"

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2005) 18 July 2007

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

(Text with EEA relevance)

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 Article 4(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[2] lays down microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. Regulation (EC) No 2073/2005 also provides that food business operators are to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I to that Regulation.

(2) Chapters 1 and 2 of Annex I to Regulation (EC) No 2073/2005 set out food safety criteria and process hygiene criteria regarding dried infant formulae and dried dietary foods for special medical purposes intended for infants below six month of age ('dried infant formulae and dried dietary foods'). Part 2.2 of Chapter 2 of that Annex provides that where dried infant formulae and dried dietary foods are tested and Enterobacteriaceae are detected in any of the sample units, the batch is to be tested for *Enterobacter sakazakii* and *Salmonella.*

(3) On 24 January 2007, the Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion with regard to Enterobacteriaceae as indicators of *Salmonella* and *Enterobacter sakazakii*. It concluded that it is not possible to establish a correlation between Enterobacteriaceae and *Salmonella,* and no universal correlation between Enterobacteriaceae and *Enterobacter sakazakii* exists. At individual plant level, a correlation between Enterobacteriaceae and *Enterobacter sakazakii* may however be established.

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1 OJ L 139, 30.4.2004, p. 1; corrected version (OJ L 226, 25.6.2004, p. 3).
2 OJ L 338, 22.12.2005, p. 1.

(4) Therefore the requirement laid down in Regulation (EC) No 2073/2005 as regards the testing of dried infant formulae and dried dietary foods for *Salmonella* and *Enterobacter sakazakii* where Enterobacteriaceae are detected in any of the sample units should no longer apply. Part 2.2 of Chapter 2 of Annex I to that Regulation should therefore be amended accordingly.

(5) In line with the opinion on the microbiological risks in infant formulae and follow-on formulae issued by the BIOHAZ Panel of EFSA on 9 September 2004, microbiological criteria on *Salmonella* and Enterobacteriaceae should be laid down for dried follow-on formulae.

(6) The BIOHAZ Panel of EFSA issued an opinion on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs on 26 and 27 January 2005. It concluded that one of the major control measures is to control temperature and to establish a system based on hazard analysis and critical control point principles. Dehydrated foods, in which the presence of spores of pathogenic *Bacillus* spp. is frequent, might permit the growth of *Bacillus cereus* once re-hydrated in warm water. Some dehydrated foods, including dried infant formulae and dried dietary foods, are consumed by potentially fragile consumers. In line with the EFSA opinion, the numbers of *Bacillus cereus* spores in dried infant formulae and dried dietary foods should be as low as possible during processing and a process hygiene criterion should be laid down in addition to good practices designed to reduce delay between preparation and consumption.

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(7) Chapter 1 of Annex I to Regulation (EC) No 2073/2005 provides for the analytical reference method for staphylococcal enterotoxins in certain cheeses, milk powder and whey powder. That method has been revised by the Community reference laboratory for coagulase positive staphylococci. The reference to that analytical reference method should therefore be amended. Chapter 1 of Annex I to that Regulation should therefore be amended accordingly.

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(8) Chapter 3 of Annex I to Regulation (EC) No 2073/2005 sets out sampling rules for carcases of cattle, pig, sheep, goats and horses for *Salmonella* analyses. Pursuant to those rules the sampling area is to cover a minimum of 100 cm^2 per site selected. However, neither the number of sampling sites nor the minimum total area of sampling is specified. In order to improve the implementation of these rules in the Community, it is appropriate to further specify in Regulation (EC) No 2073/2005 that the areas most likely to be contaminated should be selected for sampling and that the total sampling area should be increased. Chapter 3 of Annex I to that Regulation should therefore be amended accordingly.

(9) In the interests of clarity of Community legislation, it is appropriate to replace Annex I to Regulation (EC) No 2073/2005 by the text set out in the Annex to this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 2073/2005 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

"**ANNEX I**

Microbiological criteria for foodstuffs

Chapter 1. Food safety criteria

	Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan[1]		Limits[2]		Analytical reference method[3]	Stage where the criterion applies
			n	c	m	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes [4]	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2	Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g[5]		EN/ISO 11290-2[6]	Products placed on the market during their shelf-life
			5	0	Absence in 25 g[7]		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes[4,8]	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2[6]	Products placed on the market during their shelf-life

1.4	Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM)[9]	*Salmonella*	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.9	Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence In 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.10	Gelatine and collagen	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.11	Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation[10]	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.12	Milk powder and whey powder	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.13	Ice cream[11], excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.14	Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25g	EN/ISO 6579	Products placed on the market during their shelf-life
1.15	Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g or ml	EN/ISO 6579	Products placed on the market during their shelf-life
1.16	Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25g	EN/ISO 6579	Products placed on the market during their shelf-life
1.18	Sprouted seeds (ready-to-eat)[12]	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.19	Precut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.20	Unpasteurised fruit and vegetable juices (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.21	Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected in 25g	European screening method of the CRL for coagulase positive staphylococci[13]	Products placed on the market during their shelf-life
1.22	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	*Salmonella*	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.23	Dried follow-on formulae	*Salmonella*	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.24	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age[14]	*Enterobacter sakazakii*	30	0	Absence in 10 g	ISO/TS 22964	Products placed on the market during their shelf-life

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1.25	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*E. coli*[15]	1 (16)	0	230 MPN / 100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.26	Fishery products from fish species associated with a high amount of histidine[17]	Histamine	9 (18)	2	100 mg/kg	200 mg/kg	HPLC[19]	Products placed on the market during their shelf-life
1.27	Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine[17]	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC[19]	Products placed on the market during their shelf-life

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.

