Food Safety
AUTHORITY OF IRELAND

Legislation on Chemical Contaminants

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Preface

This guidance document provides an overview of the European Union and national legislation related to chemical contaminants in food, together with guidance on its interpretation. This document does not purport to be comprehensive or to be a legal interpretation or to constitute legal or other professional advice. Unless otherwise stated, the definitions and terminology used in this report relate to this document only.

References to the applicable legislation are valid, to the best knowledge of the Food Safety Authority of Ireland (FSAI), at the time of publication. Advances in scientific knowledge and changes in legislation can be expected in the future that will necessitate the updating of this document. Further information on all of the legislation covered by this guidance or introduced subsequent to its date of publication (April, 2014) is available from the FSAI website, http://www.fsai.ie/legislation.html.

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1. Introduction

This guidance document provides information for Irish industry and for enforcement officers on the European Union (EU) and national legislation related to chemical contaminants in food. A chemical contaminant is defined in the relevant national legislation (European Communities (Certain Contaminants in Foodstuffs) Regulations 2010 to 2014) as follows:

"Contaminant" means 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. This definition does not cover extraneous matter such as insect fragments, animal hair, etc.

The definition covers a wide range of chemical substances which may adventitiously be present in food, including the following:

- Persistent organic pollutants, e.g. polychlorinated dibenzodioxins (PCDDs), dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs)
- Metals, e.g. lead, cadmium, tin and mercury
- Processing or industrial contaminants, e.g. polycyclic aromatic hydrocarbons (PAHs), 3-monochloropropane-1,2-diol (3-MCPD), acrylamide
- Residues of pesticides or veterinary medicines
- Natural contaminants, e.g. mycotoxins
- Radioactive substances

The presence of such substances in food must be kept to a minimum because of their potential adverse effects on health, and a comprehensive legislative framework has been put in place at EU level and implemented in national legislation to ensure this. Regulation (EC) No 315/93 established the principle that maximum levels should be set for contaminants in foodstuffs in order to protect public health, and Commission Regulation (EC) No 1881/2006 (EC, 2006a) (as amended) currently establishes maximum levels for a number of contaminants in food, including some persistent organic pollutants, metals, mycotoxins, process contaminants, melamine and PAHs. The European Commission has published a factsheet on food contaminants which provides a useful overview of the scope and requirements of this legislation (EC 2008a), while further information is also available on the website[1] of the Directorate-General for Health and Consumers (DG SANCO), the branch of the Commission responsible for this area and food business operators have a legal responsibility to supply safe food, and to this end they must ensure that their products comply with the legislative maximum limits for contaminants in food, as laid down in Regulation (EC) No 1881/2006 (as amended) and other relevant legislation. This necessitates regular monitoring of the products they supply. National control authorities including the FSAI, the Health Service Executive (HSE), local authorities, the Sea-Fisheries Protection Authority (SFPA) and the Department of Agriculture, Food and the Marine (DAFM) are also required to have in place a national surveillance plan to monitor and help ensure compliance with the requirements of the legislation. To ensure a consistent application of the rules on contaminants in food across the EU, legislation has also been introduced on sampling and analysis procedures for contaminants in food, and any monitoring, whether for official control purposes or undertaken for surveillance purposes by a food business operator or other entity, should follow the procedures laid down. These aspects are covered in more detail in Section 3 of this guidance document.

[1] http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm

While the definition of contaminant in Regulation (EC) No 315/93 and in the implementing national legislation is very wide, the scope of this guidance document is largely limited to those contaminants covered by Regulation (EC) No 1881/2006 (as amended) and procedures for their sampling and analysis as required for official control purposes. Guidance on the legislation related to maximum residue levels of pesticides or animal remedies is not included. However, further information on this may be accessed from DAFM's website[2] as the Government department having responsibility for legislation on pesticide or veterinary drug residues in food. Short factsheets on pesticides in food or residues of animal remedies in food have however, been produced by the FSAI and are available on the FSAI's website (www.fsai.ie). The factsheets may be accessed below:

- Pesticides
- Animal Remedies

Under Service Contracts established with the FSAI, DAFM, the local authorities, the SFPA and the Marine Institute carry out regular monitoring of foodstuffs on the Irish market to test for the presence of residues of pesticides and animal remedies and to ensure that these are below the maximum levels established in the legislation. Similarly, the Radiological Protection Institute of Ireland (RPII) (www.rpii.ie) routinely monitors and reports levels of radioactivity in foodstuffs against the limits determined by Irish and international law, via a Memorandum of Understanding established with the FSAI. Legislation on maximum levels of radioactivity in foodstuffs is the responsibility of the Department of the Environment, Heritage and Local Government. This guidance also does not cover radioactive substances in food and further information should be sought from the RPII or the Department of the Environment, Heritage and Local Government.

It should be noted that in order to ensure maximum protection of human health, it is necessary to have controls in place for contaminants from 'farm to fork'. This requires that maximum levels for contaminants are set not only in food, but also in feed. A parallel stream of EU legislation has therefore been established on maximum levels of contaminants in animal feed. This legislation is under the aegis of DAFM, and also lies outside the scope of this guidance document, however, further information is available from DAFM's website[3] and the National Food Residue Database (http://nfrd.teagasc.ie) provides useful information on residues for a broad range of contaminants in food.

Section 2 of this guidance document provides information on the content and requirements of the EU legislation on certain contaminants, including information on additional regulatory measures ('emergency measures', introduced via Commission Regulations) which apply to a number of foodstuffs imported from outside the EU because of particular concerns about the presence of high levels of contaminants, notably aflatoxins, in these foodstuffs[4].
Section 3 provides guidance on procedures for sampling and analysis for contaminants in foodstuffs as required for official control purposes and for self-monitoring by food business operators.
Section 4 outlines the requirements of the national legislation implementing the EU provisions. Additionally, in this section, an overview is provided of national legislation and/or standards on contaminants in food which are not covered by the EU legislation.
Section 5 provides a brief overview of a number of contaminants in food that are not yet regulated via Regulation (EC) No 1881/2006, but whose presence in food raises concerns and which therefore should be monitored.

[2] http://www.agriculture.gov.ie
[3] http://www.agriculture.gov.ie/agri-foodindustry/feedingstuffs/
[4] http://www.fsai.ie/food_businesses/imports_non_animal_origin/intro.html

References are provided in **Section 6**.
Further guidance on all of the legislation covered by this document is available from the FSAI website, on http://www.fsai.ie/legislation.html.

A series of factsheets on the chemical nature, occurrence and toxic effects of some of the specific contaminants covered by Regulation (EC) No 1881/2006, namely mycotoxins, dioxins and PCBs, metals and polycyclic aromatic hydrocarbons (PAHs) have been produced by the FSAI and are available on the FSAI's website (www.fsai.ie), as follows:

- Mycotoxins
- Dioxins and PCBs
- Metals
- PAHs

This guidance documents does not therefore provide further information on these aspects (chemical nature, occurrence and toxic effects).

2. European Union Legislation on Contaminants

2.1 Introduction

The presence of chemical contaminants in the raw materials from which food is derived, and often in the food itself, is in most cases unavoidable as they arise as a result of, e.g. environmental pollution, growing and harvesting conditions and processing factors that are very difficult to control. The EU legislation on food safety introduced over many years has the primary objective of a high level of consumer protection, and the legislation on contaminants in particular is based on the principle of 'ALARA' (As Low as Reasonably Achievable)[5]. In practice however, it may be impossible to achieve a level that is totally protective of health, e.g. a number of the contaminants of concern may have carcinogenic properties and a genotoxic mode of action. For such substances, the conventional scientific principle is that there is no safe level of exposure. Establishment of maximum levels for chemical contaminants in food is therefore based on achieving the right balance between the risks of the contaminant and the potential benefit of the food, also taking into consideration issues such as the economic cost of achieving low/zero levels of the contaminant and the feasibility of detecting such levels by chemical analysis.
Maximum levels are set for the contaminants of greatest concern for the health of consumers, due to their toxicity or their potential prevalence in the food chain or both.
The contaminants covered by the current European Union legislation on contaminants include mycotoxins (aflatoxins, ochratoxin A, etc.), metals (lead, mercury, tin and cadmium), process contaminants (3-MCPD), PAHs, dioxins & PCBs, melamine and nitrates. The levels are set on the basis of scientific advice provided by the European Food Safety Authority (EFSA) and, previously, by the Scientific Committee on Food (SCF). Whilst the food control authorities in Member States, e.g. the FSAI in Ireland, are responsible for monitoring food products, to ensure that they comply with the legislation, the food business operators have the key responsibility to ensure that the food they produce and supply is safe and compliant (includes sampling) with all legislative requirements. Imported foodstuffs cannot be placed on the EU market unless they comply with relevant food law including the legislation on contaminants. It is the responsibility of the importer into the EU to ensure that the imported product is in compliance with the legislation, and this is controlled at EU borders and on the market.

2.2 Council Regulation (EEC) No 315/93

Council Regulation (EEC) No 315/93 of 8 February 1993 (EC, 1993), the so-called Framework Regulation, was introduced with the objective of public health protection and also of achieving harmonised EU rules on chemical contaminants in food and thereby contributing to the free movement of goods in the internal market. The Regulation provides (in Article 1) a definition of 'contaminant' (see Section 1 of this document) and applies to all contaminants in food that meet this definition with the exception of those contaminants that are covered by more specific EU legislation, e.g. legislation on plant protection products (pesticides) and veterinary medicines. The core provisions of the Regulation are contained in Article 2, as follows:

Article 2 of Council Regulation (EEC) No 315/93

Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market. Furthermore, contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages referred to in Article 1.

[5] Also known as ALARP (As Low as Reasonably Practicable)

In order to protect public health and pursuant to paragraph 1, where necessary, maximum tolerances for specific contaminants shall be established in accordance with the procedure laid down in Article 8.

These tolerances shall be adopted in the form of a non-exhaustive EU list and may include:

- Limits for the same contaminant in different foods
- Analytical detection limits
- A reference to the sampling and analysis methods to be used

Article 2(1) requires that food placed on the market should not contain an 'unacceptable' amount of a contaminant likely to present a risk to humans. The wording "at a toxicological level" means the presence of the contaminant at a level that has been shown to cause toxicity in humans or in animal studies, or can be predicted to do so. The Regulation does not however, define "unacceptable", and in practice, the "acceptable" or tolerable level of a particular contaminant in food has been established following an evaluation of the contaminant by the SCF (up to 2002) or by EFSA (from 2002 onwards). This is encapsulated in Article 3 of the Regulation.

Article 2(2) of the Regulation enshrines the principle of ALARA and its achievement by application of good practice, e.g. Good Agricultural Practice (GAP) during food production and Good Manufacturing Practice (GMP) during "manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food" and avoiding "environmental contamination". Article 2(3) of the Regulation provides the basis for establishing maximum limits for contaminants in food ("maximum tolerances for specific contaminants shall be established…") while Article 2(4) provides the basis for harmonised methodology to be used in the sampling and analysis of food for contaminants.

An objective of the Regulation (in addition to its primary objective of protecting the health of consumers) is to allow the free movement of goods in the internal market, since Member States cannot "prohibit, restrict, or impede the placing on the market of foods which comply with this Regulation or specific provisions adopted pursuant to this Regulation for reasons relating to their contaminant levels" (Article 5(1)). This means that a Member State cannot impose stricter conditions in relation to levels of contaminants in food sold in their country than those established under the Regulation and associated EC legislation. If, however, a contaminant is not yet regulated under EC legislation, a Member State can maintain or introduce national legislation on that contaminant, provided it informs the European Commission and other Member States that it is doing so (Article 5(3)).

Member States are permitted to introduce emergency national measures regarding contaminants already regulated under the EC legislation (the so-called safeguard clause, Article 4(1)), e.g. to introduce stricter measures regarding levels in food. This can be done on the basis of "new information or of a reassessment of existing information" suggesting that the contaminant in question presents risks to health not identified in the evaluation of the contaminant by the SCF or by EFSA. Again, there is an onus on the Member State introducing such measures to inform the European Commission and other Member States that it is doing so, including the scientific basis for such action. The Commission should then take steps to examine the justification and to take appropriate measures.

In practice, if the action has been taken on the basis of new scientific information, the Commission will normally refer this information to EFSA, who will undertake a re-evaluation of the contaminant and advise regarding possible risks to health not covered by previous evaluations. If such risks are identified, then the Commission will normally propose the

introduction of new risk management measures, e.g. a lowering of a previously established maximum level for the contaminant or introduction of a maximum level for the contaminant in a foodstuff not previously regulated under the EU legislation.

The Regulation also establishes, in Article 8, the legal mechanism for taking risk management measures on contaminants in food. Such measures are proposed following an opinion (based on a qualified majority voting procedure) from the Standing Committee on Plants, Animals, Feed and Food (SCoPAFF), which is a regulatory voting committee composed of government representatives from Ministries or agencies dealing with food safety at a national level. The Department of Health and the FSAI represent Ireland on this Committee. The opinion of the SCoPAFF is underpinned by scientific advice in the form of a risk assessment from EFSA, and previously from the Scientific Committee on Food. Following a positive opinion from the SCoPAFF, the Commission must formally adopt the proposed risk management measure and as a Commission Implementing Regulation, and following a period of scrutiny by the European Parliament and Council it will enter into European Law. Whilst the provisions contained in the Implementing Regulations are directly applicable in all Member States, the penalties for failure to comply with the measures are implemented into national law by way of a Statutory Instrument.

While Regulation (EC) No 315/93 established the principle that maximum levels should be set for contaminants in foodstuffs in order to protect public health, it did not contain specific provisions for individual contaminants. Maximum levels for nitrates, aflatoxins, heavy metals and 3-MCPD in specified foods were introduced initially via Commission Regulation (EC) No 466/2001 of 8 March 2001 (EC, 2001). The Regulation was subsequently amended on a number of occasions after 2001 to introduce maximum limits for further contaminants or to amend those limits already in place, and in 2006 it was replaced in its entirety by a consolidated (at that time) Regulation (EC) No 1881/2006, the content and requirements of which are described in Section 2.3., together with those of amending EU legislation introduced since 2006 and up to the date of publication of this guidance document.
As already indicated, to ensure a consistent application of the rules on contaminants in food across the EU, legislation has also been introduced on sampling and analysis procedures for contaminants in food, and any official control activity should follow the procedures laid down. These aspects are covered in more detail in Section 3 of this guidance document.

2.3 Council Regulation (EC) No 1881/2006 Setting Maximum Levels for Certain Contaminants in Foodstuffs

2.3.1 Introduction

Regulation (EC) No 1881/2006 of 19 December 2006 regarding setting maximum levels for certain contaminants in foodstuffs, as amended by Commission Regulations No 1126/2007, 565/2008, 629/2008, 105/2010, 165/2010, 420/2011, 835/2011, 1258/2011, 1259/2011, 594/2012, 1058/2012 and 1067/2013, 212/2014, 362/2014, 488/2014, 696/2014) entered into force on 1 March 2007 and revoked Regulation (EC) No 466/2001. It establishes maximum levels for the following contaminants in certain foods: nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinin), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and PCBs, melamine, erucic acid and PAHs. Annex 1 of this guidance document provides a summary of the maximum levels established for the different contaminants in the specific foodstuffs covered by the Regulation.

The legal provisions laid down in the Regulation are focussed on matters related to the maximum levels and their interpretation. The key legal requirement (in Article 1) is that the various foodstuffs listed in the Annex to the Regulation should not be placed on the market

(by a food business operator) unless the level of a particular contaminant covered by the Regulation is below the maximum level specified, without prejudice to the more general obligations applicable under general food law[6] and under food hygiene regulations[7]. These foodstuffs differ in type depending on the particular contaminant for which maximum levels are laid down. In the case of mycotoxins, for example, the foodstuffs fall mainly into the category of grain-, nut- and fruit-derived products, reflecting the potential for the primary crop to become contaminated with mycotoxin-producing fungi, while for dioxins and PCBs the foodstuffs covered are of animal origin (meat, fish, milk, eggs, etc.).

2.3.2 To which foodstuffs do the maximum levels in Regulation (EC) No 1881/2006 apply?

The maximum levels for the various contaminants laid down in Regulation (EC) No 1881/2006 refer only to the foodstuffs as defined in the Annex to the Regulation (as reproduced in Annex 1 of this guidance document). As noted in Annex 1 to this guidance document, which provides a summary of the maximum levels and the foodstuffs to which they apply, a series of footnotes are attached to a number of the foodstuffs, identifying other legislation in which the foodstuff in question is defined in legal terms. Users of the legislation are referred to these sources for a more precise definition of what is covered by a particular foodstuff description.

As indicated in Article 1(2) of the Regulation, the maximum levels apply to the edible part of the foodstuffs unless otherwise specified, e.g. the maximum levels for aflatoxins in nuts apply to shelled nuts rather than nuts in their shells.

Furthermore, if the foodstuff for which a maximum level has been set is part of a compound foodstuff, or has been dried, diluted or otherwise processed, the maximum level is subject to correction factors as outlined in the following section (see following section).

