

**EXPLANATORY MEMORANDUM TO**  
**THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES) REGULATIONS**  
**(NORTHERN IRELAND) 2009**

**2009 No. 348**

**1. Introduction**

1.1 This Explanatory Memorandum has been prepared by the Foods Standards Agency Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly

1.2 The Statutory Rule is made under powers conferred by sections 66(1), 74A and 84 of the Agriculture Act 1970 and is subject to the negative resolution procedure.

1.3 The rule is due to come into operation on 23<sup>rd</sup> November 2009.

**2. Purpose**

2.1 The carry-over of residues of coccidiostats and histomonostats – (substances intended to help prevent coccidiosis and histomoniosis, i.e. infestations of the gastrointestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry) -- into feed for other species ("non-target species") is technically unavoidable where feed compounders or on-farm mixers are producing a range of feedingstuffs using the same equipment. This cross-contamination typically occurs where residues from one production run are incorporated in the next. This instrument introduces permitted tolerance levels for such instances of carry-over.

**3. Matters of special interest to the Health Committee**

3.1 None.

**4. Legislative Background**

4.1 The tolerances for carry-over have been set at European level to ensure harmonised levels throughout the EU and thus avoid the possibility of Member States setting their own, national limits based on their differing analytical capabilities and rates of detection. The setting of different national limits could give rise to difficulties with the operation of the Single Market, particularly if the UK were to set tolerance levels lower than those of other Member States on the basis of more developed analytical capabilities, and could competitively disadvantage the UK feed industry.

4.2 The tolerance levels for residues of coccidiostats and histomonostats are being introduced at European level as an amendment to the Annex to EC Directive 2002/32 on undesirable substances in feed, and are without prejudice to the authorisation of coccidiostats and histomonostats as feed additives under EC Regulation 1831/2003. The amendment to the Directive will be transposed into law in Northern Ireland by an

amendment to Schedule 5 to the Feeding Stuffs Regulations (Northern Ireland) 2005 (as amended), and will provide the enforcement authority in Northern Ireland with the means to help confirm the safety of feed products put into circulation.

## **5. Position in Great Britain**

5.1 This Statutory Rule applies to Northern Ireland. Equivalent Statutory Instruments have been proposed in England, Scotland and Wales.

## **6. European Convention on Human Rights**

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

## **7. Policy background**

- What is being done and why

7.1 The European Food Safety Authority (EFSA) was asked by the Commission to undertake a risk assessment of the presence of residues of coccidiostats and histomonostats in feed for non-target species and published a series of Opinions in 2007-2008 setting out the likely risks to animal and human health. These Opinions were reviewed by the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section), which agreed tolerances of 3% for carry-over in feed for less sensitive non-target species and 1% for carry-over in withdrawal feed (i.e., feed used in the period before slaughter), feed for sensitive non-target species, feed for target species to which coccidiostats and histomonostats are not added, and feed for non-target species classifiable as "continuous food-producing animals" (such as dairy cows and laying hens).

7.2 The Standing Committee also agreed to set tolerance levels for residues in premixtures to ensure that the premixture will not contribute more than 50% of the total carry-over in the finished feed; and to set a specific provision for chickens reared for laying (which have longer lifespans than chickens reared for their meat) to minimise the potential for the carry-over into eggs for human consumption.

7.3 These provisions were put out for consultation with relevant stakeholder organisations while they were under discussion in the Standing Committee, but no comments were received. The provisions were eventually adopted as Commission Directive 2009/8/EC of 10 February 2009.

7.4 The measure is expected to help reduce the administrative and policy burdens on the feed and farming industries, which will no longer be required to work to a zero tolerance for the presence of residues and will thus be permitted to undertake risk-based assessments of their likely presence in feed production runs. This could mean that consignments of feed which previously would have breached the zero tolerance requirement will no longer have to be disposed of outside the feed chain, which could lead to a reduction of the costs of compliance with the legislation. However, the potential benefit is difficult to assess because the number of consignments of feed currently disposed of due to the presence of residues of coccidiostats and histomonostats is unknown.

7.5 The introduction of this measure is expected to have no impact on the public sector in Northern Ireland. The measure is, however, generally perceived as proportionate to the potential risk to animal and human health, as the maximum permitted levels are based on an independent risk assessment carried out by the European Food Safety Authority (EFSA) and endorsed by the Commission's Standing Committee on the Food Chain and Animal Health. This will ensure that both animal health and the health of consumers of livestock products are adequately protected.

- Consolidation

7.6 The Feeding Stuffs Regulations (Northern Ireland) 2005 mentioned in paragraph 4.2 above have previously been amended a number of times, but are not being consolidated on this occasion because five of the EC Directives they implement have recently been consolidated into a single EC Regulation which will apply in Member States from September 2010. The 2005 Regulations will be revoked and remade in considerably altered form to give effect to this development.

## **8. Consultation outcome**

8.1 Three responses were received to the public consultation in Northern Ireland on the draft Regulations. All were in support of the measure and content on the proposed tolerances. Parties were pleased to see a more scientific approach being adopted by the EU for clearly defined risk based tolerances for both sensitive and non-sensitive non-target species.

## **9. Guidance**

9.1 The Food Standards Agency does not currently consider that any guidance to the interpretation of the measure's provisions is necessary, as they are self-explanatory. However, the question of whether guidance may be required for enforcement officers will be kept under review by the UK's Animal Feed Law Enforcement Liaison Group (AFLELG).

## **10. Impact**

10.1 An Impact Assessment was carried out by FSA colleagues in London and is believed to be representative of the position in Northern Ireland. The impact on business, charities or voluntary bodies is summarised at paragraph 7.4 above.

10.2 The impact on the public sector is summarised at paragraph 7.5 above.

## **11. Regulating small business**

11.1 The legislation will apply to small businesses, which will not be exempted from the measure because it is not introducing any new burdens for business.

## **12. Monitoring & review**

12.1 Directive 2009/8/EC requires that the tolerance levels of residues of coccidiostats and histomonostats be reviewed in the light of developments in scientific

and technical knowledge no later than 1 July 2011. This review will be undertaken by the European Food Safety Authority and the results reported via the Standing Committee on the Food Chain and Animal Health, where any amendments would be put to a vote by the Member States.

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