[2] For points 1.1-1.25 m=M

[3] The most recent edition of the standard shall be used.

[4] Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package)
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds
- bread, biscuits and similar products
- bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products
- sugar, honey and confectionery, including cocoa and chocolate products
- live bivalve molluscs.

[5] This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.

[6] 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

[7] This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

8 Products with pH ≤ 4.4 or a_w ≤ 0.92, products with pH ≤ 5.0 and a_w ≤ 0.94, products with a shelf-life of less than five days shall be automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

9 This criterion shall apply to mechanically separated meat (MSM) produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.

10 Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.

11 Only ice creams containing milk ingredients.

12 Preliminary testing of the batch of seeds before starting the sprouting process or the sampling must be carried out at the stage where the highest probability of finding Salmonella is expected.

13 Reference: Community reference laboratory for coagulase positive staphylococci. European screening method for the detection of staphylococcal enterotoxins in milk and milk products.

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14 Parallel testing for Enterobacteriaceae and *E. sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for *E. sakazakii*. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *E. sakazakii*.

15 *E. coli* is used here as an indicator of faecal contamination.

16 A pooled sample comprising a minimum of 10 individual animals.

17 Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae.*

18 Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch is to be deemed unsafe, shall not apply.

19 References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.
2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*. J. AOAC Internat. 1999, 82, 1097-1101.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested[1].

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:
– satisfactory, if all the values observed indicate the absence of the bacterium,
– unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

– satisfactory, if all the values observed indicate the absence of the bacterium,
– unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

– satisfactory, if all the values observed are ≤ the limit,
– unsatisfactory, if any of the values are > the limit.

Salmonella in different food categories:

– satisfactory, if all the values observed indicate the absence of the bacterium,
– unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Staphylococcal enterotoxins in dairy products:

– satisfactory, if in all the sample units the enterotoxins are not detected,
– unsatisfactory, if the enterotoxins are detected in any of the sample units.

Enterobacter sakazakii in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

– satisfactory, if all the values observed indicate the absence of the bacterium,
– unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Histamine in fishery products from fish species associated with a high amount of histidine:

– satisfactory, if the following requirements are fulfilled
  1. the mean value observed is ≤ m
  2. a maximum of c/n values observed are between m and M
  3. no values observed exceed the limit of M,
– unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

[1] The test results may be used also for demonstrating the effectiveness of the hazard analysis and critical control point principles or good hygiene procedure of the process.

Chapter 2. Process hygiene criteria

2.1 Meat and products thereof

Food category		Micro-organisms	Sampling plan[1]		Limits[2]		Analytical reference method[3]	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.1.1	Carcases of cattle, sheep, goats and horses[4]	Aerobic colony count			3.5 log cfu/cm^2 daily mean log	5.0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
		Enterobacteriaceae			1.5 log cfu/cm^2 daily mean log	2.5 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2	Carcases of pigs[4]	Aerobic colony count			4.0 log cfu/cm^2 daily mean log	5.0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
		Enterobacteriaceae			2.0 log cfu/cm^2 daily mean log	3.0 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls

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2.1.3	Carcases of cattle, sheep, goats and horses	*Salmonella*	50^{5}	2^{6}	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4	Carcases of pig	*Salmonella*	50^{5}	5^{6}	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5	Poultry carcases of broilers and turkeys	*Salmonella*	50^{5}	7^{6}	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin
2.1.6	Minced meat	Aerobic colony count[7]	5	2	$5x10^{5}$ cfu/g	$5x10^{6}$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
		E. coli[8]	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

2.1.7	Mechanically separated meat (MSM)[9]	Aerobic colony count	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
		E. coli[8]	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8	Meat preparations	*E. coli*[8]	5	2	500 cfu/g or cm^2	5000 cfu/g or cm^2	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.

[2] For points 2.1.3 – 2.1.5 m=M

[3] The most recent edition of the standard shall be used.

[4] The limits (m and M) shall apply only to samples taken by the destructive method. The daily mean log shall be calculated by first taking a log value of each individual test result and then calculating the mean of these log values.

[5] The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

[6] The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.

[7] This criterion shall not apply to minced meat produced at retail level when the shelf-life of the product is less then 24 hours.

[8] *E. coli* is used here as an indicator of faecal contamination.

[9] These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcases where the limits refer to pooled samples.
The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:
– satisfactory, if the daily mean log is ≤ m,
– acceptable, if the daily mean log is between m and M,
– unsatisfactory, if the daily mean log is >M.

Salmonella in carcases:
– satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,
– unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions shall be assessed in order to obtain the n number of samples.

