Date consultation launched: 15 May 2013
Closing date for responses: 7 August 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 (Wales) Regulations 2013 will revoke the Contaminants in Food (Wales) Regulations 2010 and remake them with necessary amendments taking into account the provisions of Commission Regulations (EU). No 1258/2011 regarding maximum levels for nitrate in foodstuffs and Regulation (EU) No. 610/2012 on 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 Regulations will provide for the execution and enforcement of Regulation 610/2012 and also introduce ambulatory reference provisions to include the Articles of Regulation 1881/2006 (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009 and also references to Articles and Annexes of Commission Directives 76/621 and 80/891 on Erucic acid.
- The Regulations will also revoke national legislation on mineral hydrocarbons in food and revoke and remake, the provisions of the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.
- The proposed Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (Wales) Regulations 2010, in order to rectify and under enforcement of EC Regulation 1881/2006. Article 5 of that Regulation provides for the labelling of groundnuts, other oilseeds, derived products thereof and cereals.
What is the purpose of this consultation?
To provide interested parties with the opportunity to comment on, and express their opinion on the proposed Contaminants in Food (Wales) Regulations 2013, the revocation of the Mineral Hydrocarbons in Food Regulations and the revocation and remake of the Erucic Acid in Food Regulations and the associated Impact Assessment.

Responses to this consultation should be sent to:
Name: Vicki Reilly
Division/Branch : Food Policy Team
FOOD STANDARDS AGENCY
Tel: 029 20678952
Fax: 029 20678918

Postal address:
11th Floor, Southgate House
Wood St, Cardiff
CF10 1EW
Email: Vicki.reilly@foodstandards.gsi.gov.uk

Is an Impact Assessment included with this consultation?  Yes ☒ No ☐
The Contaminants in Food (Wales) Regulations 2013

DETAIL OF CONSULTATION

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

   i. 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 2010 contaminants in food Regulations apply 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;

   ii. Revoke the Mineral Hydrocarbons in Food Regulations 1966 (which are purely national and not EU-derived) and revoke and remake, the provisions of, the Erucic Acid in Food Regulations 1977 as amended, thus consolidating the changes into the proposed Regulations, resulting in a single Statutory Instrument;

   iii. Details of changes to the national legislation are discussed in paragraphs 8 to 21 below;

   iv. We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from these proposals as indicated in the draft Impact Assessment (IA) at Annex C.

2. Similar consultations are being carried out by the Food Standards Agency (FSA) offices on parallel Regulations in Scotland, England and Northern Ireland.

Background

European Union Legislation on Contaminants in Food

3. 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 are 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 1881/2006² 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.

¹ SI 2010 No. 2394 (W.206)
4. Commission Regulation No. 1881/2006 sets maximum levels for nitrate in leafy vegetables. 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 of certain leafy vegetables, grown and intended for human consumption in their territory with nitrate levels higher than the established maximum levels.

5. 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 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.

**Changes in contaminant levels for the revised limits of nitrate in leafy vegetables**

6. 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.

7. On 10th April 2008, at the request of the European Commission, the European Food Safety Authority’s (EFSA) Panel on Contaminants in the Food Chain (“the Panel”) adopted a Scientific Opinion on nitrate in vegetables\(^3\). 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 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 agreed with Member States that achievable maximum levels for these foods should be set.

---

Commission Regulation (EU) No. 1258/2011 ("the nitrate Regulation") introducing new maximum levels for nitrate in food

8. The nitrate Regulation 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 and sets higher, more achievable levels then those initially set for lettuce and spinach across the EU. It also for the first time 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:


Coccidiostats and Histomonostats

9. 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, in order to reduce the resulting residue in food of non-target animals.

10. 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 have been established by a Commission Directive amending Annex I to Directive 2002/32/EC.


11. 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.

12. Regulation 610/2012 was published in the OJ on 10th July 2012 and is directly applicable throughout the EU and came into force on 30th 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:

4 Ref OJ L 320, 3.12.2011
6 Ref OJ L 178, 10.7.2012, p1
National Regulations being revoked

The Mineral Hydrocarbons in Food Regulations 1966 ("the Mineral Hydrocarbons Regulations")

13. 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.

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

15. 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 under EU contaminants legislation.

16. The FSA has consulted with major trade associations about the current uses of mineral hydrocarbons, and has taken note of the recent opinion7 of the European Food Safety Authority (EFSA) on mineral oils.

17. 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. In the light of 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")\(^8\). 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.

18. 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 no risk to consumer safety from revoking these Regulations.

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

20. We are therefore recommending the 1966 Regulations be revoked.

*The Erucic Acid in Food Regulations 1977 as amended ("the 1977 Erucic Regulations")*

21. The 1977 Erucic Regulations as amended will be revoked and remade with necessary amendments.

22. Council Directive 76/621/EEC\(^9\) as amended\(^10\), 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% or less calculated on the total level of fatty acids in the fat component and allows Member States at their discretion to apply Erucic acid limits to foods with an overall fat content of 5% or less. This discretion has been used in the case of foods aimed at infants or young children, where the Erucic acid limit has been applied to all those foods, not just those which contain more than 5% oils and fats. The FSA believes that this lower limit provides for an additional safety measure for this vulnerable consumer group.

The provisions of Directive 76/621/EEC are currently implemented by the 1977 Regulations. The provisions in the Contaminants in Food Regulations 2013 will maintain the position that the limits apply only to foods for placing on the market for consumption by the final consumer. Consignments and deliveries to manufacturers for the purposes of a manufacturing business or to a caterer for their business are thus not subject to the requirements.

