

25 August 2011

This is the Seafish response to the Food Standards Agency's request for comments on the *Impact assessment accompanying proposals for the Regulations of the European Parliament and of the Council amending the "Hygiene Package" (Regulations (EC) No 852/2004, 853/2004 and 854/2004)*. It was submitted to the Food Standard Agency on 12 August 2011 following consultation with members of the Food Legislation Expert Group.

Seafish comments and preferred options are included in the document in blue type.

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**Impact assessment accompanying proposals for the Regulations of the European Parliament and of the Council amending the "Hygiene Package" (Regulations (EC) No 852/2004, 853/2004 and 854/2004)**

***Questionnaire to competent authorities and European stakeholder organisations***

**1. INTRODUCTION**

On 29 April 2004, the European Parliament and the Council adopted the "food hygiene package". It comprises three basic Acts, Regulation (EC) No 852/2004 on the hygiene of foodstuffs<sup>1</sup> and 853/2004 laying down specific hygiene rules for food of animal origin<sup>2</sup> and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>3</sup>.

The food hygiene package lays down rules on the hygiene of foodstuffs taking into account a number of principles such as the primary responsibility for food safety resting with the Food Business Operators (FBO(s)), the need to ensure food safety throughout the food chain starting from primary production ("farm to fork" principle) and the implementation of procedures based on the hazard analysis and critical control point (HACCP) principles together with the application of good hygiene practices.

The hygiene package introduced a shift in approach to food hygiene policy. The clear objective of this package was to simplify the existing legal corpus on food hygiene, make it more coherent by separating the different disciplines (public health, animal health and official controls) and concentrate on objectives to be reached by FBO rather than maintaining very detailed requirements.

The Commission adopted on 28 July 2009 a report aimed at presenting factually the experience gained, including the difficulties encountered, in 2006, 2007 and 2008 from the implementation of the hygiene package by all interested actors. The report concluded that the overall experience of applying the hygiene Regulations may be regarded as positive. The MS and private stakeholders are, in general, satisfied with the structure and the principles of the hygiene legislation. They are clearly not of the opinion that the legislation requires a fundamental overhaul. A number of suggestions for improvements have, however, been suggested e.g. when certain provisions have been interpreted and applied differently. When possible by the comitology procedure, amendments have already been laid down to address these suggestions. Certain amendments are, however, only possible by the ordinary (co-decision) procedure:

- Possible amendments in the Articles of the Regulations
- Possible amendments in Annex I of Regulation (EC) No 853/2004

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<sup>1</sup> OJ L 139, 30.4.2004, p. 1 as corrected by OJ L 226, 25.6.2004, p 3

<sup>2</sup> OJ L 139, 30.4.2004, p. 55 as corrected by OJ L 226, 25.6.2004, p 22.

<sup>3</sup> OJ L 139, 30.4.2004, p. 206 as corrected by OJ L 226, 25.6.2004, p 83

## 2. PURPOSE OF THE QUESTIONNAIRE

The purpose of the questionnaire is to provide **information needed for the impact assessment** on possible amendments with a potentially high impact and that can only be amended by the ordinary procedure. This impact assessment will accompany the draft Commission proposals for Regulations of the European Parliament and of the Council amending the hygiene Regulations. In particular this impact assessment needs to include:

- Estimations on social, economic and health impacts;
- Position of the Member States and stakeholders on the different options proposed. It allows updating previous consultations carried out in view of the drafting of the 2009 report on the implementation of the hygiene package.

This questionnaire does not provide any indication of the position of the Commission but only attempts to collect the views of private stakeholders and competent authorities.

## 3. APPROACH

Please reply to the questions below to your best knowledge or experience, allowing the Commission to take into account the information in its impact assessment. The Commission is aware of an important degree of uncertainty and variation in certain answers to be provided. The answers will therefore only be used for rough estimations at EU level and not for possible comparisons of Member States.

**Please complete the included questionnaire to your best knowledge or estimates and return to [kris.de-smet@ec.europa.eu](mailto:kris.de-smet@ec.europa.eu) before 30 September 2011. Absence of replies will be considered as absence of information.**

## 4. GENERAL INFORMATION

Competent authority of: ....., or

European stakeholders organisation: .....

