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# FOOD STANDARDS AGENCY CONSULTATION

## THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2013

### CONSULTATION SUMMARY PAGE

| Date consultation launched: | Closing date for responses: |
|---|---|
| 10th April 2013 | 5th July 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 (England) Regulations 2013 will revoke the Contaminants in Food (England) 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 (England) 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 (England) 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: Nasreen Shah**<br>**Division/Branch : Chemical Safety Division**<br>**FOOD STANDARDS AGENCY**<br>**Tel: 020 7276 8538**<br>**Fax: 020 7276 8910** | **Postal address:**<br>**Room 3B, Aviation House**<br>**125 Kingsway, London,**<br>**WC2B 6NH.**<br>**Email:** nasreen.shah@foodstandards.gsi.gov.uk |

| Is an Impact Assessment included with this consultation? | Yes ☒ | No ☐ |
| --- | --- | --- |

# THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2013

## DETAIL OF CONSULTATION

1. We would welcome your comments on The Contaminants in Food (England) Regulations 2013 ("the proposed Regulations") attached as Annex B. The proposed Regulations will revoke The Contaminants in Food (England) Regulations 2010[1] 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 will be carried out by the Food Standards Agency (FSA) offices on parallel Regulations in Scotland, Wales and Northern Ireland.

### Red Tape Challenge

3. In April 2011 the Government launched the Red Tape Challenge (RTC) initiative[2] with the purpose of getting comments from business and the public on how the burden of legislation can be reduced. Whilst the FSA is a UK non-Ministerial Department, the RTC applies to England only. On 6th May 2011 most of the FSA's legislation was published on the RTC website under the Hospitality Theme and remained on the site until 2 June 2011. The FSA has a number of initiatives being delivered under the RTC[3], including developing a simplified system of food safety legislation. This involves the consolidation and revocation of a number of domestic Statutory Instruments which are no longer required for consumer protection. The revocation of the Mineral Hydrocarbons in Food Regulations 1966[4] and (the revocation and remake of the Erucic Acid) in Food Regulations 1977[5] are part of this simplification.

[1] SI 2010 No. 2228
[2] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/
[3] http://www.food.gov.uk/enforcement/regulation/betregs/red-tape-challenge/
[4] SI 1966 No. 1073
[5] SI 1977 No. 691

## Background

### *European Union Legislation on Contaminants in Food*

4. 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 1881/2006[6] 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.

5. 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.

6. 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*

7. 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.

8. 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[7]. The Panel

[6] Ref OJ L 364, 20.12.2006, p5 – Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

[7] 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, EFSA Journal (2008), Journal No 689, p.1. http:/www.efsa.europa.eu/en/scdocs/doc/689.pdf

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***

9. The nitrate Regulation[8] 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:

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

***Coccidiostats and Histomonostats***

10. 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.

11. 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[9] 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.

***Commission Regulation (EU) No. 610/2011 ("Regulation 610/2011") amending Regulation (EC) No. 124/2009***

12. 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

[8] Ref OJ L 320, 3.12.2011

[9] Ref OJ L140, 30.5.2002, p10 – Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

ensure proper functioning of the internal market and for the protection of public health.

13. Regulation 610/2012[10] 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:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:178:0001:0003:EN:PDF

**National Regulations being revoked**

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

14. 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.

15. In addition, the Mineral Hydrocarbons Regulations specify 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 under EU contaminants legislation.

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

18. 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

[10] Ref OJ L 178, 10.7.2012, p1
[11] http://www.efsa.europa.eu/en/efsajournal/pub/2704.htm

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")[12]., 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.

19. 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.

20. 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.

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

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

22. Under the RTC we are also looking to revoke the 1977 Erucic Regulations as amended and remake them with necessary amendments.

23. Council Directive 76/621/EEC[13] as amended[14], 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.

[12] 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.
[13] OJ L 202, 28.7.1976, p 35
[14] Council Directive 76/621/EEC was last amended by Commission Regulation 807/2003, OJ Ref L122, 16.5.2003

24. 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[15].

25. 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.

26. 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***

27. 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**

28. 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 (England) 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

29. The proposed Statutory Instrument (SI) entitled The Contaminants in Food (England) 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 (England) Regulations 2010[16] and remake them with necessary amendments, taking into account the enforcement provisions of Regulation 610/2012.

30. 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 (England) Regulations 2010 due to the effect of the ambulatory reference in those Regulations. The proposed Regulations will give effect to the amendments

[15] SI 1982 No. 264
[16] SI 2010 No. 2228

made to the Articles of Regulation 1881/2006 made by the nitrate Regulation and to any subsequent amendments.

***Ambulatory references***

31. 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 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.

32. The proposed Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (England) 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.

33. 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 (England) 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 England;**

- **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.**
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34. 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 AI 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

35. During the course of negotiations with the Commission, officials of the FSA have kept other government departments informed of its progress. These included; the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office and the Office of Fair Trading. The UK fully supported the Commission's intention to set new maximum levels for nitrate in leafy vegetables. The final proposal was subsequently adopted by the SCoFCAH. To date no adverse comments have been received from any department.

**Informal Public Consultation**

36. 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/**

37. 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.

38. 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.

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

**Other relevant documents**

40. 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:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0007:0011:EN:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:122:0036:0062:EN:PDF

41. The Contaminants in Food (England) Regulations 2010 are available on the 'legislation.gov.uk' website at:

http://www.legislation.gov.uk/uksi/2010/2228/pdfs/uksi_20102228_en.pdf

42. 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:

http://www.legislation.gov.uk/uksi/1966/1073/made/data.pdf
http://www.legislation.gov.uk/uksi/1977/691/made/data.pdf
http://www.legislation.gov.uk/uksi/1982/264/made/data.pdf

**Responding to the Consultation**

43. Responses are requested by close of business on **5th July 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.

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

**Yours faithfully,**

**Nasreen Shah**
**Regulatory Officer**
**Strategy, Regulation and Business Support Unit**
**Chemical Safety Division**

**Enclosed**

**Annex A: Standard Consultation Information**

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

**Annex C: Draft Impact Assessment**

**Annex D: Commission Regulation (EU) No. 1258/2011 amending Commission Regulation 1881/2006 setting maximum levels for nitrates in foodstuffs**

**Annex E: Commission Regulation (EU) N0. 610/2012 amending Commission Regulation 124/2009 setting maximum levels for the unavoidable carry-over of coccidiostats and histomonostats in food**

**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 we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8140). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. 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 F. 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 consultation principles[17].

8. An Impact Assessment will normally be published alongside a formal consultation. Please see the Impact Assessment at Annex C.

9. 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**

10. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall

[17] http://www.bis.gov.uk/policies/bre/consultation-guidance

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**

11. 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** The questionnaire can also be used to update us about your existing contact details.

