SCOTTISH STATUTORY INSTRUMENTS

2005 No. 218

AGRICULTURE

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

Made - - - -	*19th April 2005*
Laid before the Scottish Parliament - - - -	*19th April 2005*
Coming into force - -	*11th May 2005*

The Scottish Ministers, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**) (in relation to regulations 3, 4 and 5) and by sections 6(4), 16(1), (2) and (3), 19(1)(a), 26(1), (2)(a) and (3), 48(1) and 49(2) of and paragraphs 3(1), 5(1), (2)(a) and 6(1) of Schedule 1 to the Food Safety Act 1990(**2**), and having had regard in accordance with section 48(4A) of the Food Safety Act 1990 to relevant advice given by the Food Standards Agency, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Scotland) Regulations 2005, and shall come into force on 11th May 2005.

(2) These Regulations extend to Scotland only.

(**1**) 1972 c. 68. Section 2(2) was amended by the Scotland Act 1998 (c. 46), Schedule 8, paragraph 15(3). The functions conferred upon the Minister of the Crown, insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

(**2**) 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c. 28) ("the 1999 Act"), Schedule 5, paragraph 10(3). Sections 16(1) and (2), 19(1), 48(1) and 49(2)were amended by section 40(1) and paragraph 8 of Schedule 5 to the 1999 Act, section 26(3) was amended by section 40(4) and Schedule 6 to the 1999 Act and section 48(4A) was inserted by section 40(1) and paragraph 21 of Schedule 5 to the 1999 Act. Section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C), inserted by S.I. 2004/2990. Amendments made by Schedule 5 to the 1999 Act shall be taken as pre commencement enactments for the purposes of the Scotland Act 1998 (c. 46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998. In so far as not so transferred, those functions under sections 6(4), 16, 19, 26, 48 and 49 and Schedule 1 of the 1990 Act were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

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 to be consumed by humans;

"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(**3**) as amended;

"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 amended; 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(**4**) are amended in accordance with regulations 4 and 5.

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

"(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, produced in accordance with regulation 6 of the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Scotland) Regulations 2005(**5**).".

(2) In regulation 6(9) after "collagen," insert–

"(unless it is collagen intended for human consumption in the United Kingdom, produced in accordance with regulation 6 of the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Scotland) Regulations 2005(**6**))".

(**3**) O.J. No. L 62, 15.3.93, p.49. Chapter 4, Section B of Annex II to that Directive was first inserted by Commission Decision 2003/42/EC (O.J. No. L 13, 18.1.2003, p.24) and was replaced by Commission Decision 2003/721/EC (O.J. No. L 260, 11.10.2003, p.21). The Directive was last amended by Commission Regulation (EC) No. 445/2004 (O.J. No. L 72, 11.3.2004, p.60).

(**4**) S.I. 1999/1103, amended by S.I. 1999/1544, S.S.I. 2000/62, 2000/184 and 2002/449.

(**5**) S.S.I. 2005/218.

(**6**) S.S.I. 2005/218.

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

(a) omit "gelatin or collagen produced" where it first occurs;

(b) insert "gelatin or collagen produced" at the beginning of each of sub paragraphs (a) and (b); and

(c) at the end of sub-paragraph (b) insert–

"; or

(c) collagen produced in accordance with regulation 6 of the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Scotland) Regulations 2005(**7**)

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

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

(3) Until the end of the year 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 in the United Kingdom, unless the requirements specified in paragraph 6 of Part 1 of the Schedule are complied with.

Offences and penalties

7.—(1) Any person who contravenes regulation 6 shall be guilty of an offence and shall be liable–

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three 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.

(2) 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 the date on which evidence sufficient in the opinion of the prosecutor to warrant proceedings comes to the prosecutor's knowledge,

whichever is the earlier.

(3) For the purposes of this regulation, a certificate signed by or on behalf of the prosecutor and stating the date on which evidence sufficient in the prosecutor's opinion to warrant the proceedings came to the knowledge of the prosecutor, shall be conclusive evidence of that fact.

(4) A certificate stating that matter and purporting to be so signed shall be deemed to be so signed unless the contrary is proved.

(**7**) S.S.I. 2005/218.

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)(**8**) as it applies for the purposes of section 14 or 15 with the modification that any reference to "food" shall be construed as a reference to "raw material" and any reference to "sale" shall be construed as a reference to "production";

(c) section 30(8) (which relates to documentary evidence);

(d) section 33 (obstruction etc. of officers);

(e) section 35(1) to (3)(**9**) (punishment of offences), insofar as it relates to offences under section 33(1) or (2) as applied by sub-paragraph (d) above;

(f) section 36 (offences by bodies corporate);

(g) section 36A(**10**) (offences by Scottish partnerships); and

(h) section 44 (protection of officers acting in good faith with the modification that officer of the food authority includes officer of the Scottish Ministers).

