

EXPLANATORY MEMORANDUM TO
THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2013

2013 No. 2196

1. This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument will revoke the Contaminants in Food (England) Regulations 2010¹ and remake them, with necessary amendments in order to provide for the execution and enforcement of certain amended EU requirements, namely Commission Regulations (EU) No. 1258/2011² (“the nitrate Regulation”) amending Commission Regulation 1881/2006 as regards maximum levels of nitrate in foodstuffs, Regulation (EU) No. 610/2012³ (“Regulation 610/2012”) amending Commission Regulation 124/2009 as regards maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed and EU Regulations No. 594/2012⁴ (as regards maximum levels of the contaminants ochratoxin A, non-dioxin like PCBs), 1058/2012⁵ (as regards the maximum levels of aflatoxins in figs) and 1259/2011⁶ (as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs).

2.2 This instrument will also 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 (England) 2013 and will revoke the Mineral Hydrocarbons in Food Regulations 1966 in their entirety

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The overarching requirements for food contaminants are laid down in Council Regulation 315/93/EEC⁷ (“the framework Regulation”) that was adopted on 8th February 1993. It defines a food contaminant as any substance not intentionally added to food but which is present in 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 food, or as a result of environmental contamination). Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this legislation. There are more specific measures controlling mycotoxin contamination in food, as well as

¹ SI 2010 No. 2228

² OJ No. L320, 3.12.11, pg.15

³ OJ No. L178, 10.7.2012, pg.1

⁴ OJ No. L176, 6.7.2012, pg.43

⁵ OJ No. L313, 13.11.2012, pg.14

⁶ OJ No. L320, 3.12.2011, pg.18

⁷ OJ No. L37, 13.2.93, pg.1

those chemicals that might migrate from contract materials and those that are radioactive, and which is currently laid down in other European legislation.

- 4.2 Maximum levels of chemical and other contaminants are therefore, set at defined levels that are reasonably achievable by following good agricultural and manufacturing practices and taking into account the toxicity of the contaminant in relation to the level of consumption of the affected foodstuff. In the case of contaminants which are considered to be genotoxic carcinogens, or in cases where current exposure of the population, or of vulnerable groups in the population, is close to or exceeds the tolerable level of intake, maximum levels are set as low as reasonably achievable (ALARA). This approach ensures that food business operators apply measures to prevent and reduce contamination as far as possible in order to protect public health. For the manufacturing of foods for infants and young children, a vulnerable group, the authorities establish the lowest maximum levels achievable through a strict selection of raw materials used.
- 4.3 Commission Regulations (EC) No's 124/2009 and 1881/2006 were introduced under the framework Regulation 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.
- 4.4 Council Directive 76/621/EEC⁸ 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 contents in food 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 is applied to all those foods, not just those which contain more than 5% oils and fats. The Food Standards Agency (FSA), in consultation with the Department of Health, considers this lower limit provides an additional safety measure for this vulnerable consumer group.
- 4.4 The Mineral Hydrocarbons in Food Regulations 1966⁹ (purely national 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 mineral hydrocarbons, the legislation has the unintended effect of banning the presence of residues of mineral hydrocarbons, which could be tolerated by EU contaminants legislation.

5. Territorial Extent and Application

- 5.1 This instrument applies to England only.
- 5.2 Separate but parallel legislation is being made in Scotland, Wales and Northern Ireland.

⁸ OJ No. L202, 28.7.1976, pg.35

⁹ SI 1966 No. 1073

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 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. Providing for the execution and enforcement of the new EU Regulations provides for the continuation of consumer protection against exposure from such contaminants, which could carry serious long term and unacceptable risk to consumer health, particularly amongst vulnerable people.

7.2 Commission Regulation 1881/2006 sets maximum levels for nitrate in leafy vegetables; in some cases, despite developments in good agricultural practices, the maximum levels are exceeded.

7.3 Despite the progress achieved to reduce the presence of nitrate, it has not been possible to consistently achieve levels below the current maximum levels for 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. Commission Regulation (EU) No. 1258/2011 sets higher, more achievable levels than 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.

7.4 Coccidiostats and histomonostats are veterinary medicines authorised for use in animal feeds. Because of concern about the possible carry-over into batches of feed that are not intentionally formulated with coccidiostats or histomonostats, it has been considered necessary to introduce legislation at EU level limiting the permissible amount of coccidiostats and histomonostats carried-over into feed, in order to reduce the resulting residue into food from non-target animals.

7.6 Commission Regulation 124/2009, which 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), has recently been amended by Commission Regulation (EU) No. 610/2012 as regards the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril.

7.7 Council Directive 76/621/EEC as read with Commission Directive 80/891/EEC¹⁰ (methods of analysis for determining Erucic acid levels) prescribes the levels for Erucic acid that are permissible in oils and fats for human consumption and in foodstuffs containing added oils and fats. Directive 76/621/EEC was last amended by Council Regulation (EC) No.

¹⁰ OJ Ref, L254, 27.9.1980, pg.35

807/2003¹¹. The provisions of Directive 76/621/EEC are currently implemented by The Erucic Acid in Food Regulations 1977¹² and were last amended by the Erucic Acid in Food (Amendment) Regulations 1982. The proposed Contaminants in Food (England) Regulations 2013 will revoke and remake the provisions currently contained in the 1977 Regulations as amended and will maintain the position that limits apply to foods for placing on the market for consumption by the final consumer. Consignments and deliveries to manufacturers for the purpose of manufacturing business or to a caterer for their business are thus not the subject to the requirements.

