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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Contaminants in Food (Scotland) Regulations 2013

Date: 24 June 2013
Stage: Final
Source of intervention: EU/Scotland
Type of measure: Other
Contact for enquiries: Will Munro
01224-285161
will.munro@foodstandards.gsi.gov.uk

Title of Proposal

1. The Contaminants in Food (Scotland) Regulations 2013.

Purpose and intended effect

Objectives

2. The presence of contaminants, such as nitrate, coccidiostats and histomonostats in some foods can have a detrimental impact on consumer health. Consumers are unable to assess the risk from contaminants present in foods and therefore are unable to make fully informed choices about such risk. Government intervention is necessary to address this information asymmetry and minimise the risk to health, taking into account the latest scientific evidence to provide greater clarity in enforcement.
3. These proposals are designed to meet the following policy objectives:
 - 3.1. To ensure that maximum levels set for nitrate in lettuce, spinach and rocket in Scotland are sufficient to protect consumer health but are also achievable.
 - 3.2. To ensure that levels for coccidiostats and histomonostats in food in Scotland are sufficient to protect consumer health by setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed.
 - 3.3. To revoke national legislation on mineral hydrocarbons in food and to revoke and remake with appropriate textual amendments, provisions currently contained in the Erucic Acid in Food (Scotland) Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food (Scotland) Regulations 2013 ("the proposed Contaminants Regulations").

Background

Legislative Context

4. Maximum levels for nitrates in foodstuffs Commission Regulation (EU) No. 1258/2011 ("the Nitrate Regulation"), amending Regulation (EC) No. 1881/2006
 - 4.1. Nitrates commonly occur in high concentrations in spinach and lettuce mainly due to climatic conditions. This is a particular problem for lettuce growers in northern European countries, such as the UK, because poorer light quality can restrict the energy available for assimilation of nitrate by glasshouse crops. Scientific data has shown that reduction of dietary exposure to nitrate can be achieved by setting maximum levels for foods likely to have high nitrate levels such as certain leafy vegetables reaching the market.
 - 4.2. On 10th April 2008, at the request of the European Commission, the Panel on Contaminants in the Food Chain ("the Panel") adopted a Scientific Opinion on nitrate in vegetables. The Panel compared the risks and benefits of exposure to nitrate from vegetables. In most cases the estimated exposure to nitrate from vegetables is unlikely to result in appreciable health risks; therefore, the recognised beneficial effects of consumption of vegetables prevail. In specifically considering the risks to infants and young children, the European Food Safety Authority (EFSA) concluded that concentrations of nitrate in lettuce are not a health concern, but that the concentrations of nitrate in spinach have the potential to increase dietary nitrate exposure to levels at which a health concern cannot be excluded. Increasing the maximum level by 500 mg/kg would be more health protective than the situation of local derogations from the maximum levels (for further information please see Annex).

- 4.3. EFSA has published two evaluations of the risks of nitrate in food. Excessive intake of nitrate could result in methaemaglobinaemia¹ especially in infants. This is relevant as pureed spinach is used in home prepared foods. In addition, at very high levels of intake there is a concern that nitrate could result in the formation of carcinogenic nitrosamines.
- 4.4. Maximum levels for the presence of nitrate in lettuce and spinach already exist; however these have been amended to take into account problems that some Member States have had with achieving these levels as a result of their climate. In addition, new maximum levels have been set for the presence of nitrate in rocket, where a risk has recently been identified.
- 4.5. Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs² sets maximum levels for nitrate in certain leafy vegetables. In some cases, despite developments in good agricultural practices, the maximum levels are exceeded. To give Member States time to comply, a temporary derogation was granted to certain Member States due to their respective climates, for the placing on the market of certain leafy vegetables, grown and intended for consumption in their territory, with nitrate levels higher than the established maximum levels.
- 4.6. Commission Regulation (EU) No. 1258/2011 (“the Nitrate Regulation”) of 2nd December 2011 as regards maximum levels for nitrate in foodstuffs amending Regulation (EC) No. 1881/2006 was published in the Official Journal (OJ) of the European Union on 3rd December 2011³. It came into force on 23rd December 2011. The Nitrate Regulation is directly applicable throughout the EU and sets higher, achievable levels than those initially set for lettuce and spinach across the EU. It also sets maximum levels for rocket, where a risk has been identified. A copy of the Nitrate Regulation is available to download free of charge from the following website:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:320:0015:0017:EN:PDF>

5. Commission Regulation (EU) No. 610/2012⁴ (“Regulation 610/2012”), amending Regulation (EC) No. 124/2009 (“Regulation 124/2009”).
- 5.1. Commission Regulation (EC) No. 124/2009⁵ of 10th February 2009 sets maximum levels for the presence of certain coccidiostats and histomonostats in food as the result of unavoidable carry-over into non-targeted feed. The legislation harmonises the limits for the coccidiostats and histomonostats carry-over across the EU without posing a risk to public health.
- 5.2. The unavoidable carry-over of active substances contained in authorised coccidiostats and histomonostats into non-target feed are considered as undesirable within the meaning of Directive 2002/32/EC⁶ of the European Parliament and of the Council of 7th May 2002, on undesirable substances in animal feed.
- 5.3. EFSA has published a number of opinions on coccidiostats and histomonostats in food as the result of unavoidable carry-over of these substances into feed for non-

¹ 1 Methemoglobinemia is a blood disorder in which an abnormal amount of methemoglobin -- a form of [hemoglobin](#) -- is produced. Hemoglobin is the molecule in red blood cells that distributes oxygen to the body. Methemoglobin cannot release oxygen.

² OJ L 364, 20.12.2006, p5

³ OJ L 320, 3.12.2011, p15

⁴ OJ L 178, 10.7.2012, p 1

⁵ OJ L 40, 11.2.2009, p3

⁶ OJ L 40, 30.5.2002, p10

target animals. EFSA opinions take into account the uncertainty arising from the fact that studies in non-target animals are often not available, and that a high level of carry-over in the feed mill would not be expected to be a regular event. EFSA did not identify a risk to public health from eating products of animal origin containing residues of these substances arising from unavoidable carry-over. Whilst these substances are considered undesirable, the very limited data provided no indication of an appreciable risk to consumer's health from the ingestion of these residues in products from animals exposed to cross-contaminated feed.

