FOOD STANDARDS AGENCY CONSULTATION
THE CONTAMINANTS IN FOOD (SCOTLAND) REGULATIONS 2013
CONSULTATION SUMMARY PAGE

Date consultation launched: 28 Feb 2013
Closing date for responses: 23 May 2013

Who will this consultation be of most interest to?
Manufacturers and food business operators involved in the placing on the market of foods, including importers, distributors, wholesalers and retailers, plus enforcement bodies and consumer organisations.

What is the subject of this consultation?
The proposed Contaminants in Food (Scotland) Regulations 2013 will revoke the Contaminants in Food (Scotland) Regulations 2010 and remake them with necessary amendments taking into account the following European regulations:
- Commission Regulation (EU) No 1258/2011, amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrate in foodstuffs,
- Commission Regulation (EU) No 610/2012 amending Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed,
The proposed Contaminants in Food (Scotland) Regulations 2013 will provide for the execution and enforcement of (EU) No 610/2012 and also introduce ambulatory reference provisions to include the Articles of (EC) 1881/2006 (previously only the Annex was included) and the Articles and Annex of (EC) No 124/2009.
The proposed Contaminants in Food (Scotland) Regulations 2013 will also revoke domestic legislation on mineral hydrocarbons in food; and revoke and remake the Erucic Acid in Food (Scotland) Regulations 1977 as amended. The proposed changes to provisions in European legislation and in domestic legislation controlling erucic acid will be consolidated into a single set of contaminants in food regulations.

What is the purpose of this consultation?
To provide interested parties with the opportunity to comment and express their opinion on the proposed Contaminants in Food (Scotland) Regulations 2013, the revocation of the Mineral Hydrocarbons in Food (Scotland) Regulations 1966 and the revocation and remake of the Erucic Acid in Food (Scotland) Regulations 1977 and the associated Business and Regulatory Impact Assessment.

Responses to this consultation should be sent to:
Will Munro
Food Safety Monitoring & Policy
FOOD STANDARDS AGENCY in SCOTLAND
Tel: 01224-285161
Fax: 01224-285168
Postal address: 6th Floor, St Magnus House, 25 Guild Street Aberdeen AB11 6NJ Email:will.munro@foodstandards.gsi.gov.uk

Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation? Yes ☒ No ☐ See Annex A for reason.

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.
THE CONTAMINANTS IN FOOD (SCOTLAND) REGULATIONS 2013

DETAILED OF CONSULTATION

1. We would welcome your comments on the proposed Contaminants in Food (Scotland) Regulations 2013 (“the Contaminants Regulations”) attached as Annex B. The Contaminants Regulations will revoke The Contaminants in Food (Scotland) Regulations 2010¹ and remake them with necessary amendments to provide for the enforcement of Commission Regulations 650/2012 and 1258/2011. The Contaminants Regulations will also:

   • introduce the use of ambulatory references for the purposes of Commission Regulation 124/2009 and the Articles of Regulation 1881/2006, as the ambulatory reference provision in the current Contaminants in Food (Scotland) Regulations 2010 applies only to the Annex to Commission Regulation 1881/2006. Ambulatory references will also be extended to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on erucic acid;

   • revoke the Mineral Hydrocarbons in Food (Scotland) Regulations 1966² (which are purely national and not EU-derived) and revoke and remake, with amendments, the Erucic Acid in Food (Scotland) Regulations 1977 as amended³, thus consolidating the changes into the Contaminants Regulations, creating a single, new Scottish Statutory Instrument;

2. We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from these proposals as indicated in the Business and Regulatory Impact Assessment (BRIA) at Annex C. Details of changes to the national legislation are discussed below.

3. Similar consultations will be carried out on parallel regulations in England, Wales and Northern Ireland by their respective Food Standards Agency (FSA) offices.

Background

Nitrate in food

4. Many investigations have been carried out since the initial application of European Union (EU) maximum levels of nitrate in lettuce and spinach in 1997, on the factors involved in the presence of nitrate in these foods and on the measures taken to reduce the presence of nitrate. However, despite the progress achieved in good agricultural practice to reduce the presence of nitrate, it has not been possible to consistently achieve levels below the current maximum levels of nitrate in lettuce and fresh spinach in various regions of the EU. This is primarily as the result of the climate and in particular the light conditions which are a determining factor in the presence of nitrate in spinach and lettuce, and which cannot be managed or changed by the producer.

5. 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 vegetables⁴. The Panel compared the risk and benefits of exposure to nitrate from vegetables. They found that estimated exposure to nitrate from vegetables is unlikely to result in appreciable health risks; accordingly, these are considered to be outweighed by the recognised beneficial effects of consumption of vegetables. However, the Panel did recognise that there are occasional circumstances (e.g. unfavourable local/home production conditions) for

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¹ SSI 2010 No. 329
² S.I. 1966 No.1263
³ S.I. 1977 No. 1028; as amended by S.I. 1982 No. 18
vegetables which constitute a large part of the diet, or individuals with a diet high in vegetables such as rocket, which may need to be assessed on a case-by-case basis. Following the publication of this opinion, the Commission discussed the impact with Member States and agreed that achievable maximum levels for these foods should be set.

Coccidiostats and histomonostats in food

6. Coccidiostats and histomonostats are veterinary medicines authorised for use in animal feeds. The Veterinary Medicines Directorate (VMD) normally lead on any regulatory issues, such as maximum residue limits (MRLs) in formulated feeds and the resulting limits in food. Because of the Commission’s concern about the possible carry-over into batches of feed that are not intentionally formulated with coccidiostats or histomonostats they have felt it necessary to introduce legislation limiting the permissible amount of coccidiostats and histomonostats carried-over into feed, leading to a reduction in the resulting residue in food of non-target animals.

7. The unavoidable carry-over in non-target feed of active substances consisting of authorised coccidiostats and histomonostats are considered as undesirable substances in animal feed within the meaning of Directive 2002/32/EC and their presence should not endanger animal health, human health or the environment. Therefore, maximum levels of these substances in animal feed are established by a Commission Directive amending Annex I to Directive 2002/32/EC.

National regulations being revoked

8. The Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (“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 (except in the case of four specified exemptions) the use of any mineral hydrocarbons in the composition or preparation of food 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.

9. In addition, the Mineral Hydrocarbons Regulations specify which mineral hydrocarbons can be used and includes the specifications for each of them.

10. 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 presence of residues of mineral hydrocarbons which could be tolerated by EU contaminants legislation.

11. The FSA has consulted with major trade associations about the current uses of mineral hydrocarbons, and has taken note of the 2012 opinion of the European Food Safety Authority (EFSA) on mineral oils.

12. We have considered a number of options for amending/updating the Mineral Hydrocarbons Regulations, taking account of the EFSA opinion. 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

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to intakes of mineral oils. There is also little use of these substances for other processing aid functions. In the light of this evidence that mineral hydrocarbons are currently little used in food, the FSA considers that the Mineral Hydrocarbons Regulations no longer serve any practical function; in our view an equivalent level of public health protection is achieved by the existing legislative controls on mineral hydrocarbons in EU legislation on food additives and contaminants, and by Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 ("the General Food Law"). The latter prohibits the sale or supply of unsafe food, which would apply when mineral hydrocarbons are used in food for other purposes e.g. as processing aids.

13. For enforcement purposes, once the Mineral Hydrocarbons Regulations are revoked Article 14 of General Food Law would apply if there were any concerns to 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. There is thus unlikely to be a risk to consumer safety from revoking these Regulations.

14. The revocation of the Mineral Hydrocarbons Regulations is considered by the FSA to be beneficial in terms of removal of redundant and out-of-date legislation and non-controversial in terms of food safety.

15. We are therefore recommending that the Mineral Hydrocarbons Regulations be revoked.

16. We also intend to revoke and remake the Erucic Acid in Food (Scotland) Regulations 1977 as amended by The Erucic Acid in Food (Scotland) Amendment Regulations 1982. ("the Erucic Acid Regulations") which implement Directive 76/621/EEC.

17. Council Directive 76/621/EEC as amended, relate 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 Member States at their discretion 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 controls on placing on the market for consumption by the final consumer will be maintained in the proposed Contaminants Regulations. The exemption from controls for consignments and deliveries to manufacturers for the purposes of a manufacturing business or to a caterer for their business will also be maintained. 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.

18. Council Directive 76/621/EEC (and read with Directive 80/891 method of analysis for determining Erucic acid levels) prescribes the levels of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats). The 1977 Regulations were amended by The Erucic Acid in Food (Scotland) Amendment Regulations 1982.

19. The 1977 Regulations as amended 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. Ambulatory references to changes to the two EC Directives are included in the proposed Contaminants Regulations.

20. There will be some textual changes to way in which the Directives mentioned above are implemented in the proposed Contaminants Regulations as compared with the Erucic Acid Regulations, to reflect changes in drafting practices.

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7 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.
Impact on businesses and enforcement bodies as a result of the revocation and consolidation of national regulations on mineral hydrocarbons and erucic acid in food

21. 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 is likely to be negligible.

European Union legislation on contaminants in food

22. European Union (EU) legislation on contaminants in food is made under the framework Regulation, Council Regulation 315/93/EEC. This Regulation lays down the EU procedures for dealing with contaminants in food and applies general requirements to those contaminants that not covered by other specific EU legislation. In order to continue reducing the disparities between existing laws of Member States in regard to maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulations (EC) No’s 124/2009 and 1881/2006⁸ were introduced under Regulation 315/93/EEC to protect public health and to ensure market unity while complying with the principle 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.

Maximum levels for nitrate in food

23. Commission Regulation No. 1881/2006 sets maximum levels for nitrate in leafy vegetables, however in some cases, despite developments in good agricultural practices, the maximum levels are exceeded. This resulted in a temporary derogation being granted to certain Member States due to their respective climates, for placing on the market certain leafy vegetables, grown and intended for human consumption in their territory with nitrate levels higher than the established maximum levels.

24. In view of the requirement to protect consumer health by keeping contaminants within limits that are toxicologically acceptable, the Commission investigates whether limits should be set for additional contaminants and reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Scientific data has shown that a reduction in dietary exposure to nitrate can be achieved by setting maximum levels for highly contaminated foods such as certain leafy vegetables reaching the market.

25. Commission Regulation (EU) No. 1258/2011 (“the Nitrate Regulation⁹”) was published in the Official Journal (OJ) on 3rd December 2011 and it came into force on 23rd December 2011 and is directly applicable throughout the EU. The Nitrate Regulation sets higher, more achievable levels then those initially set for lettuce and spinach across the EU. For the first time it also sets maximum levels for rocket, where a risk has been identified. A copy of the Nitrate Regulation is attached as Annex D and is also available to download free of charge from the EUR-Lex website at:


Industry reaction to the Nitrate Regulation

26. Following a meeting with stakeholders in January 2011, the FSA recognised the ability of industry to comply with the proposed limits was problematic. Consequently, the FSA conducted a risk assessment on whether the limits could be increased without creating a food safety risk for consumers. The assessment, which included data provided by the industry, was submitted to the Commission and had good support from other Member States. This resulted in increased potential limits for rocket grown in the summer and

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⁹ Ref OJ L 320, 3.12.2011
winter being agreed at the Standing Committee on the Food Chain and Animal Health (SCoFCAH). Stakeholders were also informed that the Nitrate Regulation included a requirement to continue monitoring for nitrate in all EU Member States.

27. A further meeting with stakeholders was held on 26\textsuperscript{th} 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 setting nitrate levels achievable by industry. Further explanation was given on the EFSA opinion previously published on exposure from nitrate. This found high levels in rocket, which is reflected in the maximum limits set in the Nitrate Regulation. Stakeholders were also asked to provide information on the likely impact(s), including costs and benefits to assist in the development of the Impact Assessment.

28. At the meeting, stakeholders expressed a number of concerns, in particular on rocket imported to the UK in winter and concerns regarding the achievability of the new levels. The FSA informed stakeholders that this could be raised with the Commission with raw data as supporting evidence, although the options to make any changes were limited. The FSA also confirmed that enforcement action would not take place until the application date for rocket, which was 1\textsuperscript{st} April 2012.

Maximum levels of coccidiostats and histomonostats in food

29. Commission Regulation 124/2009, sets maximum levels for the presence of coccidiostats and histomonostats in food as the result of the unavoidable carry-over (also known as cross-contamination into non-target feed), with a view to ensure proper functioning of the internal market and for the protection of public health.

30. Regulation 610/2012\textsuperscript{10} was published in the OJ on 10\textsuperscript{th} July 2012 and is directly applicable throughout the EU and came into force on 30\textsuperscript{th} July 2012; the regulation amends the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril in the Annex to Commission Regulation 124/2009. A copy of Regulation 610/2012 is attached as Annex E, and is also available to download free of charge from the EUR-Lex website at:


Purpose of the Consultation

31. The purpose of this consultation is to provide interested parties with the opportunity to comment and express their opinion on the proposed Contaminants Regulations and the associated Business & Regulatory Impact Assessment (BRIA), including the proposal to introduce the use of ambulatory references for the purposes of Commission Regulation 124/2009 and the Articles of Regulation 1881/2006.

32. The proposed Contaminants Regulations 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 regulation and to take appropriate action where foodstuffs are found to be non-compliant. The Contaminants Regulations will revoke the Contaminants in Food (Scotland) Regulations 2010 and remake them with necessary amendments, taking into account the requirements of Regulation 610/2012.

