
SCOTTISH STATUTORY INSTRUMENTS

2003 No. 568

FOOD

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

Made - - - - 26th November 2003
*Laid before the Scottish
Parliament* - - - - 27th November 2003
Coming into force - - 31st December 2003

The Scottish Ministers, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972⁽¹⁾ and of all other powers enabling them in that behalf, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Collagen and Gelatine (Intra Community Trade) (Scotland) (No. 2) Regulations 2003 and shall come into force on 31st December 2003.

(2) These Regulations extend to Scotland only.

Interpretation

2. In these Regulations—

“the Agency” means the Food Standards Agency;

“authorisation” means—

- (a) in relation to collection centres and tanneries, an authorisation under regulation 4; and
- (b) in relation to establishments producing collagen intended for human consumption, an authorisation under regulation 5;

“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](#);

(1) 1972 c. 68; section 2(2) was amended by the Scotland Act 1998 (c. 46), Schedule 8, paragraph 15(3). The function conferred upon Ministers of the Crown by section 2(2), in so far as within devolved competence, was transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

“Commission Decision [2003/721/EC](#)” means Commission Decision [2003/721/EC](#)(2) amending Council Directive [92/118/EEC](#) as regards requirements for collagen intended for human consumption and repealing Decision [2003/42/EC](#)(3); and
“food authority” has the same meaning as in the Food Safety Act 1990(4).

Amendment to the Products of Animal Origin (Import and Export) Regulations 1996

3. In Schedule 3 (Community measures relevant to intra Community trade) to the Products of Animal Origin (Import and Export) Regulations 1996(5) there shall be inserted—

- (a) in paragraph 9, after “ Council Directive [92/120/EEC](#) (OJ No. L162, 15.3.93, p.86)”–
“ and Commission Decision [2003/721/EC](#) (O.J. No. L260, 11.10.03, p.21)”;
- (b) in paragraph 12, at the end–
“;
Commission Decision [2003/721/EC](#) (O.J. No. L260, 11.10.03, p.21)”.

Authorisation of collection centres and tanneries

4.—(1) A food authority shall, on application 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 for the 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 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 the authorisation in accordance with regulation 9(2)(a).

(2) When granting an authorisation under this regulation, the food authority shall allocate a distinctive 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 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

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

(2) O.J. No. L 260, 11.10.03, p.21.

(3) O.J. No. L 13, 18.01.03, p.24, as amended by Commission Decision [2003/503/EC](#), O.J. No. L 170, 9.7.03, p.30.

(4) [1990 c. 16](#).

(5) S.I. [1996/3124](#); the relevant amending instrument is [S.S.I. 2001/169](#).

- (a) the establishment complies with the requirements set out in Chapters I, II, V, VI, VII, VIII, IX and X of Schedule 1 to the Food Safety (General Food Hygiene) Regulations 1995⁽⁶⁾;
 - (b) the proprietor of the establishment carries out that proprietor's own checks to ensure that—
 - (i) critical control 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 critical points are established and are acceptable to the food authority;
 - (iii) samples are taken for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards prescribed in accordance with Commission Decision 2003/721/EC and are analysed as appropriate in a laboratory acceptable to the food authority;
 - (iv) a record in permanent form is kept and made available to a food authority upon request and is kept in respect of the matters specified in paragraphs (i) to (iii) for a period of at least two years from the date on which the record was made;
 - (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, and any quantity of products so withdrawn shall be held under the control and supervision of the food authority until it is destroyed, used for purposes other than human consumption or, after authorisation by the food authority, reprocessed in a manner appropriate to ensure it is fit for human consumption;
 - (c) the proprietor of the establishment has arranged or established a staff training programme enabling workers to comply with the conditions of hygienic production appropriate to the tasks undertaken by such staff, unless such staff are able to show that they have adequate qualifications;
 - (d) records of the sources of all incoming raw materials and of the destination of all outgoing products in relation to the establishment are made and then kept for a period of at least two years from the date on which the record was made;
 - (e) a system is operated which makes it possible to link each production batch dispatched, the incoming raw material consignments, the production conditions and the time of production; and
 - (f) the food authority has all the information it requires to notify the Agency of the authorisation in accordance with regulation 9(2)(a).
- (2) When granting an authorisation under this regulation, the food authority shall allocate a distinctive number to the establishment producing collagen concerned.
- (3) The proprietor of the business carried on at any establishment authorised under this regulation shall give notice 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

6.—(1) A food authority may suspend or withdraw an authorisation if it is satisfied that the establishment in relation to which the authorisation was granted does not satisfy the requirements

⁽⁶⁾ S.I. 1995/1763, amended by S.I. 1995/2148 and 3205, 1996/1699, 1997/2537, 1998/994, 1999/1360 and 1540 and S.S.I. 2000/62 and 93.

specified in regulations 4(1) or 5(1), as appropriate, or that there has been a breach of regulations 4(3) or 5(3), as appropriate.