E. coli and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):
– satisfactory, if all the values observed are ≤ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.2 Milk and dairy products

Food category		Micro-organisms	Sampling plan[1]		Limits[2]		Analytical reference method[3]	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.2.1	Pasteurised milk and other pasteurised liquid dairy products[4]	Entero-bacteriaceae	5	2	<1/ml	5/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials
2.2.2	Cheeses made from milk or whey that has undergone heat treatment	*E. coli*[5]	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	At the time during the manufacturing process when the *E. coli* count is expected to be highest[6]	Improvements in production hygiene and selection of raw materials

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2.2.3	Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values $>10^5$ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4	Cheeses made from milk that has undergone a lower heat treatment than pasteurisation[7] and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment[7]	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment[7]	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manu-facturing process	Improvements in production hygiene. If values $> 10^5$ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.

2.2.6	Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E. coli*[5]	5	2	10 cfu/g	100 cfu/g	ISO 16649-1 or 2	End of the manu-facturing process	Improvements in production hygiene and selection of raw materials
2.2.7	Milk powder and whey powder[4]	Entero-bacteriaceae	5	0	10 cfu/g		ISO 21528-2	End of the manu-facturing process	Check on the efficiency of heat treatment and prevention of recontamination
		Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manu-facturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8	Ice cream[8] and frozen dairy desserts	Entero-bacteriaceae	5	2	10 cfu/g	100 cfu/g	ISO 21528-2	End of the manu-facturing process	Improvements in production hygiene

2.2.9	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Entero-bacteriaceae	10	0	Absence in 10 g		ISO 21528-1	End of the manu-facturing process	Improvements in production hygiene to minimise contamination. [9]
2.2.10	Dried follow-on formulae	Entero-bacteriaceae	5	0	Absence in 10 g		ISO 21528-1	End of the manu-facturing process	Improvements in production hygiene to minimise contamination.
2.2.11	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Presumptive *Bacillus cereus*	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932[10]	End of the manufacturing process	Improvements in production hygiene. Prevention of recontamination. Selection of raw material.

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.
[2] For points 2.2.7, 2.2.9 and 2.2.10 m=M
[3] The most recent edition of the standard shall be used.
[4] The criterion shall not apply to products intended for further processing in the food industry.
[5] *E. coli* is used here as an indicator for the level of hygiene.

[6] For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.

[7] Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.

[8] Only ice creams containing milk ingredients.

[9] Parallel testing for Enterobacteriaceae and *E. sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch has to be tested for *E. sakazakii*. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *E. sakazakii*.

[10] 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae, dried dietary foods for special medical purposes intended for infants below six months of age and dried follow-on formulae:

– satisfactory, if all the values observed indicate the absence of the bacterium,
– unsatisfactory, if the presence of the bacterium is detected in any of the sample units

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E. coli, Enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

– satisfactory, if all the values observed are $\leq$ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq$ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Presumptive *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

– satisfactory, if all the values observed are $\leq$ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq$ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.3 Egg products

Food category		Micro-organisms	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.3.1	Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manu-facturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.
[2] The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:
– satisfactory, if all the values observed are ≤ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

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2.4 Fishery products

Food category		Micro-organisms	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.4.1	Shelled and shucked products of cooked crustaceans and molluscan shellfish	*E. coli*	5	2	1/g	10/g	ISO TS 16649-3	End of the manu-facturing process	Improvements in production hygiene
		Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.
[2] The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.
E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:
– satisfactory, if all the values observed are ≤ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:
– satisfactory, if all the values observed are ≤ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

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2.5 Vegetables, fruits and products thereof

Food category		Micro-organisms	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.5.1	Precut fruit and vegetables (ready-to-eat)	*E. coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2	Unpasteurised fruit and vegetable juices (ready-to-eat)	*E. coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

[1] n = number of units comprising the sample; c = number of sample units giving values between m and M.
[2] The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in precut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices: (ready-to-eat)
– satisfactory, if all the values observed are ≤ m,
– acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
– unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

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Chapter 3. Rules for sampling and preparation of test samples

3.1 General rules for sampling and preparation of test samples

In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.

3.2 Bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604.

Five carcases shall be sampled at random during each sampling session. Sample sites must be selected taking into account the slaughter technology used in each plant.

When sampling for analyses of Enterobacteriaceae and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm² shall be obtained by the destructive method. When using the non-destructive method for this purpose, the sampling area shall cover a minimum of 100 cm² (50 cm² for small ruminant carcases) per sampling site.

When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. Areas most likely to be contaminated shall be selected. The total sampling area shall cover a minimum of 400 cm².

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Sampling rules for poultry carcases

For the *Salmonella* analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases shall be pooled before examination in order to form 5 x 25 g final samples.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Sampling frequencies for carcases, minced meat, meat preparations and mechanically separated meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcases for Enterobacteriaceae and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations and carcases, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. The salmonella sampling frequency may also be reduced if there is a national or regional salmonella control programme in place and if this programme includes testing that replaces the sampling described in this paragraph. The sampling frequency may be further reduced if the national or regional salmonella control programme demonstrates that the salmonella prevalence is low in animals purchased by the slaughterhouse.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat and meat preparations in small quantities may be exempted from these sampling frequencies."

