

24 November 2008

REFLECTION PAPER
ON
NEW COMITOLOGICAL AMENDMENTS TO
THE HYGIENE PACKAGE

Working document

Does not represent the views of the Commission

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SHEET I

ANNEX II TO REGULATION (EC) No 853/2004

Identification marking

To clarify the cases where a new mark must be applied (re-packaging activities).

To clarify the provisions for wrapped products placed in packages.

SHEET II

ANNEX II TO REGULATION (EC) No 853/2004

Food Chain Information

To adapt the '24h in advance' requirement and to broaden the situations where a MS may authorise a FBO to derogate from that requirement.

➤ **Possible proposal:**

Point 7 of Section III of Annex II to Regulation (EC) No 853/2004 is amended as follows:

'7 Food chain information may accompany the animals of all species to which it relates to the slaughterhouse, rather than arriving at least 24 hours in advance, if the competent authority so permits and if this does not jeopardise the objectives of this Regulation.

However, any item of food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, is to be made available to the slaughterhouse operator in good time before the animals arrive at the slaughterhouse.

Slaughterhouse operators must check the relevant information. If they accept the animals for slaughter, they must give the information received to the official veterinarian. Slaughter or dressing of the animals may not take place until the official veterinarian so permits.'

SHEET III

ANNEX III TO REGULATION (EC) No 853/2004

Section I – Meat of domestic ungulates

To further specify the rules under which blood intended for human consumption may be collected, stored and used.

➤ **Background**

Food business operators have the general duty to ensure that when blood is destined for human consumption, it is collected, handled and stored in such a way to avoid contamination and ensure that it may be safely used.

Due to the high sensitivity of this product and in order to better harmonise the rules applicable in this case, it is appropriate to lay down more specific provisions.

➤ **Possible proposal**

The proposed rules should include more specific requirements on the collection (equipments needed, phase of the bleeding), the pre-treatment, storage and transportation of blood.

SHEET IV

ANNEX III TO REGULATION (EC) NO 853/2004

Section II – Meat from poultry and lagomorphs

To align that should apply to poultry meat as regards storage to those already existing for red meat.

➤ **Possible proposal**

Chapter V of Section II of Annex III to Regulation (EC) No 853/2004 is amended as follows:

'CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs takes place in accordance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:
 - (a) meat intended for cutting is brought into the workrooms progressively as needed;
 - (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4°C by means of an ambient temperature of 12°C or an alternative system having an equivalent effect; and
 - (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.
2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:
 - (a) directly from the slaughter premises; or
 - (b) after a waiting period in a chilling or refrigerating room.
3. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 1(b) and remain at that temperature during storage.
4. Meat must attain the temperature specified in point 1(b) before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to enable the production of specific products, provided that:
 - (a) such transport takes place in accordance with the requirements that the competent authority specifies in respect of 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.

5. Meat intended for freezing must be frozen without undue delay.

46. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.'

SHEET V

ANNEX III TO REGULATION (EC) NO 853/2004

Section IV – Wild game meat

1. Conditions for the declaration

To give more flexibility to hunters when providing the declaration in the case of animals for which no abnormalities have been identified

➤ **Possible proposal**

Point 4(a) of Section IV, Chapter II of Annex III to Regulation (EC) No 853/2004 is amended as follows:

- '4. (a) (i) If no abnormal characteristics are found during the examination referred to in paragraph 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing. *The declaration need not be attached to the animal body and may cover more than one animal body provided that the competent authority so permits and that each animal body is appropriately identified and the declaration bears an indication of the identification number of each animal body with the corresponding date, time and place of killing. All animal bodies covered by a collective declaration can only be sent to a same game handling establishment.*
- (ii) In this case, the head and the viscera need not accompany the body, except in the case of species susceptible to Trichinosis (porcine animals, solipeds and others), whose head (except for tusks) and diaphragm must accompany the body. However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC.'

2. Trade of unskinned large wild game

To clarify the rules under which unskinned large wild game may be sent from a game handling establishment in one Member State to a game handling establishment situated in another Member State.

SHEET VI

ANNEX III TO REGULATION (EC) No 853/2004

Section VII - Live Bivalve Molluscs

1. Contaminants in LBM

To stipulate clearly that LBM containing residues or contaminants in excess are to be declared unfit for human consumption

➤ **Background**

Contaminants and residues are covered several places in Annex II to Regulation (EC) No 854/2004:

Point B(1)(d) of Chapter II of Annex II to Regulation (EC) No 854/2004:

*"1. Classified relaying and production areas must be periodically monitored to check: [...]
(d) for the presence of chemical contaminants in live bivalve molluscs."*

Point B(8) of Chapter II of Annex II to Regulation (EC) No 854/2004:

*"8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001
(NB! Correct reference is now Commission Regulation (EC) No 1881/2006)"*

Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/200:

"1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the harvesting of live bivalve molluscs. .."

Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004

However, the health standards for live bivalve molluscs found in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 do not include contaminants, etc. It may therefore appropriate to include a reference to contaminants here?

