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STATUTORY INSTRUMENTS

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**2005 No. 404**

**The Production of Bovine Collagen Intended  
for Human Consumption in the United  
Kingdom (England) Regulations 2005**

**Title, application and commencement**

1. These Regulations may be cited as the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (England) Regulations 2005, apply in relation to England and come into force on 26th March 2005.

**Interpretation**

2. In regulations 6 to 9 and the Schedule —

“the Act” means the Food Safety Act 1990;

“bovine animal” includes buffalo of the species *Bubalus bubalis* and *Bison bison*;

“collagen” means a protein-based product derived from the hide or skin of a bovine animal;

“collagen intended for human consumption” means collagen intended for consumption either as food or incorporated into or wrapped around any food or product to be consumed by humans;

the expressions “collection centre” and “establishment” have the same meaning as in Section B of Chapter 4 of Annex II to Directive [92/118/EEC](#) laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive [89/662/EEC](#) and, as regards pathogens, to Directive [90/425/EEC](#) (as that Directive is amended as at the date these Regulations are made) <sup>(1)</sup>;

“hides and skins” means cutaneous and sub-cutaneous tissues;

“slaughterhouse” has the same meaning as in Section A of Chapter 4 of Annex II to Directive [92/118/EEC](#) (as that Directive is amended as at the date these Regulations are made); and

“tanning” means the hardening of hides using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

**Amendment of the Bovines and Bovine Products (Trade) Regulations 1999**

3. The Bovines and Bovine Products (Trade) Regulations 1999<sup>(2)</sup> are amended in accordance with regulations 4 and 5.

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(1) OJNo. L62, 15.3.93, p.49. Chapter 4, Section B of Annex II to that Directive was first inserted by Commission Decision [2003/42/EC](#) (OJ No. L13, 18.1.2003, p.24) and was replaced by Commission Decision [2003/721/EC](#) (OJ No. L260, 11.10.2003, p.21). The Directive was last amended by Commission Regulation (EC) No. [445/2004](#) (OJ No. L72, 11.3.2004, p.60).

(2) S.I.1999/1103, amended by S.I. 1999/1554, S.I. 2000/656, S.I. 2000/1667 and S.I. 2002/2357.

4. For paragraph (1) of regulation 6 (production of bovine by-products and consignment and placing on the market of bovine meat, products and certain by-products), substitute the following paragraph —

“(1) No person shall —

- (a) produce any gelatin derived from a bovine animal slaughtered in the United Kingdom, being gelatin which is liable to enter the human food or animal feed chain or is destined for use in cosmetics or in medical or pharmaceutical products; or
- (b) produce any collagen, derived from a bovine animal slaughtered in the United Kingdom, being collagen which is liable to enter the human food or animal feed chain or is destined for use in cosmetics or in medical or pharmaceutical products, unless it is collagen intended for human consumption in the United Kingdom.”.

5. In paragraph (3) of regulation 9 (use of controlled bovine by-products and other products) —

- (a) delete the words “gelatin or collagen produced” where they first appear;
- (b) insert the words “gelatin or collagen produced” at the beginning of each of sub-paragraphs (a) and (b); and
- (c) insert “; or” and the following sub-paragraph after sub-paragraph (b) —

“(c) collagen produced in accordance with regulation 6 of the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (England) Regulations 2005.”.

#### **Control of production of collagen intended for human consumption in the United Kingdom derived from bovine animals slaughtered there**

6.—(1) Until the end of 2005 no person shall produce any collagen derived from any bovine animal slaughtered in the United Kingdom, being collagen intended for human consumption there, unless the requirements specified in paragraphs 1 to 5 of the Schedule are complied with.

(2) The occupier of any establishment where collagen of the kind referred to in paragraph (1) is produced shall keep records for two years —

- (a) on the sources of all incoming raw material, from the date of their receipt at the establishment; and
- (b) on all outgoing products, from the date of their dispatch.

(3) Until the end of 2005 no person shall wrap, package, store or transport any collagen derived from any bovine animal slaughtered in the United Kingdom, being collagen intended for human consumption there, unless the requirements specified in paragraph 6 of the Schedule are complied with.

#### **Offences and penalties**

7.—(1) Any person who contravenes any provision of regulation 6 shall be guilty of an offence.

(2) Any person guilty of an offence under this regulation shall be liable —

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or to both; or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(3) No prosecution for an offence under regulation 6 shall be begun after the expiry of —

- (a) three years from the commission of the offence; or

(b) one year from its discovery by the prosecutor,  
whichever is the earlier.

**Application of various provisions of the Food Safety Act 1990 for the purposes of regulations 6 and 7**

8. The following provisions of the Act shall apply for the purposes of regulations 6 and 7, with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to regulation 7 —

- (a) section 20 (offences due to fault of another person);
- (b) section 21 (defence of due diligence)(3) as it applies for the purposes of section 14 or 15;
- (c) section 30(8) (which relates to documentary evidence);
- (d) section 33(1) (obstruction etc. of officers);
- (e) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection 1(b) above” shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (d);
- (f) section 35(1)(4) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (d);
- (g) section 35(2) and (3)(5), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (e);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A(6) (offences by Scottish Partnerships); and
- (j) section 44 (protection of officers acting in good faith).

**Enforcement**

9.—(1) Regulation 6 shall be executed and enforced by the food authority within its area.

(2) On an inspection of any collagen intended for human consumption, an authorised officer of the food authority within whose area the premises where it was inspected is situated may certify that the collagen concerned has not been produced, wrapped, packaged, stored or transported in accordance with regulation 6.

(3) Where any collagen intended for human consumption is certified as mentioned in paragraph (2), it shall be treated for the purposes of section 9(7) of the Act as failing to comply with food safety requirements.

*Whitty*  
Parliamentary Under Secretary of State  
Department for Environment, Food and Rural  
Affairs

27th February 2005

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(3) Section 21 has been amended by S.I. [2004/3279](#).  
(4) Section 35(1) is amended by the Criminal Justice Act 2003 ([2003 c. 44](#)), Schedule 26, paragraph 42, from a date to be appointed.  
(5) Section 35(3) has been amended by S.I. [2004/3279](#).  
(6) Section 36A was inserted by the Food Standards Act 1999 ([1999 c. 28](#)), Schedule 5, paragraph 16.  
(7) Section 9 has been amended by S.I. [2004/3279](#).