First draft: 10.8.2012; revised 11.9.2012; 7.12.2012; 11.12.2012; 19.2.2013;

STATUTORY INSTRUMENTS

# 2013 No. 0000

# FOOD, ENGLAND

## The Contaminants in Food (England) Regulations 2013

| | |
|---|---|
| *Made - - - -* | *2013* |
| *Laid before Parliament* | *2013* |
| *Coming into force - -* | *October 2013* |

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a), (c), (e) and (f), 17(1) and (2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990(**a**), and now vested in him(**b**), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(**c**).

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

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

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, 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).. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) 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).

(**d**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 596/2009 of the European Parliament and of the Council adopting a number of instruments subject to the procedure referred to in Article 251 of the treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adoption to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p14).

# PART 1

## Introductory

### Title, application and commencement

**1.** These Regulations may be cited as the Contaminants in Food (England) Regulations 2013, apply in relation to England only and come into force on [xxxxx] 2013.

### Interpretation

**2.**—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"Directive 76/621" means Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats(**a**);

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

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

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

"Regulation 124/2009" means Commission Regulation (EC) No. 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed(**e**);

"Regulation 165/2010" means Commission Regulation (EU) No. 165/2010 amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins(**f**);

"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 the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

"port health authority" means —

(a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984(**g**) by section 7(1) of that Act), the Common Council of the City of London; and

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(**a**) OJ No. L202, 28.7.1976, p.35. This Directive was last amended by Council Regulation (EC) No. 807/2003 (OJ No. L122, 16.5.2003, p.36).
(**b**) OJ No. L254, , 27.9.1980, p.35.
(**c**) OJ No. L364, 20.12.2006, p.5. This Regulation has been amended by Commission Regulations (EC) No's 1126/2007 (OJ No. L255, 29.9.2007, p.14), 565/2008 (OJ No. L160, 19.6.2008, p.20), 629/2008 (OJ No. L173, 3.7.2008, p.6), and by Commission Regulations (EU) No's 105/2010 (OJ No.L35, 6.2.2010, p.7), 165/2010 (OJ No. L50, 27.2.2010, p.8), 420/2010 (OJ No. L111, 30.4.2011, p.3), 1258/2011 (OJ No. L320, 3.12.2011, p.15) and 1259/2011 (OJ No. L320, 3.12.2011, p.18).
(**d**) OJ No. L173, 3.7.2008, p.6.
(**e**) OJ No. L40, 11.2.2009, p.7. This Regulation has been amended by Commission Regulation (EU) No. 610/2012 (OJ No. L178, 10.7.2012, p.1).
(**f**) OJ No. L50, 27.2.2010, p.8.
(**g**) 1984 c. 22.

(b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, 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(**a**).

### Controls on erucic acid

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

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

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

# PART 3

## Contaminants in food

### Controls on contaminants in food

**5.**—(1) Subject to the transitional arrangements contained in –

(a) Article 11 of Regulation 1881/2006;

(b) Article 2 of Regulation 629/2008; or

(c) Article 2 of Regulation 165/2010,

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(**a**) OJ No. L401, 30.12.2006, p. 1, amended by Commission Regulation (EC) No 1243/2008 (OJ No. L335, 13.12.2008, p.25).

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 histomonostats 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)(**a**) with the modification that—

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(**a**) Section 21 was amended by S.I. 2004/3279.

(i) subsections (2) to (4) shall apply in relation to an offence under regulation 3 as they apply in relation to an offence under section 14 or 15, and

(ii) in subsection (4) the references to "sale" are deemed to include references to "placing on the market";

(d) section 30(8) (which relates to documentary evidence);

(e) section 33(1) (obstruction etc. of officers);

(f) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub–paragraph (e);

(g) section 35(1) (punishment of offences)(**a**), in so far as it relates to offences under section 33(1) as applied by sub–paragraph (e);

(h) section 35(2) and (3)(**b**), 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)(**c**); 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 (England) Regulations 2013, ("the EU requirements").

(2) The authorised officer may either —

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

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

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

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

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(**a**) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.

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

(**c**) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

(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), shall, for those purposes, bear the meanings that those expressions respectively bear in these Regulations.

**Consequential amendment**

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

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

**Revocations**

**10.** The —

(a) Mineral Hydrocarbons in Food Regulations(**c**);

(b) Erucic Acid in Food Regulations(**d**);

(c) Erucic Acid in Food (Amendment) Regulations 1982(**e**); and

(d) Contaminants in Food (England) Regulations 2010,

are revoked.

**Review**

**11.**—(1) The Food Standards Agency must from time to time —

(**a**) S.I. 2013/XXXX.
(**b**) S.I. 2010/2228.
(**c**) S.I. 1966/1073, last amended by S.I. 2009/3238.
(**d**) S.I. 1977/691, last amended by S.I. 1991/1476.
(**e**) S.I. 1982/264.

(a) carry out a review of the operation and effect of regulation 2 to 8 of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Agency must, so far as is reasonable, have regard to how the EU instruments mentioned in regulation 2(1) are implemented or executed and enforced in other Member States.

(3) The report must in particular —

(a) set out the objectives intended to be achieved by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Signed by authority of the Secretary of State for Health

*Minister's name*
Parliamentary Under Secretary of State
Department of Health

Date

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

**1.** These Regulations, which apply in relation to England only, revoke and re-enact with changes the Contaminants in Food (England) Regulations 2010 (S.I. 2010/2228). 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

(b) the continuing execution and enforcement of Commission Regulation (EC) No. 1881/2006 setting maximum levels for contaminants in foodstuffs (OJ No. L364, 20.12.2006, p.5) ("the Commission Regulation").

**2.** The Commission Regulation includes amendments made by —

(a) Commission Regulation (EC) No. 1126/2007 (OJ No. L255, 29.9.2007, p.14), concerning maximum permitted levels for *Fusarium* toxins in maize and maize products;

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

(c) Commission Regulation (EU) No. 105/2010 (OJ No. L35, 6.2.2010, p.7), concerning maximum permitted levels for ochratoxin A;

(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;

(f) Commission Regulation (EU) No. 835/2011 (OJ No. L215, 20.8.2011, p.4), which concerns maximum levels for polycyclic aromatic hydrocarbons;

(g) Commission Regulation (EU) No.1258/2011 (OJ No. L320, 3.12.2011, p.15), concerning revised limits for nitrates in leafy vegetables;

(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

(i) Commission Regulation (EU) No. 594/2012 (OJ No. L176, 6.7.2012, p. 43) concerning maximum permitted levels of ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs.

**3.** These Regulations also provide for the execution and enforcement of Commission Regulation (EC) No. 124/2009 (OJ No. L40, 11.2.2009, p.7) ("Regulation 124/2009"), which concerns maximum permitted levels for certain feed additives that may, in specified circumstances, occur in food. This Regulation has been amended by Commission Regulation (EU) No. 610/2012 (OJ No. L178, 10.7.2012, p.1).