➤ **Possible proposal**

The introductory part of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 is amended as follows:

‘In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, and not exceeding the limits for contaminants laid down in the relevant legislation, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.’

2. Packages for retail

To clarify that any packages of live bivalve molluscs (LBM) for retail must be closed

➤ Possible proposal

Point 2 of Chapter VI of Section VII of Annex III to Regulation (EC) No 853/2004 is amended as follows:

'All packages of live bivalve molluscs destined for retail must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.'

Deleted: Individual consumer-size

3. Sale of *Pectinidae*

To clarify the conditions for the sale of pectinidae harvested outside classified fishing areas by an auction market

- safety provisions to be made for the marketing of these products,
- provisions to be made with regard to traceability (packaging of all batches bearing an obligatory identification mark?)

➤ Possible proposal

Point 4 of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 is amended as follows:

'4. Food business operators handling pectinidae must comply:

(a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested;

and (b) with the requirements of Chapter VI, Point 2 concerning closing of all packages of live pectinidae destined for retail and Chapter VII concerning identification marking and labelling.'

Deleted: or

Deleted: ¶

Deleted: as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging,

4. Extension of the *Pectinidae* regime to other LBM, marine gastropods (e.g. abalone)...

To consider the usefulness of extending the “pectinidae regime” to other live bivalve molluscs as specified in Article 11(7) of Regulation (EC) No 853/2004.

To clarify the wording of point 2 of Chapter IX on the classification of such fishing grounds

➤ **Background**

- *Non paper regarding survey performed by the European Community Reference laboratory for monitoring bacteriological and viral contamination of bivalve molluscs*



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Implementing measur]

- *Regulatory change or Guidance?*

SHEET VII

ANNEX III TO REGULATION (EC) NO 853/2004

Section VIII - Fishery products

1. Notion of primary production

Associated operations in the fishery products sector (primary production) to see how and, if necessary, the provisions limited to “on board vessels” can be extended to aquaculture farms.

➤ **Background**

Legal basis: Point 4 of the introductory part of Section VIII of Annex III to Regulation (EC) No 853/2004.

During recent discussions in the Working Group Implementing Measures of the Hygiene Regulations it has been claimed by some Member States that in farming of live fishery products (aquaculture), associated operations in relation to farming of fishery products, as slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping, should be regarded as primary production. However, there is no legal basis in the present hygiene Regulations for such an interpretation.

In order to find whether and how to proceed on this issue, we ask Member States Measures to provide more information on:

- What are the operations that actually take place in such fish farms before the fish leave the farm?

- Is the fish that has undergone such operations on the farm only distributed in small quantities to the final consumer and retail establishments, or is it also sent to processing establishments, fish auctions, etc?

2. Legal frame for fishery products with additives

To clarify the position of fishery products containing additives.

➤ **Background**

European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners lists certain additives that can be used on inter alia fresh fishery product to ensure preservation. This may, for example, be done on a fishing vessel transporting and storing whole and gutted fish in water in accordance with Point A.5 of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004

The definition of fresh fishery product in point 3.5 of Annex II to Regulation (EC) No 853/2004 excludes from the definition fishery products that "has undergone any treatment to ensure preservation other than chilling". Consequently fishery products, on which such additives have been used as a preservative, are not fresh fishery products anymore.

This interpretation may cause confusion regarding which requirements of Section VIII of Annex III to Regulation (EC) No 853/2004 apply for such fishery products. Therefore, it may be appropriate to adjust the legislation accordingly.

3. Transport in cooled water

To clarify the rules on storage and transport of fishery products in cooled water.

Possible issues to be discussed:

1. The term "melt-water does not remain in contact with the products"

Does it create confusion that the terms like "melt-water does not remain in contact with the products" appears 4 specific places in Section VIII of Annex III to Regulation (EC) No 853/2004?

- In Point I (B)(2) of Chapter I on requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours.*
- In Point A(4) of Chapter III on requirements for fresh fishery products*
- In Point I of Chapter VI on wrapping and packaging of fishery products, and*
- In Point 3 of Chapter VIII on transport of fishery products*

2. Transport of whole and gutted fishery products

Point A.5 of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004, states

5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

The Commission has been enquired whether this provision should also apply for headed fish.

3. Does the freezing-in-brine temperature limit cause any problems when such fish are taken out of the brine?

Point II.7 of Chapter I of Annex III to Regulation (EC) No 853/2004 (Hygiene requirements for vessels):

Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than -9°C must be achieved for the product. The brine must not be a source of contamination for the fish.

Point 2 of Chapter II of Annex III to Regulation (EC) No 853/2004 (Storage of fishery products):

Frozen fishery products must be kept at a temperature of not more than -18°C in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9°C .

