EXPLANATORY MEMORANDUM TO

THE FEED (HYGIENE AND ENFORCEMENT) AND THE ANIMAL FEED (ENGLAND) (AMENDMENT) REGULATIONS 2013

2013 No. 3133

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

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

2. Purpose of the Instrument

2.1 The Regulations will provide for the enforcement in England of Commission Regulation (EU) No 225/2012 of 15 March 2012 amending Annex II to Regulation (EC) 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof.

2.2 The Regulations will also make two amendments to the Animal Feed (England) Regulations 2010, which provide for the enforcement of Regulation 767/2009 on the placing on the market and the use of feed. These amendments will (a) remove reference, in the context of ambulatory references, to an EU instrument that has now been repealed and (b) replace Schedule 1 to those Regulations, setting out the applicable provisions of Regulation 767/2009, to address what the Joint Committee on Statutory Instruments (in a request for a memorandum dated 3 November 2010) saw as deficient drafting in the original version of the Schedule. The Committee considered that, where certain provisions (Articles 6.1 and 8) in Regulation 767/2009 are phrased in terms of a restriction on a product, the domestic enforcement provisions should have identified which classes of persons should be penalised if EU restrictions were contravened. This has now been rectified by specifying that it is those who place on the market or use a product that contravenes Articles 6.1 or 8 who will be committing an offence.

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

3.1 See paragraph 2.2 above.

4. Legislative Context

4.1 Commission Regulation (EU) No 225/2012 amends Regulation (EC) 183/2005 to (a) require that the producers and processors of fats and oils of vegetable origin for use in animal feed be approved to undertake these activities rather than merely registered with competent authorities; and to (b) introduce a programme of risk-based monitoring of these fats and oils, and oils of marine origin, for the presence of dioxins and dioxin-like PCBs.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate but parallel legislation is being made in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

- What is being done and why

7.1 Regulation (EU) 225/2012 was adopted following a contamination incident in Germany in December 2010-January 2011 in which fatty acids of vegetable origin for use in pig and poultry feed were mixed with fats derived from industrial use containing high levels of dioxins. The Commission considered that this exposed a need for enhanced controls in this sector.

7.2 The producers and processors of fats and oils were previously required only to be registered under Regulation (EC) 183/2005 -- i.e., to be placed on a list maintained by the competent authority (in Great Britain, this is the local authority's trading standards department) with risk-based follow-up checks. Approval requires the prior inspection of the business to ensure that it has the procedures and equipment in place to undertake its activities to the requisite standards. Approval also requires the one-off payment of a fee to the local authority to cover the costs of the inspection work.

7.3 Regulation (EU) 225/2012 also introduces a requirement for the animal feed industry to undertake risk-based monitoring (i.e., sampling and analysis) of vegetable-derived fats and oils, and oils of marine origin, for the potential presence of dioxins and dioxin-like PCBs. The Annex to the Regulation specifies the particular fats and oils to be tested, the stages of their use at which they are to be tested, and the size of the consignments from which the samples are to be taken.

7.4 EU Regulations apply directly in Member States and their provisions cannot be repeated in national legislation. However, it is necessary to provide for the enforcement of Commission Regulation (EU) No 225/2012 by linking its provisions to the powers already available to local authority enforcement officers under Part 4 of the Feed (Hygiene and Enforcement) (England) Regulations 2005.

7.5 The Feed (Hygiene and Enforcement) and the Animal Feed (England) (Amendment) Regulations 2013 will therefore:

- re-set the definition of Regulation (EC) 183/2005 in regulation 2(1) of the Feed (Hygiene and Enforcement) (England) Regulations 2005 so that it captures the amendments introduced by Regulation (EU) 225/2012;
- insert an ambulatory reference to the Annexes of Regulation (EC) 183/2005, so that future amendments to them have effect from the application date given in the relevant EU amending Regulation and do not require to be individually referenced in domestic provisions;

- amend the designations of the competent authorities in regulation 4 of the Feed (Hygiene and Enforcement) (England) Regulations 2005 to cover the references to the competent authority in the new section on dioxin monitoring in Annex II of Regulation (EC) 183/2005 (inserted by Regulation (EU) 225/2012); and
- extend the requirement to pay a fee for approval under the Feed (Hygiene and Enforcement) England Regulations 2005 to the categories of establishments listed in the facilities and equipment section of Annex II of Regulation (EC) 183/2005 (amended by Regulation (EU) 225/2012).

