



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 11 July 2003

Interinstitutional Files:

2000/0178 (COD)

2000/0179 (COD)

2002/0141 (COD)

2000/0182 (COD)

11104/03

ADD 2

LIMITE

AGRILEG 189

DENLEG 39

CODEC 940

ADDENDUM TO REPORT

from: General Secretariat

to: Committee of permanent representatives

No. prev. doc.: 10164/03

No. Cion prop.: 10987/02 – COM(2002) 377 final

Subject: **Food hygiene** – proposals for:

- a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs
 - a Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin
 - a Regulation of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
 - a Directive of the European Parliament and of the Council repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 92/118/EEC and Decision 95/408/EC
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The draft Regulation laying down **specific hygiene rules for food of animal origin** (Regulation “H2”) contained in document 5420/03 is to be amended as set out in the Annex.

AMENDMENTS TO REGULATION “H2”

Recital 23

Recital 23 is to read as follows

- (23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption. In other circumstances it may be decided, as a matter of precaution, not to use raw milk or cream for direct human consumption in view of possible hazards that may be present.”.

Recital 29

Recital 29 is to read as follows:

- “(29) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least [one year] to elapse between entry into force and the application of the new rules, to allow the affected industries time to adapt.”.

Article 6

Article 6 is to read as follows:

“Article 6

1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:
 - (a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No [H3^{*}]/2003, of third countries from which imports of that product are permitted;
 - (b)
 - (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No [H3]/2003, of establishments from which imports of that product are permitted, when applicable,
 - (ii) in the case of fresh meat, minced meat, meat preparations and meat products, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No [H3]/2003 or in approved Community establishments, and
 - (iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;
 - (c) the product satisfies:
 - (i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;

* Official Publications Office is to insert the official number of the Regulation on the organisation of official controls.

- (ii) the requirements of Regulation (EC) No [H1 **]/2003; and
 - (iii) any import conditions laid down in accordance with Community legislation governing import controls for food of animal origin, and
 - (d) the requirements of Article 14 of Regulation (EC) No [H3]/2003 concerning certificates and documents are satisfied, when applicable.
2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No [H3]/2003.
3. Food business operators importing products of animal origin shall ensure that:
- (a) products are made available for control upon importation in accordance with Directive 97/78/EC 1;
 - (b) importation complies with the requirements of Directive 2002/99/EC 2; and
 - (c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.
4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).”.

** Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

¹ Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

² Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

Article 10(8)(a)

Article 10(8)(a) is to read as follows:

“(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption; or”.

Article 15

The following text is to replace the current first and second subparagraphs of Article 15:

“This Regulation shall enter into force on the date of its publication in the Official Journal of the European Union.

It shall apply [one year] after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) .../... on the hygiene of foodstuffs;
- (b) Regulation (EC) .../... laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption; and
- (c) Directive .../.../EC repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Directives 89/662/EEC, 91/67/EEC and 92/118/EEC.

However, it shall apply no earlier than [1 January 2006].”.

Annex II, Section III

The whole Section is replaced by the following text:

“Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse.

1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested and been provided with relevant food safety information contained in the records kept at the holding of provenance in accordance with Regulation (EC) .../... [*on the hygiene of foodstuffs*].
2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.
3. The relevant food safety information referred to in point 1 is to cover, in particular:
 - (a) the status of the holding of provenance or the regional animal health status;
 - (b) the animals’ health status;
 - (c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;¹
 - (d) the occurrence of diseases that may affect the safety of meat;²

¹ This subparagraph is consistent with the aim of European Parliament amendment 47 on Regulation H3.

² This subparagraph is consistent with the aim of European Parliament amendment 48 on Regulation H3.

- (e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;¹
 - (f) relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;
 - (g) production data, when this might indicate the presence of disease; and
 - (h) the name and address of the private veterinarian normally attending the holding of provenance.
4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:
- (i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme); or
 - (ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.
- (b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.²

¹ This subparagraph is consistent with European Parliament amendment 49 on Regulation H3.

² This provision is consistent with the aim of European Parliament amendment 51 on Regulation H3.

5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before ante-mortem inspection of the animal concerned.
6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.
7. If the competent authority so permits, food chain information may accompany the animals to which it relates to the slaughterhouse, rather than arriving at least 24 hours in advance, in the case of:
 - (a) porcine animals, poultry or farmed game that have undergone ante-mortem inspection at the holding of provenance, if a certificate that the veterinarian has signed stating that he or she examined the animals at the holding and found them to be healthy accompanies them;
 - (b) domestic solipeds;
 - (c) animals that have undergone emergency slaughter, if a declaration, that the veterinarian has signed recording the favourable outcome of the ante-mortem inspection accompanies them; and
 - (d) animals that are not delivered directly from the holding of provenance to the slaughterhouse.

Slaughterhouse operators must evaluate the relevant information. If they accept the animals for slaughter, they must give the documents mentioned in subparagraphs (a) and (c) to the official veterinarian. Slaughter or dressing of the animals may not take place until the official veterinarian so permits.

8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian.”

Annex III

Section I, Chapter VI, paragraph 9, is to refer to a “special health mark” rather than to a “special

The references, in Section II, Chapter VI, paragraph 7, and Section III, paragraph 3(j), to an “official veterinarian” are to become references to an “official veterinarian or approved

Section VII, Chapter I, paragraph 7, is to read as follows:

- “7. However, if:
- (a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs; and
 - (b) a single competent authority supervises all the establishments concerned,
- registration documents are not necessary if that competent authority so permits.”

Section VII, Chapter II, Part A, paragraph 5(b)(iii), is to read as follows:

- “(iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.”

In Section VIII, Chapter II, paragraph 4 is to read as follows:

- “4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No.../2003* , in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.”.

Section IX, Chapter V, is to read as follows:

“By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;
2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.”.



* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.