- 5.4. For full details of EFSA opinions on coccidiostats and histomonostats please see the Annex.
- 5.5. Regulation 610/2012 amending Regulation 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed was published in the OJ on 10th July 2012. Regulation 610/2012 amends the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril, in those foods as outlined in the Annex to Commission Regulation 124/2009. Regulation 610/2012 is directly applicable throughout the EU and came into force on 30th July 2012; the Regulation amends the provisions for the above listed substances in the Annex to Commission Regulation 124/2009. A copy of Regulation 610/2012 is available to download free of charge from the following website:

<http://eur-lex.europa.eu/lexuriserv/lexuriserv.do?uri=oj:l:2012:178:0001:0003:en:pdf>

Details of the national regulations being revoked

6. The Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (“the Mineral Hydrocarbons Regulations”)
- 6.1. The Mineral Hydrocarbons Regulations have been amended at various times in relation to offences and penalties; to update references to food law; and to exempt EU permitted additives from their scope. The Mineral Hydrocarbons Regulations prohibit the use of any mineral hydrocarbons in the composition or preparation of food (except in the case of four specified exemptions); and the sale or import of any food containing any mineral hydrocarbons. The four exemptions where the use of mineral hydrocarbons is permitted are:
- In chewing gum;
 - On the rind of cheese;
 - As a lubricant or greasing agent on surfaces with which food has necessarily come into contact during preparation, provided the food contains no more than 0.2 parts by weight per 100 parts by weight of the food; and,
 - When used as an EU permitted additive.
- 6.2. In addition, Mineral Hydrocarbons Regulations specify which mineral hydrocarbons can be used and includes the specifications for each of them.
- 6.3. The Mineral Hydrocarbons Regulations are based on science which is now out of date. In addition, the scope of the Regulations is too broad. By generally banning the sale or import of any food containing any mineral hydrocarbons, the legislation has the unintended effect of banning the presences of residues of mineral hydrocarbons which could be tolerated by EU contaminants legislation.

- 6.4. The FSA has consulted with major trade associations about the current uses of mineral hydrocarbons, and has taken note of the recent opinion⁷ of EFSA on mineral oils.
- 6.5. We have considered a number of options for amending/updating the legislation, taking account of the recent EFSA opinion on mineral oils. From the information we have received, there is no use of mineral hydrocarbons in the UK food industry either as grain-dusting agents or release agents for baking trays; both of which were cited by EFSA as contributors to intakes of mineral oils. There is also little use of these substances for other processing aid functions. The FSA considers that the Mineral Hydrocarbons Regulations no longer serve any practical function and should be revoked. An equivalent level of public health protection is achieved by newer legislative controls on mineral hydrocarbons in EU legislation on food additives and contaminants, and by the General Food Law (Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 (“General Food Law”))⁸. The latter prohibits the sale or supply of unsafe food when mineral hydrocarbons are used in food for other purposes e.g. as processing aids.
- 6.6. For enforcement purposes, once the Mineral Hydrocarbons Regulations are revoked, Article 14 of General Food Law would apply if there were any concerns about consumer health arising from the use of mineral hydrocarbons as processing aids or ingredients. Specific EU controls on mineral hydrocarbon additives and contaminant residues will also apply. Thus the FSA considers that revocation of these national regulations will not alter the level of consumer protection.
- 6.7. The revocation of the Mineral Hydrocarbons Regulations will remove redundant legislation and is non-controversial in terms of food safety. We are therefore recommending that the 1966 Regulations should be revoked.
7. The Erucic Acid in Food (Scotland) Regulations 1977⁹ as amended (“the Erucic Acid Regulations”)
- 7.1. Council Directive 76/621/EEC¹⁰ as amended, relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats, where the overall fat content exceeds 5%. The Directive limits the erucic acid content in foods to no more than 5% calculated on the total level of fatty acids in the fat component and allows for the discretion of Member States to apply a lower overall fat content to be equal to or less than 5%. The provisions of Directive 76/621/EEC are implemented by the Erucic Acid Regulations. The provisions in the Contaminants in Food (Scotland) Regulations 2013 for placing on the market for consumption by the final consumer will be maintained. This measure gives an exemption on consignments and deliveries to manufacturers for the purposes of a manufacturing business or to a caterer for their business. For foods aimed at infants or young children an additional provision of the lower overall total fatty acid of 0% applies. The FSA believes that this lower limit provides for an additional safety measure for this consumer group.

⁷ <http://www.efsa.europa.eu/en/efsajournal/pub/2704.htm>

⁸ OJ Ref, L 31, 1.2.2002, p 1 – 24, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

⁹ SSI 1977 No. 1028

¹⁰ OJ L 202, 28.7.1976, p 35

- 7.2. Directive 76/621/EEC and Commission 80/891/EEC¹¹ relating to the method of analysis for determining erucic acid levels, prescribes the levels of erucic acid that are permissible in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats. Directive 76/621/EEC was last amended in 2003 by Council Regulation (EC) No 807/2003¹². The Erucic Acid Regulations were amended by The Erucic Acid in Food (Scotland) Amendment Regulations 1982¹³.
- 7.3. The Erucic Acid Regulations will be revoked and remade in the proposed Contaminants Regulations. The provisions of the two EC Directives remain intact and unchanged and we do not envisage any new burdens on businesses from the proposed simplification. However, there will be some textual changes in the proposed Contaminants Regulations to the way in which the Directives mentioned above are implemented, to take into account changes in drafting techniques and practices.
8. There will also be minor textual changes to the proposed Contaminants Regulations to take into account the revocation of the Mineral Hydrocarbons Regulations and the Erucic Acid Regulations.
9. It is anticipated that Council Directive 76/620/EEC will be amended and the discussions will take place sometime in 2013 at European Council level. We will in due course consult stakeholders on any proposed changes to the Directive and any possible impact associated with the changes; there is no firm timetable for the discussions, or what the likely changes are. We will however contact stakeholders accordingly.
10. The FSA considers that the impact on both enforcement authorities and industry of the proposed revocation of the Mineral Hydrocarbons Regulations and the consolidation of the Erucic Acid Regulations will be negligible.