33. The revised maximum limits for nitrate in spinach and lettuce and the new maximum levels for rocket set out in the amended Annex to Regulation 1881/2006 are already enforceable under the Contaminants in Food (Scotland) Regulations 2010 due to the effect of the ambulatory reference in those regulations. The Contaminants Regulations will give effect to the amendments made to the Articles of Regulation 1881/2006 made by the Nitrate Regulation and to any subsequent amendments.

\textsuperscript{10} Ref OJ L 178, 10.7.2012, p1
34. The proposed Contaminants Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (Scotland) Regulations 2010 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.

35. 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 for Food Business Operators (FBOs) and enforcement bodies/officers.

Ambulatory references

36. The proposed Contaminants Regulations continue to use ambulatory references. At present the ambulatory references in the 2010 Contaminants Regulations only apply to the Annexes of Commission Regulation 1881/2006. We are proposing to extend the ambulatory references to include both Articles as well as Annexes of Regulation 1881/2006, 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 are 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.

Proposals

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<tr>
<th>Key proposals:</th>
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<tr>
<td>To revoke the Contaminants in Food (Scotland) Regulations 2010 and remake them with necessary amendments, taking into account the provisions of the two new European Regulations;</td>
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<tr>
<td>To revoke the Mineral Hydrocarbons in Food (Scotland) Regulations 1966;</td>
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<tr>
<td>To revoke and remake the Erucic Acid in Food (Scotland) Regulations 1977 (as amended, thus consolidating these provisions into the proposed Contaminants Regulations;</td>
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<tr>
<td>To provide for the execution and enforcement of Regulation 610/2012 by enforcement authorities in Scotland; and</td>
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<tr>
<td>To introduce ambulatory reference provisions to include Regulations 124/2009 and extend the existing provisions to some minor Articles in Commission Regulation 1881/2006 and Directives 76/621/EEC and 80/891/EEC.</td>
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Consultation Process

37. During the course of negotiations with the Commission, officials of the FSA have kept Scottish Government officials and other government departments informed of its progress. The UK position 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.

Informal Public Consultation

38. The FSA has consulted consistently with all its stakeholders, including industry trade bodies, enforcement authorities, consumer organisations, research laboratories and others with an interest in chemical contaminants legislation, during negotiations with the Commission and other Member States. This includes issuing several Interested Parties letters notifying stakeholders, which are available from the following link: [http://www.food.gov.uk/enforcement/regulation/](http://www.food.gov.uk/enforcement/regulation/)
39. 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.

40. Based on the comments received from stakeholders, various costs to business may arise as a result of seasonal imports, mainly during the winter months from other EU Member States (notably Spain, Italy and France). Stakeholders also commented that reference is required to the sampling methodology in any guidance issued and a clarification on the methodology of analysis, as there are differences in the techniques used by different laboratories, which will affect the results.

41. Stakeholders also commented on the possible adverse media reports, should samples be rejected due high nitrate levels, which could result in more customer/consumer concerns about the safety of fruit and vegetables.

42. This consultation is being conducted for a period of 12 weeks.

Consultation question 1
(a) Stakeholders are invited to comment on the proposal to revoke the Mineral Hydrocarbons Regulations,
(b) Stakeholders are also asked to comment on whether they agree that existing EU legislative controls are adequate to provide for consumer safety. In particular, is General Food Law adequate for this purpose where mineral hydrocarbons are used in food purposes such as processing aids.

Consultation question 2
(a) Stakeholders are asked to comment on the revocation and consolidation of the Erucic Acid Regulations by the proposed Contaminants Regulations and whether the proposed consolidation will make it easier for businesses and other stakeholders to find legislation that affects them.
(b) Stakeholders are also invited to give views on maintaining in the proposed Contaminants Regulations the exemption from controls on Erucic acid for consignments sold to food manufacturers and caterers.

Consultation question 3
Stakeholders are invited to comment on the assumption that there are unlikely to be any costs to business and enforcement bodies associated with the revocation of the Mineral Hydrocarbons and Erucic Acid Regulations.

Consultation Question 4
We would welcome comments on the introduction of ambulatory references to include Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs and the Articles and Annexes of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food and Directives 76/621/EEC and 80/891/EEC on Erucic acid.

Consultation question 5
Stakeholders are asked to comment on the inclusion of the direct enforcement of Article 5 of Regulation (EC) No. 1881/2006, which provides for the specific provisions on the labelling of groundnuts, derived products thereof and cereals.

Consultation question 6
Stakeholders are asked to comment, with supporting evidence, on the
assumption that it will take 1.5 hours to read and familiarise with the new Regulations is a sensible estimate for businesses.

Consultation question 7
(a). Stakeholders are asked to comment, with supporting evidence, on whether the assumption that it will take businesses 1.5 hours and enforcement authorities 2.25 hours to read and familiarise with the new Regulations is a sensible estimate.

(b). We would also welcome comments and estimates from enforcement bodies on enforcing the new EU legislation.

Consultation question 8
(a). It is our assumption that there are unlikely to be any additional costs for sampling and analysis as a result of the new limits for nitrate in spinach and lettuce.

(b). It is our assumption that any additional costs for sampling and analysis as a result of the new limits for nitrate in rocket will be negligible.

Consultation question 9
We would welcome your comments and supporting evidence in relation to the provisions of Regulation 610/2012 on the following:

(a). The impact of a test showing that levels are exceeded – the likely number of incidents, the cost of withdrawals and not placing the product on the market, the cost of investigation by the competent authority and other costs as appropriate.

(b). The cost of changes businesses and others would need to make to avoid exceeding the limits, e.g. cost of any additional cleaning between production runs, keeping foodstuffs separate.

Consultation question 10
(a). We would welcome comments from stakeholders on whether the costs and benefits set out above are an accurate representation of the costs and benefits to business and enforcement authorities.

(b) We would also welcome comments on the assumption that option 3 achieves all policy objectives and in addition it allows for ambulatory provisions to minimise costs to business and enforcement.

Consultation question 11
We welcome comments on whether the businesses identified adequately capture all those businesses that are likely to face impact. Specifically, are the sectors affected as displayed in the table an accurate representation.

Consultation question 12
Do you agree with our assumption that there will not be a significant impact on small businesses as a result of this legislation is a correct assumption.

Consultation Question 13
Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and national Regulations.

In all cases, please provide evidence to support your response.

43. We welcome your responses to the above questions and would be particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage
them to comment on all aspects of the proposal and its intended effect. Please provide evidence to support your views.

Other relevant documents
44. Commission Regulation (EC) No. 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-target feed is available from the EUR-Lex website at:
45. The Contaminants in Food (Scotland) Regulations 2010 are available on the ‘legislation.gov.uk’ website at:
46. The Mineral Hydrocarbons Regulations and the Erucic Acid Regulations are not available on the Legislation.gov.uk website and are therefore attached as Annexes F & G.

Responses
47. Responses are requested by close of business on 23 May 2013. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency in Scotland for participating in this public consultation.

Yours,

Will Munro
Dr Will Munro
Policy Adviser
Food Safety Monitoring & Policy Branch

Enclosed
Annex A: Standard Consultation Information
Annex B: The draft Contaminants in Food (Scotland) Regulations 2013
Annex C: partial Business & Regulatory Impact Assessment
Annex G: The Erucic Acid in Food (Scotland) Regulations 1977 (SI 1977 No. 1028)
   The Erucic Acid in Food (Scotland) Amendment Regulations 1982 (SI 1982 No.18)
Annex H: List of interested parties
Annex I: Consultation Feedback Questionnaire
Annex J: Data Protection Form
Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness, our office in St Magnus House in Aberdeen will hold a copy of the completed consultation. The FSA will also publish a summary of responses, which may include full name. Disclosure of any other personal data would be made only upon request for the full consultation response. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex H. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under ‘Other relevant documents’.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: http://www.berr.gov.uk/files/file47158.pdf The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.
Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees’ buy-in to the process is to be obtained.

Criterion 6 — Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 — Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Business & Regulatory Impact Assessment at Annex C.

10. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

12. If you would like to be included on future Food Standards - consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc. The questionnaire can also be used to update us about your existing contact details.
The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(1)(a), (c), (e) and (f), 17(1) and (2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990(a), paragraph 1A of Schedule 2 to the European Communities Act 1972(b) and all other powers enabling them to do so.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for references to an Article of or Annex to the EU instruments specified in regulation 2(3) to be construed as references to that Article or Annex as it may be amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990, they have had regard to relevant advice given by the Food Standards Agency.

There has been consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(c).

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(a) 1990 c. 16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

(b) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51) and amended by Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (2008 c.7).

PART 1
Introductory

Citation, extent and commencement

1. These Regulations may be cited as the Contaminants in Food (Scotland) Regulations 2013, extend to Scotland only and come into force on [...] October 2013.

Interpretation

2.—(1) In these Regulations —

“the Act” means the Food Safety Act 1990;

“Directive 76/621” means Council Directive 76/621/EEC 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 or fats(a);

“Directive 80/891” means Commission Directive 80/891/EEC relating to the Community method of analysis for determining the erucic acid content in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats(b);

“Regulation 1881/2006” means Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs(c);

“Regulation 629/2008” means Commission Regulation (EC) No. 629/2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs(d);

“Regulation 124/2009” means Commission Regulation (EC) No. 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-target feed(e);


“authorised officer” means any person who is authorised in writing, either generally or specifically, by a food authority to act in matters arising under these Regulations;

“food authority” has the meaning given by section 5(2) of the Act;

(2) Any other expression used in these Regulations and in Directive 76/621, Directive 80/891, Regulation 1881/2006 or Regulation 124/2009 has the same meaning in these Regulations as it bears in the Directive or Regulation concerned.

(3) [Any reference to an Article of or Annex to Directive 76/621, Directive 80/891, Regulation 1881/2006 or Regulation 124/2009 is a reference to that Article or Annex as it may be amended from time to time, and any reference to any of those Directives or Regulations is to be construed accordingly.]

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(b) OJ No. L254, 27.9.1980, p.35.
(f) OJ No. L50, 27.2.2010, p.8.
PART 2
Erucic acid in food

Scope

3.—(1) This Part applies to—
   (a) oils, fats and mixtures of the two which are intended as such for human consumption;
   (b) compound foodstuffs described directly or by implication as specially prepared for infants and young children, to which oils, fats or mixtures of the two have been added; and
   (c) compound foodstuffs other than those described directly or by implication as specially prepared for infants and young children, to which oils, fats or mixtures of the two have been added and the overall fat content of which exceeds 5%.

   (2) In paragraph (1) the expressions “infants” and “young children” have the meanings given to them in Article 2 of Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(a).

Controls on erucic acid

4.—(1) No person may place on the market, for consumption by the final consumer, a product to which this Part applies in which the level of erucic acid exceeds 5%, calculated on the total level of fatty acids in the fat component.

   (2) The level of erucic acid in a food is to be determined according to the methods of screening and analysis prescribed in Article 2 of and the Annex to Directive 80/891.

   (3) Any person who contravenes paragraph (1) is guilty of an offence.

PART 3
Contaminants in food

Controls on contaminants in food

5.—(1) Subject to the transitional arrangements contained in—
   (a) Article 11 of Regulation 1881/2006;
   (b) Article 2 of Regulation 629/2008; or
   (c) Article 2 of Regulation 165/2010,

   a person who contravenes or fails to comply with any of the EU provisions specified in paragraph (2) is guilty of an offence.

   (2) The EU provisions are—

      (a) Article 1(1) of Regulation 1881/2006 (prohibition on the placing on the market of foodstuffs containing contaminants in excess of prescribed limits contained in the Annex), as read with—

         (i) Article 1(2) (maximum levels applying to edible part of food unless otherwise specified in the Annex),

         (ii) Article 2 (provisions relating to the application of maximum levels to dried, diluted, processed and compound foodstuffs),

(iii) Article 4 (specific provisions for groundnuts, other oilseeds, tree nuts, dried fruit, rice and maize), and
(iv) the Annex;
(b) Article 3 of Regulation 1881/2006 (prohibitions on use, mixing and detoxification);
(c) Article 5 (specific labelling requirements for groundnuts, derived products thereof and cereals); and
(d) Article 1(1) of Regulation 124/2009 (prohibitions on marketing or mixing foods containing coccidiostats or histomonstats at levels in excess of prescribed limits).

PART 4
Administration and enforcement

Penalties

6. Anyone convicted of an offence under regulation 4(3) or regulation 5(1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Enforcement and competent authorities

7.—(1) It is the duty of each food authority within its area to execute and enforce these Regulations, Regulation 1881/2006 and Regulation 124/2009.
   (2) Each food authority within its area is the competent authority for the purposes of —
      (a) Article 2(2) of Regulation 1881/2006 (justification by food business operators of concentration or dilution factors); and
      (b) Article 1(1) of Regulation 124/2009 (relating to the duty to investigate the reasons for the contamination).

Application of various sections of the Food Safety Act 1990

8.—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations —
      (a) section 3 (presumptions that food intended for human consumption);
      (b) section 20 (offences due to fault of another person);
      (c) section 21 (defence of due diligence)(a) with the modification that—
         (i) subsections (2) to (4) shall apply in relation to an offence under regulation 3 as they apply in relation to an offence under section 14 or 15, and
         (ii) in subsection (4) the references to “sale” are deemed to include references to “placing on the market”;  
      (d) section 30(8) (which relates to documentary evidence);
      (e) section 33(1) (obstruction etc. of officers);
      (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (e);
      (g) section 35(1) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);

(a) Section 21 was amended by S.I. 2004/3279.
(h) section 35(2) and (3)(a), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);

(i) section 36 (offences by bodies corporate);

(j) section 36A (offences by Scottish partnerships)(b); and

(k) section 44 (protection of officers acting in good faith).

