



Guidance on The Contaminants in Food (England) Regulations 2009

Version 2, July 2009

If you require this information in an alternative format – such as audio, large print, Braille – please contact us.

CONTACT TELEPHONE 020 7276 8553

Summary

Intended audience:	This guidance is for businesses involved in the placing on the market of foods for which there is European Community legislation in respect of contaminants. The Regulations apply equally to food business operators at all stages of production, processing, import, distribution and retail.
Regional coverage:	This guidance applies to England only.
Legal status:	These guidance notes have been produced to provide informal, non-binding advice on the legal requirements of The Contaminants in Food (England) Regulations 2009 and should be read in conjunction with the pertinent EU legislation, including European Regulation (EC) No. 1881/2006 as amended as well as Commission Regulation (EC) No. 124/2009 and the accompanying Regulation on Sampling and Analysis for Official Controls.
Purpose:	This guidance provides an informal summary of The Contaminants in Food (England) Regulations 2009 to help explain the scope of the Regulations as well as the offences and penalties specified in them.

REVISION HISTORY

Revision No.	Revision date	Purpose of revision	Revised by
2	July 2009	Second version	Nasreen Shah, FSA

CONTENTS

INTENDED AUDIENCE	5
PURPOSE AND LEGAL STATUS	5
WHY YOU SHOULD READ THIS NOTE - COMPLIANCE	5
THE EUROPEAN LEGISLATION	6
THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS	8
CHANGES TO THE ENGLISH REGULATIONS	10
CONTACTS	11

INTENDED AUDIENCE

1. This guidance is aimed primarily at businesses (including small- and medium-size enterprises (SMEs), which may either use the guidance directly or learn about it via trade associations or enforcement authority contacts) that place on the market foodstuffs including those to be used as an ingredient, specified in Commission Regulation (EC) No. 1881/2006, as amended. This includes all businesses involved in the production, process, import, distribution or retail of such foodstuffs. This guidance may also be beneficial to others to whom the legislation is relevant, such as enforcement authorities. This guidance provides a short summary of the changes proposed by the new Regulations insofar as they apply to England only. The devolved administrations in Wales, Scotland and Northern Ireland will make separate but parallel legislation.

PURPOSE AND LEGAL STATUS

2. These guidance notes have been produced to provide informal, non-binding advice on the legal requirements of The Contaminants in Food (England) Regulations 2009 and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority

WHY YOU SHOULD READ THIS NOTE - COMPLIANCE

3. The purpose of The Contaminants in Food (England) Regulations 2009 is to ensure:
 - that enforcement authorities within England have powers by which to impose the requirements of Commission Regulation (EC) No. 1881/2006, as amended, and
 - also, the requirements of Commission 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, The Commission Regulations are directly applicable and binding to all Member States of the European Union, including the United Kingdom.

4. Commission Regulation (EC) No. 1881/2006, as amended specifies certain conditions in relation to contaminants in food, including the maximum permitted levels of certain contaminants in certain foodstuffs (see following section on European Legislation). All businesses that are responsible for placing on the market the foodstuffs specified, including those that are used as an ingredient, are required to comply with the legislation. Such businesses include those involved in the production, process, import, distribution or retail of the specified foodstuffs.
5. Regulation 1881/2006 also ensures sampling and analysis is done correctly under official control by the enforcement authorities.
6. It is the responsibility of the food business to ensure that their foodstuffs are compliant. Neither Commission Regulation (EC) No. 1881/2006 nor The Contaminants in Food (England) Regulations 2009, which provide an enforcement mechanism, prescribe the means by which this must be achieved.

THE EUROPEAN LEGISLATION

7. EC legislation on contaminants in food is made under the framework Regulation for food contaminants, Council Regulation 315/93/EEC of 8 February 1993, which lays down Community procedures for contaminants in food and applies to those contaminants that are not covered by other specific Community legislation.
8. Because each Member State would be likely to handle setting and enforcing laws for maximum levels of contaminants differently, to achieve consistency, Community measures have been introduced under Council Regulation 315/93/EEC.
9. The principal measure made under this Regulation is Commission Regulation (EC) No 1881/2006 of 19 December 2006 as amended, which sets maximum levels for certain contaminants in foodstuffs. The Regulation can be found in the Official Journal of the European Union at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_364/l_36420061220en00050024.

[pdf](#). Any amendments that are made to the Regulation e.g. the addition or revision of maximum levels can also be found on the Official Journal website.