23. 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 (Amendment) Regulations 1982\(^11\).

\(^8\) 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.
\(^11\) SI 1982 No. 264
24. The provisions of the 1977 Regulations as amended will be revoked and remade in the proposed Contaminants in Food Regulations 2013. 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 proposed in the draft 2013 Regulations.

25. There will be some textual changes to way in which the Directives mentioned above are implemented in the proposed Contaminants in Food Regulations as compared with the 1977 Erucic Regulations, to reflect changes in drafting practices.

**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**

26. 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 are likely to be negligible.

**Purpose of the Consultation**

27. The purpose of this consultation is to provide interested parties with the opportunity to comment and express their opinion on the proposed Contaminants in Food (Wales) Regulations 2013 and the associated Impact Assessment, 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.

28. The proposed Statutory Instrument (SI) entitled The Contaminants in Food (Wales) 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 Regulation and to take appropriate action where foodstuffs are found to be non-compliant. The proposed Regulations will revoke the Contaminants in Food (Wales) Regulations 2010 and remake them with necessary amendments, taking into account the enforcement provisions of Regulation 610/2012.

29. 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 (Wales) Regulations 2010 due to the effect of the ambulatory reference in those Regulations. The proposed 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.

**Ambulatory references**

30. The proposed Regulations continue to use ambulatory references; at present the ambulatory references in the current 2010 Contaminants Regulations only apply to the Annexes of Commission Regulation 1881/2006. We are proposing

---

12 SI 2010 No. 2394 (W.206)
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 SI 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.

31. The proposed Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (Wales) Regulations in order to rectify an under-enforcement of EC Regulation 1881/2006. Article 5 of that Regulation provides specific provisions for the labelling of groundnuts, other oilseeds, 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.

32. 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 for FBOs and enforcement bodies/officers.

Proposals

**Key proposal:**

- To revoke The Contaminants in Food (Wales) Regulations 2010 and remake them with necessary amendments, taking into account the provisions of the two new European Regulations;

- To provide for the execution and enforcement of Regulation 610/2012 by enforcement authorities in Wales;

- 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; and

- To revoke national legislation on mineral hydrocarbons in food and revoke and remake, with appropriate textual amendments, the provisions currently contained in the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

33. Any comments that interested parties are able to provide in relation to the proposed Regulations would be gratefully received. We 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.
Consultation Questions - (as read with the Impact Assessment (IA))

1(a). Stakeholders are invited to comment on the proposal to revoke the Mineral Hydrocarbons in Food Regulations 1966.

(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.

2(a). Stakeholders are asked to comment on the revocation and consolidation of the 1977 Erucic Regulations by the proposed contaminants in food 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 the exemption to exclude consignments sold to food manufacturers and caterers from the contaminants in food 2013 Regulations for Erucic acid.

If you agree or disagree with this proposal and the FSA’s assessment on the lower limits for infants and children (as discussed in paragraph 23 above), please provide evidence to support your views.

3. Stakeholders are invited to comment on the assessment that there are unlikely to be any costs to business and enforcement authorities associated with the revocation of the Mineral Hydrocarbons Regulations and the consolidation of the Erucic acid Regulations.

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

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 Annex 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.

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, oilseeds, derived products thereof and cereals.

If you agree or disagree with the inclusion of these provisions, please provide evidence to support your views.

6. We welcome comments on whether the businesses identified in Table 1 of the IA 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(a). It is our assumption that there is unlikely to be any additional costs for sampling and analysis as a result of the new limits for nitrate in spinach and lettuce. If you agree, or disagree with this assumption, please provide as detailed evidence as possible to support your view.

(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. If you agree or disagree with this assessment, please provide as detailed evidence as possible on such costs to support your views.

8. 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.

9. Stakeholders are asked to comment, with supporting evidence, on the assumption that it will take 1.5 hours (as indicated table 4a of the IA) 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.

10(a). Stakeholders are asked to comment, with supporting evidence, on the assumption that it will take 2.25 hours (as indicated in Table 5a of the IA) to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities.

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

11(a). We would welcome comments from stakeholders on whether the costs and benefits set out in Table 7 of the IA is an accurate representation of the costs and benefits to business and enforcement authorities. Please provide evidence to support your response.

(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.

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

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

Consultation Process / Impact

34. 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.

Informal Public Consultation

35. 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 on the amendments to Commission Regulation 1881/2006 and the nitrates Regulation. For example, it has released several interested parties letters notifying stakeholders as it has done so, which are available from the following link:

http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/
36. In addition, as mentioned in paragraphs 27 and 28 above, 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.

37. 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.

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

Other relevant documents

39. 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:


40. The Contaminants in Food (Wales) Regulations 2010 are available on the ‘legislation.gov.uk’ website at:


41. The Mineral Hydrocarbons in Food Regulations 1966 and the Erucic Acid in Food Regulations 1977 (as amended) are also available on the ‘legislation.gov.uk’ website at:


Responding to the Consultation

42. Responses are requested by close of business on **7 August 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.)
43. Thank you on the behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

Vicki Reilly
Food Standards Agency in Wales

Enclosed

Annex A: Standard Consultation Information

Annex B: The draft Contaminants in Food (Wales) Regulations 2013

Annex C: Draft Impact Assessment


Annex F: Interested Parties list
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 Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. 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 E. 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 let us know if you need paper copies of the consultation documents or of anything specified under ‘Other relevant documents’.

