Commission Regulation (EC) No 1662/2006 of 6 November 2006 amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1662/2006

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[(1)], and in particular Article 10(1) thereof,

Whereas:

(1) When subject to the provisions of Annex III to Regulation (EC) No 853/2004, food business operators should ensure that each product of animal origin has an identification mark applied in compliance with the provisions laid down in Section I of Annex II to that Regulation. Unless expressly indicated and for control reasons, products of animal origin should not bear more than one identification mark.

(2) Section I of Annex III to Regulation (EC) No 853/2004 lays down rules on the production and placing on the market of meat from domestic ungulates. Exceptions to the complete skinning of the carcase and other parts of the body intended for human consumption are set out in point 8 of Chapter IV of that Section. Provision should be made to extend these exceptions to the muzzle and lips from bovine animals, provided they comply with the same conditions as those applying to heads of ovine and caprine animals.

(3) The tonsils serve as a filter of all noxious agents entering the oral cavity of animals and should be removed for hygienic and safety reasons during the process of slaughtering domestic ungulates. Since the removal was inadvertently omitted as mandatory for domestic swine, the requirement for removal of porcine tonsils should be re-inserted.

(4) Section VIII of Annex III to Regulation (EC) No 853/2004 sets out the requirements governing the production and placing on the market of fishery products intended for human consumption. Fish oil is included in the definition of fishery products. Specific requirements for production and placing on the market of fish oil for human consumption should, therefore, be laid down. Transitional arrangements should also be foreseen to give the possibility to establishments in third countries to adapt to the new situation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1662/2006. (See end of Document for details)*

(5) Colostrum is considered as a product of animal origin but is not covered by the definition of raw milk as referred to in Annex I to Regulation (EC) No 853/2004. Colostrum is produced in a similar way and can be considered as presenting a similar risk to human health as raw milk. It is therefore necessary to introduce specific hygiene rules for colostrum production.

(6) Section XV of Annex III to Regulation (EC) No 853/2004 sets out the requirements for the production of collagen. It specifies that collagen must be produced using a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process. A different process resulting in a hydrolysed collagen that cannot be extruded was submitted for assessment to EFSA. EFSA adopted on 26 January 2005 an opinion on safety of collagen and a processing method for the production of collagen. It concluded that the production process proposed above ensures equivalent or higher health safety for collagen intended for human consumption compared to the safety achieved by applying the standards of Section XV. The conditions for the production of collagen should therefore be modified.

(7) Regulation (EC) No 853/2004 should be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 853/2004 is amended as follows:

1. Annex II is amended in accordance with Annex I to this Regulation.

2. Annex III is amended in accordance with Annex II to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1662/2006. (See end of Document for details)*

ANNEX I

Section I, Part A, point (2) of Annex II to Regulation (EC) No 853/2004 is replaced by the following:

2. However, when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.

ANNEX II

Annex III to Regulation (EC) No 853/2004 is amended as follows:

1. In Section I, Chapter IV is amended as follows:

(a) Point 8 is replaced by the following:

8. Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals. Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination.

(b) Point 16(a) is replaced by the following:

(a) the tonsils of bovine animals, porcine animals and solipeds must be removed hygienically;.

2. In Section VIII, Chapter III, Part E is added as follows:

E. REQUIREMENTS FOR FISH OIL FOR HUMAN CONSUMPTION

Food business operators must ensure that raw materials used in the preparation of fish oil for human consumption comply with the following requirements:

1. they must derive from fishery products which have been found fit for human consumption;

2. they must come from establishments, including vessels, approved in accordance with this Regulation;

3. they must be transported and stored until processing in hygienic conditions.

3. Section IX is replaced by the following:

SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS

For the purpose of this Section,

1. “Colostrum” means the fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1662/2006. (See end of Document for details)*

2. "Colostrum-based products" means processed products resulting from the processing of colostrum or from the further processing of such processed products.

CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

Food business operators producing, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter.

I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

1. Raw milk and colostrum must come from animals:

(a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum;

(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

(c) that do not have any udder wound likely to affect the milk and colostrum;

(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2.

3. However, raw milk from animals that does not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the alkaline phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months; or

(ii) after having undergone heat treatment such as to show a negative reaction to the alkaline phosphatase test; and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC, must not be used for human consumption.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk and colostrum.

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

A. Requirements for premises and equipment

1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.

2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

(a) that, before milking starts, the teats, udder and adjacent parts are clean;

(b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;

(c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and

(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the