



# 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 relates 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 (November, 2009) 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 (S.I. No. of 400 of 2001) as follows:

*“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, holding and/or storage of such foodstuffs, or as a result of environmental contamination. (This definition does not cover extraneous matter such as insect fragments, animal hair, etc.)”*

This definition is slightly modified compared with that in the EC legislation laying down Community procedures for contaminants in food, Council Regulation (EEC) No 315/93 of 8 February 1993 (EC, 1993), other than the inclusion of “and/or storage” in S.I. No. of 400 of 2001, in order to make it clear that the term “handling” also covers storage.

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, dibenzofurans and polychlorinated biphenyls (PCBs)
- metals, e.g. lead, cadmium and mercury
- processing or industrial contaminants, e.g. polycyclic aromatic hydrocarbons
- 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 Community 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 (EEC) No 1881/2006 (EC, 2006a) currently establishes maximum levels for a number of contaminants in food, including some persistent organic pollutants, metals, mycotoxins and PAHs. It replaces and revokes the previous Community measure establishing maximum levels for contaminants in food, Commission Regulation (EEC) No 466/2001 (EC, 2001). The European Commission has recently published a Fact Sheet 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<sup>1</sup> of the Directorate-General for Health and Consumers (DG SANCO), the branch of the Commission responsible for this area.

Food business operators (FBOs) 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 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, Fisheries and Food (DAFF) 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 Community, 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 an FBO or other entity, should follow the procedures laid down. These aspects are covered in more detail in Section 3 of this guidance document.

<sup>1</sup> [http://ec.europa.eu/food/food/chemicalsafety/contaminants/index\\_en.htm](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 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 DAFF's website<sup>2</sup> as the Government department having responsibility for legislation on pesticide or veterinary drug residues in food. Short fact sheets 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](http://www.fsai.ie)). The fact sheets may be accessed at:

Pesticides: <http://www.fsai.ie/assets/0/86/204/8653e294-d874-45a9-83a6-ea6792e1babb.pdf>

Animal Remedies: <http://www.fsai.ie/assets/0/86/204/5907b17c-5356-49e7-88a9-dff00f0ffaba.pdf>.

Under Service Contracts established with the FSAI, DAFF, 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; <http://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 Community legislation has therefore been established on maximum levels of contaminants in animal feed. This legislation is under the aegis of DAFF, and also lies outside the scope of this guidance document, however, further information is available from DAFF's website<sup>3</sup>.

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 Community legislation on certain contaminants, including information on additional regulatory measures (“safeguard measures”, introduced via Commission Decisions) 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.

**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 FBOs.

**Section 4** outlines the requirements of the national legislation implementing the Community 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 Community 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. 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>.

<sup>2</sup> <http://www.agriculture.gov.ie>

<sup>3</sup> <http://www.agriculture.gov.ie/foodsafetyconsumerissues/feedingstuffs/undesirablesubstancesinfeed>

A series of fact sheets 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](http://www.fsai.ie)), as follows:

Mycotoxins: <http://www.fsai.ie/assets/0/86/204/cf0838f1-654f-406d-af95-1025ff41e54f.pdf>

Dioxins and PCBs: <http://www.fsai.ie/assets/0/86/204/d2a7dc76-1298-4384-84f7-e3d3c658278a.pdf>

Metals: <http://www.fsai.ie/assets/0/86/204/20bf8465-efe0-4b80-b566-da0ed347240f.pdf>

PAHs: <http://www.fsai.ie/assets/0/86/204/f863e00e-38cd-49de-98b3-3de3c3dbd914.pdf>

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 European Community 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<sup>4</sup>). 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.) heavy metals (lead, mercury and cadmium), dioxins and dioxin-like PCBs 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 for 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 (FBOs) 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 Community 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 Community 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 Community 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

1. 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.
2. 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.
3. 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.
4. These tolerances shall be adopted in the form of a non-exhaustive Community 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.

<sup>4</sup> Also known as ALARP (As Low as Reasonably Practicable)

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 EC 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 Foodstuffs, 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 Children and the FSAI represent Ireland on this Committee. The opinion of the SCF is underpinned by scientific advice in the form of a risk assessment from EFSA, and previously from the Scientific Committee for Food. Following a positive opinion from the SCF, the Commission must formally adopt the proposed risk management measure and introduce it into Community legislation as a Commission Regulation or Directive. This is then 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-monochloropropane-1,2-diol (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 since 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 Community 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 Community, legislation has also been introduced on sampling and analysis procedures for contaminants in food, and any monitoring official control purposes 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 (as amended by Commission Regulations 1126/2007, 565/2008 and 629/2008) 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), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and dioxin-like PCBs and polycyclic aromatic hydrocarbons (benzo(a)pyrene). 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 FBO) 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<sup>5</sup> and under food hygiene regulations<sup>6</sup>. 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-derived 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 I 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. However, problems of interpretation can arise in relation to what is the edible part of a particular foodstuff, an example being the analysis of cadmium in crabmeat. Italy has in recent years (2007-2009) reported a number of non-compliances with the maximum level of cadmium in crabmeat, the specified limit in crustaceans in general being 0.5 mg/kg, excluding the brown meat of crab. Italy normally includes the hepatopancreas of the crab in the sample portion to be analysed, because it considers that the hepatopancreas is not brown meat and

<sup>5</sup> 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)

<sup>6</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

is likely to be eaten by Italian consumers while the other Member States use the white meat from legs and claws only. Since hepatopancreas can contain high cadmium levels, the cadmium levels of the whole sample portion can be elevated compared to white crab meat, as reported by Italy. This issue is the subject of ongoing discussions in the relevant Commission working group to ensure consistent interpretation of the legislation in all Member States.

### 2.3.3 Application of the maximum levels in Regulation (EC) No 1881/2006 to 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 (see e.g. Annex of Regulation (EC) No 1881/2006, entries 2.2.1 and 2.4.1 for mycotoxins) and also some 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...”, Annex of Regulation (EC) No 1881/2006, entry 2.1.6. Maximum levels have been established for some particularly important compound foods, notably foods for infants and young children and cereal products.

However, for many compound foods, no maximum level for a relevant contaminant will be laid down, and FBOs and enforcement officers must derive such a level for the purpose of assessing compliance with the requirements of the legislation. Regulation (EC) No 1881/2006 provides a procedure for derivation of a maximum level for a compound food, provided that the composition of compound food is known and a maximum level exists for all the individual ingredients, outlined as follows (Article 2(1)(a), (b), (c) and (d) and Article 2.

#### Article 1.

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.

#### Article 2.

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 FBO, for the purposes of official controls (monitoring by the authorities of Member States), specific processing and/or dilution factors should be provided by the FBO 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 FBO 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 and/or a maximum level does not exist for all the individual ingredients.

As already noted, maximum levels have been established for foods for infants and young children, e.g. Annex of Regulation (EC) No 1881/2006, entry 2.3.4 “Apple juice and solid apple products, including apple compote and apple puree, for infants and young children and labelled and sold as such” and entry 3.4.5 “Canned dietary foods for special medical purposes intended specifically for infants, excluding dried and powdered products”. 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, polycyclic aromatic hydrocarbons, 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 grain, 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 barley. 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 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, nuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs” (Annex of Regulation (EC) No 1881/2006, entry 2.1.3). 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 of Article 4 of Reg. 1881/2006, as outlined below:

#### Specific provisions for groundnuts, nuts, dried fruit and maize (Article 4 of Reg. 1881/2006)

Groundnuts, nuts, dried fruit and maize not complying with the appropriate maximum levels of aflatoxins laid down in points 2.1.3, 2.1.5 and 2.1.6 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, 2.1.4 and 2.1.7 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 2.1.3, 2.1.5 and 2.1.6 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 (EC 2009a) which contains *inter alia* additional information on the circumstances under which these higher maximum levels apply.

### 2.3.5 Monitoring and reporting

FBOs 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 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, DAFF, 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 the case of mycotoxins, dioxins, dioxin-like and non-dioxin-like PCBs and PAHs, the frequency of reporting and the number of samples of foodstuffs to be sampled and analysed are laid down in a series of Commission Decisions and Recommendations, e.g. Commission Recommendation 2005/108/EC on the further investigation into the levels of polycyclic aromatic hydrocarbons in certain foods (EC, 2005a), Commission Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins (EC, 2006b) and Commission Recommendation 2006/794/EC on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs (EC, 2006c)). Recommendations on monitoring are also laid down in a series of so-called "Safeguard Decisions" governing imports of potentially contaminated foodstuffs into the European Union from certain third countries, as covered in more detail in Section 2.4.

The Commission has also issued a number of Recommendations on monitoring of contaminants not yet covered by Regulation (EC) No 1881/2006, e.g. Commission Recommendation on the monitoring of the presence of furan in foodstuffs (EC, 2007c) and Commission Recommendation on the monitoring of acrylamide levels in food (EC, 2007d). All Member States are required under the Regulation (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.

In addition to the requirement laid down in Article 9 of Regulation (EC) No 1881/2006 to report the results of their monitoring programmes on a periodic basis, in the case of foodstuffs found to be non-compliant with the maximum levels for dioxins, furans and dioxin-like PCBs, 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. This requirement is laid down in a Commission Recommendation (2006/88/EC) on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs (EC 2006d), and reflects the fact that, in the majority of cases, higher than background levels of these pollutants can be traced to a specific source of contamination which can be reduced or eliminated. A typical example is provided by the recent (2008) Irish dioxin crisis arising from contamination of pork meat with dioxins and PCBs, which occurred as a result of use of contaminated transformer oil in the drying of food products destined to be used in animal feed. This was identified at an early stage, and immediate steps were taken to remove the contaminated feed and food from the market, in accordance with the approach laid down in Commission Recommendation 2006/88/EC.