Rationale for Government intervention

Policy Background – Chemical Contaminants

11. The proposal for a Scottish Statutory Instrument (SSI) entitled The Contaminants in Food (Scotland) Regulations 2013 will make provisions for the execution and enforcement of Regulation 610/2012, amending Regulation (EC) No. 124/2009. This will provide enforcement authorities with the necessary powers to enforce the Regulations and to take appropriate action where foodstuffs are found to be non-compliant. The proposed Contaminants Regulations will also revoke the Contaminants in Food (Scotland) Regulations 2010¹⁴ and remake them with necessary amendments, taking into account the requirements of Regulation 610/2012.
12. Under Option 3, the provisions to bring into force the revised maximum limits for nitrate in spinach and lettuce and the new maximum levels for rocket will be done via ambulatory references and will not require amending provisions to be made in the proposed Contaminants Regulations.

¹¹ OJ L 254, 27.9.1980, p 35

¹² OJ L122, 16.5.2003, pg36 - Adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (unanimity)

¹³ SSI 1982 No. 18

¹⁴ SSI 2010 No.329

13. The proposed Contaminants Regulations continue to use ambulatory references. At present the ambulatory references in the current 2010 Contaminants Regulations only apply to the Annex in Commission Regulation 1881/2006. We are proposing to extend the ambulatory references to Articles as well as Annexes, as sometimes technical changes can be found in the former and latter. Extending the use of ambulatory references to include Articles as well as Annexes will avoid the need to introduce a new SSI each time any of these Annexes or Articles is updated. Ambulatory references will also include the Articles/Annexes of Commission Regulation 124/2009 and Commission Directives 76/621/EEC and 80/891/EEC on erucic acid.
14. The proposed Contaminants Regulations will also make an amendment to the provisions contained in the current 2010 Contaminants Regulations in order to rectify an under enforcement of EC Regulation 1881/2006. Article 5 of that Regulation provides specific provisions for the labelling of groundnuts, derived products thereof and cereals. The provisions of Article 5 require that a clear indication of intended use must appear on the label of each individual bag, box etc or on the original accompanying document, which must have a clear link with the consignment.
15. A failure to comply with the labelling provisions in Article 5 is being included among the offences in the proposed Contaminants Regulations which will provide clarity for both Food Business Operators (FBOs) and enforcement bodies/officers.
16. European Union legislation on contaminants in food is made under the contaminants framework Regulation, Council Regulation 315/93/EEC. This Regulation lays down the EU procedures for dealing with contaminants in food and it applies general requirements to those contaminants that are not covered by other specific EU legislation. In order to continue reducing the disparities between the existing laws of Member States with regard to maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulation (EC) No. 1881/2006 was introduced under Regulation 315/93/EEC to ensure market unity while complying with the principles of proportionality. The provisions and requirements of Commission Regulation 1881/2006 (and its predecessor Regulation (EC) No. 466/2001) have applied across the EU since April 2002.
17. Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, and may *inter alia*, be authorised for use as feed additives in accordance with Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition. Authorisation of coccidiostats and histomonostats as feed additives lay down specific conditions for use such as the target animal species or categories for which the additives are intended. Feed business operators may produce, within one establishment, a broad range of feeds and different types of products may have to be manufactured one after another in the same production line. This may result in the unavoidable traces of a product remaining in the production line and ending up as an adventitious ingredient of another feed product. This transfer from one product lot to another is called 'carry-over' or 'cross-contamination' and may occur for instance when coccidiostats or histomonostats are used as authorised feed additives. This may result in the contamination of feed and subsequently, by the presence of technically unavoidable traces of those substances in non-target feed, their resulting presence in derived foodstuffs.
18. To ensure efficient functioning of the internal market, the Commission together with Member State countries including the UK have now agreed maximum tolerances for the presence of active substances contained in coccidiostats and histomonostats in food of animal origin originating from the non-target feed concerned. The provisions of Regulation (EC) No. 124/2009 are made under Council Regulation (EEC) No. 315/93

which lay down the Community procedures for contaminants in food. These contaminants are defined as:

“any substance not intentionally added to food which is present in such food as a result of its production and processing, preparation and treatment etc (including operations carried out in crop husbandry, animal husbandry and veterinary medicine) manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insects, fragments, animal hair, etc, is not covered by this definition”.

19. Regulation 610/2012 amends the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril, in those foods as outlined in the Annex to Commission Regulation 124/2009.

Industry Initiatives – Nitrate in Vegetables

20. Industry is working in collaboration with ADAS on a project exploring the use of specific agronomic practices to reduce the levels of naturally occurring nitrate in leafy vegetables – predominantly by restricting the use of nitrogen fertilisers. Like all naturally occurring contaminants, industry has limited ability to control levels compared to some other contaminants.
21. ADAS is also carrying out a monitoring programme in the UK, which is funded by the FSA. Samples are collected on a voluntary basis from farms and are analysed for nitrate and the results are submitted to the FSA. This data will be transmitted to EFSA. It is possible that the FSA may also receive data from other sources, which could be submitted to the Commission and industry might themselves respond direct to EFSA calls for data. However, the FSA funded programme on nitrate monitoring will be the main source of data submitted to EFSA.
22. The collection of samples for the FSA by ADAS is in response to the statutory requirement in the Nitrate Regulation. The farmers themselves volunteer for the scheme. This programme has been ongoing for many years but now the results will be submitted directly to EFSA. The sampling plan is being revised to take into account changes to the legislation e.g. to incorporate rocket samples.
23. Industry has relatively limited understanding of controlling nitrate levels in rocket at present compared with the extensive studies on lettuce over the years and needs more time. The rocket plant appears to be inherently more prone to nitrate accumulation.
24. Current work was sponsored by the Agriculture and Horticulture Development Board looking at nitrogen response. The link below provides details of the research and there are other reports on nitrate on their website:

http://www.hdc.org.uk/sites/default/files/research_papers/FV%20370a%20final%20psg%20v2.pdf

Industry Reaction to the EU Proposal

25. Following a meeting with stakeholders in January 2011, the FSA recognised the ability of industry to comply with the proposed limits on nitrate as being problematic; it thus, conducted a risk assessment as to whether the limits could be increased without introducing a food safety risk for consumers. The assessment was submitted to the Commission with good support from other Member States and included data provided by industry. This resulted in potential limits for rocket grown in summer and winter being increased and was agreed at the Standing Committee of the Food Chain and Animal Health (SCoFAH). Stakeholders were also informed that the Nitrate Regulation included a requirement to continue monitoring for nitrate in all EU Member States.

