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SANCO/1733/2008

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.5.2008

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council

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Draft

COMMISSION REGULATION (EC) No .../..

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laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council

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 origin¹, and in particular Articles 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 consumption², and in particular Article 16 thereof,

Whereas:

- (1) [Initial capital...].
- (2) 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:

**CHAPTER I
GENERAL PROVISION**

*Article 1
Transitional period*

For the purposes of this Regulation, a transitional period of three years ending on 31 December 2012 (hereinafter referred to as 'the transitional period') is established.

¹ OJ L 226, 25.6.2004, p. 22.

² OJ L 226, 25.6.2004, p. 83.

CHAPTER II

TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 853/2004

Article 2

Direct supply of small quantities of meat from poultry and lagomorphs

By way of derogation from Article 1(3)(d) and without prejudice to Article 1(4) of Regulation (EC) No 853/2004, the provisions laid down in that Regulation shall not apply to the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer.

Article 3

Health import conditions

1. Article 6(1) of Regulation (EC) No 853/2004 shall not apply to imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin shall be exempt from the obligation provided for in that Article.

Pending the development of a risk-based approach for the implementation of harmonised health import conditions and checks of such food products, imports shall comply with the harmonised Community rules in force before 1 January 2006 where applicable, and with the national rules implemented by the Member States before that date in other cases.

Article 4

Composition criteria and labelling requirements for minced meat

1. By way of derogation from the requirements laid down in Chapter II (1) of Section V of Annex III of Regulation (EC) No 853/2004, the food business operator must check the raw materials entering the establishment to ensure compliance with the name of the product in the table below in respect of the final product.

Table: Composition criteria checked on the basis of a daily average

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	Fat content	Connective tissue:meat protein ratio
– lean minced meat	≤ 7%	≤ 12
– minced pure beef	≤ 20%	≤ 15
– minced meat containing pigmeat	≤ 30%	≤ 18
– minced meat of other species	≤ 25%	≤ 15

2. By way of derogation from the requirements laid down in Chapter IV of Section V of Annex III of Regulation (EC) No 853/2004, the labelling must also display the following words:
 - ‘percentage of fat under...’,
 - ‘connective tissue:meat protein ratio under...’.
3. The Member States may allow the placing on their national market of minced meat which does not comply with these criteria under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

CHAPTER III

TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 854/2004

Article 5 *Health import conditions*

Chapter III of Regulation (EC) No 854/2004 shall not apply to imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

Article 6

This Regulation shall enter into force on 1 January 2010.

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

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**EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL**

Brussels, 9 June 2008

Guidance document on the implementation of certain provisions of

Regulation (EC) No 853/2004

on the hygiene of food of animal origin

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PURPOSE OF THIS DOCUMENT

This document is mainly directed at food businesses and competent authorities in the Member States, and aims to give guidance on the implementation of the new food hygiene requirements and on related subjects.

Readers in third countries may find useful elements in the document so as to better understand the scope and the purpose of EU food hygiene rules.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities, food businesses and the Commission's Food and Veterinary Office.

1. INTRODUCTION

Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin (hereafter “the Regulation”) was adopted on 29 April 2004¹. It lays down the hygiene requirements to be respected by food businesses handling food of animal origin at all stages of the food chain. Since the adoption of the Regulation, the Commission has been requested to clarify a number of aspects thereof. This document aims to follow-up these requests.

The Commission’s Health and Consumer Protection Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on a number of issues concerning the implementation and interpretation of the Regulation.

In the interest of transparency, the Commission has also promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission has organised a meeting with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of the Regulation.

It was considered that these meetings and discussions should continue in the light of the experience gained by the full application of the Regulation from 1 January 2006.

It should be noted that matters relating to the non-compliance of national legislation with the Regulation remain outside the scope of this exercise and will continue to be dealt with in accordance with established Commission procedures.

The present document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the Regulation. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

For a complete understanding of the different aspects of Regulation (EC) No 853/2004, it is essential to be also familiar with other parts of Community legislation, and in particular with the principles and definitions 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 safety² (also referred to as the General Food Law),
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs³, and

¹ OJ No L 226, 25.6.2004, p.22

² OJ No L 31, 1.2.2002, p. 1

³ OJ No L 226 of 25.6.2004, p. 3

- 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 welfare⁴,
- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs⁵,
- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004, for the organisation of official controls under Regulations (EC) No 854/2004 and (EC) No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and (EC) No 854/2004⁶,
- Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat⁷,
- 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 No 854/2004⁸.

Separate guidance documents on Regulations (EC) No 178/2002 and (EC) No 852/2004 have been established.

(See http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm)

⁴ OJ No L 165, 30.4.2004, p.1
⁵ OJ No L 338, 22.12.2005, p. 1
⁶ OJ No L 338, 22.12.2005, p. 27
⁷ OJ No L 338, 22.12.2005, p. 60
⁸ OJ No L 338, 22.12.2005, p. 83

2. OBLIGATIONS OF FOOD BUSINESS OPERATORS

The Regulation must be implemented by food businesses. They must ensure that all the requirements are properly implemented in order to ensure food safety.

Food businesses that handle food of animal origin must implement the appropriate requirements of Regulation (EC) No 853/2004 in addition to the requirements laid down in Regulation (EC) No 852/2004.

3. SCOPE (ARTICLE 1 OF THE REGULATION)

3.1. Small businesses

Until 1 January 2006, certain small businesses can only place their products on the national or local market although they have to respect food hygiene criteria, e.g.

- Under Article 4 of Directive 64/433/EEC (the fresh meat Directive) meat from low capacity slaughterhouses handling not more than 20 livestock units per week, and cutting plants which produce not more than five tonnes of boned meat per week;
- Under Article 7 of Directive 71/118/EEC (the poultry meat Directive), slaughterhouses handling under 150 000 birds per year
- Under Article 3, point A(7) of Directive 77/99/EEC (the meat products Directive), when establishments use meat that has been marked with a national health mark.

These Directives will be repealed as from 1 January 2006. From that date onwards these establishments can place their products on the Community market if they are approved by the competent authority.

From 1 January 2006, there is therefore no restriction any more as to the supply of meat for the production of meat products and the placing on the market thereof if the slaughterhouse is approved by the competent authority.

Since it is unlikely that all the administrative steps to approve small businesses have been taken on 1 January 2006, a transitional measure has been adopted that will allow current practices to continue for those small businesses that have not been approved on that date and the national health mark to be used in the meanwhile.

3.2. Establishments handling food of animal origin for which no detailed requirements are laid down

For certain products of animal origin (e.g. honey), the Regulation does not lay down detailed rules. In that event, the food of animal origin must be handled in accordance with the relevant requirements laid down in Regulation (EC) No 852/2004 and also with the general rules for products of animal origin laid down in Regulation (EC) No 853/2004 (in particular the rules on products from outside the Community referred to in Article 6).

Since for these products there are no requirements in Annex III of Regulation (EC) No 853/2004, establishments handling the products need not be approved nor need they apply an identification mark on the food.

3.3. Products covered under Regulation (EC) No 853/2004

Regulation (EC) No 853/2004 only applies to **unprocessed and processed food** of animal origin.

- **A (non-exhaustive) list of unprocessed products of animal origin** [as defined in Article 2, point 1(n) of Regulation (EC) No 852/2004] is given in Annex I hereto.
- **A (non exhaustive) list of processed products of animal origin** [as defined in Article 2, point 1(o) of Regulation (EC) No 852/2004] is given in Annex II hereto.

In determining whether a product of animal origin is processed or unprocessed it is important to have regard to **all** the relevant definitions contained in the hygiene regulations, in particular, the definitions of ‘processing’, ‘unprocessed products’ and ‘processed products’ in Article 2 of Regulation 852/2004, and the definitions of certain processed products in Section 7 of Annex I of Regulation 853/2004. The interrelationship between these definitions will impact on the decision reached.

3.4. Food containing both products of plant origin and products of animal origin

Unless expressly indicated to the contrary, the Regulation does not apply to the production of food containing both products of plant origin and **processed products of animal origin**. Such exclusion from the scope is based upon the observation that the risk posed by the ingredient of animal origin can be controlled by implementing the rules of Regulation (EC) No 852/2004 without there being a need to apply more detailed specific requirements. However, Article 1, paragraph 2 of Regulation (EC) No 853/2004 clearly spells out that the **processed products of animal origin** used in foods containing both products of plant origin and processed products of animal origin that are exempted from the scope of Regulation 853/2004, shall be obtained and handled in accordance with the requirements of Regulation (EC) No 853/2004 e.g.

- Milk powder used to prepare ice cream must have been obtained in accordance with Regulation (EC) No 853/2004, however the manufacture of ice creams is performed under Regulation (EC) No 852/2004;
- Meat products used to prepare a pizza must have been obtained in accordance with Regulation (EC) No 853/2004, but the manufacture of the pizza falls under Regulation (EC) No 852/2004.

Moreover, the addition of a product of plant origin to a processed product of animal origin does not automatically mean that the resulting food falls within the meaning of Article 1, paragraph 2 of Regulation (EC) No 853/2004, e.g.:

- Cheeses to which herbs are added or yogurts to which fruit is added remain dairy products, and their manufacture must be performed under Regulation (EC) No 853/2004;
- Sausages to which garlic or soya is added remain meat products, and their manufacture must be performed under Regulation (EC) No 853/2004.