### **2.3.6 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 to climatic conditions or particular conditions of environmental pollution. For this reason, derogations have been allowed from the requirements of the Regulation (in Article 7) in two specific areas, nitrate in lettuce and spinach and dioxins and dioxin-like PCBs in certain fish species. Monitoring results over a number of years have shown that nitrate levels in lettuce and spinach in certain northern European countries, notably Ireland, United Kingdom and France (in the case of lettuce) and Ireland, United Kingdom, Belgium and The Netherlands (in the case of spinach) are higher, at least for certain periods of the year, than those laid down in the Regulation, due to lower sunshine levels (which results in a reduction in photosynthesis/growth rates and therefore the rate of nitrate breakdown in the plant). These countries have therefore been allowed a time-limited derogation, allowing the placing on their national market of lettuce and spinach not complying with the maximum levels. Similarly, Finland and Sweden 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 dioxin-like PCBs, provided that consumers are given dietary advice regarding potential risks of over-consumption of these species. The high levels of dioxins and dioxin-like PCBs in fish from this area relates to the pollution of the Baltic sea with these contaminants.

## 2.4 Commission Safeguard Decisions Governing Imports of Potentially Contaminated Foodstuffs into the European Union from Certain Third Countries

### 2.4.1 Foodstuffs potentially contaminated by aflatoxins

A number of the foodstuffs for which maximum levels for aflatoxins 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 aflatoxins have periodically been found in imports of such products from particular third countries during routine monitoring carried by Member States, import controls aimed specifically at reducing the contaminant levels in foodstuffs placed on the EU market have been introduced via Commission Decision 2006/504/EC<sup>7</sup> (EC 2006b) as amended by Decisions 2007/459/EC (EC 2007a), 2007/563/EC (EC 2007b), 2007/759/EC (EC 2007e), and 2008/47/EC (EC 2008c).

These additional controls require that a certain percentage of each controlled product (ranging from 5 to 100%) should be sampled for analysis (by the control authorities) at the point of first import into the European Union before it is released for further distribution into the food chain. It is also a requirement of these Decisions that each consignment should be accompanied by the results of sampling and analysis by a designated laboratory in the country of origin plus a health certificate to show that it is free from aflatoxin contamination.

Table 1 shows the foodstuffs controlled under the Decisions, the countries of origin and the frequency of sampling required to be carried out on each type of foodstuff. It should be noted, however, that consignments of foodstuffs with a gross weight of less than 5kg are considered to be exempt from the requirements of Decision 2006/504/EC and its amendments.

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 point of first importation into the Community. 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 Community and must be re-dispatched to the country of origin or destroyed.

<sup>7</sup> Commission Decision 2006/504/EC has, as of October 2009, been replaced with a new Regulation. This Regulation has not yet been published in the Official Journal and hence the reference to the Commission Decision 2006/504/EC has been retained here for reference.

**Table 1. Foodstuffs controlled under Commission Decision 2006/504/EC (as amended by Decisions 2007/459/EC, 2007/563/EC, 2007/759/EC and 2008/47/EC), together with TARIC (CN) codes enabling more accurate identification of products covered by the Decisions**

| Country   | Foodstuff   | CN code  | % consignments to be controlled <sup>8</sup> |
|---|---|--|--|
| Brazil  | Brazil nuts in shell  | 0801 21 00   | 100  |
| Brazil  | Groundnuts (peanuts)  | 1202 10 90 (in shell) or<br>1202 20 00 (shelled)<br>2008 11 94 or 2008 11 98     | 50   |
|   | Roasted peanuts   | 2008 11 92 or 2008 11 96   | 50   |
| China   | Groundnuts (peanuts)  | 1202 10 90 (in shell) or<br>1202 20 00 (shelled) and<br>2008 11 94 or 2008 11 98 | 10   |
|   | Roasted peanuts   | 2008 11 92 or 2008 11 96   | 10   |
| Egypt   | Peanuts   | 1202 10 90 (in shell) or<br>1202 20 00 (shelled) and<br>2008 11 94 or 2008 11 98 | 20   |
|   | Roasted peanuts   | 2008 11 92 or 2008 11 96   | 20   |
| Iran  | Pistachios  | 0802 50 00   | 100  |
|   | Roasted pistachios  | 2008 19 13 or 2008 19 93   | 100  |
| Turkey  | Dried figs  | 0804 20 90   | 10   |
|   | Hazelnuts in shell or shelled   | 0802 21 00 (in shell) or<br>0802 22 00 (shelled)                                 | 5  |
|   | Pistachios  | 0802 50 00   | 10   |
|   | Mixtures of nuts or dried fruit containing figs, hazelnuts or pistachios  | 0813 50  | 5 for hazelnuts/10 for others                |
|   | Fig paste and hazelnut paste  | 2007 10 and 2007 99  | 5 for hazelnuts/10 for others                |
|   | Hazelnuts, figs and pistachios, prepared or preserved, including mixtures | 2008 19  | 5 for hazelnuts/10 for others                |
|   | Flour, meal and powder of hazelnuts, figs and pistachios                  | 1106 30 90   | 5 for hazelnuts/10 for others                |
|   | Cut, sliced and broken hazelnuts  |  | 5 for hazelnuts/10 for others                |
| USA (unless covered by certification from VASP) | Almonds in shell or shelled   | 0802 11 or 0802 12   | 100  |
|   | Roasted almonds   | 2008 19 13 or 2008 19 93   | 100  |
|   | Mixtures of nuts or dried fruits containing almonds                       | 0813 50  | 100  |

<sup>8</sup> To note: an updated list and amended frequency of controls has been introduced via the new Commission Regulation referred to in the text following Table 2. This guidance document will be updated to reflect the content of the new Regulation, when it has been published in the Official Journal

With the exception of products from Brazil, controls apply to both the foodstuffs themselves and also to products derived from them, along with composite food containing more than 10% of the foodstuff as an ingredient.

The recently adopted Commission Regulation (EC) No 669/2009 of 24 July 2009 (EC, 2009b), implementing Article 15.5 of Regulation 882/2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules, introduces an increased level of official controls on certain imported foodstuffs and also in animal feed, based on evidence of emerging risks. The Regulation introduces controls on aflatoxin levels and some other contaminants in produce from third countries not hitherto covered by Decision 2006/504, as shown in Table 2. This Regulation will apply from 25th January 2010.

**Table 2. Feed and food of non-animal origin subject to an increased level of official controls at the designated point of entry as of 25th January 2010<sup>9</sup>**

| Country    | Foodstuff  | CN code   | Controlled contaminant | % consignments to be controlled <sup>8</sup> |
|------------|--|---|------------------------|--|
| Argentina  | Groundnuts (peanuts) and derived products (feed and food)  | 1202 10 90<br>1202 20 00<br>2008 11   | Aflatoxins             | 10   |
| Brazil     | Groundnuts (peanuts) and derived products (feed and food)  | 1202 10 90<br>1202 20 00<br>2008 11   | Aflatoxins             | 50   |
| China      | Trace elements (feed and food)   | 2817 00 00<br>2820; 2821<br>2825 50 00<br>2833 25 00<br>2833 29 20<br>2833 29 80<br>2836 99 | Cadmium and lead       | 50   |
| Ghana      | Groundnuts (peanuts) and derived products (feed and food), in particular peanut butter (food)  | 1202 10<br>1202 20 00<br>2008 11  | Aflatoxins             | 50   |
| India      | Spices (food)<br>– <i>Capsicum</i> spp (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika)<br>– <i>Myristica fragrans</i> (nutmeg)<br>– <i>Zingiber officinale</i> (ginger)<br>– <i>Curcuma longa</i> (turmeric) | 0904 20<br>0908 10 00<br>0908 20 00<br>0910 10 00<br>0910 30 00                             | Aflatoxins             | 50   |
| India      | Groundnuts (peanuts) and derived products (feed and food)  | 1202 10 90<br>1202 20 00<br>2008 11   | Aflatoxins             | 10   |
| Nigeria    | Melon (egusi) seeds and derived products (food)  | Ex 1207 99  | Aflatoxins             | 50   |
| Uzbekistan | Dried vine fruit (food)  | 0806 20   | Ochratoxin A           | 50   |

<sup>9</sup> To note: this list contains some errors and will be updated changed before the date of application of the Regulation.

|                     |   |   |  |    |
|---------------------|---|---|--|----|
| All third countries | Chilli, chilli products, curcuma and palm oil (food)  | 0904 20 90<br>0910 99 60<br>0910 30 00<br>1511 10 90                          | Sudan dyes   | 20 |
| Vietnam             | Groundnuts (peanuts) and derived products (feed and food), in particular peanut butter (food)   | 1202 10<br>1202 20 00<br>2008 11  | Aflatoxins   | 10 |
| Pakistan            | Basmati rice for direct human consumption (food)  | ex 1006 30  | Aflatoxins   | 50 |
| India               | Basmati rice for direct human consumption (food)  | ex 1006 30  | Aflatoxins   | 10 |
| Dominican Republic  | Mangos, yard long beans ( <i>Vigna sesquipedalis</i> ), melon bitter ( <i>Momordica charantia</i> ), Lauki, ( <i>Lagenaria siceraria</i> ), peppers and aubergines (food) | ex 0804 50 00<br>0708 20 00<br>0807 11 00<br>0707 00<br>0709 60<br>0709 30 00 | Pesticide residues analysed with multiresidue methods based on GC-MS and LC-MS | 50 |
| Dominican Republic  | Bananas   | 0803 00 11  | Pesticide residues analysed with multiresidue methods based on GC-MS and LC-MS | 10 |
| Turkey              | Vegetables, fresh, chilled or frozen (peppers, courgettes or tomatoes)  | 0709 60<br>0709 90 70<br>0702 00 00   | Pesticides: methomyl and oxamyl  | 10 |
| Turkey              | Pears   | 0808 20 10  | Pesticide: amitraz   | 10 |
| Thailand            | Vegetables, fresh, chilled or frozen<br>– yard long beans ( <i>Vignas sesquipedalis</i><br>– aubergines<br>– Brassica vegetables  | 0708 20 10<br>0709 30 00<br>0704  | Organo-phosphorous pesticide residues  | 50 |

A new Commission Regulation<sup>10</sup> amending and repealing Decision 2006/504 on controls of imports from certain third countries due to contamination with aflatoxins, bringing the existing measures into line with Regulation (EC) No 669/2009, will come into force on 1 January 2010. In terms of the specific provisions, the threshold for control of a designated commodity in a composite product will be increased to 20%, and the minimum commodity size subject to the controls will be 20kg.