**5. QUESTIONS RELATED TO REGULATION (EC) NO 852/2004**

**5.1. Scope (Article 1)**

*5.1.1. The principle of whole chain compliance*

Should it be possible to lay down specific conditions for certain establishments deferring from the scope of the Regulation when they handle raw material for the production of highly refined food, for example enzymes, food additives, isinglass, rennet, glucosamine, gelatine and collagen, etc.) if based on scientific assessments and the final products are considered safe?

YES/NO/**No opinion**

Which raw materials for which products should this apply for ?

.....

**5.2. Definitions (Article 2)**

Should the possibility be include to amend definitions by delegated acts e.g. when differences in interpretation are observed or new technologies have been developed?

YES/NO/**No opinion**

**5.3. Notification of adaptation by national national measures (Article 13(6))**

Should the procedure to notify national measures to introduce adaptations to the Annexes of the Regulation be simplified?

YES/**NO**/No opinion

The procedure does not need simplification. The time periods mentioned in Article 13(6) should not be shortened. However, Commission consultations with the Standing Committee are sometimes lengthy and any initiatives to speed this process would be welcomed.

**6. QUESTIONS RELATED TO REGULATION (EC) NO 853/2004**

**6.1. Scope (Article 1)**

6.1.1. Should the exclusion under Article 1(3)(d), currently under the transitional period<sup>4</sup> applied to all meat, including processed products from poultry and lagomorphs, made permanent?

YES/NO/No opinion

6.1.2. Should exclusions similar to the one for poultry and lagomorphs under Article 1(3)(d) be considered also for other species?

YES/NO/No opinion

If yes, please clarify and provide options:

.....

6.1.3. Should the wild game and wild game meat, when they are excluded from application of Regulation (EC) No 853/2004 and thus Regulation (EC) No 854/2004 in accordance with Article 1(3)(e), be subject to mandatory *Trichinella* testing?

YES/NO/No opinion

**6.2. Import (Article 6)**

6.2.1. Listing of third country establishments: Should it be made clearer in the legal text which third country's establishments throughout the food chain are included in the requirement for EU-listing when products are to imported to the EU?

YES/NO/**No opinion**

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4 Regulation (EC) No 1162/2009, OJ L 314, 1.12. 2009

6.2.2. Should the provisions in Article 6, paragraph 1 to 3 of be applied to the import of of the following composite products:

- None
- All
- The composite products for which animal health requirements are laid down in Commission Decision 2007/275/EC
- **At least the composite products for which animal health requirements are laid down in Commission Decision 2007/275/EC + the possibility should be created to laid down and amend a list by deleted act on a risk-based approach (alerts, EFSA assessment)**
- Other option: .....

**6.3. Legal basis to amend Annex I (Definitions) (possible amendment of Article 10(1))**

Should the possibility be included to amend definitions in Annex I by delegated acts e.g. when differences in interpretation are observed or new technologies have been developed?

YES/NO/No opinion

**6.4. Notification of adaptation by national national measures (Article 10(6))**

Should the procedure to notify national measures to introduce adaptations to the Annexes of the Regulation be simplified?

YES/NO/No opinion

The procedure does not need simplification. The time periods mentioned in Article 10(6) should not be shortened. However, Commission consultations with the Standing Committee are sometimes lengthy and any initiatives to speed this process would be welcomed.

**6.5. Amendments to the Annex I**

Would you like to introduce/amend the definitions for:

*6.5.1. Reefer vessel.*

Should the present definition of "freezer vessel" be broadened to include so-called "reefer vessels" (refrigerating vessels)? These are dedicated vessels that transport frozen fishery products caught and frozen by other vessels to the landing/import site. However, they do not catch fish themselves.

YES/NO/No opinion

Freezer vessels are covered by particular aspects of legislation, and including refrigerating vessels (reefer vessels) within the definition of 'freezer vessel' will make the reefer vessels subject to the same requirements as freezer vessels. This will create several anomalies, since the vessels have different functions. A reefer vessel is essentially a 'floating cold store' whereas a freezer vessel is very often a fishing vessel with the capacity to freeze its catch.