**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) (England) 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 —

(a) Commission Regulation (EC) No. 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ No. L70, 9.3.2006, p.12), as amended by Commission Regulation (EU) No 178/2010 (OJ No. L52, 3.3.2010, p.32);

(b) Commission Regulation (EC) No. 1882/2006 laying down methods of sampling and analysis for the official control of levels of nitrates in certain foodstuffs (OJ No. L364, 20.12.2006, p.25);

(c) Commission Regulation (EC) No.333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (OJ No. L88, 29.3.2007, p29), amended by Commission Regulation (EU) No. 836/2011 (OJ No. L215, 20.8.2011, p.9); and

(d) Commission Regulation (EU) No. 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006 (OJ No. L84, 23.3.2012, p.1).

**6.** A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Chemical Safety Group of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the website of the National Archives.

| Title: The Contaminants in Food (England) Regulations 2013<br>IA No: FOOD0099<br>Lead department or agency:<br>FOOD STANDARDS AGENCY<br>Other departments or agencies: | Impact Assessment (IA)<br>Date: April 2013<br>Stage: Consultation<br>Source of intervention: EU<br>Type of measure: Secondary legislation<br>Contact for enquiries: Nasreen Shah, Telephone: 020 7276 8538, Email: nasreen.shah@foodstandards.gsi.gov.uk |
|---|---|

## Summary: Intervention and Options

RPC:

| Cost of Preferred (or more likely) Option | | | | |
|---|---|---|---|---|
| Total Net Present Value | Business Net Present Value | Net cost to business per year (EANCB on 2009 prices) | In scope of One-In, One-Out? | Measure qualifies as |
| -£0.63m | £0.07m | £0.07m | No | In/Out/zero net cost |

**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 England are sufficient to protect consumer health but are also achievable.
- To ensure that levels set for coccidiostats and histomonostats in food in England 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

| Does implementation go beyond minimum EU requirements? | | | No | | |
|---|---|---|---|---|---|
| Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. | **Micro**<br>Yes | **< 20**<br>Yes | **Small**<br>Yes | **Medium**<br>Yes | **Large**<br>Yes |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:**<br>N/A | **Non-traded:**<br>N/A | |

***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:*** 05.04.13

DIRECTOR OF OPERATIONS.

## Summary: Analysis & Evidence — Policy Option 1

**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**

| Price Base Year 2009 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate: N/A** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | N/A | | N/A | **N/A** |

**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.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | | | | |

**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 — **Discount rate (%)** 3.5%

Assumes that none of the policy options will be introduced

**BUSINESS ASSESSMENT (Option 1)**

| Direct impact on business (Equivalent Annual) £m: | | | In scope of OIOO? | Measure qualifies as |
|---|---|---|---|---|
| **Costs: N/A** | **Benefits: N/A** | **Net: N/A** | No | IN/OUT/Zero net cost |

## 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**

| Price Base Year 2009 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate: -0.63** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | 1 | Optional | **Optional** |
| **Best Estimate** | £0.63 | | £0 | **£0.63** |

**Description and scale of key monetised costs by 'main affected groups'**

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

**Other key non-monetised costs by 'main affected groups'**

None

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | £0 | | £0 | **£0** |

**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: | | | In scope of OIOO? | Measure qualifies as |
|---|---|---|---|---|
| **Costs:** £0.07 | **Benefits: £0** | **Net: £0.07** | Yes/No | 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**

| Price Base Year 2009 | PV Base Year 2012 | Time Period Years 10 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate: -0.63** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | 1 | Optional | **Optional** |
| **Best Estimate** | £0.63 | | £0 | **£0.63** |

**Description and scale of key monetised costs by 'main affected groups'**

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

**Other key non-monetised costs by 'main affected groups'**

None

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | Optional | | Optional | **Optional** |
| **High** | Optional | | Optional | **Optional** |
| **Best Estimate** | £0 | | £0 | **£0** |

**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: | | | In scope of OIOO? | Measure qualifies as |
|---|---|---|---|---|
| **Costs:** £0.07 | **Benefits: £0** | **Net: £0.07** | Yes/No | 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 England are sufficient to protect consumer health but are also achievable.
   - To ensure that levels for coccidiostats and histomonostats in food in England 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

### *Maximum levels for nitrates in foodstuffs (Commission Regulation (EU) No. 1258/2011 ("the nitrate Regulation"), amending Regulation (EC) No. 1881/2006*

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 methaemaglobinaemia[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

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[1] 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, EFSA Journal (2008), Journal No 689, p.1. http:/www.efsa.europa.eu/en/scdocs/doc/689.pdf

[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[3] 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[4]. 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:

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

***Commission Regulation (EU) No. 610/2012[5] ("Regulation 610/2012"), amending Regulation (EC) No. 124/2009***

9. Commission Regulation (EC) No. 124/2009[6] 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[7] 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:

**http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:178:0001:0003:EN:PDF**

[3] OJ L 364, 20.12.2006, p5
[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

## Red Tape Challenge

13. In April 2011 the Government launched the Red Tape Challenge (RTC) initiative[8] with the purpose of getting comments from business and the public on how the burden of legislation can be reduced. Whilst the FSA is a UK non-Ministerial Department, the RTC applies to England only. On 6th May 2011 most of the FSA's legislation was published on the RTC website under the Hospitality Theme and remained on the site until 2 June 2011. The FSA has a number of initiatives being delivered under the RTC[9], including developing a simplified system of food safety legislation. This involves the consolidation and revocation (where they are no longer required for consumer protection) of a number of domestic Statutory Instruments. The revocation of the Mineral Hydrocarbons in Food Regulations 1966[10] and (the revocation and remake of the Erucic Acid) in Food Regulations 1977[11] are part of this simplification.

### 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 presences 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"))[12]. 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.

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[8] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/

[9] http://www.food.gov.uk/enforcement/regulation/betregs/red-tape-challenge/

[10] SI 1966 No. 1073

[11] SI 1977 No. 691

[12] 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.

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**

**(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.**

***The Erucic Acid in Food Regulations 1977[13] as amended ("the 1977 Erucic Regulations")***

20. We are also looking to revoke the 1977 Erucic Regulations as amended and remake them with necessary amendments.

21. Council Directive 76/621/EEC[14] 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.

23. Directive 76/621/EEC and Commission Directive 80/891/EEC[15] (method of analysis for determining Erucic acid levels) prescribes the levels of Erucic acid that are permissible in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats). Directive 76/621/EEC was last amended in 2003 by Council Regulation (EC) No 807/2003[16]. The 1977 Regulations were amended by The Erucic Acid in Food (Amendment) Regulations 1982[17].

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.