The new Regulation will also change the frequency of controls laid down in Decision 2006/504 based on consideration of risk, as shown in Table 3. The new Regulation also requires a Common Entry Document (in accordance with Commission Regulation (EC) No 669/2009) to be completed.

<sup>10</sup> To note: this list contains some errors and will be updated changed before the date of application of the Regulation

**Table 3. Changes in the frequency of controls on certain foodstuffs compared with Decision 2006/504 (as shown in Table 1)**

| Country | Commodity  | Change of control frequency          |
|---------|------------|--------------------------------------|
| China   | Groundnuts | Increased from 10% to 20%            |
| Egypt   | Groundnuts | Kept at 20%                          |
| Iran    | Pistachios | Reduced from 100% to 50%             |
| Turkey  | Dried figs | Increased from 10% to 50%            |
| Turkey  | Hazelnuts  | Increased from 5% to 10%             |
| Turkey  | Pistachios | Increased from 10% to 50%            |
| USA     | Almonds    | Decreased from 5% to random controls |

As stressed already in this guidance document, any monitoring carried out for official control purposes in compliance with these Decisions or 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 (EC 2009a) contains additional information on monitoring procedures under the Commission Decisions.

#### 2.4.2 Foodstuffs potentially contaminated by other contaminants

While aflatoxins are the most important contaminants regulated by Commission Safeguard Decisions governing imports of potentially contaminated foodstuffs into the European Union from certain third countries, certain other contaminants are controlled via specific Decisions. These include Sudan dyes<sup>11</sup>, pentachlorophenol/dioxin, non-food grade mineral oil and melamine. 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. Table 3 provides an overview of the currently applicable Decisions, the contaminants controlled and applicable maximum levels and the foodstuffs in which they are controlled.

<sup>11</sup> Sudan dyes fall within the scope of Commission Regulation (EC) No 669/2009 as of 25th January, 2010, and will no longer be covered by a Commission Decision.

**Table 3. Foodstuffs controlled under Commission Safeguard Decisions (other than those listed in Tables 1 and 2), their TARIC (CN) codes, the country of origin, the contaminant(s) regulated and the levels applicable (if any)**

| Commission Decision (reference)            | Country             | Foodstuff  | CN code  | Controlled contaminant                       | Maximum level of contaminant permitted   |
|--|---------------------|--|--|--|--|
| 2005/402/EC (EC 2005b) <sup>12</sup>       | All third countries | chilli, chilli products, curcuma and palm oil  | 0904 20 90<br>0910 50<br>0910 30<br>1511 10 90 | Sudan I<br>Sudan II<br>Sudan III<br>Sudan IV | Zero*  |
| 2008/352 (EC 2008d)                        | India               | guar gum and compound feedingstuffs and foodstuffs containing at least 10 % guar gum (feed and food) | 1302 32 90                                     | Pentachloro-phenol                           | 0.1%   |
| 2008/433 (EC 2008e)                        | Ukraine             | Sunflower oil  | 1512 11<br>91 1512<br>19 90 10                 | Mineral oil                                  | “unacceptable levels”  |
| 2008/798 (EC 2008f)<br>2008/921 (EC 2008g) | China               | milk, milk products, soya or soya products, ammonium bicarbonate                                     | –  | Melamine                                     | The import and sale of all infant formula and follow on formula and products containing milk, milk products, soya or soya products intended for the particular nutritional use of infants and young children from China is prohibited<br><br>Limit of 2.5 mg/kg melamine in all other foodstuffs and feed from China |

\*An “action limit” of 500ug/kg for illegal dyes in food ingredients was agreed by Member States and the Commission in 2006, being the Limit of Detection for the conventional HPLC method used to detect these dyes in food at that time. Member States and the Commission have agreed however that the presence of such contaminants in food is illegal, and that every effort should be made to attain zero levels or at least lower than the 500ug/kg “action limit”.

As is the case for the Decisions related to foodstuffs contaminated by aflatoxins, each consignment of the controlled foodstuffs should be accompanied by the results of sampling and analysis by a designated laboratory (and approved examiner) in the country of origin plus a health certificate to show that it is free from contamination, and Member States are required to undertake documentary checks of each consignment of the controlled products at the point of first importation into the Community.

<sup>12</sup> These products fall within the scope of Commission Regulation (EC) No 669/2009 as of 25th January, 2010, and Commission Decision 2005/402/EC will be repealed

Other foodstuffs controlled under Commission Safeguard Decisions (Commission Decision 2002/247/EEC and 2004/374/EC, together with Directive 2003/52) (EC, 2002; EC 2004a; EC 2003c) include jelly confectionery, including jelly mini-cups containing the food additive E 425 konjac, which have been shown to present a choking hazard to small children. Use of E 425 konjac in the manufacture of jelly confectionery is also prohibited. However, strictly speaking, this is not due to the presence of a chemical contaminant, but to a physical hazard, and further information is not provided here. See the FSAI website for further details: [http://www.fsai.ie/legislation/food\\_legislation/foodstuffs\\_with\\_specific\\_conditions\\_emergency\\_decisions/special\\_conditions.html](http://www.fsai.ie/legislation/food_legislation/foodstuffs_with_specific_conditions_emergency_decisions/special_conditions.html)

## 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 the presence of contaminants in food, and the particular requirement laid down in the Commission Recommendations and Decisions described in Sections 2.3.5 and 2.4 to monitor food placed on the European market or imported from outside the Community 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. 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 Decisions outlined in Section 2.4. The European Commission guidance for national authorities for the control of compliance with the EU legislation on aflatoxins (EC 2009a) 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 Decisions that provide an effective barrier to the import of high-risk foods from third countries outside the Community.

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 Community, Codex Alimentarius and national level, on contaminants such as acrylamide and mycotoxins. A non-exhaustive list of such guidance is provided in Table 5.

**Table 5. Guidance/Codes of practice on the reduction or prevention of contaminants in foodstuffs**

| Contaminant                  | Title of guidance   | Reference number/reference                    |
|------------------------------|---|---|
| Acrylamide                   | Information on Ways to Lower the Levels of Acrylamide Formed in Food  | EC (2003a)                                    |
|                              | The CIAA Acrylamide “Toolbox”   | CIAA (2007)                                   |
|                              | Draft Codex Alimentarius Code of practice for the reduction of acrylamide in food   | Under discussion in Codex Alimentarius (2009) |
| Aflatoxin                    | Codex Alimentarius Code of practice for the prevention and reduction of Aflatoxin Contamination in Peanuts                        | CAC/RCP 55<br>Codex Alimentarius (2004a).     |
|                              | Codex Alimentarius Code of practice for the prevention and reduction of Aflatoxin Contamination in Tree nuts                      | CAC/RCP 59.<br>Codex Alimentarius (2005a)     |
|                              | Codex Alimentarius Code of practice for the prevention and reduction of Aflatoxin Contamination in Dried Figs                     | CAC/RCP 65.<br>Codex Alimentarius (2008b)     |
| Chemicals (in general)       | Codex Alimentarius Code of practice for source directed measures to reduce contamination of food with chemicals                   | CAC/RCP 49-2001<br>Codex Alimentarius (2001)  |
| Dioxin and dioxin- like PCBs | Codex Alimentarius Code of practice for the prevention and reduction of dioxin and dioxin like PCB contamination in food and feed | CAC/RCP 62<br>Codex Alimentarius (2006)       |

|   |  |   |
|---|--|---|
| Fusarium Toxins                         | Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products)<br><br>Code of Practice on the prevention and reduction of Fusarium Mycotoxins in cereals (drawn up by the Department of Agriculture, Fisheries and Food in conjunction with Teagasc, Food Safety Authority of Ireland, Irish Farmers Association, Irish Grain and Feed Association, Irish Grain Assurance Scheme | EC (2006e)<br><br><a href="http://www.agriculture.gov.ie/media/migration/agri-foodindustry/feedingstuffs/whatsnew/Code_Practice_FusariumMycotoxinsincereals.doc">http://www.agriculture.gov.ie/media/migration/agri-foodindustry/feedingstuffs/whatsnew/Code_Practice_FusariumMycotoxinsincereals.doc</a> |
| Lead                                    | Codex Alimentarius Code of practice for the prevention and reduction of lead contamination in foods  | CAC/RCP 56<br>Codex Alimentarius (2004b).   |
| 3-Monochloropropane-1,2-diol (3-MCPD)   | Codex Alimentarius 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.<br>Codex Alimentarius (2008a).  |
| Mycotoxins                              | Codex Alimentarius 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<br>Codex Alimentarius (2003a)   |
| Ochratoxin A                            | Codex Alimentarius Code of practice for the prevention and reduction of ochratoxin A contamination in wine<br><br>Draft Codex Alimentarius Code of practice for the prevention and reduction of ochratoxin A contamination in coffee   | CAC/RCP 63<br>Codex Alimentarius (2007)<br><br>Under discussion in Codex Alimentarius (2009)  |
| Patulin                                 | 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<br><br>Codex Alimentarius Code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages  | EC (2003b)<br><br>CAC/RCP 50<br>Codex Alimentarius (2003b)  |
| Polycyclic aromatic hydrocarbons (PAHs) | Draft Codex Alimentarius Code of practice for the reduction of contamination of food with Polycyclic aromatic hydrocarbons (PAHs) from smoking and direct drying processes   | Under discussion in Codex Alimentarius (2009)   |
| Tin                                     | Codex Alimentarius Code of practice for the prevention and reduction of tin contamination in canned foods  | CAC/RCP 60<br>Codex Alimentarius (2005b)  |

A series of fact sheets 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](http://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 Community, 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 Community 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 (EC 2009a).

