

**FOOD STANDARDS AGENCY
(DEPARTMENT OF HEALTH)**

DRAFT REGULATORY IMPACT ASSESSMENT

**THE GELATINE (INTRA-COMMUNITY TRADE)
(ENGLAND) REGULATIONS 2001**

2. PURPOSE AND INTENDED EFFECT OF THE PROPOSAL

(i) Objective

The regulation of trade, in England, of gelatine and raw materials for the manufacture of gelatine for human consumption.

(ii) Issue:

(a) Commission Decision 1999/724/EC (which applies to all Member States) governs intra-Community trade in raw materials and gelatine, and the import of raw materials and gelatine from third countries. For those companies involved in or wishing to trade with other Member States in these items, the Commission Decision introduces specific requirements for the storage of raw materials for the manufacture of gelatine for human consumption. The specific requirements include conditions for establishments producing gelatine; requirements for raw materials including their transport and storage; conditions to be complied with for the manufacture of gelatine including the requirements for packaging, storage and transport and for finished products; and requirements for the import of gelatine from third countries. It also introduces specific requirements for the manufacture of gelatine for the purpose of intra-Community trade.

(b) It is proposed that the Gelatine (Intra-Community Trade) (England) Regulations 2001 should implement that part of Commission Decision

1999/724/EC governing intra-Community trade; the Products of Animal Origin (Third Country Import) (England and Wales) Regulations 2001 will implement the requirements governing the import of raw materials and gelatine from third countries. (MAFF, who are responsible for these Regulations, plan to have them in place in May/June 2001.)

(c) Commission Decision 1999/724/EC does not cover the manufacture of gelatine intended for pharmaceutical use, cosmetics, medical devices or other technical uses.

(iii) **Risk Assessment:**

(a) In England, the production of gelatine for human consumption in the UK will be covered by the Food Safety (General Food Hygiene) Regulations 1995, as amended. The Gelatine (Intra-Community Trade) (England) Regulations 2001 would implement, into English legislation, the requirements for intra-Community trade given in Commission Decision 1999/724/EC. This includes giving powers to food authorities in England to authorise collection centres and tanneries that supply raw materials for the manufacture of gelatine providing, that is, they meet the relevant criteria. The draft Regulations also allow for the suspension and withdrawal of authorisations where the competent authority is satisfied that the premises concerned no longer meets the requirements of the Regulations. A right of appeal, to a magistrates' court, against the non-authorisation, suspension or withdrawal of an authorisation has also been included in the draft Regulations.

(b) Premises manufacturing and trading in gelatine for human consumption will also need to be authorised and registered. The relevant requirements for these premises are specified in Commission Decision 1999/724/EC. Similar provisions exist to allow for the suspension and withdrawal of authorisations where the competent authority is satisfied that the premises concerned no longer meets the requirements of the Regulations.

3. OPTIONS AND ISSUES OF EQUITY AND FAIRNESS

(i) **The Options**

Two options have been identified:

Option A: continue as now and do not implement Commission Decision 1999/724/EC;

Option B: implement Commission Decision 1999/724/EC in full as the Gelatine (Intra-Community Trade) (England) Regulations 2001;

(ii) **Discussion of the Options**

These two options are discussed below:

Option A: *not to implement EC Decision 1999/724/EC* would allow industry to carry on using raw materials, storing and transporting raw materials and manufacturing and blending gelatine, as now. But the export of finished product for food use could not be traded with other Member States as it would not have been manufactured in accordance with Commission Decision 1999/724/EC – the appropriate documentation to accompany such consignments could not be provided.

The UK has an obligation to implement EC legislation. Not to do so will lead to challenge from the Commission and could lead to demands for judicial review from consumers. For the same reasons, partial implementation of this Commission Decision is not considered appropriate. Neither is administrative implementation or introduction of a voluntary code of practice.

Option B: *to implement Commission Decision 1999/724/EC in full as the Gelatine (Intra-Community Trade) (England) Regulations 2001* would meet our obligation to implement EC legislation. Full implementation of and compliance with the requirements of Commission Decision 1999/724 would allow trade in gelatine and raw materials for the manufacture of gelatine for human consumption within the Community.

(iii) **Issues of Equity and Fairness**

(a) It is perceived that the hygiene requirements in Commission Decision 1999/724/EC (and in the proposed Gelatine (Intra-Community Trade) (England) Regulations 2001) should impact equally across all businesses

trading in manufactured or blended gelatine for human consumption. This includes those that trade in and store raw materials (collection centres and tanneries) for the manufacture of this gelatine.

(b) We are unaware of any small businesses in this industry sector. Nevertheless, we do not consider the likely burden on a small business to be any more onerous, in relation to size, than it would be for a larger business.

Comments from industry would be welcome on this please.