There is a requirement for freezer vessels to have the capacity to freeze fish rapidly to  $-18^{\circ}\text{C}$  or lower: this is in Regulation 853/2004, Section VIII, Chapter I, Part I (C) "Requirements for freezer vessels". Reefer vessels would have the capacity to maintain fishery products at  $-18^{\circ}\text{C}$  or lower, but would not necessarily themselves have the capacity to lower the temperature rapidly to freeze fish.

If the reefer vessel is defined as a freezer vessel, will the reefer vessel need to be approved as in Article 6 of Regulation 852/2004? Also, if the reefer vessel is flagged by a third country, and its fish is destined for the EU, will it need to "appear on a list" as required for freezer vessels in Article 15(2)(a) of Regulation 854//2004?. Currently, transport operations are exempted from requiring approval (Regulation 853/2004 Article 4(2)(b)), and reefer vessels should certainly be seen as links in the transport chain.

Reefer vessels should be seen as 'floating cold stores' and they are important links in the cold chain. Fishery products originating on (approved) freezer vessels and destined for (approved) establishments on land are being transported by unapproved reefer vessels. The same applies to fishery products being transported from land-based establishments on refrigerated vessels. Perhaps the underlying question here is this: Is there sufficient monitoring and control of vessels transporting fishery products to ensure that they do not compromise the integrity of the cold chain?

Although there is a legal requirement for frozen fishery products to be maintained at  $-18^{\circ}\text{C}$  or colder, even during transport, there should be further minimum requirements for transport vessels. There is no need to distinguish between transport vessels that load their fishery products from a land establishment or from a freezer or factory vessel. Possibly these requirements would be similar to the requirements of Regulation 852/2004 Annex II, Chapter IV "Transport", which includes temperature monitoring.

If yes, please provide proposal: .....

#### 6.5.2. *Crocodile meat/.*

Should a new definition for crocodile meat/ be introduced in order to provide harmonised EU rules for such products in Annex III to Regulation (EC) No 853/2004?

YES/NO/No opinion

If yes, please provide proposal: .....

6.5.3. *Rodents*

Should the definition of lagomorphs be amended to keep edible rodents within the definition while excluding rodents that cannot/are not used for food from the definition of lagomorphs?

YES/NO/No opinion

If yes, please provide proposal(s) of edible rodents which should appear on the list): .....

6.5.4. *Other definitions*

YES/NO/No opinion

If yes, please provide proposal: .....

See also section 8 and 9 requesting specific information as regards the definition of meat products meat preparation and mechanically separated meat in view of an amendment of Annex I or the development of guidance.



## **7. QUESTIONS RELATED TO REGULATION (EC) NO 854/2004**

A questionnaire on the review of meat inspection has been forwarded in spring 2011 and provided a lot of input for the development of the impact assessment/proposal for ordinary procedure. Additional details on the cost of meat inspection are asked in section 10.

This part of the questionnaire is limited to other issues.

### **7.1. Health marking of carcasses (Article 5(2))**

Should the obligation for health marking of carcasses be extended to ratites?

YES/NO/No opinion

### **7.2. Notification of adaptation by national national measures (Article 17(6))**

Should the procedure to notify national measures to introduce adaptations to the Annexes of the Regulation be simplified?

YES/NO/No opinion

## 8. QUESTIONS RELATED TO MEAT PRODUCTS AND MEAT PREPARATIONS

The purpose of this part is to identify and, to the extent possible, quantify differences in products considered either as meat products or meat preparations.