However, when the ingredient of plant origin, which is added to a processed animal product, has a technological function and modifies the initial product to such an extent that the resulting food cannot remain within the definition of "processed products of animal origin" as laid down in Article 1, point (o) of Regulation (EC) No 852/2004, then such products fall within the meaning of Article 1, paragraph 2 of Regulation (EC) No 853/2004, e.g.:

- Spreadable fats where the milk fats have been replaced by fats of plant origin.

Annex III gives an overview of the scope of Regulations (EC) No 852/2004 and 853/2004. The overview is non exhaustive and therefore purely indicative. It may be subject to review in function of experience gained with the new rules.

Remark: *an establishment manufacturing both products of animal origin and other products may apply the identification mark required for products of animal origin also on the other products (see Annex II, Section I, point B.7 of Regulation (EC) No 853/2004).*

3.5. Retail

Unless expressly indicated to the contrary, **Regulation (EC) No 853/2004 does not apply to retail** [Article 1, paragraph 5(a)].

The definition of retail sale is in Article 3, point 7 of Regulation (EC) No 178/2002. It reads as follows:

“retail” means the handling and/ or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

As explained in recitals 12 and 13 of Regulation (EC) No 853/2004, this definition which includes wholesale operations was considered to be too wide for food hygiene purposes. In the context of food hygiene, retail should generally have a more limited meaning as follows: “activities involving direct sale or supply of food of animal origin to the final consumer”. This means that:

- For activities involving direct sale or supply of food of animal origin to the final consumer, Regulation (EC) No 852/2004 would suffice. In accordance with the definition of “retail”, the term “activities” includes processing (e.g. the preparation of bakery products containing products of animal origin, the preparation of meat products in a local butcher shop) at the point of sale to the final consumer.
- With regard to wholesale activities (i.e. when a wholesale or retail establishment carries out operations with a view to supplying food of animal origin to another establishment), Regulation (EC) No 853/2004 applies except for:
 - Establishments for which the wholesale activities consist only of storage and transport. In that case, the requirements of Regulation (EC) No 852/2004, and the temperature requirements laid down in Regulation (EC) No 853/2004 apply,
 - The supply is, in accordance with national law, a **marginal, localised and restricted** activity of a retail establishment that mainly supplies the final consumer. In that event, only Regulation (EC) No 852/2004 applies.

However, in accordance with Article 1, paragraph 5(c), Member States may decide to extend the provisions of Regulation (EC) No 853/2004 to retail establishments situated on their territory to which they would not apply. In

applying this possibility, Member States should be led by the general principles of food law, i.e. proportionality and the need to have rules that are risk based.

3.6. **The notion “marginal, localised and restricted activity” as referred to in Article 1 paragraph 5, point b)ii of Regulation (EC) No 853/2004.**

That notion allows genuine retail shops supplying the final consumer (e.g. a butcher) to supply food of animal origin to another local retail business under the requirements of Regulation (EC) No 852/2004 only. The requirements of Regulation (EC) No 853/2004 (e.g. the approval of the establishment, the application of an identification mark) would not apply.

In general terms, the notion “marginal, localised and restricted activity” should allow current practices as they exist in the Member States to continue.

The notion “marginal, localised and restricted supply” stems from the observation that retail establishments supplying the final consumer as their main trade should in effect trade their products locally (even if the destination is in another Member State) and so are not engaged in long distance trade which requires more attention and supervision in particular as regards transport and cold chain conditions. In the case of a large Member State it would therefore not be in line with the Regulation to extend geographically the notion “marginal, localised and restricted supply” to the entire territory of that Member State.

The notion is further explained in recital (13), where it is spelled out that such supply should be only a small part of the supplying establishment’s business; the establishment supplied should be in its immediate vicinity, and the supply should concern only certain types of products or establishments.

In some cases retailers (e.g. butchers) may produce small quantities (in absolute terms) of food, most of which is supplied to caterers and/or to other retailers. In such cases it would be in line with the intention of the Regulation to enable the continued use of traditional methods of distribution, considering that “marginal” should include the notion of small quantities. “Marginal” should therefore be interpreted as a small amount of food of animal origin in absolute terms **or** as a small part of the establishment’s businesses. At any rate, the combination of the three criteria provided for by the Regulation should allow an appropriate qualification of most situations.

3.7. **Primary production covered under Regulation (EC) No 853/2004**

For certain products of animal origin, the notion “primary production” referred to in Regulation (EC) No 852/2004 is further developed under Regulation (EC) No 853/2004:

Live bivalve molluscs [Annex III, Section VII, point 4(a)]

With regard to live bivalve molluscs, primary production covers operations that take place before live bivalve molluscs arrive at a dispatch, purification centre or processing establishment.

Fishery products [Annex III, Section VIII, point 4 and Annex III, Section VIII, points 3(a) and (b)].

With regard to fishery products, primary production:

- Includes farming/fishing/collection of live fishery products (*whether from sea water or fresh water*) with a view to their being placed on the market, and
- Includes the following associated operations:
 - Slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping for transport carried out on board fishing vessels,
 - The transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within farms on land, and
 - The transport of fishery products (*whether from sea water or fresh water*) the nature of which has not substantially been altered, including live fishery products, from the place of production to the first establishment of destination.

Raw milk [Annex III, Section IX, Chapter 1]

The Regulation covers requirements to be respected at the farm, in particular with regard to the health of the animals, hygiene on milk production holdings, and criteria to be respected for raw milk.

Eggs [Annex III, Section X, Chapter 1]

The Regulation covers the handling of eggs at the producer's premises, and lays down that eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.

4. APPROVAL OF ESTABLISHMENTS (ARTICLE 4 OF THE REGULATION)

4.1. Establishments subject to approval

Establishments [except those carrying out only primary production, transport operations, the storage of products not requiring temperature controlled storage conditions or retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b)] handling those products for which Annex III of Regulation (EC) No 853/2004 lays down requirements must be approved. This entails a wide range of establishments, including establishments handling non-processed products and processed products of animal origin.

A non-exhaustive list of establishment categories subject to approval in accordance with Regulation (EC) No 853/2004 is given in Annex IV to the present document.

As retail (activities involving direct sale or supply of food of animal origin to the final consumer) is not covered by the scope of Regulation (EC) No 853/2004, the approval of retail establishments is not required under that Regulation.

4.2. The approval of small establishments

Additionally small establishments handling food of animal origin must be approved by the competent authority.

The approval requirements for such establishments are largely the requirements that applied already to them under the current rules. The new approval requirement should not therefore impose an important new burden provided these establishments already complied with the food hygiene rules applicable to them under the relevant Community rules (e.g. Directives 64/433/EEC and 77/99/EEC).

Remark:

Regulation (EC) No 853/2004 excludes retail (i.e. the handling and/or processing of food and its storage at the point of sale) from its scope. This means that where cheese is manufactured and sold at a retail premise (e.g. at the farm), these activities can be carried under the respect of the requirements laid down in Regulation (EC) No 852/2004 only, requiring registration but no approval.

4.3. Meat from animals slaughtered at the farm

Slaughter activities at the farm must be carried out in accordance with the appropriate requirements of Regulation (EC) No 852/2004 and with the specific food hygiene rules for meat production laid down in Regulation (EC) No 853/2004. This includes that the slaughter facilities must be approved by the competent authority.

Where it is felt that the infrastructural requirements of Regulations (EC) No 852/2004 and 853/2004 are disproportionate for on-the-farm slaughter Member States may adapt those requirements in accordance with the procedure laid down for that purpose in Article 13 of Regulation (EC) No 852/2004 and/or Article 10 of Regulation (EC) No 853/2004.

Remarks:

- *The direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer, fall outside the scope of Regulation (EC) No 853/2004. Member States shall establish national rules to ensure the safety of such meat [see Article], paragraph (d) of the Regulation].*
- *In the case of “slaughter for private domestic consumption”, such activity is undertaken by a private person who cannot be considered as being a food*

business operator. In addition, meat resulting from such slaughter is not placed on the market. Slaughter for private domestic consumption falls therefore out of the scope of Regulations (EC) No 852/2004 and 853/2004. Member States may have national rules in place with regard to this type of slaughter.

4.4. The approval of cold stores

Article 1, paragraph 5(a) of Regulation (EC) No 853/2004 lays down that “*Unless expressly indicated to the contrary, this Regulation shall not apply to retail*”.

Since cold stores could be considered as retail establishments in the broader sense of the definition in Article 3, paragraph 7 of Regulation (EC) No 178/2002, one might conclude that cold stores are generally excluded from the scope of Regulation (EC) No 853/2004 and are therefore not the subject of approval by the competent authorities (see Article 1, paragraph 5(a) of Regulation (EC) No 853/2004).

However, with regard to cold storage, Regulation (EC) No 853/2004 lays down requirements which must be considered as **expressly indicating** that cold storage operations fall within the scope of the Regulation, e.g.:

- Annex III, Section I, Chapter VII of Regulation (EC) No 853/2004 contains requirements regarding cold storage for meat, and cold stores for meat are therefore establishments handling products for which Annex III to the Regulation lays down requirements. Such establishments shall not operate unless the competent authority has approved them;
- Article 4 of Regulation (EC) No 853/2004 expressly excludes storage of products not requiring temperature-controlled storage conditions from the approval obligations, it being understood that establishments proceeding to cold storage must be approved.

Cold stores must therefore be approved insofar as they are used in relation with activities for which Annex III of Regulation 853/2004 lays down requirements.

However, in the light of Article 1, paragraph 5(b), cold stores operated by genuine retail outlets not covered by the Regulation are not subject to the Regulation, and cold stores that are involved in wholesale operations which are physically limited to transport and storage, do not need to be approved but remain subject to the temperature requirements. When wholesale activities include more than storage and transport (for instance re-wrapping), the cold stores remain establishments to be approved in accordance with Article 4.