(2) Subject to paragraph (3), section 9 of the Act (inspection and seizure of suspected food) applies for the purposes of these Regulations as if it read as follows —

“9.—(1) An authorised officer of a food authority may at all reasonable times inspect any food intended for human consumption which has been placed on the market and subsections (2) to (7) below shall apply where, on such an inspection, it appears to the authorised officer that the placing on the market of any food fails to comply with any of the requirements specified in regulation 4(1) or 5(2) of the Contaminants in Food (Scotland) Regulations 2013, (“the EU requirements”).

(2) The authorised officer may either —

(a) give notice to the person in charge of the food that, until the notice is withdrawn, the food or any specified portion of it —

(i) is not to be used for human consumption, and

(ii) either is not to be removed or is to be removed to a place at which there are facilities to carry out sampling in the manner required by law; or

(b) seize the food and remove it in order to have it dealt with by a sheriff.

(3) Where the authorised officer exercises the power conferred by subsection (2)(a) above, that officer shall, as soon as is reasonably practicable and in any event within 21 days, determine whether or not the food complies with the EU requirements and —

(a) if satisfied that it does comply, shall forthwith withdraw the notice;

(b) if not so satisfied, shall seize the food and remove it in order to have it dealt with by a sheriff.

(4) Where an authorised officer exercises the powers conferred by subsection (2)(b) or (3)(b) above, the officer shall inform the person in charge of the food of the intention to have it dealt with by a sheriff and any person who in connection with any of the EU requirements might be liable to a prosecution in respect of the food shall, if that person attends before the sheriff by whom the food falls to be dealt with, be entitled to be heard and to call witnesses.

(5) If it appears to a sheriff, on the basis of such evidence as the sheriff considers appropriate in the circumstances, that any food falling to be dealt with under this section fails to comply with any of the EU requirements the sheriff shall condemn the food and order —

(a) the food to be destroyed or to be so disposed of as to prevent it from being used for human consumption; and

(b) any expenses reasonably incurred in connection with the destruction or disposal to be defrayed by the owner of the food.

(6) If a notice under subsection (2)(a) above is withdrawn, or the sheriff by whom any food falls to be dealt with under this section refuses to condemn it, the food authority shall compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

(7) Any disputed question as to the right to or the amount of any compensation payable under subsection (6) above shall be determined by a single arbiter appointed, failing agreement between the parties, by the sheriff.

(a) Section 35(3) was amended by S.I. 2004/3279.

(b) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.
(8) Any person who knowingly contravenes the requirements of a notice under subsection (2)(a) above shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.”

(3) The expressions “authorised officer” and “food authority” which are used in section 9 of the Act so far as it applies for the purposes of these Regulations by virtue of paragraph (2), shall, for those purposes, bear the meanings that those expressions respectively bear in these Regulations.

Consequential amendment

9. In Schedule 1 to the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013(a) (provisions to which those Regulations do not apply), for the entry relating to the Contaminants in Food (Scotland) Regulations 2010(b) substitute —

“The Contaminants in Food (Scotland) Regulations 2013 (to the extent that a sample falls to be prepared and analysed in accordance with Regulation 1881/2006 as that expression is defined in those Regulations)” S.S.I. 2013/----.”

Revocations

10. The Regulations specified in the Schedule are revoked.

St Andrew’s House
Edinburgh
2013

Authorised to sign by the Scottish Ministers

(a) S.I. 2013/XXXX.
(b) S.S.I. 2010/329.
SCHEDULE

Regulation 10

Revocations

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PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Contaminants in Food (Scotland) Regulations 2013

Date: 28 Feb 2013
Stage: Consultation
Source of intervention: EU/Scotland
Type of measure: Other
Contact for enquiries: Will Munro
01224-285161
will.munro@foodstandards.gsi.gov.uk
1. **Title of Proposal**

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

2. **Purpose and intended effect**

   **Objectives**

2.1. The presence or 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.

2.2. These proposals are designed to meet the following policy objectives:

   - 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.
   
   - 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.
   
   - 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**


3.1.1. Nitrate 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 highly contaminated foods such as certain leafy vegetables reaching the market.

3.1.2. 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 risk 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, 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).

3.1.3. EFSA has published two evaluations of the risks of nitrate in food. Excessive intake of nitrate could result in methaemoglobinemia\(^1\) 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 concern that nitrate could result in formation of carcinogenic nitrosamines.

3.1.4. Maximum levels for the presence of nitrate in lettuce and spinach already exist; however, these have been amended to take into account problems in some Member States 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.

3.1.5. Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs\(^2\) 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.

3.1.6. 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 (EU) on 3rd December 2011\(^3\). 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 attached to the consultation letter as Annex D and is also available to download free of charge from the following website:


3.2.1. Commission Regulation (EC) No. 124/2009\(^5\) of 10\(^{th}\) 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.

3.2.2. 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/EC\(^6\) of the European

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\(1\) 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.


\(3\) OJ L 320, 3.12.2011, p15

\(4\) OJ L 178, 10.7.2012, p1

\(5\) OJ L 40, 11.2.2009, p3

\(6\) OJ L 40, 30.5.2002, p10

3.2.3. 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-target animals. The 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.

3.2.4. For full details of the EFSA opinions on coccidiostats and histomonostats please see Annex.

3.2.5. 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 attached to the consultation letter as Annex E, and is also available to download free of charge from the following website:


Details of the national regulations being revoked

3.3. The Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (“the Mineral Hydrocarbons Regulations”)

3.3.1. 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 (except in the case of four specified exemptions) the use of any mineral hydrocarbons in the composition or preparation of food; 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.

3.3.2. In addition, the 1966 legislation specifies which mineral hydrocarbons can be used and includes the specifications for each of them.
3.3.3. 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.

3.3.4. The FSA has consulted with major trade associations about the current uses of mineral hydrocarbons, and has taken note of the recent opinion\(^7\) of the EFSA on mineral oils.

3.3.5. 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.

3.3.6. For enforcement purposes, once the Mineral Hydrocarbons Regulations are revoked Article 14 of General Food Law would apply if there were any concerns to 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.

3.3.7. 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.

**Consultation question 1**

(a) Stakeholders are invited to comment on the proposal to revoke the Mineral Hydrocarbons Regulations,

(b). Stakeholders are also asked to comment on whether they agree that existing EU legislative controls are adequate to provide for consumer safety. In particular, is General Food Law adequate for this purpose where mineral hydrocarbons are used in food purposes such as processing aids.

If you agree or disagree, please provide evidence to support your views.

3.4. The Erucic Acid in Food (Scotland)Regulations 1977\(^9\) as amended (“the Erucic Acid Regulations”)


\(^8\) 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
3.4.1. Council Directive 76/621/EEC\textsuperscript{10} 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 at 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 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.

3.4.2. Directive 76/621/EEC and Commission 80/891/EEC\textsuperscript{11} (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 807/2003\textsuperscript{12}. The Erucic Acid Regulations were amended by The Erucic Acid in Food (Scotland) Amendment Regulations 1982\textsuperscript{13}.

3.4.3. 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.

3.5. 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 1977 Erucic Acid Regulations.

3.6. 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.

3.7. 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.

\textsuperscript{10} OJ L 202, 28.7.1976, p 35  
\textsuperscript{11} OJ L 254, 27.9.1980, p 35  
\textsuperscript{12} OJ L 122, 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)  
\textsuperscript{13} SSI 1982 No. 18
Consultation question 2

(a). Stakeholders are asked to comment on the revocation and consolidation of the Erucic Acid Regulations by the proposed Contaminants Regulations and whether the proposed consolidation will make it easier for businesses and other stakeholders to find legislation that affects them.

(b). Stakeholders are also invited to give views on maintaining in the proposed Contaminants Regulations the exemption from controls on Erucic acid for consignments sold to food manufacturers and caterers.

If you agree or disagree with this proposal and the FSA's assessment on the lower limits for infants and children, please provide evidence to support your views.

Consultation question 3

Stakeholders are invited to comment on the assumption that there are unlikely to be any costs to business and enforcement bodies associated with the revocation of the Mineral Hydrocarbons and Erucic Acid Regulations.

If you agree or disagree, please provide evidence to support your views.

Rationale for Government intervention

Policy Background – Chemical Contaminants

4.1. 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 2013 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.

4.2. 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.

4.3. The proposed Contaminants Regulations continue to use ambulatory references. At present the ambulatory references in the current 2010 Contaminants Regulations only apply to the Annexes 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 SSI 2010 No.329
Consultation Question 4
We would welcome comments on the introduction of ambulatory references to include Articles of Regulation 1881/2006 regarding the maximum levels of nitrate in foodstuffs and the Articles and Annexes of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food and Directives 76/621/EEC and 80/891/EEC on Erucic acid.
If you disagree with this assessment, please provide evidence to support your views.

4.4. The proposed Contaminants Regulations will also make an amendment to the provisions contained in the current Contaminants Regulations in order to rectify an under enforcement of EC Regulations 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.

4.5. A failure to comply with the labelling provisions in Article 5 is being included among the offences in the proposed 2013 Regulations; this will provide clarity for both Food Business Operators (FBOs) and enforcement bodies/officers.

Consultation question 5
Stakeholders are asked to comment on the inclusion of the direct enforcement of Article 5 of Regulation (EC) No. 1881/2006, which provides for the specific provisions on the labelling of groundnuts, derived products thereof and cereals.
If you agree or disagree, please provide evidence to support your views.

4.6. 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 in 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.

4.7. 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 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.

4.8. 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”.


Industry Initiatives – Nitrate in Vegetables

4.10. 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.

4.11. ADAS is also carry 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.

4.12. The collection of samples for the FSA by ADAS is in response to the statutory requirement in the nitrate Regulation. The farmers themselves volunteer into the scheme. This programme has been ongoing for many years but now the results will be submitted directly to EFSA. The sampling plan has been/is being revised to take into account changes to the legislation e.g. to incorporate rocket samples.

4.13. 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.

4.14. Current work was sponsored by the Agriculture and Horticulture Development Board looking at nitrogen response. The link below provides details of the research:

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

4.15. There are other reports on nitrate on their website.
Industry Reaction to the EU Proposal

4.16. 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 to be increased and agreed at the Standing Committee of the Food Chain and Animal Health (SCoFCAH). Stakeholders were also informed that the Nitrate Regulation included a requirement to continue monitoring for nitrate in all EU Member States.

4.17. 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.

4.18. 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 to raise this with the Commission with raw data to support as 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

5.1. 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

5.2. The FSA has consulted with all its stakeholders including industry trade bodies, enforcement authorities, consumer organisations, research laboratories and others with an interest in chemical contaminants legislation consistently during negotiations with the Commission and other EU Member States on the amendments to Commission Regulation 1881/2006 and the Nitrate Regulation. For example, it has released several interested parties letters notifying stakeholders as it has done so, and which are available from the following link:

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

Informal Consultation

5.3. 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.

Enforcement

5.4. 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.

Statutory Review

5.5. 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 in other Member States. 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.

Options

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

6.1. 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.

6.2. 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.

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

6.3. 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.

6.4. 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.

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.

6.5. 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.

6.6. 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.

6.7. 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

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

6.8. 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.

6.9. Consumer safety may also be compromised and the potential for consumers to be exposed to harmful levels of contaminants such as nitrate.

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

Benefits to Consumers

6.10. 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.

6.11. 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
6.12. 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.

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

6.13. 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

6.14. 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).

6.15. 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

6.16. 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

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

Costs to Industry
One-off Familiarisation Costs

6.17. 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.

6.18. 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\(^{15}\), 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 UK industry of £613,183, see Table 1 below.

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

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

Consultation question 6

Stakeholders are asked to comment, with supporting evidence, on the assumption that it will take 1.5 hours to read and familiarise with the new Regulations is a sensible estimate for businesses.

If you agree or disagree with this assessment please provide documentary evidence to support your views.

Equivalent Annual Costs (EAC)

6.19. 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\(^{16}\). Under Standard HMT Green book guidance a discount rate of 3.5% is used.

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\(^{15}\) Wage rate obtained from The Annual Survey of Household Earnings (2011) (http://www.ons.gov.uk/ons/guide-method/surveys/list-of-surveys/search/index.html?survey=Annual+Survey+of+Hours+and+Earnings+%28ASHE%29&content-type=Dataset&content-type=Reference+table&sortDirection=DESCENDING&sortBy=pubdate). Median hourly wage of a production manager (£20.08 which has been uprated by 30% to cover overheads: £20.08 * 1.3 = £26.10

\(^{16}\) EACB = PVCB/a\(_r\), Where a\(_r\) is the annuity rate given by:
6.20. 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

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAC</td>
<td>64,118</td>
<td>1,683</td>
<td>3,366</td>
<td>2,070</td>
<td>71,237</td>
</tr>
</tbody>
</table>

Costs to Enforcement Authorities

#### One-off Familiarisation Costs

6.21. 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.

6.22. 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.

6.23. 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.

### Consultation question 7

(a). Stakeholders are asked to comment, with supporting evidence, on whether the assumption that it will take businesses 1.5 hours and enforcement authorities 2.25 hours to read and familiarise with the new Regulations is a sensible estimate.

(b). We would also welcome comments and estimates from enforcement bodies on enforcing the new EU legislation.

6.24. 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\(^\text{17}\), whilst the median hourly wage

\[
a_{t,r} = \sum_{j=0}^{t-1} \frac{j}{1 + r_j}
\]

PVCB is the present value of costs, \(r\) is the social discount rate and \(t\) is the time period over which the policy is being appraised.

rate of a TSO is £21.01\textsuperscript{18}. 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 the UK results in a total familiarisation cost to UK enforcement of £20,294, see Table 3 below. (Note that all presented figures are rounded.)