[13] SI 1977 No. 691

[14] OJ L 202, 28.7.1976, p 35

[15] OJ L 254, 27.9.1980, p 35

[16] 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)

[17] SI 1982 No. 264

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 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 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 (England) 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 (England) Regulations 2010[18] 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

[18] SI 2010 No. 2228

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.**

30. The proposed Regulations will also make an amendment to the provisions currently contained in the Contaminants in Food (England) 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 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[19]. 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[20]. 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.

[19] 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, EFSA Journal (2008), Journal No 689, p.1. http:/www.efsa.europa.eu/en/scdocs/doc/689.pdf
[20] OJ L 37, 13.2.1993, p. 1

34. Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, and may *inter alia,* be authorised for use as feed additives in accordance with Regulation (EC) No. 1831/2003 of the European Parliament and of the Council[21] 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.

35. 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".

36. 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**

37. 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.

38. 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.

39. 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.

40. 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

41. There are other reports on nitrate on AHDB website.

## Sectors and Groups Affected

### Industry

***Primary Producers***

[21] 22 September 2003 – OJ L268, 18.10.2003, p.29

42. 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.

43. 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.

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

***Retail and Wholesalers***

45. 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).[22] Table 1 below summarises those sectors that are likely to be affected by the Regulation.

**Table 1: Type of Businesses Affected**

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

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

[22] http://www.ons.gov.uk/ons/rel/bus-register/uk-business/2012/rft-uk-business-2012.xls

**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 15,660 businesses in the above sectors that are affected by the Regulation in the UK. Table 2 below shows the number of businesses affected by Employment Size and UK country.

**Table 2: Businesses Affected by Employment Size and UK Country**

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

**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**

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

**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 England 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 England. 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 26.10[23], generating a total cost of familiarisation per business of £39.15. Multiplying the total cost of familiarisation per business by the total number of businesses affected (See Table 2) generates a total cost of familiarisation to UK industry of £613,183, see Table 4a below.

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

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

**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[24]. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

69. The total one off cost to UK industry of the Regulation is an estimated £613,183 (see Table 4a). This yields an EAC of approximately £71,237 in the UK 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**

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

## 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.

[23] 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

[24] EACB = PVCB/$a_{tr}$, Where $a_{tr}$ is the annuity rate given by:

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

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.

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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.

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 £20.46[25], whilst the median hourly wage rate of a TSO is £21.01[26]. Using the EHO wage rate as a lower bound estimate and the TSO wage rate as an upper estimate, we can calculate a central estimate of the per hour wage cost of £20.74. Multiplying the central estimate by the number of hours required (2.25) results in a total cost per enforcement authority of £46.65. Multiplying this figure with the total number of enforcement authorities in the UK (435, see Table 3), results in a total familiarisation cost to UK enforcement of £20,294, see Table 5a below. (Note that all presented figures are rounded).

**Table 5a: Familiarisation Costs to UK Enforcement, by UK Country**

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

**Equivalent Annual Costs (EAC)**

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 to the UK of the Regulation is an estimated £20,294 (see Table 5a). This yields an EAC of approximately £2,358 in the UK over 10 years, which per country equates to £1,919 in England, £125 in Wales, £173 in Scotland and £141 in Northern Ireland. Table 5b displays the breakdown of the EAC per country.

**Table 5b: Equivalent Annual Costs of Familiarisation to UK Enforcement, by UK Country**

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

## Benefits

[25] Wage rage 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=pubdate3). Median hourly wage of an 'Environmental health officer' is used, £15.74, plus 30% overheads totalling £20.46.

[26] Wage rage 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=pubdate3). Median hourly wage of a 'Trading Standards Officer' is used, £16.16, plus 30% overheads totalling £21.08.

**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.

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

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

**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.

### Summary of All Costs and Benefits under Option 3

84. Table 7 below summarises all costs under Option 2. To note is that this option also have benefits in terms of simplification, that we have been unable to monetise. The present value of the total cost of Option 3 is £633,477, calculated over a period of ten years.

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

| COSTS | Year 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Total | EAC | PV |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Business | 613,183 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 613,183 | 71,237 | 613,183 |
| Enforcement | 20,294 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20,294 | 2,358 | 20,294 |
| Total | 633,477 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 633,477 | 73,594 | 633,477 |
| **BENEFITS** | | | | | | | | | | | | | |
| Business | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Enforcement | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Total | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| | | | | | | | | | | | | | |
| **NET COST** | 633,477 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 633,477 | 73,594 | 633,477 |

**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

### Within Government

85. During the course of negotiations with the Commission, officials of the FSA have kept other government departments informed of its progress. These included; the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office and the Office of Fair Trading. The UK fully supported the Commissions intention to set new maximum levels for nitrate in leafy vegetables. The final proposal was subsequently adopted by the SCoFCAH. To date no adverse comments have been received from any department.

### Public Consultation

86. 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

87. 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

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

### Statutory Review

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

## SPECIFIC IMPACT TESTS

### Competition

90. We have fully considered the questions posed by in the Office of Fair Trading competition assessment test[27] 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.

91. 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

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

**Consultation question 12**

**Do you agree with our assumption that there will not be a significant impact on small businesses as a result of this legislation is a correct assumption? If you agree or disagree with this assessment, please provide evidence to support your response.**

[27] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

**Sustainability**

93. 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.

94. 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**

95. 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.
EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on possible health risks for infants and young children from the presence of nitrates in leafy vegetables. EFSA Journal 2010; 8(12):1935. [42 pp.]: http://www.efsa.europa.eu/en/search/doc/1935.pdf

## 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”
Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by Maduramicin authorised for use as a feed additive, The EFSA Journal (2008) 594, 1-30

***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

[1] OJ L 37, 13.2.1993, p. 1.
[2] OJ L 364, 20.12.2006, p. 5.
[3] 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, *EFSA Journal* (2008), Journal No 689, p. 1. http://www.efsa.europa.eu/en/scdocs/doc/689.pdf
[4] EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on possible health risks for infants and young children from the presence of nitrates in leafy vegetables. *EFSA Journal* 2010; 8(12):1935. doi:10.2903/j.efsa.2010.1935. http://www.efsa.europa.eu/en/scdocs/doc/1935.pdf

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

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

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

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

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

HAS ADOPTED THIS REGULATION:

*Article 1*

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

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

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

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

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

*Article 2*

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

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

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

Done at Brussels, 2 December 2011.

