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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, ~~29.6~~17.7.2006

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

**amending 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**

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amending 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

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 origin¹, and in particular Article 10(1) thereof,

Whereas:

~~(1) Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin.~~

~~(2)~~(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 Annex II, Section I to that Regulation. Unless expressly indicated and for control reasons, products of animal origin should not bear more than one identification mark. ~~Regulation (EC) No 853/2004 should be amended accordingly.~~

~~(3)~~(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 carcass and other parts of the body intended for human consumption are set out in Chapter IV, point 8 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.

~~(4)~~(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 slaughter process of domestic ungulates. However, this is not practicable in the case of sheep and goats. Since the removal was inadvertently omitted as mandatory for domestic swine, ~~Regulation (EC) No 853/2004 should be amended accordingly.~~

¹ OJ L 139, 30.4.2004, p.55. Corrected by OJ L 226, 25.6.2004, p. 22.

~~(5)~~(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.

~~(6)~~(5) ~~Regulation (EC) No 853/2004 lays down specific hygiene rules for food of animal origin.~~ 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 ~~and amend Annex III accordingly.~~

~~(7)~~(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, laid down in Section XV of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.

(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 of Regulation (EC) No 853/2004~~ is amended in accordance with Annex I to this Regulation.

Article 2

2. ~~Annex III of Regulation (EC) No 853/2004~~ is amended in accordance with Annex II to this Regulation.

Article 32

This Regulation shall enter into force on the seventh day following that of 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, [...]

For the Commission

[...]

Member of the Commission

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. Carcasses 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 3 to 5 days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.
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 or, 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;
 - (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk 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;
 - (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.
 - (a) In particular, as regards brucellosis, raw milk and colostrum must come from:
 - (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC², is free or officially free of brucellosis;
 - (ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC³; or
 - (iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.
 - (b) As regards tuberculosis, raw milk and colostrum must come from:

² Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 21, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

³ Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p.1).

- (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or
 - (ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.
 - (c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.
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 – 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 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 European Parliament and of the

Council of 16 February 1998 concerning the placing of biocidal products on the market⁴:

- (f) that colostrum is milked separately and not mixed together with raw milk.
2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.
 - (a) Milk must be cooled immediately to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily;
 - (b) Colostrum must be stored separately and immediately cooled to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily, or frozen.
 3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10°C.
 4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:
 - (a) the milk is processed within 2 hours of milking; or
 - (b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. Staff hygiene

1. Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes.
2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.

III. CRITERIA FOR RAW MILK AND COLOSTRUM

1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.

⁴ OJ L 123, 24.4.1998, p. 1.

- (b) National criteria for colostrum, as regards plate count, somatic cell count and antibiotic residues, apply pending the establishment of specific Community legislation.
2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of:
- (a) the food business operator producing the milk;
- (b) the food business operator collecting or processing the milk;
- (c) a group of food business operators; or
- (d) in the context of a national or regional control scheme.
3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

Plate count at 30°C (per ml)	$\leq 100\ 000^{(*)}$
Somatic cell count (per ml)	$\leq 400\ 000^{(**)}$

(ii) for raw milk from other species:

Plate count at 30°C (per ml)	$\leq 1\ 500\ 000^{(*)}$
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- (b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion.

Plate count at 30 °C (per ml)	$\leq 500\ 000^{(*)}$
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(*) Rolling geometric average over a two-month period, with at least two samples per month.

(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:

- (a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90⁵, exceeds the levels authorised under that Regulation; or
 - (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.
5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment,
- (a) milk is quickly cooled to not more than 6°C;
 - (b) colostrum is quickly cooled to not more than 6°C or maintained frozen,

and kept at that temperature until processed.

2. However, food business operators may keep milk and colostrum at a higher temperature if:
- (a) processing begins immediately after milking, or within 4 hours of acceptance at the processing establishment; or
 - (b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:
- (a) Pasteurisation is achieved by a treatment involving:

⁵ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 324/2004 (OJ L 58, 26.2.2004, p. 16).

- (i) a high temperature for a short time (at least 72°C for 15 seconds);
- (ii) a low temperature for a long time (at least 63°C for 30 minutes); or
- (iii) any other combination of time-temperature conditions to obtain an equivalent effect,

such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment."

(b) Ultra High Temperature (UHT) treatment is achieved by a treatment:

- (i) involving a continuous flow of heat at a high temperature for a short time (not less than 135°C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and
- (ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30°C in closed containers or for 7 days at 55°C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied."

2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must:

- (a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and
- (b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.

III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

- (a) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml; and
- (b) processed cows' milk used to prepare dairy products has a plate count at 30°C of less than 100 000 per ml.

2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:
 - (a) in the case of raw milk intended for direct human consumption, the words "raw milk";
 - (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words "made with raw milk";
 - (c) in case of colostrum, the word "colostrum";
 - (d) in case of products made with colostrum, the words "made with colostrum".
2. The requirements of paragraph 1 apply to products destined for retail trade. The term "labelling" includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

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.'
4. In Section XV, Chapter III, point 1 is replaced by the following:
- '1. Collagen must be produced by 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. The extrusion step may be not carried out when manufacturing low molecular collagen from raw materials of non-ruminant origin.'