

[29 April 2009](#)

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REFLECTION PAPER
ON
NEW COMITOLOGICAL AMENDMENTS TO
THE HYGIENE PACKAGE

Revision [2](#)

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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. Requirements on production areas for certain marine gastropods

To adapt classification requirements for marine gastropods which are not filter feeders

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

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UK LBMs Appendix
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➤ Possible proposal: Already covered (see SANCO/4449/2009)

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2. Contaminants in LBM

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

➤ **Possible proposal**

Following the discussions on 23 January 2009 the issue will not be pursued.

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No proposal for legislative change seems necessary.

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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.

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3. 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 \(see SANCO/4449/2009\)](#)

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4. 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 \(see SANCO/4449/2009\)](#)

5. Concept of "harvested outside classified production areas"

Clarification of the term "harvested outside classified production areas"

➤ Background

The "*pectinidae* regime" for *pectinidae* harvested outside classified production areas is specified in Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 and in Chapter III of Annex II to Regulation (EC) No 854/2004

The term "harvested outside classified production areas" may open for harvesting in areas influenced by faecal contamination that has not been classified. There is a need for clarification of the term.

➤ Possible proposal:

Substitute the term ""harvested outside classified production areas" with " harvested outside classified production areas in open water not influenced by faecal contamination" in Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 and in Chapter III of Annex II to Regulation (EC) No 854/2004.

(FR proposal: "au large en eaux profondes")

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

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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.

➤ **Background**

The "pectinidae regime" for pectinidae harvested outside classified production areas is specified in Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 and in Chapter III of Annex II to Regulation (EC) No 854/2004

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A specific request has been presented for extending the exception from microbiological classification of areas for pectinidae harvested outside classified areas to other live bivalve molluscs as specified in Article 11(7) of Regulation (EC) No 853/2004.

➤ **Possible proposal:**

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Substitute the term "pectinidae" with "live bivalve molluscs" in Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 and in Chapter III of Annex II to Regulation (EC) No 854/2004

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7. The term "classified fishing grounds" for pectinidae in relation to "classified production areas"

To clarify the wording of point 2 of Chapter IX on the possible classification of Pectinidae of fishing grounds outside classified areas in relation to the requirements for official control of such areas

➤ **Background**

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Point 2 of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 states:

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2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Chapter II, Part A, apply by analogy to pectinidae.

According to the definition of a "Production Area" in Point 2.5 of Annex II to Regulation (EC) No 853/2004 a fishing ground is included in that definition.

For both the food business operators and the Competent Authority the same requirements apply regarding classified fishing grounds as for classified harvesting areas. Classification of a fishing ground for pectinidae also means that the total official control regime specified in Chapter II of Annex II to Regulation (EC) No 854/2004 applies.

It may seem to be appropriate some of the controls for such classified fishing grounds may take place as for specified in Chapter III of Annex II to Regulation (EC) No 854/2004 for pectinidae harvested open water not influenced by faecal contamination.

➤ **Possible proposal:**

To modify Chapter I of Annex II to Regulation (EC) No 854/2004 by adding a new point as follows:

2. For pectinidae harvested at fishing grounds classified in accordance with Point 2 of Chapter IX of Section VII of Annex III Regulation (EC) No 853/2004, and being areas in open water not influenced by faecal contamination, the official microbiological monitoring of such fishing grounds may take place as specified in Chapter III of this Annex.'

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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**

The legal basis to be discussed is found in Point 4 of the introductory part of Section VIII of Annex III to Regulation (EC) No 853/2004.

Point 4 (b) of the introductory part of Section VIII of Annex III to Regulation (EC) No 853/2004 specifically list which associated operations that can take place in primary production if carried out on a fishing vessel: "Slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping".

Though this point may not be perfect, it is clear from the text that the listed associated operations above for fishing vessels do not apply for a primary production on a fish farm. Points 4 (b), 1 and 2 of the introductory part of Section VIII of Annex III to Regulation (EC) No 853/2004 limit the associated operations on a fish farm to transport and storage operations within fish farms and transport from the place of production to the first establishment of destination.

The use of the term "fishery products the nature of which has not been substantially altered" does not authorise additional operations in aquaculture primary production than storage and transport.

Member States has been asked to provide more information on what are the operations that actually take place in such fish farms before the fish leave the farm. The conclusion is that not all farmed fish are transported live to the first establishment of destination and that some aquaculture farms perform other associated operations than storage and transport.

➤ **Possible proposal:**

To adjust point 4 to avoid interpretive difficulties and to extend some or all of the permitted associated operations in primary production that may take place on-board fishing vessels to aquaculture farms.

2. Primary production and associated operations in the case of small-scale fishing

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To consider whether associated operations to primary production in small scale coastal fishing can take place when the boat come ashore

One Member State (Finland) reported difficulties for operators engaged in small-scale coastal fishing. The problem is caused by the fact that in fisheries the associated operations are not primary production if done by a fisherman when he brings the fish ashore.

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It has therefore proposed to extend the associated operations considered as primary production to include such operations performed on land immediately after fishing, in case of operators engaged in small-scale coastal fishing within the meaning of Article 26(1) of Council Regulation (EC) No 1198/2006?