- 7.8 The proposed Regulations will also revoke The Mineral Hydrocarbons in Food Regulations. The FSA has 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 received by the FSA, there is no use of mineral hydrocarbons in the UK food industry. There is also little use of these substances for other processing functions; thus, the FSA considers that the Mineral Hydrocarbons Regulations no longer serve any practical function and that 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.
- 7.10 This instrument is a component of one of a number of initiatives being delivered under the Red Tape Challenge, namely developing a simplified system of food safety legislation. This involves consolidation and revocation of a number of domestic Statutory Instruments which are no longer required for consumer protection.
- 7.11 The 2013 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. It is being proposed to extend the ambulatory references to include both Articles as well as Annexes of Regulation 1881/2006, as sometimes the technical changes are found in the former and latter. Extending the use of ambulatory reference 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.

8. Consultation outcome

Within Government

- 8.1 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

¹¹ OJ Ref, L122, 15.5.2003, pg.36 – 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)

¹² SI 1977 No.691

to set new maximum levels for nitrate in leafy vegetables. The final proposal was subsequently adopted by the Standing Committee for the Food Chain and Animal Health (SCoFAH). To date no adverse comments have been received from any department.

Informal Public Consultation

- 8.2 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 Regulation 1881/2006 and the new Regulation setting limits for nitrate.
- 8.2 The FSA held two meetings with stakeholders and industry trade bodies in January and October 2011, informing businesses on the EU negotiations and plans for implementation of the maximum limits for nitrate in spinach, lettuce and rocket. The meetings 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.
- 8.3 Comments received from stakeholders highlighted various cost to business 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 issue and a clarification on the methodology of analysis, as there are differences in the techniques used by different laboratories, which will affect the results.

Formal Public Consultation

- 8.4 The FSA conducted a formal public consultation from 10th April to 5th July 2013, seeking comments on the draft consolidated instrument; all stakeholders on the contaminants consultation database were consulted. These included food industry organisations, sector specific organisations, consumer groups, non-government organisations, enforcement bodies (including port health authorities) public and independent laboratories and others with an interest in chemical contaminants legislation.
- 8.5 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 (CRN). Comments mainly focused on the estimated costs associated with the draft consolidated Regulations, as reflected in the Impact Assessment (IA).
- 8.6 There was a general consensus amongst the respondents in support of the revocation of the mineral hydrocarbons Regulation; they also collectively agreed that existing EU legislative controls exist to adequately provide 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. These respondents also supported 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.

- 8.7 Please refer to the Summary of Comments in the Impact Assessment for further details.
- 8.9 Comments received in response to the consultation have been reflected, where necessary, in the Impact Assessment attached to this memorandum.
- 8.10 A full summary of the comments received in response to the consultation will be published on the FSA's website.

9. Guidance

- 9.1 Existing guidance will be updated to take into account the new revised limits for nitrate and coccidiostats and histomonostats. The revised guidance will be published on the FSA website at www.food.gov.uk/policy-advice/

10. Impact

- 10.1 As set out in the Impact Assessment, the proposed Regulations will affect retailers and wholesalers, importers, primary producers and any food business operators (FBOs) responsible for placing on the market products covered by the nitrate Regulation. Retailers and wholesalers that sell green leafy vegetables will need to be aware of the revised/new limits and will incur a small familiarisation cost.
- 10.2 For producers of rocket, the nitrate Regulation introduces new limits for nitrate and these producers will also incur a cost for familiarisation; the new limits for nitrate in lettuce and spinach have been relaxed; producers in this sector are already aware of the existing limits, as well as the changes to these limits. Therefore, producers of lettuce and spinach will incur costs for familiarisation, but these are expected to be minimal. The levels for nitrate in rocket were raised during EU negotiations in response to comments from industry during informal consultation. Also 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.
- 10.3 Feed manufacturers will also incur a small familiarisation cost associated with the new limits for the presence of coccidiostats and histomonostats, resulting from the carry-over of these substances to non-target feed introduced by Regulation 610/2012. There may also be a cost for sampling and analysis.
- 10.4 There is no particular impact on charities or voluntary bodies, rural areas or on members of the ethnic communities of any particular racial group that can

be identified. No comments were received from such bodies on the effects of the proposal on them.

- 10.5 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

- 11.1 The instrument will apply to all businesses, small and large.

12. Monitoring & review

Monitoring

- 12.1 The FSA will publish a review of the Regulations in 2018 in accordance with regulation 11. Local Authorities and Port Health Authorities are responsible for enforcing much of the food safety legislation, including the maximum levels for contaminants in food. Local Government Regulation, the Association of Port Health Authorities and the Association of public Analysts are consulted specifically through established liaison mechanisms and provide feedback to the FSA about the effectiveness of these instruments. Business operators act similarly through their representative bodies and directly in response to consultation mechanisms.
- 12.2 Central and local authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work carried out by the FSA are published and are openly available on the FSA's website at:
<http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/>
- 12.3 The European Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Such limits may be moved upwards or downwards in the light of on-going monitoring and of advances in scientific knowledge within the EU as a whole.

13 Contact

- 13.1 Nasreen Shah at the Food Standards Agency, Tel: 020 7276 8538, Email: nasreen.shah@foodstandards.gsi.gov.uk, can answer any queries regarding the instrument.