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

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAs &amp; PHAs</td>
<td>16,515</td>
<td>1,073</td>
<td>1,493</td>
<td>1,213</td>
<td>20,294</td>
</tr>
</tbody>
</table>

Equivalent Annual Costs (EAC)

6.25. 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**

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAC</td>
<td>1,919</td>
<td>125</td>
<td>173</td>
<td>141</td>
<td>2,358</td>
</tr>
</tbody>
</table>

6.26. 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**

6.27. 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.

**Consultation question 8**

(a). It is our assumption that there are unlikely to be any additional costs for sampling and analysis as a result of the new limits for nitrate in spinach and lettuce.

(b). It is our assumption that any additional costs for sampling and analysis as

6.28. 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.

**Consultation question 9**

We would welcome your comments and supporting evidence in relation to the provisions of Regulation 610/2012 on the following:

(a). The impact of a test showing that levels are exceeded – the likely number of incidents, the cost of withdrawals and not placing the product on the market, the cost of investigation by the competent authority and other costs as appropriate.

(b). The cost of changes businesses and others would need to make to avoid exceeding the limits, e.g. cost of any additional cleaning between production runs, keeping foodstuffs separate.

Please provide evidence to support your views.

6.29. 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.

**Impact on other Government Bodies**

6.30. 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.

6.31. 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

<table>
<thead>
<tr>
<th></th>
<th>England</th>
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<th>Scotland</th>
<th>NI</th>
<th>UK</th>
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<tr>
<td>LAs &amp; PHAs</td>
<td>354</td>
<td>23</td>
<td>32</td>
<td>26</td>
<td>435</td>
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Table 6: Summary of all Costs under Option 2 (£)

<table>
<thead>
<tr>
<th>Year</th>
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<th>Total</th>
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<th>PV</th>
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<td>1</td>
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<td>0</td>
<td>0</td>
<td>2,358</td>
<td>20,294</td>
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<td>0</td>
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<td>0</td>
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<td>20,294</td>
<td>633,477</td>
<td>73,594</td>
<td>633,477</td>
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</table>

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

6.32. 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

6.33. 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).

6.34. 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.

6.35. 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 7: Summary of all Costs under Option 3 (£)

<table>
<thead>
<tr>
<th>COSTS</th>
<th>Year 0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>Total</th>
<th>EAC</th>
<th>PV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business</td>
<td>613,183</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>613,183</td>
<td>71,237</td>
<td>613,183</td>
</tr>
<tr>
<td>Enforcement</td>
<td>20,294</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>20,294</td>
<td>2,358</td>
<td>20,294</td>
</tr>
<tr>
<td>Total</td>
<td>633,477</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>633,477</td>
<td>73,594</td>
<td>633,477</td>
</tr>
</tbody>
</table>

Consultation question 10
(a) We would welcome comments from stakeholders on whether the costs and benefits set out above are an accurate representation of the costs and benefits to business and enforcement authorities.
(b) We would also welcome comments on the assumption that option 3 achieves all policy objectives and in addition it allows for ambulatory provisions to minimise costs to business and enforcement.
Please provide evidence to support your views.

7. Scottish Firms Impact Test

Industry
Primary Producers
7.1. The new Regulations impact on any FBO, including primary producers, that 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.

7.2. 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.

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

Retail and Wholesalers
7.4. 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
7.5. 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

7.6. 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.

7.7. 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).\(^\text{19}\) Table 8 below summarises those sectors that are likely to be affected by the Regulation.

**Table 8: Type of Businesses Affected**

<table>
<thead>
<tr>
<th>SIC Code</th>
<th>Type of Business</th>
<th>Includes</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.13</td>
<td>Growers of vegetables and melons, roots and tubers</td>
<td>Growing, including import, of leafy vegetables such as spinach, lettuce</td>
<td>Familiarisation</td>
</tr>
<tr>
<td>10.39</td>
<td>Other processing and preserving of fruit and vegetables</td>
<td>Manufacture, including import, of perishable vegetables such as packaged salads</td>
<td>Familiarisation</td>
</tr>
<tr>
<td>46.31</td>
<td>Wholesale of fruit and vegetables</td>
<td>Wholesale of fresh vegetables</td>
<td>Familiarisation</td>
</tr>
<tr>
<td>47.21</td>
<td>Retail of fruit and vegetables in specialised stores</td>
<td>Retail sale of fresh vegetables</td>
<td>Familiarisation</td>
</tr>
</tbody>
</table>

**Regulation on Coccidiostats and Histomonostats**

<table>
<thead>
<tr>
<th>SIC Code</th>
<th>Type of Business</th>
<th>Includes</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.91</td>
<td>Manufacturers of prepared feeds for farm animals</td>
<td></td>
<td>Familiarisation</td>
</tr>
</tbody>
</table>

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

**Consultation question 11**

We welcome comments on whether the businesses identified adequately capture all those businesses that are likely to face impact. Specifically, are the sectors affected as displayed in the table an accurate representation.

If you agree or disagree with this assessment please provide evidence to support your response.

7.8. 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

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

Competition Assessment

7.9. We have fully considered the questions posed by in the Office of Fair Trading competition assessment test\(^\text{20}\) 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.

7.10. 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

7.11. 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 their views forward their views throughout the consultation procedure and we very much welcome their representation from them and their representative organisations.

Consultation question 12

Do you agree with our assumption that there will not be a significant impact on small businesses as a result of this legislation is a correct assumption.

Please provide evidence to support your views.

Test run of business forms

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

Legal Aid Impact Test

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

Consultation Question 13
Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and national Regulations. Please provide evidence to support your response.

Enforcement, sanctions and monitoring

Enforcement

10.1. 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 by Local Authority Environmental Health Departments.

Sanctions

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

Monitoring

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

I have read the impact assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Ministers signature  ............................................................

Ministers title  ............................................................

Date  ............................................................

Contact point
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

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.

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.

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, The EFSA Journal (2008) Journal number, 689, 1-79.: http://www.efsa.europa.eu/en/efsajournal/pub/689.htm

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.


Coccidiostats and histomonostats

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.

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.

The 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. The EFSA conclusions on the substances mentioned in the Commission Regulations are reproduced below:

Lasalocid
“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.”


Maduramicin

“ 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”


Nicarbazin

“ 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.”


Diclazuril

“ 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. “

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, 1-31

COMMISSION REGULATION (EU) No 1258/2011
of 2 December 2011
amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrates in foodstuffs
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (1), and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (2) sets maximum levels for nitrates in certain leafy vegetables.

(2) In some cases, despite developments in good agricultural practice, the maximum levels are exceeded and therefore a temporary derogation was granted to certain Member States 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.

(3) Since the application of the maximum levels of nitrates in lettuce and spinach, many investigations have been performed on the factors involved in the presence of nitrates in lettuce and spinach and on the measures to be taken to reduce the presence of nitrates in lettuce and spinach as much as possible. Despite the progress achieved in the good agricultural practice to reduce the presence of nitrates in lettuce and spinach and a strict application of this good agricultural practice, it is not possible to achieve in a consistent way nitrate levels in lettuce and fresh spinach below the current maximum levels in certain regions of the Union. The reason is that the climate and in particular the light conditions are the main determinant factor in the presence of nitrates in lettuce and spinach. These climate conditions cannot be managed or changed by the producer.

(4) To provide an up-to-date scientific basis for the long-term strategy for managing the risk arising from nitrates in vegetables, a scientific risk assessment by the European Food Safety Authority (EFSA), taking into account new information, was needed. Such assessment had to take into account any relevant considerations on risks and benefits, for example, weighing the possible negative impact of nitrate versus the possible positive effects of eating vegetables, such as antioxidant activities or other properties that might in some way counteract or provide a balance to the risks arising from nitrates and the resulting nitroso-compounds.

(5) On request of the Commission, the Panel on Contaminants in the Food Chain (the Panel) adopted on 10 April 2008 a Scientific opinion on nitrate in vegetables (3). The Panel compared the risk and benefits of exposure to nitrate from vegetables. Overall, 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. The Panel recognised that there are occasional circumstances (e.g. unfavourable local/home production conditions) for vegetables which constitute a large part of the diet, or individuals with a diet high in vegetables such as rucola which need to be assessed on a case-by-case basis.

(6) Following discussion on appropriate measures and concerns expressed as regards possible risks for infants and young children following acute dietary intake exposure, the Commission asked EFSA for a complementary scientific statement on nitrates in vegetables, whereby the possible risks for infants and young children related to the presence of nitrates in fresh vegetables are assessed in more detail, also considering the acute dietary intake, taking into account recent occurrence data on the presence of nitrates in vegetables, more detailed consumption data of vegetables by infants and young children and the possibility of the establishment of slightly higher than the current maximum levels for nitrates in leafy vegetables. The Panel adopted on 1 December 2010 a Statement on possible public health risks for infants and young children from the presence of nitrates in leafy vegetables (4).

(7) In that statement the Panel concluded that exposure to nitrate at the current or envisaged maximum levels in spinach cooked from fresh spinach is unlikely to be a health concern, although a risk for some infants eating more than one spinach meal per day cannot be excluded. EFSA noted that it did not take into account possible changes of the nitrate content due to processing of the food commodities, such as washing, peeling and/or cooking, as this could not be considered due to lack of

representative data. The non-consideration of the quantitative impact of food processing on nitrate levels may consequently lead to an overestimation of the exposure. It was furthermore concluded that levels of nitrate in lettuce are not a health concern for children. Enforcing the current maximum levels for nitrate in lettuce and spinach, or envisaged maximum levels at 500 mg/kg higher than the current maximum levels, would have a minor impact.

(8) In order to provide legal security for the producer in all regions of the European Union which applies strictly the good agricultural practices to reduce the presence of nitrates in spinach and lettuce as much as possible, it is therefore appropriate to slightly increase the maximum level for nitrates in fresh spinach and lettuce without endangering public health.

(9) Given the sometimes very high levels of nitrates found in rucola, it is appropriate to set a maximum level for rucola. The maximum level for rucola should be reviewed in 2 years in view of a reduction of the levels after having identified the factors involved in the presence of nitrate in rucola and the full implementation of good agricultural practice in rucola to minimise the nitrate content.

(10) Given that EFSA has been mandated by the Commission to compile all occurrence data on contaminants, including nitrates, in food into one database, it is appropriate to communicate the results directly to EFSA.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1881/2006 is amended as follows:

(1) in Article 7, paragraphs 1, 2 and 3 are deleted;

(2) in Article 9, paragraph 1 is replaced by the following:

‘1. Member States shall monitor nitrate levels in vegetables which may contain significant levels, in particular green leaf vegetables, and communicate the result to EFSA on a regular basis.’;

(3) in the Annex, Section 1: Nitrate is replaced by the Section in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

It shall apply from the date of its entry into force. However, the maximum levels for rucola provided for in point 1.5 of the Annex shall apply from 1 April 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 December 2011.

For the Commission
The President
José Manuel BARROSO
ANNEX

'Section 1: Nitrate

<table>
<thead>
<tr>
<th>Foodstuffs (1)</th>
<th>Maximum levels (mg NO₃/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Fresh spinach (<em>Spinacia oleracea</em>) (2)</td>
<td>3 500</td>
</tr>
<tr>
<td>1.2 Preserved, deep-frozen or frozen spinach</td>
<td>2 000</td>
</tr>
<tr>
<td>1.3 Fresh Lettuce (<em>Lactuca sativa</em> L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4</td>
<td>Harvested 1 October to 31 March: lettuce grown under cover 5 000, lettuce grown in the open air 4 000; Harvested 1 April to 30 September: lettuce grown under cover 4 000, lettuce grown in the open air 3 000</td>
</tr>
<tr>
<td>1.4 “Iceberg” type lettuce</td>
<td>Harvested 1 October to 31 March: lettuce grown under cover 2 500, lettuce grown in the open air 2 000</td>
</tr>
<tr>
<td>1.5 Rucola (<em>Eruca sativa</em>, <em>Diplotaxis</em> sp., <em>Brassica tenuifolia</em>, <em>Sisymbrium tenuifolium</em>)</td>
<td>Harvested 1 October to 31 March: lettuce grown under cover 7 000, lettuce grown in the open air 6 000</td>
</tr>
<tr>
<td>1.6 Processed cereal-based foods and baby foods for infants and young children (1) (4)</td>
<td>200'</td>
</tr>
</tbody>
</table>
II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 610/2012
of 9 July 2012
amending Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (1), and in particular Article 2(3) thereof,

Whereas:

(1) Maximum levels have been set for certain coccidiostats and histomonostats in food by Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (2) in order to ensure a proper functioning of the internal market and to protect public health.


(3) Maximum residue limits have been established for lasalocid sodium in food of animal origin from bovine species in the framework of Regulation (EC) No 470/2009 by Commission Implementing Regulation (EU) No 86/2012 of 1 February 2012 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance lasalocid (5).

Therefore, it is necessary to amend the provisions as regards lasalocid sodium.

(4) New technical information, namely specific studies on transfer ratio of maduramicin from feed into eggs from laying hens has become available. These studies demonstrate that feed for laying hens containing maduramicin due to cross-contamination but below the maximum level results in levels of maduramicin in eggs higher than the currently allowed maximum level. In accordance with the conclusions of the EFSA opinion on cross-contamination of non-target feedingstuffs by maduramicin (6) and the scientific opinion on safety and efficacy of maduramicin ammonium for chickens for fattening (7), these higher levels do not result in an appreciable risk.