SANCO/2696/2006 Rev. 10

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.07.2007
C (2007)

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat

(Text with EEA relevance)

(Memorandum from Mr Markos KYPRIANOU)

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[1], and in particular Article 16 and Article 18 (3), (7) and (12) thereof,

Whereas:

(1) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[2], Regulation (EC) No 854/2004, and 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] lay down the health rules and requirements regarding food of animal origin and the official controls required.

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1 OJ L 139, 30.4.2004, p.206; corrected version (OJ L 226, 25.6.2004, p. 83). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

2 OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22). Regulation as last amended by Regulation (EC) No 1791/2006.

3 OJ L 165, 30.4.2004, p. 1; corrected version (OJ L 191, 28.5.2004, p. 1). Regulation as last amended by Regulation (EC) No 1791/2006.

(2) Implementing rules for those Regulations are laid down in Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[4].

(3) In accordance with Regulation (EC) No 854/2004, the competent authority may decide that the official veterinarian need not be present at all times during post-mortem inspections in certain slaughterhouses or game handling establishments identified on the basis of a risk analysis. In such cases, an official auxiliary is to perform the post mortem inspection activities, which might contribute to reducing the financial burden for establishments with a low throughput.

(4) The criteria for such derogations should be determined on the basis of a risk analysis. In particular, establishments carrying out discontinuous slaughter or processing activities fulfil a social and economic function in rural communities. It should therefore be possible for those establishments to benefit from such derogations provided that they comply with the legal and hygiene requirements.

(5) In accordance with Regulation (EC) No 854/2004 the competent authority may decide that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need only undergo visual inspection. More specific requirements should be laid down for the conditions under which such reduced, but risk-based meat inspection procedures should be allowed.

(6) On 24 February 2000, the Scientific Committee on Veterinary Measures relating to Public Health adopted an opinion on "Revision of meat inspection procedures", which deals with the general principles relating to meat inspections. It concludes that current meat inspection systems can be improved when supplemented with information from the complete production chain, use of the Hazard Analysis, Critical Control Point (HACCP) principles in the slaughter plant and microbiological monitoring of faecal indicator organisms.

(7) On 20 and 21 June 2001, the Scientific Committee on Veterinary Measures relating to Public Health adopted an opinion on "Identification of species/categories of meat-producing animals in integrated production systems where meat inspection may be revised". It concludes that there are already a number of production systems in Member States where the criteria for application of a simplified meat inspection system are fulfilled.

[4] OJ L 338, 22.12.2005, p. 27. Regulation as amended by Regulation (EC) No 1664/2006 (OJ L 320, 18.11.2006, p. 13)..

(8) On 14 and 15 April 2003, the Scientific Committee on Veterinary Measures relating to Public Health adopted an opinion on "Revision of meat inspection in veal calves", which states that visual inspection of veal calves reared in integrated systems is sufficient for routine inspection, but that as long as bovine tuberculosis has not been eradicated, surveillance for bovine tuberculosis should be maintained in bovine animals at both farm and abattoir levels.

(9) On 26 November 2003, the European Food Safety Authority (EFSA) adopted an opinion on "Tuberculosis in bovine animals: risks for human health and control strategies", which concludes that efficient post-mortem examination of specified lymph nodes and of the lungs represents an important element of national bovine tuberculosis eradication programmes, as well as being an integral part of veterinary meat inspection programmes aimed at the protection of human health.

(10) On 1 December 2004, the EFSA adopted an opinion on "Revision of meat inspection for beef raised in integrated production systems", which states that the incision of lymph nodes should continue as part of a revised post mortem meat inspection system in order to be able to detect tuberculous lesions.

(11) On 18 May 2006, the EFSA adopted an opinion on "An assessment of the public and animal health risks associated with the adoption of a visual inspection system in veal calves raised in a Member State (or part of a Member State) considered free of bovine tuberculosis". It states that in case of veal calves reared in integrated production units and in officially bovine tuberculosis-free herds, post-mortem inspection can be restricted to observation and palpation of lymph nodes.

(12) On 22 April 2004, the EFSA adopted an opinion on "Meat inspection procedures for lambs and goats". It states that the important pathological conditions seen at meat inspection of lambs and goat kids can be diagnosed by visual inspection, thus preventing cross contamination by less manipulation.

(13) On 27 and 28 September 2000, the Scientific Committee on Veterinary Measures relating to Public Health adopted an opinion on "The control of taeniosis/cysticercosis in man and animals". It specifies the prerequisites necessary to ensure cysticercosis-free conditions.

(14) On 26 and 27 January 2005, the EFSA adopted an opinion on "The risk assessment of a revised inspection of slaughter animals in areas with low prevalence of *Cysticercus"*. It emphasises the need for risk profiling of the different calf production systems. Simplified post-mortem inspection can be applied for calves coming from integrated production systems previously assessed as of low-risk profile.

(15) Based on those scientific opinions the conditions for a reduced, but risk based meat inspection procedure of ruminants of a young age should be laid down.