26. A further meeting with stakeholders was held on 26th October 2011 to make them aware of the maximum levels of nitrate in spinach, lettuce and rocket and provided an overview of the negotiations, which focused on making nitrate levels achievable by industry. Further explanation was given on the EFSA opinion previously published on exposure to nitrate, which found high levels in rocket, which is reflected in the Nitrate Regulation in the form of maximum limits. Stakeholders were also asked to provide information on the likely impact(s) that can be identified (including benefits) that would assist in developing an Impact Assessment.
27. At the meeting stakeholders expressed a number of concerns, in particular on rocket that is imported to the UK in winter; stakeholders expressed concerns regarding the achievability of the new levels. The FSA also informed stakeholders that there was the possibility of raising this with the Commission with raw data too as supporting evidence, although the options to make any changes are limited. The FSA also confirmed that enforcement action would not take place until the implementation date for rocket, which was 1st April 2012.

Consultation

Within Government

28. During the course of negotiations with the Commission, officials of the FSA have kept other government departments informed of its progress. The UK fully supported the Commission's intention to set new maximum levels for nitrate in leafy vegetables. The final proposal was subsequently adopted by the SCoFCAH. To date no adverse comments have been received from any department.

Public Consultation

29. The FSA conducted a full 12 week consultation running from 28 February 2013 to 23 May 2013 with all its stakeholders including industry trade bodies, enforcement authorities, consumer organisations, research laboratories and others with an interest in chemical contaminants legislation. Two substantive responses were received. The FSA has also kept its stakeholders informed throughout the development of the regulations by means of several interested parties letters which are available from the following link:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/>

Business Consultation

30. In addition, the FSA held two meetings with stakeholders and industry trade bodies in January and October 2011, which informed businesses on the EU negotiations and plans for implementation of the maximum limits for nitrate in spinach, lettuce and rocket. The meeting highlighted potential compliance issues with rocket, for which stakeholders agreed to provide data on the number of businesses likely to be affected by the new nitrate limits for rocket.

31. Enforcement

32. The new maximum limits for nitrate in spinach, lettuce and rocket, are enforceable under existing 2010 Regulations, and that will be carried forward unchanged into the proposed 2013 Regulations, thus providing for the continuity of enforcement.

Options

33. Option 1 – Do Nothing – Do not implement the new nitrate limits in leafy vegetables, or set maximum levels set for coccidiostats and histomonostats in food

34. Under this option the Nitrate Regulation and Regulation (EU) 610/2012 will still be applicable in Scotland and the rest of the UK. The two EU Regulations have been applicable since 22nd November 2011 and 10th July 2012 respectively and are already legally binding in the EU. However, enforcement authorities will not have the necessary powers to enable them to enforce the provisions of the two EU Regulations, which could consequently have adverse impacts on public health.

35. This option would also mean that the UK fails to meet its Treaty obligations to put in place legislation to provide for the enforcement of EU law and may lead to the UK being liable to infraction proceedings.

36. Option 2 – Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulation (EU) No. 610/2012 on maximum levels set for coccidiostats and histomonostats in food and implement the new nitrate limits in leafy vegetables

37. This option would provide enforcement authorities with the necessary powers under existing food contaminants legislation for enforcement of the new nitrate limits in leafy vegetables and provide for the execution and enforcement of Regulation 610/2012, amending Regulation (EC) No 124/2009, setting maximum levels for the unavoidable carry-over of coccidiostats and histomonostats. This ensures that enforcement authorities continue to fulfil their responsibilities under the Food Safety Act 1990.

38. This option also meets the Government's commitment to fulfil its EU obligations and contributes significantly to provide for the means of protecting consumers from ingesting harmful chemical contaminants in food. European Regulations are binding in their entirety and directly applicable in Member States from the date they take effect. The UK has a legal obligation to ensure that the provisions are in place to provide for the enforcement in full of the new EU Regulations.

39. Option 3 - As Option 2 but in addition, make ambulatory provisions in the domestic Regulations to include the Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. It extends the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on erucic acid and revokes the mineral hydrocarbons in food legislation

40. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the Regulations in Scotland. This ensures that enforcement authorities fulfil the requirements placed upon them and that the Courts can impose penalties that are in line with others elsewhere in food law.

41. This option would also make ambulatory provisions in the proposed Contaminants Regulations to include the Articles and Annexes of Regulation 1881/2006 regarding maximum levels of nitrate in foodstuffs and also extend ambulatory references to include Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats, and Directives 76/621/EEC and 80/891/EEC on erucic acid.

42. In addition, this option will also go towards meeting the FSA's commitment to simplify the legislation on chemical contaminants in food by revoking national legislation on mineral hydrocarbons in food and to revoke and remake with appropriate textual amendments, provisions currently contained in the Erucic Acid in Food (Scotland) Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants Regulations.