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (1), and in particular Article 2(3) thereof,

Whereas:

to consumers' health. Therefore it is appropriate to amend the provisions as regards maduramicin accordingly.

(5) The conditions of authorisation of nicarbazin and diclazuril as feed additives have been modified by Commission Regulation (EU) No 875/2010 of 5 October 2010 concerning the authorisation for 10 years of an additive in feedingstuffs (1) and Commission Regulation (EU) No 169/2011 of 23 February 2011 concerning the authorisation of diclazuril as a feed additive for guinea fowls (2) respectively. Those developments require significant changes to the maximum levels set for nicarbazin and minor changes for diclazuril in the Annex to Regulation (EC) No 124/2009. In accordance with the conclusions of the EFSA opinion on cross-contamination of non-target feedingstuffs by nicarbazin (3) and the scientific opinion on safety and efficacy of nicarbazin for chickens for fattening (4), the proposed maximum levels for nicarbazin in food as a consequence of unavoidable carry-over in non-target feed do not result in an appreciable risk to consumers’ health. Therefore it is appropriate to amend the provisions as regards diclazuril and nicarbazin.

(6) Therefore, Regulation (EC) No 124/2009 should be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 124/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 July 2012.

For the Commission

The President

José Manuel BARROSO

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ANNEX

The Annex to Regulation (EC) No 124/2009 is amended as follows:

(1) The entry No 1 concerning Lasalocid sodium is replaced by the following:

<table>
<thead>
<tr>
<th>*1. Lasalocid sodium</th>
<th>Food of animal origin from animal species other than poultry and bovine:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>— milk: 1</td>
</tr>
<tr>
<td></td>
<td>— liver: 50</td>
</tr>
<tr>
<td></td>
<td>— kidney: 20</td>
</tr>
<tr>
<td></td>
<td>— other food: 5*</td>
</tr>
</tbody>
</table>

(2) The entry No 6 concerning Maduramicin is replaced by the following:

<table>
<thead>
<tr>
<th>*6. Maduramicin</th>
<th>Food of animal origin from animal species other than chickens for fattening and turkeys:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>— eggs: 12</td>
</tr>
<tr>
<td></td>
<td>— other food: 2*</td>
</tr>
</tbody>
</table>

(3) The entry No 10 concerning Nicarbazin is replaced by the following:

<table>
<thead>
<tr>
<th>*10. Nicarbazin (residue: 4,4’-dinitrocarbanilide (DNC))</th>
<th>Food of animal origin from animal species other than chickens for fattening:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>— eggs: 300</td>
</tr>
<tr>
<td></td>
<td>— milk: 5</td>
</tr>
<tr>
<td></td>
<td>— liver: 300</td>
</tr>
<tr>
<td></td>
<td>— kidney: 100</td>
</tr>
<tr>
<td></td>
<td>— other food: 50*</td>
</tr>
</tbody>
</table>

(4) The entry No 11 concerning Diclazuril is replaced by the following:

<table>
<thead>
<tr>
<th>*11. Diclazuril</th>
<th>Food of animal origin from animal species other than chickens for fattening, turkeys for fattening, guinea fowl, rabbits for fattening and breeding, ruminants and porcine:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>— eggs: 2</td>
</tr>
<tr>
<td></td>
<td>— liver and kidney: 40</td>
</tr>
<tr>
<td></td>
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The Mineral Hydrocarbons in Food (Scotland) Regulations 1966

Made 30th September 1966
Laid before Parliament 14th October 1966
Coming into force 17th October 1966

In exercise of the powers conferred on me by sections 4 and 56 of the Food and Drugs (Scotland) Act 1956(a) and of all other powers enabling me in that behalf, and after consultation with such organisations as appear to me to be representative of interests substantially affected by these regulations, I hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Mineral Hydrocarbons in Food (Scotland) Regulations 1966 and shall come into operation on 17th October 1966.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—
"the Act" means the Food and Drugs (Scotland) Act 1956;
"chewing compound" means chewing gum and other products of a like nature and use;
"dried fruit" means prunes, currants, sultanas and raisins;
"food" means food intended for sale for human consumption and includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products;
"human consumption" includes use in the preparation of food for human consumption;
"mineral hydrocarbon" means any hydrocarbon product, whether liquid, semi-liquid or solid, derived from any substance of mineral origin and includes liquid paraffin, white oil, petroleum jelly, hard paraffin and microcrystalline wax;
"sell" includes offer or expose for sale or have in possession for sale; and "sale" shall be construed accordingly;
and other expressions have the same meaning as in the Act.

(2) The Interpretation Act 1889(b) shall apply for the interpretation of these regulations as it applies for the interpretation of an Act of Parliament.

Enforcement

3.—(1) The local authority of any area shall, subject to the provisions of the next following paragraph, enforce and execute the provisions of these regulations within their area.
(a) 1956 c. 30.
(b) 1889 c. 63.
(2) Where any part of the area of a local authority lies within the area of a port local authority such of the functions of the local authority under these regulations in relation to any food imported into that part shall, in so far as these functions fall to be exercised by the port local authority by virtue of any order made under section 172 of the Public Health (Scotland) Act 1897a, be exercised by that port local authority.

(3) In this regulation "local authority" means the council of a county or of a large burgh within the meaning of the Local Government (Scotland) Act 1947b; and any small burgh within the meaning of that Act shall, for the purposes of these regulations, be included in the county in which it is situated; and "port local authority" includes a joint port local authority.

Exemptions

4.—(1) Regulation 5 of these regulations shall not apply in relation to—

(a) any dried fruit containing not more than 0·5 part by weight of mineral hydrocarbon per 100 parts by weight of dried fruit;

(b) any citrus fruit containing not more than 0·1 part by weight of mineral hydrocarbon per 100 parts by weight of citrus fruit;

(c) any sugar confectionery containing mineral hydrocarbon by reason of the use of mineral hydrocarbon as a polishing or glazing agent for confectionery if such confectionery contains by reason thereof not more than 0·2 part by weight of mineral hydrocarbon per 100 parts by weight of such confectionery;

(d) any food containing mineral hydrocarbon—

(i) by reason of the use in the composition of such food of dried fruit, citrus fruit or sugar confectionery, or any one or more of these commodities, containing mineral hydrocarbon not in excess of the relevant quantities permitted in accordance with sub-paragraphs (a), (b) and (c) of this paragraph;

(ii) by reason not of the inclusion of mineral hydrocarbon as an ingredient in such food but because of the use of mineral hydrocarbon as a lubricant or greasing agent on some surface with which such food has necessarily to come into contact during the course of preparation if such food contains by reason thereof not more than 0·2 part by weight of mineral hydrocarbon per 100 parts by weight of the food;

(e) any chewing compound which—

(i) contains no more than 60 parts by weight of solid mineral hydrocarbon per 100 parts by weight of chewing compound, and

(ii) contains no mineral hydrocarbon other than any mineral hydrocarbon which complies with the specification therefor set forth in paragraph 4 of Part I of the schedule to these regulations;

(f) the rind of any whole pressed cheese;

(g) any egg, laid by any domestic fowl or domestic duck, which contains mineral hydrocarbon by reason of its having been subjected to a process of preservation consisting of being dipped in, sprayed with or otherwise treated with mineral hydrocarbon and which

\[\text{1897 c. 38}\]
\[\text{1947 c. 43}\]
before sale or exposure for sale is required (by section 3 of the Agricultural Produce (Grading and Marketing) Act 1928 and regulations made thereunder) to be marked on the shell with the word "SEALED";

(h) any food intended for exportation to any place outside the United Kingdom.

(2) Any reference in paragraph (1) of this regulation to any mineral hydrocarbon shall mean any liquid mineral hydrocarbon, any semi-liquid mineral hydrocarbon or any solid mineral hydrocarbon, as the case may be, which complies with the specifications therefor set forth respectively in paragraphs 1, 2 and 3 of Part I of the schedule to these regulations or a mixture of such liquid, semi-liquid or solid mineral hydrocarbons:

Provided that the reference in paragraph (1)(e) of this regulation to solid mineral hydrocarbon shall mean solid mineral hydrocarbon which complies with the specification therefor set forth in paragraph 4 of the said Part of the said schedule.

(3) An exemption provided for in paragraph (1)(a) to (g) of this regulation shall not apply if the food contains any mineral hydrocarbon other than mineral hydrocarbon of a kind referred to in paragraph (2) of this regulation.

Prohibition of mineral hydrocarbon in food

5. Subject to the provisions of these regulations—

(a) no person shall use or permit to be used any mineral hydrocarbon in the composition or preparation of any food;

(b) no person shall sell, consign or deliver, or import into Scotland, any food containing any mineral hydrocarbon.

Condemnation of food containing mineral hydrocarbon

6. Where any food is certified by a public analyst as being food in the composition or preparation of which any mineral hydrocarbon has been used which it is an offence against the foregoing provisions of these regulations to use, permit to be used, sell, consign or deliver, or import into Scotland, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

Penalties

7.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence under these regulations.

(2) Any person who is guilty of an offence under these regulations shall be liable:—

(a) on summary conviction to:—

(ii) in the case of a continuing offence to a further fine not exceeding £10 for every day during which the offence is continued; or

(b) on conviction on indictment to:—

\[c 1928 c. 19\]

\[d S.I. 1965/1021 (1965 I, p. 2477)\]
(i) a fine not exceeding £500 or to imprisonment for a term not exceeding one year or to both such fine and imprisonment; and

(ii) in the case of a continuing offence, to a further fine not exceeding £50 for every day during which the offence is continued.

Application of various sections of the Act
8.—(1) Sections 41(2) and (5) (which relates to proceedings), 42(1), (2) and (3) (which relates to evidence of certificates of analysis), 44 (which relates to the power of a court to require analysis by the Government Chemist), 46(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 47 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken under the Act included references to proceedings, or a prosecution as the case may be, taken for an offence against these regulations and in addition as if—

(a) in the case of section 44(1) of the Act, the reference therein to section 41(5) of the Act included a reference to said section 41(5) as applied by these regulations; and

(b) in the case of section 47(1) and (2) of the Act, the references therein to an offence against the Act included references to an offence against these regulations.

(2) Section 41(4) of the Act shall apply for the purposes of these regulations as if the reference therein to section 47 of the Act included a reference to said section 47 as applied by these regulations.

Revocation
9.—(1) The Mineral Hydrocarbons in Food (Scotland) Regulations 1964 are hereby revoked.

(2) Section 38 of the Interpretation Act 1889 shall apply as if these regulations were an Act of Parliament and as if the regulations revoked by these regulations were an Act of Parliament repealed by an Act of Parliament.

William Ross, One of Her Majesty's Principal Secretaries of State.

St. Andrew's House, Edinburgh, 1.

30th September 1966.
Regulation 4(2)

**SCHEDULE**

**PART I**

**SPECIFICATIONS FOR LIQUID MINERAL HYDROCARBON, SEMI-LIQUID MINERAL HYDROCARBON AND SOLID MINERAL HYDROCARBON**

**Specification for liquid mineral hydrocarbon**

1. Liquid mineral hydrocarbon—
   (a) shall be a transparent, almost colourless and tasteless mixture of liquid mineral hydrocarbons;
   (b) shall have an ultra-violet extinction (otherwise called absorbance) over the range 240–280 millimicrons not greater than 0.04 for a 1 centimetre layer of a solution in iso-octane containing 1 gram per litre, that is to say, E 0.1%/1 cm. shall not be greater than 0.04 where 
   \[ E = \log_{10} \left( \frac{I_0}{I} \right) \]
   and Io and I are the intensities of the incident radiation and of the transmitted radiation respectively; and
   (c) shall comply with the tests for acidity or alkalinity, carbonisable substances, solid paraffins, and sulphur compounds given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963.

**Specification for semi-liquid mineral hydrocarbon**

2. Semi-liquid mineral hydrocarbon—
   (a) shall be a white translucent unctuous mixture, barely fluorescent in daylight, of semi-liquid mineral hydrocarbons;
   (b) shall contain not more than 0.1 per cent. by weight of sulphated ash;
   (c) shall have an ultra-violet extinction (otherwise called absorbance) at 290 millimicrons not greater than 1.0 for a 1 centimetre layer of a solution in iso-octane containing 1 gram per litre, that is to say, E 0.1%/1 cm shall not be greater than 1.0 where 
   \[ E = \log_{10} \left( \frac{I_0}{I} \right) \]
   and Io and I are the intensities of the incident radiation and of the transmitted radiation respectively; and
   (d) shall comply with the tests for acidity or alkalinity and sulphur compounds given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963.

**Specification for solid mineral hydrocarbon other than any solid mineral hydrocarbon used or intended for use in chewing compounds**

3. Solid mineral hydrocarbon other than any solid mineral hydrocarbon used or intended for use in chewing compounds—
   (a) shall be an almost odourless and tasteless mixture of solid mineral hydrocarbons;
   (b) shall contain not more than 0.1 per cent, by weight of sulphated ash;
   (c) shall comply with the test for acidity or alkalinity given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963;
   (d) shall comply with the test for sulphur compounds given in the monograph referred to in the preceding sub-paragraph of this paragraph: Provided that such test shall be carried out at 70°C. or at 5°C. above the congealing point of the solid mineral hydrocarbon, whichever is the higher;
(e) shall comply with the requirements specified in one of the following sub-paragraphs, namely—

(i) shall have been tested, before being used in the composition or preparation of any food, for the presence of polycyclic hydrocarbon by the method described in Part II of this schedule with the result described in paragraph 6 of the said Part II, and if such solid mineral hydrocarbon is tested subsequently by the said method, shall give the said result; or

(ii) have a viscosity at 99°C. not greater than 7.0 centistokes and an ultra-violet extinction (otherwise called absorbance) at 290 millimicrons not greater than 0.04 for a 1 centimetre layer of a solution in iso-octane containing 1 gram per litre, that is to say, E 0.1%/1 cm shall not be greater than 0.04 where E=\log_{10} (I_o/I) and I_o and I are the intensities of the incident radiation and of the transmitted radiation respectively; or

(iii) have a viscosity at 99°C. not less than 10.0 centistokes and an ultra-violet extinction (otherwise called absorbance) at 290 millimicrons not greater than 1.0 for a 1 centimetre layer of a solution in iso-octane containing 1 gram per litre, that is to say, E 0.1%/1 cm shall not be greater than 1.0 where E=\log_{10} (I_o/I) and I_o and I are the intensities of the incident radiation and of the transmitted radiation respectively.

