

REGULATORY APPRAISAL

AGRICULTURE, WALES

FOOD, WALES

THE PRODUCTION OF BOVINE COLLAGEN INTENDED FOR HUMAN CONSUMPTION IN THE UNITED KINGDOM (WALES) REGULATIONS 2005

Purpose and intended effect of the measure

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 Wales by the Bovine and Bovine Products (Trade) Regulations 1999 (SI 1999/1103), as amended. 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.
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) was *“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.”*
3. EU law continues to prohibit the export of collagen (the fibrous protein constituent of skin, cartilage, bone and other connective tissue). Although the EU Transmissible Spongiform Encephalopathies (TSE) Regulations 2001 places no restriction on trade in collagen, provided that such trade meets the specific health conditions for production of collagen for human consumption laid down in EC Decision 2003/721/EEC (which amended Council Directive 92/118/EC), EC legal advisers have advised that EC Decision 96/239/EEC (which bans the export of beef from the UK) takes precedence over the TSE Regulation. However, the EU has confirmed that EU law does not prohibit the domestic sale of collagen. Therefore, without the introduction of these Regulations the Assembly could be open to legal challenge from those who consider that they are being commercially disadvantaged.
4. The intended effect of these Regulations is, therefore, to lift the prohibition on the production of collagen derived from a bovine animal slaughtered in the United Kingdom and intended for human consumption. The prohibition on exporting such collagen remains. These Regulations also impose free-standing production conditions, in the Schedule, which, for consistency, mirror (as far as possible) those contained in Annex II to Council Directive 92/118/EC, to production of that collagen, until 1 January 2006. From 1 January 2006, new EU requirements on collagen will come into effect.
5. As mentioned above, Annex II to Council Directive 92/118/EEC sets out the conditions of production of collagen for human consumption for intra-

Community trade. Those requirements are implemented in Wales by the Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003 (SI 2003/3229) (in relation to production from foreign origin collagen) and cover the production establishments themselves; the raw materials which may be used in production and the conditions attaching to their use; transport and storage of such raw materials; the process of production; appropriate measures to be taken to ensure that production batches meet specified criteria; and packaging, storage and transport.

Risk Assessment

6. Since the 1996 beef export ban, international scientific opinion has moved on and it is now accepted by organisations, such as SEAC, the World Health Organisation, Office International des Epizooties (international animal health organisation) and the EC's Standing Scientific Committee, that collagen derived from bovine hides presents a negligible risk provided the hides are from a safe source and appropriate production processes are used.

Options

Do nothing

7. This would lay the Assembly open to legal challenge as described in paragraph 3 above. Although no manufacturers in Wales have currently expressed an interest, manufacturers in the future would be disadvantaged if the Regulations were not made. UK manufacturers are finding difficulty in sourcing enough collagen from abroad to make sausage skins in order to meet both their main Japanese markets and domestic markets.

Make the Legislation

8. This would allow manufacturers to source UK bovine collagen in order to meet domestic demand.

Benefits

9. UK collagen manufacturers are struggling to source collagen following the closure of the Japanese market to material sourced from the USA after the first BSE case in the USA was discovered in December 2003. The commercial urgency of this issue has been made clear by the industry and it is evident that sourcing difficulties are becoming more and more critical. The removal of the current prohibition will greatly ease sourcing difficulties. The Regulations would benefit UK manufacturers by allowing UK sourced collagen to meet domestic demand.

Costs

10. These Regulations represent a de-regulatory measure and should encourage greater commercial demand for UK hides and the collagen produced from them, thereby improving the financial viability of the beef supply chain. No additional costs have been identified for the industry, Assembly, or the voluntary sector arising from these Regulations.

Impact on small businesses

11. Lifting the prohibition should have no effect on small businesses. The matter was raised by the major UK collagen manufacturer, Devro plc, who highlighted that it was having critical sourcing problems.

Competition assessment

12. The major manufacturer is Devro plc, based in Scotland. It is possible (but not likely) that suppliers of collagen for other non-technical uses (animal feed, cosmetics, pharmaceutical and medical products) could complain that their interests have been overlooked. However, there is no immediate prospect of amendment of the Regulations for these purposes. A meeting of the Spongiform Encephalopathy Advisory Committee (SEAC) on 29 April 2004 addressed these issues but agreed the need for additional information on the Regulations governing the end-use of collagen in these products and on the prevalence of BSE in other European countries before they could consider the relative risk of different sources of bovine hide collagen. Informal enquiries have established that no Welsh companies have expressed an interest in using collagen derived from the hides of UK bovines for the UK market for food use.

Consultation

With Stakeholders

13. A 12-week consultation on the proposed changes and draft Statutory Instrument was conducted between 25 August 2004 and 17 November 2004. An extensive list of potentially interested bodies was consulted, in the areas of agriculture, health (Statutory Advisory Committees, Local Health Boards and NHS Trusts), local authorities and a variety of other Committees and Groups. A list of consultees is attached at Annex A.

