

2004 No. 7

FOOD

**Collagen and Gelatine (Intra-Community Trade)
Regulations (Northern Ireland) 2004**

Made - - - - - *12th January 2004*

Coming into operation *23rd February 2004*

The Department of Health, Social Services and Public Safety, being a Department designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to the common agricultural policy of the European Community, in exercise of the powers conferred on it by that section and of all other powers enabling it in that behalf, 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(c), hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Collagen and Gelatine (Intra-Community Trade) Regulations (Northern Ireland) 2004 and shall come into operation on 23rd February 2004.

Interpretation

2.—(1) In these Regulations –

“the Agency” means the Food Standards Agency(d);

“collagen intended for human consumption”, “collection centre”, “establishment producing collagen”, “raw material” and “tannery” have the same meaning as in Commission Decision 2003/721/EC; and

“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(e).

(2) The Interpretation Act (Northern Ireland) 1954(f) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

(a) S.I. 2000/2812

(b) 1972 c. 68

(c) O.J. No. L31, 1.2.2001, p. 1

(d) Established by s. 1 of the Food Standards Act 1999 (c. 28)

(e) O.J. No. L260, 11.10.2003, p. 21

(f) 1954 c. 33 (N.I.)

Amendments to the Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

3.—(1) The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998^(a) are amended in accordance with paragraphs (2) and (3).

(2) In paragraph 9 of Schedule 3 (Directives to be complied with for intra-Community trade), immediately before “and as amended by” there shall be inserted “and Commission Decision 2003/721/EC (O.J. No. L260, 11.10.2003, p. 21)”.

(3) In paragraph 12 of Schedule 3 there shall be inserted at the end “Commission Decision 2003/721/EC (O.J. No. L260, 11.10.2003, p. 21);”.

Authorisation of collection centres and tanneries

4.—(1) A district council 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 it 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 (Northern Ireland) 1998 is or will be stored or processed in the premises of the collection centre or tannery, it is or, as appropriate, will be, segregated throughout the period of receipt, storage, processing and dispatch from raw material which does so comply; and
- (e) the district council has all the information it requires to notify the Agency of an authorisation in accordance with regulation 9(2)(a).

(2) When granting any authorisation under this regulation, the district council 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 district council 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

5.—(1) A district council shall, on application being made under this regulation, authorise an establishment for the production of collagen intended for human consumption if the district council 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 district council,
 - (ii) methods for monitoring and controlling such points are established and are acceptable to the district council,
 - (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 district council,

(a) S.R. 1998 No. 45; the relevant amending Regulations are S.R. 2001 No. 226

- (v) the district council 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 heads (i) to (iii) of paragraph (a) and the results of the analysis referred to in head (iv) of that paragraph, and that it is kept for a period of at least two years and is made available to the district council 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 district council has all the information it requires to notify the Agency of an authorisation in accordance with regulation 9(2)(a).
- (2) When granting an authorisation under this regulation, the district council 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 district council 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

6.—(1) A district council may suspend or withdraw an authorisation granted under regulation 4 or 5 if it is satisfied that the collection centre, tannery or establishment concerned (“the premises”) does not satisfy the requirements specified in regulation 4(1) or 5(1) as appropriate, or that the proprietor of the premises has failed to comply with regulation 4(3) or 5(3), as appropriate.

(2) A district council 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 district council proposes to suspend or, as the case may be, withdraw the authorisation;
- (b) identify each requirement specified in regulation 4(1) or (3) or, as appropriate, regulation 5(1) or (3) which the district council 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 district council 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

7.—(1) A person who is aggrieved by a decision of a district council under these Regulations to refuse, suspend or withdraw an authorisation may appeal to a court of summary jurisdiction.

(2) Article 37(2), (2A) and (3) of the Food Safety (Northern Ireland) Order 1991(a) shall have effect in relation to appeals under this regulation as it has effect in relation to appeals under that Article.

(3) The withdrawal or suspension of any authorisation granted under regulation 4 or 5 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

- 8.** A district council shall cancel an authorisation under regulation 4 or 5 –
- (a) at the request of the proprietor of the business in relation to which the premises are authorised; or
 - (b) if the district council is satisfied that the business carried on at the premises is no longer being carried on there.

Registration

9.—(1) The Agency shall maintain a register of premises authorised under regulation 4 or 5.

(2) Every district council shall notify the Agency, by such means as may be reasonably required by the Agency, of –

- (a) every authorisation issued by the district council under regulation 4 or 5;
- (b) every withdrawal, suspension or cancellation of such an authorisation;
- (c) every notice issued under regulation 6(2)(a);
- (d) any change of the proprietor of the business carried on at premises authorised under regulation 4 or 5; and
- (e) any error or omission in the information in the register which comes to the attention of the district council.

(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 4(2) or 5(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 4 or 5 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

10. These Regulations shall be enforced by each district council within its district, and regulation 5 of the Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998 shall apply in relation to a district council enforcing these Regulations.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 12th January 2004.

(L.S.)

Deirdre Kenny

A Senior Officer of the Department of Health, Social Services and Public Safety

(a) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12) and paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c. 28

EXPLANATORY NOTE

(This note is not part of the Regulations.)

1. These Regulations implement Commission Decision 2003/721/EC amending Council Directive 92/118/EEC as regards requirements for collagen intended for human consumption (O.J. No. L260, 11.10.2003, p. 21) – “the Commission Decision” – so far as it relates to trade between member States of the European Community.

2. The provisions of Council Directive 92/118/EEC (O.J. No. L62, 15.3.93, p. 49) which relate to intra-Community trade are implemented by the Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998, as already amended (“the 1998 Regulations”).

3. The Commission Decision amends Annex II to Council Directive 92/118/EEC by –
- (a) amending 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 new requirements relating to collagen intended for human consumption.

4. These Regulations amend the 1998 Regulations to give effect to the amendment described in paragraph 3(a), and to the requirements referred to in paragraph 3(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 3(3)).

5. In implementation of the remainder of the requirements referred to in paragraph 3(b), these Regulations also –

- (a) by means of an amendment to paragraph 9 of Schedule 3 to the 1998 Regulations –
 - (i) disapply in respect of establishments producing collagen intended for human consumption the registration requirements in regulation 10 of the 1998 Regulations which would otherwise apply in relation to them, and
 - (ii) continue to disapply in respect of such establishments the notification requirements in regulation 11 of those Regulations (regulation 3(2)); and
- (b) give power to district councils, 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 4 to 8).

6. The Food Standards Agency is required to maintain a register of premises authorised by district councils under regulations 4 and 5, and district councils are required to give the Agency certain information about authorisations granted by them (regulation 9).

7. These Regulations provide for their enforcement by district councils, and, for the purposes of such enforcement, apply regulation 5 of the 1998 Regulations (regulation 10).

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