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(Acts whose publication is obligatory)

**REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL
of 29 April 2004
on the hygiene of foodstuffs**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission ¹,

Having regard to the Opinion of the Economic and Social Committee ²,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ³,

1 OJ C 365 E, 19.12.2000, p. 43.

2 OJ C 155, 29.5.2001, p. 39.

3 Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

Article 5

Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:
 - (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - (c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
 - (d) establishing and implementing effective monitoring procedures at critical control points;
 - (e) establishing corrective actions when monitoring indicates that a critical control point is not
 - (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
 - (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;

(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;

(c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

Article 6

Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

(a) under the national law of the Member State in which the establishment is located;

(b) under Regulation (EC) No/2004 *; or

(c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.