7. 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.

8. Criterion 2 states that Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

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

10. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2B, 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 Agency 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

13. The questionnaire can also be used to update us about your existing contact details.
2013 No. (W.)

FOOD, WALES

The Contaminants in Food (Wales) Regulations 2013

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to Wales, revoke and re-enact with changes the Contaminants in Food (Wales) Regulations 2010 (S.I. 2010/2010 (W.206)). They make provision for—

(a) the continuing implementation of 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 (OJ No. L202, 28.7.1976, p.35) and of 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 (OJ No. L254, 29.9.1980, p.35); and


2. The Commission Regulation includes amendments made by—


(b) Commission Regulation (EC) No. 629/2008 (OJ No. L173, 3.7.2008, p.6), concerning maximum permitted levels for certain heavy metals;


(d) Commission Regulation (EU) No. 165/2010 (OJ No. L50, 27.2.2010, p.8), concerning maximum levels for aflatoxins and the treatment of certain foods found to contain aflatoxins in excess of those levels;

(e) Commission Regulation (EU) No.420/2011 (OJ No. L111, 30.4.2011, p.3), which concerns the collection of occurrence data by Member States;


(h) Commission Regulation (EU) No.1259/2011 (OJ No. L320, 3.12.2011, p.18), concerning maximum permitted levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs; and


4. The Regulations —
   
   (a) provide that it is an offence, (except in certain cases relating to food placed on the market before a date specified in the relevant EU legislation) —
   
   (i) to place specified foods on the market containing erucic acid in excess of permitted levels (regulations 3 and 4);
   
   (ii) to place on the market certain foods if they contain contaminants of any kind specified in the Commission Regulation or in Regulation 124/2009 at levels exceeding those specified,
   
   (iii) to use food containing contaminants at levels in excess of those permitted by the Commission Regulation as ingredients in the production of certain foods,
   
   (iv) to mix foods that do not comply with the maximum levels prescribed by the Commission Regulation or Regulation 124/2009 with foods which do comply,
   
   (v) to mix foods to which the Commission Regulation relates and which are intended for direct consumption or as food ingredients with foods to which the Commission Regulation relates and which are intended to be sorted or otherwise treated prior to consumption, or
   
   (vi) to detoxify by chemical treatment food containing mycotoxins in excess of the limits specified in the Commission Regulation (regulation 5);
   
   (b) provide for penalties on conviction for an offence under these Regulations (regulation 6) and specify the enforcement authorities (regulation 7);
   
   (c) provide for the application of specified provisions of the Food Safety Act 1990 for the purposes of these Regulations (regulation 8);
   
   (d) make a consequential amendment to the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 (regulation 9), the effect being to disapply the sampling and analysis provisions of those Regulations only to the extent that those matters are regulated by the EU instruments mentioned in paragraph 5(a) to (d).

5. The Commission Regulation specifies the European Union methods of sampling and analysis that are required to be used for the official control of levels of the substances covered by it. Those methods are set out in —


6. The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Food Standards Agency at Food Standards Agency Wales, 11th Floor, Southgate House, Wood Street, Cardiff CF10 1EW
The Welsh 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(1), and now vested in them(2), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(3).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State 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.

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(4), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

---

(1) 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. 2004/2.

(2) Functions formerly exercisable by “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

(3) 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

Title, application and commencement

1.—(1) The title of these Regulations is the Contaminants in Food (Wales) Regulations 2013.
(2) These Regulations apply in relation to Wales and come into force on [XXXX] 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(1);
“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(2);

---

(2) OJ No. L254, 27.9.1980, p.35.
“Regulation 1881/2006” means Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs(1);


“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(3);


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

“food authority” does not include a port health authority;

“port health authority” means, in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984(5), a port health authority for that district constituted by order under section 2(4) of that 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.]

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(6).

---


(5) 1984 c.22.

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 and each port health authority within its district to execute and enforce these Regulations, Regulation 1881/2006 and Regulation 124/2009.
(2) 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),
is the authority having the duty to enforce under paragraph (1).

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) with the modification that—
(i) subsections (2) to (4) 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” is 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);
(h) section 35(2) and (3)(3), 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); 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 (Wales) 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

(1) Section 21 was amended by S.I. 2004/3279.
(2) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.
(3) Section 35(3) was amended by S.I. 2004/3279.
(4) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.
(b) seize the food and remove it in order to have it dealt with by a justice of the peace.

(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 justice of the peace.

(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 justice of the peace and —

(a) 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 justice of the peace by whom the food falls to be dealt with, be entitled to be heard and to call witnesses; and

(b) that justice of the peace may, but need not, be a member of the court before which any person is proceeded against for an offence in connection with any of the EU requirements in relation to that food.

(5) If it appears to a justice of the peace, on the basis of such evidence as the justice 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 justice 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 justice of the peace 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 arbitration.

(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), will, 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) (Wales) Regulations 2013(1) (provisions to which those Regulations do not apply), for the entry relating to the Contaminants in Food (Wales) Regulations 2010(2) substitute the following entry —

““The Contaminants in Food (Wales) Regulations 2013 (to the extent that a sample falls to be prepared and analysed in accordance with Regulation”

(1) S.I. 2013/479 (W.55).
(2) S.I. 2010/2228.
1881/2006 as that expression is defined in those Regulations

Revocations

10. The —
   (a) Mineral Hydrocarbons in Food Regulations(1);
   (b) Erucic Acid in Food Regulations(2);
   (c) Erucic Acid in Food (Amendment) Regulations 1982(3); and
   (d) Contaminants in Food (Wales) Regulations 2010(4),

are revoked.