*For the Commission*

*The President*

José Manuel BARROSO

*ANNEX*

*'Section 1: Nitrate*

| Foodstuffs [1] | | Maximum levels (mg $NO_3$/kg) | |
|---|---|---|---|
| 1.1 | Fresh spinach (*Spinacia oleracea*) [2] | | 3 500 |
| 1.2 | Preserved, deep-frozen or frozen spinach | | 2 000 |
| 1.3 | Fresh Lettuce (*Lactuca sativa* L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4 | Harvested 1 October to 31 March:<br>lettuce grown under cover<br>lettuce grown in the open air<br><br>Harvested 1 April to 30 September:<br>lettuce grown under cover<br>lettuce grown in the open air | <br>5 000<br>4 000<br><br><br>4 000<br>3 000 |
| 1.4 | "Iceberg" type lettuce | Lettuce grown under cover<br><br>Lettuce grown in the open air | 2 500<br><br>2 000 |
| 1.5 | Rucola (*Eruca sativa, Diplotaxis* sp., *Brassica tenuifolia, Sisymbrium tenuifolium*) | Harvested 1 October to 31 March:<br><br>Harvested 1 April to 30 September: | 7 000<br><br>6 000 |
| 1.6 | Processed cereal-based foods and baby foods for infants and young children [3] [4] | | 200' |

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.

(2) The maximum levels should be continuously adapted in order to take account of developments in scientific and technical knowledge and the changes of maximum residue limits established for the specific food concerned in the framework of Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [3] or in the framework of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [4].

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

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

[1] OJ L 37, 13.2.1993, p. 1.
[2] OJ L 40, 11.2.2009, p. 7.
[3] OJ L 152, 16.6.2009, p. 11.
[4] OJ L 268, 18.10.2003, p. 29.
[5] OJ L 30, 2.2.2012, p. 6.
[6] Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by maduramicin authorised for use as a feed additive, *The EFSA Journal* (2008) 594, 1-30, Available online: http://www.efsa.europa.eu/en/efsajournal/doc/594.pdf
[7] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on safety and efficacy of Cygro® 10G (maduramicin ammonium α) for chickens for fattening. EFSA Journal 2011;9(1):1952. [2 pp.]. doi:10.2903/j.efsa.2011.1952. Available online: www.efsa.europa.eu/efsajournal

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

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

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

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

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

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

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

Done at Brussels, 9 July 2012.

*For the Commission*

*The President*

José Manuel BARROSO

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[1] OJ L 263, 6.10.2010, p. 4.

[2] OJ L 49, 24.2.2001, p. 6.

[3] 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, Available online: http://www.efsa.europa.eu/en/efsajournal/doc/690.pdf

[4] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of Koffogran (nicarbazin) as a feed additive for chickens for fattening. EFSA Journal 2010; 8(3):1551. [40 pp.]. doi:10.2903/j.efsa.2010.1551. Available online: www.efsa.europa.eu

*ANNEX*

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

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

| | | |
|---|---|---|
| "1. Lasalocid sodium | Food of animal origin from animal species other than poultry and bovine: | |
| | — milk; | 1 |
| | — liver; | 50 |
| | — kidney; | 20 |
| | — other food. | 5" |

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

| | | |
|---|---|---|
| "6. Maduramicin | Food of animal origin from animal species other than chickens for fattening and turkeys: | |
| | — eggs; | 12 |
| | — other food. | 2" |

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

| | | |
|---|---|---|
| "10. Nicarbazin (residue: 4,4'-dinitrocarbanilide (DNC)) | Food of animal origin from animal species other than chickens for fattening: | |
| | — eggs; | 300 |
| | — milk; | 5 |
| | — liver; | 300 |
| | — kidney; | 100 |
| | — other food. | 50" |

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

| | | |
|---|---|---|
| "11. Diclazuril | 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: | |
| | — eggs; | 2 |
| | — liver and kidney; | 40 |
| | — other food. | 5" |

**Interested Parties List**

**A**
A H Allen & Partners
A H Warren Limited
A Turner
Aberdeen Public analyst Laboratory
ADAS Environment
Adgen Diagnostics Systems Ltd
ADM Milling Ltd
Adur District Council
Age Concern
AgrEvo UK Limited
Agricultural Industries Confederation
Agrimar (UK) Ltd
Alliance for Natural Health
Alliance of Independent Retailers
Allied Bakers Ltd
Allied Brewery Traders' Association
Allied Domecq Spirits & Wine (UK) Ltd
Allied Technical Centre Ltd
Allnut Health Foods Ltd
Almond Board of California
American Embassy
ANALAB
Anchor Seafoods Ltd
ANEIOA
Anglian Soil Analysis Ltd
Araches Ltd
Arrow Chemicals Ltd
ASDA Stores Limited
Ashbourne Biscuits
Ashford (PHLS Thames)
Aspall Cider
Associate Parliamentary Food & Health Forum
Associated Cooperative Creameries
Association for Consumer Research
Association of Bakery Ingredient Manufacturers
Association of Cereal Food Manufacturers Ltd
Association of Convenience Stores
Association of District Committees for the
Association of Greater Manchester Authorities
Association of Licensed Multiple Retailers
Association of London Chief Environmental Health Officers
Association of London Government
Association of Malt Product Manufacturers
Association of Meat Inspectors (UK) Ltd
Association of Port Health Authorities
Association of Public Analysts
Aston University
Astor Chemicals
Astra Pharmaceuticals Ltd
Australia, New Zealand Food Authority (ANZFA)
International Pectin Producers Association
International Strategic Alliances Ltd
Ipswich Borough Council
Irish Yogurts Ltd
ISP Alginates
ITRI
International Meat Trade Association of Butchers

**J**
J A Sharwood and Co
J Bibby Agriculture Ltd
J J Barker Ltd
J L Moore & Sons of Darlington
J Pao and Co Ltd
J Sainsbury Plc
Jacobs Bakery Group
James Bowman & Sons Ltd.
James White Drinks
JJ Baker (Southfleet) Ltd
John West Foods Ltd
Johnson Fresh Products Ltd
Joint Food Service Industry Group

**K**
K & S Fruit Washers Limited
Kas Mycotoxins
Kellogg Supply Services (Europe) Ltd
KENKO
Kent County Council/Scientific Services
Kentish Cobnuts Association
Kerry Ingredients Ltd
Kettering Laboratory Services
Kettle foods Ltd
Kinnersley Brothers Ltd
Kirby & West Ltd.
Kirdford Growers Ltd
Kiril Mischeff
KP Foods
KP Nuts
Kraft Foods International
Kraft Jacobs Suchard
KS Fruit Washers

**L**
Laboratory of the Government Chemist (LGC)
Labtech International Ltd
Lancashire County Council Laboratory
Law Laboratories Ltd
Le Lien Ltd
Leatherhead Food International Limited
Leeds (PHLS North)
Leeds City Council
Legislation & Consumer Affairs Committee, Anglia County

Aynsome Laboratories ltd

**B**
Bacardi Martini
Bakery & Allied Traders Association
Barrow Lane & Ballard Ltd.
Basildon Chemical Co. Ltd.
Bayer plc
Bayer UK Limited
BBSRC Institute of Food Research
Berry Ottaway Associates Ltd
Besana UK Ltd
BFP Wholesale
Bibra Iinternational

