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REFLECTION PAPER
ON
NEW COMITOLOGICAL AMENDMENTS TO
THE HYGIENE PACKAGE

Revision 1

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: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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 as 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 (equipment needed, phase of bleeding), the pre-treatment, storage and transportation of blood.

It may include the following requirements:

1. Bleeding should be as complete as possible. (Codex alimentarius)
2. If blood is intended for food, it should be collected and handled in a hygienic manner. (Codex alimentarius)
3. Traceability of a carcass and other relevant parts (including blood as appropriate) shall be maintained until post-mortem inspection is complete. (Codex alimentarius)

NB.

(i) Need to discuss extension to other species e.g. poultry (geese)?

(ii) Need to discuss format of such proposed rules.

SHEET IV

ANNEX III TO REGULATION (EC) NO 853/2004

Section II – Meat from poultry and lagomorphs

To align and apply what already exists for red meat to poultry meat as regards storage

- Possible proposal: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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 in 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 rearing 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 854/2004:

"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. May it therefore be appropriate to include a reference to contaminants here?

➤ **Possible proposal**

[No proposal for legislative change seems necessary. The general rules in Regulation \(EC\) No 178/2002 seem to be sufficient. Additional reference to EC Regulation on contaminants in live bivalve molluscs in Regulation \(EC\) No 853/2004 or Regulation \(EC\) No 854/2004 may create a need for references to other legislation.](#)

2. Packages for retail

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

➤ Possible proposal: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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.

If done, it must be applied to areas with a very low risk of faecal contamination. So far there is no proposal for species or areas.

The classification requirement for harvesting areas for gastropods, etc

Should the classification requirements for gastropods except filter feeding gastropods (e.g. slipper limpets) be removed?

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?

UK has provided a technical background note on classification and monitoring of Marine Gastropods, Tunicates and Echinoderms:



UK LBMs Appendix
1.doc

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.

➤ Possible proposal: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

➤ 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?

2. Legal frame for fishery products with additives

To clarify the position of fishery products containing additives.

➤ Possible proposal: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

➤ 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 "have 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 proposal**

No proposal for legislative change has been made at this stage. Clarification of issues like those below may be done by guidance.

Storage and transport

There is a difference between draining of melt water when stored under ice, and use of cooled water for the chilling.

"Storage and transport under ice"

When fishery products are kept under ice, it must be ensured that the melt water does not remain in contact with the products. This is mentioned 4 specific places in Section VIII of Annex III.

"Storage and transport in water"

Whole and gutted fresh fishery products can be transported and stored in cooled water onboard vessels, until the first establishment on land carrying out activities other than transport or sorting. The fact that it is not mentioned in the Regulation how such cooled water is to be kept cold, indicates that the use of ice in the water may be acceptable on certain terms.

Use of cooled water in production

Potable water and clean seawater may be used for the handling and washing of fishery products in production. This includes use of cooled water.

➤ **Background**

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 in 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 asked whether this provision should also apply for headed fish.

4. Fishery products in brine

➤ **Possible proposal:** [Already covered by a proposal \(see SANCO/4449/2009\)](#)

➤ **Background**

A problem has been reported by third countries. When the brine method for freezing of whole fish intended for canning is used, the brine is removed from the fish when it has been frozen to a temperature below minus 9 °C. This often happens on the vessel using this freezing method. The English version of Section VIII of Annex III to Regulations (EC) No 853/2004 may be read as when fish frozen in brine and intended for canning are stored outside the brine at the canning factory before processing temperature of the fish has to be lowered from -9° to -18 °C.

This does not apply to other major language versions. Other major language versions indicate that the temperature requirement of maximum minus 9 °C applies when the brine method has been used for freezing whole fish intended for canning.

As the English version of the hygiene Regulations was the master version, a clarification is probably best done through the comitology procedure, and not through a corrigendum.

A similar confusion may also arise from the English version of the repealed Directive 91/493/EEC. However, it should be noted that the work on Directive 91/493/EEC initially took place on a French language version.

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

English version:

Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than $-9\text{ }^{\circ}\text{C}$ must be achieved for the product. The brine must not be a source of contamination for the fish.

French version:

7. Lorsque des poissons entiers destinés à l'industrie de la conserve sont congelés en saumure, ils doivent atteindre une température ne dépassant pas $-9\text{ }^{\circ}\text{C}$. La saumure ne doit pas constituer une source de contamination des poissons.

Chapter VII (2): Storage of fishery products of Section VIII of Annex III to Regulation (EC) No 853/2004:

English version:

2. Frozen fishery products must be kept at a temperature of not more than $-18\text{ }^{\circ}\text{C}$ 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 $-9\text{ }^{\circ}\text{C}$.

2) les produits de la pêche congelés doivent être maintenus à une température ne dépassant pas $-18\text{ }^{\circ}\text{C}$ en tous points; cependant, **les poissons entiers congelés en saumure** et destinés à l'industrie de la conserve peuvent être maintenus à une température ne dépassant pas $-9\text{ }^{\circ}\text{C}$;

Chapter VIII (1)(b): Transport of fishery products of Section VIII of Annex III to Regulation (EC) No 853/2004:

English version:

(b) frozen fishery products, with the exception of **frozen fish in brine** intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than $-18\text{ }^{\circ}\text{C}$ in all parts of the product, possibly with short upward fluctuations of not more than $3\text{ }^{\circ}\text{C}$.

French version:

b) les produits de la pêche congelés, à l'exception **des poissons congelés en saumure** et destinés à l'industrie de la conserve, doivent être maintenus pendant le transport à une température homogène ne dépassant pas $-18\text{ }^{\circ}\text{C}$ en tous points, de brèves fluctuations vers le haut de $3\text{ }^{\circ}\text{C}$ au maximum étant tolérées;

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: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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: [Already covered by a proposal \(see SANCO/4449/2009\)](#)

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, the 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 was a lack of occurrence data on residues of veterinary medicines and chemical contaminants in these species, and therefore, a risk assessment of potential contaminants was 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 of reptile meat.

FVO missions to third countries were carried out in respect of 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: **[Already covered by a proposal \(see SANCO/4456/2009\)](#)**