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 dioxin-like 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)
- for levels of heavy metals, 3-MCPD, inorganic tin and benzo(a)pyrene levels: Commission Regulation (EC) No 333/2007 (EC, 2007f)
- for levels of dioxins and PCBs: Commission Regulation (EC) No 1883/2006 (EC, 2006c)
- 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 FBOs 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 Directives 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 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 and Commission Decision 2006/504/EC<sup>13</sup>). The provisions of Regulation (EC) No 401/2006 are implemented in Ireland via S.I. No. of 412 of 2006. 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 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 almost every case, 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 Community 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 aflatoxin 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.

<sup>13</sup> Commission Decision 2006/504/EC has, as of October 2009, been replaced with a new Regulation. This Regulation has not yet been published in the Official Journal and hence the reference to the Commission Decision 2006/504/EC has been retained here for reference.

### 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 2006/504/EC<sup>14</sup> (EC, 2006b) (particularly those requiring 100% control) 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.
2. Consignments of commodities controlled by Regulation (EC) No 1881/2006 (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 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.
4. Consignments that have already been cleared for free circulation by another EC Member State, and for which the Irish FBO 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 FBO 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, and normal sampling procedures, e.g. collection of three sub-samples etc, should be followed.

<sup>14</sup> Commission Decision 2006/504/EC has, as of October 2009, been replaced with a new Regulation. This Regulation has not yet been published in the Official Journal and hence the reference to the Commission Decision 2006/504/EC has been retained here for reference.

### 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 the requirements of Commission Decision 2006/504/EC<sup>15</sup> (EC, 2006b), as amended, different frequencies of controls have been established at the first point of import into the Community. Details 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 an FBO.

### 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 FBO 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 FBO 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 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.

<sup>15</sup> Commission Decision 2006/504/EC has, as of October 2009, been replaced with a new Regulation. This Regulation has not yet been published in the Official Journal and hence the reference to the Commission Decision 2006/504/EC has been retained here for reference.

**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 sublots of 44 tonnes (two containers). Representative sampling must be performed on the sublots 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 is not detrimental to 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 aflatoxins). This can be done by performing a representative sampling of all containers, in accordance with Regulation (EC) 401/2006 (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 even if the product is identical (in this particular case from the 8 tonnes, 80 incremental samples of 300g resulting in a sample of 24kg and, from the batch of 15 tonnes, 100 incremental samples of 300g resulting in a sample of 30kg). 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, 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, 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 groundnuts, nuts, dried figs (lots  $\geq$  15 tonnes)**

Provided that a subplot can be separated physically, each lot must be subdivided into the number of sublots described in Annex 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may vary from the mentioned weight by a maximum of 20%. If, after the division of a lot into sublots, the weight of the subplot exceeds the weight of the subplot as indicated in Annex 2 by more than 20%, the number of sublots has to be increased, even if by so doing, the weight of the subplot is lower than the weight indicated. Each subplot must be sampled separately.

**Method of sampling groundnuts, nuts, dried figs (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

**Sampling of groundnuts, nuts, dried figs and derived products in vacuum packs**

Groundnuts, the edible nuts pistachios and Brazil nuts, and 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.

Edible nuts other than pistachios and Brazil nuts

For lots equal to or more than 15 tonnes, at least 25 incremental samples resulting in a 30kg aggregate sample shall be taken and 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.

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 subplot can be separated physically, each lot shall be subdivided into sublots 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 sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20%. Each subplot 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  $\geq$ 15 tonnes), with the exception of figs**

Provided that the subplot can be separated physically, each lot shall be subdivided into sublots 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 sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20%. Each subplot 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 100grams.

**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 subplot and interpretation of results**

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

For groundnuts, nuts and dried fruit subjected to a sorting or other physical treatment 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<sup>7</sup>,
- 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<sup>16</sup>.

For groundnuts, nuts and dried figs intended for direct human consumption:

- acceptance if none of the laboratory samples exceeds the maximum level, taking into account the expanded measurement uncertainty and the correction for recovery<sup>7</sup>.
- rejection if one or more of the laboratory samples exceeds the maximum level beyond reasonable doubt taking into account the expanded measurement uncertainty and correction for recovery<sup>7</sup>.

Where the aggregate sample is equal to or below 10kg:

- acceptance if the aggregate sample conforms to the maximum level, taking into account the expanded measurement uncertainty and the correction for recovery<sup>7</sup>.
- rejection if the aggregate sample exceeds the maximum level beyond reasonable doubt taking into account the expanded measurement uncertainty and correction for recovery<sup>7</sup>.

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

Dr Rhodri Evans, Food Science and Standards Division, Food Safety Authority of Ireland  
Tel: (01) 8171303 Fax: (01) 8171203 E-mail: revans@fsai.ie

<sup>16</sup> 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.

### 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 direct 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

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 (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) of 28 March 2007 for lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene 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 1883/2006 (EC 2006i) of 19 December 2006 for dioxins and dioxin-like 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 benzo(a)pyrene) and Annex 5 (for dioxins and dioxin-like 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 and Regulation 1883/2007, 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 this 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 FBOs 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 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:

Dr Rhodri Evans

Food Science and Standards Division, Food Safety Authority of Ireland

Tel: (01) 8171303 Fax: (01) 8171203 E-mail: revans@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 and Children. 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, 2001, S.I. No.400 of 2001, is the Statutory Instrument giving effect to Council Regulation (EEC) No 315/93, the framework Regulation on contaminants in food (see Section 2.2). S.I. No. 400 of 2001 signposts the EU legislation and provides for enforcement, offences and penalties. The essential provisions of Regulation (EC) No 315/93 and the Articles of Regulation (EC) No 466/2001 are restated in S.I. No. 400 of 2001, which provides the legal framework for enforcement of the Community legislation on contaminants in Ireland, including provision of enforcement powers to authorised officers and approved examiners. However, since the applicable Community legislation on maximum levels (Regulation (EC) No 1881/2006 and the earlier Regulation (EC) No 466/2001) takes the form of Regulations rather than Directives, which are directly binding on and applicable in Member States, these maximum levels are not re-stated in S.I. No.400 of 2001. Therefore, Annex I of Regulation (EC) No. 1881/2006 as amended (see Section 2.3 of this guidance document) provides the legally-binding standard in relation to maximum levels for contaminants in food.

The Department of Health and Children is currently finalising a new Statutory Instrument to give effect to the current European Union legislation on contaminants, including Regulation (EC) No 1881/2006. It is anticipated that the updated European Communities (Certain Contaminants in Foodstuffs) Regulations will be signed into force by the Minister for Health and Children by the end of 2009, at which stage, this guidance document will be updated to reflect the new legislation.

As already indicated, in order to ensure a consistent application of the rules on contaminants in food across the Community, legislation has also been introduced on sampling and analysis procedures for contaminants in food. The European Communities (Sampling methods and the methods of analysis for the official control of the levels of certain contaminants in foodstuffs)(No2) Regulations, 2006 (S.I. No. 412 of 2006) give effect to Commission Regulation (EC) No 401/2006 (EC, 2006g) on sampling and analysis for the official control of the levels of mycotoxins in foodstuffs as well as to earlier Commission Directives on sampling and analysis for contaminants. Since 2006, the Community law on sampling and analysis for contaminants in food has been enacted as Commission Regulations which, like the legislation on maximum levels are directly binding on and applicable in Member States. Therefore, these Regulations await transposition into national legislation (see above) to provide for enforcement, offences and penalties. They have not been transposed into national law, but are listed for the convenience of the reader as follows:

- Commission Regulation (EC) No. 1882/2006 (EC 2006h) on sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.
- Commission Regulation (EC) No1883/2006 (EC 2006i) of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs.
- Commission Regulation (EC) No 333/2007 (EC, 2007f) of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

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.

## 5. Contaminants in Food Not Yet Regulated via Regulation (EC) No 1881/2006

The European Community 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 or for a new contaminant, or 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. A recent example of such activities include the controls that have been put in place following the detection of melamine in certain products, notably dairy-based products, originating in China, and the reports of the deaths of infants in that country as a result of consuming such products.

Each working group has an ongoing 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 ongoing 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. Limits for Ochratoxin A in spices are also under discussion at European level, as is the approach to be adopted to control nitrates in leafy vegetables in the light of the derogations for certain Member States being at an end.

### 5.2 Industrial Contaminants

This working group is considering measures on acrylamide, organotins, furan, arsenic and ethyl carbamate, plus further measures on cadmium.

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. In Germany, a minimisation concept was introduced in 2002, based on a classification of foodstuffs into defined commodity groups. The German initiative has not been followed elsewhere in Europe, rather, the onus has been placed on manufacturers to observe the ALARA principle (As Low As Reasonably Achievable), by developing measures to reduce the levels of acrylamide in their products. As already mentioned in Section 2.3.5, the European Commission has made a Recommendation to Member States (EC 2007d) in 2007 on the monitoring of acrylamide levels in food. The CIAA (European Food and Drink Confederation) have published a "Toolbox" (CIAA, 2007), which provides a strategy for minimising the acrylamide content of manufactured food products, addressing measures under 4 main areas: (1) Agronomical, (2) Recipes, (3) Processing, (4) Final Preparation. The manufacturing industry is advised to follow the Toolbox closely in order to ensure the safety of the products they place on the market.