### 8.1. Approach

What is in your views the most appropriate way to ensure a harmonised application of the definitions of meat preparations and meat products e.g. when differences in interpretation are observed or new technologies have been developed:

- Guidance document
- Amendments of definitions by ordinary procedure
- Amendments of current legal provisions (by ordinary procedure) to allow future amendments by delegated acts

### 8.2. Interpretation of definitions (if you consider different replies relevant for different species, please copy and paste the questions and provide answers per species)

8.2.1. How do you currently assess following products for placing on the market, including proper labelling and official controls:

- Marinated meat so that the marinade (mixture of herbs, salts, oil and acids) was distributed throughout the product and has reached the centre of the meat portion e.g. gyros, injection of marinade: meat preparation / meat products / depends on .....
- Meat not completely marinated as the marinade (mixture of herbs, salts, oil and acids) is only surface coating and has not penetrated to the centre of the meat portion: meat preparation / meat products / depends on .....
- Cured meat (= distribution of salts throughout the product (see former Directive 77/99/EEC) e.g. by injection, including brines and mixtures with potassium nitrates or sodium nitrite, sole processing until the centre of the meat, no other processing such as drying): meat preparation / meat products / depends on .....
- Semi-processed products such as flash fried meat (not marinated or cured before application of heat treatment), still containing raw/fresh meat in the centre of the product: meat preparation / meat products / depends on .....
- Semi-processed products such as flash fried meat marinated or cured before application of heat treatment, still containing visually raw/fresh meat in the

centre of the product: meat preparation / meat products / depends on .....

- Semi-processed products such as fried meat, no more containing visually raw/fresh meat in the middle, but requiring cooking before consumption: meat preparation / meat products / depends on .....

8.2.2. Which parameters and information are you using for the above classification

- simple visual inspection to evaluate if there are characteristics of fresh/raw meat at retail,
- decision made on the analysis of all the information relevant for the production of the product, including traceability
- histological analysis to evaluate the modifications to the fibre structure at retail, If so, method used: .....
- Based on research on the effects of certain processing on the characteristics of fresh/raw meat or the internal fibre structure. If so, provide references to research: .....

.....

8.2.3. Are you aware of any products that might result in different interpretations of definitions of meat preparation or meat products by different food business ?

YES/NO

If yes, please describe:

.....

8.2.4. How would you like to place the following products in future on the market:

- Marinated meat so that the marinade (mixture of herbs, salts, oil and acids) was distributed throughout the product and has reached the centre of the meat portion e.g. gyros, injection of marinade: meat preparation / meat products / depends on .....
- Meat not completely marinated as the marinade (mixture of herbs, salts, oil and acids) is only surface coating and has not penetrated to the centre of the meat portion: meat preparation / meat products / depends on .....

- Cured meat (= distribution of salts throughout the product (see former Directive 77/99/EEC) e.g. by injection, including brines and mixtures with potassium nitrates or sodium nitrite, sole processing until the centre of the meat, no other processing such as drying): meat preparation / meat products / depends on .....
- Semi-processed products such as flash fried meat (not marinated or cured before application of heat treatment), still containing raw/fresh meat in the centre of the product: meat preparation / meat products / depends on .....
- Semi-processed products such as flash fried meat marinated or cured before application of heat treatment, still containing visually raw/fresh meat in the centre of the product: meat preparation / meat products / depends on .....
- Semi-processed products such as fried meat, no more containing visually raw/fresh meat in the middle, but requiring cooking before consumption: meat preparation / meat products / depends on .....

8.2.5. What is the justification of your position on question 8.2.4 (economic, sanitary, ...)?

- Marinated meat so that the marinade (mixture of herbs, salts, oil and acids) was distributed throughout the product and has reached the centre of the meat portion e.g. gyros, injection of marinade: .....
- Meat not completely marinated as the marinade (mixture of herbs, salts, oil and acids) is only surface coating and has not penetrated to the centre of the meat portion: .....
- Cured meat (= distribution of salts throughout the product (see former Directive 77/99/EEC) e.g. by injection, including brines and mixtures with potassium nitrates or sodium nitrite, sole processing until the centre of the meat, no other processing such as drying): .....
- Semi-processed products such as flash fried meat (not marinated or cured before application of heat treatment), still containing raw/fresh meat in the centre of the product: .....
- Semi-processed products such as flash fried meat marinated or cured before application of heat treatment, still containing visually raw/fresh meat in the centre of the product: .....

- .....
- Semi-processed products such as fried meat, no more containing visually raw/fresh meat in the middle, but requiring cooking before consumption:
- .....

