Welsh Statutory Instrument 2005 No. 1397 (W.111)

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

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STATUTORY INSTRUMENTS

2005 No. 1397 (W.111)

AGRICULTURE, WALES

FOOD, WALES

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

Made	*24 May 2005*
Coming into force	*1 June 2005*

The National Assembly for Wales, being designated[1] for the purposes of section 2(2) of the European Communities Act 1972[2] in relation to the common agricultural policy of the European Community, in exercise of the powers conferred upon it by that section (in relation to regulations 3, 4 and 5) and by sections 16(1), (2) and (3), 19(1), 26(1)(a), (b), (2) and (3) and 48(1) of and paragraphs 3(1), 5(1) and (2)(a) and 6(1) of Schedule 1 to the Food Safety Act 1990[3], and now vested in it[4], having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency 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[5], hereby makes the following Regulations:

Title, commencement and application

1. The title of these Regulations is the Production of Bovine Collagen Intended for Human Consumption in the United Kingdom (Wales) Regulations 2005, they apply in relation to Wales and come into force on 1 June 2005.

Interpretation

2. In regulations 6 to 9 and the Schedule -

"the Act" ("*y Ddeddf*") means the Food Safety Act 1990;

"bovine animal" ("*anifail buchol*") includes buffalo of the species Bubalus bubalis and Bison bison;

"collagen" ("*colagen*") means a protein-based product derived from the hide or skin of a bovine animal;

"collagen intended for human consumption" ("*colagen y bwriedir i bobl ei fwyta*") 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) [6];

"hides and skins" ("*crwyn*") means cutaneous and sub-cutaneous tissues;

"slaughterhouse" ("*lladd-dy*") 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" ("*barcio*") 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[7] are amended in accordance with regulations 4 and 5.

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 will -

(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 (Wales) 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 will 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 will 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 will 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 will be guilty of an offence.

(2) Any person guilty of an offence under this regulation will 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 will 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 will apply for the purposes of regulations 6 and 7, with the modification that any reference in those provisions to the Act or Part thereof will 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;

(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" will 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)[9] (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)[10], 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[11] (offences by Scottish Partnerships); and

(j) section 44 (protection of officers acting in good faith).

Enforcement

9. - (1) Regulation 6 will 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 will be treated for the purposes of section 9[12] of the Act as failing to comply with food safety requirements.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998[13].

D. Elis-Thomas
The Presiding Officer of the National Assembly

24 May 2005

THE 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 are to be derived from bovine animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection.

(4) Raw materials are to come from slaughterhouses, collection centres or tanneries.

(5) Collection centres and tanneries supplying raw materials must be

authorised under regulation 6 of the Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003[14].

Transport and storage of raw materials

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

(2) Subject to sub-paragraph (3) raw materials are to be transported and stored in a chilled or frozen state, unless they are processed within 24 hours of 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 are to 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 are to 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 must take place in an establishment authorised under regulation 5 of the Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003.

(2) There is to 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 is to 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.

(2) Collagen produced in accordance with sub-paragraph (1) will undergo no further processing other than a drying process.

(3) Collagen not intended for human consumption must 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[15] (as that Directive is amended as at the date these Regulations are made), is prohibited.

Finished products

5. - (1) Appropriate measures, including tests, will be taken to ensure that, subject to sub-paragraph (2), each production batch of collagen meets the microbiological and residues criteria set out 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 will 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;

(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 giving the following particulars -

(i) the name "United Kingdom" or initial letters "UK",

(ii) followed by the registration number of the establishment and the initials "EC"; and

(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.

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 or 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: . . . . . .

. . . . . .

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 (Wales) 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
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 Wales only, amend the Bovines and Bovine Products (Trade) Regulations 1999 (S.I. 1999/1103, as amended by S.I. 1999/1554, S.I. 2000/656, S.I. 2002/1174, S.I. 2002/2325 - "the BBPTR") in so far as they apply in relation to Wales. The BBPTR give effect to Commission Decisions 98/692/EC (OJ No. L238, 4.12.98, p.28) and 98/564/EC (OJ No. L273, 9.10.98, p.37) which amended Council Decision 98/256/EC (OJ No. L113, 15.4.98, p.32). The Regulations amend the BBPTR to -

- lift the prohibition on the production of collagen derived from 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 regulation 9 of the BBPTR to enable use of such collagen in products for human consumption in the United Kingdom (regulation 5).

The Regulations also impose requirements on the production of collagen derived from a bovine animal slaughtered in the United Kingdom and intended for human consumption in the United Kingdom until the end of 2005 (regulation 6) ("domestic production"). The Regulations apply to domestic production requirements that reflect those which, under Council Directive 92/118/EEC[16], 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 (The 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 respectively of the Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003 (S.I. 2003/3229) which implement the requirements of Commission Decision 2003/721/EC amending Council Directive 92/118/EEC (The 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, as amended by S.I. 2004/2990) for the purposes of regulation 6 and 7, and provide for the enforcement of regulation 6 by the relevant food authority (regulations 7, 8 and 9).

A regulatory appraisal has been prepared for this instrument. Copies may be obtained from the Animal Health Division of the Welsh Assembly Government, Cathays Park, Cardiff CF10 3NQ.

Notes:

[1] S.I. 1999/2788.back

[2] 1972 c.68.back

[3] 1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the Food Standards Act 1999 (1999 c.28) and S.I. 2004/2990.back

[4] Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c.28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act. Sections 16(1) and (2), 19(1) and 48(1) were amended by paragraph 8 of Schedule 5 to the 1999 Act, section 26(3) was amended by Schedule 6 to that Act and section 48(4A) was inserted by paragraph 21 of Schedule 5 to that Act. Section 48 was also amended by S.I. 2004/2990.back

[5] OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 1642/2003 (OJ No. L245, 29.9.2003, p.4). By virtue of regulation 5 of the Food Safety Act 1990 (Amendment) Regulations 2004 (S.I. 2004/2990) with effect from 7th December 2004 the consultation requirement contained in section 48(4) of the 1990 Act is disapplied in any case in which consultation is required by Article 9 of Regulation (EC) No. 178/2002.back

[6] OJ No. 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).back

[7] S.I. 1999/1103, as amended by S.I. 1999/1154, S.I. 2000/656, S.I. 2002/1174, S.I. 2002/2325.back

[8] Section 21 has been amended by S.I. 2004/3279.back

[9] Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.back

[10] Section 35(3) has been amended by S.I. 2004/3279.back

[11] Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.back

[12] Section 9 has been amended by S.I. 2004/3279.back

[13] 1998 c.38.back

[14] S.I. 2003/3229back

[15] OJ No. L61, 18.3.95, p.1, as last amended by Directive 2003/114/EC of the European Parliament and of the Council (OJ No. L24, 29.1.2004, p.58).back

[16] OJ No. L62, 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 (OJ No. L72, 11.3.2004, p. 60).back

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Cymraeg (Welsh)

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