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 (Provisions with regard to export and re-export of non-complying consignments – Article 12 – applicable from 1 January 2005)

[7] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

2.3.3 Application of the maximum levels in Regulation (EC) no 1881/2006 to dried, diluted, processed and compound foods

There are many compound foods that contain one or more of the foodstuffs controlled by Regulation (EC) No 1881/2001, e.g. meat or cereals, for which it may be necessary to derive a maximum limit for a particular contaminant for purposes of monitoring. As indicated in Section 2.3.1 of this guidance document, the maximum levels for the various contaminants laid down in Regulation (EC) No 1881/2006 refer only to the foodstuffs as defined in the Annex. These include foods in their 'natural' state, e.g. 'unprocessed cereals' and also some processed and/or compound foods, i.e. foods manufactured from a primary ('natural') foodstuff likely to contain the contaminant in question, e.g. "All cereals and all products derived from cereals, including processed cereal products, with the exception of…". Maximum levels have been established for some particularly important compound foods, notably foods for infants and young children and cereal products.

Similarly, maximum levels set out in the Annex can be applied to the dried, diluted or processed version of the food via application of correction factors, provided that no maximum levels have been fixed for these dried, diluted or processed foodstuffs already.

Article 2 of Regulation (EC) No 1881/2006

When applying the maximum levels in foodstuffs which are dried, diluted, processed or composed of more than one ingredient, the following shall be taken into account:

a) Changes of the concentration of the contaminant caused by drying or dilution processes (of the individual ingredients)
b) Changes of the concentration of the contaminant caused by processing (of the individual ingredients)
c) The relative proportions of the ingredients in the product
d) The analytical limit of quantification

The specific concentration or dilution factors for the drying, dilution, processing and/or mixing operations concerned or for the dried, diluted, processed and/or compound foodstuffs concerned shall be provided and justified by the food business operator, when the competent authority carries out an official control.

If the food business operator does not provide the necessary concentration or dilution factor or if the competent authority deems the factor inappropriate in view of the justification given, the authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health.

In practice, these provisions may be difficult to apply. They depend on detailed knowledge of the manufacturing process used to derive the compound food, and while these may be available to the food business operator, for the purposes of official controls (monitoring by the authorities of Member States), specific processing and/or dilution factors should be provided by the food business operator to enable the authorities to derive the appropriate maximum level for the product (Article 2). The prohibition, contained in Article 3 of the Regulation, on mixing contaminated product (containing higher levels of contaminants than those specified in the legislation) with non-contaminated, compliant produce in order to bring the total batch or consignment into compliance, must be remembered in applying these general principles (see Section 2.3.4 of this guidance document).

In some cases, e.g. a compound food with several processed/dried ingredients, if the food business operator is not in a position to provide detailed information, then the default

position is to use the maximum levels applicable to the major ingredient(s) as being applicable to the compound food as a whole. This approach may also be used when the composition of the compound food is not known exactly.

As already noted, maximum levels for certain contaminants have been established for foods for infants and young children. However, reflecting the particular need to protect the health of infants and young children, who may be more susceptible to contaminants for a number of reasons, and the potential for their exposure to contaminants from compound foods, Article 2(4) of the Regulation makes provision for Member States to establish specific maximum levels for contaminants in such foods in national legislation, where these do not already exist in the Annex. As with emergency national measures regarding contaminants introduced under the so-called safeguard clause of Regulation (EC) No 315/93/EEC, the need for new maximum levels related to food for infants and young children will ultimately be reviewed at European level and harmonised rules introduced as appropriate.

2.3.4 Effect of processing of raw materials on assigned maximum limits for contaminants in food

A core provision of Regulation (EC) No 1881/2006 is that raw materials/foodstuffs containing contaminants at higher levels than those laid down in the Regulation should not be used as food ingredients, although it may be possible to use them as animal feed, provided they comply with the maximum levels laid down in the relevant animal feed legislation. An important and direct consequence of this restriction is the prohibition, contained in Article 3 of the Regulation, on mixing contaminated product (containing higher levels of contaminants than those specified in the legislation or product designated for sorting before use, see below) with non-contaminated, compliant produce in order to bring the total batch or consignment into compliance.

This prohibition applies to all foodstuffs covered by the Regulation, whatever the contaminant, mycotoxins, dioxins, PAHs, etc. A further restriction on processing, as it relates to maximum levels, is that foodstuffs containing mycotoxins should not be chemically treated to remove the mycotoxins present (article 3(4) of the Regulation). Chemical purification is permitted, however, for certain other foodstuffs/contaminants, e.g. fish oils containing high levels of dioxins/PCBs may undergo a clean-up process designed to remove these contaminants.

Certain types of processing result in the reduction of the level of the contaminant in the food. The level of a particular contaminant in a foodstuff may be affected by the initial processing and treatment of the bulk commodity. This is specifically the case for mycotoxins in foodstuffs such as grains, nuts and dried fruit, since contamination by mycotoxin-producing fungi is largely confined to the outer layers, and any process that reduces the surface contamination will also reduce the level of contamination in the next stage food product.

For example, processes such as cleaning, sorting and grading of cereals and fruits may reduce mycotoxin content by a factor of two. Processing of cereals involving milling and refining to produce flour may also reduce some mycotoxin content of the food product. Thermal processing, such as heating, roasting, baking, may inactivate some mycotoxins. Conversely, processing activities that involve germination of cereals such as malting/mashing/ fermentation of barley have the potential to increase mycotoxin release and/or production from mycotoxigenic fungi which may be present on the cereal. The effect of food processing on removal or inactivation of mycotoxins varies for the different mycotoxins.

The fact that processes such as cleaning, sorting and grading of cereals and fruits may reduce mycotoxin content is reflected in the maximum levels established in Reg. 1881/2006, where, for example, higher levels of aflatoxins are permitted in "Groundnuts (peanuts) and other oilseeds to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs" (Annex of Regulation (EC) No 1881/2006, entry 2.1.1) compared with "Groundnuts (peanuts) and other oilseeds and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs" (Annex of Regulation (EC) No 1881/2006, entry 2.1.5). Similarly, the maximum level of ochratoxin A permitted in unprocessed cereals is higher than that permitted in products derived from such cereals. In the main, the less stringent maximum levels for contaminants apply primarily to aflatoxins in groundnuts, dried fruit and maize and are subject to the specific requirements as outlined below:

Specific provisions provided for in Articles 4, 5 and 6 of Regulation 1881/2006/EC

Specific provisions for groundnuts, other oilseeds, tree nuts, dried fruit, rice and maize (Article 4)

Groundnuts (peanuts), other oilseeds, tree nuts, dried fruit, rice and maize not complying with the appropriate maximum levels of aflatoxins laid down in points 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.1.10 and 2.1.11 of the Annex can be placed on the market provided that these foodstuffs:

(a) Are not intended for direct human consumption or use as an ingredient in foodstuffs
(b) Comply with the appropriate maximum levels laid down in points 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.9 and 2.1.12 of the Annex
(c) Are subjected to a treatment involving sorting or other physical treatment and that after this treatment the maximum levels laid down in points 2.1.5, 2.1.6, 2.1.7, 2.1.8, 2.1.10 and 2.1.11 of the Annex are not exceeded, and this treatment does not result in other harmful residues
(d) Are labelled clearly showing their use, and bearing the indication 'product shall be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs'. The indication shall be included on the label of each individual bag, box etc. or on the original accompanying document. The consignment/batch identification code shall be indelibly marked on each individual bag, box etc. of the consignment and on the original accompanying document

In order to avail of these higher maximum levels, the intended use or further treatment of raw products such as groundnuts and cereals must be clearly identified on the label and in accompanying documentation, as indicated in Article 4(d) (above) and in Article 5 of the Regulation, enabling full traceability of the consignment. The European Commission has produced detailed guidance for national authorities for the control of compliance with the EU legislation on aflatoxins[8] which contains inter alia additional information on the circumstances under which these higher maximum levels apply. These guidelines are currently under review and an updated version is expected for early 2015.

Specific provisions for groundnuts, derived products thereof and cereals (Article 5)

A clear indication of the intended use must appear on the label of each individual bag, box, etc. or on the original accompanying document. This accompanying document must have a

[8] Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins Available at: http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-2010.pdf (update expected in 2015)

clear link with the consignment by means of mentioning the consignment identification code, which is on each individual bag, box, etc. of the consignment. In addition the business activity of the consignee of the consignment given on the accompanying document must be compatible with the intended use. In the absence of a clear indication that their intended use is not for human consumption, the maximum levels laid down in points 2.1.3 and 2.1.6 of the Annex shall apply to all groundnuts, derived products thereof and cereals placed on the market.

Specific provisions for lettuce (Article 6)

Unless lettuce grown under cover (protected lettuce) is labelled as such, maximum levels set in the Annex for lettuce grown in the open air (open-grown lettuce) shall apply.

2.3.5 Derogations from the maximum levels laid down in Regulation (EC) No 1881/2006

While the maximum levels established via Regulation (EC) No 1881/2006 represent levels that are generally technically achievable and offer a high level of consumer protection, produce in some Member States may not be able to meet these standards due particular conditions of environmental pollution. For this reason, derogations have been allowed from the requirements of the Regulation (in Article 7) in the area of dioxins and PCBs in certain fish species. Some of the Baltic States have a derogation allowing them to place on their national markets certain fish species originating in the Baltic region that have higher than the maximum levels of dioxins and PCBs, provided that consumers are given dietary advice regarding potential risks of over-consumption of these species. The high levels of dioxins and PCBs in fish from this area relates to the pollution of the Baltic sea with these contaminants. A considerable number of Member States, including Ireland, also opted to avail of a three year derogation to retain higher maximum limits for PAHs in in traditionally smoked meat and meat products and traditionally smoked fish and fishery products. This derogation will cease in 2017.

2.4 Monitoring and Reporting

Food business operators should carry out monitoring of the food products they place on the market and also of the raw materials used in manufacture, in order to ensure that they are in compliance with the legislation. It is important to note that, in order to ensure a consistent application of the rules on contaminants in food, the sampling and analysis procedures used in monitoring should, as far as is practicable (see Section 3.4) comply with those laid down in European Union legislation, as covered in more detail in Section 3 of this guidance document.

Similarly, Member States are expected to monitor products on their market for the presence of these contaminants, as part of their official control and general surveillance programmes, to ensure they comply with the maximum levels established by the legislation. In Ireland, the FSAI in collaboration with its agencies, including the Public Analyst Laboratories, the Environmental Health Service, DAFM, local authorities, the SFPA and the Marine Institute, carry out regular checks on levels of contaminants in food.

Regulation (EC) No 1881/2006 (Article 9) requires Member States to report the results of such monitoring to the European Commission on a periodic basis. In addition to this requirement, in the case of foodstuffs found to be non-compliant with the maximum levels, Member States are expected to initiate investigations to identify the source of the contamination that has led to these high levels and to take measures to reduce or eliminate the source of contamination.

For some contaminants (including contaminants regulated via Regulation 1881/2006/EC and contaminants not covered by Regulation 1881/2006/EC) specific monitoring recommendations have been developed and/or specific conditions apply on third country imports of food/feed stuffs likely to contain these contaminants. While aflatoxins are the most important contaminants subject to specific additional import conditions, certain other contaminants including pentachlorophenol/dioxin and melamine are also covered. These contaminants have been specifically regulated due to their detection in imported foodstuffs in recent years, and following an assessment of the risk they present to health. The following section provides details on monitoring, reporting and/or special import conditions for each contaminant as applicable.

2.4.1 Specific monitoring/reporting requirements including special import conditions

2.4.1.1 Nitrate

All Member States are required under Regulation 1881/2006 (Article 9(1)) to monitor nitrate levels in vegetables, in particular green leafy vegetables, with a view to extending the maximum levels for nitrate in lettuce and spinach to other crops such as rocket and root vegetables, that could contribute significantly to dietary exposure to nitrate. The results are reported by Member States to the European Commission on an annual basis.

2.4.1.2 Dioxins and PCBs

In the case of dioxins, dioxin-like and non-dioxin-like PCBs, general and specific monitoring and reporting requirements are laid down in Commission Recommendation 2013/711/EU on the reduction of the presence of dioxins, furans and PCBs in feed and food. The latter also implements action levels for dioxins and dioxin-like PCBs, which are aimed at identifying cases where higher than normal background levels are detected. In case of exceedance of the actions levels, Member States are expected to initiate investigations to identify the source of the contamination that has led to these high levels and to take measures to reduce or eliminate the source of contamination as well as to check for the presence of non-dioxin-like PCBs.

In addition, special conditions on the imports of guar gum originating in or from India due to contamination risks by pentachlorophenol (PCP) and dioxins apply via Regulation EC No 258/2010. The latter requires documentary, identity and physical checks, including laboratory analysis on the consignments of (a) guar gum, falling within CN code 1302 32 90, originating in or consigned from India, and intended for animal or human consumption and (b) feed and food containing at least 10% guar gum originating in or consigned from India. Identity and physical checks, including sampling and analysis to control the presence of PCP, shall be carried out on at least 5% of the consignments. The documentary checks shall be carried out at control points specifically designated by the Member States for that purpose. Any product found to contain more than 0.01mg/kg PCP, taking into account the expanded measurement uncertainty, following controls performed in accordance with Article 5 of Regulation 258/2010, shall not enter the feed and food chain. Member States shall inform the Commission through the Rapid Alert System for Food and Feed (RASFF) of all consignments which are found to contain PCP above 0.01mg/kg taking into account the expanded measurement uncertainty and submit to the Commission every three months a report on all analytical results of the controls undertaken. The Commission however, intends to align these control provision to other similar provisions, since findings of a series of FVO visits showed that, while lab controls in India appeared to be protecting the EU, there were still a lot of instances of product being withheld in India with a lack of follow-up investigation.

2.4.1.3 Melamine

Special conditions governing the import of certain products originating in or consigned from China have been introduced via Regulation EC No 1135/2009. The latter prohibits the import

of products containing milk, milk products, soya or soya products intended for the particular nutritional use of infants and young children within the meaning of Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses originating or consigned from the People's Republic of China into the EU. It further requires documentary, identity and physical checks, including laboratory analysis on the consignments originating in or consigned from China, which are to be imported into the EU, of ammonium bicarbonate intended for food and feed and of feed and food containing milk, milk products, soya or soya products other than those prohibited from import. Identity and physical checks, including sampling and analysis to control the presence of melamine, shall be carried out on approximately 20% of such consignments. The documentary checks shall be carried out at control points specifically designated by the Member States for that purpose. Any product found to contain more than 2.5mg/kg melamine shall not enter the feed and food chain and shall be safely disposed of. Member States shall submit to the Commission every three months a report of all analytical results of the controls carried out. This Regulation is expected to be repealed in 2015 due to the absence of non-compliance over the last few years.

2.4.1.4 Mycotoxins

A number of the foodstuffs for which maximum levels for mycotoxins have been established under Regulation (EC) No 1881/2006, as listed in Section 2 of the Table in Annex I to this guidance document, are grown in countries outside the European Union and are imported into the EU. These include nuts and certain dried fruits such as figs. Reflecting the fact that very high levels of mycotoxins have periodically been found in imports of such products from particular third countries, import controls aimed specifically at reducing the contaminant levels in foodstuffs placed on the EU market have been introduced via

INCREASED OFFICIAL CONTROLS

- Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC[9] (as amended)

This Regulation implements Article 15.5 of Regulation (EC) No 882/2004, which sets out the requirements for increased official controls, and includes amongst others, the increased level of official control of certain foodstuffs from certain countries for mycotoxins such as Aflatoxins and Ochratoxin A. The specific requirements are subject to quarterly review and should hence be obtained by referring to the most up to date Annex to Regulation 669/2009 and other specific amendments.

EMERGENCY MEASURES

Article 53 of Regulation (EC) No 178/2002 on General Food Law sets out the provision for bringing in emergency measures for third country imports and the following emergency measures applicable to mycotoxins are currently in place under Regulation (EC) No 178/2002:

- Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) 1152/2009

[9] 2006/504/EC has been replaced by Regulation 1152/2009/EC which in turn was repealed by Regulation 884/2014/EU

Foodstuffs currently covered by this Regulation, the countries of origin and the frequency of sampling required to be carried out on each type of foodstuff, are listed in Table 1. These emergency measures require that pre-export checks must be carried out by the country of origin or the country the consignment was consigned from. A health certificate and the results of analysis must accompany the consignment. The health certificate must be completed, signed and verified by an authorised representative. Each consignment must have a unique identification code and be accompanied by a common entry document (CED) form.

Note: The CED form to be completed is in Annex II of Regulation (EC) No 669/2009 and the form was amended in Regulation (EC) No 323/2014. There are specific notes for the completion of the CED form for consignments subject to Regulation 1152's replacement in Annex II to that Regulation.

All consignments must firstly come through a designated point of entry (DPE) where the documentary check will take place (check on the CED, health certificate and analytical certificate). In some cases the DPE may only be authorised to do the documentary checks (usually because the facilities to do the other checks are not available). Identity and physical checks must be carried out at a designated point of import (DPI) on consignments at the frequency set out in Annex I to Regulation 884/2014/EU (see Table 1).