- (2) A food authority shall not suspend or withdraw an authorisation under this regulation unless—
- (a) it has served a notice complying with paragraph (3) on the proprietor of the business carried on at the establishment; and
 - (b) it is satisfied, after the time for compliance with the notice has expired, that the establishment does 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 4(1) or (3), or, as appropriate, regulation 5(1) or (3), which the food authority is satisfied has not been complied with in relation to the establishment;
 - (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 the notice, the authorisation may be suspended or, as the case may be, withdrawn.

Right of appeal

7.—(1) A person who is aggrieved by a decision of a food authority to refuse an authorisation under regulation 4 or 5 or to suspend or withdraw an authorisation under regulation 6 may appeal to the sheriff.

(2) Section 37(4), (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 an appeal under that section.

(3) The withdrawal or suspension of an authorisation 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 food authority shall cancel an authorisation—
- (a) on the request of the proprietor of the business in relation to which the establishment is authorised; or
 - (b) if the food authority is satisfied that the business carried on at the establishment in respect of which the authorisation was granted is no longer being carried on there.

Registration

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

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

- (a) every authorisation issued by the food authority under regulation 4 or 5;
- (b) every withdrawal, suspension or cancellation of such an authorisation;
- (c) every notice served under regulation 6(2)(a);
- (d) any change of the proprietor of the business carried on at an establishment authorised by the food authority under regulation 4 or 5; and

- (e) any error or omission which comes to the attention of the food authority in the information in the register relating to any establishment authorised by the food authority under regulation 4 or 5.
- (3) Every notification under paragraph (2) shall contain the following information:–
- (a) the address of the establishment;
 - (b) the name of the proprietor of the business carried on at the establishment;
 - (c) any trade name or other name (not being the name of the proprietor) by which the business carried on at the establishment is known;
 - (d) the number allocated under regulation 4(2) or 5(2);
 - (e) whether the premises are authorised as a collection centre, as a tannery or as an establishment producing collagen; and
 - (f) the date from which authorisation has effect and the date any suspension, withdrawal or cancellation of 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 the food authority in its area and regulation 6(2) to (6)(7) 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.

St Andrew's House, Edinburgh
26th November 2003

TOM McCABE
Authorised to sign by the Scottish Ministers

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, implement Commission Decision [2003/721/EC](#) (O.J. No. L260, 11.10.03, p.21) (“the Commission Decision”) amending Council Directive [92/118/EEC](#) (O.J. No. L 62, 15.3.93, p.49) as regards requirements for collagen intended for human consumption and repealing Commission Decision [2003/42/EC](#) (O.J. No. L 13, 18.01.03, p.24) (“the old Decision”) so far as it relates to trade between Member States of the European Community.

The old Decision (as amended by Commission Decision [2003/503/EC](#) (O.J. No. L170, 9.07.03, p. 30)) was implemented in relation to Scotland, in so far as it related to trade between Member States of the European Community by the Collagen and Gelatine (Intra Community Trade) (Scotland) Regulations 2003 ([S.S.I. 2003/299](#)) as amended by the Collagen and Gelatine (Intra Community Trade) (Scotland) Amendment Regulations 2003 ([S.S.I. 2003/328](#)) and the Collagen and Gelatine (Intra Community Trade) (Scotland) Amendment (No. 2) Regulations 2003 ([S.S.I. 2003/405](#)). Those Regulations and the amendments made by them to the Products of Animal Origin (Import and Export) Regulations 1996 ([S.I.1996/3124](#)) (“the 1996 Regulations”) were revoked by the Collagen and Gelatine (Intra Community Trade) (Scotland) Revocation Regulations 2003 ([S.S.I. 2003/466](#)) immediately following the repeal of the old Decision.

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

- (a) imposing new requirements relating to collagen intended for human consumption (which are the same as those previously inserted into it by the old Decision, save as regards one minor particular in the commercial document model for raw material destined for the production of collagen); and
- (b) modifying in minor respects (and in the same manner as the old Decision), the model commercial document for raw material destined for the production of gelatine intended for human consumption contained in Commission Decision [1999/724/EC](#) (O.J. No. L 290, 12.11.99, p.32) amending Annex II to Council 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](#) (O.J. No. L 395, 30.12.89, p.13, corrig. O.J. No. L 151, 15.6.90, p.40) and, as regards pathogens, to Directive [90/425/EEC](#) (O.J. No. L 290, 12.11.99, p.32).

The provisions of Directive [92/118/EEC](#) relating to intra-Community trade are implemented in relation to Great Britain as a whole by the 1996 Regulations. These Regulations amend the 1996 Regulations to give effect to the changes made by the Commission Decision (regulation 3).

The Commission Decision requires collection centres and tanneries which supply raw materials for the manufacture of collagen for human consumption for intra-Community trade and establishments producing collagen for human consumption for intra-Community trade to be authorised for this purpose and the Regulations give power to food authorities to issue, suspend, withdraw and cancel authorisations of collection centres and tanneries which supply raw materials for the manufacture of collagen intended for human consumption, and authorisations of establishments producing collagen intended for human consumption (regulations 4, 5, 6, 7 and 8). The Food Standards Agency is required to maintain a register of establishments so authorised (regulation 9). These Regulations are enforced by the food authority in its area and powers contained in regulation 6(2) to (6) of the 1996 Regulations are applied to such enforcement (regulation 10).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect which these Regulations have on business costs, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.