4.5. Re-wrapping establishments

Re-wrapping establishments proceed to the unwrapping of products of animal origin that were previously wrapped in another establishment. Such unwrapping

and re-wrapping operations may be combined with operations such as slicing and cutting of food.

Re-wrapping establishments handle exposed products of animal origin. It must be considered that, when they handle products of animal origin that are covered in Annex III of the Regulation, they fall within the scope of Article 4, paragraph 2 of the Regulation. Their approval is therefore required. This is a logical approach since new hazards may be introduced at the level of such establishments.

In order to ensure traceability, food business operators should not place on the market products of animal origin handled in rewrapping establishments unless the identification mark of the rewrapping establishment is applied.

4.6. Wholesale markets

It appears from Article 3, paragraph 3 of Regulation (EC) No 854/2004 that wholesale markets manufacturing products of animal origin need approval before they can place on the market their products. Since in a wholesale market several infrastructures and equipment (e.g. water supply, cold stores) are shared by several units, it seems appropriate that a person/body is held responsible for ensuring that the hygiene requirements for those common infrastructures and equipment are met.

5. TECHNICAL ISSUES

MEAT

5.1. Clean animals

The requirement for animals to be clean is referred to in several parts of the new Hygiene rules:

- Farmers must take adequate measures, as far as possible, to ensure the cleanliness of the animals going to slaughter (Annex I, Part A, point II. 4(c) of Regulation (EC) No 852/2004);
- Slaughterhouse operators must ensure that animals are clean (Annex III, Section I, Chapter IV, point 4 of Regulation (EC) No 853/2004);
- The official veterinarian is to verify compliance with the requirement to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter are not slaughtered unless they are cleaned beforehand (Annex I, Section II, Chapter III, point 3 of Regulation (EC) No 854/2004)

The background for this requirement is that there is substantial proof that unclean animals have been at the source of carcass contamination and subsequent food poisoning.

The objective of the requirement is to avoid contamination of the meat during slaughter so as to ensure that the microbiological quality required by Community law is achieved.

Developing the means for reaching the objective is a task to be achieved by the food business operators concerned. There are different means of reaching the objective, including:

- The effective cleaning of animals, or
- The sorting of the animals in accordance with cleanliness and developing an appropriate slaughter scheme, or
- Developing procedures for the hygienic dressing of animals that must protect carcasses from unnecessary contamination, or
- Other appropriate procedures.

Guides to good practice may be an appropriate tool to assist slaughterhouse operators in defining these means.

It is the task of the competent authority to verify whether the procedures developed by the operators are carried out properly.

5.2. Lairage facilities and waiting pens

Annex III, Section I, Chapter II, point 1(a) of the Regulation lays down that *“Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them.”*

As is the case for other requirements, the principle of proportionality must be respected in deciding about the nature of lairages or waiting pens. For small slaughterhouses, slaughtering few animals, there is no need to require sophisticated or extensive infrastructures, and the equipment for watering and if necessary for feeding the animals may be simple (e.g. movable equipment).

5.3. Equipment for the sterilisation of knives

Annex III, Section I, Chapter II, point 3 of the Regulation lays down that slaughterhouses *“must have facilities for disinfecting tools with hot water supplied at not less than 82°C or an alternative system having an equivalent effect.”*

Worries have been expressed by operators of small slaughterhouses that this requirement, with regard to the sterilisation of knives, may create the need for having available multiple facilities in the slaughter room.

The objective of the requirement is to ensure that meat is not contaminated through equipment, e.g. knives. This objective can be achieved through different means, such as:

- Having sterilising equipment for knives at key places in the slaughterhouses directly accessible by the workers. Such equipment may be the appropriate choice in the bigger slaughterhouses.
- Sterilising in a single operation a number of knives sufficient to ensure that clean knives are available throughout the slaughter operations. This solution may be appropriate in low capacity slaughterhouses.

5.4. Transport of meat at temperatures that must enable the production of specific products

Annex I, Chapter XIV, point 66 of Directive 64/433/EEC lays down that:

“Fresh meat must be chilled immediately after the post-mortem inspection and kept at a constant internal temperature of not more than + 7 °C for carcasses and cuts and + 3 °C for offal.

Derogations from this requirements may, for technical reasons relating to the maturation of meat, be granted by the competent authority on a case-by-case basis for the transportation of meat to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that such transport takes not more than two hours”.

At several occasions, the Commission has been questioned by food business operators who fear that this possibility has not been carried over in Regulation (EC) No 853/2004. However, the possibility of temperature derogations for the transport of meat has been maintained, and has even been broadened in Annex III, Section I, Chapter VII, point 3 of that Regulation which lays down that:

*“Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to **enable production of specific products**, provided that:*

(a) *such transport takes place in accordance with the requirements that the competent authority specifies in respect of the transport from one given establishment to another,*

and

(b) *the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises immediately and **transport takes no more than two hours.**”*

“Specific products” must be understood as any product for which the competent authority grants an authorisation and specifies the requirements to be respected.

5.5. Scrap trimmings and scrap cuttings

Annex III, Section V, Chapter II, point 1(c)(i) lays down that “*the raw material used to prepare minced meat must not derive from scrap trimmings and scrap cuttings (other than whole muscle cuttings)*”.

Since the word “scrap” may mean either “small pieces” or “waste”, several requests have been made to clarify what is to be understood under the terms “scrap trimmings and scrap cuttings”.

In general terms, it would not seem logical to ban products fit for human consumption from being used for human consumption. The use of small pieces (trimmings and cuttings) of meat that are fit for human consumption for the preparation of minced meat should therefore not pose a problem, it being understood that the microbiological quality of the minced meat must be guaranteed at all times, and that they have been obtained from whole muscle.

5.6. The evaluation of the food chain information by the slaughterhouse operator

With regard to the food chain information, Annex II, Section III, point 5 of Regulation (EC) No 853/2004 lays down that the slaughterhouse operators must, in order to check whether or not to accept animals on their premises, evaluate the relevant information before making it available to the official veterinarian.

In practice, the slaughterhouse operator shall **check** that the food chain information that is presented is complete with no obvious errors or omissions, and can be deemed effective to support his decision. It does not impose on the slaughterhouse operator to make a professional evaluation of the information since such evaluation can only be performed in a professional way by the official veterinarian.

5.7. Mobile slaughterhouse

The wording of Regulation (EC) No 852/2004 and (EC) No 853/2004 does not prevent the use of mobile facilities for the slaughter of animals, provided that these facilities comply with the relevant requirements laid down in those Regulations.

Possible adaptations may be granted by Member States as regards the construction, layout and equipment of these establishments in compliance with the procedure laid down in Articles 13 of Regulation (EC) No 852/2004 and 10 of Regulation (EC) No 853/2004.

MILK AND MILK PRODUCTS

5.8. Identification mark

It seems to be common in the dairy sector to apply several identification marks on a single package with an indication as to what mark is the valid one.

The wording of Regulation (EC) No 853/2004 does not seem to prevent such practice.

5.9. Automatic milking installations

Annex III, Section IX, Chapter I, Part II, Subpart B, Point 1(b) of Regulation (EC) No 853/2004 lays down that milk from each animal must be “checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results”.

Traditionally the milker checks the milk from each animal by visual inspection. Other methods achieving similar results may be used.

Other methods are necessary if milking is performed using fully automated milking installations. In particular, it would be good practice that automatic milking installations should be able to detect abnormal milk automatically and separate it from the human consumption supply. An internationally recognised ISO standard concerning the requirements for automated milking installations is being developed and is expected to be finalised in the autumn of 2005. It will include the methods used to check for organoleptic or physico-chemical abnormalities in the milk.

Draft ISO document on automated milking installations:

- Automatic milking installations – Requirements and testing (ISO/CD 20966)

5.10. Labelling

Chapter IV of Annex III, Section IX of Regulation 853/2004 prescribes the labelling of raw milk and products made with raw milk intended for human consumption in the context of labelling Directive 2000/13. This entails that the labelling information concerning products made from raw milk applies up to the point of sale. They shall be given to the consumer to allow him to make his choice. They may be provided with packaging, document, notice, label, ring or collar accompanying or referring to the concerned products.

The terms “physical or chemical treatment” referred to in point 1(b) of the same chapter should be understood as treatments to reduce possible microbiological hazards linked to raw milk or raw milk products (e.g. microfiltration).

5.11. Criteria for cow’s milk

Annex III, Section IX, Chapter II, III (1) (b) lays down that processed cow's milk used to prepare dairy products has a plate count of less than 100 000 per ml. The background of this requirement is that processed milk (e.g. pasteurised milk) that is used as a raw material has to comply with this limit before entering into a new processing step. It is not the intention therefore to require milk that has already entered into a new processing step (e.g. to which additional flora has been added for processing reasons - production of yoghurt or cheese) to comply with this criterion.

5.12. Animal species

Annex I, point 4.1 of Regulation (EC) No 853/2004 defines 'raw milk' as "*milk produced by the secretion of the mammary gland of farmed animals (...)*". This definition covers therefore animals other than the common dairy species (cows, ewes and goats).

In practice, placing on the market of milk from mare, asses, camel or other farmed animals is possible provided that their production and processing comply with the relevant requirements laid down in Regulations (EC) No 852/2004 and (EC) No 853/2004.