(16) The availability of food chain information 24 hours in advance of slaughter should be a prerequisite for a risk based meat inspection without incision procedures. Consequently, whenever such a simplified meat inspection procedure is applied, the food business operator should not be able to benefit from the transitional arrangements laid down in Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[5].

(17) Regulation (EC) No 2074/2005 establishes the analytical methods for the detection of the amnesic shellfish poison (ASP) content of edible parts of molluscs. The 2006.02 ASP ELISA Method, as published in the AOAC Journal of June 2006, should be considered as an alternative screening method to the high-performance liquid chromatography (HPLC) method for the detection of ASP in bivalve molluscs. The ELISA method has the advantage of being able to screen a large number of samples in a relatively cheap way.

(18) Part D of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004 provides for that, where appropriate, solipeds are to be examined for glanders. A detailed post-mortem examination for glanders should be mandatory for those solipeds or meat thereof that originates from countries that are not free of the disease.

(19) Regulation (EC) No 2074/2005 should therefore be amended accordingly.

(20) The measures provided in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2074/2005 is amended as follows:

(1) The following Article is inserted:

"*Article 6 b*

Requirements concerning official controls for the inspection of meat for the purpose of Regulation (EC) No 854/2004

Requirements concerning official controls for the inspection of meat are laid down in Annex VI b."

(2) Chapter II of Annex III is amended in accordance with Annex I to this Regulation.

(3) The text in Annex II to this Regulation is inserted as Annex VI b."

[5] OJ L 338, 22.12.2005, p. 83. Regulation as last amended by Regulation (EC) No 479/2007 (OJ L 111, 28.4.2007, p. 46).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

In Annex III to Regulation (EC) No 2074/2005, Chapter II is replaced by the following:

"CHAPTER II

AMNESIC SHELLFISH POISON (ASP) DETECTION METHOD

The total content of amnesic shellfish poison (ASP) of edible parts of molluscs (the entire body or any part edible separately) must be detected using the high-performance liquid chromatography (HPLC) method or any other internationally recognised method.

However, for screening purposes, the 2006.02 ASP ELISA method as published in the AOAC Journal of June 2006 may also be used to detect the total content of ASP of edible parts of molluscs.

If the results are challenged, the reference method shall be the HPLC method."

ANNEX II

"ANNEX VI b
REQUIREMENTS APPLICABLE TO THE OFFICIAL CONTROLS FOR THE INSPECTION OF MEAT

1. For the purpose of this Annex, the following definitions shall apply:

   (a) "controlled housing conditions and integrated production systems" means a type of animal husbandry where animals are kept under conditions in compliance with criteria set out in the Appendix;

   (b) "young bovine animal" means a bovine animal of either gender, which is not older than 8 months;

   (c) "young ovine animal" means an ovine animal of either gender, not having any permanent incisor erupted and not older than 12 months;

   (d) "young caprine animal" means a caprine animal of either gender, not older than 6 months of age;

   (e) "herd" means an animal or group of animals kept on a holding as an epidemiological unit; if more than one herd is kept on a holding, each of these herds shall form a distinct epidemiological unit;

   (f) "holding" means any establishment, construction or, in the case of an open-air farm, any place situated within the territory of the same Member State, in which animals are held, kept or handled;

   (g) "establishment carrying out discontinuous slaughter or game handling activities" means a slaughterhouse or game handling establishment designated by the competent authority on the basis of a risk analysis, in which, in particular, the slaughter or game handling activities do not take place either during the entire working day or during subsequent working days of the week.

2. Post mortem inspections in establishments carrying out discontinuous slaughter or game handling activities.

   (a) In accordance with point 2(b) of Chapter II of Section III of Annex I to Regulation (EC) No 854/2004, the competent authority may decide that the official veterinarian need not be present at all times during post-mortem inspection, provided that the following conditions are complied with:

      (i) the establishment concerned is an establishment carrying out discontinuous slaughter or game handling activities and has sufficient facilities to store meat with abnormalities until a final post-mortem inspection by the official veterinarian can take place;

      (ii) an official auxiliary performs the post-mortem inspection activities;

      (iii) the official veterinarian visits the establishment at least once a day when slaughter activities take place or have taken place;

(iv) the competent authority has put in place a procedure to assess on a regular basis the performance of official auxiliaries in these establishments, including:

– monitoring individual performance,

– verification of documentation with regard to inspection findings and comparison with the corresponding carcases,

– checks of carcases in the storage room.

(b) The risk analysis carried out by the competent authority as referred to in point 1(g) to identify the establishments that may benefit from the derogation as laid down in point 2(a) shall at least take account of the following elements:

(i) the number of animals slaughtered or handled per hour or per day;

(ii) the species and class of animals slaughtered or handled;

(iii) the throughput of the establishment;

(iv) the historical performance of slaughter or handling activities;

(v) the effectiveness of any additional measures in the food chain for procurement of animals for slaughter taken to guarantee food safety;

(vi) the effectiveness of the HACCP based system in place;

(vii) audit records;

(viii) the competent authority's historical records of ante-mortem and post-mortem inspections.