Specification for solid mineral hydrocarbon in chewing compounds

4. Solid mineral hydrocarbon used or intended for use in any chewing compound—

(a) shall comply with the requirements contained in sub-paragraphs (a), (b), (c) and (d) of paragraph 3 of this Part of this schedule; and

(b) shall have been tested, before being used in the composition of any chewing compound, for the presence of polycyclic hydrocarbon by the method described in Part II of this schedule with the result described in paragraph 6 of the said Part II, and if such solid mineral hydrocarbon is tested subsequently by the said method, shall give the said result.

PART II

METHOD OF TESTING SOLID MINERAL HYDROCARBON FOR THE PRESENCE OF POLYCYCLIC HYDROCARBON

Principle of method

1. The method is based on the maximum extinction within four wavelength ranges of an extract prepared by various physical and chemical processes on an iso-octane solution of a sample of solid mineral hydrocarbon.

General Instructions

2. Because of the sensitivity of the test, the possibility of errors arising from contamination is great. All glassware including stoppers and stopcocks shall be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. and shall be examined under ultra-violet light to detect any residual fluorescent contamination. All glassware shall be rinsed with purified iso-octane immediately before use. No grease shall be used on stopcocks or joints. Great care shall be taken to avoid contamination of the samples in handling and to ensure absence of any extraneous material arising from inadequate packaging. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure shall be carried out under subdued light.

Apparatus

3.—(1) The following apparatus shall be used—
(a) separatory funnels of 250 millilitre, 500 millilitre, 1 litre and 2 litre capacity, equipped with tetrafluoroethylene polymer stopcocks;

(b) a reservoir of 500 millilitre capacity, equipped with a 24/29 British Standard 572:1960 taper male fitting at the bottom and a suitable balljoint at the top for connecting to the nitrogen supply; the male fitting shall be equipped with glass hooks;

(c) a chromatographic tube, 180 millimetres in length, inside diameter to be 15.7 millimetres ±0.1 millimetre, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/29 British Standard 572:1960 tapered fitting at the opposite end; the female fitting shall be equipped with glass hooks;

(d) a tetrafluoroethylene polymer disc, 5 centimetres diameter and approximately 5 millimetres thick with a hole bored in the centre closely to fit the stem of the chromatographic tube;

(e) a heating jacket, conical, for a 500 millilitre separatory funnel, with variable transformer heat control;

(f) a suction flask being either a 250 or 500 millilitre filter flask;

(g) a condenser with 24/29 British Standard 572:1960 joints, fitted with a drying tube of optional length;

(h) a vacuum distillation assembly, all glass (for purification of dimethyl sulphoxide) consisting of a 2 litre distillation flask with heating mantle; a Vigreaux vacuum-jacketed condenser (or equivalent) 45 centimetres in length and distilling head with separable cold finger condenser; tetrafluoroethylene polymer sleeves on the glass joints shall be used to prevent freezing;

(i) spectrophotometric cells of fused quartz, optical path length in the range of 4.000 centimetres ±0.005 centimetres;

(j) a spectrophotometer with a spectral range of 250–400 millimicrons;

(k) a cylinder of nitrogen (water-pumped or of equivalent purity) which shall be equipped with regulator and valve to control the flow at 5 pounds per square inch gauge.

(2) The following additional apparatus may be used, namely an evaporation flask of 250 millilitre or 500 millilitre capacity, equipped with British Standard 572:1960 taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Reagents

4.—(1) The following reagents shall be used. They shall be prepared in accordance with any instructions contained in the following sub-paragraphs and shall comply with the appropriate specifications and tests described therein.

(a) Organic Solvents:

(i) Iso-octane (2,2,4-trimethylpentane) shall pass the test described in sub-paragraph (v) of this sub-paragraph. For this test, 180 millilitres of iso-octane shall be used. It shall be purified, if necessary, by passage through a column of activated silica gel about 90 centimetres in length and 5–8 centimetres in diameter.

(ii) Benzene shall be of reagent grade and shall pass the test described in sub-paragraph (v) of this sub-paragraph. For this test, 150 millilitres of benzene shall be used. It shall be purified, if necessary by distillation or otherwise.
(iii) Acetone shall be of reagent grade and shall pass the test described in sub-paragraph (v) of this sub-paragraph. For this test, 200 millilitres of acetone shall be used. It shall be purified, if necessary, by distillation.

(iv) Methyl alcohol shall be of reagent grade and shall pass the test described in sub-paragraph (v) of this sub-paragraph. For this test, 10.0 millilitres of methyl alcohol shall be used. It shall be purified, if necessary, by distillation.

(v) Test for Organic solvents. The purity test for organic solvents shall be carried out as follows—

To the specified quantity of solvent in a 250 millilitre Erlenmeyer flask, 1 millilitre of purified n-hexadecane shall be added, and the mixture shall be evaporated on the steam bath under a stream of nitrogen. A loose aluminium foil jacket may be placed around the flask to speed evaporation. Evaporation shall be discontinued when not more than 1 millilitre of residue remains.

In the case of the residue from benzene, a 10 millilitre portion of purified iso-octane shall be added, and the mixture shall be re-evaporated. A further 10 millilitre portion of purified iso-octane shall be added, and the mixture re-evaporated to ensure complete removal of benzene.

If the evaporation time is reduced by using the optional evaporation flask, the solvent and n-hexadecane shall be placed in the flask on the steam bath, the tube assembly shall be inserted, and a stream of nitrogen shall be fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

The 1 millilitre of n-hexadecane residue shall be dissolved in iso-octane and made to 25 millilitres volume. The extinction in the 4 centimetre path length cells compared to iso-octane as reference shall be determined. The extinction of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimetre path length between 280 and 400 millimicrons. For methyl alcohol this extinction value shall be 0.00.

(b) Eluting mixtures:

(i) 10 per cent. benzene in iso-octane. The mixture shall be prepared by placing by means of a pipette 50 millilitres of benzene in a 500 millilitre glass-stoppered volumetric flask, adjusting to volume with iso-octane, and mixing.

(ii) 20 per cent. benzene in iso-octane. The mixture shall be prepared by transferring by means of a pipette 50 millilitres of benzene into a 250 millilitre glass-stoppered volumetric flask, adjusting to volume with iso-octane, and mixing.

(iii) Acetone-benzene-water mixture. The mixture shall be prepared by adding 20 millilitres of water to 380 millilitres of acetone and 200 millilitres of benzene, and mixing.

(c) n-Hexadecane shall be 99 per cent. olefine-free and shall pass the following test—

1.0 millilitre of n-hexadecane shall be diluted to 25 millilitres with iso-octane. The extinction in a 4 centimetre path length cell compared to iso-octane as reference point between 280 and 400 millimicrons shall be determined. The extinction per centimetre path length shall not exceed 0.00 in this range. The n-hexadecane shall be purified, if necessary, by percolation through activated silica gel or by distillation.

(d) Dimethyl sulphoxide shall be of pure grade, clear water-white, and shall have a melting point of not less than 18°C. It shall pass the following test—
120 millilitres of dimethyl sulphoxide shall be diluted with 240 millilitres of distilled water in a 500 millilitre separatory funnel, mixed and allowed to cool for 5–10 minutes. 40 millilitres of iso-octane shall be added to the solution which shall be extracted by shaking the funnel vigorously for 2 minutes. The lower aqueous layer shall be drawn off into a second 500 millilitre separatory funnel and the extraction repeated with 40 millilitres of iso-octane. The aqueous layer shall be drawn off and discarded. Each of the 40 millilitre extractives shall be washed three times with 50 millilitre portions of distilled water. Each wash shall be shaken for 1 minute. The aqueous layers shall be discarded. The first extractive shall be filtered through anhydrous sodium sulphate pre-washed with iso-octane into a 250 millilitre Erlenmeyer flask, or optionally into the evaporating flask. The filter shall be prepared as described in sub-paragraph (j) of this paragraph. The first separatory funnel shall be washed with the second 40 millilitre iso-octane extractive, and passed through the sodium sulphate into the flask. The second and first separatory funnels shall be washed with a 10 millilitre portion of iso-octane, and the solvent passed through the sodium sulphate into the flask. 1 millilitre of n-hexadecane shall be added and the iso-octane evaporated on the steam bath under nitrogen. Evaporation shall be discontinued when not more than 1 millilitre of residue remains. A 10 millilitre portion of iso-octane shall be added to the residue and the mixture shall be re-evaporated to 1 millilitre of n-hexadecane. 10 millilitres of iso-octane shall be added to the residue and the mixture evaporated to 1 millilitre of n-hexadecane to ensure complete removal of all volatile materials. The 1 millilitre of n-hexadecane shall be dissolved in iso-octane and made up to 25 millilitre volume. The extinction in 4 centimetre path length cells compared to iso-octane as reference shall be determined. The extinction of the solution shall not exceed 0.02 per centimetre path length between 280 and 400 millimicrons. (Note: Difficulty in meeting this extinction specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulphoxide will disclose their presence. If necessary to meet the specification, the water shall be purified by re-distillation over alkaline permanganate, passage through an ion-exchange resin, or by any other suitable method.)

The dimethyl sulphoxide shall be purified, if necessary, by the following procedure:

To 1,500 millilitres of dimethyl sulphoxide in a 2 litre glass-stoppered flask, shall be added 6.0 millilitres of phosphoric acid and 50 grams of alkaline decolourizing carbon. The flask shall be stoppered, and using a magnetic stirrer (tetrafluoroethylene polymer coated bar) the solvent shall be stirred for 15 minutes. The dimethyl sulphoxide shall be filtered through four thicknesses of fluted paper 18.5 centimetres in diameter. If the initial filtrate contains carbon fines, the filtrate shall be refiltered through the same filter until a clear filtrate is obtained. The sulphoxide shall be protected from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of iso-octane. The filtrate shall be transferred to a 2 litre separatory funnel and the dimethyl sulphoxide drawn off into the 2 litre distillation flask of the vacuum distillation assembly and distilled at approximately 3 millimetres mercury pressure or less. The first 200 millilitre fraction of the distillate shall be discarded and the distillate collection flask replaced with a clean one. The distillation shall be continued until 1 litre of the sulphoxide has been collected. Because the reagent is very hygroscopic and will react with some metal containers in the presence of air, it shall be stored at the completion of distillation in glass-stoppered bottles.

(e) Phosphoric acid shall be of 85 per cent. strength, reagent grade.

(f) Sodium borohydride shall be of 98 per cent. purity.

(g) Heavy magnesium oxide shall be of reagent grade and shall be prepared as follows—
100 grams of the magnesium oxide shall be placed in a large beaker, 700 millilitres of distilled water shall be added to make a thin slurry, and the mixture shall be heated, with intermittent stirring, on a steam bath for 30 minutes. The mixture shall be stirred well initially to ensure that all the magnesium oxide is completely wetted. The mixture shall be filtered with suction, using a Buchner funnel and a filter paper of suitable diameter. Suction shall be continued until water no longer drips from the funnel. The magnesium oxide shall be transferred to a glass trough lined with aluminium foil which shall be free from rolling oil. The magnesium oxide shall be broken up with a clean spatula and spread out on the aluminium foil in a layer 1-2 centimetres thick. It shall be dried for 24 hours at 160°C. ±1°C. The magnesium oxide shall be pulverised with mortar and pestle. The pulverised magnesium oxide shall be sieved through a 60 mesh British Standard 410:1962 sieve.

(h) Diatomaceous earth.

(i) Magnesium oxide-diatomaceous earth mixture shall be a mixture of the reagents described in sub-paragraphs (g) and (h) of this paragraph and shall be prepared as follows—

The magnesium oxide and the diatomaceous earth in two to one proportions, respectively, by weight shall be placed in a glass-stoppered flask large enough for adequate mixing, which shall be shaken vigorously for 10 minutes. The mixture shall be transferred to a glass trough lined with aluminium foil which shall be free from rolling oil, and spread out in a layer 1-2 centimetres thick. The mixture shall be reheated at 160°C. ±1°C. for 2 hours, and stored in a tightly closed flask.

(j) Sodium sulphate shall be anhydrous of reagent grade, in granular form and shall be prepared as follows—

For each bottle of sodium sulphate used, the necessary sodium sulphate pre-wash shall be established as follows to provide the filters required in the method. 35 grams of anhydrous sodium sulphate shall be placed in a 30 millilitre coarse, fritted-glass funnel or in a 65 millimetre filter funnel with glass wool plug and washed with successive 15 millilitre portions of the indicated solvent until a 15 millilitre portion of the wash shows 0.00 extinction per centimetre path length between 280 and 400 millimicrons when tested as prescribed in paragraph 4(1)(a)(v) of this Part of this schedule. (Note: It will be found that three portions of wash solvent are normally sufficient.)