Biddenden Vinyards Ltd
Biotechnology & Biological Sciences Research Council
Birds Eye Walls Ltd
Birmingham (PHLS Midlands)
Birmingham City Laboratories
Biscuit, Cake, Chocolate & Confectionery Alliance
Blue Crest
Bluebird Confectionery
Bond Commodities Ltd
Bonduelle Ltd
Booker PLC
Boots PLC
Borough Council of King's Lynn & West Norfolk
BP Chemicals Ltd
BP Nutrition UK Ltd
BPEX
Brand Partnership Ltd
Brand Technical Centre
Brent Council
Brewers of Europe
Brewing Research Foundation
Brewing Research International
Bridge Farm Dairies Ltd
Brighton (PHLS Thames)
Brighton and Hove Local Authority
Bristol (PHLS South West)
Bristol City Council Scientific Services
British Agrochemical Association
British Association of Feed Supplement
British Association of Shooting & Conservation
British Bakeries Ltd
British Beer & Pub Association
British Chemical Distribution and
British Coatings Federation Ltd
British Coffee Association
British Egg Industry Council (BEIC)
British Fermentation Products
British Food Importers & Distributors Association
Council
Leicester (PHLS Trent)
Leicestershire County Council
Lever Bros. Ltd.
LGC LTD
Liebside Laboratory
Lilly Research Centre
Lincoln (PHLS Trent)
Lincolne Sutton & Wood Ltd
Liverpool City Council
Local Authority Caterers Association (LACA)
Local Government Association
London Borough of Hackney
London Borough of Harrow
London Borough of Hillingdon
London Food, Water & Environmental Laboratory (PHLS Thames)
London Port Health Authority
Lord Rayleigh's Farms Limited
Luton (PHLS East)
Lyons Tetley Ltd

**M**
M & M Dairies Ltd.
Mack Multiples Division
Malaysian Palm Oil Board
Maltsters Association of Great Britain
Marchwood Scientific Services
Margarine & Spreads Association (MSA)
Mark Toney & Co. Ltd.
Marks & Spencer's Ltd
Mars Confectionary
Marubeni Europe Plc
MBM Produce
McDougall's Foods
MDC Foods Ltd
Meat and Livestock Commission (MLC)
Medical Research Centre
Melling & Ardern Ltd
Menstrie
Metal Packaging Manufacturers Association
Mexican Trade Commission
MG Gas Products Ltd
Mid Suffolk District Council
Middlesbrough Council
Middlesbrough (PHLS North)
Milk Development Council
Minerva Scientific Ltd
Morrison's PLC
MRC Institute for Environment & Health
Mushroom Growers Association

**N**
Nabisco Ltd

British Frozen Food Federation
British Fruit & Vegetable Canners Assoc
British Fruit Juice Association
British Hospitality Association
British Importers Association
British Independent Fruit Growers' Association
British Leafy Salads Association
British Meat Processors Association
British Medical Association
British Nutrition Foundation
British Oat and Barley Millers Association
British Pasta Product Association
British Peanut Council Ltd
British Pharmacopeia Commission
British Pig Association
British Ports Association
British Potato Council
British Poultry Council
British Retail Consortium (BRC)
British Sandwich Association
British Sheep Dairy Association
British Soft Drinks Association
British Soluble Coffee Manufacturer's Association
British Standards Institute
British Starch Industry Association
British Trout Association
British Veterinary Association
Britvic Soft Drinks Ltd
Budgens Stores Limited
Business & Professional Women UK Ltd
Business in Sport and Leisure
Butterworth's Law of Food & Drugs

**C**

C Marston & Sons Ltd.
Cabi Bioscience
Cabinet Office
Cadbury Schweppes European Beverages
Campbell Grocery Products
CAMedica
Campbell's Europe
Campden & Chorleywood Food Research Association
Cancer Prevention Research Trust
Canon Garth Ltd
Canterbury City Council
Cardinal Health UK 414 Ltd
Cargill (Importers & Cereal Merchants)
Cargill's plc (Milling Division)
Carlisle (PHLS North West)
Carr's Food International Ltd
Casella GMSS Ltd
Castle Brand
Cavanagh & Gray Group Ltd
Cawston Vale

National Federation of Fisherman's Organisation
National Association of British & Irish Millers (NABIM)
National Association of British Market Authorities
National Association of Cider Makers
National Association of Health Stores
National Association of Master Bakers
National Association of Speciality Food & Drink Producers
National Association of Women's Clubs
National Beef Association
National Cattle Association
National Citizens Advice Bureau Council
National Consumer Council
National Consumer Federation (NCF)
National Council of Women
National Dairy Council
National Dairymen's Association
National Dried Fruit Trade Association
National Edible Oil Distributors Association
National Farmers Union (NFU)
National Federation of Community Organisations
National Federation of Consumer Groups
National Federation of Fish Fryers
National Federation of Fishermen's Organisations
National Federation of Food & Meat Traders
National Federation of Women's' Institutes
National Food Alliance (SUSTAIN)
National Housewives' Association
National Dried Fruit Trade Association
National Market Traders' Federation
National Milk Laboratories
National Peanut Council of America
National Pharmaceutical Association
National Starch & Chemical Ltd
National Vegetable Society
Natural Resources Institute
Neasham Nurseries
Neath Port Talbot County Borough Council
Nestle Grocery Division
Nestle UK Ltd
Nestle York PTC
Neville Cradock Associates
New England Seafood
Newcastle (PHLS North)
Newtec Laboratories Ltd
Norfolk County Council Trading Standards
North Yorkshire County Council
Northampton General Hospital
Northamptonshire Trading Standards
Northern Foods Plc
Norton Rose
Norwich (PHLS East)
Novis Group
NRM
Nut Company, the

Central Hygiene Ltd
Central Lobby Consultants
Central Science Laboratory
Centre for Environment, Fisheries & Aquaculture Science (CEFAS)
Cereal Ingredient Manufacturers Association (CIMA)
Cereal Partners UK
Cerestar UK Ltd
Charles Baker
Chartered Institute of Environmental Health (CIEH)
Chelmsford (PHLS East)
Chemical Industries Association
Cherry Valley Farms Ltd
Cheshire Scientific
Chester (PHLS North West)
Chilled Food Association Ltd
CHR Hansen
CIAA
Cima Food Ltd
Clive Webster Ltd
CMS Cameron McKenna
Coca Cola GB & Ireland
Cocoa Association of London Ltd
CoE Food Safety & Chemistry
Coffee Trade Federation Ltd
Cold Storage & Distribution Federation
Collier Provisions Ltd
Colman's of Norwich
Combined Edible Nut Trade Association (CENTA)
Community Foods Ltd
Consultant
Consultant Chemist
Consultant of Food Law & Legal Metrology
Consumer & Scientific Services
Consumers' Association
Continental & American Food Co. Ltd
Continental Fig Company Ltd, c/o Langdon's (Coffee & Tea Ltd.)
Contract Food Ltd
Cookery and Food Association
Co-operative Group (CWS) Ltd
Co-operative Women's Guild
Coppella Fruit Juices
CoSIC
Cotton Orchard
Council for Responsible Nutrition (CRN)
County Analyst for Staffordshire
Covington & Burling
Cow & Gate
CP Kelco
CPA Micro Bac
CPC (United Kingdom) Ltd
Craft Guild of Chefs
Cranfield Biotechnology Centre
Nutritech