Benefits

43. Option 1 – Do Nothing: Do not implement the new nitrate limits in leafy vegetables, or set maximum levels set for coccidiostats and histomonostats in food.
44. There are no incremental benefits (or costs) under Option 1 as this is the baseline which all other options are appraised against. However, the risk of not having the Regulations in place would mean that enforcement authorities would not have the necessary powers to enable them to enforce the EU Regulations. This would lead the UK Government being cited in infraction proceedings by the Commission and this in turn could result in financial penalties being incurred.
45. Consumer safety may also be compromised and the potential for consumers to be exposed to harmful levels of contaminants such as nitrate.
46. Option 2 - Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulation (EU) No. 610/2012 and implement the new nitrate limits in leafy vegetables

Benefits to Consumers

47. The presence of contaminants such as nitrate and coccidiostats and histomonostats can pose a threat to consumer health. The Nitrate Regulation sets new maximum limits for the presence of nitrate in rocket and Regulation 610/2012 for the presence of coccidiostats and histomonostats in food, and can therefore have a benefit to consumers in terms of consumer health. We have, however, been unable to monetise this benefit.
48. For spinach and lettuce, the Nitrate Regulation raises the existing maximum limits. Based on the Panel's 2008 opinion on nitrates in vegetables (see paragraph 15), we envisage this impact to be neutral on consumers.

Wider Benefits

49. This option would harmonise standards across the Member States and prevent any barrier to trade occurring as a result of different regulations in different Member States. This could encourage additional trade and may introduce greater market competition with benefits for the wider UK economy. It is also anticipated that businesses may benefit financially as a consequence of maximum levels for nitrate in rocket being increased, making compliance easier. This would reduce food wastage as fewer commodities are rejected and removed from the supply chain, reducing the marginal costs to FBOs. In a competitive market this may be reflected through lower consumer prices and an increase in consumer benefit. We have, however, been unable to quantify these benefits.
50. Option 3 - As Option 2 but in addition, make ambulatory provisions in the domestic Regulations to include the Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. It extends the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on erucic acid and revokes the mineral hydrocarbons in food legislation.

Benefits

Benefits to Consumers

51. Just as under Option 2, the Nitrate Regulation will have health benefits to consumers from new maximum levels for nitrate in rocket and for coccidiostats and histomonostats in food. We have, however, been unable to quantify these benefits.

Benefits to Industry

52. Under Option 3, ambulatory provisions will be introduced in the proposed Contaminants Regulations, which will affect future amendments to the Articles and Annexes of EU Regulations 1881/2006, 124/2009 and to Directives 76/621/EEC and 80/891/EEC on erucic acid and may reduce the regulatory burden on businesses in the future. We are, however, unable to monetise these benefits, as we do not have any information whether or not the EU legislation is likely to be amended in the future, or the associated number of changes (if any).

53. We assume that simplification may also benefit businesses as a result of the consolidation of contaminants in food legislation, which could lead to a reduction in the time it takes for new entrants to become familiar with the legislation.

Benefits to Enforcement Authorities

54. The use of ambulatory references could reduce future regulatory burdens on enforcement authorities as it will reduce the time costs of reading and familiarising themselves with any future changes to the EU legislation. We are, however, unable to monetise these benefits, as we do not have any information whether or not the EU legislation is likely to be amended in the future, or the associated number of changes (if any). Enforcement authorities may also benefit from simplification of the contaminants legislation, as a result of consolidation.

Costs

55. Option 2 - Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulation (EU) No. 610/2012 and implement the new nitrate limits in leafy vegetables.

Costs to Industry

One-off Familiarisation Costs

56. There will be a one-off cost to businesses for reading and familiarising themselves with the provisions of the Nitrate Regulation. We have assumed that one official per business will invest 45 minutes reading and familiarising themselves with the Nitrate Regulation. In addition, we have estimated that each official uses a further 45 minutes for dissemination to key staff within the organisation, meaning a total of one hour and 30 minutes per business for familiarisation and dissemination.

57. Familiarisation costs are quantified by multiplying the wage rate of the official carrying out the familiarisation by the number of hours required (1.5). We assume that familiarisation is the responsibility of the production manager. The median hourly wage rate of a production manager is £26.10, generating a total cost of familiarisation per business of £39.15. Multiplying the total cost of familiarisation per business by the total number of businesses affected (See Table 9) generates a total cost of familiarisation to Scottish industry of £28,975, see Table 1 below.

Table 1: Familiarisation Costs to UK Industry, by UK Country and Firm Size

	Micro	Small	Medium	Large	Total
England	493,048	48,988	8,458	1,410	551,904
Wales	12,943	1,286	222	37	14,488
Scotland	25,885	2,572	444	74	28,975
NI	15,916	1,581	273	46	17,816
UK	547,792	54,427	9,397	1,566	613,183

Equivalent Annual Costs (EAC)

58. In order for 'one-off' familiarisation costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula. Under Standard HMT Green book guidance a discount rate of 3.5% is used.
59. The total one off cost to UK industry of the Regulation is an estimated £613,183 (see Table 6). This yields an EAC of approximately £71,237 in the UK over 10 years. Table 2 displays the breakdown of the EAC by country.

Table 2: Equivalent Annual Costs of Familiarisation to UK Industry, by UK Country

	England	Wales	Scotland	NI	UK
EAC	64,118	1,683	3,366	2,070	71,237

Costs to Enforcement AuthoritiesOne-off Familiarisation Costs

60. As with industry, there will be a small one-off cost to enforcement authorities for reading and familiarising themselves with the provisions of the two EU Regulations. The enforcement of food law is devolved to the enforcement authorities. In some cases this is divided between the Environmental Health Departments and the Trading Standards Departments. In some instances these two departments of the different levels in local government liaise closely and deal with issues in common to make it easier for consumers and businesses.
61. Each food authority in its area is responsible for enforcing the legislation with respect to food safety and food hygiene. It has responsibility for enforcing the contaminants in food legislation and will, as outlined above, be affected by these proposals.
62. It is expected that one Environmental Health Officer (EHO) or one Trading Standards Officer (TSO) from each LA will read the Nitrate Regulation and disseminate the information to key staff. We estimate that each enforcement officer will invest 45 minutes reading and familiarising themselves with the Nitrate Regulation and 45 minutes for Regulation 610/2012 and a further 45 minutes disseminating to key staff in the organisation; meaning a total of 2.25 hours for familiarising.