10. The intention of Commission Regulation (EC) No. 1881/2006 as amended is to provide consumers with an increased measure of protection by setting EC maximum levels for specific mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The Regulation aims to keep these contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. They also harmonise Member States' existing measures, thereby facilitating trade.
11. The specific maximum levels and the exact description of the categories of foods to which they apply are laid down in the Annex to Regulation 1881/2006 and its amendments. In addition, the provisions in the various Articles to the Regulation must be taken into account when checking compliance with the legislation.
12. The Regulation also specifies the prescribed legislation for methods of sampling and analysis that are required to be used for the official control of levels of the substances specified in the legislation. These methods are set out in a number of allied Commission Regulations, details of which can be found in Commission Regulation (EC) No. 1881/2006 or where applicable its amendments. The sampling and analysis legislation is already implemented by the Commission Regulation and thus does not need further implementation in the English Regulations.
13. In order to harmonise rules on the issue of unavoidable carry-over of authorised coccidiostats or histomonstats in non-target feed and their resulting presence in derived foodstuffs. The European Commission together with Member States countries including the UK have now agreed maximum units for the presence of active substances contained in coccidiostats and histomonstats 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 lays down the Community procedures for contaminants in food. These contaminants are defined as:

- “any substance not intentionally added to food which is present in such food as a result of its production and processing, preparation and treatment etc (including operations carried out in crop husbandry, animal husbandry and veterinary medicine) manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insects, fragments, animal hair etc, is not covered by this definition”.
14. In the case of the unavoidable carry-over into non-target animal feed of active substances contained in authorised coccidiostats and histomonostats, these are considered as undesirable substances in animal feed within the meaning of Directive 2002/32/EC and maximum levels for these substances in animal feed are therefore established by a Commission Directive amending Annex I to the 2002 Directive. These controls on animal feed, as opposed to food, are being implemented in domestic law by separate legislation.
15. Limits for undesirable substances in animal feeds are found in Schedule 5 of the Feeding Stuffs (England) Regulations 2005 (Statutory Instrument No. 3281/2005) as amended. Any food redirected as feed must not exceed these limits.
16. In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, as an ongoing task, the European Commission in co-operation with Member States investigates whether limits should be set for additional contaminants and reviews the maximum levels of those contaminants currently covered by the legislation.
17. Copies of the relevant pieces of European legislation with regard to contaminants in food are available from the Commission website at http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm.

THE CONTAMINANTS IN FOOD (ENGLAND) REGULATIONS 2009

18. The requirements of Commission Regulation (EC) No. 1881/2006, as amended, have previously been enforced in a Statutory Instrument i.e. previous versions of The Contaminants in Food (England) Regulations, since 2002.

19. They enforce the requirements of Commission Regulations (EC) No. 1881/2006 as amended and 124/2009 as they:

provide that it is an offence (regulation 3)

- (i) to place on the market certain foods if they contain contaminants of any kind specified in the Commission Regulation at levels exceeding those specified (subject to a derogation applicable to certain types of lettuce and fresh spinach in relation to the limits for nitrate);
 - (ii) to use products which do not comply with the maximum levels as food ingredients for the production of compound or other foodstuffs;
 - (iii) to mix foods which do not comply with the maximum levels referred to above with foods which do comply;
 - (iv) in relation to aflatoxins, to mix foods to which the Commission Regulation relates and which are intended for direct consumption with foods to which the Commission Regulation relates and which are intended to be sorted or otherwise treated prior to consumption, or
 - (v) in relation to mycotoxins, to detoxify by chemical treatment food not complying with the limits specified in the Commission Regulation
- (b) specify the enforcement authorities (regulation 4);
- (c) provide for the application of specified provisions of the Food Safety Act 1990 for the purposes thereof (regulation 5);
- (d) make consequential amendments to the Food Safety (Sampling and Qualifications) Regulations 1990 as far as they apply in relation to England (regulation 6);
- (e) revoke the Contaminants in Food (England) Regulations 2007 and the Contaminants in Food (England) (Amendment) (No.2) Regulations 2007¹ (regulation 7(a) and (b) (and re-enact them with necessary amendments, thus implementing in one consolidated instrument);

¹ Statutory Instrument No. 2007/2983

20. A fine not exceeding level 5 (£5000) on the standard scale may apply in the case of breaches of the offences listed in regulation 3 part (a) and (b).

CHANGES TO THE ENGLISH REGULATIONS

21. There have recently been amendments to Commission Regulation (EC) No. 1881/2006. These include Commission Regulation (EC) No 565/2008 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver; and Commission Regulation (EC) No. 629/2008 setting maximum levels for certain contaminants in foodstuffs.
22. Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, which 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 Council² on additives for use in animal nutrition. Authorisations 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.
23. The Contaminants in Food (England) Regulations 2009 will thus make provision for the enforcement of the two amending Commission Regulations in addition to the provisions that it has previously made and provide for the enforcement of Regulation (EC) 124/2009.
24. Additionally, The Contaminants in Food (England) Regulations 2009 will introduce ambulatory provisions with the purpose of introducing enforcement

² 22 September 2003 – OJ L268, 18.10.2003, p.29

provisions for future amendments to Commission Regulation (EC) No. 1881/2006 automatically. An ambulatory reference is a provision in UK legislation that allows future amendments specified in EC legislation to take effect in national law without having to be specifically implemented or enforced via new or amending domestic regulations.

CONTACTS

25. If you have any questions about these Regulations please contact:

Nasreen Shah
Food Standards Agency
Food Safety: Contaminants
4th Floor, Zone 4C,
Aviation House
125 Kingsway
London, WC2B 6NH.
Tel: 020 7276 8553
Fax: 020 7276 8446
E-mail: nasreen.a.shah@foodstandards.gsi.gov.uk