**O**

Oakfield Farm Products
Oakwood Overseas Ltd
Oldham Metropolitan Borough
Orchard House Foods
Orchard World Ltd
Orchid Drinks
Organic Herb Trading Company
Organico Real Foods Ltd
Organix Brands PLC
Oxford Agricultural Trials (OAT)

**P**

PA Consulting Group
PAGB
Pasta Products Association
Pattinson Scientific Services
Payne's (Confectionery Division Northern Foods)
Penguin Confectionery Ltd
Percy Dalton (Holdings) Ltd.
Pet Food Manufacturers' Association
Peter Black Healthcare Ltd
Phytopharm Plc
Pickles and Sauces Association
Pizza, Pasta & Italian Food Association
Plain English Campaign
Plymouth (PHLS South West)
PORIM (Europe)
Potato Processors Association
Pre-Packed Flour Association (PPFA)
Prepared Fish Products Association
Preston (PHLS North West)
Primacy Healthcare Ltd

Pritchit Foods
Processed Vegetables Growers Association
Provision Trade Federation
Public Analyst for Devon and Cornwall

**Q**

Quaker Oats Ltd
Quality Milk Producers Ltd
Quality Nuts Products Ltd

**R**

R Twining & Co Ltd
Rafsanjan Pistachio Producers Cooperative (RPPC)
Rank Hovis Ltd
Rathbones Bakeries
R-Biopharm AG
R-Biopharm Rhone Ltd

Crawley Borough Council
Croda Food Services Ltd
Cromer Crab Company Ltd
Crop Protection Association UK Ltd
Crown Cork & Seal Co Inc
CWS Ltd

**D**
Dairy Crest Group plc
Dairy UK
Dale Farm Dairy Group Ltd
Dalgety Agriculture Ltd
Damco Sea & Air
Danisco Ingredients Production Ltd
DARDNI, Food Policy Branch
DCMA, CIMA, SGPPA, PSA & SSA
Dearne Valley Foods Ltd
Defra
Del Monte Foods Ltd
Demos Ciclitira Ltd
Department of Agriculture & Rural Development
Derbyshire County Council
Devonshire House
Diamond Seafood UK Ltd
Digen Ltd.
Direct Sellers' Co-operative Ltd
DMS
Doncaster Metropolitan Borough Council
Dorset Chilled Foods
Doves Farm Foods
Dr Bernard Dyer & Partners
DTI
Durham City Council (095)
Duskin Farm Ltd

**E**
E E and Brian Smith
East Northamptonshire Council
Ebrahimoff & Sons
Eclipse Scientific Ltd
Eden Vale
Editor-Food Policy Update
Edward Langridte
EKP Ltd
Elkes B
Enco Products
English Apples and Pears Ltd
Environmental Health Division
Enza foods New Zealand Ltd
EPPA (UK) Ltd
ESNR International
ESSO Petroleum Co Ltd
EU Food Law
Eurofins Scientific Ltd

Readifoods Ltd
Reading (PHLS East)
Reading Scientific Services Limited (RSSL)
Ready-Bake Ltd
Real Coffee Association
Red Flint Ltd.
Refreshment Spectrum Ltd
Regulatory Affairs
Restaurant Association
Restec Laboratories Ltd
Retail Brands Ltd
RGCA
RHM Grocery
RHM Research & Engineering
RHM Technology Ltd
Rice Association
Ringden Farm
RKM Ingredients
Roast & Ground Coffee Association
Robert Hutchison Ltd.
Robert Wiseman & Sons Ltd
Ross Biosciences
Royal Association of British Dairy Farmers
Royal College of Veterinary Surgeons
Royal College of Midwives Trust
Royal Institute of Public Health & Hygiene
Royal Pharmaceutical Society of GB
Royal Society for the Promotion of Health
Royal Society of Chemistry
Royal Society of Health
RPPC
Ruddock & Sherratt
Royal Association of British Dairy Farmers

**S**
S W Trading Ltd
SAC
SAFE Alliance
Safeway Stores plc
Safeway Technical Operations
Salamon & Seaber
Salmon & Trout Association
Salvesen Food Services
School of Biological Sciences
Scientific & Regulatory Affairs Division
Scientific Analysis Laboratories Ltd
Scientific Committee on Food
Scientific Co-ordinator Europe
SCOPA (Seed Crushers' and Oil Processors' Association)
Scotch Whiskey Association
Scotch Whisky Research Institute
Scottish Consumer Council
Scottish Food & Drink Federation
Sea Fish Industry Society

European Cereal Ingredients Association
European Consumers' Organisation
European Sales & Marketing Association
European Spice Association (FDF)
Exeter & District Consumer Group
Exeter (PHLS South West)
Express Dairy
Express Food Groups Ltd

**F**
F W P Matthews Ltd.
F. Duerr & Sons Limited
Falkland Islands Government
Farley Health Products
Farm & Food Society
Fayrefield Foods (Ireland) Ltd
Federation of Agricultural Co-operatives UK
Federation of Bakers
Federation of Fresh Meat Wholesalers
Federation of Master Bakers
Federation of Milk Groups (UK)
Federation of Small Businesses
Federation of Wholesale Distributors
Fertiliser Manufacturers Association
Fishmeal Information Network (FIN)
Flagship Fruit & Nut Ltd
Florapak Ltd
Flour Advisory Bureau
Food & Agricultural Office
Food & Drink Federation (FDF)
Food & Health Research
Food & Industrial Ingredients Europe, Tate & Lyle
Food Additives & Ingredients Association (FAIA)
Food Chemical Risk Analysis (FCRA)
Food Commission (UK) Ltd
Food from Britain
Food Ingredients Bureau
Food Policy Update
Food Safety & Pesticide Control
Food Safety Advisory Centre
Food Trades Protection Society Ltd
Foodaware
Foodialog
Forum of Private Business
Forum Products Ltd
FOSFA International
Freeworld Trading Ltd.
Fresh Fruit & Vegetable Information Bureau
Fresh Produce Consortium (UK)
Friends of the Earth UK Ltd
Fruit Preparation Manufacturers Association (FPMA)

