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(**1**).

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.

(**1**) S.I.2003/3229

(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(**2**) (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.

(**2**) OJNo. 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).

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

Microbiological parameters	*Limit*
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