[Name]
Title of Minister, one of the Welsh Ministers

Date

---

(3) S.I. 1982/264.
(4) S.I. 2010/2394 (W.206).
Summary: Intervention and Options

<table>
<thead>
<tr>
<th>Cost of Preferred (or more likely) Option</th>
<th>RPC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Net Present Value</td>
<td>-£0.63m</td>
</tr>
<tr>
<td>Business Net Present Value</td>
<td>£0.07m</td>
</tr>
<tr>
<td>Net cost to business per year (EANCB on 2009 prices)</td>
<td>£0.07m</td>
</tr>
<tr>
<td>In scope of One-In, One-Out?</td>
<td>No</td>
</tr>
<tr>
<td>Measure qualifies as In/Out/zero net cost</td>
<td></td>
</tr>
</tbody>
</table>

What is the problem under consideration? Why is government intervention necessary?
The presence of contaminants, such as nitrate, coccidiostats and histomonostats, in foods can have a detrimental impact on consumer health. Consumers are unable to assess the risk from contaminants present in their 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.

What are the policy objectives and the intended effects?
The purpose of these proposals is to meet the following policy objectives:

- To ensure that maximum levels set for nitrate in lettuce, spinach and rocket in Wales are sufficient to protect consumer health but are also achievable.
- To ensure that levels set for coccidiostats and histomonostats in food in Wales are sufficient to protect consumer health by setting maximum levels for their presence in food resulting from the unavoidable carry-over in non-targeted feed.
- To revoke national legislation on mineral hydrocarbons in food and revoke and remake the provisions currently contained in the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Three options are being considered:

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

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

**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 and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. To extend the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on Erucic acid and revoke the mineral hydrocarbons in food legislation.

Option 3 is preferred as it achieves all policy objectives; allows for ambulatory provisions; the consolidation of all the contaminants legislation in one statutory instrument.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 10/2017
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.

Signed by the responsible Chief Executive: __________________________:  __________________________

Date
Summary: Analysis & Evidence

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

FULL ECONOMIC ASSESSMENT

| Description | Do Nothing – Do not implement the new nitrate limits in leafy vegetables, or set maximum levels set for coccidiostats and histomonostats in food |

| Policy Option 1 |

<table>
<thead>
<tr>
<th>Price Base Year 2009</th>
<th>PV Base Year 2012</th>
<th>Time Period Years 10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low: Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High: Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

There are no costs or benefits associated with this option as it is the baseline against which all other options are appraised.

Other key non-monetised costs by ‘main affected groups’

There are no costs or benefits associated with this option as it is the baseline against which all other options are appraised.

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

There are no costs or benefits associated with this option as it is the baseline against which all other options are appraised.

Other key non-monetised benefits by ‘main affected groups’

There are no costs or benefits associated with this option as it is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks

Assumes that none of the policy options will be introduced

Discount rate (%) 3.5%

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:

<table>
<thead>
<tr>
<th>Costs: N/A</th>
<th>Benefits: N/A</th>
<th>Net: N/A</th>
</tr>
</thead>
</table>

In scope of OIOO? No

Measure qualifies as IN/OUT/Zero net cost

3
Summary: Analysis & Evidence

Policy Option 2

Description: – 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

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2009</th>
<th>PV Base Year 2012</th>
<th>Time Period Years 10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low: Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High: Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: -0.63</td>
</tr>
</tbody>
</table>

COSTS (£m)

<table>
<thead>
<tr>
<th>Low</th>
<th>Optional</th>
<th></th>
<th>1</th>
<th>Optional</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Optional</td>
<td></td>
<td></td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>£0.63</td>
<td></td>
<td></td>
<td></td>
<td>£0.63</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

One off familiarisation cost to UK industry of £613,183 (NPV over ten years, EAC of £71,237)
One off familiarisation cost to UK enforcement of £20,294 (NPV over ten years, EAC of £2,358)

Other key non-monetised costs by ‘main affected groups’

None

BENEFITS (£m)

<table>
<thead>
<tr>
<th>Low</th>
<th>Optional</th>
<th></th>
<th></th>
<th>Optional</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Optional</td>
<td></td>
<td></td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>£0</td>
<td></td>
<td></td>
<td>£0</td>
<td>£0</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

None

Other key non-monetised benefits by ‘main affected groups’

Consumer health benefits from introduction of limits on contaminants in rocket and animal feed
Potential wider benefits in terms of reducing barriers to trade, increased market competition, reduction in food wastage

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%
Due to lack of data, we assume that additional sampling, tests and analysis of rocket can be carried out at the same time as sampling, tests and analysis of lettuce and spinach (therefore costs are negligible)

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:
Costs: £0.07  Benefits: £0  Net: £0.07  In scope of OIOO? Yes/No  Measure qualifies as IN/OUT/Zero net cost
Summary: Analysis & Evidence

Policy Option 3

Description: – 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 and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. To extend the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on Erucic acid and revoke the mineral hydrocarbons in food legislation.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2009</th>
<th>PV Base Year 2012</th>
<th>Time Period Years 10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low: Optional</td>
<td>High: Optional</td>
<td>Best Estimate: -0.63</td>
<td></td>
</tr>
</tbody>
</table>

COSTS (£m)

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
<th>Best Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>£0.63</td>
<td>£0</td>
<td>£0.63</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