Enforcement

9.—(1) Each food authority within its area shall, and the Scottish Ministers may, execute and enforce regulation 6.

(2) On an inspection of any collagen intended for human consumption, an authorised officer of the food authority within whose area the place where it was inspected is situated or of the Scottish Ministers 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 of the Act(**11**) as failing to comply with food safety requirements.

St Andrew's House, Edinburgh
19th April 2005

ROSS FINNIE
A member of the Scottish Executive

(**8**) Section 21 has been amended by S.I. 2004/3279.
(**9**) Section 35(3) has been amended by S.I. 2004/3279.
(**10**) Section 36A was inserted by the Food Standards Act 1999 (1999 c. 28), Schedule 5, paragraph 16.
(**11**) Section 9 has been amended by S.I. 2004/3279.

SCHEDULE Regulation 6

PART 1

General provisions

Raw materials and establishments supplying raw materials

1.—(1) Only the hides and skins of bovine animals may, subject to sub-paragraph (2), be used as raw materials for the production of collagen intended for human consumption in the United Kingdom.

(2) The use as raw materials of hides and skins submitted to tanning processes is prohibited.

(3) Raw materials shall be derived from bovine animals which have been slaughtered in a slaughterhouse and whose meat can be legally sold for human consumption.

(4) Raw materials shall be derived from bovine animals which have been found fit for human consumption following ante and post mortem inspection and that fact shall be certified in the commercial document referred to in paragraph 2(5) below.

(5) Raw materials shall come from slaughterhouses, collection centres or tanneries.

(6) Collection centres and tanneries supplying raw materials shall be authorised under regulation 4 of the Collagen and Gelatine (Intra–Community Trade) (Scotland) (No. 2) Regulations 2003(**12**).

(7) If raw material not in conformity with sub paragraphs (1) to (6) above is stored and/or processed in collection centres or tanneries supplying raw material for the purposes of these Regulations, it must be segregated throughout the period of receipt, storage, processing and dispatch from raw material in conformity with sub-paragraphs (1) to (6) above.

Transport and storage of raw materials

2.—(1) Raw materials destined for the production of collagen shall be transported under clean conditions using appropriate means of transport.

(2) Subject to sub paragraph (3) raw materials shall be transported and stored in a chilled or frozen state, unless they are processed within 24 hours of their dispatch.

(3) Salted, dried and limed hides and skins and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

(4) Storage rooms shall be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

(5) During transportation and at the time of delivery at collection centres and establishments producing collagen, raw materials shall be accompanied by a commercial document in accordance with the model laid down in Part 2 of this Schedule.

Establishments producing collagen

3.—(1) The production of collagen intended for human consumption shall take place in an establishment authorised under regulation 5 of the Collagen and Gelatine (Intra–Community Trade) (Scotland) (No. 2) Regulations 2003.

(**12**) S.S.I. 2003/568.

(2) There shall be implemented at the establishment a system that makes it possible to link each production batch dispatched with the associated incoming raw material consignments, the production conditions and the time of production.

Manufacture of collagen

4.—(1) Collagen shall 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 equivalent process approved by the Commission after consultation with the appropriate Scientific Committee.

(2) Collagen produced in accordance with sub paragraph (1) shall not undergo further processing other than a drying process.

(3) Collagen not intended for human consumption shall not be produced and stored in the same establishment as collagen intended for human consumption unless the collagen not intended for human consumption is produced and stored under the same conditions as set out in this Schedule.

(4) The use of preservatives other than those permitted under European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners(**13**) (as that Directive is amended as at the date these Regulations are made) is prohibited.

Finished products

5.—(1) Appropriate measures, including tests, shall be carried out to ensure that, subject to sub paragraph (2), each production batch of collagen meets the microbiological and residues criteria set in the Table in Part 3 of this Schedule.

(2) Where the nature of a finished product is such that it would be inappropriate to require it to comply with the moisture and ash limits specified in Part 3 of this Schedule, those limits shall not apply to that product.

Wrapping, packaging, storage and transport

6.—(1) Collagen intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions, and in particular–

(a) a room must be provided for storing, wrapping and packaging materials; and

(b) wrapping and packaging must take place in a room or in a place intended solely for that purpose.

(2) Wrappings and packages containing collagen must–

(a) bear an identification mark containing the name “United Kingdom” or initial letters “UK” followed by the registration number of the establishment and the initials “EC”;

(b) carry the words “Collagen fit for human consumption in the United Kingdom”; and

(c) bear the date of preparation and the batch number.

(3) Collagen must be accompanied during transportation by a commercial document which must bear–

(a) the words “Collagen fit for human consumption in the United Kingdom”; and

(b) the date of preparation and the batch number.

(**13**) O.J. No. L 161, 18.3.95, p.1 as last amended by Regulation (EC) No. 1882/2003 (O.J. No. L 284, 31.10.2003 p.1).