SHEET VIII

ANNEX III TO REGULATION (EC) No 853/2004

Section XIV - Gelatine

To clarify the rules applying to raw materials used for the manufacture of gelatine intended for human consumption

➤ **Possible proposal**

Point 1 of Section XIV, Chapter I of Annex III to Regulation (EC) No 853/2004 is amended as follows:

- '1. For the production of gelatine intended for use in food, the following raw materials may be used:
- (a) bones, *other than specified risk materials as referred to in Regulation (EC) No 999/2001*;
 - (b) hides and skins of farmed ruminant animals;
 - (c) pig skins;
 - (d) poultry skin;
 - (e) tendons and sinews;
 - (f) wild game hides and skins; and
 - (g) fish skin and bones.'

SHEET IX

ANNEX III TO REGULATION (EC) No 853/2004

Section XV - Collagen

To clarify the rules applying to raw materials used for the manufacture of collagen intended for human consumption

➤ **Possible proposal**

Point 1 of Section XV, Chapter I of Annex III to Regulation (EC) No 853/2004 is amended as follows:

'1. For the production of collagen intended for use in food, the following raw materials may be used:

(a) bones, other than specified risk materials as referred to in Regulation (EC) No 999/2001;

(b) hides and skins of farmed ruminant animals;

(c) pig skins and bones;

(d) poultry skin and bones;

(e) tendons;

(f) wild game hides and skins; and

(g) fish skin and bones.'

SHEET X

ANNEX III TO REGULATION (EC) NO 853/2004

Section XVI – Meat or products from exotic species

To introduce a new Section regulating the placing on the market of exotic products

To firstly lay down rules for reptile meat

➤ **Background**

Currently trade in reptile meat is not harmonised by Community legislation. As a result, some Member States prohibit the import of reptile meat, while others permit import on a bilateral basis under certain conditions. However, once reptile meat has entered the Community, it may end up on the market of a Member State that prohibits its import from third countries.

Discussions on possible EU requirements were launched in 2004. Two areas of interest were identified – conditions for the production of reptile meat at EU level (in some Member States farms with crocodiles already exist) and conditions for the import of reptile meat from third countries. A proposal to amend Regulation (EC) No 853/2004 in this respect was presented by the Commission to Member States in 2006. Some Member States considered that it was too early to discuss the proposed conditions because public health risks relating to the consumption of reptile meat were not known and, therefore, scientific basis for the proposed rules was missing.

In 2006 The Commission submitted a question to EFSA on the public health risks involved in the human consumption of reptile meat. The Panel on Biological risks (BIOHAZ) and the Panel on Contaminants in the Food Chain (CONTAM) were involved in the assessment. The scientific opinion "Public health risks involved in the human consumption of reptile meat" ¹ was adopted on 18 October 2007 and published on 21 November 2007. The Nile crocodile (*Crocodylus niloticus*), the European pond terrapin (*Emys orbicularis*), and the Ocellated lizard (formerly *Lacerta lepida*, recently reclassified as *Timon lepidus*) are the main species considered in this opinion. Only farmed or ranched reptiles were considered. The risk assessment deals with disease agents (viruses, prions, bacteria, fungi, parasites) as well as chemical substances (e.g., residues of veterinary drugs, hormones, and heavy metals) that might be of public health concern.

The BIOHAZ Panel concluded that certain bacteria such as *Salmonella* and parasites such as *Spirometra* are the main risks associated with the consumption. However, no concrete recommendations for biological risks were included in the Opinion.

¹ Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on public health risks involved in the human consumption of reptile meat. The EFSA Journal The EFSA Journal (2007) 578, 1-55

The CONTAM Panel concluded that there is a lack of occurrence data on residues of veterinary medicines and chemical contaminants in these species, and therefore, a risk assessment of potential contaminants is not possible. In regard to environmental contaminants and residues of veterinary medicines, the CONTAM Panel noted that measures equivalent to EU legislation on feed should also be applied in the production of such imported foods. The CONTAM Panel recommended that data on the occurrence of chemical hazards in reptile meat need to be collected.

Risks related to *Trichinella* were not considered since it represents a known biological hazard to humans through reptile meat consumption. The requirements for the *Trichinella* testing of reptile meat are already laid down in Regulation (EC) No 2075/2005. The predilection sites for crocodiles are laid down in Annex III of the Regulation. Derogations from the obligatory *Trichinella* testing laid down for the meat of domestic swine according to Article 3 of the Regulation (e.g. freezing treatment) are not foreseen to be used in respect to reptile meat.

FVO missions to third countries were carried out in respect to crocodile meat: in 2003 to Zimbabwe (No 9134/2003) and in 2007 to South Africa (No 2007/7585).

➤ **Possible proposal**

Introducing harmonised rules on reptile meat may imply amending Regulations (EC) No 853/2004, No 854/2004, No 2073/2005 and No 2074/2005 as indicated in Annex to this document.

SHEET XI

ANNEX I TO REGULATION (EC) No 854/2004

Section II – New OIE classification system for animal diseases

➤ **Possible proposal**

Point (e) of Section II, Chapter V (1) of Annex I to Regulation (EC) No 854/2004 is amended as follows:

- '(e) derives from animals affected by an OIE ~~List A or, where appropriate, OIE List B~~ listed disease, unless otherwise provided for in Section IV;'