In many cases, the DPE will also be designated as a DPI in which case all the checks can be carried out in the one place but there is an option to have the identity and physical checks required carried out in a DPI which is not at the point of entry into the EU. All DPEs and DPIs must be designated by the Member State's competent authorities and published. The importer has to give one day's prior notification to the DPE and where the DPI is at different from the DPE, the importer must also give one day's notice prior to arrival of the consignment at the DPI from the DPE. No product can be released for free circulation, i.e. imported into the EU until all the checks have been completed and there is a favourable report and the CED form is completed.

	Mixtures of nuts or dried fruits containing figs	ex 0813 50		20
	Fig paste	ex 2007 10 or 2007 99		

[10] Provisions in this table are subject to periodic change and Annex I to Regulation 884/2014/EU should be consulted for the most up to date status. For further information see also:
http://www.fsai.ie/food_businesses/imports_non_animal_origin/intro.html

India (IN)	Groundnuts (peanuts), in shell	1202 41 00		20
	Groundnuts (peanuts), shelled	1202 42 00		

As indicated, Member States are required to undertake documentary checks, e.g. of the accompanying health certificate and results of sampling and analysis, of each consignment of the controlled products at the DPE. In addition, a certain specified percentage must undergo sampling and analysis before release for free circulation. This means that if a consignment of a controlled product is imported directly into Ireland from one of the designated third countries, it is the responsibility of the Irish control authorities to undertake such checks in order to ensure that the product is in compliance. However, if the product is first imported into another European Union country and then transported to Ireland, it is the responsibility of the country of first import to carry out these checks. Where a consignment is not accompanied by the results of sampling and analysis, or a health certificate, the consignment may not be imported into the EU and must be re-dispatched to the country of origin or destroyed.

PRE EXPORT CHECKS

Article 23 of Regulation (EC) No 882/2004 provides that pre-export checks carried out by a third country on feed and food immediately prior to export to the EU with a view of verifying that the exported products comply with the EU requirements may be approved.

Such an approval may only be granted to a third country after a EU audit has shown that feed or food exported to the EU meets EU requirements or equivalent requirements and that the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in EU law.

Such an approval has been granted to the United States of America (USA) via

- Commission Decision approving the pre-export checks carried out by the United States of America on peanuts and derived products thereof as regards the presence of aflatoxins (2008/47/EC)

The latter approves pre-export checks carried out by the United States Department of Agriculture (USDA) of the USA prior to export to the EU for aflatoxins in peanuts and derived products thereof, which were produced on the territory of the USA. An approval of pre-

export checks for almonds from the United States of America has been proposed and is likely to be adopted in 2015.

Table 2. Peanuts originating in the USA for which pre export checks as regards the presence of aflatoxins carried out by the United States of America has been approved (2008/47/EC)

Foodstuffs originating in or consigned from	Foodstuff	Falling within CN codes
United States of America	Peanuts	CN code 1202 10 90 or 1202 20 00
	Peanuts	CN code 2008 11 94 (in immediate packings of a net content exceeding 1kg) or 2008 11 98 (in immediate packings of a net content not exceeding 1kg)
	Roasted peanuts	CN codes 2008 11 92 (in immediate packings of a net content exceeding 1kg) or 2008 11 96 (in immediate packings of a net content not exceeding 1kg)

The above listed consignments must be accompanied the results of sampling and analysis performed by a USDA approved laboratory carried out in accordance with or equivalent to the provisions of Regulation (EC) No 401/2006 and a certificate as set out in Decision 2008/47/EC

The official controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check and shall be performed at the point of first arrival in the EU and evidence of this check will accompany the consignment. As a consequence of the approved pre-export checks, the frequency of import controls may be reduced. However, Member States shall carry out official controls on consignments imported in accordance with the approval so as to ensure that the pre-export checks carried out in the USA remain effective. If it is found that, in a significant number of consignments, the goods do not correspond to the information in the certificates that USDA has issued, the reduced frequency shall no longer apply.

As stressed already in this guidance document, any monitoring carried out for official control purposes in compliance with these Regulations should follow the procedures laid down on sampling and analysis procedures for contaminants in food. These aspects are covered in more detail in Section 3 of this guidance document, while the detailed guidance for national authorities for the control of compliance with the EU legislation on aflatoxins produced by the European Commission[8] contains additional information on monitoring procedures under the Commission Decisions.

2.4.1.5 Contaminants not (yet) covered by Regulation (EC) No 1881/2006

The Commission has also issued a number of Recommendations on monitoring of contaminants not yet covered by Regulation (EC) No 1881/2006, e.g. furan, ethylcarbamate, perfluoroalkylated substances, brominated flame retardants and acrylamide in accordance with Commission Recommendations 2007/196/EC, 2010/133/EU, 2010/161/EU, 2014/118/EU, 2010/307/EU and 2013/647/EU. A monitoring recommendation for perchlorate is likely to be adopted in 2015.

2.5 Notifications to the Rapid Alert System for Food and Feed

The Rapid Alert System for Food and Feed (RASFF) is a notification system managed by the European Commission to exchange information between Member States on hazards identified in food and feed. 'Alert notifications' are issued where a food which may pose a risk to health has been placed on the market, and 'information notifications' are issued where a problem is identified with a food but it has either not been placed on the market or may no longer be on the market, or may have been placed on the market but is deemed not to require rapid action.

Given the importance attached to controlling the presence of contaminants in food, and the particular requirement laid down in the Commission Regulations described in Section 2.4 to monitor food placed on the European market or imported from outside the EU to ensure its compliance with Regulation (EC) No 1881/2006, the RASFF is used extensively to alert Member States to the presence of non-compliant product. With regard to contaminants, this applies both to foodstuffs produced nationally that do not comply with the maximum levels set for mycotoxins, dioxins and PCBs, heavy metals or the other contaminants covered by Regulation (EC) No 1881/2006 and to foodstuffs imported from third countries and covered by the Commission Regulations covered in Section 2.4. The European Commission guidance for national authorities for the control of compliance with the EU legislation on aflatoxins[8] indicates that:

"each observed non-compliance shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network;

The Member States shall also notify the Commission under the rapid alert system of any measure they have taken, including rejection of a consignment of food by a competent authority at a designated point of import within the European Union, aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food in order to protect public health.

The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network".

The guidance also indicates that, in the case of non-compliance of the documentation that is required to accompany imported products, minor non-compliances should be notified to RASFF but will not necessarily be circulated within the RASFF system. However, documentary evidence of possible fraud or possible recurrent problems related to a particular third country have to be notified to RASFF and these notifications will, in principle, be circulated for information within the RASFF system.

2.6 Guidance on Methods of Reducing Contaminant Levels in Potentially Contaminated Foodstuffs

Previous sections of the guidance document have outlined the various risk management measures that have been developed under the European Union legislation on contaminants, including the legislative framework establishing maximum levels, the obligation placed on Member States to monitor the compliance of food placed on their market with these limits and to take appropriate control action in relation to non-compliant food, and the series of Commission Regulations that provide an effective barrier to the import of high-risk foods from third countries outside the EU.

Guidance on measures designed to prevent the formation or occurrence of particular contaminants in food during production and processing represents an important additional aspect of risk management, and such guidance/codes of practice have been developed both at EU, Codex Alimentarius and national level, on contaminants such as acrylamide and mycotoxins. A non-exhaustive list of such guidance is provided in Table 3.

Table 2. Guidance/Codes of practice on the reduction or prevention of contaminants in foodstuffs

Contaminant	Title of guidance	Reference number/reference
3-MCPD	Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid- HVPs	CAC/RCP 64-2008
Acrylamide	Code of Practice for the Reduction of Acrylamide in Foods	CAC/RCP 67-2009
	Information on Ways to Lower the Levels of Acrylamide Formed in Food	EC (2003a)
	The Food Drink Europe Acrylamide "Toolbox"	Food Drink Europe, 2013
Aflatoxin	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs	CAC/RCP 65-2008
	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts	CAC/RCP 55-2004
	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts	CAC/RCP 59-2005
	Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals	CAC/RCP 45-1997
Chemicals (in general)	Code of Practice Concerning Source Directed Measures to Reduce Contamination of Foods with Chemicals	CAC/RCP 49-2001
	General Standard for Contaminants and Toxins in Food and Feed	CODEX STAN 193-1995
Dioxins	Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds	CAC/RCP 62-2006 (last updated 2006)
Ethyl Carbamate	Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates	CAC/RCP 70-2011
	Commission Recommendation of 2 March 2010 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages (133/2010)	EC (2010)

Fusarium Toxins	Code of Practice on the prevention and reduction of Fusarium Mycotoxins in cereals (drawn up by the Department of Agriculture, Food and the Marine in conjunction with Teagasc, Food Safety Authority of Ireland, Irish Farmers Association, Irish Grain and Feed Association, Irish Grain Assurance Scheme	http://www.agriculture.gov.ie/media/migration/agri-foodindustry/feedingstuffs/whatsnew/Code_Practice_FusariumMycotoxinsincereals.doc
	Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products)	EC (2006e)
HCN	Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava Products	CAC/RCP 73-2013
Lead	Code of Practice for the Prevention and Reduction of Lead Contamination in Foods	CAC/RCP 56-2004
Mycotoxins	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes	CAC/RCP 51-2003
Ochratoxin A	Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Cocoa	CAC/RCP 72-2013
	Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee	CAC/RCP 69-2009
	Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine	CAC/RCP 63-2007
PAHs	Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes	CAC/RCP 68-2009
Patulin	Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages	CAC/RCP 50-2003
	Commission Recommendation 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages	EC (2003b)
Tin	Code of Practice for the Prevention and Reduction of Tin Contamination in Canned Foods	CAC/RCP 60-2005

A series of factsheets on the specific contaminants covered by Regulation (EC) No 1881/2006, namely mycotoxins, dioxins and PCBs, metals and polycyclic aromatic hydrocarbons (PAHs) produced by the FSAI also provide some guidance on measures to prevent the formation or occurrence of particular contaminants in food during production and processing and are available on the FSAI's website (www.fsai.ie).

3. Sampling and Analysis Procedures for Contaminants in Food

3.1 General Introduction

As already indicated in this guidance document, in order to ensure a consistent application of the rules on contaminants in food across the EU, legislation has also been introduced on sampling and analysis procedures for contaminants in food, and any monitoring for official control purposes should follow the procedures laid down.

Application of the maximum levels for contaminants established in the EU legislation for official control or quality control purposes requires that the sample or samples taken for analysis must be representative of a larger batch or lot of the foodstuff as placed on the market, because of the frequently non-uniform distribution of many of these contaminants in the food in which they are found. An analytical result based on a single sample is hence not acceptable in order to confirm the compliance/acceptability of the bulk foodstuff as placed on the market for official control purposes. This requires defined sampling frequencies and quantities, definition of what constitutes a batch or lot, and the laying down of prescribed sampling methodology in the legislation aims to reduce uncertainty or dispute in interpreting results against regulatory limits.

The mycotoxins in particular are very unevenly distributed in the raw materials originally infected by the contaminating fungus and consequently in the products derived from these raw materials, as detailed further in Section 3.2. The required minimum sample size to obtain a single representative sample depends on the overall size of the lot to be sampled, the homogeneity of the foodstuff and the size of the individual particles or components contained in it, with larger samples being required with increasing particle size and heterogeneity. The sampling provisions for the official control of the maximum levels for mycotoxins are hence very complex, to the extent that the European Commission has also issued a guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins[8].

The other contaminants and commodities covered by the legislation, while less susceptible than mycotoxins to variations in the levels of a contaminant within the foodstuff, still present methodological problems. For example, the level of dioxins and PCBs in fish can be different dependent on the size and or age of the fish, and is not necessarily the same in all parts of the fish. Similarly, determination of nitrates in vegetables is dependent on how the samples are treated and stored after harvesting. For this reason, a defined approach to the sampling of commodities has been developed for each of the contaminants falling within the scope of Regulation (EC) No 1881/2006 (as amended), as follows:

- For levels of mycotoxins: Commission Regulation (EC) 401/2006 (EC, 2006g) amended by Commission Regulations (EU) No 178/2010 and (EU) No 519/2014
- For levels of heavy metals, 3-MCPD, inorganic tin and polycyclic aromatic hydrocarbons levels: Commission Regulation (EC) No 333/2007 (EC, 2007f) amended by Commission Regulation (EU) No 836/2011
- For levels of dioxins and PCBs: Commission Regulation (EU) No 589/2014
- For levels of nitrates: Commission Regulation (EC) 1882/2006 (EC, 2006f)

The following sections of this chapter provide more detail regarding the sampling of commodities under this legislation for official control purposes, with particular emphasis being given to sampling for mycotoxins (Section 3.2). It is recognised, however, that sampling and analysis of commodities to determine levels of contaminants may be undertaken by food business operators or by enforcement authorities for purposes other

than official controls, e.g. for routine surveillance purposes at retail level and/or monitoring of acceptability of raw ingredients. The approach to sampling and analysis in such circumstances is briefly discussed in Section 3.4.

A further consideration in the generation and interpretation of results related to maximum levels for contaminants in foodstuffs is the analytical approach taken to generate those results. The analytical method chosen must be validated and must meet certain performance criteria as laid down in the individual EC Regulations on sampling and analysis. There are a number of analytical considerations which prevent the uniform implementation of legislative standards, in particular, problems concerning the use of recovery correction when calculating and reporting an analytical result, the treatment of analytical variability (or "measurement uncertainty") in the interpretation of a specification, and even the approach taken to expressing results, e.g. the number of significant figures taken into account when reporting results, and interpreting them in relation to maximum levels. The European Commission has published a report (EC, 2004b) on these aspects which should be consulted for further information, and analytical specifications are also covered in the individual sampling and analysis Regulations listed above.

3.2 Sampling and Analysis for Mycotoxins in Foodstuffs

3.2.1 Introduction

Commission Regulation (EC) No 401/2006 (as amended) sets out the requirements for sampling and analysis of products in respect of the control of mycotoxins established in the legislation on contaminants in food (Commission Regulation (EC) No 1881/2006 (as amended) and Regulations on special import conditions (see section 2.4.1). The provisions of Regulation (EC) No 401/2006 (as amended) are implemented in Ireland via the European Communities (Certain Contaminants in Foodstuffs) Regulations 2010 to 2014. While broad guidelines on sampling frequency are provided in Annex 2 of this guidance document, the information provided is not exhaustive. Full details of sampling requirements are set out in Regulation (EC) No 401/2006 (as amended) and this should be consulted before sampling is undertaken.

Typically, aflatoxins and other mycotoxins are not distributed uniformly through a field of corn or lot of grain. Rather, there are local 'hot spots' or areas within the field or lot where high levels of contamination are found. This phenomenon is reflected in the maximum levels that have been established, and which represent 'average contamination' of a lot. Therefore, incorrect sampling of the commodity may result in misleading (either too high or too low) results when samples are analysed for mycotoxin content. It is extremely important to collect samples that are representative of an entire lot. A valid composite sample should consist of sub-samples taken from every part of a lot, bin or unit. Therefore, the sampling element of the analysis is vital to the accuracy of the result.

3.2.2 Sampling for mycotoxins

Given the potentially heterogeneous nature of mycotoxin contamination within a given batch of a commodity, sampling must be undertaken in such a way as to ensure it is fully representative. Therefore, it is important that the incremental samples are taken throughout the batch. In some cases, the truck or container will have to be unloaded for the sampling. Unloading should not expose the product to adverse weather conditions or excessive moisture.

The area designated for sampling and storage of a consignment should not expose it to any risk of contamination or degradation. Food hygiene provisions are applicable. Care should be taken to use clean sampling equipment and sample bags and containers free of contamination to avoid any cross-contamination.

3.2.2.1 Sampling at import/wholesale level for the purposes of official controls

Sampling of raw materials at an early stage in the supply chain can identify contamination before processing, packaging and distribution complicate sampling considerations. Therefore, checks should be done as close as possible to the point of import of the raw material. The sampling provisions for mycotoxins focus on official control at import/wholesale level and maximum levels established by EU legislation are designed to judge the quality of lots of large size. Where the appropriate sampling procedures have been followed to obtain a fully representative sample of a lot, the samples analysed will reflect an 'average contamination' for the lot. The level of contamination determined from analysis of such samples does not reflect the possible occurrence of high-level 'hot-spots' or, indeed, low-level 'cold-spots' within the lot, but is appropriate for determining compliance with maximum levels specified in legislation. It is for this reason that sampling at retail level is generally considered impractical, as the levels of mycotoxin found in single retail sized bags or packs cannot be taken as representative of the larger lot from which they originated. Furthermore, maximum levels set by legislation are not based on acute toxic effects of the toxins, but rather on the ALARA principle. Low to medium chronic exposure is considered to be of concern from a human health point of view. Therefore, monitoring at import/wholesale level is considered most effective in minimising the risk to consumers as it controls product before it is placed on the market for retail sale.