(k) Pre-equilibrated sulphoxide-phosphoric acid mixture and pre-equilibrated iso-octane shall be prepared as follows—

300 millilitres of dimethyl sulphoxide shall be placed in a 1 litre separatory funnel and 75 millilitres of phosphoric acid added. The contents of the funnel shall be mixed and allowed to stand for 10 minutes. (As the reaction between the sulphoxide and the acid is exothermic, the pressure shall be released after mixing, and the funnel thereafter kept stoppered.) 150 millilitres of iso-octane shall be added and the mixture shaken to pre-equilibrate the solvents. The individual layers shall be drawn off and stored in glass-stoppered flasks.

(2) Before proceeding with analysis of a sample, the extinction in a 4 centimetre path length cell between 250 and 400 millimicrons for the reagent blank shall be determined by carrying out the procedure, without a solid mineral hydrocarbon sample, at room temperature, recording the spectra after the extraction stage and after the complete procedure as described. The extinction per centimetre path length following the extraction stage shall not exceed 0.040 in the wavelength range between 280 and 400 millimicrons; the extinction per centimetre path length following the complete procedure shall not exceed 0.070 in the wavelength range between 280 and 299 millimicrons inclusive, nor 0.045 in the wavelength
range between 300 and 400 millimicrons. If either spectrum shows the characteristic benzene peaks in the 250–260 millimicrons region, the benzene shall be removed by the procedure described in paragraph 4(1)(a)(v) of this Part of this schedule and the extinction recorded again.

Method of Conducting Test

5. The test shall be carried out as follows—

A representative 1 kilogram sample of solid mineral hydrocarbon or, if this amount is not available, the entire sample shall be placed in a beaker of a capacity three times the volume of the sample and heated with occasional stirring on a steam bath until the sample is completely melted and homogeneous. Four 25 gram ±0.2 gram portions of the melted sample shall be weighed in separate 100 millilitre beakers. Three of the portions shall be reserved for later replicate analysis as necessary. One weighed portion shall be poured immediately after remelting on the steam bath into a 500 millilitre separatory funnel containing 100 millilitres of the pre-equilibrated sulphoxide-phosphoric acid mixture which has been heated in the heating jacket at a temperature just high enough to keep the sample melted. (Note: In pre-heating the sulphoxide-acid mixture, the stopper of the separatory funnel shall be removed at intervals to release the pressure.)

The transfer of the sample to the funnel in the jacket with portions of the pre-equilibrated iso-octane shall be promptly completed, warming the beaker, if necessary, and using a total volume of just 50 millilitres of the solvent. If the sample comes out of solution during these operations, the stoppered funnel shall be left in the jacket until the sample redissolves. The stopper shall be removed from the funnel at intervals to release pressure. When the sample is in solution, the funnel shall be removed from the jacket and shaken vigorously for 2 minutes. Three 250 millilitre separately funnels shall be set up, each containing 30 millilitres of pre-equilibrated iso-octane. After separation of the liquid phases, the contents shall be allowed to cool until the main portion of the sample in iso-octane solution begins to show a precipitate. The funnel shall be gently swirled when precipitation first occurs on the inside surface of the funnel to accelerate the process. The lower layer shall be carefully drawn off, filtered through a thin layer of glass wool fitted loosely in a filter funnel into the first 250 millilitre separatory funnel, and washed in tandem with the 30 millilitre portions of iso-octane contained in the 250 millilitre separatory funnels. The shaking time for each wash shall be 1 minute. The extraction operation shall be repeated with two additional portions of the sulphoxide-acid mixture. The funnel shall be replaced in the jacket after each extraction to keep the sample in solution and each extractive shall be washed in tandem through the same three portions of iso-octane.

The successive extractives (totalling 300 millilitres) shall be collected in a 2 litre separatory funnel, containing 480 millilitres of distilled water, mixed, and allowed to cool for a few minutes after the last extractive has been added. 80 millilitres of iso-octane shall be added to the solution and extracted by shaking the funnel vigorously for 2 minutes. The lower aqueous layer shall be drawn off into a second separatory funnel (preferably 2 litre) and the extraction repeated with 80 millilitres of iso-octane. The aqueous layer shall be drawn off and discarded. Each of the 80 millilitre extractives shall be washed three times with 100 millilitre portions of distilled water. The shaking time for each wash shall be 1 minute. The aqueous layers shall be discarded. The first extractive shall be filtered through anhydrous sodium sulphate pre-washed with iso-octane prepared as directed in paragraph 4(1)(j) of this Part of this schedule into a 250 millilitre Erlenmeyer flask (or optionally into the evaporation flask). The first separatory funnel shall be washed with the second 80 millilitre iso-octane extractive and passed through the sodium sulphate. The second and first separatory funnels shall be washed
successively with a 20 millilitre portion of iso-octane, and the solvent passed through the sodium sulphate into the flask. 1 millilitre of n-hexadecane shall be added to the contents of the flask and the iso-octane evaporated on the steam bath under nitrogen. Evaporation shall be discontinued when not more than 1 millilitre of residue remains. A 10 millilitre portion of iso-octane shall be added to the residue and the mixture re-evaporated to 1 millilitre of n-hexadecane. This operation shall be repeated once.

The residue shall be quantitatively transferred with iso-octane to a 25 millilitre volumetric flask, made to volume and mixed. The extinction of the solution in the 4 centimetre path length cells compared to iso-octane as reference between 280 and 400 millimicrons shall be determined, taking care to lose none of the solution in filling the sample cell. The extinction values shall be corrected for any extinction derived from reagents as determined by carrying out the procedure without a solid mineral hydrocarbon sample. If the corrected extinction does not exceed the limits prescribed in paragraph 6 of this Part of this schedule, the sample shall be deemed to satisfy the requirements of the test. If the corrected extinction per centimetre path length exceeds the limits prescribed, the test shall be continued as follows:

The iso-octane solution shall be quantitatively transferred to a 125 millilitre flask, equipped with 24/29 British Standard 572:1960 joint, and the iso-octane evaporated on the steam bath under a stream of nitrogen to a volume of 1 millilitre of n-hexadecane. 10 millilitres of methyl alcohol and approximately 0.3 gram of sodium borohydride shall be added to the contents of the flask. (In order to minimise exposure of the borohydride to the atmosphere, a measuring dipper may be used.) A water-cooled condenser equipped with a 24/29 British Standard 572:1960 joint and with a drying tube shall be fitted to the flask immediately. The flask shall be shaken until the borohydride is dissolved, and allowed to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, the flask shall be disconnected and the methyl alcohol evaporated on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. 10 millilitres of iso-octane shall then be added and the mixture evaporated to a volume of about 2–3 millilitres. A further 10 millilitres of iso-octane shall be added and the mixture concentrated to a volume of approximately 5 millilitres. The flask shall be swirled repeatedly to ensure adequate washing of the sodium borohydride residues.

The tetrafluoroethylene polymer disc shall be fitted on the upper part of the stem of the chromatographic tube. The tube with the disc shall be placed on the suction flask and the vacuum applied (approximately 135 millimetres mercury pressure). 14 grams of the 2:1 magnesium oxide-diatomaceous earth mixture shall be weighed and the adsorbent mixture poured into the chromatographic tube in approximately 3 centimetre layers. After the addition of each layer, the top of the adsorbent shall be levelled off with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. The topmost few millimetres of each adsorbent layer shall be loosened with the end of a metal rod before the addition of the next layer. Packing in this manner shall be continued until all the 14 grams of the adsorbent have been added to the tube. The top of the adsorbent shall be levelled off by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimetres. The vacuum shall then be turned off and the suction flask removed. The 500 millilitre reservoir shall be fitted onto the top of the chromatographic column and the column pre-wetted by passing 100 millilitres of iso-octane through the column. The nitrogen pressure shall be adjusted so that the rate of descent of the iso-octane coming off the column is between 2–3 millilitres per minute.

Pressure shall be discontinued just before the last of the iso-octane reaches the level of the adsorbent. (Caution: The liquid level must not, at any time, recede below the adsorbent level.)
The reservoir shall be removed and the 5 millilitre iso-octane concentrate solution decanted onto the column. With slight pressure again the liquid level shall be allowed to recede to barely above the adsorbent level. The flask and the residue shall be thoroughly washed with two 5 millilitre portions of iso-octane which shall be rapidly transferred to the column in a similar manner. Just before the final 5 millilitres wash reaches the top of the adsorbent, 100 millilitres of iso-octane shall be added to the reservoir, and the percolation continued at the 2–3 millilitres per minute rate. Just before the last of the iso-octane reaches the adsorbent level, 100 millilitres of 10 per cent. benzene in iso-octane shall be added to the reservoir, and the percolation at the aforementioned rate continued. Just before the solvent mixture reaches the adsorbent level, 25 millilitres of 20 per cent. benzene in iso-octane shall be added to the reservoir and the percolation continued at 2–3 millilitres per minute until all this solvent mixture has been removed from the column. All the elution solvents collected up to this point shall be discarded. 300 millilitres of the acetone-benzene-water mixture shall be added to the reservoir, and the mixture percolated through the column to elute the polynuclear compounds.

The eluate shall be collected in a clean 1 litre separatory funnel. The column shall be allowed to drain until most of the solvent mixture has been removed. The eluate shall be washed three times with 300 millilitre portions of distilled water, shaking well for each wash. (Small amounts of sodium chloride may be added to facilitate separation.) The aqueous layer shall be discarded after each wash. After the final separation, the residual benzene shall be filtered through anhydrous sodium sulphate pre-washed with benzene (prepared as directed in paragraph 4(1)(j) of this Part of this schedule) into a 250 millilitre Erlenmeyer flask (or into the evaporation flask). The separatory funnel shall be washed with two additional 20 millilitre portions of benzene which shall also be filtered through the sodium sulphate. 1 millilitre of n-hexadecane shall be added and the benzene completely removed by evaporation under nitrogen, using the special procedure to eliminate benzene described in paragraph 4(1)(a)(v) of this Part of this schedule. The residue shall be quantitatively transferred with iso-octane to a 25 millilitre volumetric flask and adjusted to volume. The extinction of the solution in the 4 centimetre path length cells compared to iso-octane as reference between 250 and 400 millimicrons shall be determined. Correction shall be made for any extinction derived from the reagents, as determined by carrying out the procedure without a solid mineral hydrocarbon sample.

If either spectrum shows the characteristic benzene peaks in the 250–260 millimicrons region, the solution shall be evaporated to remove benzene by the procedure described in paragraph 4(1)(a)(v) of this Part of this schedule. The residue shall be dissolved and transferred quantitatively, and adjusted to volume in iso-octane in a 25 millilitre volumetric flask. The extinction shall again be recorded. If the corrected extinction does not exceed the limits prescribed in paragraph 6 of this Part of this schedule, the sample shall be deemed to satisfy the requirements of the test.

Result of test

6. The tested solid mineral hydrocarbon shall be deemed to have satisfied the test if the following result is obtained, namely if the light extinction of the extract per centimetre path length does not exceed the following limits:

Wavelength range (millimicrons)  
Extinction limit  
0.15, 0.12, 0.08, 0.02.
EXPLANATORY NOTE
(This Note is not part of the Regulations.)

These regulations, which supersede the Mineral Hydrocarbons in Food (Scotland) Regulations 1964, apply to Scotland only, and come into operation on 17th October 1966.

The regulations prohibit (subject to certain exemptions relating to dried fruit, citrus fruit, sugar confectionery, food of which dried fruit, citrus fruit or sugar confectionery is an ingredient, lubricants, the rind of pressed cheese, and eggs) the use of any mineral hydrocarbon in the composition or preparation of food, the sale of food containing any mineral hydrocarbon, and the consignment, delivery or importation of any food containing any mineral hydrocarbon (regulation 5). The regulations do not apply to any food intended for exportation to any place outside the United Kingdom (regulation 4).

The regulations lay down revised specifications for mineral hydrocarbons the use of which is regulated in relation to the permitted exemptions, including a test for limits of content of certain polycyclic aromatic hydrocarbons (regulation 4(2) and schedule).

The regulations also make provision for the following:

(a) the condemnation of food containing mineral hydrocarbons in contravention of the regulations (regulation 6);

(b) penalties for infringement of the regulations (regulation 7);

(c) enforcement by local authorities or (as regards the provisions of regulations 5 and 6 in so far as they relate to importation) by port local authorities (regulation 3(2)); and

(d) application of certain sections of the Food and Drugs (Scotland) Act 1956 relating to legal proceedings (regulation 8).
FOOD AND DRUGS

COMPOSITION

The Erucic Acid in Food (Scotland) Regulations 1977

Made

Laid before Parliament

Coming into force

13th June 1977

29th June 1977

21st July 1977

In exercise of the powers conferred on me by sections 4, 26(3) and 56 of the Food and Drugs (Scotland) Act 1956(a) as amended by section 4(1) of, and paragraph 3(1) of Schedule 4 to, the European Communities Act 1972(b), and of all other powers enabling me in that behalf, and after consultation with such organisations as appear to me to be representative of interests substantially affected by these regulations, I hereby make the following regulations:—

Citation and commencement

1. These regulations shall be cited as the Erucic Acid in Food (Scotland) Regulations 1977 and shall come into operation on 21st July 1977.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires—

"the Act" means the Food and Drugs (Scotland) Act 1956;

"erucic acid" means the fatty acid cis-docos-13-enoic acid;

"fatty acid" means any carboxylic acid obtained by the hydrolysis of oil or fat, and includes any such acid existing in a free state in oil or fat;

"food" means food intended for sale for human consumption and includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products, but does not include—

(a) water, live animals or birds,

(b) fodder or feeding stuffs for animals, birds or fish, or

(c) articles or substances used only as drugs;

"human consumption" includes use in the preparation of food for human consumption;
"oil or fat" means oil or fat derived from any animal, bird, fish or plant and intended for sale for human consumption, but does not include any essential oil;

"sell" includes offer or expose for sale or have in possession for sale and

"sale" and "sold" shall be construed accordingly;

AND other expressions have the same meaning as in the Act.