63. Familiarisation costs are monetised by multiplying the wage rate of the official responsible for familiarisation with the number of hours required for familiarisation. The median hourly wage rate of an EHO is £20.46, whilst the median hourly wage rate of a TSO is £21.01. Using the EHO wage rate as a lower bound estimate and the TSO wage rate as an upper estimate, we can calculate a central estimate of the per hour wage cost of £20.74. Multiplying the central estimate by the number of hours required (2.25) results in a total cost per enforcement authority of £46.65. Multiplying this figure with the total number of enforcement authorities in Scotland results in a total familiarisation cost to Scottish enforcement of £1,493, see Table 3 below. (Note that all presented figures are rounded.)

Table 3: Familiarisation Costs to UK Enforcement, by UK Country

	England	Wales	Scotland	NI	UK
LAs & PHAs	16,515	1,073	1,493	1,213	20,294

Equivalent Annual Costs (EAC)

64. In order for 'one-off' familiarisation costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula (see paragraph 50 above). The total one off cost to UK enforcement of the Regulation is an estimated £20,294 (see Table 4). This yields an EAC of approximately £173 in Scotland over 10 years. Across the UK the EAC is £2,358 which per country equates to £1,919 in England, £125 in Wales, and £141 in Northern Ireland. Table 5 displays the breakdown of the EAC per country.

Table 4: Equivalent Annual Costs of Familiarisation to UK Enforcement, by UK Country

	England	Wales	Scotland	NI	UK
EAC	1,919	125	173	141	2,358

65. Table 6 summarise costs under Option 2. Note is that this option also has benefits in terms of simplification, that we have been unable to monetise. The present value of the total cost of Option 2 is £633,477, calculated over a period of ten years.

Sampling and Analysis Costs

66. We do not envisage any additional costs for sampling and analysis as a result of the Nitrate Regulation; sampling and analysis is already in place for spinach and lettuce. For rocket, we envisage that the additional cost of sample collection and analysis will be negligible, as it can be carried out in parallel with the monitoring and enforcement of other leafy vegetables.

67. There may also be additional costs associated with testing foodstuffs for coccidiostats and histomonostats to determine the presence of residues for these substances. However, the FSA believes that these are likely to be minimal. There may also be some costs to businesses from complying with the new maximum limits, for example, additional cleaning required between production runs.

68. There are 32 local authorities in Scotland with responsibility for the enforcement of food legislation. Across the UK, there are 435 authorities including Local Authorities (LAs) and Port Health Authorities (PHAs), this includes 354 authorities in England; 23

in Wales, 32 in Scotland; and 26 authorities in Northern Ireland, as shown in Table 5 below.

69. Impact on other Government Bodies

70. Government departments such as the FSA could be affected as and when they carry out any surveys on foods. This impact could involve having to carry out more research on chemical contaminants in food, for determining such contamination to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure to harmful contaminants in food. We do not, however, envisage any additional food surveys taking place as a direct result of the Nitrate Regulation.

71. Member States are also required to monitor nitrate levels in vegetables which may contain significant levels, in particular green leafy vegetables, and communicate the result to EFSA on a regular basis, as required by the Nitrate Regulation. The requirement to monitor nitrate levels in vegetables is not new, it is an existing requirement under Article 9 of Regulation (EC) No 1881/2006; which requires Member States to monitor nitrate levels in vegetables that may contain significant levels, in particular green leafy vegetables and the results to be communicated to the Commission by the end of June each year. The only change from introducing the nitrate Regulation is the addition of rocket for nitrate limits. We envisage that this additional cost will be negligible, as this could be carried out in parallel with the existing reporting on other leafy vegetables.

Table 5: Enforcement Authorities Affected by UK Country

	England	Wales	Scotland	NI	UK
LAs & PHAs	354	23	32	26	435

72. Option 3 - As Option 2 but in addition, make ambulatory provisions in the domestic Regulations to include the Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. It extends the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on erucic acid and revokes the mineral hydrocarbons in food legislation.

Costs to Industry

73. There will be a one-off cost to industry from reading and familiarising themselves with the new limits. As the only difference between Option 2 and 3 is the ambulatory provisions, which do not have any impact on businesses, the familiarisation costs to businesses will be the same under Option 3 as under Option 2 (see Tables 6 & 7).

Costs to Enforcement Authorities

74. There will be a one-off cost to enforcement authorities from reading and familiarising themselves with the new limits. The only difference between Option 2 and 3 are the ambulatory provisions, which have no impact on enforcement authorities. Familiarisation costs to enforcement authorities will therefore be the same under Option 3 as under Option 2 (see Table 6 & 7).

75. The FSA considers that the impact on both enforcement authorities and industry from the proposed revocation of the Mineral Hydrocarbons Regulations and the revocation, remake and consolidation of the Erucic Acid Regulations is likely to be negligible.

76. Table 7 summarise costs under Option 3. Note is that this option also has benefits in terms of simplification, that we have been unable to monetise. The present value of the total cost of Option 3 is £633,477, calculated over a period of ten years.

Table 6: Summary of all Costs under Option 2 (£)

	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC	PV
Business	613,183	0	0	0	0	0	0	0	0	0	613,183	71,237	613,183
Enforcement	20,294	0	0	0	0	0	0	0	0	0	20,294	2,358	20,294
Total	633,477	0	0	0	0	0	0	0	0	0	633,477	73,594	633,477

Table 7: Summary of all Costs under Option 3 (£)

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC	PV
Business	613,183	0	0	0	0	0	0	0	0	0	613,183	71,237	613,183
Enforcement	20,294	0	0	0	0	0	0	0	0	0	20,294	2,358	20,294
Total	633,477	0	0	0	0	0	0	0	0	0	633,477	73,594	633,477

Scottish Firms Impact Test

Industry

Primary Producers

77. The new Regulations impact on any FBO, including primary producers, which place on the market products covered by the new Nitrate Regulation, i.e. rocket, spinach and lettuce. All these will have to ensure compliance with the new or revised limits for nitrate, and will therefore need to be familiar with these limits.