Sampling should focus on food business operations handling bulk consignments of products subject to control of mycotoxins under contaminants legislation.

3.2.2.2 Sampling at retail level for the purposes of official controls

The legislation notes that the same sampling approach used at import level can be applied for retail sampling. However, in most cases smaller volumes, e.g. packets, small bags, etc., are involved in retail sampling. Such sampling is not considered to be sufficiently representative, and is not appropriate for the purposes of official controls, although it may be used for surveillance purposes (see Section 3.4). High levels of mycotoxins found in small volumes of a commodity at retail level do not necessarily reflect unsatisfactory quality of a whole batch or consignment. Equally, low levels cannot guarantee satisfactory quality of a batch or consignment. Sampling at wholesale level is considered to be more appropriate because the lot can be defined as a delivery or single batch and action can be taken before the product is distributed. Therefore, the sampling controls should be at points before the foodstuffs are made available for retail sale.

In summary, sampling at retail level for the purposes of official controls is considered to be impractical, and unsatisfactory, for the following reasons:

- The correct sampling procedure for a lot generally cannot be followed
- Elevated, or low, levels detected in a sample that is not representative of the whole lot cannot be used to judge the quality of the lot. Therefore, a retail sample cannot be used as grounds to recall products from the same batch
- The original batch is likely to be unavailable for follow-up sampling and analysis

Therefore, samples should not normally be taken at retail level for products which have been shipped as bulk consignments, rather controls should be focussed at a point where fully representative samples can be taken.

3.2.2.3 Sampling procedures

Selection of consignments for sampling

When determining which consignments/commodities should be selected for control purposes, the FSAI considers that sampling, whether undertaken at the port or at wholesale level, should be prioritised in the following order:

1. Consignments arriving in Ireland as the first point of import into the EC, which are required to be controlled under Commission Implementing Regulation (EU) No 884/2014 (EC, 2014) and also those identified under Article 15.5 of Regulation (EC) No 882/2004/EC as being of high risk as set out in Annex 1 of Regulation (EC) No 669/2009 (as amended)
2. Consignments of commodities controlled by Regulation (EC) No 1881/2006 (as amended), i.e. other than those controlled by legislation mentioned in point 1) and for which no accompanying certificate of analysis is available)

Sampling of the following consignments is considered to be of very low priority

3. Consignments of peanuts and derived products controlled by Regulation (EC) No 1881/2006 (as amended) from the United States of America, for which pre-export checks have been carried out under the authority of the USDA in conformity with the EU approval in accordance with Article 23 of Regulation (EC) No 882/2004 (reduced frequency of sampling)
4. Consignments that have already been cleared for free circulation by another EC Member State and for which a certificate of analysis from the exporting country is available
5. Consignments that have already been cleared for free circulation by another EC Member State, and for which the Irish food business operator has undertaken sampling and analysis which shows the product to be compliant

Product which has already been packaged into retail or catering packs by the food business operator should not normally be sampled for official control purposes given the difficulty in ensuring samples are representative of the original consignment. However, samples of such products may be taken for surveillance purposes. Retail sampling, if considered necessary, should be restricted to those products considered to be homogenous when packaged, for example peanut butter, fruit juices and vegetables oils, and normal sampling procedures, e.g. collection of three sub-samples etc., should be followed.

Frequency of official controls

For products which are not subject to specific safeguard measures, samples should be taken during routine inspections of wholesalers or other premises, such as packers and distributors, which handle bulk packages of commodities.

However, for products which are subject to specific import controls (see Section 2.4), different frequencies of controls have been established at the first point of import into the EU. Details of some of these requirements have already been given in Table 1 in Section 2. The indicated frequency of control for these products should be considered to be the minimum requirement, and the frequency of controls should be increased if the analytical results indicate that this is necessary in order to safeguard public health.

In all cases, care must be taken that the selection of samples or consignments is random, ensuring a proportionate and equal treatment of businesses concerned. Nevertheless, the frequency of controls should take into account the history of compliance/non-compliance of the products placed on the market by a food business operator.

Access to samples
Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, requires that feed and food business operators co-operate with any inspection carried out in accordance with the Regulation and assist staff of the competent authority in the accomplishment of their tasks. This means that the food business operator must make available sufficient human resources and logistics to unload the consignment so as to enable representative sampling to be undertaken. In addition, in the case of special transport and/or specific forms of packaging, the food business operator or other responsible person must make available to the official inspector the appropriate sampling equipment insofar as the sampling cannot be representatively performed with the usual sampling equipment.

Sampling provisions for a batch/lot/consignment
The following information is intended as a general guide to be taken into consideration when sampling bulk consignments. Not all eventualities are addressed and additional specific guidance is available in other documents, such as in the Commission Guidance Document for competent authorities for the control of compliance with the EU legislation on aflatoxins (EC 2009). The FSAI may be able to offer additional information if required, on a case-by-case basis.

Commission Regulation (EC) 401/2006 (as amended) provides that each lot must be sampled separately. A lot is an identifiable quantity of a food commodity delivered at one time and determined by the official inspector to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.

The following gives guidance on certain specific examples of situations that may be encountered by competent authority personnel.

Consignment/lot consisting of several containers
If a consignment of peanuts (for example) consists of 10 containers, each of 22 tonnes, resulting in a consignment of 220 tonnes with the same batch identification code, the legislation provides that the consignment has to be split into five sub-lots of 44 tonnes (two containers). Representative sampling must be performed on the sub-lots each consisting of two containers.

Article 14(6) of Regulation (EC) 178/2002 provides that "where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe". However, this article does not affect the right of a second opinion for the operator as provided for in Article 11(5) of Regulation (EC) 882/2004.

This means that when, on the basis of an official control and after the operator has been given the right for a second opinion as foreseen in Article 11(5) of Regulation (EC) No 882/2004, the controlled part of a consignment has been found to be non-compliant, accordingly the other containers from the consignment/lot/batch should be presumed to be also non-compliant unless the food business operator can demonstrate following a detailed assessment, that the other parts of the consignment are safe, i.e. compliant with EU legislation as regards mycotoxins. This can be done by performing a representative sampling of all containers, in accordance with Regulation (EC) 401/2006 (as amended) (see Annex 2 for details).

Two or more consignments/lots in one container/truck
If a container or truck contains two lots of peanuts (for example), one lot of 8 tonnes and another of 15 tonnes, each with a separate batch/lot identification code, then the two batches/lots must be sampled separately, in accordance with the provisions of Regulation (EC) No 401/2006 (as amended) even if the product is identical (in this particular case from the 8 tonnes, 80 incremental samples of 200g resulting in a sample of 16kg and, from the batch of 15 tonnes, 100 incremental samples of 200g resulting in a sample of 20kg). It is important that each batch/lot has a health certificate.

3.2.3 Specific guidance on sampling for mycotoxins in particular commodities

Annex 2 of this guidance document contains frequencies of sampling lots of certain commodities as set out in Commission Regulation (EC) No 401/2006 (as amended), including the number of sub-lots that should be taken. The list in Annex 2 is not intended to be exhaustive and the Regulation also contains among others, protocols for sampling cereals and cereal products, milk and milk products, roasted and soluble coffee, infant/baby foods, vegetable oils and fruit juices. Full details for all commodities are set out in the Regulation and this should be consulted before sampling is undertaken. In addition, upon reaching the laboratory, each sample must be ground finely to achieve complete homogenisation, in accordance with the provisions laid down in the Regulation.

In addition to the information in Annex 2, the following guidance may also be useful:

Method of sampling for dried figs (including derived products with a relatively large particle size) and fig paste (lots ≥ 15 tonnes)
Provided that a sub-lot can be separated physically, each lot must be subdivided into the number of sub-lots described in Annex 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may vary from the mentioned weight by a maximum of 20%. If, after the division of a lot into sub-lots, the weight of the sub-lot exceeds the weight of the sub-lot as indicated in Annex 2 by more than 20%, the number of sub-lots has to be increased, even if by so doing, the weight of the sub-lot is lower than the weight indicated. Each sub-lot must be sampled separately.

Method of sampling for dried figs (including derived products with a relatively large particle size) and fig paste (lots < 15 tonnes)
In the case of lots less than 15 tonnes, the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100 (see Annex 2).

In cases where the aggregate sample weights are less than 30kg, the aggregate sample must be divided into laboratory samples according to the following guidance:

* < 12kg: no division into laboratory samples
* ≥ 12 and < 24kg: division into two laboratory samples
* ≥ 24kg: division into three laboratory samples

Method of sampling for products derived from fig with a relatively small particle size
For very large consignments the consignment has to be divided into sub-lots of 100 tonnes for consignments between 50 and 300 tonnes, into three sub-lots for consignments between 300 and 1,500 tonnes and into sub-lots of 500 tonnes for consignments more than 1,500 tonnes.

For lots of less than 50 tonnes, the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The weight of the incremental sample is about 100 grams, resulting in an aggregate sample of between 1-10kg.

Sampling of dried figs and derived products in vacuum packs
Dried figs
For lots equal to or more than 15 tonnes, at least 50 incremental samples resulting in a 30kg aggregate sample shall be taken. For lots of less than 15 tonnes, 50% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Products derived from dried figs with small particle size
For lots equal to or more than 50 tonnes, at least 25 incremental samples resulting in a 10kg aggregate sample shall be taken and for lots less than 50 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Because of the possible significant economic damage resulting from sampling, an alternative method other than the one described in this section may be applied if the individual vacuum packs are larger than 10kg.

Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (including derived products with a relatively large particle size) (lots ≥ 15 tonnes)
Provided that a sub-lot can be separated physically, each lot must be subdivided into the number of sub-lots described in Annex 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may vary from the mentioned weight by a maximum of 20%. If, after the division of a lot into sub-lots, the weight of the sub-lot exceeds the weight of the sub-lot as indicated in Annex 2 by more than 20%, the number of sub-lots has to be increased, even if by so doing, the weight of the sub-lot is lower than the weight indicated. Each sub-lot must be sampled separately.

Method of sampling groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (including derived products with a relatively large particle size) (lots < 15 tonnes)
In the case of lots less than 15 tonnes, the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100 (see Annex 2).

The weight of the aggregate sample is 20kg which shall be mixed and divided into two equal laboratory samples of 10kg before grinding (this division into two laboratory samples is not necessary in case of groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 20kg sample).

In cases where the aggregate sample weights are less than 20kg, the aggregate sample must be divided into laboratory samples according to the following guidance:

* < 12kg: no division into laboratory samples
* ≥ 12kg: division into two laboratory samples

Method of sampling for products derived from groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts with a relatively small particle size
For very large consignments the consignment has to be divided into sub-lots of 100 tonnes for consignments between 50 and 300 tonnes, into three sub-lots for consignments between 300 and 1,500 tonnes and into sub-lots of 500 tonnes for consignments more than 1,500 tonnes.

For lots of less than 50 tonnes the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The weight of the incremental sample is about 100 grams, resulting in an aggregate sample of between 1-10kg.

Sampling of groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts and derived products in vacuum packs
Pistachios, groundnuts and Brazil nuts
For lots equal to or more than 15 tonnes, at least 50 incremental samples resulting in a 20kg aggregate sample shall be taken. For lots of less than 15 tonnes, 50% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Apricot kernels, tree nuts other than pistachios and Brazil nuts, oilseeds other than peanuts
For lots equal to or more than 15 tonnes, at least 25 incremental samples resulting in a 20kg aggregate sample shall be taken. For lots of less than 15 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Products derived from or containing tree nuts, apricot kernels, groundnuts and other oilseeds with small particle size
For lots equal to or more than 50 tonnes, at least 25 incremental samples resulting in a 10kg aggregate sample shall be taken and for lots less than 50 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Because of the possible significant economic damage resulting from sampling, an alternative method other than the one described in this section may be applied if the individual vacuum packs are larger than 10kg.

Method of sampling for spices (lots ≥15 tonnes)
On condition that the sub-lot can be separated physically, each lot shall be subdivided into sub-lots as described in Annex 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may exceed the mentioned weight by a maximum of 20%. Each sub-lot shall be sampled separately.
If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of forms of packaging, means of transport, etc.), an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

Method of sampling for spices (lots < 15 tonnes)
For lots equal to or more than 15 tonnes, at least 25 incremental samples resulting in a 10kg aggregate sample shall be taken. For lots less than 15 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Sampling of spices traded in vacuum packs
For lots equal to or more than 15 tonnes, at least 25 incremental samples resulting in a 10kg aggregate sample shall be taken. For lots less than 15 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken resulting in an aggregate sample which is representative of the sampled lot.

Method of sampling for dried fruit (lots ≥15 tonnes), with the exception of figs
Provided that the sub-lot can be separated physically, each lot shall be subdivided into sub-lots as described in Annex 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may exceed the mentioned weight by a maximum of 20%. Each sub-lot shall be sampled separately.

Method of sampling for dried fruit (lots < 15 tonnes), with the exception of figs
For dried fruit lots, with the exception of figs, less than 15 tonnes the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10kg. The weight of the incremental sample shall be about 100 grams.

Sampling of dried fruit other than dried figs traded in vacuum packs
For lots equal to or more than 15 tonnes, at least 25 incremental samples (resulting in a 10kg aggregate sample) shall be taken. For lots of less than 15 tonnes, 25% of the number of incremental samples mentioned in Annex 2 shall be taken, resulting in an aggregate sample which is representative of the sampled lot.

3.2.4 Acceptance of a lot or sub-lot and interpretation of results

The following is intended to aid in the interpretation of analytical results when determining whether a consignment is acceptable.

For dried figs subjected to sorting or other physical treatment:
- Acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty
- Rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty

For dried figs intended for direct human consumption:
- Acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty
- Rejection if one or more of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty
-

In cases where the aggregate sample is < 12kg:
- Acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty

– Rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty

For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to a sorting or other physical treatment:
– Acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty
– Rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty

For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts intended for direct human consumption:
– Acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty
– Rejection if one or both of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty

In cases where the aggregate sample is 12kg or less:
– Acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty
– Rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty

For dried fruit and spices
– Acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum level, taking into account the expanded measurement uncertainty and the correction for recovery[11]
– Rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum level beyond reasonable doubt taking into account the expanded measurement uncertainty and correction for recovery[11]

Further clarification on any of the above issues can be obtained from:

The FSAI Advice line: 1890 33 66 77 E-mail: info@fsai.ie

3.2.5 Analysis of official control samples

Dublin Public Analyst Laboratory (PAL) is the National Reference Laboratory in Ireland for mycotoxin analysis and the laboratory is equipped to prepare and analyse bulk samples for mycotoxins. Therefore, it has been decided that Dublin PAL will undertake analysis of all samples taken under the national sampling programme until further notice. Sampling should be focussed on food business operators which import or trade in bulk consignments of commodities in which mycotoxins may be present and any samples should be forwarded directly to Dublin PAL. The laboratory should be contacted in advance of proposed sampling to confirm when the samples are to be taken and to clarify with the laboratory the likely sample volume/numbers.

Dublin Public Analyst's Laboratory, Sir Patrick Duns Lower Grand Canal Street, Dublin 2, Tel: (01) 6612022.

[11] The expanded measurement uncertainty should be subtracted from the analytical result after correction for recovery. This result is the analytical result which should be used when judging compliance of a consignment with EU legislation.

Where samples are intended solely for surveillance purposes, e.g. retail samples, these can also be sent to the Public Analyst Laboratories in Cork or Galway for analysis (in addition to the Dublin laboratory). Contact should be made with these laboratories in advance of sampling to determine laboratory capacity and to arrange sample delivery.

3.3 Official Sampling and Analysis for Other Contaminants in Foodstuffs

Various Commission Regulations set out the requirements for sampling and analysis of products in respect of the official controls for contaminants other than aflatoxins in foodstuffs, as follows:

- Commission Regulation 1882/2006 (EC 2006h) for nitrates falling within the scope of Commission Regulation 1881/2006 (as amended) (nitrates in spinach, lettuce and processed cereal-based foods and baby foods for infants and young children)
- Commission Regulation (EC) No 333/2007 (EC, 2007f) (as amended) for lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons (PAHs) in the wide range of foodstuffs for which maximum levels of these contaminants have been established (as shown in Annex 1)
- Commission Regulation (EC) No 589/2014 for dioxins and PCBs in the range of foodstuffs for which maximum levels of these contaminants have been established (as shown in Annex 1)

Broad guidance on sampling is provided in Annex 3 (for nitrates), Annex 4 (for lead, cadmium, mercury, inorganic tin, 3-MCPD and PAHs) and Annex 5 (for dioxins and PCBs) of this guidance document, however, the information provided is not exhaustive. Full details of sampling requirements are set out in Regulation 1882/2006, Regulation 333/2007 (as amended) and Regulation 589/2014, respectively, and the appropriate Regulation should be consulted before sampling is undertaken.

These Regulations also contain detailed provisions on analytical aspects, which should be consulted by the analytical laboratory before proceeding with the analysis. See also Section 3.2.5 for information on analysis of official control samples. The information in Section 3.2.5, while focussing on mycotoxins, is also applicable to all other contaminants controlled under Regulation 1881/2006.