(a) 1956 c. 30.

(b) 1972 c. 68.

(2) The Interpretation Act 1889(a) shall apply for the interpretation of these regulations as it applies for the interpretation of an Act of Parliament.

(3) All proportions mentioned in these regulations are proportions calculated by weight and, unless the context otherwise requires, are calculated on the total weight of the product, such weight being ascertained, in the case of a food sold in dried or concentrated form, after reconstitution in accordance with any instructions which accompany it.

(4) For the purpose of these regulations, the supply of food, otherwise than by sale, at, in or from any place where food is supplied in the course of a business, shall be deemed to be a sale of that food.

Exemptions

3. The provisions of these regulations shall not apply—

(a) to any oil, fat or food which is intended at the time of sale, consignment or delivery, as the case may be, for exportation to any place outside the United Kingdom;

(b) to any food which contains not more than five per centum oil or fat unless it is described directly or by implication as specially prepared for infants or young children;

(c) to any oil, fat or food sold, consigned or delivered to a manufacturer for the purposes of his manufacturing business or to a caterer for the purposes of his catering business; or

(d) to any oil, fat or food manufactured before 21st July 1977.

Sale, etc., of oil or fat and of food to which oil or fat has been added

4.—(1) Subject to paragraph (2) of this regulation, no person shall sell, consign or deliver—

(a) any oil or fat or any mixture thereof, if erucic acid constitutes more than five per centum of its fatty acid content; or

(b) any food to which oil or fat or a mixture thereof has been added, if erucic acid constitutes more than five per centum of the fatty acid content of all the oil and fat in the food.

(2) In relation to any oil, fat or food manufactured before 1st July 1979, these regulations shall have effect as if the percentages specified in paragraph (1)(a) and (b) of this regulation were in each case ten instead of five.

Penalties
6.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence under these regulations.

(2) Any person who is guilty of an offence under these regulations shall be liable—

(a) on summary conviction to—

(i) a fine not exceeding £100 or to imprisonment for a term not exceeding six months, or to both such fine and imprisonment; and

(ii) in the case of a continuing offence, to a further fine not exceeding £10 for every day during which the offence is continued; or

(a) 1889 c. 63.

(b) on conviction on indictment to—

(i) a fine not exceeding £500 or to imprisonment for a term not exceeding one year or to both such fine and imprisonment; and

(ii) in the case of a continuing offence, to a further fine not exceeding £50 for every day during which the offence is continued.

Enforcement

7. Each regional and islands council shall enforce and execute the provisions of these regulations within their area.

Application of various sections of the Act

8.—(1) Sections 41(2) and (5) (proceedings), 42(1), (2) and (3) (evidence of certificates of analysis), 44 (power of a court to require analysis by the Government Chemist), 46(2) (conditions under which a warranty may be pleaded as a defence) and 47 (offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken under the Act included references to proceedings, or a prosecution, as the case may be, taken for an offence against these regulations and in addition as if—

(a) in the case of section 44(1) of the Act, the reference therein to section 41(5) of the Act included a reference to said section 41(5) as applied by these regulations; and

(b) in the case of section 47(1) and (2) of the Act, the references therein to an offence against the Act included references to an offence against these regulations.

(2) Section 41(4) of the Act shall apply for the purposes of these regulations as if the reference therein to section 47 of the Act included a reference to said section 47 as applied by these regulations.

Bruce Millan, One of Her Majesty's Principal Secretaries of State.

New St. Andrew's House, Edinburgh.

13th June 1977.
EXPLANATORY NOTE

(This Note is not part of the Regulations.)


The Regulations restrict the erucic acid content of oil or fat and of food to which oil or fat has been added. In relation to any oil, fat or food manufactured before 1st July 1979 the limit is 10%, calculated on the fatty acid content of the oil or fat component, and, in relation to any oil, fat or food manufactured after that date, the limit is 5%, similarly calculated.

The Regulations do not apply to oil, fat or food intended for export, to food which contains not more than 5% oil or fat unless it is described as specially prepared for infants or young children, to food intended for manufacturing or catering purposes or to food manufactured before 21st July 1977.
FOOD

COMPOSITION

The Erucic Acid in Food (Scotland) Amendment Regulations 1982

Made 8th January 1982

Laid before Parliament 13th January 1982

Coming into force 3rd February 1982

In exercise of the powers conferred on me by sections 4, 56 and 56A of the Food and Drugs (Scotland) Act 1956(a) and of all other powers enabling me in that behalf, and after consultation in accordance with section 56(6) of the said Act, with such organisations as appear to me to be representative of interests substantially affected by these regulations, I hereby make the following regulations:—

Citation and commencement

1.—These regulations may be cited as the Erucic Acid in Food (Scotland) Amendment Regulations 1982 and shall come into operation on 3rd February 1982.

Amendment of the Erucic Acid in Food (Scotland) Regulations 1977

2. The Erucic Acid in Food (Scotland) Regulations 1977(b) are hereby amended by inserting after regulation 4 the following regulation:—

"5. The erucic acid content of the oils, fats and foods referred to in regulation 4 of these regulations shall be determined by the following procedure:

(1) For screening purposes, whenever screening is deemed to be desirable, either the total docosenoic acid content or the total cisdocosenoic acid content may be determined, using the appropriate method provided by Article 2.1 of the Commission Directive of 25 July 1980 (80/891/EEC) relating to the Community method of analysis for

(a) 1956 c. 30; section 4 was amended, and section 56A inserted, by the European Communities Act 1972 (c. 68), section 4(1) and Schedule 4, paragraph 3(1) and 2(b).

(b) S.I. 1977/1028.

determining the erucic acid content in oils and fats intended to be used as such for human consumption and foodstuffs containing added oils or fats (a) (hereinafter called "the Directive").

(2) If the screening process is dispensed with, or if the total content of either docosenoic or cis-docosenoic acid determined by it exceeds five per cent or, in the case of any oil, fat or food manufactured before 1 July
1979, ten per cent, the erucic acid content shall be determined by the method set out in the Annex to the Directive."

George Younger, One of Her Majesty's Principal Secretaries of State.

New St Andrew's House, Edinburgh.

8th January 1982.

(a) O.J. No. L254, 27.9.80, p. 35.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These regulations amend the Erucic Acid in Food (Scotland) Regulations 1977 by providing a Community method of analysis for determining the erucic acid content of oils, fats and foods intended for human consumption, in implementation of the Commission Directive 80/891/EEC (O.J. No. L254, 27.9.80, p. 35).
Draft Contaminants in Food (Scotland) Regulations 2013 Consultation Feedback Questionnaire

We would be interested in what you thought of this consultation package. We would be grateful if you could spend a few minutes to complete the following questionnaire and return it even if you do not intend to respond to the consultation itself. Please return the questionnaire no later than 23 May 2013 to:

Will Munro
Food Safety Monitoring & Policy Branch
Food Standards Agency Scotland
6th Floor, St Magnus House
25 Guild Street
Aberdeen, AB11 6NJ
Tel: 01224 285161
Fax: 01224 285168
Or by email to: will.munro@foodstandards.gsi.gov.uk

1. How did you become aware of this consultation exercise?
   - Our consultation list included your/your organisation’s name [    ]
   - Via the FSA website (www.food.gov.uk) [    ]
   - Via the UK Online website (www.ukonline.gov.uk) [    ]
   - Through a FSA publication (please specify title)_____________________
   - Other publication (please specify title)_________________________________
   - Other means (please specify)____________________________________ [    ]

2. If you / your organisation are not responding to the consultation, is it because:
   - You are not working on this subject area [    ]
   - The consultation topic is not relevant to you [    ]
   - You do not have the time / resources to reply [    ]
   - Other reason (please specify)____________________ [    ]

3. Do you feel you were given enough time to respond to the issues / proposals in the consultation?
   - YES [    ]
   - NO [    ]

4. Were the issues / proposals clearly set out and easy to understand?
   - YES [    ]
   - NO [    ]
5. Do you have any suggestions on how the consultation package could have been improved?

6. Do you have any other comments about this consultation exercise? (Please continue overleaf if required)

7. If you received this consultation direct, were the contact and address details correct? If not please kindly provide the correct contact details for us to use in the future.

8. Do you still wish to remain on our consultation list?

   YES [ ]

   NO [ ]

9. Are there any other Food Standard Agency subject areas on which you would be interested in receiving future consultations?

   Name:…………………………………………
   Organisation:………………………………
   ……………………………………………
   ……………………………………………
   Date:……………………………………

THANK YOU FOR TAKING THE TIME TO COMPLETE AND RETURN THIS FEEDBACK QUESTIONNAIRE
Privacy Statement

The FOOD STANDARDS AGENCY is totally committed to complying with the 1998 Data Protection Act principles that protect facts and opinions about the individual. Any personal information that you provide will only be used for a specific purpose. We will not pass on personal information to others outside of our organisation unless the Data Protection Act allows us to do so. If you have concerns about your personal data please contact the Food Standards Agency Data Protection Officer at Data.Protection@foodstandards.gsi.gov.uk.

Publication of Personal Data

Please note that the Food Standards Agency may publish details that you supply in legitimate pursuit of the functions of the organisation.

As the publication of responses in full may include personal data (such as your full name and contact address details), would you please let us know if you object to us using this information.

Please tick the box below, complete the relevant details and return this form (together with your response) to indicate your objection.

☐ I do not agree to the publication of my personal details.

* If no objection is received we will assume that you consent to full disclosure of your personal details and these may be published.

Full Name

Full postal address

To comply with the Data Protection Act 1998, it is essential that we keep our records up to date. Would you therefore please inform us if your personal details change in any way.

This form has been issued by: Food Standards Agency in Scotland

If you have any queries, please contact: Will Munro, Food Safety Monitoring and Policy Branch, Food Standards Agency Scotland, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ

General information about the most recent Data Protection Act can be viewed on the Information Commissioner’s Office website at www.dataprotection.gov.uk. For general enquiries you may contact Tel: 01625 545745
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Annex H

JWC Services Ltd.
Kettle Produce Ltd.
Kingdom Bakers Ltd
Klinge Foods Ltd.
Lactalis McLelland Limited
Larder Bytes Ltd
Loch Fyne Oysters Ltd
M A Mackinnon's Marmalade
M Corson
M&D Catering
M.D. Longhorn & Co
Macduff Shellfish (Scotland) Ltd
MacPhie of Glenbervie Ltd
Macsween of Edinburgh
Marine Harvest (Scotland) Ltd
Marine Scotland
McAusland Crawford
McIntosh Donald
Middleton Food Products
Midlothian Council
Moredun Research Institute
Munlochy GM Vigil
Mylnefield Research Services Ltd.
Neogen Europe Ltd.
Neville Craddock Association
NFU Scotland
NHS Ayrshire & Arran
NHS Borders
NHS Fife
NHS Grampian
NHS Highland
NHS Tayside
Nor-Sea Foods Ltd
North Ayrshire Council
North Lanarkshire Council
Orkney Fisheries Association
Orkney Herring Co Ltd
Orkney Islands Council
Pan Fish Scotland Ltd
Paterson Arran Limited
Perth & Kinross Council
Pinneys of Scotland LTD
Quality Meat Scotland
R-Biopharm Rhone Ltd
Renfrewshire Council
Royal Environmental Health Institute for Scotland
Ruma
Rural Directorate
SAC
Sangs (Banff) Ltd
Scotch Whisky Association
Scotch Whisky Research Institute
Scottish Agricultural Science Agency
Scottish Association of Meat Wholesalers
Scottish Bakers
Scottish Beef Cattle Association
Scottish Borders Council
Scottish Chambers of Commerce
Scottish Crofting Foundation
Scottish Food & Drink Federation
Scottish Food Enforcement Liaison Committee
Scottish Food Enforcement liaison Committee
Scottish Food Enforcement Officers Association
Scottish Food Guide
Scottish Food Quality Certification Ltd
Scottish Government
Scottish Grocers Federation
Scottish Midland Co-op Society
Scottish Salmon Producers Organisation
Scottish Sea Farms Ltd.
Sea Fish Industry Authority
Seachill
Seafish Industry Authority
Shetland Catch Ltd
Shetland Islands Council
Shetland NHS Board
Shortbread House of Edinburgh Ltd
Soil Association Scotland
South Ayrshire Council
South Lanarkshire Council
Spiceman's Ltd.
Stirling Council (Catering & Cleaning)
SUSTAIN
Tan International Scotland
Tayside Contracts
Tayside Scientific Services
TESCO Stores Ltd
The Association of Meat Inspectors
The British Dietetic Association
The Cheese Company
The Highland Council
The Infant & Dietetic Foods Association Ltd
The Moray Council
The Really Garlicky Company
Thomas Tunnock Ltd
Tods of Orkney Ltd.
Trading Standards Institute
University of Aberdeen
University of Dundee
University of Glasgow
University Of Paisley
Untie the Union
Verner Wheelock Associates
Vion
Walkers Shortbread Ltd
Wellington Church
West Dunbartonshire Council
West Lothian Council
West Minch Salmon
Which?
William Yule & Son Ltd
Women's Food & Farming Union
WTS Forsyth & Son
Youngs Seafood