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STATUTORY INSTRUMENTS

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**2003 No. 3003**

**FOOD, ENGLAND**

The Collagen and Gelatine (Intra-Community  
Trade) (England) (No. 2) Regulations 2003

<i>Made</i>	- - - -	<i>20th November 2003</i>
<i>Laid before Parliament</i>		<i>28th November 2003</i>
<i>Coming into force</i>		
<i>Regulations 1 to 4</i>		<i>23rd December 2003</i>
<i>Regulations 5-12</i>		<i>31st December 2003</i>

The Secretary of State, being a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to the common agricultural policy of the European Community, in exercise of the powers conferred on him by that section and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(3)</sup>, makes the following Regulations:

**Title, application and commencement**

1.—(1) These Regulations may be cited as the Collagen and Gelatine (Intra-Community Trade) (England) (No. 2) Regulations 2003 and apply in relation to England only.

(2) Regulations 1 to 4 shall come into force on 23rd December 2003 and regulations 5 to 12 shall come into force on 31st December 2003.

**Interpretation**

2. In these Regulations —

“the Agency” means the Food Standards Agency;

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(1) S.I. 1972/1811, amended by S.I. 2002/794.

(2) 1972 c. 68.

(3) OJ No. L31, 1.2.2001, p.1.

each of the expressions “collagen intended for human consumption”, “collection centre”, “establishment producing collagen”, “raw material” and “tannery” has the same meaning as in Commission Decision [2003/721/EC](#);

“Commission Decision [2003/721/EC](#)” means Commission Decision [2003/721/EC](#) amending Council Directive [92/118/EEC](#) as regards requirements for collagen intended for human consumption and repealing Decision [2003/42/EC](#)(4); and

“food authority” has the same meaning as in the Food Safety Act 1990(5).

### **Revocation of the Collagen and Gelatine (Intra-Community Trade) (England) Regulations 2003**

3. The Collagen and Gelatine (Intra-Community Trade) (England) Regulations 2003(6) are revoked.

### **Amendments to the Products of Animal Origin (Import and Export) Regulations 1996**

4.—(1) In so far as they apply in relation to England, the Products of Animal Origin (Import and Export) Regulations 1996(7) are amended in accordance with paragraphs (2) and (3).

(2) In paragraph 9 of Schedule 3 (Community measures relevant to intra-Community trade) the phrase “and Commission Decision [2003/42/EC](#) (OJ No. L13, 18.1.2003, p.24) as amended by Commission Decision [2003/503/EC](#) (OJ No. L170, 9.7.2003, p.30)” is deleted.

(3) In paragraph 12 of Schedule 3 the phrase “Commission Decision [2003/42/EC](#) (OJ No. L13, 18.1.2003, p.24) as amended by Commission Decision [2003/503/EC](#) (OJ No. L170, 9.7.2003, p.30);” is deleted.

5.—(1) In so far as they apply in relation to England the Products of Animal Origin (Import and Export) Regulations 1996 are amended in accordance with paragraphs (2) and (3).

(2) In paragraph 9 of Schedule 3 the phrase “and Commission Decision [2003/721/EC](#) (OJ No. L260, 11.10.2003, p.21)” is inserted immediately before the phrase “and as amended by”.

(3) In paragraph 12 of Schedule 3 the phrase “Commission Decision [2003/721/EC](#) (OJ No. L260, 11.10.2003, p.21);” is inserted at the end.

### **Authorisation of collection centres and tanneries**

6.—(1) A food authority shall, on application being made under this regulation, authorise a collection centre or tannery for the purpose of supplying raw materials for the production of collagen intended for human consumption if the food authority is satisfied that —

- (a) the collection centre or tannery has storage rooms with hard floors and smooth walls which are easy to clean and disinfect;
- (b) where appropriate, the collection centre or tannery is provided with refrigeration facilities;
- (c) the storage rooms of the collection centre or tannery are kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination of raw materials;
- (d) where any raw material which does not comply with a requirement imposed by virtue of the Products of Animal Origin (Import and Export) Regulations 1996 is or will be stored or processed in the premises of the collection centre or tannery, it is or, as appropriate, will

(4) OJ No. L260, 11.10.2003, p.21.

(5) [1990 c. 16](#).

(6) S.I. [2003/1736](#).

(7) S.I. [1996/3124](#); the relevant amending instruments are S.I. [1997/3023](#), S.I. [2000/256](#), S.I. [2001/1553](#) and S.I. [2003/1736](#).

be, segregated throughout the period of receipt, storage, processing and dispatch from raw material which does so comply; and

- (e) the food authority has all the information it requires to notify the Agency of an authorisation in accordance with regulation 11(2)(a).