3.4 Sampling and Analysis for Contaminants in Foodstuffs for Surveillance/'Own Checks' Purposes

As already indicated in the introduction to this section, sampling and analysis of food commodities to determine the levels of contaminants present may be undertaken by food business operators or by enforcement authorities for purposes other than official controls, e.g. for routine surveillance purposes at retail level and/or monitoring of acceptability of raw ingredients or final products ('own checks'). The sampling procedures outlined in Section 3.2 above for official controls on mycotoxins in food, which are similar to those laid down for other contaminants controlled under Regulation 1881/2006, are labour- and expertise-intensive and are somewhat cumbersome to implement in practice. As has been stressed in Section 3.2 of this guidance document, these sampling methodologies must however be applied in order to prove compliance with the legislation.

For the purposes of 'own checks' or in the case of surveillance studies aiming to give a snapshot of levels of contaminants in food at a particular point in time, e.g. to compare levels in different brands of the same food category such as breakfast cereals, it may be

more convenient and easier to implement if so-called spot samples are taken for analysis in the first instance. The results of analysis of such spot samples can never be used to establish compliance or non-compliance with the requirements of the legislation, because of the non-representative nature of the sample. Nevertheless such samples may provide useful information, particularly in serving as a trigger to carry out further sampling and analysis, possibly but not necessarily for official control purposes. This approach has been used by the FSAI in carrying out some surveillance studies of contaminants in food on the Irish market. When sampling at retail level or for the purposes of monitoring of acceptability of raw ingredients or final products using spot checks, it is advisable to sample the commodity under investigation on as representative a basis as possible. For example, 10 individual samples of 100ml or 100g each should be taken, to provide a sample of 1 litre or 1kg for analysis, rather than taking a single sample to provide the same volume for analysis.
Further clarification on any of the above issues can be obtained from:
The FSAI Advice line: 1890 33 66 77 E-mail: info@fsai.ie

4. National Legislation on Contaminants

The European Union legislation on contaminants in food is implemented in national legislation made by the Department of Health. Further guidance on this legislation is available from the FSAI website, on http://www.fsai.ie/legislation.html.

The European Communities (Certain Contaminants in Foodstuffs) Regulations, 2010, S.I. No. 218 of 2010, replaces previous statutory instruments covering legislative limits (S.I. No. 401 of 2001) and provisions on sampling and analysis for official control (S.I. No. 412 of 2006). It has been amended four times so far by S.I. No. 276 of 2012, S.I. No. 348 of 2012, S.I. No. 380 of 2013 and S.I. No. 143 of 2014. The Principal Regulations (2010), the Regulations of 2012, the Regulations of 2013 and the Regulations of 2014 may be cited together as the European Communities (Certain Contaminants in Foodstuffs) Regulations, 2010 to 2014.

These statutory instruments provide the legal framework for enforcement of the EU legislation on contaminants in Ireland, including provision of enforcement powers to authorised officers and approved examiners and give effect to:

- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down EU procedures for contaminants in food
- Regulation (EC) No 1881/2006 of 19 December 2006 regarding setting maximum levels for certain contaminants in foodstuffs, as amended by Commission Regulation (EC) No. 1126/2007 of 28 September 2007, Commission Regulation (EC) No 565/2008 of 18 June 2008, Commission Regulation (EC) No 629/2008 of 2 July 2008, Commission Regulation (EU) No. 105/2010 of 5 February 2010, Commission Regulation (EU) No 165/2010 of 26 February 2010, Commission Regulation (EU) No 420/2011 of 29 April 2011, Commission Regulation (EU) No 835/2011 of 19 August 2011, Commission Regulation (EU) No 1258/2011 of 2 December 2011, Commission Regulation (EU) No 1259/2011 of 2 December 2011, Commission Regulation (EU) No 594/2012 of 5 July 2012, Commission Regulation (EU) No 1058/2012 of 12 November 2012 and Commission Regulation (EU) No 1067/2013 of 30 October 2013
- Commission Regulation (EC) No 401/2006 of 23 February 2006 as amended by Commission Regulation (EU) No 178/2010 of 2 March 2010 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
- Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs
- Commission Regulation (EC) No 333/2007 of 28 March 2007, as amended by Commission Regulation (EU) No 836/2011 of 19 August laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs
- Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006

There are certain contaminants found in food that are covered by national legislation but which are not yet included in European legislation. Principal among these is arsenic, which is covered by S.I. No. 44/1972: The Health (Arsenic and Lead in Food) Regulations, 1972 as amended by S.I. No. 72/1992. The Regulations also cover lead in certain foodstuffs. These Regulations restrict the amounts of arsenic and of lead which may be present in food which is imported, distributed, sold or exposed for sale. In respect of food generally, the Regulations provide for a limit of one part per million by weight of arsenic and two parts per million by weight of lead. In respect of certain specified foods, special limits are prescribed.

The Regulations also provide that where a sample of food has been certified not to comply with the Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption, and in certain circumstances, destroy it. Special Import Conditions (see section 2.4) of relevance to contaminants are covered by S.I. No. 650 of 2011 European Union (Special Conditions Governing the Import of Certain Foodstuffs From Certain Third Countries Due to Contamination Risk By Aflatoxins) Regulations, 2011 and S.I. No. 391 of 2010 European Communities (Official Controls on the Import of Food of Non-Animal Origin) Regulations, 2010.

5. Contaminants in Food not yet regulated via Regulation (EC) No 1881/2006

The EU regulatory measures on chemical contaminants in food, including the maximum levels for certain contaminants summarised in Annex 1 of this guidance document, have been introduced following extensive discussions between the Member States and the Commission.

These take place in specific working groups devoted to, for example, agricultural contaminants such as mycotoxins, so-called industrial contaminants such as polycyclic aromatic hydrocarbons, and persistent organic pollutants (POPs) such as dioxins. These working groups consider the need for lowering existing maximum levels, the introduction of new maximum levels for a particular contaminant in a foodstuff hitherto not falling within the scope of Regulation (EC) No 1881/2006 (as amended) or for a new contaminant, or development of other risk management measures such as codes of practice.

Emerging risks from new contaminants or from existing contaminants occurring at high levels in foodstuffs not previously monitored are identified as a result of surveillance activities in Member States or in the international regulatory community, e.g. the US Food and Drug Administration. These findings are brought to the attention of the Commission and discussed in the relevant working group, and regulatory measures may be proposed, usually following an assessment of the risk by EFSA as previously mentioned in Section 2.2 of this document and the gathering of occurrence/exposure data by the Member States for consideration by EFSA.

Each working group has an on-going list of priority chemical contaminants that are under consideration for regulatory control. These are briefly described in the following, using the headings of the relevant working group in which they are under discussion.

5.1 Agricultural Contaminants

The area of agricultural contaminants in food and feed is becoming increasingly important from both a food and feed safety and also an economic perspective. As part of on-going work to ensure that the health of consumers is protected, the European Commission, Member States and stakeholders meet annually to discuss the latest available information on the formation, occurrence, and mitigation strategies for Fusarium toxins in food and feed. This information is then used to determine whether additional controls are required and for example, possible controls for the Fusarium toxins T-2 and HT-2 in a range of cereals are under consideration, but it is apparent that more data need to be assembled on occurrence, particularly on how this varies from year to year, and this monitoring is the subject of a Commission Recommendation.

5.2 Industrial Contaminants

This working group is currently considering measures on acrylamide, organotins, furan, arsenic, perchlorate, 3-MPCD- and 2-MCPD-esters and ethyl carbamate, plus reviewing existing legislation on cadmium and lead.

On **acrylamide**, no specific maximum levels in food have as yet been introduced in the European Union or elsewhere in the world, although there have been extensive discussions regarding this aspect. Currently, the onus has been placed on manufacturers to observe the ALARA principle by developing measures to reduce the levels of acrylamide in their products. The European Food and Drink Confederation, Food Drink Europe (FDE), has published a 'Toolbox'[12], which provides strategies for minimising the acrylamide content of manufactured food products, addressing measures under 4 main areas: (1) Agronomical practices, (2) Recipes, (3) Processing, (4) Final Preparation. The food manufacturing industry is advised to follow the Toolbox closely in order to ensure the safety of the products they place on the market.

As already mentioned in Section 2.3.5, the European Commission has made a Recommendation to Member States on the monitoring of acrylamide levels in food[13] and EFSA has evaluated these data on a yearly basis. Based on the data analysis and also in order to evaluate the effectiveness of the FDE Toolbox, on 10 January 2011, the European Commission adopted a Recommendation on investigations on the levels of acrylamide in food, which has recently been replaced by Recommendation 2013/647/EU. These recommendations introduced the concept of 'indicative values' which are to be used as guidance values for typical levels found in food monitored over the years. In cases where the levels of acrylamide in a foodstuff, tested in the monitoring exercise, exceed certain acrylamide indicative values, the Member States are recommended to further investigate the findings and report the results back to the Commission on a yearly basis. An EFSA scientific opinion on the potential risks for human health of acrylamide in food is expected to be finalised in 2015 and will determine future risk management decisions. The FSAI has developed a factsheet on acrylamide.

Furan has been identified in a number of foodstuffs that undergo heat treatment, such as canned and jarred foodstuffs. EFSA is currently collecting more data on furan, e.g. on its mode of formation, levels in food and toxicity, and the European Commission made a Recommendation to Member States in 2007 on the monitoring of furan levels in food (2007/196/EC). The setting of maximum levels will be considered when more occurrence data are available and EFSA can carry out a detailed risk assessment.

Ethyl carbamate is a compound that can occur naturally in fermented foods and beverages. It often occurs in alcoholic beverages (in particular, stone fruit brandies). Ethyl carbamate is formed from ethanol and certain precursors in the fruit mash under the influence of light during the distillation process. On 2 March 2010 the Commission adopted a Commission Recommendation on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages (133/2010/EC). Subsequent evaluation by EFSA of the available monitoring data indicated that the Code of Practice (COP) did not have a measurable effect over the monitoring period and current discussions are aimed at strengthening the application of the COP and to eventually discuss setting target level for ethyl carbamate.

[12] http://ec.europa.eu/food/food/chemicalsafety/contaminants/toolbox_acrylamide_201401_en.pdf
[13] Recommendation on the monitoring of acrylamide levels in food (2010/307/EU). http://ec.europa.eu/food/food/chemicalsafety/contaminants/recommendation_10012011_acrylamide_food_en.pdf

Organotins can be found in water systems due to their presence in paints as anti-biofouling agents that are used, for example, on the hulls of ships and marine apparatus. Ultimately they may be found in food, in particular fish and fish products. EFSA has issued an opinion on the health risks to consumers associated with exposure to organotins, indicating that exposure from food is well below the Tolerable Daily Intake (TDI). Thus, the need for maximum levels in fish and fish products has been queried and is still under review.
The establishment of maximum limits for **inorganic arsenic** is currently being considered for rice and rice products. Discussions on the exact rice food categories to be included are on-going, and levels are expected to be adopted in 2015.

On **cadmium**, after extensive discussions the working group has agreed the setting of new maximum levels for commodities currently not regulated, i.e. cocoa products and infant foods. The review of existing maximum levels has been postponed and the a recommendation on the reduction of the presence of cadmium in foodstuffs was adopted in April 2014 (2014/193/EU) and is aimed to support Member States to take action over the next 5 years on the issues of highest national concern to them. Review of the lead legislation is on-going with the proposed establishment of new maximum limits for foods for infants and young children and for honey and revisions of the maximum levels for the vegetable, fruit juices and fish/shellfish groups.

A recommendation on the monitoring of the presence of the process contaminants **2 and 3-monochloropropane-1,2-diol (2 and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters** in food was published in September 2014 (2014/661/EU) and will provide further occurrence data to EFSA for further assessment.

Occurrence of **perchlorate** in food was reported to the Commission in early 2013. Following initial findings, a more extensive monitoring indicated that the presence of perchlorate in fruits and vegetables is more widespread than initially expected. Since then, efforts have been made to identify the source of contamination (most likely fertilisers) and to identify suitable mitigation strategies. Affected Member States have been requested to provide further monitoring data and EFSA has been requested to deliver a scientific opinion on the risk for public health resulting from the presence of perchlorate in food and in fruits and vegetables. In the interim, the Commission and Member States have agreed on an interim intra-Union trade solution to remove any potential barriers from trade. Levels of perchlorate as reference for intra-Union trade have been set for food/fruits and vegetables at 0.5 mg/kg, with the exception of citrus fruits, pome fruit, root and tuber vegetables, table grapes, spinach, melons and watermelons for which an interim level of 0.2mg/kg has been agreed and except leafy vegetables (except spinach), fresh herbs and celery – grown in glasshouses/under cover for which an interim level of 1.0mg/kg has been agreed. A statement endorsing this agreement was published by the Standing Committee of the Food Chain and Animal Health in July 2013[14]. Following the publication of the EFSA opinion (EFSA, 2014) it was agreed to evaluate the most up to date monitoring data which should already reflect any mitigation strategies employed. Following analysis of the latter, discussion will commence on further risk management actions.

5.3 Persistent Organic Pollutants (POPs)

A group of POPs that have been under consideration at European level for some time are the brominated flame retardants and Member States have been asked to carry out monitoring of these contaminants in feed and food. Based on these data the Scientific Panel on

[14] Statement as regards the presence of perchlorate in food agreed by the Standing Committee of the Food Chain and Animal Health on 16 July 2013; http://ec.europa.eu/food/food/chemicalsafety/contaminants/statement-perchlorate_en.pdf

Contaminants in Food of EFSA has adopted six scientific opinions[15] on different classes of brominated flame retardants between September 2010 and September 2012. For a number of those classes, further data on levels in food and in humans need to be gathered and the Commission adopted a monitoring recommendation (2014/118/EU) (EU, 2014) on brominated flame retardants in March 2014.

A further group for which data have been collected following a monitoring recommendation (2010/161/EC), are perfluoroalkylated substances in food.

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Annex 1: Summary of Maximum Levels Specified for Certain Contaminants in Specified Foodstuffs

Note:

- All levels given in Annex I are from Regulation (EC) No 1881/2006, as amended by Commission Regulations (EC) No 1126/2007 , (EC) No 629/2008, (EC) No 565/2008, (EC) No 165/2010, (EC) No 105/2010, (EC) No 420/2011, (EC) No 1258/2011, (EC) No 1259/2011, (EC) No 594/2012 and (EC) No 1067/2013
- Specific footnotes (numbered in brackets) attached to entries in the Commission Regulation have been included and are listed under Section 9

Section 1: Nitrate

Entry No (in Reg 1881/2006)	Foodstuffs	Maximum levels (mg NO3/kg)	
1.1	Fresh spinach (*Spinacia oleracea*) (2)		3,500
1.2	Preserved, deep-frozen or frozen spinach		2,000
1.3	Fresh Lettuce (Lactuca sativa L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4	Harvested 1 October to 31 March:	
		Lettuce grown under cover	5,000
		Lettuce grown in the open air	4,000
		Harvested 1 April to 30 September:	
		Lettuce grown under cover	4,000
		Lettuce grown in the open air	3,000
1.4	'Iceberg' type lettuce	Lettuce grown under cover	2,500
		Lettuce grown in the open air	2,000
1.5	Rucola (Eruca sativa, Diplotaxis sp., Brassica tenuifolia, Sisymbrium tenuifolium)	Harvested 1 October to 31 March:	7,000
		Harvested 1 April to 30 September:	6,000

Section 2: Mycotoxins

Entry No (in Reg 1881/2006)	Foodstuffs	Mycotoxin	Maximum levels (µg/kg)
2.1	Aflatoxins		
2.1.1	Groundnuts (peanuts) and other oilseeds (40), to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs, with the exception of: — groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production	Aflatoxin B1	8.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	15.0 (5)
2.1.2	Almonds, pistachios and apricot kernels to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	12.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	15.0 (5)
2.1.3	Hazelnuts and Brazil nuts, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	8.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	15.0 (5)
2.1.4	Tree nuts, other than the tree nuts listed in 2.1.2 and 2.1.3, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	5.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	10.0 (5)
2.1.5	Groundnuts (peanuts) and other oilseeds (40) and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of: — crude vegetable oils destined for refining — refined vegetable oils	Aflatoxin B1	2.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	4.0 (5)
2.1.6	Almonds, pistachios and apricot kernels, intended for direct human consumption or use as an ingredient in foodstuffs (41)	Aflatoxin B1	8.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	10.0 (5)
2.1.7	Hazelnuts and Brazil nuts, intended for direct human consumption or use as an ingredient in foodstuffs (41)	Aflatoxin B1	5.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	10.0 (5)
2.1.8	Tree nuts, other than the tree nuts listed in 2.1.6 and 2.1.7, and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	2.0 (5)
		Sum of Aflatoxin B1, B2, G1 and G2	4.0 (5)
2.1.9	Dried fruit, other than dried figs, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	5.0
		Sum of Aflatoxin B1, B2, G1 and G2	10.0

