

Title: The Contaminants in Food (England) Regulations 2013 IA No: FOOD0099 Lead department or agency: FOOD STANDARDS AGENCY Other departments or agencies:	Impact Assessment (IA)		
	Date: August 2013		
	Stage: Final		
	Source of intervention: EU		
	Type of measure: Secondary legislation		
Contact for enquiries: Nasreen Shah, Telephone: 020 7276 8538, Email: nasreen.shah@foodstandards.gsi.gov.uk			
Summary: Intervention and Options			RPC: N/A

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, Measure qualifies as One-Out?
-£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 Yes	< 20 Yes	Small Yes	Medium Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A		Non-traded: 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 Minister:

Anna Soubry

Date

3rd September
2013

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	1	Optional		Optional	
High	Optional		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'						
Potential compliance costs to producers of rocket						
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)	
Low	Optional	1	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	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	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'

Potential compliance costs to producers of rocket

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.
 Potential benefits to industry and enforcement from the consolidation and harmonisation of contaminants in food regulations.

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	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 vegetables¹. 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, European Food Safety Authority (EFSA) concluded that concentrations of nitrate in lettuce are not a health concern, but that the concentrations of nitrate in spinach have the potential to increase dietary nitrate exposure to levels at which a health concern cannot be excluded. Increasing the maximum level by 500 mg/kg would be more health protective than the situation of local derogations from the maximum levels (for further information please see Annex 1 to this document).
5. EFSA has published two evaluations of the risks of nitrate in food. Excessive intake of nitrate could result in methaemaglobinaemia² 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

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 foodstuffs³ 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 2011⁴. It came into force on 23rd December 2011. The nitrate Regulation is directly applicable throughout the EU and sets higher, achievable levels than those initially set for lettuce and spinach across the EU. It also sets maximum levels for rocket, where a risk has been identified. A copy of the nitrate Regulation is available to download free of charge from the following website:

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

Commission Regulation (EU) No. 610/2012⁵ (“Regulation 610/2012”), amending Regulation (EC) No. 124/2009

9. Commission Regulation (EC) No. 124/2009⁶ 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/EC⁷ 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/ is available to download free of charge from the following website:

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

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) initiative⁸ 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 RTC⁹, 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 1966¹⁰ and the revocation and remake of the Erucic Acid in Food Regulations 1977¹¹ 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.

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 risks 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.

The Erucic Acid in Food Regulations 1977¹³ 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/EEC¹⁴ 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/EEC¹⁵ (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 807/2003¹⁶. The 1977 Regulations were amended by The Erucic Acid in Food (Amendment) Regulations 1982¹⁷.
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 23 are implemented, to take into account changes in drafting techniques and practices.
25. It is anticipated that Council Directive 76/621/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.

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.

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

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 Articles/Annexes of Commission Regulation 124/2009 and Commission 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.
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 vegetables¹⁹. 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/EEC²⁰. 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.

¹⁸ SI 2010 No. 2228

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 Council²¹ 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. Article 1 of Regulation 315/93 defines these contaminants as:
 - "any substance not intentionally added to food which is present in such food as a result of the production (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, insect 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. As with 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. During informal consultation with stakeholders, potential compliance costs were identified as a result of introducing the new nitrate limits for rocket. However, to date, we have not been able to monetise this potential impact with stakeholders. We will continue to engage with the relevant stakeholders post implementation and will review the policy as appropriate.

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

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

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

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.

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.

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 26.10²³, 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

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 formula²⁴. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

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:

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

Compliance Costs to Rocket Producers

70. During informal consultation with stakeholders, potential compliance costs were identified as a result of introducing the new nitrate limits for rocket. However, to date, we have not been able to monetise this potential impact with stakeholders. We will continue to engage with the relevant stakeholders post implementation and will review the policy as appropriate.

Costs to Enforcement Authorities

One-off Familiarisation Costs

71. 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.
72. 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.
73. 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.
74. 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 £20.46²⁵, whilst the median hourly wage rate of a TSO is £21.01²⁶. 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

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

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.

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

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

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

Equivalent Annual Costs (EAC)

75. 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

Benefits to Consumers

76. 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.

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

Wider Benefits

78. 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 (£)

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													
Consumers	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
Wider	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

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 to Industry

One-off Familiarisation Costs

79. 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).

Compliance Costs to Rocket Producers

80. During informal consultation with stakeholders, potential compliance costs were identified as a result of introducing the new nitrate limits for rocket. However, to date, we have not been able to monetise this potential impact with stakeholders. We will continue to engage with the relevant stakeholders post implementation and will review the policy as appropriate.

Costs to Enforcement Authorities

One-off Familiarisation Costs

81. 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).

82. 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

83. 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 75 and 76), we have however not been able to monetise these.

Wider Benefits

84. Just as under Option 2, we assume there will be wider benefits from the harmonisation of standards (see paragraph 77).

Benefits to Industry

85. 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. We have, however, been unable to monetise this potential benefit.

Benefits to Enforcement Authorities

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

87. Option 3 extends the use of ambulatory references to include Articles as well as Annexes. This constitutes a benefit to the Food standards Agency as it will avoid the need to introduce a new SI each time any of these Annexes or Articles is updated. We have however been unable to monetise this benefit as we do not know how frequently Annexes and Articles will be updated in the future.

Summary of All Costs and Benefits under Option 3

88. 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
Consumers	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
Wider	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

Within Government

89. 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.