3. Requirements for a risk-based meat inspection without incision procedures.

(a) In accordance with point 2 of Part B of Chapter IV of Section IV of Annex I to Regulation (EC) No 854/5004, the competent authority may limit the post-mortem inspection procedures of fattening pigs to a visual inspection, provided that the following conditions are complied with:

(i) the food business operator ensures that the animals are kept under controlled housing conditions and integrated production systems as laid down in the Appendix to this Annex;

(ii) the food business operator does not benefit from the transitional arrangements with regard to food chain information as laid down in Article 8 of Commission Regulation (EC) No 2076/2005;

(iii) the competent authority implements or orders the implementation of regular serological and/or microbiological monitoring of a selected number of animals based on a risk analysis of food safety hazards which are present in live animals and relevant at the farm level.

(b) By way of derogation from the specific requirements of Chapters I and II of Section IV of Annex I to Regulation (EC) No 854/2004, the post-mortem inspection procedures of young bovine, ovine and caprine animals may be reduced to a visual inspection with limited palpation, provided that the following conditions are complied with:

(i) the food business operator ensures that young bovine animals are kept under controlled housing conditions and in an integrated production system as laid down in the Appendix to this Annex;

(ii) the food business operator ensures that young bovine animals are reared in an officially bovine tuberculosis-free herd;

(iii) the food business operator does not benefit from the transitional arrangements with regard to food chain information as laid down in Article 8 of Regulation (EC) No 2076/2005;

(iv) the competent authority implements or orders the implementation of regular serological and/or microbiological monitoring of a selected number of animals based on a risk analysis of food safety hazards which are present in live animals and relevant at the farm level;

(v) post-mortem inspection of young bovine animals includes at all times palpation of the retropharyngeal, bronchial and mediastinal lymph nodes.

(c) In the case of any abnormality detected, the carcase and offal shall be subjected to a full post-mortem inspection as provided for in Chapters I and II of Section IV of Regulation (EC) No 854/2004. However, the competent authority may decide on the basis of a risk analysis that meat with certain minor abnormalities as defined by the competent authorities, which pose no risk to animal or human health, does not need to be subjected to a full post-mortem inspection.

(d) Young bovine, ovine and caprine animals and weaned pigs that do not go directly from the farm of birth to a slaughterhouse may be moved on one occasion to another farm (for rearing or fattening) prior to dispatch to a slaughterhouse. In such cases:

(i) regulated assembly centres may be used for young bovine, ovine or caprine animals between the farm of origin and the rearing or fattening farm, as well as between these farms and the slaughterhouse;

(ii) traceability shall be ensured at the level of the individual animal or batch of animals.

4. Additional requirement for the post-mortem examination of solipeds.

(a) Fresh meat from solipeds reared in countries not free of glanders in accordance with Article 2.5.8.2. of the *Terrestrial Animal Health Code* of the World Organisation for Animal Health shall not be placed on the market, unless such meat is derived from solipeds examined for glanders in accordance with point D of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004.

(b) Fresh meat from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption as provided for in point D of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004.

Appendix to Annex VI b

For the purposes of this Annex, "controlled housing conditions and integrated production systems" means that the food business operator needs to comply with the criteria set out below:

(a) All feed has been obtained from a facility which produces feed in accordance with the requirements provided for in Articles 4 and 5 of Regulation (EC) No 183/2005 of the European Parliament and of the Council[6]; when roughage or crops are provided to the animals as feed, it shall be treated appropriately, and where possible, dried and/or pelleted.

(b) an all-in/all-out system is applied as far as possible. Where animals are introduced into the herd, they shall be kept in isolation as long as required by the veterinary services to prevent introduction of diseases.

(c) none of the animals has access to outdoor facilities unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of disease in the herd;

(d) detailed information is available concerning the animals from birth to slaughter and their management conditions as laid down in Section III of Annex II to Regulation (EC) No 853/2004.

(e) if bedding is provided for the animals, the presence or introduction of disease is avoided by appropriate treatment of the bedding material;

(f) farm staff comply with the general hygiene provisions as laid down in Annex I to Regulation (EC) No 852/2004;

(g) procedures are in place that control access to the premises where animals are kept;

(h) the holding does not provide facilities for tourists or for camping unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the facilities are sufficiently separated from the animal rearing units that direct and indirect contact between humans and animals is not possible;

(i) animals do not have access to garbage dumps or household garbage;

(j) a pest management and control plan is in place;

(k) silage feeding is not used unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the feed can not transmit any hazards to the animals;

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6 OJ L 35, 8.2.2005, p. 1.

(l) effluent and sediment from sewage treatment plants are not released in areas accessible to the animals or be used for fertilising pastures used to grow crops, which are used to feed animals, unless treated appropriately and to the satisfaction of the competent authority.