ANNEX I

Non exhaustive list of unprocessed products of animal origin

- Fresh meat/minced meat/Mechanically Separated Meat
- Untreated intestines, stomachs and bladders
- Meat preparations that have not been processed
- Blood
- Fresh fishery products
- Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods
- Raw milk
- Whole eggs and liquid egg
- Frogs' legs
- Snails
- Honey
- Other

An unprocessed product with a product of plant origin remains a raw product e.g.

- skewer containing fresh meat and vegetables
- preparations of fresh fishery products (e.g. fish fillets) with food of plant origin

Remarks:

- Unprocessed products can be classified as “raw products”, i.e. they have not undergone processing (i.e. any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes). Frozen products of animal origin remain unprocessed products.
- “Fresh” (with regard to meat) means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped in a controlled atmosphere.
- “Fresh” (with regard to fishery products) means unprocessed fishery products, whether whole or prepared, including products packaged vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.

ANNEX II

Non-exhaustive list of processed products of animal origin

Processed products are obtained by submitting raw products to a process such as heating, smoking, curing, maturing, drying, marinating, etc. The process must lead to a substantial alteration of the initial product.

- **Meat products (ham, salami, etc.)**
- **Processed fishery products (smoked fish, marinated fish etc)**
- **Dairy products (heat treated milk, cheese, yoghurt, etc.)**
- **Egg products (egg powder etc.)**
- **Rendered animal fat**
- **Greaves**
- **Gelatine**
- **Collagen**
- **Treated intestines, stomachs and bladders etc.**

Processed products also include:

- **A combination of processed products e.g. cheese with ham**
- **Products that have undergone several processing operations e.g. cheese from pasteurised milk.**

Substances to give special characteristics may be added e.g.

- **sausage with garlic**
- **yoghurt with fruit**
- **cheese with herbs**

Remark:

- **Processed products may include certain meat preparations such as marinated and cured meat.**

ANNEX III
Classification in accordance with activities

Activity	Regulation (EC) No	Risk	Non-exhaustive list of examples
Assembly of food of plant origin with processed food of animal origin further processed together.	852/2004	The risk associated can be controlled by implementing the rules of Regulation (EC) No 852/2004.	<ul style="list-style-type: none"> • Canning food made from processed meat with vegetables • Assembly of pizzas containing processed ingredients of animal origin (such as cheese, processed fish or processed meat) • Producing soup made with meat extract
Assembly of food of plant origin with processed food of animal origin, and placed on the market as such.	852/2004	The risk associated can be controlled by implementing the rules of Regulation (EC) No 852/2004.	<ul style="list-style-type: none"> • Making sandwiches with ham or cheese • Manufacturing edible ices made from processed milk (heat treated milk, milk powder) • Making bakery products • Assembling or manufacturing ready to eat meals composed of processed products of animal origin (e.g. processed meat) and vegetables • Manufacturing confectionery (e.g. chocolate containing milk) • Producing mayonnaise made with egg product
Assembly of food of plant origin with unprocessed food of	853/2004	The risk is identical to the one posed when manufacturing processed food of animal origin,	<ul style="list-style-type: none"> • Canning products made from vegetables and fresh meat • Ice cream from raw milk

<p>animal origin further processed together.</p>		<p>e.g. meat products. This justifies that the rules of Regulation (EC) No 853/2004 should apply. Approval of premises is required by EU rules and an identification mark may be applied to such foods.</p>	<p>See remarks made under point 3.4</p>
<p>Assembly of food of plant origin with unprocessed food of animal origin and placed on the market as such.</p>	<p>853/2004</p>	<p>The risk is identical to the one posed when handling raw products of animal origin, e.g. fresh meat etc. Approval of premises is required by EU rules and an identification mark may be applied to such foods.</p>	<ul style="list-style-type: none"> • Assembling raw meat/fish skewer with vegetables

ANNEX IV

NON-EXHAUSTIVE LIST OF ESTABLISHMENTS SUBJECT TO APPROVAL

- Meat
 - Slaughterhouses
 - Cutting plants
 - Slaughter on farm (except in the case of the direct supply by the producer of small quantities of meat from poultry-lagomorphs slaughtered on the farm to the final consumer and to retail establishments)
 - Game handling establishment
 - Establishments producing minced meat, meat preparations and MSM
 - Establishment manufacturing meat products
- Live bivalve molluscs
 - Dispatch centres
 - Purification centres
- Fishery products
 - freezer vessels and factory vessels
 - Establishments on land
- Milk and dairy products
 - Establishments processing raw milk into heat treated milk and into dairy products made from raw milk
 - Establishments making dairy products from already processed dairy products (e.g. butter from pasteurised cream, cheese from pasteurised milk of milk powder)
 - Milk collection centres
- Egg products
 - Establishments processing eggs
- Frogs' legs and snails
 - Establishments preparing and/or processing frogs' legs and snails

- Rendered animal fats and greaves
 - Establishments collecting, storing or processing raw materials
- Stomachs and bladders
 - Establishments treating bladders, stomachs and intestines
- Gelatine
 - Establishments processing raw materials
- Collagen
 - Establishments processing raw materials
- Establishments proceeding to the re-wrapping of the above products whether of not associated with other operations such as slicing, cutting.
- Cold stores insofar as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements.
- Wholesale markets insofar products of animal origin are manufactured.

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**EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL**

Brussels, 9 June 2008

Guidance document on the implementation of certain provisions of

Regulation (EC) No 852/2004

On the hygiene of foodstuffs

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PURPOSE OF THIS DOCUMENT

This document is mainly directed at food businesses and competent authorities, and aims to give guidance on the implementation of the new food hygiene requirements and on related subjects.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities, food businesses and the Commission's Food and Veterinary Office.

1. INTRODUCTION

Regulation (EC) No 852/2004 on the hygiene of foodstuffs¹ (hereafter “the Regulation”) was adopted on 29 April 2004. It lays down general hygiene requirements to be respected by food businesses at all stages of the food chain. Since the adoption of the Regulation, the Commission has been requested to clarify a number of aspects thereof. This document aims to follow-up these requests.

The Commission’s Health and Consumer Protection Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on a number of issues concerning the implementation of the Regulation.

In the interest of transparency, the Commission has also promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission has organised a meeting with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of the Regulation.

It was considered that these meetings and discussions should continue in the light of the experience gained by the full application of the Regulation from 1 January 2006.

It should be noted that matters relating to the non-compliance of national legislation with the Regulation remain outside the scope of this exercise and will continue to be dealt with in accordance with established Commission procedures.

The present document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the Regulation. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

For a complete understanding of the different aspects of Regulation (EC) No 852/2004, it is essential to be also familiar with other parts of Community legislation, and in particular with the principles and definitions 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 safety².(also referred to as the General Food Law),
- 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 welfare³,

¹ OJ No L 226, 25.6.2004, p. 3

² OJ No L 31, 1.2.2002, p. 1

³ OJ No L 191, 28.5.2004, p. 1

- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs⁴, and
- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulations (EC) No 854/2004 and No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and No 854/2004⁵.

A separate guidance document on Regulation (EC) No 178/2002 has been established.

(See http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm)

2. OBLIGATIONS OF FOOD BUSINESS OPERATORS

The Regulation must be implemented by food businesses. They must ensure that all the requirements are properly implemented in order to ensure food safety.

Food businesses that handle food of animal origin must, in addition to Regulation (EC) No 852/2004, also implement the appropriate requirements of Regulation (EC) No 853/2004.

3. SCOPE

3.1. Primary production

The Regulation covers primary production.

Primary production is defined in Article 3(17) of Regulation (EC) No 178/2002:

‘Primary production’ means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

The rules applicable to primary production are laid down in Annex I, Part A, point I(1) of Regulation (EC) No 852/2004.

Annex I, Part A, point I(1) of Regulation (EC) No 852/2004 also covers the following operations that are associated with primary production:

- The transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
- The transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
- In the case of products of plant origin and fishery products: transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

Therefore the term “primary production” in this guidance document should be understood as primary products including these associated operations.

Primary production is a term to describe activities at the farm or at a similar level and includes *inter alia*:

- Production, rearing or growing of plant products such as grains, fruits, vegetables and herbs as well as their transport within and storage and handling of products (without substantially changing their nature) at the farm and their further transport to an establishment.
- Production, rearing or growing of food producing animals at the farm and any activity linked therewith as well as the transport of meat producing animals to a market, a slaughterhouse or the transport of animals between farms.
- Production, rearing and growing of snails at the farm and their possible transport to a processing establishment or to a market.
- Milking and the storage of milk at the farm.
- The production and collection of eggs at the producer's premises, but not egg packaging operations.
- Fishing, the handling of fishery products (without changing their nature substantially) on board vessels (except freezer and factory vessels) and their transport to the first establishment (including auction halls) on land. This includes the fishing, handling and transport of fish caught in fresh water (rivers, lakes).
- Production, rearing, growing and harvesting of fish in aquaculture farms and their transport to an establishment.
- The production, rearing, growing, relaying and harvesting of live bivalve molluscs and their transport to a dispatch centre, purification centre or processing establishment.
- The harvesting of mushrooms, berries, snails etc. in the wild and their transport to an establishment.