**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 (EC 2007c) in 2007 on the monitoring of furan levels in food. 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 by ethanol and certain precursors in the fruit mash under the influence of light during the distillation process. EFSA is currently collecting data on the presence of ethyl carbamate in foodstuffs and when more occurrence data are available, will carry out a detailed risk assessment. The setting of maximum levels will be considered at that stage.

EFSA is also carrying out a risk assessment on **arsenic**, after which the setting of maximum levels will be considered.

**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 Acceptable Daily Intake (ADI). Thus, the need for maximum levels in fish and fish products has been queried and is still under review.

On **cadmium**, the working group has discussed the lowering of some current maximum levels and the setting of new ones for commodities currently not regulated, in the light of a new risk assessment from EFSA. Some commodities are being looked at in more detail, e.g. cereals and cereal products, e.g. pasta, bread, etc., horse meat, kidney of bovine animals, certain fish species, etc. Oilseeds (important foods for vegetarians) and chocolate/cocoa products (important foods for children) have been proposed by the Commission to be looked at in more detail.

### 5.3 Persistent Organic Pollutants (POPs)

Maximum limits for non-dioxin-like PCBs in food have been under discussion for several years, and an EFSA risk assessment is available for these compounds. A further group of POPs that are under discussion are the brominated flame retardants and Member States have been asked to carry out monitoring of these contaminants in feed and food, after which, EFSA will be asked for advice on potential risks to health. Ireland has an active, ongoing surveillance programme monitoring levels of a range of emerging and currently regulated POPs in food and this information is used in discussions with the European Commission and other Member States when possible new control measures are being considered or existing ones reviewed.

## 6. References

**CIAA** (2007) The CIAA Acrylamide “Toolbox”

<http://www.ciaa.be/documents/brochures/toolbox%20rev11%20nov%202007final.pdf>

Code of Practice on the prevention and reduction of Fusarium Mycotoxins in cereals (drawn up by the Department of Agriculture and Food 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](http://www.agriculture.gov.ie/media/migration/agri-foodindustry/feedingstuffs/whatsnew/Code_Practice_FusariumMycotoxinsincereals.doc)

**Codex Alimentarius** (2001) Code of practice for source directed measures to reduce contamination of food with chemicals. CAC/RCP 49-2001

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=373](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=373)

**Codex Alimentarius** (2003a) 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

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=406](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=406)

**Codex Alimentarius** (2003b) Code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages. CAC/RCP 50

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=405](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=405)

**Codex Alimentarius** (2004a) Code of practice for the prevention and reduction of Aflatoxin Contamination in Peanuts. CAC/RCP 55

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10084](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10084)

**Codex Alimentarius** (2004b) Codex Alimentarius Code of practice for the prevention and reduction of lead contamination in foods. CAC/RCP 56

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10099](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10099)

**Codex Alimentarius** (2005a) Code of practice for the prevention and reduction of Aflatoxin Contamination in Tree nuts. CAC/RCP 59

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10221](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10221)

**Codex Alimentarius** (2005b) Codex Alimentarius Code of practice for the prevention and reduction of tin contamination in foods. CAC/RCP 60

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10217](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10217)

**Codex Alimentarius** (2006) Codex Alimentarius Code of practice for the prevention and reduction of dioxin and dioxin like PCB contamination in food and feed. CAC/RCP 62

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10693](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10693)

**Codex Alimentarius** (2007) Codex Alimentarius Code of practice for the prevention and reduction of ochratoxin A contamination in wine. CAC/RCP 63

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=10750](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10750)

**Codex Alimentarius** (2008a) 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

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=11024](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11024)

**Codex Alimentarius** (2008b) Codex Alimentarius Code of practice for the prevention and reduction of Aflatoxin Contamination in Dried Figs. CAC/RCP 65.

[http://www.codexalimentarius.net/web/more\\_info.jsp?id\\_sta=11025](http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11025)

- EC** (1993) Council Regulation (EC) No. 315/93/EEC of 8 February 1993 laying down Community procedures for contaminants in food. *Official Journal L 37, 13/02/1993 p. 1 – 3*
- EC** (2001) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs. *Official Journal L 77, 16/03/2001 p. 1 – 13*  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001R0466:EN:HTML>
- EC** (2002) Commission Decision 2002/247/EC of 27 March 2002 suspending the placing on the market and import of jelly confectionery containing the food additive E 425 konjac (2002/247/EC)
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[http://ec.europa.eu/food/food/chemicalsafety/contaminants/acryl\\_guidance.pdf](http://ec.europa.eu/food/food/chemicalsafety/contaminants/acryl_guidance.pdf)
- EC** (2003b) 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 (2003/598/EC)
- EC** (2003c) Directive of the European Parliament and of the Council of 18 June 2003 (OJ L178, p23, 17.7.2003) amending Directive 95/2/EC as regards the conditions of use for a food additive E 425 konjac (Directive 2003/52/EC)
- EC** (2004a) Commission Decision 2004/374/EC of 13 April 2004 suspending the placing on the market and import of jelly mini-cups containing the food additives E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417 and/or E 418. (2004/374/EC)
- EC** (2004b) Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU Food and Feed legislation.  
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- EC** (2005a) Commission Recommendation of 4 February 2005 on the further investigation into the levels of polycyclic aromatic hydrocarbons in certain foods (*number C(2005) 256*) (2005/108/EC)
- EC** (2005b) Commission Decision 2005/402/EC of 23 May 2005 (EC 2005) on emergency measures regarding chilli, chilli products, curcuma and palm oil (2005/402/EC)
- EC** (2006a) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs *Official Journal L 364, 20.12.2006, p. 5–24*
- EC** (2006b) Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins (2006/504/EC)
- EC** (2006c) Commission Recommendation of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs (2006/794/EC)
- EC** (2006d) Commission Recommendation of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs (2006/88/EC)
- EC** (2006e) Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products (2006/583/EC)
- EC** (2006f) 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
- EC** (2006g) Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

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**EC (2007b)** Commission Decision 2007/563/EC of 1 August 2007 amending Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins as regards almonds and derived products originating in or consigned from the United States of America (2007/563/EC)

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**EC (2007d)** Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food (2007/331/EC)

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**EC (2008b)** Commission Regulation (EC) No 565/2008 of 18 June 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver  
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**EC (2008d)** Commission Decision 2008/352 of 29 April 2008 imposing special conditions governing guar gum originating in or consigned from India due to contamination risks of those products by pentachlorophenol and dioxins (2008/352)

**EC (2008e)** Commission Decision 2008/433/EC of 10 June 2008 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil (2008/433/EC)

**EC (2008f)** Commission Decision 2008/798/EC of 14 October 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China and repealing Commission decision 2008/757/EC

**EC** (2008g) Commission Decision 2008/912/EC amending Commission Decision 2008/798/EC

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Health (Arsenic and Lead in Food) Regulations, 1972 (S.I. No. 44/1972) as amended by S.I. No. 72/1992

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

(NB: specific footnotes (x) attached to entries in the Commission Regulation have been included but not explained in this Table, and should be checked in the Regulation)

## Section 1: Nitrate

| Entry No (in Reg 1881/2006) | Foodstuffs (1)   | Maximum levels (mg NO <sub>3</sub> /kg)                         |      |
|-----------------------------|--|---|------|
| 1.1                         | Fresh spinach ( <i>Spinacia oleracea</i> ) (2)   | Harvested 1 October to 31 March                                 | 3000 |
|                             |  | Harvested 1 April to 30 September                               | 2500 |
| 1.2                         | Preserved, deep-frozen or frozen spinach   |   |      |
| 1.3                         | Fresh Lettuce ( <i>Lactuca sativa</i> L.) (protected and open-grown lettuce) excluding lettuce listed in point 1.4 | Harvested 1 October to 31 March:<br>lettuce grown under cover   | 4500 |
|                             |  | lettuce grown in the open air                                   | 4000 |
|                             |  | Harvested 1 April to 30 September:<br>lettuce grown under cover | 3500 |
|                             |  | lettuce grown in the open air                                   | 2500 |
| 1.4                         | Iceberg-type lettuce   | Lettuce grown under cover                                       | 2500 |
|                             |  | Lettuce grown in the open air                                   | 2000 |
| 1.5                         | Processed cereal-based foods and baby foods for infants and young children (3) (4)                                 |   |      |