One off familiarisation cost to UK industry of £613,183 (NPV over ten years, EAC of £71,237)
One off familiarisation cost to UK enforcement of £20,294 (NPV over ten years, EAC of £2,358)

Other key non-monetised costs by ‘main affected groups’

None

BENEFITS (£m)

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
<th>Best Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>£0</td>
<td>£0</td>
<td>£0</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

None

Other key non-monetised benefits by ‘main affected groups’

Consumer health benefits from introduction of limits on contaminants in rocket and animal feed
Potential wider benefits in terms of reducing barriers to trade, increased market competition, reduction in food wastage

Key assumptions/sensitivities/risks

Discount rate (%): 3.5%

Due to lack of data, we assume that additional sampling, tests and analysis of rocket can be carried out at the same time as sampling, tests and analysis of lettuce and spinach (therefore costs are negligible)

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:
Costs: £0.07
Benefits: £0
Net: £0.07
In scope of OIOO? Yes/No
Measure qualifies as IN/OUT/Zero net cost
Evidence Base (for summary sheets)

Problem under Consideration and Rationale for Intervention

1. The presence of contaminants, such as nitrate, coccidiostats and histomonostats in some foods can have a detrimental impact on consumer health. Consumers are unable to assess the risk from contaminants present in foods and therefore, are unable to make fully informed choices about such risk. Government intervention is necessary to address this information asymmetry and minimise the risk to health, taking into account the latest scientific evidence to provide greater clarity in enforcement.

Policy Objective

2. The purpose of these proposals is to meet the following policy objectives:

- To ensure that maximum levels set for nitrate in lettuce, spinach and rocket in Wales are sufficient to protect consumer health but are also achievable.
- To ensure that levels for coccidiostats and histomonostats in food in Wales are sufficient to protect consumer health by setting maximum levels for their presence in food resulting from the unavoidable carry-over in non-targeted feed.
- To revoke national legislation on mineral hydrocarbons in food and to revoke and remake, provisions currently contained in the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

Legislative Context


3. Nitrates commonly occur in high concentrations in spinach and lettuce mainly due to climatic conditions. This is a particular problem for lettuce growers in northern European countries, such as the UK, because poorer light quality can restrict the energy available for assimilation of nitrate by glasshouse crops. Scientific data has shown that reduction of dietary exposure to nitrate can be achieved by setting maximum levels for highly contaminated foods such as certain leafy vegetables reaching the market.

4. 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\(^1\). 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 vegetable 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 1 to this document).

5. EFSA has published two evaluations of the risks of nitrate in food. Excessive intake of nitrate could result in methaemoglobinemia\(^2\) 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.

6. 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


\(^2\) 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.
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.

7. Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs 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 (including the UK) 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.

8. 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. 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 as Annex D to the consultation and is also available to download free of charge from the following website:


9. Commission Regulation (EC) No. 124/2009 of 10th February 2009 sets maximum levels for the presence of certain coccidiostats and histomonostats in food as the result of unavoidable carry-over into non-targeted feed. The legislation harmonises the limits for the coccidiostats and histomonostats carry-over across the EU without posing a risk to public health. 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 of the European Parliament and of the Council of 7th May 2002, on undesirable substances in animal feed.

10. 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 a risk to consumer’s health from the ingestion of these residues in products from animals exposed to cross-contaminated feed.

11. For details of the EFSA opinions on coccidiostats and histomonostats, please see Annex 1 to this document.

12. 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 as Annex E, and is also available to download free of charge from the following website:


4 OJ L 320, 3.12.2011, p15
5 OJ L 178, 10.7.2012, p 1
6 OJ L 40, 11.2.2009, p3
7 OJ L 40, 30.5.2002, p10
The Contaminants in Food (Wales) Regulations 2013 will revoke the Mineral Hydrocarbons in Food Regulations 1966\(^8\) and revoke and remake the Erucic Acid in Food Regulations 1977\(^9\).

**Details of the national Regulations being revoked**

The Mineral Hydrocarbons in Food Regulations 1966 ("the Mineral Hydrocarbons Regulations")

14. **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 of the food; and
- When used as an EU permitted additive.

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.

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

16. 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.

17. We have considered a number of options for amending/updating the legislation, taking account of the recent EFSA opinion on mineral oils and have consulted major trade associations about the current uses of mineral hydrocarbons. 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; 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")). 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.

18. 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.

19. 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**

\(^8\) SI 1966 No. 1073

\(^9\) SI 1977 No. 691

\(^{10}\) 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.
20. We are also looking to revoke the 1977 Erucic Regulations as amended and remake them with necessary amendments.

21. Council Directive 76/621/EEC12 as amended, relates 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 to apply Erucic acid limits to foods with an overall fat content of 5% or less. This discretion has been used in the case of foods aimed at infants or young children, where the Erucic acid limit has been applied to all those foods, not just those which contain more than 5% oils and fats. The FSA believes that this lower limit provides an additional safety measure for this vulnerable consumer group.

22. The provisions of Directive 76/621/EEC are currently implemented by the 1977 Regulations. The provisions in the Contaminants in Food Regulations 2013 will maintain the position that the limits apply only to foods for placing on the market for consumption by the final consumer. Consignments and deliveries to manufacturers for the purposes of a manufacturing business or to a caterer for their business are thus not subject to the requirements.