Remarks on primary production:

- **General rules on primary production** are laid down in Annex I to Regulation (EC) No 853/2004. In addition, for certain food (e.g. raw milk, live bivalve molluscs), more **detailed rules** are laid down in Regulation (EC) No 853/2004 (see section 3.7 of the guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin).
- **Fishery products the nature of which has not been substantially altered:** see guidance given under point 3.7.
- **Egg packing centres:** in accordance with the definitions and requirements of the new food hygiene rules, egg packing centres (even when situated at the farm of production) are not considered primary production.
- **Milk collection centres:** once raw milk has been collected from the farm, the product has left the level of primary production. Milk collection centres where raw milk is stored after collection from a farm and before dispatch to a milk processing establishment are not considered primary production.
- **Honey and other food from bee production:** all the beekeeping activities must be considered as primary production. This includes beekeeping (even if this activity extends to having bee-hives at a distance from the bee-keeper's premises), the collection of honey, its centrifugation and the wrapping and/or packaging at the beekeeper's premises. Other operations outside the beekeeper's premises (e.g. the centrifugation and/or wrapping/packaging of honey) cannot be considered as primary production, including those carried out on behalf of beekeepers by collective establishments (e.g. cooperatives).
- **Freezer and factory vessels:** the handling, storage and transport of fishery products on board freezer and factory vessels are not covered by the term "primary production".

3.2. Primary products

Primary products are defined in Article 2, paragraph 1, point (b) of Regulation (EC) No 852/2004 as follows:

‘primary products’ means products of primary production including products of the soil, of stock farming, of hunting and fishing.

Primary products include *inter alia*:

- Products of plant origin, e.g. grains, fruits, vegetables, herbs, mushrooms.
- Products of animal origin, e.g. eggs, raw milk, honey, fishery products, live bivalve molluscs.
- Products harvested wild either from plant or animal origin, e.g. mushrooms, berries, snails etc.

Remarks on primary products:

- **Fresh meat** is not a primary product since it is obtained after slaughter.
- **Fishery products** remain primary products even after slaughter, bleeding, handling, gutting, removing fins, refrigeration and placing in containers for transport at the level of primary production. The products resulting from further handling of fishery products (e.g. filleting, packaging under vacuum etc.) are not primary products.

3.3. “Small quantities” of primary products as referred to in Article 1, paragraph 2(c) of the Regulation

The Regulation does not apply to small quantities of primary products supplied directly by the producer to the final consumer or to local retail establishments directly supplying the final consumer.

In general terms, the notion “small quantities” should be broad enough to allow *inter alia*:

- Farmers to sell primary products (vegetables, fruits, eggs, raw milk⁶ etc.) directly to the final consumer e.g. farm gate sales or sales at local markets, to local retail shops for direct sale to the final consumer and to local restaurants.
- Individuals who collect products in the wild such as mushrooms and berries to deliver their yield directly to the final consumer or to local retail shops for direct sale to the final consumer and to local restaurants.

Pursuant to Article 1, paragraph 3 of Regulation (EC) No 852/2004, it is up to Member States to further refine the notion of small quantities depending on the local situation, and to lay down under national law the rules necessary to ensure that the safety of the food is guaranteed (risk based approach).

In general, the rules under national law established by the Member States in respect of small quantities as referred to in Article 1, paragraph 2(c) should allow current practices to continue to apply, provided they ensure the achievements of the objectives of the Regulation.

3.4. Cross-border trade of small quantities of primary products

Article 1, paragraph 3 of the Regulation requires Member States to establish under national law the rules governing the supply by the producer of small quantities of primary products to the final consumer or to local retail establishments.

Occasionally, such supply may take place across borders in particular where the producer's farm is situated in the neighbourhood of Member States' borders.

The national rules to be adopted pursuant to Article 1, paragraph 3 of Regulation (EC) No 852/2004 must be subject to the general rules of the Treaty.

3.5. Processing of primary products at the farm

Primary products can be processed at the farm, e.g. raw milk is processed into cheese, juice is extracted from fruit. These operations fall outside the activities described as primary production and are therefore the subject of the food hygiene requirements of Annex II of the Regulation and, ***with regard to food of animal origin***, also of the appropriate requirements in Regulation (EC) No 853/2004.

Examples:

- The preparation of fruit juice at the farm

If a farm uses its harvest or part of its harvest (e.g. apples) to produce fruit juice at its premises, such farm exceeds the level of primary production. The activity of producing fruit juice is to be considered as an activity after

⁶ Under Article 10(8) of Regulation 853/2004, Member States may establish national rules prohibiting or restricting the placing on the market of raw milk intended for direct human consumption.

primary production and it is therefore subject to the appropriate requirements of Regulation (EC) No 852/2004.

- The production of cheese at the farm

Cheese is the result of processing raw or heat treated milk. Cheese is not, therefore, a primary product, even when made at the farm.

As a consequence, cheese production at the farm must comply with the appropriate requirements of food hygiene laid down in Regulation (EC) No 852/2004 and of Regulation (EC) No 853/2004.

Remarks:

1) Regulation (EC) No 853/2004 generally excludes retail (i.e. the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer) from its scope. This means that where cheese is manufactured and sold entirely at the farm or at a local market (e.g. weekly market, farmers market etc.) to final consumers, these activities can be carried out in compliance with the appropriate requirements laid down in Regulation (EC) No 852/2004, in particular in its Annex II, while not having to comply with the requirements of Regulation (EC) No 853/2004 apart from the requirements for raw milk. Where appropriate, compliance will also need to be ensured with national measures established under national law in the Member States on the basis of Article 1, paragraph 5(c) of Regulation (EC) No 853/2004.

2) In order to accommodate processing at the farm or in order to preserve traditional methods of production, Member States may introduce national measures adapting the relevant infrastructural requirements in accordance with the procedure laid down for that purpose in Article 13 of Regulation (EC) No 852/2004 and in Article 10 of Regulation (EC) No 853/2004, where the traditional methods cannot be accommodated within the requirements the Regulations lay down.

3.6. Eggs and primary production

Taking into account the definition of primary production in Article 3(17) of Regulation 178/2002, and Annex I, Part A, point I(1) of Regulation 852/2004, primary production of eggs includes the handling of eggs, i.e. the collection and transport between buildings, and storage of eggs at the production site, provided that this does not substantially alter their nature. The packaging of eggs, either at the site of production or at a separate packing establishment falls outside the activities of primary production. These activities must therefore comply with the relevant requirements of Annex II to Regulation (EC) No 852/2004, and of Annex III, Section X of Regulation (EC) No 853/2004 and of Regulation (EC) No 1907/90 on certain marketing standards for eggs.

3.7. At the level of primary production, primary products may be transported, stored and handled provided that does not substantially alter their nature [see Annex I, Part A, point I.1(a) of the Regulation].

At the level of primary production, primary products are often subject to operations so as to ensure a better presentation, such as:

- Washing of vegetables, removing leaves from vegetables, the sorting of fruit etc.
- The drying of cereals,
- The slaughter, bleeding, gutting, removing fins, refrigeration and wrapping of fish,
- Centrifugation of honey to remove honeycombs.

Such operations must be considered as normal routine operations at the level of primary production and must not lead to the need to satisfy food safety requirements in addition to the ones already applying to primary production.

On the other hand, certain operations carried out on the farm are likely to alter the products and/or to introduce new hazards to food e.g. the peeling of potatoes, the slicing of carrots, the bagging of salads and the application of preservation gases. These operations cannot be considered as normal routine operations at the level of primary production nor as operations associated with primary production.

3.8. The occasional handling, preparation, storage and serving of food by private persons

Operations such as the occasional handling, preparation, storage and serving of food by private persons at events such as church, school or village fairs are not covered by the scope of the Regulation. This is made clear in recital 9 of Regulation (EC) No 852/2004. The second sentence states that:

"Community rules should only apply to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation".

The term "undertaking" is integrated in the definition of a "food business" (in accordance with Article 3(2) of the General Food Law (Regulation (EC) No 178/2002), a "food business" must be an "undertaking"). Somebody who handles, prepares, stores or serves food occasionally and on a small scale (e.g. a church, school or village fair and other situations such as organised charities comprising individual volunteers where the food is prepared occasionally) cannot be considered as an "undertaking" and is therefore not subject to the requirements of Community hygiene legislation.

3.9. Food businesses and internet sales

Certain businesses offer their goods for sale via the internet. Although such trade is not specifically referred to in the Regulation, such businesses fall within the definition of a food business and the relevant requirements of food law are applicable to them.

4. THE TERMS “WHERE NECESSARY”, “WHERE APPROPRIATE”, “ADEQUATE” AND “SUFFICIENT”.

Where the Annexes to the Regulation use the terminology “where necessary”, “where appropriate”, “adequate” or “sufficient”, it is up to the food business operator in first instance to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of Regulation (EC) 852/2004.

In determining whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Regulation, account should be taken of the nature of the food and of its intended use.

The operator may justify his choice under the procedures based on the HACCP principles or under the operational procedures of his business. Also the guides to good practice referred to in Article 7 of the Regulation may offer useful guidance and indicate what is best practice in cases where the words “where necessary”, “where appropriate”, “adequate” and “sufficient” are used.

5. FLEXIBILITY

5.1. General background

The Regulation lays down principles to be applied by all food businesses. In order to ensure that solutions for specific situations are available without compromising food safety, the Regulation provides for flexibility. For that purpose, Member States may take national measures adapting the requirements of certain Annexes of the Regulation. National measures shall:

- Have the aim of enabling the continued use of traditional methods of production, processing and distribution of food, or
- Have the aim of accommodating the needs of food businesses situated in regions that are subject to geographical constraints.
- In other cases, they shall apply only to the construction, layout and equipment of establishments.

Member States wishing to adopt national measures shall, for reasons of transparency, notify the Commission and the other Member States thereof (see Article 13, paragraph 5 of Regulation (EC) No 852/2004). The Commission and the other Member States have the right to make comments. Where these

comments lead to diverging views, the matter shall be brought to the Standing Committee and a decision may be taken.