Public Consultation

90. 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

91. 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. However, to date, we have not been able to monetise this potential impact with stakeholders.

Formal Public Consultation

92. The FSA conducted a formal public consultation from 10th April to 5th July 2013²⁷, seeking comments on the draft consolidated instrument and associated *draft* Impact Assessment. In total 800 stakeholders were consulted on these proposals; these ranged from sector specific (e.g. growers, importers etc. of green leafy vegetables); retailers and wholesalers of such products and FBO's placing these products on the market. Enforcement bodies, consumer groups, OGD's, non-government organisations, public and independent test laboratories, and others with an interest in chemical contaminants in foods were also consulted.

93. In total 5 responses were received; one from the Food and Drink Federation (FDF), one from the Government Chemist (GC), one from the Trading Standards Institute (TSI), one from a private individual and one from the Council for Responsible Nutrition.

²⁷ <http://www.food.gov.uk/news-updates/consultations/consultations-england/2013/contaminantsinfood-engconsult2013>

94. Stakeholders, enforcement bodies in particular, were asked to comment with supporting evidence on the cost of enforcing the new legislation and to comment on the assumptions that it will take 2.5 hours for enforcement authorities and 1.5 hours for businesses to read, familiarise and to disseminate to key staff within their respective organisations. They were also asked to comment on any other costs associated with the Commission Regulations, in particular on the new limits for nitrate in spinach and lettuce and rocket and the new maximum limits for coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed.
95. Stakeholders were asked to comment on the revocation of the mineral hydrocarbons Regulations and the revocation and remake of the Erucic acid Regulations in the proposed consolidated 2013 Regulations and on whether the new Regulations introduce any additional burden.
96. Stakeholders were also asked to comment on the introduction of ambulatory references to include Articles of Regulation 188/2006 regarding 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 to extend their use to Directives 76/621/EEC and 80/891/EEC on Erucic acid.
97. A list of the questions asked in the consultation can be found at Annex 2, to this document.

Summary of Comments

98. Four of the five respondents (TSI, GC, FDF and CRN (the fifth respondent did not comment)) supported the revocation of the mineral hydrocarbons Regulation and they also collectively agreed that existing EU legislative controls are in place, i.e. the General Food Law, to provide adequate consumer safety. Both TSI and GC also supported the revocation and remake of the Erucic acid Regulations and their consolidation in the proposed 2013 Regulations. The TSI, GC and CRN agreed with the FSA assessment that there were no costs to business and enforcement bodies associated with the revocation/remake of these Regulations. One food analyst commented that method of analysis prescribed in Directive 80/891/EEC is no longer fit-for-purpose. He suggested that an alternative, which uses capillary GC (Gas Chromatography), is adopted. The method in that Directive uses low temperature argumentation TLC (Thin Layer Chromatography) followed by conventional packed column GC. (Ideally, no method should be specified but a set of method criteria given (LoD (Limit of Detection), LoQ (Limit of Quantification), peak resolutions etc.).
99. Four of the five respondents (TSI, GC, FDF and CRN(the fifth respondent did not comment)) support the use of ambulatory references to cover the Articles of EC Regulation 1881/2006 and the Articles and Annex of 124/2009 and their extension to include Directives 76/621/EEC and 80/891/EEC on Erucic acid. They also added that this was a useful approach, thereby reducing the need for regular amendments to the national Regulations.
100. Both the TSI and GC supported the FSA's assumption that there were no additional costs for sampling as a result of the new limits for nitrate in spinach and lettuce and for the new nitrate limits for rocket. The TSI added however, that it was not known whether there will be additional analysis costs, as these are set by Official Control Laboratories and not the TSI. The GC commented that it was important that laboratories responsible for carrying out the analysis for enforcement purposes see sufficient volume of such work to maintain professional competence.
101. Both the TSI and GC supported the FSA's assumption that the time of 2.25 hours for enforcement bodies to familiarise themselves with the Regulations as indicated in Table 5a of the Impact assessment was an accurate representation of the time required.
102. A full summary of the comments received in response to the consultation will be published on the FSA's website in due course.

Enforcement

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

Statutory Review

104. The FSA is required to carry out a review every five years of 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

105. We have fully considered the questions posed by in the Office of Fair Trading competition assessment test²⁸ 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.
106. 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 on EU Member States and the businesses that trade within them as soon as they come into force, which is generally after 20 days following publication.

Small Firms

107. Small businesses and their trade associations were encouraged to comment throughout the consultation. The Federation of Small Businesses and small businesses themselves, including those that are members of trade associations, were consulted throughout the negotiations on the legislation. This was being 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 micro and small businesses did not identify any additional costs to them at the levels proposed.
108. No comments were received from small businesses or their representatives to the formal written consultation.

Sustainability

109. Impacts under the three pillars (environment, economic and social) of sustainable development have been considered in the preparation of this Impact Assessment. The FSA's remit of consumer protection in relation to food safety continues to be central. Although both Options 2 and 3 are economically sustainable and, will benefit growers of rocket, lettuce and spinach in the UK; however, Option 3 is 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. They may also be potential benefit from the extension/introduction of ambulatory references to include the Erucic acid Directive and Regulation 124/2009. 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.
110. The case for option 3 being better seems to be based more on the ambulatory provisions being administratively efficient and the consolidation making it easier for businesses and enforcers to find the relevant legislation.

²⁸ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf

111. 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

112. 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.

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) animal 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>

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.