**G**
G Costa & Co
Seaforth Corn Mills
Seasoning and Spice Association
Seawing International
Seed Crushers & Oil Producers Association
SEFCOL Ingredients Limited
Sefton MBC
Seven Seas Ltd
Sevenoaks District Council
Shellfish Association of Great Britain
Shipton Mill Ltd
Shoreham Port Health Authority
Shrewsbury & Telford (PHLS Midlands)
Sigma Associates
Silver Trout Ltd
Small Business Service
Small Farmers Association
Smithkline Beecham
Smiths Flour Mills Head Office
Snack, Nut & Crisps Manufacturers Association
Society of Independent Brewers
Society of Public Health
Soil Association
Somerfield Stores Ltd
Somerset Scientific Services
Somerset Trading Standards Dept.
South Hams District Council
Southampton (PHLS Wessex)
Southampton City Council
Southern Port Services (Shoreham) Ltd
Spar (UK) Ltd
Specialist Cheesemakers Association
Speedibrews
Spelthorne Borough Council
Spice and Seasoning Association
Spillers Foods
Spitalfields Market Tenants Association
St Bartholomew's and the Royal London
Staple Dairy Products Ltd.
State General Laboratory
Stoke (PHLS Midlands)
Stoke on Trent City Council
Suffolk County Council
Sun Valley Peanuts
Sundora Foods Ltd
Superdrug Stores plc
Sustain - The Alliance for Better Food & Farming
Swedish Food Administration & EUFIC
Syngenta Crop Protection
Sun Valley Peanuts

**T**
T Choithram & Sons (Stores Ltd)
T M Douche and Sons Ltd
Tate & Lyle Plc

G Garrat & Sons Ltd.
Gala Coffee & Tea Limited
Geest Plc
General Foods Group
General Mills Europe Ltd
Gerber Foods
Gin & Vodka Association of Great Britain
Glanbia Cheese Ltd
Glanbia Consumer Meats
Glanbia Food Service
Glanbia Foods Ltd
Glanbia Milk Ltd
Glasgow Caledonian University
Gloucester (PHLS South West)
Gold Crown Foods Limited
Golden Wonder
Good Housekeeping Institute
GR Micro Ltd
Grain & Feed Trade Association (GAFTA)
Granovita UK Ltd
Greenangle Ltd
Greencore Group
Greens Flour Mills Ltd.
Greyling
Griffith Laboratories Ltd
Grimsby Fish Dock Enterprises Ltd
Guinness Supplies

**H**
H Cotterell
H J Heinz Co Ltd
H R Higgins (Coffee-Man) Ltd
Hall Farm Merchants Ltd.
Halliwell Landau
Hamman and Associates
Hampshire Scientific Services
Handels- und Unweltschutzlaboratorium
Hapico
Harper Adams University College
Harrods Ltd
Hawkins
Hayman Horticultural Consultancy
Hazlewood Foods Ltd
Health Food Manufacturers Association (HFMA)
Heinz Co Ltd
Herbert Smith Solicitors
Hereford & Worcester Scientific Services
Hereford (PHLS South West)
Heygates Ltd
HG Millard Ltd
HGCA
Hipp UK Ltd
Holland & Barrett
Holland & Barrett Retail Ltd

Taylors of Harrogate
TDL Wells Division Unit 5
Technical Indexes Ltd
Technical Input
Technical Manager, McDougall's Foods Ltd
Telford Foods Ltd
Tepnel Bio Systems Ltd
Tesco Stores plc
Tetley GB
Thames & Chiltern Vineyards Association
The Old Vicarage
Tickle & Reynolds
TNO BIBRA International Ltd
Torre Fruit Farm
Torside Farm
Townswomen's Guild
Trade Union Congress
Trading Standards Institute
Trading Standards Service, Norfolk County Council
Trading Standards Services, Basildon
Trafford
Trebor Bassett Ltd
Tropicana
Truro (PHLS South West)

**U**
UK Agricultural Supply & Trade Assoc. Ltd
UK Association of Frozen Food Producers
UK Association of Manufacturers of Baker's Yeast
UK Federation of Business
UK Maize Millers Association
UK Preserves Manufacturers Association
Unigate Dairy Group
Unilever Ice Cream & Frozen Food
Unilever Research
United Biscuits (UK) Ltd
United Biscuits Group Technical
United Kingdom Vineyards Association
United Milk Producers
United States Department of Agriculture
Unitrition
University of Bristol
University of Reading
University of Surrey
University of Sussex

**V**
Van den Bergh Foods
Vegan Society
VEGA-Vegetarian Economy & Green Agriculture
Vegetable Protein Association
Vegetarian Society (UK) Ltd
Verner Wheelock Associates Limited
Veterinary Laboratory Agency (VLA)

Home Grown Cereals Authority
Home Grown Fruits Ltd
Hong Kong Economic & Trade office
Horticulture Development Council
Horticulture Research International
Hotel Catering & Institutional Management Assoc
House of Commons Library
Housing & Consumer Protection Dept
HP Bulmer Holdings Ltd
Hull (PHLS North)
Huntingdon Life Sciences
Huntingdon Research Association
Hurstwood Farm, The Hurst Crouch
Hyperactive Children's Support Group

**I**
IACR-Rothamsted
Ice Cream Alliance Ltd.
Ice Fresh Foods Ltd
Iceland Frozen Foods PLC
ICI Agrochemicals
ICS Occupational Health
IGD
ILS Ltd
IMKO The Nut Company
Imperial Chemical Industries Plc
Imperial College
Independent Food Retailers Confederation
Independent Milk Producers and Processors
Independent Toxicologist
Infant & Dietetic Foods Association (IDFA)
Information Centre
Institute of Grocery Distribution
Institute for Environment & Health
Institute of Brewing and Distilling
Institute of British Bakers Ltd
Institute of Chemical Engineers
Institute of Food Research
Institute of Food Science & Technology
Institute of Grocery Distribution (IGD)
Institute of Master Bakers Ltd
Institute of Trading Standards Administration
Institution of Chemical Engineers
Institute of Food Research
International Food Hygiene
International Brewers' Guild
International Coffee Organisation
International Food Hygiene Magazine
International Food Information Service
International General Produce Association
International Laboratory Services Ltd
International Meat Trade Association of Butchers
International Mycological Institute

**W**
Waitrose Ltd
Wakefield Metropolitan District Council
Warner Jenkins Europe Ltd
Warwickshire County Council
Waterford Juices
Weetabix Ltd
Welsh Office
West Somerset District Council
West Wilts District Council
West Yorkshire Analytical Services
West Yorkshire Trading Standards Service
Westler Foods Limited
Westmill Foods Ltd
WHICH?
Whitehall International
Whitworth Food Group
Whole Earth Foods Ltd
Wholesale Confectionary & Tobacco Alliance
Wholesale Grocers' Association of Scotland
WI Country Markets Ltd
Wine Standards Board
Wine& Spirit Association
Women's Farming Union
Women's Food & Farming Union
Worcester Royal Infirmary
Worcestershire Scientific Services
William Morrison Supermarket Plc

**Z**
Zagros International Ltd
Zeina Foods