7.6 The Feed (Hygiene and Enforcement) and the Animal Feed (England) (Amendment) Regulations 2013 will also:

- substitute in Schedule 2 to the Feed (Hygiene and Enforcement) (England) Regulations 2005 the term "substances" for "additives", to confirm that operators using bioproteins formerly covered by Council Directive 82/471/EEC are still required to be approved. This amendment is necessary following the revocation of Council Directive 82/471/EEC on certain products (bioproteins) used in animal nutrition by European Parliament and Council Regulation (EC) No. 767/2009 of 13 July 2009 on the placing on the market and use of feed, which has created a legal uncertainty over whether establishments using or manufacturing the bioproteins formerly covered by the Directive are subject to approval; and
- provide a clarified regulation 4(1) and Schedule 1 to the Animal Feed (England) Regulations 2010.

8. Consultation outcome

8.1 The Food Standards Agency consulted informally with the feed industry during the negotiations in Brussels on what became Regulation (EU) 225/2012, and in response to industry representations successfully intervened in those negotiations to persuade the Commission to withdraw its original proposal for 100% monitoring of fats and oils at all stages of their use (even where they had been previously tested and found to be compliant) and instead focus on the testing of higher-risk fats and oils.

8.2 A formal public consultation on the draft Feed (Hygiene and Enforcement) and the Animal Feed (England) (Amendment) Regulations 2013 ran from 5 July 2013 to 27 September 2013, but attracted only three responses. One indicated general support for the legislation; the second made general comments about the potential for monitoring to raise the costs of the material being monitored; the third claimed that the Regulation was an over-reaction by the Commission to an incident in another Member State which would not have occurred had the existing rules been followed, but endorsed the figures for costs given in the consultation-stage Impact Assessment. More details of these consultation responses are provided in the attached final Impact Assessment.

9. Guidance

9.1 The consultation package for the draft Feed (Hygiene and Enforcement) and the Animal Feed (England) (Amendment) Regulations 2013 included two draft guidance documents, on the application by industry of the sampling requirements and the procedures to be followed by laboratories in reporting breaches of dioxin thresholds to competent authorities. Industry was invited to suggest additional issues

which these documents could cover. The guidance has been revised to include the additional points raised, and is to be published on the Food Standards Agency's website.

10. Impact

10.1 The producers and processors of fats and oils estimate that the annual costs to them of sampling for dioxins and dioxin-like PCBs will be around £184,000; feed compounders, the end-users of these fats and oils, estimate their costs will be around £58,000. The total fees payable by the producers and processors of fats and oils (around 21 firms) for the approval of their activities is estimated as around £7,100. The fee is a one-off payment; another fee would only be payable following a change of activity, when a re-assessment and re-approval would be required. The feed industry has indicated that it has no significant concerns about these costs, which are a very small fraction of the UK feed industry's estimated annual turnover of £5 billion. The industry had additionally been pro-active on monitoring for dioxins, introducing (in advance of the legislation) a programme of its own alongside its existing HACCP-based feed safety managements systems.

10.2 A final Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the National Archive website.

11. Regulating Small Business

11.1 The legislation will apply equally to small businesses. However, in this particular instance it is thought that none of the affected businesses, although individually not particularly large, would be categorised as small and medium-sized enterprises. In any case, to exempt small and medium-sized enterprises would be a breach of Regulation (EU) 225/2012 and could potentially compromise the safety of the feed chain.

12. Monitoring and Review

12.1 The Annex to Regulation (EU) 225/2012 states that the dioxin-monitoring requirements are to be reviewed by 16 March 2014. The Food Standards Agency will seek feedback from the UK feed industry and enforcement bodies on the application of the Regulation to help inform its future contribution to these reviews. Continuing stakeholder engagement (from formal and informal feedback and meetings with key stakeholder groups, including annual feed stakeholder meetings) will be the main means of obtaining this feedback.

13. Contact

Tim Franck or Joseph Nicholas in the Animal Feed Branch at the Food Standards Agency can answer queries regarding the instrument -- telephone 020 7276 8471 or e-mail <tim.franck@foodstandards.gsi.gov.uk> (Tim Franck) or telephone 020 7276 8462 or e-mail <joseph.nicholas@foodstandards.gsi.gov.uk> (Joseph Nicholas).