PART 2

Commercial document to accompany raw materials derived from bovine animals destined for the production of collagen intended for human consumption in the United Kingdom

Commercial document number: .....

1. Identification of the raw material

Nature (i.e. hides and skins): ....

Net weight (kg): ....

Identification mark (pallet or container): .....

2. Origin of the raw material

– *Slaughterhouse*

Address of the establishment: .....

....

Veterinary approval/registration number: ....

– *Collection centre*

Address of the establishment: .....

.....

Registration number: ....

Tannery

Address of the establishment: .....

.....

Registration number: .....

3. Destination of the raw material

Name of the collection centre/establishment producing collagen(**Note 1**) where the raw material is sent: ....

.....

Address: .....

.....

(Note 1) Delete as appropriate.

4. Declaration

I, the undersigned, declare that I have read and understood the provisions of paragraphs 1 and 2 of the Schedule to the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Scotland) Regulations 2005, and that hides/skins(**Note 1**) from bovine animals as described above are derived from animals that have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following *ante* and *post mortem* inspection.

Done at..... on .....

(place) (date)

. ...

(Signature of the owner of the plant or his/her representative)(**Note 2**)

.....

(Name in block letters)

(Note 1) Delete as appropriate.

(Note 2) The signature must be a colour different from that of printing.

PART 3

Microbiological and residues criteria for collagen intended for human consumption

Microbiological criteria

Microbiological parameters	*Limit*
Total aerobic bacteria	10^3/g
Coliforms (30°C)	0/g
Coliforms (44.5°C)	0/10g
Anaerobic sulphite–reducing bacteria (no gas production)	10/g
Clostridium perfringens	0/g
Staphylococcus aureus	0/g
Salmonella	0/25g

Residues

Elements	*Limit*
As	1 ppm
Pb	5 ppm
Cd	0.5 ppm

Elements	*Limit*
Hg	0.15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
Moisture (105°C)	15%
Ash (550°C)	2%
SO_2 (Reith Williems)	50 ppm
H_2O_2 (European Pharmacopia 1986 (V_2O_2))	10 ppm

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply in relation to Scotland only, amend the Bovines and Bovine Products (Trade) Regulations 1999 (S.I.1999/1103, as amended by S.I. 1999/1554, S.S.I. 2000/62, 2000/184 and 2002/449 – "the BBPTR"). The BBPTR give effect to Commission Decisions 98/692/EC (O.J. No. L 328, 4.12.98, p.28) and 98/564/EC (O.J. No. L 273, 9.10.98, p.37) which amended Council Decision 98/256/EC (O.J. No. L 113, 15.4.98, p.32). The Regulations amend the BBPTR to–

- lift the prohibition on the production of collagen derived from the hides and skins of bovine animals slaughtered in the United Kingdom and intended for human consumption in the United Kingdom (regulations 3 and 4). The prohibition on export of such collagen from Great Britain remains in force (regulation 4 of the BBPTR); and
- make consequential amendments to regulations 6(9) and 9(3) to enable use of such collagen in products for human consumption in the United Kingdom (regulations 4 and 5).

The Regulations also impose requirements on the production of collagen derived from the hide and/or skin of a bovine animal slaughtered in the United Kingdom and intended for human consumption in the United Kingdom until 1st January 2006 (regulation 6). The Regulations apply to such domestic production requirements that reflect those which, under Council Directive 92/118/EEC(**14**) apply to production of collagen for human consumption for intra–Community trade. The Regulations–

- apply requirements relating to raw materials and establishments supplying them, transport and storage of raw materials, establishments producing collagen, manufacture of collagen, finished products, and wrapping, packaging, storage and transport of collagen intended for human consumption in the United Kingdom (Schedule, Part 1);
- require establishments producing collagen and collection centres and tanneries supplying the raw materials for such production to be authorised in accordance with regulations 4 and 5 of the Collagen and Gelatine (Intra–Community Trade) (Scotland) (No. 2) Regulations 2003

(**14**) (O.J. No. L 62, 15.3.93, p. 49, 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 last amended by Commission Regulation (EC) No. 445/2004 (O.J. No. L72, 11.3.2004, p. 60).

(S.S.I. 2003/568) which implement the requirements of Commission Decision 2003/721/EC amending Council Directive 92/118/EEC (Schedule, Part 1); and

- provide that contravention of the requirements of regulation 6 is an offence, specify penalties for that offence, apply certain provisions of the Food Safety Act 1990 (1990 c. 16, amended by S.I. 2004/2990) for the purposes of regulations 6 and 7 and provide for the enforcement of regulation 6 by the relevant food authority (and/or the Scottish Ministers) (regulations 7, 8 and 9).

No Regulatory Impact Assessment has been prepared in respect of these Regulations.