24. While the 1977 Erucic Regulations and its amending Regulations will be revoked and remade, in the proposed Contaminants in Food Regulations 2013, the provisions of the two EC Directives remain 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 in Food Regulations 2013 to the way in which the Directives mentioned in paragraph 22 are implemented, to take into account changes in drafting techniques and practices.

25. 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, if any, will be.

Consultation question 2

(a). Stakeholders are invited to comment on the revocation and consolidation of the 1977 Erucic Regulations by the proposed Contaminants in Food Regulations and whether the proposed consolidation will make it easier for businesses and other stakeholders to find

11 SI 1977 No. 691
13 OJ L 254, 27.9.1980, p 35
14 OJ L122, 16.5.2003, pg36 - Adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (unanimity)
15 SI 1982 No. 264
legislation that affects them? (b). Stakeholders are also invited to give views on maintaining the exemption to exclude consignments sold to food manufacturers and caterers from the contaminants in food 2013 Regulations for Erucic acid.

If you agree or disagree with this proposal and the FSA’s assessment on the lower limits for infants and children (as discussed in paragraph 21 above), please provide evidence to support your views.

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

26. 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.

Consultation question 3

Stakeholders are invited to comment on the assessment that there are unlikely to be any costs to business and enforcement authorities associated with the revocation of the Mineral Hydrocarbons Regulations and the consolidation of the Erucic acid Regulations.

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

Policy Background – Chemical Contaminants

27. The proposal for a Statutory Instrument entitled The Contaminants in Food (Wales) Regulations 2013 (“the proposed 2013 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 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 (Wales) Regulations 2010 and remake them with necessary amendments, taking into account the enforcement requirements of Regulation 610/2012.

28. 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 Regulations.

29. The proposed Regulations continue to use ambulatory references; at present the ambulatory references in the current 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 as well as the latter. Extending the use of ambulatory references to include Articles as well as Annexes will avoid the need to introduce a new SI 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.

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 Annex 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.

16 SI 2010 No. 2394 (W.206)
30. The proposed Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (Wales) Regulations 2010 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, other oilseeds, 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.

31. 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 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, oilseeds, derived products thereof and cereals.

If you agree or disagree with the inclusion of these provisions, please provide evidence to support your views.

32. On 10\textsuperscript{th} April 2008, at the request of the European Commission, the European Food Safety Authority’s (EFSA) Panel on Contaminants in the Food Chain (“the Panel”) adopted a Scientific Opinion on nitrate in vegetables\textsuperscript{17}. The Panel compared the risk and benefits of exposure to nitrate from vegetables. Overall 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. However, the Panel did recognise 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 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.

33. European Union legislation on contaminants in food is made under the contaminants framework Regulation, Council Regulation 315/93/EEC\textsuperscript{18}. 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.

34. Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, and may \textit{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\textsuperscript{19} 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.

\textsuperscript{18} OJ L37, 13.2.1993, p. 1
\textsuperscript{19} 22 September 2003 – OJ L268, 18.10.2003, p.29
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”.

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

Industry Initiatives – Nitrate in Vegetables

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.

ADAS is also carrying out a monitoring programme in the UK, which is funded by the FSA. Samples are collected on a voluntary basis from farms and are analysed for nitrate and the results are submitted to the FSA; this data will be transmitted to EFSA. It is possible that the FSA may also receive data from other sources, which could be submitted to the Commission and industry might themselves respond direct to EFSA calls for data. However, the FSA funded programme on nitrate monitoring will be the main source of data submitted to EFSA.

The collection of samples for the FSA by ADAS is in response to the statutory requirement in the nitrate Regulation to collect data for submission. 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.

Current work was sponsored by the Agriculture and Horticulture Development Board (AHDB) 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

There are other reports on nitrate on AHDB website.

Sectors and Groups Affected

Industry

Primary Producers

The new Regulations impact on any food business operator (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.

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.

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

Retail and Wholesalers

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**

46. 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**

47. 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.

48. 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). Table 1 below summarises those sectors that are likely to be affected by the Regulation.

**Table 1: 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>

49. 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 6**

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.

---

50. Using the IDBR, we estimate that there are approximately 370 businesses in the above sectors that are affected by the Regulation in the Wales. Table 2 below shows the number of businesses affected by Employment Size and UK country.

<table>
<thead>
<tr>
<th>Table 2: Businesses Affected by Employment Size and UK Country</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>England</td>
</tr>
<tr>
<td>Wales</td>
</tr>
<tr>
<td>Scotland</td>
</tr>
<tr>
<td>NI</td>
</tr>
<tr>
<td>UK</td>
</tr>
</tbody>
</table>

**Enforcement Authorities**

**Familiarisation Costs**

51. Enforcement Authorities will be affected by the nitrate Regulation and Regulation 610/2012. Under both options 2 and 3, enforcement authorities will be required to read and familiarise themselves with the new maximum limits for nitrate and the limits for coccidiostats and histomonostats.

**Sampling and Analysis Costs**

52. 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 7**

(a). It is our assumption that there is unlikely to be any additional costs for sampling and analysis as a result of the new limits for nitrate in spinach and lettuce. If you agree, or disagree with this assumption, please provide as detailed evidence as possible to support your view.

(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. If you agree or disagree with this assessment, please provide as detailed evidence as possible on such costs to support your views.

53. 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 8**

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.
54. There are 435 authorities in the UK, including Local Authorities (LAs) and Port Health Authorities (PHAs), with responsibility for the enforcement of food legislation. This includes 354 authorities in England; 23 in Wales, 32 in Scotland; and 26 authorities in Northern Ireland, as shown in Table 3 below.