4. **BENEFITS**

(i) **Identifying the Benefits**

Option A: there is no perceived benefit to *not implementing this EC Decision as the Gelatine (Intra-Community Trade) (England) Regulations 2001*. There would be no public health benefit to non-implementation of this Decision. Trade in raw materials and finished gelatine that did not comply with the requirements of Commission Decision 1999/724/EC could not be traded with other Member States. Neither would we be fulfilling our obligation to implement EC legislation.

Option B: *to implement this EC Decision in full as the Gelatine (Intra-Community Trade) (England) Regulations 2001* would be a public health gain because the Decision sets hygienic standards for the trade in raw materials and finished gelatine for human consumption. It also provides a level playing field throughout the European Community and across this industry sector; it also fulfils our obligation to implement EC legislation.

(ii) **Quantifying and Valuing the Benefits**

Option A: *non-implementation of this EC Decision* will not improve the current hygienic manufacturing standards for the production of gelatine for human consumption as there will be no control on the import of raw materials or on the import of gelatine for further blending for use in UK products (sweets, desserts, etc). There will be no additional cost of enforcement if the Commission Decision is not implemented. Neither will there be any additional cost to industry of upgrading premises, machinery or work

practices. But there is likely to be an unquantifiable cost to industry in lost trade with other Member States.

Option B: *to implement this EC Decision in full as the Gelatine (Intra-Community Trade) (England) Regulations 2001* will ensure equal standards of hygiene throughout the industry and would permit trade within the EU on an equal basis. There is likely to be an additional overall cost to those food authorities with gelatine manufacturers or blenders in their areas, particularly where this means several visits to help with the initial compliance of the implementing Regulations. But, in England, there are very few gelatine manufacturers or blenders and the overall cost to food authorities is expected to be small. Similarly, those premises storing raw materials for the manufacture of gelatine for human consumption will need to meet the relevant criteria of the proposed Regulations in order to become authorised and registered to store the raw materials. Each business will have different compliance costs, depending on how closely they currently meet the requirements of the Commission Decision/implementing Regulations. Full implementation of this Commission Decision will meet our Community obligation.

5. COMPLIANCE COSTS FOR BUSINESSES

(i) The Affected Business Sectors

In England we are aware of:

- 4 manufacturers of gelatine for human consumption*;
- 2 blenders of gelatine for human consumption;
- 2 tanneries/collection centres.

* There are only two named companies involved: one of the companies has three sites that manufacture gelatine for human consumption.

There may also be an additional one or two businesses that store raw materials for the manufacture of gelatine for human consumption as part of a larger business operation.

(ii) **Compliance Costs for a Typical Business**

From initial enquiries made of the gelatine manufacturing industry (including those that store raw materials) in England, implementation of Commission Decision 1999/724/EC will mean possible costs, as follows:

- the capital cost of making changes to the fabric of buildings to comply with the Decision, in particular the requirement for 'storage rooms' for raw material. The cost of constructing new storage rooms and modifying existing storage areas is estimated, by one company, to be about £500,000.
- the conditions imposed by Commission Decision 1999/724/EC on tanneries and collection centres in third countries providing raw materials. Industry has suggested that these conditions are potentially onerous on those businesses. Those that do upgrade their premises to comply with the conditions of Commission Decision 1999/724/EC may pass these costs on to their European (including UK) customers – gelatine manufacturers. One company estimates the costs of this to be “tens of thousands of pounds” spread over several years.

It has also been suggested by industry that there is a plentiful market for these products elsewhere in the world and that third country tanneries may decide to withdraw from supplying the European market.

Any additional information on the costs of compliance with these proposed Regulations would be appreciated, please and will be added to the final Regulatory Impact Assessment.

(iii) **Total Compliance Costs**

(a) “Copy-out” has been used, as necessary, in the implementation of Commission Decision 1999/724. The proposed draft Regulations require the local food authority to supervise and enforce these Regulations in premises that store raw materials for the manufacture of gelatine for human consumption where these raw materials are the subject of intra-Community trade. They also require the local food authority to supervise and enforce

these Regulations in premises that manufacture or blend gelatine for human consumption where that gelatine is the subject of intra-Community trade.

(b) Supervision and enforcement of premises that manufacture and blend gelatine, in England, is currently under the Food Hygiene (General Food Hygiene) Regulations 1995. The frequency of inspection is determined by the food authority carrying out a risk assessment, as per the Annex to Code of Practice no. 9. Implementation of the Gelatine (Intra-Community Trade) Regulations 2001 will mean additional costs will be incurred by local authorities through the initial inspection and authorisation of these premises. The frequency of inspection of these premises under the Gelatine (Intra-Community Trade) Regulations 2001 will also be determined by the food authority carrying out a risk assessment, as per the Annex to Code of Practice no. 9, of the premises and the processes in operation at those premises. However, because of the small number of premises that will be affected by these Regulations, the overall cost of enforcement is expected to be minimal.