Entry No (in Reg 1881/2006)	Foodstuffs	Mycotoxin	Maximum levels (µg/kg)
2.1.10	Dried fruit, other than dried figs, and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	2.0
		Sum of Aflatoxin B1, B2, G1 and G2	4.0
2.1.11	All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs listed in 2.1.12, 2.1.15 and 2.1.17	Aflatoxin B1	2.0
		Sum of Aflatoxin B1, B2, G1 and G2	4.0
2.1.12	Maize and rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs	Aflatoxin B1	5.0
		Sum of Aflatoxin B1, B2, G1 and G2	10.0
2.1.13	Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	Aflatoxin M1	0.05
2.1.14	Following species of spices: Capsicum spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) Piper spp. (fruits thereof, including white and black pepper) Myristica fragrans (nutmeg) Zingiber officinale (ginger) Curcuma longa (turmeric) Mixtures of spices containing one or more of the abovementioned spices	Aflatoxin B1	5.0
		Sum of Aflatoxin B1, B2, G1 and G2	10.0
2.1.15	Processed cereal-based foods and baby foods for infants and young children (3) (7)	Aflatoxin B1	0.1
2.1.16	Infant formulae and follow-on formulae, including infant milk and follow-on milk (4) (8)	Aflatoxin M1	0.025
2.1.17	Dietary foods for special medical purposes (9) (10) intended specifically for infants	Aflatoxin B1	0.1
		Aflatoxin M1	0.025
2.1.18	Dried figs	Aflatoxin B1	6.0
		Sum of Aflatoxin B1, B2, G1 and G2	10.0
2.2	Ochratoxins		
2.2.1	Unprocessed cereals	Ochratoxin A	5.0
2.2.2	All products derived from unprocessed cereals, including processed cereal products and cereals intended for direct human consumption with the exception of foodstuffs listed in 2.2.9, 2.2.10 and 2.2.13	Ochratoxin A	3.0
2.2.3	Dried vine fruit (currants, raisins and sultanas)	Ochratoxin A	10.0
2.2.4	Roasted coffee beans and ground roasted coffee, excluding soluble coffee	Ochratoxin A	5.0

Entry No (in Reg 1881/2006)	Foodstuffs	Mycotoxin	Maximum levels (µg/kg)
2.2.5	Soluble coffee (instant coffee)	Ochratoxin A	1.0
2.2.6	Wine (including sparkling wine, excluding liqueur wine and wine with an alcoholic strength of not less than 15% vol) and fruit wine (11)	Ochratoxin A	2.0 (12)
2.2.7	Aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails (13)	Ochratoxin A	2.0 (12)
2.2.8	Grape juice, concentrated grape juice as reconstituted, grape nectar, grape must and concentrated grape must as reconstituted, intended for direct human consumption (14)	Ochratoxin A	2.0 (12)
2.2.9	Processed cereal-based foods and baby foods for infants and young children (3) (7)	Ochratoxin A	0.50
2.2.10	Dietary foods for special medical purposes (9) (10) intended specifically for infants	Ochratoxin A	0.50
2.2.11	Spices, including dried spices Piper spp (fruits thereof, including white and black pepper) Myristica fragrans (nutmeg) Zingiber officinale (ginger) Curcuma longa (turmeric)	Ochratoxin A	15
	Capsicum spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika)		30µg/kg until 31.12.2014 15µg/kg as from 1.1.2015
	Mixtures of spices containing one of the abovementioned spices		15
2.2.12	Liquorice (Glycyrrhiza glabra, Glycyrrhiza inflate and other species)	Ochratoxin A	
2.2.12.1	Liquorice root, ingredient for herbal infusion	Ochratoxin A	20
2.2.12.2	Liquorice extract (42), for use in food in particular beverages and confectionary	Ochratoxin A	80
2.2.13	Wheat gluten not sold directly to the consumer	Ochratoxin A	8.0
2.3	Patulin		
2.3.1	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars (14)	Patulin	50
2.3.2	Spirit drinks (15), cider and other fermented drinks derived from apples or containing apple juice	Patulin	50

Entry No (in Reg 1881/2006)	Foodstuffs	Mycotoxin	Maximum levels (µg/kg)
2.3.3	Solid apple products, including apple compote, apple puree intended for direct consumption with the exception of foodstuffs listed in 2.3.4 and 2.3.5	Patulin	25
2.3.4	Apple juice and solid apple products, including apple compote and apple puree, for infants and young children (16) and labelled and sold as such (4)	Patulin	10.0
2.3.5	Baby foods other than processed cereal-based foods for infants and young children (3) (4)	Patulin	10.0
2.4	Fumonisins: Deoxynivalenol		
2.4.1	Unprocessed cereals (18) (19) other than durum wheat, oats and maize	Deoxynivalenol (17)	1,250
2.4.2	Unprocessed durum wheat and oats (18) (19)	Deoxynivalenol (17)	1,750
2.4.3	Unprocessed maize (18), with the exception of unprocessed maize intended to be processed by wet milling (37)	Deoxynivalenol (17)	1,750 (20)
2.4.4	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed in 2.4.7, 2.4.8 and 2.4.9	Deoxynivalenol (17)	750
2.4.5	Pasta (dry) (22)	Deoxynivalenol (17)	750
2.4.6	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals	Deoxynivalenol (17)	500
2.4.7	Processed cereal-based foods and baby foods for infants and young children (3) (7)	Deoxynivalenol (17)	200
2.4.8	Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 10 10	Deoxynivalenol (17)	750 (20)
2.4.9	Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 10 10	Deoxynivalenol (17)	1,250 (20)
2.5	Fumonisins: Zearalenone		
2.5.1	Unprocessed cereals (18) (19) other than maize	Zearalenone (17)	100
2.5.2	Unprocessed maize (18) with the exception of unprocessed maize intended to be processed by wet milling (37)	Zearalenone (17)	350 (20)

Entry No (in Reg 1881/2006)	Foodstuffs	Mycotoxin	Maximum levels (µg/kg)
2.5.3	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed in 2.5.6, 2.5.7, 2.5.8, 2.5.9 and 2.5.10	Zearalenone (17)	75
2.5.4	Refined maize oil	Zearalenone (17)	400 (20)
2.5.5	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals, excluding maize- snacks and maize-based breakfast cereals	Zearalenone (17)	50
2.5.6	Maize intended for direct human consumption, maize- based snacks and maize-based breakfast cereals	Zearalenone (17)	100 (20)
2.5.7	Processed cereal-based foods (excluding processed maize-based foods) and baby foods for infants and young children (3) (7)	Zearalenone (17)	20
2.5.8	Processed maize-based foods for infants and young children (3) (7)	Zearalenone (17)	20 (20)
2.5.9	Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 10 10	Zearalenone (17)	200 (20)
2.5.10	Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 10 10	Zearalenone (17)	300 (20)
2.6	Fumonisins: sum of fumonisin B1 and B2		
2.6.1	Unprocessed maize (18), with the exception of unprocessed maize intended to be processed by wet milling (37)	Fumonisins (sum of B1 and B2)	4,000 (23)
2.6.2	Maize intended for direct human consumption, maize- based foods for direct human consumption, with the exception of foodstuffs listed in 2.6.3 and 2.6.4	Fumonisins (sum of B1 and B2)	1,000 (23)
2.6.3	Maize-based breakfast cereals and maize-based snacks	Fumonisins (sum of B1 and B2)	800 (23)
2.6.4	Processed maize-based foods and baby foods for infants and young children (3) (7)	Fumonisins (sum of B1 and B2)	200 (23)

2.8.1	Food supplements based on rice fermented with red yeast Monascus purpureus	Citrinin	2,000 (§)

Section 3: Metals

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (mg/kg wet weight)
3.1	Lead	
3.1.1	Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	0.020
3.1.2	Infant formulae and follow-on formulae (4) (8)	0.02
3.1.3	Meat (excluding offal) of bovine animals, sheep, pig and poultry (6)	0.1
3.1.4	Offal of bovine animals, sheep, pig and poultry (6)	0.5
3.1.5	Muscle meat of fish (24) (25)	0.3
3.1.6	Crustaceans (26): Muscle meat from appendages and abdomen (44). In case of crabs and crab-like crustaceans (Brachyura and Anomura) muscle meat from appendages.	0.5
3.1.7	Bivalve molluscs (26)	1.5
3.1.8	Cephalopods (without viscera) (26)	1.0
3.1.9	Legume vegetables (27), cereals and pulses	0.2
3.1.10	Vegetables, excluding brassica vegetables, leaf vegetables, fresh herbs, fungi and seaweed (27). For potatoes the maximum level applies to peeled potatoes.	0.10
3.1.11	Brassica vegetables, leaf vegetables (43) and the following fungi (27): Agaricus bisporus (common mushroom), Pleurotus ostreatus (Oyster mushroom), Lentinula edodes (Shiitake mushroom)	0.30
3.1.12	Fruit, excluding berries and small fruit (27)	0.10
3.1.13	Berries and small fruit (27)	0.20
3.1.14	Fats and oils, including milk fat	0.10
3.1.15	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars (14)	0.050
3.1.16	Wine (including sparkling wine, excluding liqueur wine), cider, perry and fruit wine (11)	0.20 (28)
3.1.17	Aromatized wine, aromatized wine-based drinks and aromatized wine-product cocktails (13)	0.20 (28)
3.1.18	Food supplements (39)	3.0
3.3	Mercury	
3.3.1	Fishery products (26) and muscle meat of fish (24) (25), excluding species listed in 3.3.2. The maximum level for crustaceans applies to muscle meat from appendages and abdomen (44). In case of crabs and crab-like crustaceans (Brachyura and Anomura) it applies to muscle meat from appendages.	0.50

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (mg/ kg wet weight)
3.3.2	Muscle meat of the following fish (24) (25): anglerfish (Lophius species) Atlantic catfish (Anarhichas lupus) bonito (Sarda sarda) eel (Anguilla species) emperor, orange roughy, rosy soldierfish (Hoplostethus species) grenadier (Coryphaenoides rupestris) halibut (Hippoglossus hippoglossus) kingklip (Genypterus capensis) marlin (Makaira species) megrim (Lepidorhombus species) mullet (Mullus species) pink cusk eel (Genypterus blacodes) pike (Esox lucius) plain bonito (Orcynopsis unicolor) poor cod (Tricopterus minutes) Portuguese dogfish (Centroscymnus coelolepis) rays (Raja species) redfish (Sebastes marinus, S. mentella, S. viviparus) sail fish (Istiophorus platypterus) scabbard fish (Lepidopus caudatus, Aphanopus carbo) seabream, pandora (Pagellus species) shark (all species) snake mackerel or butterfish (Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens) sturgeon (Acipenser species) swordfish (Xiphias gladius) tuna (Thunnus species, Euthynnus species, Katsuwonus pelamis)	1.0
3.3.3	Food supplements (39)	0.10
3.4	Tin (inorganic)	
3.4.1	Canned foods other than beverages	200
3.4.2	Canned beverages, including fruit juices and vegetable juices	100
3.4.3	Canned baby foods and processed cereal-based foods for infants and young children, excluding dried and powdered products (3) (29)	50
3.4.4	Canned infant formulae and follow-on formulae (including infant milk and follow-on milk), excluding dried and powdered products (8) (29)	50
3.4.5	Canned dietary foods for special medical purposes (9) (29) intended specifically for infants, excluding dried and powdered products	50
3.2	Cadmium	
3.2.1	Vegetables and fruit, excluding root and tuber vegetables, leaf vegetables, fresh herbs, leafy brassica, stem vegetables, fungi and seaweed (27)	0.05

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (mg/kg wet weight)
3.2.2	Root and tuber vegetables (excluding celeriac, parsnips, salsify and horseradish), stem vegetables (excluding celery) (27). For potatoes, the maximum level applies to peeled potatoes	0.1
3.2.3	Leaf vegetables, fresh herbs, leafy brassica, celery, celeriac, parsnips, salsify, horseradish and the following fungi (27): Agaricus bisporus (common mushroom), Pleurotus ostreatus (Oyster mushroom), Lentinula edodes (Shiitake mushroom)	0.2
3.2.4	Fungi, excluding those listed in point 3.2.3(27)	1
3.2.5	Cereal grains excluding wheat and rice	0.1
3.2.6	— Wheat grains, rice grains	0.2
	— Wheat bran and wheat germ for direct consumption	
	— Soy beans	
3.2.7	Specific cocoa and chocolate products as listed below (49)	
	— Milk chocolate with < 30% total dry cocoa solids	0.1 as from 1 January 2019
	— Chocolate with < 50% total dry cocoa solids; milk chocolate with ≥ 30% total dry cocoa solids	0.30 as from 1 January 2019
	— Chocolate with ≥ 50% total dry cocoa solids	0.80 as from 1 January 2019
	— Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate)	0.60 as from 1 January 2019
3.2.8	Meat (excluding offal) of bovine animals, sheep, pig and poultry (6)	0.05
3.2.9	Horsemeat, excluding offal (6)	0.2
3.2.10	Liver of bovine animals, sheep, pig, poultry and horse (6)	0.5
3.2.11	Kidney of bovine animals, sheep, pig, poultry and horse (6)	1
3.2.12	Muscle meat of fish (24) (25), excluding species listed in points 3.2.13, 3.2.14 and 3.2.15	0.05
3.2.13	Muscle meat of the following fish (24) (25): mackerel (Scomber species), tuna (Thunnus species, Katsuwonus pelamis, Euthynnus species), bichique (Sicyopterus lagocephalus)	0.1
3.2.14	Muscle meat of the following fish (24) (25): bullet tuna (Auxis species)	0.15
3.2.15	Muscle meat of the following fish (24) (25): anchovy (Engraulis species) swordfish (Xiphias gladius) sardine (Sardina pilchardus)	0.25
3.2.16	Crustaceans (26): muscle meat from appendages and abdomen (44). In case of crabs and crab-like crustaceans (Brachyura and Anomura) muscle meat from appendages	0.5

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (mg/ kg wet weight)
3.2.17	Bivalve molluscs (26)	1
3.2.18	Cephalopods (without viscera) (26)	1
3.2.19	Infant formulae and follow on-formulae (8) (29)	
	— powdered formulae manufactured from cows' milk proteins or protein hydrolysates	0.010 as from 1 January 2015
	— liquid formulae manufactured from cows' milk proteins or protein hydrolysates	0.005 as from 1 January 2015
	— powdered formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins	0.020 as from 1 January 2015
	— liquid formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins	0.010 as from 1 January 2015
3.2.20	Processed cereal-based foods and baby foods for infants and young children (3) (29)	0.040 as from 1 January 2015
3.2.21	Food supplements (39) excl. food supplements listed in point 3.2.22	1
3.2.22	Food supplements (39) consisting exclusively or mainly of dried seaweed, products derived from seaweed, or of dried bivalve molluscs	3

Section 4: 3-monochloropropane-1,2-diol (3-MCPD)

Section 5: Dioxins and PCBs (31)

		Sum of dioxins (WHO PCDD/ F TEQ) (32)	Sum of dioxins and dioxin like PCBS (WHO PCDD/F PCB TEQ) (32)	Sum of PCB28, PCB52, PCB101, PCB138, PCB153 PCB180 (ICES 6) (32)
5.1	Meat and meat products (excluding edible offal) of the following animals (6):			
	— bovine animals and sheep	2.5pg/g fat (33)	4.0pg/g fat (33)	40ng/g fat (33)
	— poultry	1.75pg/g fat (33)	3.0pg/g fat (33)	40ng/g fat (33)
	— pigs	1.0pg/g fat (33)	1.25pg/g fat (33)	40ng/g fat (33)
5.2	Liver of terrestrial animals referred to in 5.1 with the exception of sheep and derived products thereof	0.3pg/g wet weight	0.5pg/g wet weight	3ng/g wet weight
	Liver of sheep and derived products thereof	1.25pg/g wet weight	2.0pg/g wet weight	3ng/g wet weight
5.3	Muscle meat of fish and fishery products and products thereof (25) (34), with the exemption of: — wild caught eel — wild caught fresh water fish, with the exception of diadromous fish species caught in fresh water — fish liver and derived products — marine oils The maximum level for crustaceans applies to muscle meat from appendages and abdomen (44). In case of crabs and crab-like crustaceans (Brachyura and Anomura) it applies to muscle meat from appendages.	3.5pg/g wet weight	6.5pg/g wet weight	75ng/g wet weight

	— bovine animals and sheep	2.5pg/g fat	4.0pg/g fat	40ng/g fat
	— poultry	1.75pg/g fat	3.0pg/g fat	40ng/g fat
	— pigs	1.0pg/g fat	1.25pg/g fat	40ng/g fat
5.11	Mixed animal fats	1.5pg/g fat	2.50pg/g fat	40ng/g fat
5.12	Vegetable oils and fats	0.75pg/g fat	1.25pg/g fat	40ng/g fat
5.13	Foods for infants and young children (4)	0.1pg/g wet weight	0.2pg/g wet weight	1.0ng/g wet weight