**8.3. Economic importance poultry meat production (if not possible to estimate at EU level, European stakeholders are invited to address the question below for a number of representative Member States)**

8.3.1. What amount of poultry meat is placed on the market as meat preparations or meat product at retail level:

- Meat preparations: .... tonnes
- Meat products: .... Tonnes

8.3.2. What % of the total amount referred to in question 8.3.1 (meat products and meat preparations together) is placed on the market at retail level as:

- Marinated meat so that the marinade (mixture of herbs, salts, oil and acids) was distributed throughout the product and has reached the centre of the meat portion e.g. gyros, injection of marinade: ..... %
- Meat not completely marinated as the marinade (mixture of herbs, salts, oil and acids) is only surface coating and has not penetrated to the centre of the meat portion: ..... %
- Cured meat (= distribution of salts throughout the product (see former Directive 77/99/EEC) e.g. by injection, including brines and mixtures with potassium nitrates or sodium nitrite, sole processing until the centre of the meat, no other processing such as drying): ..... %
- Semi-processed products such as flash fried meat (not marinated or cured before application of heat treatment), still containing raw/fresh meat in the centre of the product: ..... %
- Semi-processed products such as flash fried meat marinated or cured before application of heat treatment, still containing visually raw/fresh meat in the centre of the product: ..... %
- Semi-processed products such as fried meat, no more containing visually raw/fresh meat in the middle, but requiring cooking before consumption: ..... %

**8.4. Economic importance red meat production (if not possible to estimate at EU level, European stakeholders are invited to address the question below for a number of representative Member States)**

8.4.1. What amount of red meat is placed on the market as meat preparations or meat product at retail level (= all meat except fresh meat).

- Meat preparations: .... tonnes
- Meat products: .... Tonnes

8.4.2. What % of the total amount referred to in question 8.4.1 (meat products and meat preparations together) is placed on the market at retail level as:

- Marinated meat so that the marinade (mixture of herbs, salts, oil and acids) was distributed throughout the product and has reached the centre of the meat portion e.g. gyros, injection of marinade: ..... %
- Meat not completely marinated as the marinade (mixture of herbs, salts, oil and acids) is only surface coating and has not penetrated to the centre of the meat portion: ..... %
- Cured meat (= distribution of salts throughout the product (see former Directive 77/99/EEC) e.g. by injection, including brines and mixtures with potassium nitrates or sodium nitrite, sole processing until the centre of the meat, no other processing such as drying): ..... %
- Semi-processed products such as flash fried meat (not marinated or cured before application of heat treatment), still containing raw/fresh meat in the centre of the product: ..... %
- Semi-processed products such as flash fried meat marinated or cured before application of heat treatment, still containing visually raw/fresh meat in the centre of the product: ..... %
- Semi-processed products such as fried meat, no more containing visually raw/fresh meat in the middle, but requiring cooking before consumption: ..... %

## 9. QUESTIONS RELATED TO MECHANICALLY SEPARATED MEAT

The purpose of this part is to identify and, to the extent possible, quantify differences in products considered either as mechanically separated meat (MSM). The outcome will be used to decide if possible differences can be solved by guidance or by changes of definition in the hygiene regulations.

### 9.1. Approach

What is in your views the most appropriate way to ensure a harmonised application of the definitions of MSM:

- Guidance document
- Amendment of definition by ordinary procedure
- Amendment of current legal provisions (by ordinary procedure) to allow future amendments by delegated acts

### 9.2. Interpretation of definition

9.2.1. How do you currently place the following products on the market:

- Product obtained from the mechanical separation of fresh meat and tendons (no bones in starting material). The obtained product has the same visual and histological aspect as meat that has been minced: MSM/Other in particular: ...../Not produced.
- Product obtained from the mechanical separation of fresh meat and bones. The obtained product has the same visual and histological aspect as meat that has been minced: MSM/Other in particular: ...../Not produced.
- Product obtained from the separation of cooked meat and bones: MSM/meat product/Other in particular: ...../Not produced.
- Are you aware of other products that may result in different interpretations of the definition?

YES/NO

If yes, please describe:

.....

9.2.2. Which criteria are you using to classify a product as MSM?

- Degree of destruction or modification of muscle structure

- Starting material (e.g. with bones)
- Technology used for mechanical separation

9.2.3. How is the modification or destruction of the fibre structure evaluated?

- Histological methods, in particular.....
- Visual aspects.
- Other, in particular .....