## Section 2: Mycotoxins

Note: all levels given in Section 2 are from Regulation (EC) No 1881/2006, other than those for Entry Nos. 2.4.8, 2.4.9, 2.5.9 and 2.5.10.; 2.65.5 and 2.6.6, which are introduced via the amending Commission Regulation (EC) No 1126/2007 of 28 September 2007 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards Fusarium toxins in maize and maize products

| Entry No (in Reg 1881/2006) | Foodstuffs (1)  | Mycotoxin  | Max. level (µg/kg) |
|-----------------------------|---|--|--------------------|
| <b>2.1</b>                  | <b>Aflatoxins</b>   |  |                    |
| 2.1.1                       | Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs  | Aflatoxin B <sub>1</sub>   | 8.0 (5)            |
|                             |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 15.0 (5)           |
| 2.1.2                       | Nuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs        | Aflatoxin B <sub>1</sub>   | 5.0 (5)            |
|                             |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 10.0 (5)           |
| 2.1.3                       | Groundnuts, nuts and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs        | Aflatoxin B <sub>1</sub>   | 2.0 (5)            |
|                             |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 4.0 (5)            |
| 2.1.4                       | Dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs | Aflatoxin B <sub>1</sub>   | 5.0                |
|                             |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 10.0               |
| 2.1.5                       | Dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs             | Aflatoxin B <sub>1</sub>   | 2.0                |
|                             |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 4.0                |

|            |   |  |          |
|------------|---|--|----------|
| 2.1.6      | All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs listed in 2.1.7, 2.1.10 and 2.1.12   | Aflatoxin B <sub>1</sub>   | 2.0      |
|            |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 4.0      |
| 2.1.7      | Maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs   | Aflatoxin B <sub>1</sub>   | 5.0      |
|            |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 10.0     |
| 2.1.8      | Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products and as defined by Council Directive 92/46/EEC)  | Aflatoxin M <sub>1</sub>   | 0.05     |
| 2.1.9      | Following species of spices:<br><i>Capsicum spp.</i> (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne, and paprika), <i>Piper spp.</i> (fruits thereof, including white and black pepper), <i>Myristica fragrans</i> (nutmeg), <i>Zingiber officinale</i> (ginger), <i>Curcuma longa</i> (turmeric) | Aflatoxin B <sub>1</sub>   | 5.0      |
|            |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | 10.0     |
| 2.1.10     | Processed cereal-based foods and baby foods for infants and young children (3) (7)  | Aflatoxin B <sub>1</sub>   | 0.1      |
|            |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | -        |
| 2.1.11     | Infant formulae and follow-on formulae, including infant milk and follow-on milk (4) (8)  | Aflatoxin M <sub>1</sub>   | 0.025    |
| 2.1.12     | Dietary foods for special medical purposes intended specifically for infants (9) (10)   | Aflatoxin B <sub>1</sub>   | 0.1      |
|            |   | Total B <sub>1</sub> +B <sub>2</sub> +G <sub>1</sub> +G <sub>2</sub> | -        |
|            |   | Aflatoxin M <sub>1</sub>   | 0.025    |
| <b>2.2</b> | <b>Ochratoxins</b>  |  |          |
| 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 and 2.2.10  | 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      |
| 2.2.5      | Soluble coffee (instant coffee)   | Ochratoxin A   | 10.0     |
| 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        | 0.5        |
| 2.2.10     | Dietary foods for special medical purposes intended specifically for infants (9) (10)  | Ochratoxin A        | 0.5        |
| 2.2.11     | Green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat products, spices and liquorice  | Ochratoxin A        | -          |
| <b>2.3</b> | <b>Patulin</b>   |                     |            |
| 2.3.1      | Fruit juices, concentrated fruit juice as reconstituted and fruit nectars (14)   | Patulin             | 50.0       |
| 2.3.2      | Spirit drinks (15), cider and other fermented drinks derived from apples or containing apple juice   | Patulin             | 50.0       |
| 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             | 25.0       |
| 2.3.4      | Apple juice and solid apple products, including apple compote and apple puree, for infants (16) and young children 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       |
| <b>2.4</b> | <b>Fumonisin: deoxynivalenol</b>   |                     |            |
| 2.4.1      | Unprocessed cereals (18) (19) other than durum wheat, oats and maize   | Deoxynivalenol (17) | 1250.0     |
| 2.4.2      | Unprocessed durum wheat and oats (18) (19)   | Deoxynivalenol (17) | 1750.0     |
| 2.4.3      | Unprocessed maize (18), with the exception of unprocessed maize intended to be processed by wet milling  | Deoxynivalenol (17) | 1750.0 (2) |
| 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) | 750.0      |
| 2.4.5      | Pasta (dry) (22)   | Deoxynivalenol (17) | 750.0      |
| 2.4.6      | Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals  | Deoxynivalenol (17) | 500.0      |
| 2.4.7      | Processed cereal-based foods and baby foods for infants and young children (3) (7)   | Deoxynivalenol (17) | 200.0      |
| 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) | 750.0 (20) |

|            |  |                     |             |
|------------|--|---------------------|-------------|
| 2.4.9      | Milling fractions of maize with particle size $\leq$ 500 micron falling within CN code 1102 20 and other maize milling products with particle size $\leq$ 500 micron not used for direct human consumption falling within CN code 1904 10 10         | Deoxynivalenol (17) | 1250.0 (20) |
| <b>2.5</b> | <b>Fumonisin: zearalenone</b>  |                     |             |
| 2.5.1      | Unprocessed cereals (18) (19) other than maize   | Zearalenone (17)    | 100.0       |
| 2.5.2      | Unprocessed maize (18) with the exception of unprocessed maize intended to be processed by wet milling (*)   | Zearalenone (17)    | 350.0 (20)  |
| 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)    | 75.0        |
| 2.5.4      | Refined maize oil  | Zearalenone (17)    | 400.0 (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)    | 50.0        |
| 2.5.6      | Maize intended for direct human consumption, maize-based snacks and maize-based breakfast cereals  | Zearalenone (17)    | 100.0 (20)  |
| 2.5.7      | Processed cereal-based foods (excluding maize-based foods) and baby foods for infants and young children (3) (7)   | Zearalenone (17)    | 20.0        |
| 2.5.8      | Processed maize-based foods for infants and young children (3) (7)   | Zearalenone (17)    | 20.0 (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)    | 200.0 (20)  |
| 2.5.10     | Milling fractions of maize with particle size $\leq$ 500 micron falling within CN code 1102 20 and other maize milling products with particle size $\leq$ 500 micron not used for direct human consumption falling within CN code 1904 10 10         | Zearalenone (17)    | 300.0 (20)  |

| <b>2.6 Fumonisin: sum of fumonisin B1 and B2</b> |  |                              |           |
|--|--|------------------------------|-----------|
| 2.6.1  | Unprocessed maize (18) with the exception of unprocessed maize intended to be processed by wet milling (*)   | Fumonisin (sum of B1 and B2) | 4000 (23) |
| 2.6.2  | Maize intended for direct human consumption, maize-based snacks and maize-based breakfast cereals with the exception of foodstuffs listed in 2.6.3 and 2.6.4.  | Fumonisin (sum of B1 and B2) | 1000 (23) |
| 2.6.3  | Maize-based breakfast cereals and maize-based snacks   | Fumonisin (sum of B1 and B2) | 800 (23)  |
| 2.6.4  | Processed maize-based foods and baby foods for infants and young children (3) (7)  | Fumonisin (sum of B1 and B2) | 200 (23)  |
| 2.6.5  | 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 | Fumonisin (sum of B1 and B2) | 1400 (23) |
| 2.6.6  | 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               | Fumonisin (sum of B1 and B2) | 2000 (23) |
| <b>2.7 Fumonisin:T2 and HT-2 toxin</b>           |  |                              |           |
| 2.7.1  | Unprocessed cereals (18) and cereal products   | T-2 and HT-2 toxin (17)      |           |

## Section 3: Metals

Note: Note: all levels given in Section 3 are from Regulation (EC) No 1881/2006, other than those for Entry Nos. 3.1.11, 3.1.18, all entries for cadmium (3.2) and Entry 3.3.2 which are introduced via the amending Commission Regulation (EC) No 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs. In the following Table, for food supplements (\*) the maximum level applies to the food supplements as sold.

| Entry No<br>(in Reg 1881/2006) | Foodstuffs (1)   | Maximum levels<br>(mg/kg wet weight) |
|--------------------------------|--|--------------------------------------|
| <b>3.1</b>                     | <b>Lead</b>  |                                      |
| 3.1.1                          | Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products  | 0.02                                 |
| 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                          | Edible 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, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) (26)                                 | 0.5                                  |
| 3.1.7                          | Bivalve molluscs (26)  | 1.5                                  |
| 3.1.8                          | Cephalopods (without viscera) (26)   | 1.0                                  |
| 3.1.9                          | Cereals, legumes and pulses  | 0.2                                  |
| 3.1.10                         | Vegetables, excluding brassica vegetables, leaf vegetables, fresh herbs and fungi (27). For potatoes the maximum level applies to peeled potatoes  | 0.1                                  |
| 3.1.11                         | Brassica vegetables, leaf vegetables and the following fungi (27): <i>Agaricus bisporus</i> (common mushroom), <i>Pleurotus ostreatus</i> (Oyster mushroom), <i>Lentinula edodes</i> (Shiitake mushroom) | 0.3                                  |
| 3.1.12                         | Fruit, excluding berries and small fruit (27)  | 0.1                                  |
| 3.1.13                         | Berries and small fruit (27)   | 0.2                                  |
| 3.1.14                         | Fats and oils, including milk fat  | 0.1                                  |
| 3.1.15                         | Fruit juices, concentrated fruit juices as reconstituted and fruit nectars (14)  | 0.05                                 |
| 3.1.16                         | Wine (including sparkling wine, excluding liqueur wine), cider, perry and fruit wine (11)  | 0.2 (28)                             |
| 3.1.17                         | Aromatized wine, aromatized wine-based drinks and aromatized wine-product cocktails (13)   | 0.2 (28)                             |
| 3.1.18                         | Food supplements (*)   | 3.0                                  |
| <b>3.2</b>                     | <b>Cadmium</b>   |                                      |
| 3.2.1                          | Meat (excluding edible offal) of bovine animals, sheep, pig and poultry (6)  | 0.05                                 |
| 3.2.2                          | Horsemeat, excluding offal (6)   | 0.2                                  |
| 3.2.3                          | Liver of bovine animals, sheep, pig, poultry and horse (6)   | 0.5                                  |
| 3.2.4                          | Kidney of bovine animals, sheep, pig, poultry and horse (6)  | 1.0                                  |
| 3.2.5                          | Muscle meat of fish (24) (25), excluding species listed in points 3.2.6, 3.2.7 and 3.2.8   | 0.05                                 |