Section 6: Polycyclic aromatic hydrocarbons

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Polycyclic Aromatic Hydrocarbon	Maximum levels (µg/kg)
6.1	Polycyclic Aromatic Hydrocarbons		
6.1.10	Dietary foods for special medical purposes (9) (29) intended specifically for infants	Benzo(a)pyrene	10
		Sum of PAH4 (45)	10
6.1.1	Oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food	Benzo(a)pyrene	20
		Sum of PAH4 (45)	100
6.1.2	Cocoa beans and derived products	Benzo(a)pyrene	5.0µg/kg fat as from 1.4.2013
		Sum of PAH4 (45)	35.0µg/kg fat as from 1.4.2013 until 31.3.2015 30.0µg/kg fat as from 1.4.2015
6.1.3	Coconut oil intended for direct human consumption or use as an ingredient in food	Benzo(a)pyrene	20
		Sum of PAH4 (45)	200
6.1.4	Smoked meat and smoked meat products	Benzo(a)pyrene	5.0 until 31.8.2014 2.0 as from 1.9.2014
		Sum of PAH4 (45)	30.0 as from 1.9.2012 until 31.8.2014* 12.0 as from 1.9.2014
6.1.5	Muscle meat of smoked fish and smoked fishery products (25) (36), excluding fishery products listed in points 6.1.6 and 6.1.7. The maximum level for smoked crustaceans applies to muscle meat from appendages and abdomen (44). In case of smoked crabs and crab-like crustaceans (Brachyura and Anomura) it applies to muscle meat from appendages.	Benzo(a)pyrene	5.0 until 31.8.2014 2.0 as from 1.9.2014
		Sum of PAH4 (45)	30.0 as from 1.9.2012 until 31.8.2014* 12.0 as from 1.9.2014
6.1.6	Smoked sprats and canned smoked sprats (25) (47) (sprattus sprattus); bivalve molluscs (fresh, chilled or frozen) (26); heat treated meat and heat treated meat products (46) sold to the final consumer	Benzo(a)pyrene	50
		Sum of PAH4 (45)	300
6.1.7	Bivalve molluscs (36) (smoked)	Benzo(a)pyrene	60
		Sum of PAH4 (45)	350

6.1.8	Processed cereal-based foods and baby foods for infants and young children (3) (29)	Benzo(a)pyrene	10
		Sum of PAH4 (45)	10
6.1.9	Infant formulae and follow-on formulae, including infant milk and follow-on milk (8) (29)	Benzo(a)pyrene	10
		Sum of PAH4 (45)	10
PAH4 = benzo(a) pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene * Ireland, amongst a number of other Member States, was granted a derogation to retain the higher levels until 2017			

Section 7: Melamine

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (mg/kg wet weight)
7.1.	Melamine	
7.1.1	Food with the exception of infant formulae and follow-on formulae (48)	2.5
7.1.2	Powdered infant formulae and follow-on formulae	1

Section 8: Inherent plant toxins

Entry No (in Reg 1881/2006)	Foodstuffs (1)	Maximum levels (g/kg)
8.1	Erucic acid	(#)
8.1.1	Vegetable oils and fats	50(#)
8.1.2	Foods containing added vegetable oils and fats with the exception of the foods referred to in 8.1.3	50(#)
8.1.3	Infant formulae and follow-on formulae (8)	10(#)
(#) the maximum level refers to the level of erucic acid, calculated on the total level of fatty acids in the fat component in food		

Section 9: Footnotes

Footnotes in Regulation 1881/2006 (as amended)
(§) The maximum level is to be reviewed before 1 January 2016 in the light of information on exposure to citrinin from other foodstuffs and updated information on the toxicity of citrinin in particular as regards carcinogenicity and genotoxicity.
(1) As regards fruits, vegetables and cereals, reference is made to the foodstuffs listed in the relevant category as defined in Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) as last amended by Regulation (EC) No 178/2006 (OJ L 29, 2.2.2006, p. 3). This means, *inter alia*, that buckwheat (*Fagopyrum* sp) is included in 'cereals' and buckwheat products are included in 'cereal products'. Tree nuts are not covered by the maximum level for fruit.
(2) The maximum levels do not apply for fresh spinach to be subjected to processing and which is directly transported in bulk from field to processing plant.
(3) Foodstuffs listed in this category as defined in Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).
(4) The maximum level refers to the products ready to use (marketed as such or after reconstitution as instructed by the manufacturer).
(5) The maximum levels refer to the edible part of groundnuts (peanuts) and tree nuts. If groundnuts (peanuts) and tree nuts 'in shell' are analysed, it is assumed when calculating the aflatoxin content all the contamination is on the edible part, except in the case of Brazil nuts.
(6) Foodstuffs listed in this category as defined in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 226, 25.6.2004, p. 22).
(7) The maximum level refers to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.
(8) Foodstuffs listed in this category as defined in Commission Directive 2006/141/EC (OJ L 401, 30.12.2006, p. 1).
(9) Foodstuffs listed in this category as defined in Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).
(10) The maximum level refers in the case of milk and milk products, to the products ready for use (marketed as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk and milk products, to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.
(11) Foodstuffs listed in this category as defined in Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine as last amended by the Protocol concerning the conditions and arrangements for admission of the Republic of Bulgaria and Romania to the European Union (OJ L 157, 21.6.2005, p. 29).
(12) The maximum level applies to products produced from the 2005 harvest onwards.
(13) Foodstuffs listed in this category as defined in Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails (OJ L 149, 14.6.1991, p.1) as last amended by the Protocol concerning the conditions and arrangements for admission of the Republic of Bulgaria and Romania to the European Union. The maximum level for OTA applicable to these beverages is function of the proportion of wine and/or grape must present in the finished product.
(14) Foodstuffs listed in this category as defined in Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).
(15) Foodstuffs listed in this category as defined in Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of

Footnotes in Regulation 1881/2006 (as amended)
spirit drinks (OJ L 160, 12.6.1989, p.1), as last amended by the Protocol concerning the conditions and arrangements for admission of the Republic of Bulgaria and Romania to the European Union.
(16) Infants and young children as defined in Directive 2006/141/EC (OJ L 401, 30.12.2006, p. 1) and Directive 2006/125/ EC.
(17) For the purpose of the application of maximum levels for deoxynivalenol, zearalenone, T-2 and HT-2 toxin established in points 2.4, 2.5 and 2.7 rice is not included in 'cereals' and rice products are not included in 'cereal products'.
(18) The maximum level applies to unprocessed cereals placed on the market for first-stage processing. 'First-stage processing' shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be 'first-stage processing' insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting. In integrated production and processing systems, the maximum level applies to the unprocessed cereals in case they are intended for first-stage processing.
(19) The maximum level applies to cereals harvested and taken over, as from the 2005/06 marketing year, in accordance with Commission Regulation (EC) No 824/2000 of 19 April 2000 establishing procedures for the taking-over of cereals by intervention agencies and laying down methods of analysis for determining the quality of cereals (OJ L 100, 20.4.2000, p. 31), as last amended by Regulation (EC) No 1068/2005 (OJ L 174, 7.7.2005, p. 65).
(20) Maximum level shall apply from 1 October 2007.
(21) -
(22) Pasta (dry) means pasta with a water content of approximately 12%.
(23) Maximum level shall apply from 1 October 2007.
(24) Fish listed in this category as defined in category (a), with the exclusion of fish liver falling under code CN 0302 70 00, of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22) as last amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 33). In case of dried, diluted, processed and/or compound foodstuffs Article 2(1) and 2(2) apply.
(25) Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.
(26) Foodstuffs falling within category (c) and (f) of the list in Article 1 of Regulation (EC) No 104/2000, as appropriate (species as listed in the relevant entry). In case of dried, diluted, processed and/or compound foodstuffs Article 2(1) and 2(2) apply. 'In case of Pecten maximus, the maximum level applies to the adductor muscle and gonad only.
(27) The maximum level applies after washing of the fruit or vegetables and separating the edible part.
(28) The maximum level applies to products produced from the 2001 fruit harvest onwards.
(29) The maximum level refers to the product as sold.
(30) The maximum level is given for the liquid product containing 40% dry matter, corresponding to a maximum level of 50µg/kg in the dry matter. The level needs to be adjusted proportionally according to the dry matter content of the products.
(31) Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO-toxic equivalency factors (WHO-TEFs)) and sum of dioxins and dioxin-like PCBs (sum of PCDDs, PCDFs and polychlorinated biphenyls (PCBs), expressed as WHO toxic equivalent using the WHO-TEFs). WHO-TEFs for human risk assessment based on the conclusions of the World Health Organization (WHO) – International Programme on

Footnotes in Regulation 1881/2006 (as amended)
Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg *et al.*, The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006))
(32) Upperbound concentrations: Upperbound concentrations are calculated on the assumption that all the values of the different congeners below the limit of quantification are equal to the limit of quantification.
(33) The maximum level expressed on fat is not applicable for foods containing < 2% fat. For foods containing less than 2% fat, the maximum level applicable is the level on product basis corresponding to the level on product basis for the food containing 2% fat, calculated from the maximum level established on fat basis, making use of following formula: Maximum level expressed on product basis for foods containing less than 2% fat = maximum level expressed on fat for that food x 0.02.
(34) Foodstuffs listed in this category as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Regulation (EC) No 104/2000, with the exclusion of fish liver referred to in point 5.11.
(35) -
(36) Foodstuffs listed in this category as defined in categories (b), (c), and (f) of the list in Article 1 of Regulation 104/2000.
(37) The exemption applies only for maize for which it is evident, e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production).
(38) In the case of canned fish liver, the maximum level applies to the whole edible content of the can.
(39) The maximum level applies to the food supplements as sold.
(40) Oilseeds falling under codes CN 1201, 1202, 1203, 1204, 1205, 1206, 1207 and derived products CN 1208; melon seeds fall under code ex 1207 99.
(41) In case derived/processed products thereof are derived/processed solely or almost solely from the tree nuts concerned, the maximum levels as established for the corresponding tree nuts apply also to the derived/processed products. In other cases, Article 2(1) and 2(2) apply for the derived/processed products.
(42) The maximum level applies to the pure and undiluted extract, obtained whereby 1kg of extract is obtained from 3 to 4kg liquorice root.
(43) The maximum level for leaf vegetables does not apply to fresh herbs (falling under Code number 0256000 in Annex I to Regulation (EC) No 396/2005).
(44) This definition excludes the cephalothorax of crustaceans.
(45) Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.
(46) Meat and meat products that have undergone a heat treatment potentially resulting in formation of PAH, i.e. only grilling and barbecuing.
(47) For the canned product the analysis shall be carried out on the whole content of the can. As regards the maximum level for the whole composite product Art. 2(1)(c) and 2(2) shall apply.
(48) The maximum level does not apply to food for which it can be proven that the level of melamine higher than 2.5mg/kg is the consequence of authorized use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine.
(49):For the specific cocoa and chocolate products the definitions set out in points A. 2, 3 and 4 of Annex I to Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption (OJ L 197, 3.8.2000, p. 19) apply.

Annex 2: Sampling frequencies for groundnuts, other oilseeds, apricot kernels and tree nuts, dried figs, other dried fruit and spices (established by Commission Regulation (EC) No 401/2006/EC)

See also 3.2 Sampling and Analysis for Mycotoxins in Foodstuffs

			40	200	8

			10	200	2
**** See also Table on "Derived products with (very) small particle weight"**					

Commodity	Lot weight (tonnes)	Weight or number of sub lots	Number of incremental samples	Weight of incremental sample (g)	Aggregate sample Weight (kg)
Spices	≥ 15	25 tonnes	100	100	10
	> 10.0-< 15.0	—	100	100	10
	> 5.0-≤ 10.0	—	80	100	8
	> 2.0-≤ 5.0	—	60	100	6
	> 1.0-≤ 2.0	—	40	100	4
	> 0.5-≤ 1.0	—	30	100	3
	> 0.2-≤ 0.5	—	20	100	2
	> 0.1-≤ 0.2	—	15	100	15
	> 0.01-≤ 0.1	—	10	100	1
	≤ 0.01	—	5	100	5

Commodity	Lot weight (tonnes)	Weight or number of sub lots	Number of incremental samples	Weight of incremental sample (g)	Aggregate sample Weight (kg)
****Derived products with (very) small particle weight**	> 20 – ≤ 50	—	100	100	10
	> 10 – ≤ 20	—	60	100	6
	> 3 – ≤ 10	—	40	100	4
	> 1 – ≤ 3	—	20	100	2
	≤ 1	—	10	100	1

Annex 3: Requirements for sampling and analysis of products in respect of the controls of nitrates falling within the scope of Commission Regulation (EC) No 1881/2006

A.2. Definitions

For the purpose of this Annex, the following definitions apply:

A.2.1. "lot" means an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety or soil type within a maximum area of x hectares, type of packing, packer, consignor or markings
A.2.2. "sub-lot" means a designated part of a large lot in order to apply the sampling method on that designated part; each sub-lot must be physically separate and identifiable
A.2.3. "incremental sample or unit" means a quantity of material taken from a single place in the lot or sub-lot. In this case, it may be a single lettuce or spinach head, or handful of baby leaf, or one bag of cut leaves
A.2.4. "aggregate sample" means the combined total of all the incremental samples taken from the lot or sub-lot
A.2.5. "laboratory sample" means a sample intended for the laboratory
A.2.6. "field" means a specified area of land of the same soil type and cultivation practice, containing a single variety of lettuce or spinach at same growth stage
A.2.7. "area under cover" means a specified area of land covered by a glasshouse or a polytunnel containing a single variety of lettuce or spinach at the same growth stage

A.3. General Provisions

A.3.1 Personnel

Sampling for official control should be carried out by an authorised person as designated by the FSAI.

A.3.2 Material to be sampled

Each lot which is to be examined should be sampled separately. Large lots, i.e. lots of more than 30 tonnes or larger than 3 hectares, should be subdivided into sub-lots to be sampled separately.

A.3.3 Precautions to be taken

In the course of sampling and preparation of the samples, precautions should be taken to avoid any changes, which would affect:

- The nitrate content, adversely affect the analytical determination or make the aggregate samples unrepresentative, e.g. the presence of soil on lettuce or spinach during sample preparation
- The food safety or integrity of the lots to be sampled

Also, all measures necessary to ensure the safety of the persons taking the samples should be taken.

A.3.4 Incremental samples

As far as possible incremental samples should be taken at various places distributed throughout the lot or sub-lot.

Departure from such procedure should be recorded in the record provided for under A.3.8 of the Annex to Regulation (EC) No 1881/2006.

A.3.5 Preparation of the aggregate sample
The aggregate sample should be made up by combining the incremental samples.

A.3.6 Replicate samples
The replicate samples for enforcement, defence and reference purposes should be taken from the homogenised aggregate sample, unless such procedure conflicts with the national rules regarding the rights of the food business operator.

A.3.7 Packaging and transmission of samples
Each sample should be placed in a clean, inert sealed opaque plastic bag to prevent loss of moisture and offering adequate protection against any damage or contamination. The sample must be transferred to the laboratory within 24 hours of sampling and should be kept cool during transport. If this is not possible, the sample should be deep-frozen within 24 hours and kept frozen (up to a maximum of six weeks). All additional necessary precautions should be taken to avoid any change in composition of the sample, which might arise during transportation or storage.

A.3.8 Sealing and labelling of samples
Each sample taken for official use should be sealed at the place of sampling and identified following national rules. A record should be kept of each sampling, permitting each lot to be identified unambiguously and the sampling officer should record the variety, grower, production method, date, place of sampling, food business operator responsible for consignment, and any other relevant information likely to be of assistance to the analyst.

Different Types of Lots
Food commodities may be traded in bulk or in containers, including sacks, bags and crates, or in individual retail packings. The method of sampling may be applied to all the different forms in which the commodities are put on the market.

Method of Sampling
As far as possible, incremental samples should be taken at various places throughout the lot or sub-lot.

1. Sampling in the field
If it is considered necessary to sample the lettuce or spinach in the field, the sampling has to be performed as follows:

- Incremental samples should not be collected from areas that appear to be unrepresentative of the field or area under cover
- Areas with different soil types, which have been subjected to different cultivation practices or contain different lettuce or spinach varieties, or to be harvested at a different time, should be treated as separate lots or fields
- If the field is larger than three hectares, the field should be divided into sub-lots of two hectares and each sub-lot should be sampled separately
- Incremental samples should be collected by walking a 'W' or 'X' shaped pattern across the field. Crops harvested from narrow beds or area under cover should be harvested in a 'W' or 'X' shaped pattern from several beds and pooled to form the aggregate sample
- Plants must be cut at ground level

The sample must contain at least 10 plants, and the aggregate sample of 10 plants must weigh at least 1kg. Only units of a marketable size should be sampled. Soil, outer non-edible and damaged leaves should be removed from each unit.

Sampling of lots of spinach, lettuce, baby foods and processed cereal based food for Infants and young children on the market
The sampling method is applicable to lots smaller than or equal to 25 tonnes. In the case of large lots (lots > 30 tonnes), the lot should be subdivided into sub-lots of in principle 25 tonnes on condition that the sub-lot may be separated physically. Taking into account that the weight of the lot is not always an exact multiple of 25 tonnes, the weight of the sub-lot may exceed the mentioned weight by a maximum of 20%. This means that the sub-lot may have weight ranging from 15 to 30 tonnes. In case the lot is not or cannot be physically separated into sub-lots, the sample is taken from the lot.