5.2. Traditional methods of production

In the Member States, food may be manufactured in accordance with longstanding traditions that have proven their safety although not always fully in line with certain technical requirements of the Regulation. The Regulation recognises the need for maintaining these traditional methods of production which are proof of the cultural diversity of Europe, and provides therefore for the flexibility needed by food businesses.

There is no intention in the context of this document to proceed to making an inventory of the traditional methods of production in the Member States. It is up to the competent authorities to take the necessary initiatives or act on possible requests from food businesses for flexibility.

5.3. HACCP and flexibility

The HACCP methodology is flexible by its very nature, being based on a limited set of principles and procedures supporting the objective of food safety, without compelling food businesses to comply with rules or to implement procedures which are not relevant or adapted to the specific context for their activity.

Guides to good practice for hygiene and for the application of the HACCP principles developed by the food business sectors themselves, either at national or at Community level, should help businesses to implement HACCP-based procedures tailored to the characteristics of their production.

The Commission issued guidance explaining the main possibilities for flexibility with regard to the implementation of HACCP-based procedures.

6. THE REGISTRATION AND APPROVAL OF FOOD BUSINESSES

6.1. What does registration of food businesses mean in practice?

Article 6, paragraph 2 of Regulation (EC) No 852/2004 requires food businesses to be registered with the competent authority.

The purpose of registration is to allow the competent authorities in the Member States to know where food businesses are situated and what their activities are so as to enable official controls to be carried out whenever judged necessary by the national competent authority and in accordance with the general principles laid down in Article 31 of Regulation (EC) No 882/2004 which requires competent authorities in the Member States to establish procedures for feed and food business operators to follow when applying for registration.

Registration should be a simple procedure whereby the competent authority is informed about the address of the establishment and the activity carried out.

Where this information is already available from other sources e.g. registration for environmental or animal health purposes or for other administrative purposes, that information may also be used for food hygiene purposes.

Certain businesses are specialised in trading food (brokers). While they may arrange for the movement of food between suppliers or to retailers, they do not necessarily handle the food or even store it on their premises (which may effectively be an office). Provided they meet the definition of “food business” and “food business operator”, then the registration requirement applies.

6.2. The approval of food businesses

Community law requires certain food businesses that handle food of animal origin to be approved before they can place their products on the market. For more information see section 4 of the guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin.

6.3. The approval of food businesses under national law

The Regulation allows Member States to require the approval of food establishments for which Community law (including Regulation (EC) No 853/2004) does not require approval.

If this procedure is applied by the Member States, Community law does not impose the use of an identification mark or any restriction on the placing on the market of food from establishments that are the subject of a national approval procedure.

7. GUIDES TO GOOD PRACTICE FOR HYGIENE AND FOR THE APPLICATION OF THE HACCP PRINCIPLES

Articles 7-9 of the Regulation provide for the development of guides to good practice for hygiene and for the application of the HACCP principles.

Although they are a voluntary instrument, such guides enable food business sectors (**at the level of primary production and after primary production**) to describe in more detail how operators can comply with the legal requirements which are expressed in more general terms in the Regulation.

In the new food hygiene rules, a number of requirements are laid down that:

- Leave room for judgement to the food business operator: for that purpose, the terms “where necessary”, “where appropriate”, “adequate” and “sufficient” are introduced into the Regulation (e.g. “*an adequate number of washbasins is to be available*”, or, “*cleaning and disinfection of equipment are to take place at a frequency sufficient to avoid any risk of contamination*”), or
- Are formulated as an objective to be reached, but where the food business operator must develop the means to reach the objective (e.g. with regard to

the heat treatment in hermetically sealed containers, “*any treatment is to prevent the product from becoming contaminated during the process.*”)

Guides to good practice are a useful tool to assist food business operators in:

- Making a judgement on the necessity, appropriateness, adequacy or sufficiency of a particular requirement, e.g. to indicate what an adequate number of washbasins is, and
- Defining the means to reach the objectives that are defined in the Regulation e.g. to indicate what the frequency of cleaning and disinfection of equipment should be.

Guides may also usefully include procedures that must ensure a proper implementation of the Regulation, such as:

- Procedures to prevent the introduction of hazards at the level primary production,
- A procedure for the cleaning and disinfection of food businesses,
- A procedure for pest control, and
- A procedure to ensure that the requirement to develop HACCP-based procedures is fulfilled.

8. DOCUMENTATION

8.1. The Regulation creates the need for food business operators to establish, under the HACCP-based procedures, documentation **commensurate with the nature and the size of the business.**

8.2. **Although not required by the Regulation,** it may be good practice for food business operators to establish also other documentation that could assist in meeting the objectives of the Regulation. In establishing such documentation, food business operators may wish to take account of the following:

Documentation on structural requirements

Documentation may relate to structural requirements in order to clarify a number of requirements of a general nature contained in the Regulation, such as:

- Annex II, Chapter II, point 1, (a) and (b), where the surfaces of floors and wall are required to be “of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate”, and (f), where the surfaces in general are to be of “smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate”.

- Annex II, Chapter III, point 2(b), where the surfaces in contact with food are required to be of “smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate”.

Documentation of operational requirements

Documentation may relate to operational requirements such as:

- Annex II, Chapter IX, point 4: “Adequate procedures are to be in place to control pests”.
- The need to justify choices with regard to the terms “where necessary”, “where appropriate”, “adequate” and “sufficient”.
- The procedures and records based on HACCP principles.

8.3. Together, this documentation will constitute operational procedures that are an important element in ensuring food safety.

There are different possibilities for establishing that documentation:

- Guides to good practice may contain part or all of the documentation that is needed.
- Food businesses may decide to establish ad hoc documentation appropriate for their situation.
- Under the HACCP-based procedures (taking into account the flexibility needed for food businesses, in particular for small businesses).

Documentation could be provided in the form of results of laboratory tests, pest control reports, temperature measurements, and in the form of literature citations, documentation provided by the supplier of the construction materials etc.

9. TECHNICAL ISSUES (ANNEXES)

9.1. Heat treatment (Annex II, Chapter XI)

In the case of a heat treatment of food placed on the market in a hermetically sealed container, the Regulation requires food business operators to apply a heat treatment process that conforms to an internationally recognised standard. Such standards have for example been developed by Codex Alimentarius, e.g.:

- Code of Hygienic practice for Milk and milk products (CAC/RCP 57-2004).
- Recommended International Code of Hygienic Practice for Low and Acidified Acid Canned Foods (CAC/RCP 23-1979, rev. 2 (1993)).

- Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid foods (CAC/RCP 40-1993).
- Recommended International Code of Hygienic Practice for Canned Fish (CAC/RCP 10-1976).

9.2. Training (Annex II, Chapter XII)

Training is an important tool to ensure effective application of good hygienic practices.

Training as referred to in Annex II, Chapter XII of the Regulation should be commensurate to the tasks of staff in a particular food business and be appropriate for the work to be carried out.

Training can be achieved in different ways. These include in-house training, the organisation of training courses, information campaigns from professional organisations or from the competent authorities, guides to good practice etc.

With regard to HACCP training for staff in small businesses, it must be kept in mind that such training should be proportionate to the size and the nature of the business and should relate to the way that HACCP is applied in the food business. If guides to good practice for hygiene and for the application of HACCP principles are used, training should aim to make staff familiar with the content of such guides. If it is admitted that in certain food business where food safety can be achieved by implementing prerequisite requirements, training should be adapted to that situation.

9.3. Transport (Annex II, Chapter IV)

Adequate transport systems must be in place to ensure that foods remain safe and suitable for human consumption upon delivery.

In the case of transport of bulk foodstuffs in liquid, granulate or powder form, the Regulation requires food business operators to use dedicated transport means.

The background for this requirement is that there is substantial proof about the higher risk for these foods to be contaminated due to their nature, when transported in vehicles or containers that were used beforehand for other purposes. This remains true even after cleaning of these means.

Since the word "granulate" may mean "in granular form" or "in grains", several requests have been made to clarify what is understood under that wording. In general terms, it would be logical to limit this requirement to foodstuffs that have been given a granular characteristic after processing (e.g. sugar). This should therefore exclude primary products such as grains, rice...

9.4. Water supply (Annex II, Chapter VII)

The provision for food business operators to possibly use clean water on fishery products is referred to in several parts of the new Hygiene rules:

- *'Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing'* (Annex II, Chapter VII, Point 1 (b) of Regulation (EC) 852/2004);
- *'Clean seawater may be used with fishery products for all purposes, including washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking'* (Annex III, Section VIII, Point 3 (c) of Regulation (EC) No 853/2004).

When deciding to use such water and/or when developing procedures based on the HACCP principles, food business operators should pay attention to different aspects, which must include:

- Studying the composition of the water at the intake water point and its possible variations,
- Assessing the impact of natural contamination sources and the possible protective measures to address them (a river mouth, dredging operations, etc.),
- Describing the water production, storage and distribution systems,

When making use of such water, they must ensure that it is not a source of contamination for fishery products. There are different means of reaching this objective, including:

- Pumping water for the production of clean water from a position that avoids contamination of the water supply (avoiding frequently polluted areas, pumping water in depth, pumping water in remote areas). This may be enough for vessels operating in open water, and/or
- Using a water treatment system to ensure that the requirements for clean water are met. This may involve a particle retention step, followed by an adsorption step and a sanitising step, and/or
- Other appropriate procedures.

Guides to good practice may be an appropriate tool to assist operators in defining these means.