78. For rocket producers, the Nitrate Regulation introduces new limits, and these producers will therefore incur a cost of familiarisation. For spinach and lettuce producers, maximum limits already exist, but will be relaxed under the Nitrate Regulation. Producers in this sector are already aware of existing limits as well as the changes to these limits; we therefore envisage that familiarisation costs to lettuce and spinach producers will be minimal.

79. We do not envisage any other costs than familiarisation to primary producers.

Retail and Wholesalers

80. Retailers and wholesalers that sell leafy vegetables will need to be aware of the new or revised limits, and we therefore envisage a small familiarisation cost to these sectors.

Importers

81. Consultation with stakeholders suggested that there could be an impact on importers of rocket as a result of the Nitrate Regulation, due to the seasonal characteristics of the product. As a result of the new limits, importers may have to increase their imports from other Member States. Stakeholders were however unable to quantify or provide any detailed information on the likely costs associated with any additional imports. We envisage small familiarisation costs to these businesses.

Feed Manufacturers

82. Regulation 610/2012 also introduces new limits for the presence of coccidiostats and histomonostats in food resulting from the carry-over of these substances to non-targeted feed. For these businesses we envisage a small familiarisation cost and possibly a cost for sampling and analysis.

83. In order to identify the businesses affected we have used the 2012 Standard Industrial Classification (SIC) codes taken from the Office for National Statistics (ONS) Interdepartmental Business Register (IDBR).¹⁵ Table 8 below summarises those sectors that are likely to be affected by the Regulation.

Table 8: Type of Businesses Affected

Nitrate Regulation			
SIC Code	Type of Business	Includes	Impact
01.13	Growers of vegetables and melons, roots and tubers	Growing, including import, of leafy vegetables such as spinach, lettuce	Familiarisation
10.39	Other processing and preserving of fruit and vegetables	Manufacture, including import, of perishable vegetables such as packaged salads	Familiarisation
46.31	Wholesale of fruit and vegetables	Wholesale of fresh vegetables	Familiarisation
47.21	Retail of fruit and vegetables in specialised stores	Retail sale of fresh vegetables	Familiarisation
Regulation on Coccidiostats and Histomonostats			
SIC Code	Type of Business	Includes	Impact
10.91	Manufacturers of prepared feeds for farm animals		Familiarisation

The above table sets out the businesses that we have identified as being affected by each of the options in the Impact Assessment.

¹⁵ <http://www.ons.gov.uk/ons/rel/bus-register/uk-business/2012/rft-uk-business-2012.xls>

84. Using the IDBR, we estimate that there are approximately 15,660 businesses in the above sectors that are affected by the Regulation in the UK. Table 9 below shows the number of businesses affected by Employment Size and UK country.

Table 9: Businesses Affected by Employment Size and UK Country

	Micro	Small	Medium	Large	Total
England	12,592	1,251	216	36	14,095
Wales	331	33	6	1	370
Scotland	661	66	11	2	740
NI	406	40	7	1	455
UK	13,990	1,390	240	40	15,660

Competition Assessment

85. We have fully considered the questions posed in the Office of Fair Trading competition assessment test¹⁶ and have concluded that maximum limits for nitrate in foodstuffs contained in the Nitrate Regulation and Regulation 610/2012 are unlikely to hinder the range or number of businesses or the ability for operators to compete. The proposals contained in this IA are unlikely to significantly affect competition. The proposals do not contain a strong competition element or any significant new or additional burden. This is not expected to result in any reduction or change in businesses operating in this area, nor in their competitiveness or incentive to compete.

86. Although there is no current requirement for industry to carry out sampling and analysis in accordance with EU methods referred to in Commission Regulation 1881/2006, businesses may wish to do so (and may already be doing so) when carrying out their existing programme of checks. This is applicable to all food businesses operating in the import, production, processing, storage, distribution and sale of food and in this respect is not likely to have a disproportionate effect on any business or group of businesses. The EU Regulations are binding in their entirety after 20 days following publication on EU Member States and the businesses that trade within them.

Small Firms

87. Stakeholders including those that are members of trade associations have been consulted throughout the negotiations on the legislation. This has been done via interested parties letters and formal meetings with FSA colleagues. These identified that the majority of businesses likely to be affected by the proposed legislation are micro businesses which is reflected in the Impact Assessment. The discussions with small businesses did not identify any additional costs to them at the levels proposed. However, small businesses and their trade associations are encouraged to put forward their views throughout the consultation procedure and we very much welcome representation from them and their representative organisations.

88. All but the Mineral Hydrocarbons Regulations revocation are technical amendments of EU legislation and the domestic regulations relate to enforcement measures which remain as before therefore specific face-to-face meetings were not held. Feedback from the salad grower industry stakeholder meetings on nitrates in January and October 2011 was provided to the European Commission to inform the legislative process. Re the domestic Mineral Hydrocarbons Regulations, again face-to-face

¹⁶ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf

meetings were not held as this is a removal of redundant legislation which simplifies domestic food contaminants regulations.

Test run of business forms

89. No new or additional forms will be introduced by this proposal therefore no test run need be completed.

Legal Aid Impact Test

90. These Regulations will not introduce new criminal sanctions or civil penalties therefore there are no legal aid implications.

Enforcement, sanctions and monitoring

Enforcement

91. The new maximum limits for nitrate in spinach, lettuce and rocket, are enforceable under existing 2010 Regulations, and will be carried forward unchanged into the proposed 2013 Regulations, thus providing for the continuity of enforcement by Local Authority Environmental Health Departments.

Sanctions

92. No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

Monitoring

93. The effectiveness and impact of the Regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. FSA mechanisms for monitoring and review include open fora, stakeholder meetings, surveys and general enquiries.

Implementation and delivery plan

94. The publication of the Contaminants in Food (Scotland) Regulations 2013 will be communicated to stakeholders by Interested Party letter and Monthly Enforcement Report.

Post-implementation Review

95. The FSA is required to carry out a review every five years on the way in which EU legislation for which the FSA has enforcement oversight is implemented and enforced. This review period begins when the proposed Regulations that are the subject of this Impact Assessment come into force. In carrying out the review, the FSA is required to produce a report that will assess whether the Regulations achieved their intended objectives. The report will also assess if these objectives could be achieved by means that impose less Regulation.