The aggregate sample should be at least 1kg, except where it is not possible, e.g. when sampling a single head or package. The minimum number of incremental samples to be taken from the lot should be as given in Table 3.

Table 3. Minimum number of incremental samples to be taken from the lot

Weight of lot (in kg)	Minimum number of incremental samples to be taken	Aggregate sample minimum weight (kg)
< 50	3	1
50 – 500	5	1
> 500	10	1

If the lot consists of individual packages, then the number of packages, which should be taken to form the aggregate sample, is given in Table 4.

Table 4. Number of packages (incremental samples) which should be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot	Number of packages or units to be taken	Aggregate sample minimum weight (kg)
1 – 25	1	1
26 – 100	about 5%, at least 2 packages or units	1
> 100	about 5%, at maximum 10 packages or units	1

Each lot or sub-lot to be checked for compliance must be sampled separately. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging formats, means of transport, etc.) then an alternative method of sampling may be applied, provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. The position from which a sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.

2. Sampling at retail stage

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the sampling provisions set out in B 2 of the Annex to Regulation (EC) No 1881/2006. Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented

Part C: Sample Preparation and Analysis

These parts are specifically related to the analytical procedures and are beyond the scope of this guidance. Regulation (EC) No 1882/2006 should be consulted by the analytical laboratory before proceeding with the analysis.

Assessment of Compliance of a Lot or Sub-lot

- Acceptance if the laboratory sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery
- Rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery, i.e. the analytical result corrected for recovery and minus the expanded measurement uncertainty is used to assess compliance

Annex 4: Requirements for sampling and analysis of products in respect of the controls of the levels of lead, cadmium, mercury, inorganic tin, 3- MCPD and polycyclic aromatic hydrocarbons in foodstuffs falling within the scope of Commission Regulation (EC) No 1881/2006

A.4. Definitions/Sampling Methods

A.4.1 "lot" means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics (such as origin, variety type of packing, packer, consignor or markings). In the case of fish, also the size of fish should be comparable.
A.4.2 "sub-lot" means a designated part of a large lot in order to apply the sampling method on that designated part; each sub-lot must be physically separate and identifiable.
A.4.3 "incremental sample" means a quantity of material taken from a single place in the lot or sub-lot.
A.4.4 "aggregate sample" means the combined total of all the incremental samples taken from the lot or sub-lot; aggregate samples should be considered as representative of the lots or sub-lots from which they are taken.
A.4.5 "laboratory sample" means a sample intended for the laboratory.

B.4. General Provisions

B.4.1 Personnel
Sampling for official control should be carried out by an authorised person as designated by the FSAI.
B.4.2 Material to be sampled
Each lot or sub-lot which is to be examined should be sampled separately.
B.4.3 Precautions to be taken
In the course of sampling, precautions should be taken to avoid any changes which would affect the levels of contaminants, adversely affect the analytical determination or make the aggregate samples unrepresentative.
B.4.4 Incremental samples
As far as possible incremental samples should be taken at various places distributed throughout the lot or sub-lot.
Departure from such procedure should be recorded in the record provided for under point B.1.8. of the Annex to Regulation (EC) No 333/2007 as amended.
B.4.5 Preparation of the aggregate sample
The aggregate sample should be made up by combining the incremental samples.
B.4.6 Samples for enforcement, defence and referee purposes
The samples for enforcement, defence and referee purposes should be taken from the homogenised aggregate sample unless this conflicts with the national rules as regards the rights of the food business operator.
B.4.7 Packaging and transmission of samples
Each sample should be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions should be taken to avoid any change in composition of the sample which might arise during transportation or storage.
In case of sampling for PAH analysis, plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of

solid samples, by wrapping the sample in aluminium foil before placing it in the sampling container.

B.4.8 Sealing and labelling of samples:

- Each sample taken for official use should be sealed at the place of sampling and identified following the national rules
- A record should be kept of each sampling, permitting each lot or sub-lot to be identified unambiguously (reference to the lot number should be given) and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst

Sampling Plans

Large lots should be divided into sub-lots on condition that the sub-lot may be separated physically. For products traded in bulk consignments, e.g. cereals, Table 5 should apply. For other products Table 7 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may exceed the mentioned weight by a maximum of 20%.

The aggregate sample should be at least 1kg or 1 litre except where it is not possible, e.g. when the sample consists of 1 package or unit.

The minimum number of incremental samples to be taken from the lot or sub-lot should be as given in Table 7.

In the case of bulk liquid products, the lot or sub-lot should be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or sub-lot. It is therefore sufficient to take three incremental samples from a lot or sub-lot to form the aggregate sample.

The incremental samples should be of similar weight. The weight of an incremental sample should be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1kg or 1 litre. Departure from this method should be recorded in the record provided for under point B.1.8 of the Annex to Regulation (EC) No 333/2007 as amended.

Table 5. Subdivision of lots into sub lots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sub-lots
≥ 1,500	500 tonnes
> 300 and < 1 500	3 sub-lots
≥ 50 and ≤ 300	100 tonnes
< 50	–

Table 6. Subdivision of lots into sub lots for other products	
Lot weight (ton)	Weight or number of sub-lots
≥ 15	15-30 tonnes
< 15	–

Table 7. Minimum number of incremental samples to be taken from the lot or sub lot	
Weight or volume of lot/sub-lot (in kg or litre)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

If the lot or sub-lot consists of individual packages or units, then the number of packages or units which should be taken to form the aggregate sample is given in Table 8.

Table 8. Number of packages or units (incremental samples) which should be taken to form the aggregate sample if the lot or sub lot consists of individual packages or units	
Number of packages or units in the lot/sub-lot	Number of packages or units to be taken
1 to 25	At least 1 package or unit
26 to 100	About 5%, at least 2 packages or units
> 100	About 5%, at maximum 10 packages or units

The maximum levels for inorganic tin apply to the contents of each can, but for practical reasons it is necessary to use an aggregate sampling approach. If the result of the test for an aggregate sample of cans is less than but close to the maximum level of inorganic tin and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations.

Where it is not possible to carry out the method of sampling set out in this chapter because of the unacceptable commercial consequences, e.g. because of packaging forms, damage to the lot, etc., or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sub-lot and is fully documented.

Specific provisions for the sampling of large fish arriving in large lots

In case the lot or sub-lot to be sampled contains large fish (individual fish weighing more than about 1kg) and the lot or sub-lot weighs more than 500kg, the incremental sample shall consist of the middle part of the fish. Each incremental sample shall weigh at least 100g.

Sampling at retail stage

Sampling of foodstuffs at retail stage should be done where possible in accordance with the sampling provisions set out in points B.1 and B.2 of the Annex to Regulation (EC) No 333/2007.

Where it is not possible to carry out the method of sampling set out in point B.2.2 because of the unacceptable commercial consequences, e.g. because of packaging forms, damage to the lot, etc., or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sub-lot and is fully documented.

Part C: Sample Preparation and Analysis

These parts are specifically related to the analytical procedures and are beyond the scope of this guidance. Regulation (EC) No 333/2007 should be consulted by the analytical laboratory before proceeding with the analysis.

Assessment of Compliance of a Lot or Sub-lot

- Acceptance if the laboratory sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery.
- Rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt, taking into account, the measurement uncertainty and correction for recovery, i.e. the analytical result corrected for recovery and minus the expanded measurement uncertainty is used to assess compliance.

Annex 5: Requirements for sampling and analysis of products in respect of the controls of the levels of dioxins and dioxin-like PCBs in foodstuffs falling within the scope of Commission Regulation (EC) No 1881/2006

I. Definitions

1.9 'Lot' means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish and fishery products, also the size of fish shall be comparable. In case the size and/or weight of the fish is not comparable within a consignment, the consignment may still be considered as a lot but a specific sampling procedure has to be applied.
1.10 'Sub-lot' means designated part of a large lot in order to apply the sampling method on that designated part. Each sub-lot must be physically separated and identifiable.
1.11 'Incremental sample' means a quantity of material taken from a single place in the lot or sub-lot.
1.12 'Aggregate sample' means the combined total of all the incremental samples taken from the lot or sub-lot.
1.13 'Laboratory sample' means a representative part/quantity of the aggregate sample intended for the laboratory.

II. General Provisions

1. Personnel
Sampling shall be performed by an authorised person as designated by the Member State.
2. Material to be sampled
Each lot or sub-lot, which is to be examined, shall be sampled separately.
3. Precautions to be taken
In the course of sampling and preparation of the samples, precautions shall be taken to avoid any changes, which would affect the content of dioxins and PCBs, adversely affect the analytical determination or make the aggregate samples unrepresentative.
4. Incremental samples
As far as possible incremental samples shall be taken at various places distributed throughout the lot or sub-lot. Departure from such procedure shall be recorded in the record provided for under point II.8 of the Annex to Regulation 589/2014.
5. Preparation of the aggregate sample
The aggregate sample shall be made up by combining the incremental samples. It shall be at least 1kg unless not practical, e.g. when a single package has been sampled or when the product has a very high commercial value.
6. Replicate samples
The replicate samples for enforcement, defence and reference purposes shall be taken from the homogenised aggregate sample, unless such procedure conflicts with Member States' rules as regard the rights of the food business operator. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.
7. Packaging and transmission of samples
Each sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample, which might arise during transportation or storage.
8. Sealing and labelling of samples
Each sample taken for official use shall be sealed at the place of sampling and identified following the rules of the Member States.

A record shall be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

III. Sampling Plan

The sampling method applied shall ensure that the aggregate sample is representative for the (sub) lot that is to be controlled.

Division of lots into sub-lots

Large lots should be divided into sub-lots on condition that the sub-lot can be separated physically. For products traded in large bulk consignments, e.g. vegetable oils, Table 9 should apply. For other products, Table 11 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sub-lots, the weight of the sub-lot may exceed the mentioned weight by a maximum of 20%.

Table 9. Subdivision of lots into sub lots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sub-lots
≥ 1,500	500 tonnes
> 300 and < 1 500	3 sub-lots
≥ 50 and ≤ 300	100 tonnes
< 50	—

Table 10. Subdivision of lots into sub lots for other products

Lot weight (ton)	Weight or number of sub-lots
≥ 15	15-30 tonnes
< 15	–

Number of incremental samples

The aggregate sample uniting all incremental samples should be at least 1kg (see part II.5 of the Annex to Regulation (EC) No 589/2014).

The minimum number of incremental samples to be taken from the lot or sub-lot should be as given in Table 11 and Table 12.

In the case of bulk liquid products, the lot or sub-lot should be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or sub-lot. It is therefore sufficient to take three incremental samples from a lot or sub-lot to form the aggregate sample.

The incremental samples should be of similar weight. The weight of an incremental sample should be at least 100 grams.

Departure from this procedure must be recorded in the record provided for under part II.8 of the Annex to Regulation (EC) No 589/2014. In accordance with the provisions of Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and

residues thereof in certain animal products[16], the aggregate sample size for hen eggs is at least 12 eggs (for bulk lots as well for lots consisting of individual packages, Table 11 and Table 12 apply).

Table 11. Minimum number of incremental samples to be taken from the lot or sub lot

Weight or volume of lot/sub-lot (in kg or litre)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

If the lot or sub-lot consists of individual packages or units, then the number of packages or units which should be taken to form the aggregate sample is given in Table 12.

Table 12. Number of packages or units (incremental samples) which should be taken to form the aggregate sample if the lot or sub lot consists of individual packages or units

Number of packages or units in the lot/sub-lot	Number of packages or units to be taken
1 to 25	At least 1 package or unit
26 to 100	About 5%, at least 2 packages or units
> 100	About 5%, at maximum 10 packages or units

Specific provisions for the sampling of lots containing whole fish of comparable size and weight

Fish are considered as being of comparable size and weight in case the difference in size and weight does not exceed about 50%.

The number of incremental samples to be taken from the lot is defined in Table 11. The aggregate sample uniting all incremental samples should be at least 1kg (see point II.5 of the Annex to Regulation (EC) No 589/2014

In case the lot to be sampled contains small fish (individual fish weighing < about 1kg), the whole fish is taken as incremental sample to form the aggregate sample. In case the resulting aggregate sample weighs more than 3kg, the incremental samples may consist of the middle part, weighing each at least 100 grams, of the fish forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenisation of the sample.

The middle part of the fish is where the centre of gravity is. This is located in most cases at the dorsal fin (in case the fish has a dorsal fin) or halfway between the gill opening and the anus.
In case the lot to be sampled contains larger fish (individual fish weighing more than about 1kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams.

[16] OJ L 303, 6.11.1997, p. 12.

For fish of intermediate size (about 1-6kg) the incremental sample is taken as a slice of the fish from backbone to belly in the middle part of the fish.

For very large fish, e.g. > about 6kg, the incremental part is taken from the right side (frontal view) dorso-lateral muscle meat in the middle part of the fish In case the taking of such a piece of the middle part of the fish would result in an significant economic damage, taking of three incremental samples of at least 350 grams each may be considered as being sufficient, independently of the size of the lot or alternatively an equal part of the muscled meat close to the tail part and the muscle meat close to the head part of one fish may be taken to form the incremental sample being representative for the level of dioxins in the whole fish.

Sampling of lots of fish containing whole fish of different size and/or weight

The provisions of point III.5 of the Annex to Regulation (EC) No 589/2014 as regards sample constitution are applicable.

In case a size or weight class/category is predominant (about 80% or more of the batch), the sample is taken from fish with the predominant size or weight. This sample is to be considered as being representative for the whole batch.

In case no particular size or weight class/category predominates, then it must be ensured that the fish selected for the sample are representative for the consignment. Specific guidance for such cases is provided in *Guidance document for the sampling of lots of fish containing whole fish of different size and/or weight*[17].

Sampling at retail stage

Sampling of foodstuffs at retail stage should be done where possible in accordance with the sampling provisions set out in part III.2 of the Annex to Regulation (EC) No 589/2014. Where this is not possible, an alternative method of sampling at retail stage may be used provided that it ensures sufficient representativeness for the sampled lot or sub-lot.

IV. Compliance of the Lot or Sub-lot with the Specification

Regarding non-dioxin-like PCBs

- The lot is accepted, if the analytical result does not exceed the maximum level of non-dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty.
- The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound[18] analytical result confirmed by duplicate analysis[19], exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.

The measurement uncertainty may be taken into account according to one of the following approaches:

[17] http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/dioxins_en.htm

[18] The concept of "upperbound" requires using the limit of quantification for the contribution of each non-quantified congener to the Toxic Equivalent (TEQ). The concept of "lowerbound" requires using zero for the contribution of each non-quantified congener to the TEQ. The concept of "mediumbound" requires using half of the limit of quantification calculating the contribution of each non- quantified congener to the TEQ.

[19] The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. The first analysis, taking into account the measurement uncertainty is used for verification of compliance. In case the analysis is performed in the frame of a dioxin contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the dioxin contamination incident.

- By calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%. A lot or sub-lot is non-compliant if the measured value minus U is above the established permitted level
- By establishing the decision limit (CCα) according to the provisions of Decision 2002/657/EC (point 3.1.2.5 of Annex I to that Decision — the case of substances with an established permitted level). A lot or sub-lot is non- compliant if the measured value is equal to or above the CCα

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

As regards dioxins (PCDD/PCDF) and dioxin-like PCBs

The lot is accepted, if the result of a single analysis:

- Performed by a screening method with a false-compliant rate below 5% indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006,
- Performed by a confirmatory method does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty

For screening assays a cut-off value shall be established for the decision on the compliance with the respective levels of interest set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs.

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound[18] analytical result obtained with a confirmatory method and confirmed by duplicate analysis[19], exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.

The measurement uncertainty may be taken into account according to one of the following approaches by:

- Calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%. A lot or sub-lot is non-compliant if the measured value minus U is above the established permitted level. In case of a separate determination of PCDD/Fs and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs has to be used for the estimated expanded uncertainty of the sum of PCDD/Fs and dioxin-like PCBs
- Establishing the decision limit (CCα) according to the provisions of Decision 2002/657/EC[20] (point 3.1.2.5 of Annex I to that Decision — the case of substances with established permitted level) a lot or sub-lot is non- compliant if the measured value is equal to or above the CCα

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

[20] OJ L 221, 17.8.2002, p. 8.

V. Exceedance of action levels

Action levels serve as tool for selection of samples in those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Screening methods shall establish appropriate cut-off values for selection of these samples. The efforts necessary to identify a source and to reduce or eliminate the contamination shall be deployed only if exceedance of the action level is confirmed by duplicate analysis using a confirmatory method and taking into account the measurement uncertainty.

VI. Sample Preparation and Analysis

These parts are specifically related to the analytical procedures and are beyond the scope of this guidance. Regulation (EC) No 589/2014 should be consulted by the analytical laboratory before proceeding with the analysis.