|        |  |      |
|--------|--|------|
| 3.2.6  | Muscle meat of the following fish (24) (25):<br>bonito ( <i>Sarda sarda</i> )<br>common two-banded seabream ( <i>Diplodus vulgaris</i> )<br>eel ( <i>Anguilla anguilla</i> )<br>grey mullet ( <i>Mugil labrosus labrosus</i> )<br>horse mackerel or scad ( <i>Trachurus species</i> )<br>louvar or luvar ( <i>Luvarus imperialis</i> )<br>mackerel ( <i>Scomber species</i> )<br>sardine ( <i>Sardina pilchardus</i> )<br>sardinops ( <i>Sardinops species</i> )<br>tuna ( <i>Thunnus species</i> , <i>Euthynnus species</i> , <i>Katsuwonus pelamis</i> )<br>wedge sole ( <i>Dicologlossa cuneata</i> ) | 0.1  |
| 3.2.7  | Muscle meat of the following fish (24) (25): bullet tuna ( <i>Auxis species</i> )  | 0.2  |
| 3.2.8  | Muscle meat of the following fish (24) (25):<br>anchovy ( <i>Engraulis species</i> )<br>swordfish ( <i>Xiphias gladius</i> )   | 0.3  |
| 3.2.9  | Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) (26)   | 0.5  |
| 3.2.10 | Bivalve molluscs (26)  | 1.0  |
| 3.2.11 | Cephalopods (without viscera) (26)   | 1.0  |
| 3.2.12 | Cereals excluding bran, germ, wheat and rice   | 0.1  |
| 3.2.13 | Bran, germ, wheat and rice   | 0.2  |
| 3.2.14 | Soybeans   | 0.2  |
| 3.2.15 | Vegetables and fruit, excluding leaf vegetables, fresh herbs, fungi, stem vegetables, root vegetables and potatoes (27)  | 0.05 |
| 3.2.16 | Stem vegetables, root vegetables and potatoes, excluding celeriac (27)<br>For potatoes, the maximum level applies to peeled potatoes   | 0.1  |
| 3.2.17 | Leaf vegetables, fresh herbs, celeriac and the following fungi (27)<br><i>Agaricus bisporus</i> (common mushroom), <i>Pleurotus ostreatus</i> (Oyster mushroom), <i>Lentinula edodes</i> (Shiitake mushroom)   | 0.2  |
| 3.2.18 | Fungi, excluding those listed in point 3.2.17 (27)   | 1.0  |
| 3.2.19 | Food supplements (*) excl. food supplements listed in point 3.2.20   | 1.0  |
| 3.2.20 | Food supplements (*) consisting exclusively or mainly of dried seaweed or of products derived from seaweed   | 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 applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) | 0.5 |
|-------|--|-----|

|            |   |     |
|------------|---|-----|
| 3.3.2      | Muscle meat of the following fish (24) (25):<br>anglerfish ( <i>Lophius species</i> )<br>Atlantic catfish ( <i>Anarhichas lupus</i> )<br>bonito ( <i>Sarda sarda</i> )<br>eel ( <i>Anguilla species</i> )<br>emperor, orange roughy, rosy soldierfish ( <i>Hoplostethus species</i> )<br>grenadier ( <i>Coryphaenoides rupestris</i> )<br>halibut ( <i>Hippoglossus hippoglossus</i> )<br>kingklip ( <i>Genypterus capensis</i> )<br>marlin ( <i>Makaira species</i> )<br>megrin ( <i>Lepidorhombus species</i> )<br>mullet ( <i>Mullus species</i> )<br>pink cusk eel ( <i>Genypterus blacodes</i> )<br>pike ( <i>Esox lucius</i> )<br>plain bonito ( <i>Orcynopsis unicolor</i> )<br>poor cod ( <i>Tricopterus minutus</i> )<br>Portuguese dogfish ( <i>Centroscymnus coelolepis</i> )<br>rays ( <i>Raja species</i> )<br>redfish ( <i>Sebastes marinus</i> , <i>S. mentella</i> , <i>S. viviparus</i> )<br>sail fish ( <i>Istiophorus platypterus</i> )<br>scabbard fish ( <i>Lepidopus caudatus</i> , <i>Aphanopus carbo</i> )<br>seabream, pandora ( <i>Pagellus species</i> )<br>shark (all species)<br>snake mackerel or butterfish ( <i>Lepidocybium flavobrunneum</i> , <i>Ruvettus pretiosus</i> , <i>Gempylus serpens</i> )<br>sturgeon ( <i>Acipenser species</i> )<br>swordfish ( <i>Xiphias gladius</i> )<br>tuna ( <i>Thunnus species</i> , <i>Euthynnus species</i> , <i>Katsuwonus pelamis</i> ) | 1.0 |
| 3.3.3      | Food supplements *  | 0.1 |
| <b>3.4</b> | <b>Tin</b>  |     |
| 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  |

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

| Entry No<br>(in Reg 1881/2006) | Foodstuffs (1)                    | Maximum levels<br>(mg/kg wet weight) |
|--------------------------------|-----------------------------------|--------------------------------------|
| 4.1                            | Hydrolysed vegetable protein (30) |                                      |
| 4.2                            | Soy sauce (30)                    | 0.02                                 |

## Section 5: Dioxins and PCBs (31)

Note: all levels given in Section 5 are from Regulation (EC) No 1881/2006, other than those for Entry Nos. 5.11 which was introduced via the amending Commission Regulation (EC) No 565/2008 of 18 June 2008 (EC, 2008b) amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver.

| Entry No<br>(in Reg 1881/2006) | Foodstuffs (1)  | Maximum levels   |  |
|--------------------------------|---|--|--|
|                                |   | Sum of dioxins<br>(WHO-PCDD/<br>F-TEQ) <sup>(32)</sup> | Sum of dioxins<br>and dioxin-like<br>PCBs (WHO-<br>PCDD/F-PCB-<br>TEQ) <sup>(32)</sup> |
| 5.1                            | Meat and meat products (excluding edible offal) of the following animals (6)  |  |  |
|                                | – bovine animals and sheep  | 3 pg/g fat (33)  | 4.5 pg/g fat (33)  |
|                                | – poultry   | 2 pg/g fat (33)  | 4 pg/g fat (33)  |
|                                | – pigs  | 1 pg/g fat (33)  | 1.5 pg/g fat (33)  |
| 5.2                            | Liver of terrestrial animals referred to in 5.1 (6) and derived products thereof  | 6 pg/g fat(33)   | 12 pg/g fat (33)   |
| 5.3                            | Muscle meat of fish and fishery products and products thereof with the exception of eel (25) (34). The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) | 4 pg/g fresh weight                                    | 8 pg/g fresh weight  |
| 5.4                            | Muscle meat of eel ( <i>Anguilla anguilla</i> ) and products thereof  | 4 pg/g fresh weight                                    | 12 pg/g fresh weight   |
| 5.5                            | Raw milk (6) and dairy products (6), including butter fat   | 3 pg/g fat (33)  | 6 pg/g fat (33)  |
| 5.6                            | Hen eggs and egg products (6)   | 3 pg/g fat (33)  | 6 pg/g fat (33)  |
| 5.7                            | Fat of the following animals  |  |  |
|                                | – bovine animals and sheep  | 3 pg/g fat   | 4.5 pg/g fat   |
|                                | – poultry and farmed game   | 2 pg/g fat   | 4 pg/g fat   |
|                                | – pigs  | 1 pg/g fat   | 1.5 pg/g fat   |
| 5.8                            | Mixed fats  | 2.0 pg/g fat   | 3 pg/g fat   |
| 5.9                            | Vegetable Oils and fats   | 0.75 pg/g fat  | 1.5 pg/g fat   |
| 5.10                           | Marine oil (fish body oil, fish liver oil and oils from other marine organisms intended for human consumption)  | 2 pg/g fat   | 10 pg/g fat  |
| 5.11                           | Fish liver and derived products thereof with the exception of marine oils referred to in point 5.10   | –  | 25.0 pg/g wet weight (32) (38)   |

## Section 6: Polycyclic aromatic hydrocarbons

| Entry No<br>(in Reg 1881/2006) | Foodstuffs  | Maximum levels<br>(mg/kg wet weight) |
|--------------------------------|---|--------------------------------------|
| <b>6.1</b>                     | <b>Benzo(a)pyrene (35)</b>  |                                      |
| 6.1.1                          | Oils and fats (excluding cocoa butter) intended for direct human consumption or use as an ingredient in foods   | 2.0                                  |
| 6.1.2                          | Smoked meats and smoked meat products   | 5.0                                  |
| 6.1.3                          | Muscle meat of smoked fish and smoked fishery products (25) (36), excluding bivalve molluscs. The maximum level applies to smoked crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) | 5.0                                  |
| 6.1.4                          | Muscle meat of fish (24) (25), other than smoked fish   | 2.0                                  |
| 6.1.5                          | Crustaceans, cephalopods, other than smoked (26). The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )  | 5.0                                  |
| 6.1.6                          | Bivalve molluscs (26)   | 10.0                                 |
| 6.1.7                          | Processed cereal-based foods and baby foods for infants and young children (3) (29)   | 1.0                                  |
| 6.1.8                          | Infant formulae and follow-on formulae, including infant milk and follow-on milk (8) (29)   | 1.0                                  |
| 6.1.9                          | Dietary foods for special medical purposes (9) (29) intended specifically for infants   | 1.0                                  |