Procedures to monitor the safety/quality of the water must be put in place by operators. It is the task of the competent authority to verify whether the procedures developed by the operators are carried out properly.

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SANCO/1730/2008

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.09.2008

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

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

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 the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ¹, and in particular Article 10(1) 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 consumption², and in particular Article 16 thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 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.

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

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 854/2004³ provides for a derogation from the requirements for fish oil for human consumption laid down in Section VIII of Annex III to Regulation (EC) No 853/2004 for food business operators so that they may continue, until 31 October 2008, 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 1664/2006⁴.
- (4) The requirements for the production of fish oil for human consumption in Regulation (EC) No 853/2004 were amended by Regulation [SANCO/43/2008] to address the practical difficulties experienced by third countries in adjusting the processing conditions in fish oil producing establishments.
- (5) In order to avoid unnecessary disruption of trade related to the administrative procedures in connection with approval/listing of establishments covered by the amended legislation, it is appropriate to extend the derogation in Article 7(3) of Regulation (EC) No 2076/2005 until 30 April 2009.
- (6) In addition, Article 7(4)(b) 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 854/2004⁵, 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 2008, which may be imported into the Community until 31 December 2008.
- (7) The derogation provided for in Article 7(4)(b) of Regulation (EC) No 2076/2005 should also be extended until 30 June 2009 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 30 April 2009.
- (8) Regulation (EC) No 2076/2005 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,

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 2008' is replaced by '30 April 2009'.
2. In paragraph 4, point (b) is amended as follows:
 - (a) the date of '31 October 2008' is replaced by '30 April 2009';
 - (b) the date of '31 December 2008' is replaced by '30 June 2009'.

Article 2

This Regulation shall enter into force on the [20th] 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

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SANCO/1729/2008

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 9.6.2008

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Commission Regulation (EC) No 2074/2005 as regards TVB-N limits

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Commission Regulation (EC) No 2074/2005 as regards TVB-N limits

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 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) Section VIII of Annex III to Regulation (EC) No 853/2004 provides that food business operators must carry out specific checks in order to prevent fishery products which are unfit for human consumption from being placed on the market. These checks include checking total volatile basic nitrogen (TVB-N), in particular when organoleptic assessment of unprocessed fishery products has raised doubts as to their freshness.
- (2) According to Annex III of Regulation (EC) No 853/2004, when vessels that have not been designed and equipped to preserve fresh fishery product for more than 24 hours are landing their catch, fresh fishery products must undergo chilling as soon as possible after landing and be stored at the temperature of melting ice.
- (3) However, when whole fishery products handled in such vessels are used directly in the preparation of fish oil for human consumption, the raw material may be processed up to 36 hours without chilling after the catch/loading on the fishing vessel, provided that fish still meet the freshness criteria. It is therefore necessary to set down a generic level of TVB-N that should not be exceeded in fish species used for the direct production of fish oil for human consumption, when using that possibility.
- (4) Due to variation between species, it may also be appropriate to set higher TVB-N limits for certain species. Pending the harmonisation at Community level of these higher TVB-N limits, the Member States should be allowed to apply national limits.
- (5) Regulation (EC) No 2074/2005 should therefore be amended accordingly.

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

- (6) 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 II to Commission Regulation (EC) No 2074/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the [20th] 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

In Annex II, Section II, Chapter I of Regulation (EC) No 2074/2005, point 1 is replaced by the following:

- '1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:
 - (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II;
 - (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II;
 - (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II;
 - (d) 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption as referred to in Point B (1)(b) of Section VIII, Chapter IV of Annex III to Regulation (EC) No 853/2004.

Provided that the raw material complies with points (i) to (iii) of Part B(1)(a) in that Chapter, national limits may be set at a higher level for certain species pending the establishment of specific Community legislation .

The reference method to be used for checking the TVB-N limit involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.'

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SANCO/44/2008 Rev. 3

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 09.06.2008

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annexes I, II and III to Regulation (EC) No 854/2004 of the European Parliament and the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption and repealing certain provisions of Commission Regulation (EC) No 2076/2005

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annexes I, II and III to Regulation (EC) No 854/2004 of the European Parliament and the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption and repealing certain provisions of Commission Regulation (EC) No 2076/2005

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 the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption¹, and in particular Article 17 thereof,

Whereas:

- (1) Provisions regarding health marking laid down in Section I of Annex I to Regulation (EC) No 854/2004 have led to implementing difficulties in some Member States and created confusion in the identification of products produced on the Community territory and products produced outside that territory. It is therefore appropriate to clarify those provisions in order to ensure their smooth implementation.
- (2) Article 5(6) of Regulation (EC) No 854/2004 allows Member States to authorise slaughterhouse staff to carry out certain control tasks of official auxiliaries in relation to the production of meat from poultry and lagomorphs. This authorisation may only be granted if the staff of the establishment have been trained, to the satisfaction of the competent authority, in the same way as official auxiliaries for the tasks of official auxiliaries. During the transitional period provided for by Regulation (EC) No 2076/2005², the training requirement may be limited to ensuring that slaughterhouse staff is trained for the specific tasks they are allowed to carry out.
- (3) Since limiting the training to the specific tasks for which slaughterhouse staff has been authorised to perform does not undermine the objective set out in Article 5, it is appropriate to permit the Member States to implement a complete or limited training system and to decide upon its practical arrangements.

¹ OJ L 139, 30.4.2004, p. 206; corrected version OJ L226, 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. 83

- (4) According to the general principle laid down in Annex II, Chapter II, Part A, point 4 of Regulation (EC) No 854/2004, live bivalve molluscs from classified B areas must not exceed the limits of 4600 *E.coli* per 100 g of flesh and intravalvular liquid. Regulation (EC) No 2076/2005 introduces a tolerance in 10% of samples for live bivalve molluscs originating from those areas on a transitional basis.
- (5) Since allowing this tolerance does not represent a risk for public health provided that in the 10% of samples, live bivalve molluscs do not exceed an upper limit of 46000 *E. coli* per 100g of flesh and intravalvular liquid, it is therefore appropriate to retain this tolerance with an upper limit on a permanent basis.
- (6) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if not consumed under certain conditions. Regulation (EC) No 854/2004 as amended by Commission Regulation (EC) No 2074/2005³ requires competent authorities in the Member States to carry out checks regarding the marketing conditions that food business operators must comply with in relation to these fishery products.
- (7) These conditions apply to fresh, prepared and processed fishery products derived from these species. However, similar risks for the consumer may be encountered with frozen fishery products derived from this fish family. It is therefore appropriate to require competent authorities to carry out also checks for this latter presentation of the products.
- (8) Regulation (EC) No 854/2004 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

Regulation (EC) No 854/2004 is amended in accordance with the Annex to this Regulation.

Article 2

Articles 14 and 17a of Regulation (EC) No 2076/2005 are hereby deleted.

Article 3

This Regulation shall enter into force on the [\[20th\]](#) day following that of its publication in the *Official Journal of the European Union*.

³ OJ L 338, 22.12.2005, p. 27

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

Regulation (EC) No 854/2004 is amended as follows:

1. Annex I is amended as follows:

(a) In Chapter III of Section I, Point (c) of Paragraph 3 is replaced by the following:

'(c) When applied in a slaughterhouse located within the Community, the mark must include the abbreviation CE, EB, EC, EF, EG, EK, EO, EY, ES, EÜ, EK or WE.

However, that abbreviation can only be included in marks applied in slaughterhouses located within the Community.'

(b) In Chapter III of Section III, Point (a) of Part A is replaced by the following:

'(a) Where the establishment has used good hygiene practice in accordance with Article 4, paragraph 4 of this Regulation and the HACCP procedure for at least twelve months, the competent authority may authorise staff of the establishment to carry out tasks of official auxiliaries. This authorisation may only be granted if the staff of the establishment have been trained, to the satisfaction of the competent authority, in the same way as the official auxiliaries for the tasks of official auxiliaries or for the specific tasks they are authorised to perform. This staff must be placed under the supervision, direction and responsibility of the official veterinarian. In these circumstances, the official veterinarian shall be present at ante-mortem and post-mortem examinations, shall supervise these activities and carry out regular performance tests to ensure that the performance of the slaughterhouse staff meets the specific criteria laid down by the competent authority, and shall document the results of those performance tests. Detailed rules for the performance tests may be laid down in accordance with the procedure set out in Article 18. Where the level of hygiene of the establishment is affected by the work of this staff, where this staff does not carry out the tasks properly or where in general this staff carries out its work in a manner that the competent authority considers unsatisfactory, this staff shall be replaced by official auxiliaries.

[Responsibilities for production and inspection in the establishment must be kept separate and any establishment wishing to use the establishment's own inspectors must be certified in accordance with international standards, such as relevant EN ISO standards on quality management or food safety.]'

2. In Part A of Chapter II to Annexe II, Point 4 is replaced by the following:

- '4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed, in 90% of the samples, 4600 *E. coli* per 100 g of flesh and intravalvular liquid. In the remaining 10% of samples, live bivalve molluscs must not exceed 46000 *E. coli* per 100 g of flesh and intravalvular liquid.

The reference method for this analysis is the five-tube, three dilutions Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.'

3. In Chapter II of Annex III, Part G is replaced by the following:

'G. POISONOUS FISHERY PRODUCTS

Checks are to take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae;
2. fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, are only placed on the market in wrapped/packaged form and are appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific and the common names appear on the label;

and

3. fishery products containing biotoxins such as Ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No853/2004 and comply with the standards laid down in Chapter V, point 2, of that Section.'