Table 3: Enforcement Authorities Affected 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>354</td>
<td>23</td>
<td>32</td>
<td>26</td>
<td>435</td>
</tr>
</tbody>
</table>

**Impact on other Government Bodies**

55. 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.

56. Member States are also required to monitor nitrate levels in vegetables which may contain significant levels, in particular green leafy vegetables, and communicate the results 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. This 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.

**Options Considered**

**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**

57. Under this option the nitrate Regulation and Regulation 610/2012 will still be applicable in Wales 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.

58. 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**

59. 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.

60. 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 and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. To extend the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on Erucic acid and revoke the mineral hydrocarbons in food legislation.

61. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the new Regulations in Wales. 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.

62. This option would also make ambulatory provisions in the domestic 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.

63. 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 Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

Option Appraisal

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

Costs and Benefits

64. There are no incremental costs or benefits 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.

65. 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

Costs

Costs to Industry

One-off Familiarisation Costs

66. 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.

67. 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 £20.08 which has been uprated by 30% to cover overheads: £20.08 * 1.3 = £26.10

21 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
cost of familiarisation per business by the total number of businesses affected (See Table 2) generates a total cost of familiarisation to industry in Wales of £14,488, see Table 4a below.

Table 4a: Familiarisation Costs to UK Industry, by UK Country and Firm Size

<table>
<thead>
<tr>
<th>Country</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>
</tr>
<tr>
<td>Wales</td>
<td>12,943</td>
<td>1,286</td>
<td>222</td>
<td>37</td>
<td>14,488</td>
</tr>
<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 9

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)

68. 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\(^{22}\). Under Standard HMT Green book guidance a discount rate of 3.5% is used.

69. The total one off cost to industry in Wales of the Regulation is an estimated £14,488 (see Table 4a). This yields an EAC of approximately £1,683 in Wales over 10 years. Table 4b displays the breakdown of the EAC by country.

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

<table>
<thead>
<tr>
<th>EAC</th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td></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

70. As with industry, there will be a small one-off cost to enforcement authorities and port health 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 of the local, district/borough etc, councils and the Trading Standards Departments of the county councils. 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.

71. Each food authority in its area and each port health authority in its district are responsible for enforcing the legislation with respect to food safety and food hygiene. They have responsibility for enforcing the contaminants in food legislation and will, as outlined above, be affected by these proposals.

\(^{22}\) EACB = PVCB/\(a_r\), Where \(a_r\) is the annuity rate given by:

\[ a_{r,i} = \sum_{j=0}^{r-1} i \prod_{i=0}^{r-1} \left( \frac{1}{1 + r_i} \right) \]

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.
72. It is expected that one Environmental Health Officer (EHO) or one Trading Standards Officer (TSO) from each LA and PHA 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 10
(a). Stakeholders are asked to comment, with supporting evidence, on the assumption that it will take 2.25 hours to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities.
(b). We would also welcome comments and estimates from enforcement bodies of enforcing the new EC legislation.

73. 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 £20.4623, whilst the median hourly wage rate of a TSO is £21.0124. 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 Wales (23, see Table 3), results in a total familiarisation cost to Welsh enforcers of £1,073, see Table 5a below. (Note that all presented figures are rounded).

Table 5a: 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)

74. 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 71 above). The total one off cost in Wales of the Regulation is an estimated £1,073 (see Table 5a). This yields an EAC of approximately £2,358 in the UK over 10 years, which per country equates to £125 in Wales. Table 5b displays the breakdown of the EAC per country.

Table 5b: 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>

Benefits

Benefits to Consumers

75. 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.

76. For spinach and lettuce, the Regulation raises the existing maximum limits. Based on the Panels 2008 opinion on nitrates in vegetables (see paragraph 31), we envisage this impact to be neutral on consumers.

Wider Benefits

77. This option would harmonise standards across the Member States with proposed contaminants legislation 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. 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 and the Articles and Annex of Commission Regulation 124/2009 setting maximum levels of coccidiostats and histomonostats in food. To extend the ambulatory provisions to include the Articles and Annexes of Directives 76/621/EEC and 80/891/EEC on Erucic acid and revoke the mineral hydrocarbons in food legislation. Costs

Costs to Industry

78. 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 Table 4).

Costs to Enforcement Authorities

79. 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 5).

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

Benefits

Benefits to Consumers

81. 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, (see paragraphs 79 and 80), we have however not been able to monetise these.

Benefits to Industry

82. Under Option 3 we assume that simplification may 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

83. Enforcement authorities may benefit from simplification of the contaminants legislation, as a result of the consolidation.

Consultation question 11

(a). We would welcome comments from stakeholders on whether the costs and benefits set out in Table 7 above are an accurate representation of the costs and benefits to business and enforcement authorities. Please provide evidence to support your response.
(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

Public Consultation
84. The FSA has also 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
85. 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
86. 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.

SPECIFIC IMPACT TESTS

Competition
87. We have fully considered the questions posed by in the Office of Fair Trading competition assessment test 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.