(2) When granting an authorisation under this regulation, the food authority shall allocate a unique identification number to the collection centre or tannery concerned.

(3) The proprietor of the business carried on at any establishment authorised under this regulation shall give notice immediately to the food authority of —

- (a) any change, or intended change, of the proprietorship of such business; or
- (b) any material change, or intended material change, in the operation of such business.

### **Authorisation of establishments producing collagen intended for human consumption**

7.—(1) A food authority shall, on application being made under this regulation, authorise an establishment for the production of collagen intended for human consumption if the food authority is satisfied that —

- (a) the proprietor of the establishment carries out checks to ensure that —
  - (i) critical points in the establishment relative to the production process used are identified and are acceptable to the food authority,
  - (ii) methods for monitoring and controlling such points are established and are acceptable to the food authority,
  - (iii) samples are taken for the purposes of checking cleaning and disinfection methods and compliance with the standards prescribed in accordance with Commission Decision [2003/721/EC](#),
  - (iv) such samples are analysed as appropriate in a laboratory acceptable to the food authority,
  - (v) the food authority is notified immediately when a laboratory examination of samples or any other information at the proprietor's disposal reveals a serious health risk, and
  - (vi) in the event of an imminent health risk, the quantity of products, obtained in technologically similar conditions and likely to present the same risk, is withdrawn from the market;
- (b) the proprietor of the establishment has a system in place for ensuring that a record is made in permanent form in respect of the matters specified in divisions (i) to (iii) of paragraph (a) and the results of the analysis referred to in division (iv) of that paragraph, and that it is kept for a period of at least two years and is made available to the food authority upon request;
- (c) the proprietor of the establishment has arranged or established a staff training programme to enable staff engaged in the production of collagen intended for human consumption, and who do not already have qualifications which are adequate and relevant for that purpose, to comply with the conditions of hygienic production appropriate to their duties; and
- (d) the food authority has all the information it requires to notify the Agency of an authorisation in accordance with regulation 11(2)(a).

(2) When granting an authorisation under this regulation, the food authority shall allocate a unique identification number to the establishment concerned.

(3) The proprietor of the business carried on at any establishment authorised under this regulation shall give notice immediately to the food authority of —

- (a) any change, or intended change, of the proprietorship of such business; or
- (b) any material change, or intended material change, in the operation of such business.

### **Suspension and withdrawal of authorisations**

**8.**—(1) A food authority may suspend or withdraw an authorisation granted under regulation 6 or 7 if it is satisfied that the collection centre, tannery or establishment concerned (“the premises”) does not satisfy the requirements specified in regulation 6(1) or 7(1) as appropriate, or that the proprietor of the premises has failed to comply with regulation 6(3) or 7(3), as appropriate.

(2) A food authority shall not suspend or withdraw an authorisation under this regulation unless —

- (a) it has served a notice on the proprietor of the business carried on at the premises; and
- (b) it is satisfied, after the time for compliance with the notice has expired, that the premises do not comply with the requirements specified in the notice.

(3) A notice served under paragraph (2)(a) shall —

- (a) state that the food authority proposes to suspend or, as the case may be, withdraw the authorisation;
- (b) identify each requirement specified in regulation 6(1) or (3) or, as appropriate, regulation 7(1) or (3) which the food authority is satisfied has not been complied with in relation to the premises;
- (c) in relation to each requirement identified under sub-paragraph (b), give reasons why the food authority is satisfied that that requirement has not been complied with; and
- (d) state that, unless the proprietor of the business complies with the requirements specified in the notice within such reasonable time as is stated in it, the authorisation may be suspended or withdrawn.

### **Right of appeal**

**9.**—(1) A person who is aggrieved by a decision of a food authority under these Regulations to refuse, suspend or withdraw an authorisation may appeal to a magistrates' court.

(2) Section 37(3), (5) and (6) of the Food Safety Act 1990 shall have effect in relation to appeals under this regulation as they have effect in relation to appeals under that section.

(3) The withdrawal or suspension of any authorisation granted under regulation 6 or 7 shall not take effect until the time for appealing against it has expired and, if an appeal is lodged, until the appeal is finally disposed of.

### **Cancellation of authorisation**

**10.** A food authority shall cancel an authorisation granted under regulation 6 or 7 —

- (a) at the request of the proprietor of the business in relation to which the premises are authorised; or
- (b) if the food authority is satisfied that the business carried on at the premises is no longer being carried on there.