The results of a recent enquiry indicates that though 2 other Member States experience the same problem as Finland there is no unanimous support for such a proposal.

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3. 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 fishery products.

For fresh fishery products this applies to sodium citrates, potassium citrates and calcium citrates. For fresh crustaceans and cephalopods it applies to sulphur dioxide (sulphites).

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 to clarify that such treatment on-board vessels does not exclude that the normal requirements for fresh fishery products do not apply.

It should be noted that when clean seawater is used together with fresh fishery products the products remains a fresh fishery product as the salt water is not used for the preservation of the products.

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

4. Drainage of melt water when ice is used for chilling fishery products

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Use of ice for chilling of fishery products

➤ Background

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When fishery products are kept under ice, it must be ensured that the “melt water does not remain in contact with the products”. This term appears in 4 specific places in Section VIII of Annex III to Regulation (EC) No 853/2004:

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- 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.

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- 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

According to feed-back from Member States this does not create any confusion and there is no need for further guidance.

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➤ Possible proposal: No need for legislative changes

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5. Biotoxins limits in processed LBM

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To ensure that processed bivalve molluscs comply with limits for marine biotoxins

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

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5. Transport and storage of whole and gutted fishery products on board vessels in cooled water

To clarify the rules on storage and transport of fishery products in cooled water on board vessels to the first establishment ashore.

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➤ Background

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According to Point A.5 of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 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 on how cooled water in (5) is to be kept cold indicates that even the use of ice in the water may be acceptable on certain terms. Thus, if the ice is produced in conformity with Annex III, Section VIII, Chapter I, point II (5) of the Hygiene Regulation, there is no objection to making use of this option. Compliance with the temperature limits set in Annex III, Section VIII, Chapter I, point I.B.3 should of course be ensured.

The Commission has been asked whether this provision may also apply for headed fish. During these discussions it became clear that headed fish is more exposed to hygienic contamination than whole fish or fish that has been gutted. Headed fish will also be more susceptible to uptake of water than whole fish or fish that has been only gutted. Data showing what happens during chilling and storage of headed fish in water has not been provided.

The related question, on whether fresh fishery products can be stored in cooled water after reaching an establishment on land in cooled water, has also been discussed. It was then concluded that the wording of Annex III, Section VIII, Chapter III, A (1) and (5) of Regulation (EC) No 853/2004 gives enough scope (flexibility) for practical solutions in each establishment for a short time storage of whole and gutted fresh fishery products in cooled water after they arrive at the first establishment on land carrying out activities other than transport or sorting.

➤ **Possible proposal:**

No need for legislative changes. If clarification is needed, this may be done by guidance.

6. Fishery products in brine

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Temperature requirement for fish that have been frozen using the brine method and are intended for canning

➤ **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. A similar confusion also arose 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.

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. [An amendment of the legislation would also allow for a clarification of the text.](#)

Another issue is that loins from such fish are transported from the first establishments to a second establishment for canning after being frozen to minus -18 ° C. Such loins may be precooked or raw before freezing. Concerns have been raised how it is ensured that such loins that have not heat treated before transport to the second establishment is really used for canning. This issue has, however, not been addressed in the existing legislation, nor in the draft proposal.

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➤ **Possible proposal:** Already covered by a proposal (see SANCO/4449/2009).

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7. Parasites in fishery products

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To review the provisions for parasites in fishery products

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➤ Background

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The issue of parasites in fishery products was discussed in a dedicated meeting of the Working Group Implementing Measures 1 December 2008. In a previous version of SANCO/4449/2009 a draft was included addressing a possible future outline of a revised Chapter III, D of Section VIII of Annex III to Regulation (EC) No 853/2004 ("Requirements concerning parasites").

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EFSA has been requested to provide opinions on certain aspects related to parasites in fishery products, which may influence of the amendments of Chapter V on "Health standards for fishery products" and probably also Chapter III, D on "Requirements concerning parasites". EFSA has been requested to provide opinions:

- (1) Assessing the food safety concerns due to possible allergic reactions in consumers caused by parasites that may be present in fishery products;
- (2) Identifying alternative treatments for killing viable parasites in fishery products and assessing their effectiveness compared to the freezing method described in the hygiene Regulations;
- (3) Identifying criteria for determining when fishing grounds for wild catch and fishery products from aquaculture do not present a health hazard with regard to the presence of parasites if eaten raw or almost raw, and an assessment of available documentation for farmed Atlantic salmon.

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➤ Possible proposal: **None pending EFSA opinion.**

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

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

REGULATION (EC) NO 854/2004

1. ANNEX I – Meat

To take on board the new OIE classification system for animal disease

- Possible proposal: [Already covered by a proposal \(see SANCO/4456/2009\)](#)

2. ANNEX II – Live bivalve molluscs

To adapt classification requirements for marine gastropods which are not filter feeders

- Possible proposal: [Already covered by a proposal \(see SANCO/4456/2009\)](#)

3. ANNEX III – Fishery products

To ensure that processed bivalve molluscs comply with limits for marine biotoxins

- Possible proposal: [Already covered by a proposal \(see SANCO/4456/2009\)](#)