88. 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
89. Stakeholders, including the Enterprise Directorate in BIS have been consulted throughout the negotiations on the legislation. This has been done via interested parties letters and formal meetings. 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 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? If you agree or disagree with this assessment, please provide evidence to support your response.*

**Sustainability**

90. Impacts under the three pillars (environment, economic and social) of sustainable development have been and continue to be considered in the preparation of this Impact Assessment. The FSA’s remit of consumer protection in relation to food safety continues to be central. Option 3 is more economically sustainable, which will benefit growers of rocket in the UK. This option is also more sustainable as businesses and enforcement authorities will benefit from having one set of Regulations containing all the provisions on chemical contaminants in food that they need to refer to. Additionally, higher maximum levels for nitrate in spinach, lettuce and rocket have been agreed, in order to allow for the differences in climate across the EU. This will benefit UK growers of these foods, whilst maintaining consumer safety. 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 limits for nitrate in spinach and lettuce being relaxed, making compliance easier and reducing food waste.

91. The impact in terms of financial costs will be a one-off cost, in familiarising and reading the two EU Regulations and the proposed national Regulations. The proposals would have little if any impact on the delivery of the Government’s five principles of sustainable development, on the environment or in relation to public health.

**Race/Gender/Disability Equality Issues**

92. The FSA believes that the proposal will not have an impact on race, gender, or disability equality issues. Charities and voluntary organisations are also unlikely to be affected by these proposals.

**Consultation Question 13**

*Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and national Regulation? Please provide evidence to support your response.*
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.” Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on Cross-contamination of non-target feedingstuffs by Lasalocid authorised for use as a feed additive, The EFSA Journal (2007)553, 1-46: http://www.efsa.europa.eu/en/efsajournal/doc/553.pdf

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.” Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by Nicarbazin authorised for use as a feed additive, The EFSA Journal (2008) 690, 1-34. http://www.efsa.europa.eu/en/efsajournal/doc/690.pdf

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 http://www.efsa.europa.eu/en/efsajournal/doc/716.pdf
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 longer-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
## 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></td>
</tr>
<tr>
<td>Harvested 1 October to 31 March:</td>
<td></td>
</tr>
<tr>
<td>lettuce grown under cover</td>
<td>5 000</td>
</tr>
<tr>
<td>lettuce grown in the open air</td>
<td>4 000</td>
</tr>
<tr>
<td>Harvested 1 April to 30 September:</td>
<td></td>
</tr>
<tr>
<td>lettuce grown under cover</td>
<td>4 000</td>
</tr>
<tr>
<td>lettuce grown in the open air</td>
<td>3 000</td>
</tr>
<tr>
<td>1.4 “Iceberg” type lettuce</td>
<td></td>
</tr>
<tr>
<td>Lettuce grown under cover</td>
<td>2 500</td>
</tr>
<tr>
<td>Lettuce grown in the open air</td>
<td>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></td>
</tr>
<tr>
<td>Harvested 1 October to 31 March:</td>
<td>7 000</td>
</tr>
<tr>
<td>Harvested 1 April to 30 September:</td>
<td>6 000</td>
</tr>
<tr>
<td>1.6 Processed cereal-based foods and baby foods for infants and young children (1) (3)</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 feedingstufs 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 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

---

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>
<td>— other food. 5°</td>
</tr>
</tbody>
</table>
### Interested Parties List

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cate Barrow</td>
<td></td>
<td>ADAS Holdings Limited</td>
</tr>
<tr>
<td>Julie Barratt</td>
<td></td>
<td>Chartered Institute of Environmental Health</td>
</tr>
<tr>
<td>David Handley</td>
<td></td>
<td>Farmers For Action</td>
</tr>
<tr>
<td>Nick Fenwick</td>
<td></td>
<td>Farmers Union of Wales</td>
</tr>
<tr>
<td>Dai Davies</td>
<td></td>
<td>Federation of Small Businesses, Wales</td>
</tr>
<tr>
<td>Pete Riley</td>
<td></td>
<td>GM Freeze Campaign</td>
</tr>
<tr>
<td>Heather McCalman</td>
<td></td>
<td>Grassland Development Centre, IGER</td>
</tr>
<tr>
<td>Dave Ellis</td>
<td></td>
<td>Merlin Biodevelopment Ltd</td>
</tr>
<tr>
<td>Cath Smith</td>
<td></td>
<td>Mid Wales Food and Land Trust Ltd</td>
</tr>
<tr>
<td>John Robinson</td>
<td></td>
<td>Minton, Treharne &amp; Davies Limited</td>
</tr>
<tr>
<td>Stella Owen</td>
<td></td>
<td>National Farmers Union Cymru</td>
</tr>
<tr>
<td>Dylan Morgan</td>
<td></td>
<td>National Farmers Union Cymru Wales</td>
</tr>
<tr>
<td>Helen Davies</td>
<td></td>
<td>National Sheep Association Cymru Wales</td>
</tr>
<tr>
<td>David Walters</td>
<td></td>
<td>Royal Welsh Agricultural Society</td>
</tr>
<tr>
<td>Barrie Jones</td>
<td></td>
<td>Royal Welsh Agricultural Society</td>
</tr>
<tr>
<td>Tim Keohane</td>
<td></td>
<td>Trading Standards Institute</td>
</tr>
<tr>
<td>Gareth Walters</td>
<td></td>
<td>Trading Standards Institute</td>
</tr>
<tr>
<td>Prysor Williams</td>
<td></td>
<td>University of Wales Bangor</td>
</tr>
<tr>
<td>Elinor Plow</td>
<td></td>
<td>Welsh Food Alliance</td>
</tr>
<tr>
<td>John Davies</td>
<td></td>
<td>Welsh Local Government Association</td>
</tr>
<tr>
<td>Marilyn James</td>
<td></td>
<td>Welsh Organic Scheme</td>
</tr>
</tbody>
</table>