SANCO/99/2007 Rev 3

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.07.2007
C (2007)

Draft

COMMISSION REGULATION

of

**amending Annex I to Regulation (EC) No 2075/2005,
as regards the use of liquid pepsin for the detection of *Trichinella* in meat**

(Text with EEA relevance)

(Memorandum from Mr Markos KYPRIANOU)

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

Draft

COMMISSION REGULATION

of

amending Annex I to Regulation (EC) No 2075/2005,
as regards the use of liquid pepsin for the detection of *Trichinella* in meat

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[1], and in particular Article 18 (9) and (10) thereof,

Whereas:

(1) Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific hygiene rules on official controls for *Trichinella* in meat[2] provides for methods of detection of *Trichinella* in samples of carcases. The reference method laid down in Annex I to that Regulation requires that for the detection of *Trichinella* larvae in meat samples, 10 ± 0,2 g of pepsin is to be added to the sample.

(2) Reports have been published[3] indicating that pepsin powder can cause allergic reactions in certain susceptible individuals.

(3) Investigations by the Community Reference Laboratory for Parasites indicated that the sensitivity of the reference method of detection for *Trichinella* is not altered when liquid pepsin is used according to the manufacturer's specifications instead of pepsin powder. Such an alternative should therefore be provided both for the reference method and the equivalent method of detection of *Trichinella* in meat.

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1 OJ L 139, 30.4.2004, p. 206; corrected version (OJ L 226, 25.6.2004, p. 83). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

2 OJ L 338, 22.12.2005, p. 60. Regulation as amended by Regulation (EC) No 1665/2006 (OJ L 320, 18.11.2006, p. 46).

3 J Investig Allergol Clin Immunol (2006) **16**, 136-137.

(4) Regulation (EC) No 2075/2005 should therefore be amended accordingly.

(5) The measures provided in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 2075/2005 is amended as follows:

(1) Chapter I is amended as follows:

(a) Point 1(p) is replaced by the following:

"(p) Pepsin, strength: 1: 10 000 NF (US National Formulary) corresponding to 1: 12 500 BP (British Pharmacopoea) and to 2 000 FIP (Fédération internationale de pharmacie), or stabilized liquid pepsin with minimum 660 European Pharmacopoea units/ml"

(b) Point 3.I (b) is replaced by the following:

"(b) 10 ± 0,2 g of pepsin or 30 ± 0,5 ml liquid pepsin is added."

(2) Chapter II is amended as follows:

(a) Point A. 1. (q) is replaced by the following:

"(q) Pepsin, strength: 1: 10 000 NF (US National Formulary) corresponding to 1: 12 500 BP (British Pharmacopoea) and to 2 000 FIP (Fédération internationale de pharmacie), or stabilized liquid pepsin with minimum 660 European Pharmacopoea units/ml",

(b) Point A. 3. II. (a) (v) is replaced by the following:

"(v) Lastly, 6 g pepsin or 18 ml liquid pepsin is added. This order must be followed strictly to avoid decomposition of the pepsin."

(c) Point C. 3. I. (h) is replaced by the following:

"(h) Lastly, add 7 g of pepsin or 21 ml liquid pepsin. This order must be followed strictly to avoid decomposition of the pepsin."

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission

SANCO/2162/2007 Rev. 1

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.7.2007

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Regulation (EC) No 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption

(Text with EEA relevance)

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

Draft

COMMISSION REGULATION (EC) No …/..

of

amending Regulation (EC) No 2076/2005 as regards the extension of the transitional period granted to food business operators importing fish oil intended for human consumption

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[1], and in particular Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[2], and in particular Article 16 thereof,

Whereas:

(1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. That Regulation provides that food business operators producing fish oil intended for human consumption are to comply with the relevant provisions of Annex III thereto.

(2) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin. It applies in respect of activities and persons to which Regulation (EC) No 853/2004 applies.

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1 OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

2 OJ L 139, 30.4.2004, p. 206; corrected version (OJ L 226, 25.6.2004, p. 83). Regulation as last amended by Regulation (EC) No 1791/2006.).

(3) Article 7(3) of Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[3] provides for a derogation from the requirements for fish oil for human consumption laid down in Part E of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 for food business operators so that they may continue, until 31 October 2007, to import fish oil from establishments in third countries that were approved for that purpose before the date of the entry into force of Commission Regulation (EC) No 1664/2006[4].

(4) In addition, Article 7(4) of Regulation (EC) No 2076/2005 provides for a derogation from Annex VI to Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[5], for fish oil for which a certificate has been issued in accordance with national rules applicable before the date of the entry into force of Regulation (EC) No 2074/2005, duly completed and signed prior to 31 October 2007, which may be imported into the Community until 31 December 2007.

(5) It now appears that third countries will be unable to comply with the requirements for fish oil for human consumption laid down in Annex III to Regulation (EC) No 853/2004 by 31 October 2007. In particular, third countries are experiencing practical difficulties in adjusting the processing conditions in fish oil producing establishments in order to comply with those requirements. As the importation of fish oil on the basis of the existing requirements does not pose any additional risk for human health, and in order to avoid any disruption in trade, it is appropriate to extend by one year the period of the derogation. The derogation provided for in Article 7(3) of Regulation (EC) No 2076/2005 should therefore be extended until 31 October 2008.

(6) The derogation provided for in Article 7(4)(b) of Regulation (EC) No 2076/2005 should also be extended until 31 December 2008 for imports into the Community of fish oil accompanied by the relevant certificate. In addition, such certificates should be duly completed and signed prior to 31 October 2008.