### **Registration**

**11.**—(1) The Agency shall maintain a register of premises authorised under regulation 6 or 7.

(2) Every food authority shall notify the Agency, by such means as may be reasonably required by the Agency, of —

- (a) every authorisation granted by the food authority under regulation 6 or 7;
- (b) every withdrawal, suspension or cancellation of such an authorisation;

- (c) every notice served under regulation 8(2)(a);
  - (d) any change of the proprietor of the business carried on at premises authorised under regulation 6 or 7; and
  - (e) any error or omission in the information in the register which comes to the attention of the food authority.
- (3) Every notification under paragraph (2) shall contain the following information —
- (a) the address of the premises;
  - (b) the name of the proprietor of the business carried on at the premises;
  - (c) any trade name or other name (not being the name of the proprietor) by which the business carried on at the premises is known;
  - (d) the number allocated under regulation 6(2) or 7(2);
  - (e) whether the premises are authorised as a collection centre, a tannery or an establishment producing collagen; and
  - (f) the date from which any authorisation granted under regulation 6 or 7 has effect and the date from which any suspension, withdrawal or cancellation of such authorisation took effect.
- (4) The Agency shall take reasonable measures to make the information on the register available to the public at reasonable times.

### **Enforcement**

**12.** These Regulations shall be enforced by the food authority in its area and regulation 6(2) to (6) of the Products of Animal Origin (Import and Export) Regulations 1996 shall apply in relation to a food authority enforcing these Regulations as it applies in relation to a local authority enforcing those Regulations.

Signed by authority of the Secretary of State for Health

20th November 2003

*Melanie Johnson*  
Parliamentary Under Secretary of State,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations, which apply in relation to England only, implement in relation to England Commission Decision [2003/721/EC](#) amending Council Directive [92/118/EEC](#) as regards requirements for collagen intended for human consumption and repealing Decision [2003/42/EC](#) (OJ No. L260, 11.10.2003, p.21) – “the new Decision” – so far as it relates to trade between Member States of the European Community.

2. Commission Decision [2003/42/EC](#) as amended (revoked by the new Decision) was implemented in relation to England, in so far as it related to trade between Member States of the European Community, by the Collagen and Gelatine (Intra-Community Trade) (England) Regulations 2003 (S.I.[2003/1736](#)). With effect from 23rd December 2003 these Regulations revoke those Regulations and the amendments made by them to the Products of Animal Origin (Import and Export) Regulations 1996 (S.I. [1996/3124](#) as already amended, “the 1996 Regulations”) (*regulations 3 and 4*).

3. The provisions of Council Directive [92/118/EEC](#) (OJ No. L62, 15.3.93, p.49) which relate to intra-Community trade are implemented in relation to Great Britain as a whole by the 1996 Regulations.

4. With effect from 31st December 2003 the new Decision amends Annex II to Council Directive [92/118/EEC](#) by —

- (a) amending, in the same manner as the revoked Decision previously did, the commercial document for raw material destined for the production of gelatine for human consumption which is contained in Chapter IV of that Annex; and
- (b) inserting into that Annex requirements relating to collagen intended for human consumption which are the same as those previously inserted into it by the revoked Decision, save as regards one minor particular in the commercial document model for raw material destined for the production of collagen.

5. With effect from 31st December 2003 these Regulations amend the 1996 Regulations to give effect to the amendment described in paragraph 4(a), and to the requirements referred to in paragraph 4(b) which relate to —

- (a) production establishments;
- (b) the raw materials which may be used in production and the conditions attaching to their use;
- (c) transport and storage of such raw materials;
- (d) the process of production;
- (e) appropriate measures to be taken to ensure that production batches meet specified criteria; and
- (f) packaging, storage and transport (*regulation 5(3)*).

6. In implementation of the remainder of the requirements referred to in paragraph 4(b), with effect from 31st December 2003 these Regulations also —

- (a) by means of an amendment to paragraph 9 of Schedule 3 to the 1996 Regulations —

- (i) disapply in respect of establishments producing collagen intended for human consumption the registration requirements in regulation 11 of the 1996 Regulations which would otherwise apply in relation to them, and
  - (ii) continue to disapply in respect of such establishments the notification requirements in regulation 12 of those Regulations (*regulation 5(2)*); and
- (b) give power to food authorities in England, and subject to a right of appeal, to grant, suspend, withdraw or cancel authorisations of —
- (i) collection centres and tanneries which supply raw materials for the production of collagen intended for human consumption, and
  - (ii) establishments which produce collagen intended for human consumption (*regulations 6–10*).

**7.** The Food Standards Agency is required to maintain a register of premises authorised by food authorities under regulations 6 and 7 and food authorities are required to give the Agency certain information about authorisations granted by them (*regulation 11*).

**8.** These Regulations provide for their enforcement by the relevant food authority and, for the purposes of such enforcement, apply regulation 6(2) to (6) of the 1996 Regulations (*regulation 12*).

**9.** A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed on the library of each House of Parliament. Copies may be obtained from the Microbiological Safety Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.