(c) Tanneries and collection centres will also be brought within the local authority supervision and inspection regime for the first time. There will be a cost to local authorities through the initial inspection, authorisation and registration of these premises, as required by the draft Gelatine (Intra-Community Trade) Regulations 2001. Following authorisation and registration of these premises, the frequency of inspection will be determined by the food authority carrying out a risk assessment, as per the Annex to Code of Practice no. 9, of the premises and the processes in operation. However, because of the small number of premises that will be affected by these Regulations, the overall cost of enforcement is expected to be minimal.

(d) Based on the information we have received so far from industry, the cost of compliance with this legislation will include the upgrading of storage facilities at collection centres, tanneries and gelatine manufacturers or blenders. Third country operators - collection centres, tanneries, general storage facilities for raw materials and gelatine manufacturers - may also have to upgrade their premises. It has been suggested that these costs may be passed on to European customers over a number of years (see paragraph 5(ii) above).

6. **IMPACT ON SMALL BUSINESS**

(i) **Small business litmus test**

As stated in paragraph 3(iii)(b) above, we are unaware of any small businesses in this industry sector. ***If there is any small business that receives this letter and that feels they would be affected by these draft Regulations we would welcome any information that they can supply on their anticipated compliance costs.***

7. **OTHER COSTS**

None. See paragraph 5(iii) above.

8. RESULTS OF CONSULTATIONS

To date letters have been sent to interested organisations as follows:

23/11/99 – letter sent by MAFF advising interested organisations of Commission Decision 1999/724/EC;

8/6/2000 – letter sent by MAFF notifying interested organisations of details of the model public health certificate that must accompany imports from third countries of gelatine intended for human consumption and of raw materials for gelatine for human consumption;

23/8/2000 – letter sent by the FSA advising interested organisations that the FSA has taken over the implementation of Commission Decision 1999/724 and asking for preliminary details of costs that they might incur as a result of implementation of this Decision. Three responses to this consultation were received and have been reflected in this draft RIA.

The final version of this RIA will summarise the results of the main public consultation of the draft Gelatine (Intra-Community Trade) (England) Regulations 2001.

9. SUMMARY OF RECOMMENDATIONS AND CONCLUSIONS

[To be added following the consultation.]

10. ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW

Enforcement

(a) Up to now the Food Safety (General Food Hygiene) Regulations 1995, as amended, have been used, by the local food authorities, to enforce hygiene conditions at the premises of gelatine manufacturers and blenders. The frequency of supervision in establishments where these Regulations

apply is based on an assessment of the operation, calculated using the Annex to Code of Practice Number 9.

(b) Similarly, the frequency of inspection required by the Gelatine (Intra-Community Trade) (England) Regulations 2001 will be determined by the food authority carrying out a risk assessment of the premises (collection centres, tanneries, manufacturers and blenders) and the processes in operation at those premises, as per the Annex of Code of Practice no. 9

(c) Collection centres, tanneries, manufacturers and blenders of gelatine for human consumption must be authorised and registered by the local authority if their product is to be the subject of trade. Any new premises would also have to be authorised and registered by the local authority before trading could begin.

Sanctions

(d) The enforcement of the Gelatine (Intra-Community Trade) (England) Regulations 2001 is by local food authorities. Under the Regulations it will be possible for the food authority to suspend or withdraw the authorisation of a collection centre or a tannery if they do not meet the requirements of these Regulations. Similarly, the authorisation of a gelatine producer may also be suspended or withdrawn if the requirements of the relevant legislation are not met.

(e) Premises that no longer satisfy the conditions for which they were authorised may have their authorisation suspended or withdrawn (regulation 5 refers). Before authorisation is suspended or withdrawn the local authority must issue a notice to the proprietor of the business specifying which part of the Regulations are not being complied with. The notice must also give a reasonable time within which full compliance with the Regulations is required. If, at the end of that time compliance has not been achieved, authorisation may be suspended or withdrawn. Appeal against suspension or withdrawal of the authorisation is to a magistrates' court.

Monitoring and Review

(f) It is proposed that formal guidance on the application of these Regulations will be issued to accompany these Regulations. Both the Guidance and the Regulations will be issued to food authorities and to those in industry with an interest.

(g) Despite the very small number of businesses in this sector, consultation with consumer groups, food authorities and industry has been very comprehensive. Problems are not expected but if they arise they can be swiftly dealt with and revised guidance issued to food authorities and industry, as necessary.

(h) Monitoring and reviewing the implementation of these Regulations will be a continuous process. It will be based on questions raised by local food authorities and industry after implementation of the Regulations and the issue of the guidance. Local food authorities and staff in the FSA are available to answer questions raised on the implementation of the Regulations.

(i) The European Commission's proposals for regulations to consolidate and simplify EC food hygiene legislation includes proposals for the hygienic manufacture of gelatine for human consumption. The trade provisions in the Gelatine (Intra-Community Trade) (England) Regulations 2001 for tanneries, collection centres, gelatine manufactures and blenders will need to be reviewed as a result of this consolidation.

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