(7) Regulation (EC) No 2076/2005 should be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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[3] OJ L 338, 22.12.2005, p. 83. Regulation as last amended by Regulation (EC) No 479/2007 (OJ L 111, 28.4.2007, p. 46).

[4] OJ L 320, 18.11.2006, p. 13.

[5] OJ L 338, 22.12.2005, p. 27. Regulation as amended by Regulation (EC) No 1664/2006 (OJ L 320, 18.11.2006, p. 13).

HAS ADOPTED THIS REGULATION:

Article 1

Article 7 of Regulation (EC) No 2076/2005 is amended as follows:

(1) In paragraph 3, the date of '31 October 2007' is replaced by '31 October 2008'.

(2) In paragraph 4, point (b) is amended as follows:

(a) the date of '31 October 2007' is replaced by '31 October 2008';

(b) the date of '31 December 2007' is replaced by '31 December 2008'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission

Member of the Commission

List of Interested Parties

Names
ADAS
Anglian Poultry Processors Action Group
Association of Bakery Ingredients Manufacturers
Association of British Abattoir Operators
Association of British Ports
Association of British Salted Fish Couriers and Exporters
Association of Convenience Stores
Association of Independent Meat Suppliers
Association of Meat Inspectors
Association of Port Health Authorities
Association of Public Analysts
Association of Sea Fisheries Committee
Association of Sea Fisheries Committee of England and Wales
Association of Unpasteurised Milk Producers and Consumers
Assured Food Standards
Automatic Vending Association
Bakers of Nailsea Ltd
Bernard Matthews
Biotechnology and Biological Sciences Research Council
Biscuit, Cake, Chocolate & Confectionery Alliance
British Association for Shooting and Conservation
British Cattle Veterinary Association
British Deer Farmers Association
British Deer Society
British Egg Industry Council
British Goat Society
British Hospitality Association
British Institute of Agricultural Consultants
British Meat Processors Association
British Oat and Barley Millers Association
British Pig Association
British Poultry Council
British Retail Consortium
British Soft Drinks Association
British Veterinary Association
British Wild Boar Association
Cabinet Office

C A Leech & Son
C S Morphet & Son Ltd
Campden and Chorleywood Food Research Association
CEFAS
Chamber of Shipping
Chartered Institute of Environmental Health
Chilled Food Association
CMi Consulting
COCERAL
Cold Storage and Distribution Federation
Compassion in World Farming
Co-op
Country Land and Business Association
Crab Processors Association
Dairy Council
Dairy UK
Deer Initiative
Deer Management Qualification
Defra
Environment Agency
Farming and Countryside Education UK
Federation of British Port Wholesale Fish Merchants' Association
Federation of Wholesale Distributors
Food and Drink Federation
Food Commission
Food Ethics Council
Foodaware
Forum of Private Business
Games Conservancy Trust
Geest
Grimsby Fishing Vessel Owners Association
Guild of Lamb and Beef Suppliers
H J Heinz
Haemolytic Uraemic Syndrome Help
Halal Food Authority
Health Protection Agency
Health and Safety Executive
Highfield
Human BSE Foundation
Iceland Frozen Foods
Inglehurst Foods
Institute of Fisheries Management
Institute of Food Science and Technology
International Meat Traders Association
Islamic Cultural Centre
Jamie Gibson

LACORS
Lawlabs
LEAF
Leatherhead Food Research Association
Marks & Spencer
Meat and Livestock Commission
Meat Hygiene Service
Meat Training Council
Medvék Consultancy Limited
Milk Development Council
Muslim Council of Britain
National Association of Agricultural Contractors
National Association of British and Irish Millers
National Association of British Market Authorities
National Association of Catering Butchers
National Association of Master Bakers
National Beef Association
National Consumer Council
National Consumer Federation
National Council of Shechita Boards
National Council of Women
National Dairy Council
National Farmers Union
National Federation of Fishermen's Organisations
National Federation of Fishmongers Ltd
National Federation of Meat and Food Traders
National Federation of Women's Institutes
National Game Dealers Association
National Gamekeepers Association
National Pig Association
National Sheep Association
Neville Craddock Associates
Port of Felixstowe
Provision Trade Federation
Rachel's Dairy
Romford Wholesale Meats
Royal Association of British Dairy Farmers
Royal College of Veterinary Surgeons
Royal Institute of Public Health And Hygiene
Royal Society for the Promotion of Health
RSPCA
Rural Payments Agency
Sainsbury
Salmon and Trout Association

Sea Fish Authority
Seafood Processors Association
Shellfish Association of Great Britain
Small Abattoir Federation
Small Business Service
Smithfield Tenants' Association
Soil Association
Somerfield Stores
Specialist Cheese Makers Association
St Helen's Farm
State Veterinary Service
Stilton Cheese Makers Association
Sustain
TAPPAG
Tenant Farmers Association
Tesco
Townswomen's Guild
Trading Standards Institute
Traditional Farm Fresh Turkey Association
UK Association of Fish Meal Manufacturers
UNISON
VEGA
Veterinary Public Health Association
Which?