14. The consultation process elicited 6 responses only, as follows:

- The Food Standards Agency (FSA) commented in detail on the production conditions that should be included in the Statutory Instrument. Welsh Assembly Government and Defra officials agreed with the comments and detailed discussions ensued to ensure that these were incorporated into these Regulations;
- A separate response was received from the Veterinary and Technical Support Unit of the Meat Hygiene Service, which is part of the FSA. The response noted but offered no particular comment on the proposals but asked to be kept updated on the outcomes, in order that it may take the necessary steps to ensure that any changes affecting public health, animal health or animal welfare policy are communicated to its staff in the plants that it supervises;
- Hybu Cig Cymru/Meat Promotion Wales commented that, following SEAC's consideration of the issue at its April 2004 meeting, it agreed that there was no longer any justification for continuing to prohibit the production of collagen from the hides of UK cattle;

- The Farmers' Union of Wales commented that in view of the scientific evidence and current Regulations regarding animals entering the food chain, it fully agreed that there was no longer any justification for continuing to prohibit the production of collagen from the hides of British cattle, which have been passed fit for human consumption; and
- The Welsh Consumer Council and the Board of Community Health Councils in Wales noted the consultation, but made no comments.

With Subject Committee

15. These Regulations were notified to the Environment, Planning and Countryside Committee via the list of forthcoming legislation on 6 October 2004 (EPC(2)-09-04 (p.4) Annex 1, item No. 51) and again on 2 February 2005 (EPC (2)-02-05 (p.3) Part 1), but were not identified for detailed scrutiny.

Significant costs

16. None have been identified

Enforcement, sanctions, monitoring and review

17. There is no requirement for a review. Premises where the production of collagen intended for human consumption takes place will be subject to inspection by authorised officers of a food authority. Manufacturers will be barred from production if they do not comply with the requirements specified in the Regulations.

Summary

18. The Regulatory option has been identified as the most effective way of addressing the issue because not making the Instrument could lead to legal proceedings. It is essentially a de-regulatory measure that will not lead to any additional costs for the industry, Assembly or the voluntary sector.

Annex A - List of Organisations Consulted

AGRICULTURE

ADAS WALES

Agricultural Industries Confederation (AIC)
Agri food Partnership for Wales
British Veterinary Association North
British Veterinary Association South
Campaign for the Protection of Rural Wales
Chair of Welsh Lamb and Beef Suppliers
Coleg Llyfasi
Countryside Alliance
Countryside Council for Wales
Country Landowners' Association Wales
Farmers Union of Wales
Farming & Livestock Concern UK
Guild of Welsh Lamb & Beef Suppliers
Hybu Cig Cymru
Meat Hygiene Service Wales
National Beef Association
National Farmers Union Wales
Quality Welsh Food Certification Ltd
Red Meat Strategy Group
Royal Welsh Agricultural Society
WDA Food Directorate
Welsh Institute for Rural Studies
Welsh Lamb and Beef Promotions
Welsh Livestock Auctioneers Association
Welsh Local Government Association
Welsh Meat Company
Women in Agriculture
Womens' Food and Farming Union
Young Farmers Club Wales

HEALTH

STATUTORY ADVISORY COMMITTEES

Welsh Medical Committee (WMC)
Welsh Dental Committee (WDC)
Welsh Nursing and Midwifery Committee (WNMC)
Welsh Optical Committee (WOC)
Welsh Pharmaceutical Committee (WPhC)
Welsh Scientific Advisory Committee (WSAC)
Welsh Therapies Advisory Committee (WTAC)

LOCAL HEALTH BOARDS

Chief Executives
Directors of Public Health
Directors of Dental Public Health
Directors of Pharmaceutical Public Health
Directors of Primary Care
Consultants in Communicable Diseases
Immunisation Co-ordinators

NHS TRUSTS

Chief Executives
Medical Directors
Nursing Directors
Clinical Directors

Chief Pharmacists
Hospital Planning Leads
Emergency Planning Leads
Consultants in Public Health Medicine
GUM Consultants
Managers GUM Clinics

LOCAL AUTHORITIES

Chief Executives
Directors of Social Services
Directors of Education
Chief Environmental Officers
Emergency Planning Officers
Co-ordinators of Regulatory Standards
LACORS (Welsh Officer)
Welsh Port Health Authorities
Unitary Authorities

COMMITTEES/GROUPS/OTHERS

Business Eye
Federation of Small Businesses in UK
The Welsh Language Board
Welsh Local Government Association
Welsh General Medical Committee
BMA Wales
Welsh Medical Committee
Welsh Nursing and Midwifery Committee
Welsh Pharmaceutical Committee
Welsh Scientific Advisory Committee
Welsh Optometric Committee
Welsh Dental Committee
Welsh Hospital Acquired Sub Group
Royal College of GPs Wales
Royal College of Nursing Wales
Welsh Council of the Royal College of Pathologists
Welsh GP Committee
Welsh Board of Royal College of Midwifery
Welsh Association of Local Health Groups
Chief Officer Welsh Community Health Councils
Society of Directors of Public Protection Wales
Welsh Infection Control Nurses Association
Chemical Incident Management Support Unit
Food Standards Agency Wales
Directors PHLS
Director CDSC
Environment Agency
Deans Medical Post Graduate

CONSUMER

Welsh Consumer Council