EN

SANCO/43/2008 Rev. 3

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 09.06.2008

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and repealing certain provisions of Commission Regulation (EC) No 2076/2005

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and repealing certain provisions of Commission Regulation (EC) No 2076/2005

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 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) Provisions regarding identification marking laid down in Annex II to Regulation (EC) No 853/2004 have led to implementing difficulties in some Member States and created confusion in the identification of products produced on the Community territory and products produced outside that territory. It is therefore appropriate to clarify those provisions in order to ensure their smooth implementation.
- (2) Notwithstanding the general principle laid down in Article 3(2) of Regulation (EC) No 853/2004 whereby food business operators are not to use, where hygiene so requires, any substance other than potable water, provisions allowing the use of clean water for the handling of fish are set out in Chapter VII of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs² and Part II of Chapter I and Chapters III and IV of Section VIII of Annex III to Regulation (EC) No 853/2004, in particular for handling fishery products on board vessels.
- (3) Commission Regulation (EC) No 2076/2005³ lays down a transitional measure extending the scope of the relevant provisions in Regulation (EC) No 853/2004 to land-based establishments during the transitional period.
- (4) It has long been scientifically recognised that the use of seawater is of technological interest for fishery products as it helps in maintaining intact their organoleptic characteristics by eliminating the risk of osmotic shock.

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

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

³ OJ L 338, 22.12.2005, p. 83.

- (5) Since the use of clean seawater does not represent a risk for public health as long as control procedures based, in particular, on the HACCP principles have been developed and put in place by food business operators to ensure that it complies with the definition laid down in Regulation (EC) No 852/2004, it is appropriate to make this transitional measure permanent.
- (6) Section VIII of Annex III to Regulation (EC) No 853/2004 as amended by Commission Regulation (EC) No 1662/2006⁴ sets out the requirements governing the production and placing on the market of fishery products intended for human consumption, including fish oil.
- (7) There have been difficulties in implementing these specific requirements in some Member States and third countries. These difficulties mainly relate to the requirements applying to raw materials in order to ensure their suitability for the production of fish oil destined for human consumption and to food manufacturing practices usually in place in the fish oil industry. It is therefore appropriate to clarify those provisions in order to harmonise their implementation.
- (8) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if not consumed under certain conditions. Regulation (EC) No 853/2004 as amended by Regulation (EC) No 2074/2005⁵ lays down specific marketing conditions to these fishery products.
- (9) These conditions apply to fresh, prepared and processed fishery products derived from these species. However, similar risks for the consumer may be encountered with frozen fishery products derived from this fish family. It is therefore appropriate to require similar protective and informative conditions for this latter presentation of the products.
- (10) Part III(1)(a) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 provides that food business operators manufacturing dairy products must ensure that raw cows' milk meets a limit criterion before processing.
- (11) Compliance with this limit is particularly important for food safety where the milk has to be heat-treated by a pasteurisation process or a process lower than a pasteurisation, and has not been heat-treated so within a pre-defined time. In such circumstances, the application of such heat-treatments does not have a sufficient bactericidal effect, which may lead to an early spoilage of the resulting dairy product. Regulation (EC) No 2076/2005 provides for a transitional measure aiming at limiting the verification of compliance with this criterion to such circumstances. It is therefore appropriate to retain these requirements on a permanent basis.

⁴ OJ L 320, 18.11.2006, p. 1.

⁵ OJ L 338, 22.12.2005, p. 27.

- (12) Section X of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for eggs and egg products. According to Chapter I (2), eggs must be stored and transported at a constant temperature that is best suited to ensuring optimal conservation of their hygiene properties.
- (13) Before 1 January 2006 Member States were authorised to apply controlled temperature standards within their territory to egg storage facilities and to transport from one facility to another until sale to the consumer. Regulation (EC) No 2076/2005 provides for an extension of such national arrangements, if still authorised by the competent authority, on a transitional basis. Since this possibility for competent authorities in the Member States does not interfere with the food safety objectives laid down in Regulation (EC) No 853/2004, it is therefore appropriate to make this transitional measure permanent.
- (14) Under Part II (1) of Chapter II of Section X of Annex III to Regulation (EC) No 853/2004, cracked eggs may be used for the manufacture of egg products under certain conditions. Since the use of such eggs in the production of liquid egg does not represent a risk for public health as long as it complies with the strict conditions under which such derogation can be granted to establishments manufacturing egg products, it is appropriate to extend this possibility to the establishments producing liquid egg.
- (15) Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (16) 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 II to Regulation (EC) No 853/2004 is amended in accordance with the Annex I to this Regulation.

Article 2

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

Article 3

Articles 11, 12 and 13 of Regulation (EC) No 2076/2005 are hereby deleted.

Article 4

This Regulation shall enter into force on the [\[20th\]](#) 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 I

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

1. In Section I, Parts A and B are amended as follows:

(a) Points 1 and 3 of Part A are replaced by the following:

- '1. The identification mark must be applied before the product leaves the establishment of its production.
3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Regulation (EC) No 1028/2006⁶.'

(b) Point 8 of Part B is replaced by the following:

- '8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EB, EC, EF, EG, EK, EO, EY, ES, EÜ, EK or WE.

However, that abbreviation can only be included in marks applied in establishments located within the Community.'

2. In Section III:

(a) Point 1 is replaced by the following:

- '1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested, and been provided with, relevant food chain information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004.'

(b) In Point 3, the introduction is replaced by the following:

- '3. The relevant food chain information referred to in point 1 is to cover, in particular:'

⁶ OJ L 186, 7.7.2006, p. 1.

ANNEX II

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

1. In Section VIII, the introductory Part and Chapters I, III, IV and V are amended as follows:
 - (a) In the introductory Part of Section VIII, point 2 is replaced by the following:
 - '2. Chapter III, Parts A, C and D, Chapter IV, Part A and Chapter V apply to retail.'
 - (b) In the introductory Part of Section VIII, a new point (c) is added to point 3 as follows:
 - '(c) In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation. Clean seawater may be used with fishery products for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking.'
 - (c) In Chapter I, point 2 of Part II is replaced by the following:
 - '2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat.'
 - (d) In Chapter I, point 5 of Part II is hereby deleted.
 - (e) In Chapter I, point 6 of Part II is replaced by the following:
 - '6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.'
 - (f) In Chapter III, Point 2 of Part A is replaced by the following:
 - '2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly immediately after these operations.'
 - (g) In Chapter III, Part E is deleted.

(h) Chapter IV is replaced by the following:

'Chapter IV: REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling certain processed fishery products.

A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS

1. Rapid cooling must follow cooking. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VII.

B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION

1. Raw materials used in the preparation of fish oil for human consumption must:
 - (a) (i) come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;
 - (ii) derive from fish which are fit for human consumption and comply with the provisions laid down in this Section;
 - (iii) be transported and stored in hygienic conditions;
 - (iv) be chilled as soon as possible and remain at the temperatures specified in Chapter VII.
- (b) By way of derogation from the provisions of Point 1 (a)(iv), when whole fishery products are used directly in the preparation of fish oil for human consumption, the raw material may be processed within 36 hours after loading, provided that the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products meet the requirements of Annex II of Commission Regulation (EC) No 2074/2005.

2. The production process for fish oil must ensure that all raw material intended to produce crude oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.
3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment
4. National standards for fish oil to be placed on the market for the final consumer apply pending the establishment of specific Community legislation.

- (i) In Chapter V, the introductory sentence is amended as follows:

'In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. The requirements of points B and D are not applicable to fish that are used directly for the preparation of fish oil intended for human consumption.'

- (j) In Chapter V, Point 1 of Part E is replaced by the following:

'1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae. Fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific name must accompany the common name on the label.'

2. In Section IX, Point 1 of Part III to Chapter II is replaced by the following:

'1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before being heat treated and if its period of acceptance defined in the HACCP-based procedures is exceeded:

- (a) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml;

and

- (b) heat treated cows' milk used to prepare dairy products has a plate count at 30°C of less than 100 000 per ml.'

3. In Section X, Chapters I and II are amended as follows:
- (a) In Chapter I, Point 2 is replaced by the following:
- '2. Eggs must be stored and transported until sale to the consumer at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties, unless the competent authorities impose national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities.'
- (b) In Chapter II, Point 1 of Part II is replaced by the following:
- '1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of liquid egg or egg products if the establishment of production or a packing centre delivers them directly to an establishment approved for the manufacture of liquid egg or a processing establishment, where they must be broken as soon as possible.'

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 09.06.2008

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

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 the Council of 29 April 2004 on the hygiene of foodstuffs¹, and in particular Article 13(1) thereof,

Whereas:

- (1) Regulation (EC) No 852/2004 lays down the general hygiene requirements that must be complied with by all food business operators. In particular, with regard to water supply, Chapter VII of Annex II stipulates that potable water must be used, whenever necessary, to ensure that foodstuffs are not contaminated. Provisions are also set out in the same Chapter to allow the use of clean water for the handling of fish, live bivalve molluscs, echinoderms, tunicates and marine gastropods.
- (2) Food business operators willing to use clean water should ensure that it is not a source of contamination for the fishery products.
- (3) Regulation (EC) No 852/2004 should therefore be amended accordingly.
- (4) 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 II to Regulation (EC) No 852/2004 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the [\[20th\]](#) 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.

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

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX

In Chapter VII of Annex II to Regulation (EC) No 852/2004, Point 1(b) is replaced by the following:

- '(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply to ensure that it is not a source of contamination for the foodstuff.'