Summary and recommendation

96. The FSA recommends Option 3, to revoke & replace the Contaminants in Food (Scotland) Regulations 2010 with the Contaminants in Food (Scotland) Regulations 2013 to provide for the enforcement of Regulations 1881/2006 and 124/2009 and extend ambulatory references for these regulations

97. Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those, elsewhere in Food Law.

98. Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to trade with all Member States.

Table 10: Summary Costs and Benefits

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social - Policy and Administrative
Do Nothing – Do not implement the new nitrate limits in leafy vegetables, or set maximum levels set for coccidiostats and histomonostats in food	No benefits identified.	Risk of infraction proceedings for failure to implement EU Regulations Detrimental effect on the health of consumers from food contaminants
Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulation (EU) No. 610/2012 on maximum levels set for coccidiostats and histomonostats in food and implement the new nitrate limits in leafy vegetables	Allows Scottish Government to meet its EU obligations. Protects the health of consumers Provides enforcement authorities with necessary powers Harmonises standards across Member States & removes barriers to trade	Minimal cost of familiarisation with new regulations Possible additional cost of testing for nitrate levels in rocket and for testing foodstuffs for coccidiostats and histomonostats residues
As Option 2 but in addition, make ambulatory provisions in the domestic Regulations to include the Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. It extends the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on erucic acid and revokes the mineral hydrocarbons in food legislation	Allows Scottish Government to meet its EU obligations. Protects the health of consumers Provides enforcement authorities with necessary powers Harmonises standards across Member States & removes barriers to trade Simplifies food contaminants legislation into one instrument and makes provision for future updates by ambulatory reference	Minimal cost of familiarisation with new regulations Possible additional cost of testing for nitrate levels in rocket and for testing foodstuffs for coccidiostats and histomonostats residues

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that the business impact has been assessed with the support of business in Scotland.

Minister's signature

Minister's title

Date

Contact point

Dr Will Munro
Food Safety Monitoring & Policy Branch
Food Standards Agency in Scotland
6th floor, St Magnus House,
25 Guild Street,
Aberdeen,
AB11 6NJ

Tel: 01224 285161
e-mail: will.munro@foodstandards.gsi.gov.uk

Annex

Nitrate

1. Nitrate is a naturally occurring compound present in vegetables, the consumption of which can contribute significantly to nitrate dietary exposure. Some vegetables, particularly leafy vegetables such as lettuce and spinach, have been shown to have relatively high levels of nitrate which are increased when grown under cover (e.g. in glass houses) and/or in conditions of reduced lighting.
2. EFSA has published two evaluations of the risks of nitrate in food. Excessive intake of nitrate could result in methaemaglobinaemia, especially in infants. This is relevant as pureed spinach is used in home prepared infant foods. In addition at very high levels of intake there is concern that nitrate could result in formation of carcinogenic nitrosamines.
3. Based on the available data on nitrate in foods available in the EU, EFSA concluded that the estimated exposures to nitrate from vegetables are unlikely to result in appreciable health risks, therefore the recognised beneficial effects of consumption of vegetables prevail. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission to perform a scientific risk assessment on nitrate in vegetables is published in [The EFSA Journal \(2008\), 689, pp 1-79](#).
4. In specifically considering the risks to infants and young children, EFSA concluded that concentrations of nitrate in lettuce are not a health concern, but that the concentrations of nitrate in spinach have the potential to increase dietary nitrate exposure to levels at which a health concern cannot be excluded. Increasing the maximum level by 500 mg/kg would be more health protective than the situation of local derogations from the maximum levels.
5. EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on possible health risks for infants and young children from the presence of nitrates in leafy vegetables. [EFSA Journal \(2010\) 8\(12\), 1935 pp1-42](#).

Coccidiostats and histomonostats

6. EFSA has published a number of opinions on coccidiostats and histomonostats in food as the result of unavoidable carry-over of these substances into feed for non-target animals.
7. These substances are authorised for use as feed additives for specific (target) animals species. It is generally acknowledged that under practical conditions during the production of mixed feeds, a certain percentage of a feed batch remains in the production circuit and these residual amounts can carry over into the subsequent feed batches. This carry-over may result in the exposure of non-target animal species, and hence in potential health risks for non-target animal species as well as potential residues in foods derived from these non-target animal species.
8. EFSA opinions take into account the uncertainty arising from the fact that studies in non-target animals are often not available, and that a high level of carry-over in the feed mill would not be expected to be a regular event. EFSA did not identify a risk to public health from eating products of animal origin containing residues of these substances arising from unavoidable carry-over. EFSA conclusions on the substances mentioned in the Commission Regulations are reproduced below:

Lasalocid

9. “Given the fact that exposure to lasalocid residues resulting from cross-contamination of feed is likely to be rare, the CONTAM Panel concluded that adverse health effects in consumers resulting from exposure to lasalocid residues in products from animals exposed to feed cross-contaminated even up to a level of 10%, is unlikely.”
10. Source: Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on Cross-contamination of non-target feedingstuffs by lasalocid authorised for use as a feed additive, [The EFSA Journal \(2007\) 553, pp1-46](#).

Maduramicin

11. “the very limited data provided no indication of an appreciable risk to consumers’ health from the ingestion of maduramicin residues in products from animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum authorised level”
12. Source: Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by maduramicin authorised for use as a feed additive, [The EFSA Journal \(2008\) 594, pp1-30](#).

Nicarbazin

13. “there is no indication of an appreciable risk to consumers’ health from the ingestion of nicarbazin residues in products from animals exposed to cross-contaminated feed up to a hypothetical level of 10% of the maximum authorised level.”
14. Source: Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by nicarbazin authorised for use as a feed additive, [The EFSA Journal \(2008\) 690, pp1-34](#).

Diclazuril

15. “the limited dataset provides no indication of an appreciable risk to consumers’ health from the ingestion of diclazuril residues in products from animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum authorised level for diclazuril in target animal species.”
16. Source: Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by diclazuril authorised for use as a feed additive, [The EFSA Journal \(2008\) 716, pp1-31](#).