

EXPLANATORY MEMORANDUM TO
THE PRODUCTION OF BOVINE COLLAGEN INTENDED FOR HUMAN
CONSUMPTION IN THE UNITED KINGDOM (ENGLAND) REGULATIONS 2005

2005 No.404

1. This explanatory memorandum has been prepared by Defra and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

- 2.1 This instrument lifts the prohibition on the production of collagen derived from the hides or skins of bovines slaughtered in the United Kingdom intended for human consumption in the United Kingdom. The prohibition on the export of such collagen remains in force.
- 2.2 This instrument also specifies food safety conditions for the production of such collagen.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

- 3.1 This instrument lifts the prohibition in the Bovines and Bovine Products (Trade) Regulations 1999 (SI 1999/1103 (as amended) (“BBPT Regulations”) on the production of collagen derived from a bovine animal slaughtered in the United Kingdom and intended for human consumption, by amending (under s.2(2)ECA 1972) that prohibition to carve out an exception for collagen produced from bovines slaughtered in the UK and for human consumption in the UK. The prohibition on exporting such collagen remains. The instrument also imposes free-standing requirements under the Food Safety Act 1990, reflecting those contained in Annex II to Council Directive 92/118/EC, to production of that collagen, until 1st January 2006.
- 3.2 Annex II to Council Directive 92/118/EEC (OJ No. L 62, 15.3.93, p.9) sets out the conditions of production of collagen for human consumption for intra-Community trade. Those requirements are implemented in the UK by the Collagen and Gelatine (Intra-Community Trade) (England) (No.2) Regulations 2003 (SI 2003/3003) (in relation to production from foreign origin collagen).
- 3.3 Because the intention is to mirror the EU regime for domestic production, this instrument adopts the same terminology, as far as possible, in the definitions (regulation 2) and the Schedule.
- 3.4 Furthermore, in so far as the requirements relate to raw materials and establishments supplying them, and establishments producing collagen, this instrument adopts the authorisation procedures provided for in regulations 6 and 7 of the Collagen and Gelatine (Intra-Community Trade) (England) (No 2) Regulations 2003 (SI 2003/3003).

4. Legislative Background

4.1 These Regulations amend the Bovines and Bovine Products (Trade) Regulations 1999 (SI 1999/1103 (as amended) under section 2(2) of the European Communities Act 1972, and impose new requirements on the production of collagen for human consumption in the United Kingdom in accordance with powers vested in the Secretary of State by the Food Safety Act 1990.

5. Extent

5.1 This instrument applies to England.

5.2 Equivalent legislation is being prepared in Wales, Scotland and Northern Ireland.

6. European Convention on Human Rights

6.1 Not applicable

7. Policy background

7.1 The ban on the export of bovines and bovine products from the UK, which was imposed by the EU in March 1996, includes a ban on the export of UK bovine collagen. This element of the beef export ban is implemented in England by the BBPT Regulations. These Regulations ban the production of bovine collagen for certain uses (food, animal feed, cosmetic, medical or pharmaceutical use) from cattle slaughtered in the UK, whether for export or the domestic market.

7.2 International scientific authorities have subsequently concluded that collagen from bovine hides and skins is suitable for human consumption. At its meeting on 29 April 2004 the UK Spongiform Encephalopathy Advisory Committee (SEAC) were “content with the proposed use of UK collagen for food use as the potential risk would be minimal given that the collagen would be sourced from animals fit for human consumption.”

7.3 For consistency, the Food Standards Agency decided to impose food safety requirements mirroring (as far as possible) those contained in Annex II to Council Directive 92/118/EC, which sets out the conditions of production of collagen for human consumption for intra-Community trade, until 1st January 2006. From 1 January 2006, new EU requirements on collagen production will come into effect.

7.4 A consultation letter explaining the intention to make legislation authorizing the production of collagen for human consumption from bovines slaughtered in the UK, subject to the food safety requirements described above, was sent to interested parties who were given 3 months to comment on this proposal. Several replies in support of the proposal were received. No objections were received.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it is a de-regulatory measure.

9. Contact

9.1 Stan Sadowski at the Department for Environment, Food and Rural Affairs
Tel: 0207 904 6313 or e-mail: stan.sadowski@defra.gsi.gov.uk can answer any queries regarding the instrument.