9.2.4. Would you like to place the following products in future on the market as MSM:

- Product obtained from the separation of fresh meat and tendons (no bones in starting material). The obtained product has the same visual and histological aspect as meat that has been minced: YES/NO/No opinion.
- Product obtained from the separation of fresh meat and bones. The obtained product has the same visual and histological aspect as meat that has been minced: YES/NO/No opinion.
- Product obtained from the separation of cooked meat and bones: YES/NO/No opinion.

9.2.5. If you replied "NO" to one of the questions in 9.2.3, how would you like to call these products:

- Product obtained from the separation of fresh meat and tendons (no bones in starting material). The obtained product has the same visual and histological aspect as meat that has been minced:
  - Minced meat
  - Meat preparation
  - Something else in particular: .....
- Product obtained from the separation of fresh meat and bones. The obtained product has the same visual and histological aspect as meat that has been minced:
  - Minced meat
  - Meat preparation



- Something else in particular: .....
- Product obtained from the separation of cooked meat and bones:
  - Minced meat
  - Meat preparation
  - Meat product
  - Something else in particular: .....

### 9.3. Economic importance

What is the difference in value of low pressure MSM compared to minced meat as raw material for further processing?

.... € per tonne

**10. QUESTIONS RELATED TO COST OF MEAT INSPECTION**

(a) Please indicate estimated mean cost per hour (Euro). It should be the cost for the food business operator in case of slaughterhouse staff and the cost for competent authority in the case of official auxiliaries or official veterinarian.

- Slaughterhouse staff: .....
- Official auxiliary:.....
- Official veterinarian: .....

(b) Please indicate estimated mean time for meat inspection (minutes):

- 1000 broilers:
- 1000 turkeys
- 1 pig:
- 1 adult cattle:
- 1 veal calve:
- 1 sheep:
- 1 horse:

(c) Do you have evidence/arguments/experiences to assume reluctance of third countries to accept exported meat if tasks on red meat inspections would be delegated to slaughterhouse staff?

YES/NO/No opinion

If yes, please clarify:

.....

(d) Do you have evidence/arguments/experiences to assume an impact the safety of red meat from third countries if third countries would delegate meat inspection to slaughterhouse staff?

YES/NO/No opinion

If yes, please clarify:

.....

- (e) Do you have objective data to demonstrate if more public health concerns emerge in poultry slaughterhouse using slaughterhouse staff compared to other?

YES/NO/No opinion

If yes, please clarify:

.....

**11. SPECIAL PROVISIONS FOR IMPORT OF FISHERY PRODUCTS (ARTICLE 15 OF REGULATION (EC) No 854/2004)**

**11.1. Freezer and factory vessels under long-term charter arrangements with companies in other countries.**

Today the responsibility for inspection of such vessels can be delegated to the competent authority in another listed third country or in a Member State. However, the right to approve and request EU-listing of such vessels cannot be delegated to the competent authority of another state. Should also the right to approve/request for EU listing be opened for delegation?

YES/NO/**No opinion**

**11.2. Documents and certificates for importing frozen fishery products to the EU**

Should the documents and certificates for import of frozen fishery products to the EU be scrutinized in order to improve the routines without changing the present level of protection? This may include:

- Documents to be used when fishery products are imported directly into the EU from third country's freezer and factory vessels
- Documents/certificates to be used when fishery products are imported directly into the EU from third country's freezer and factory vessels by means of reefer vessels (refrigerating vessels)
- Documents/certificates to be used when EU vessels land their catch in third countries for further transshipment to the EU.

**YES**/NO/No opinion

If yes, please clarify and provide options:

Fishery products are regularly landed in the UK from freezer and dedicated chilled fish transport vessels. These are mostly Norwegian, Faroese or Icelandic vessels and thus exempt from many of the documentary requirements that third country vessels would have. However there is a small amount of frozen fish landed in Scotland directly from Russian vessels. I am not aware of any particular administrative issues. However, if the procedures can be made more efficient without compromising the current level of protection, we would welcome that.