## Annex 2: Sampling Frequencies for Groundnuts, Pistachios, Brazil Nuts, Dried Figs, other Dried Fruit and Spices (Established by Commission Regulation (EC) No 401/2006/EC)

| Commodity  | Lot weight (tonnes) | Weight or no. of sub-lots | No. of incremental samples | Weight of incremental samples (g) | Aggregate Sample Weight (kg) |
|------------|---------------------|---------------------------|----------------------------|-----------------------------------|------------------------------|
| Dried figs | ≤ 0.1               | No division required      | 10                         | 300                               | 3                            |
|            | > 0.1 – ≤ 0.2       |                           | 15                         | 300                               | 4.5                          |
|            | > 0.2 – ≤ 0.5       |                           | 20                         | 300                               | 6                            |
|            | > 0.5 – ≤ 1.0       |                           | 30                         | 300                               | 9                            |
|            | > 1.0 – ≤ 2.0       |                           | 40                         | 300                               | 12                           |
|            | > 2.0 – ≤ 5.0       |                           | 60                         | 300                               | 18                           |
|            | > 5.0 – ≤ 10.0      |                           | 80                         | 300                               | 24                           |
|            | > 10.0 – ≤ 15.0     | 100                       | 300                        | 30                                |                              |
| ≥ 15       | 15-30 tonnes        | 100                       | 300                        | 30                                |                              |

| Commodity                   | Lot weight (tonnes) | Weight or no. of sub-lots | No. of incremental samples | Weight of incremental samples (g) | Aggregate Sample Weight (kg) |
|-----------------------------|---------------------|---------------------------|----------------------------|-----------------------------------|------------------------------|
| Dried fruit other than figs | ≤ 0.1               | No division required      | 10                         | 100                               | 1                            |
|                             | > 0.1 – ≤ 0.2       |                           | 15                         | 100                               | 1.5                          |
|                             | > 0.2 – ≤ 0.5       |                           | 20                         | 100                               | 2                            |
|                             | > 0.5 – ≤ 1.0       |                           | 30                         | 100                               | 3                            |
|                             | > 1.0 – ≤ 2.0       |                           | 40                         | 100                               | 4                            |
|                             | > 2.0 – ≤ 5.0       |                           | 60                         | 100                               | 6                            |
|                             | > 5.0 – ≤ 10.0      |                           | 80                         | 100                               | 8                            |
|                             | > 10.0 – ≤ 15.0     | 100                       | 100                        | 10                                |                              |
| ≥ 15                        | 15-30 tonnes        | 100                       | 100                        | 10                                |                              |

| Commodity                               | Lot weight (tonnes) | Weight or no. of sub-lots | No. of incremental samples | Weight of incremental samples (g) | Aggregate Sample Weight (kg) |
|---|---------------------|---------------------------|----------------------------|-----------------------------------|------------------------------|
| Groundnuts<br>Pistachios<br>Brazil nuts | ≤ 0.1               | No division required      | 10                         | 300                               | 3                            |
|   | > 0.1 – ≤ 0.2       |                           | 15                         | 300                               | 4.5                          |
|   | > 0.2 – ≤ 0.5       |                           | 20                         | 300                               | 6                            |
|   | > 0.5 – ≤ 1.0       |                           | 30                         | 300                               | 9                            |
|   | > 1.0 – ≤ 2.0       |                           | 40                         | 300                               | 12                           |
|   | > 2.0 – ≤ 5.0       |                           | 60                         | 300                               | 18                           |
|   | > 5.0 – ≤ 10.0      |                           | 80                         | 300                               | 24                           |
|   | > 10.0 – ≤ 15.0     |                           | 100                        | 300                               | 30                           |
|   | ≥ 15 and ≤ 125      | 25 tonnes                 | 100                        | 300                               | 30                           |
|   | ≥ 125 and < 500     | 5 sub-lots                | 100                        | 300                               | 30                           |
|   | ≥ 500               | 100 tonnes                | 100                        | 300                               | 30                           |

| Commodity | Lot weight (tonnes) | Weight or no. of sub-lots | No. of incremental samples | Weight of incremental samples (g) | Aggregate Sample Weight (kg) |
|-----------|---------------------|---------------------------|----------------------------|-----------------------------------|------------------------------|
| Spices    | ≤ 0.01              | No division required      | 5                          | 100                               | 0.5                          |
|           | > 0.01 – ≤ 0.1      |                           | 10                         | 100                               | 1                            |
|           | > 0.1 – ≤ 0.2       |                           | 15                         | 100                               | 1.5                          |
|           | > 0.2 – ≤ 0.5       |                           | 20                         | 100                               | 2                            |
|           | > 0.5 – ≤ 1.0       |                           | 30                         | 100                               | 3                            |
|           | > 1.0 – ≤ 2.0       |                           | 40                         | 100                               | 4                            |
|           | > 2.0 – ≤ 5.0       |                           | 60                         | 100                               | 6                            |
|           | > 5.0 – ≤ 10.0      |                           | 80                         | 100                               | 8                            |
|           | > 10.0 – ≤ 15.0     |                           | 100                        | 100                               | 10                           |
|           | > 15                | 25 tonnes                 | 100                        | 100                               | 10                           |

## 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.3. Definitions

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

**A.3.1. "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.3.2. "sublot"** means a designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separate and identifiable.

**A.3.3. "incremental sample or unit"** means a quantity of material taken from a single place in the lot or sublot. In this case, it may be a single lettuce or spinach head, or handful of baby leaf, or one bag of cut leaves.

**A.3.4. "aggregate sample"** means the combined total of all the incremental samples taken from the lot or sublot.

**A.3.5. "laboratory sample"** means a sample intended for the laboratory.

**A.3.6. "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.3.7. "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.3.1 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 sublots 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 sublot. Departure from such procedure should be recorded in the record provided for under A.3.8.

#### 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 as regards 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. 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 subplot.

### 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 3 hectares, the field should be divided into sublots of 2 hectares and each subplot 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.

## 2. 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 sublots of in principle 25 tonnes on condition that the subplot 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 subplot may exceed the mentioned weight by a maximum of 20%. This means that the subplot may have weight ranging from 15 to 30 tonnes. In case the lot is not or cannot be physically separated into sublots, 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 1.

**Table 1. 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 2.

**Table 2. 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 subplot 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.

### 3. 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 2. 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.

### 4. Assessment of Compliance of a Lot or Sublot

- 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 Benzo(A)Pyrene in Foodstuffs Falling within the Scope of Commission Regulation (EC) No 1881/2006

### A.4. Definitions

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

**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. “sublot”** means a designated part of a large lot in order to apply the sampling method on that designated part; each subplot 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 subplot

**A.4.4. “aggregate sample”** means the combined total of all the incremental samples taken from the lot or subplot; aggregate samples should be considered as representative of the lots or sublots from which they are taken

**A.4.5. “laboratory sample”** means a sample intended for the laboratory.

### 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 subplot 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 subplot. Departure from such procedure should be recorded in the record provided for under point B.1.8. of this Annex.

### 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.

### 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 subplot 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.

## 2. Sampling Plans

Large lots should be divided into sublots on condition that the subplot may be separated physically. For products traded in bulk consignments, e.g. cereals. Table 1 should apply. For other products Table 2 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot 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 subplot should be as given in Table 3.

In the case of bulk liquid products the lot or subplot 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 subplot. It is therefore sufficient to take three incremental samples from a lot or subplot 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 this Annex.

**Table 1. Subdivision of lots into sublots for products traded in bulk consignments**

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

**Table 2. Subdivision of lots into sublots for other products**

| Lot weight (ton) | Weight or number of sublots |
|------------------|-----------------------------|
| ≥ 15             | 15-30 tonnes                |
| < 15             | -                           |

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

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

If the lot or subplot 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 4.

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

| Number of packages or units in the lot/sublot | 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.

### 3. 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 this Annex. 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 subplot.

### 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.

### 4. Assessment of Compliance of a Lot or Sublot

- 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

## Definitions

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

**A.5.1. “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 and fishery products, also the size of fish should 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

**A.5.2. “sublot”** means a designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separate and identifiable

**A.5.3. “incremental sample”** means a quantity of material taken from a single place in the lot or sublot

**A.5.4. “aggregate sample”** means the combined total of all the incremental samples taken from the lot or sublot; aggregate samples should be considered as representative of the lots or sublots from which they are taken

**A.5.5. “laboratory sample”** means a sample intended for the laboratory.

## 5.1 Personnel

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

## 5.2 Material to be sampled

Each lot or sublot which is to be examined should be sampled separately.

## 5.3 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 content of dioxins and dioxin-like PCBs, adversely affect the analytical determination or make the aggregate samples unrepresentative.

## 5.4 Incremental samples

As far as possible incremental samples should be taken at various places distributed throughout the lot or sublot. Departure from such procedure should be recorded in the record provided for under part 3.8 of this Annex.

## 5.5 Preparation of the aggregate sample

The aggregate sample should be made up by combining the incremental samples. It should be at least 1kg unless not practical, e.g. when a single package has been sampled.

## 5.6 Replicate samples

The replicate samples for enforcement, trade (defence) and reference (referee) purposes should be taken from the homogenised aggregate sample, unless such procedure conflicts with national rules as regard the rights of the food business operator. The size of the laboratory samples for enforcement should be sufficient to allow at least for duplicate analyses.

## 5.7 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.

## 5.8 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 giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

## 4. Sampling Plans

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

### 4.1 Division of lots into sublots

Large lots should be divided into sublots on condition that the subplot can be separated physically. For products traded in large bulk consignments, e.g. vegetable oils, Table 1 should apply. For other products, Table 2 should apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20%.

**Table 1. Subdivision of lots into sublots for products traded in bulk consignments**

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

**Table 2. Subdivision of lots into sublots for other products**

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

### 4.2 Number of Incremental Samples

- The aggregate sample uniting all incremental samples should be at least 1 kg (see part 3.5 of this Annex).
- The minimum number of incremental samples to be taken from the lot or subplot should be as given in Tables 3 and 4
- In the case of bulk liquid products the lot or subplot 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 subplot. It is therefore sufficient to take three incremental samples from a lot or subplot 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 3.8 of this Annex. 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<sup>17</sup>, the aggregate sample size for hen eggs is at least 12 eggs (for bulk lots as well for lots consisting of individual packages, tables 3 and 4).

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

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

If the lot or subplot 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 4.

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

| Number of packages or units in the lot/sublot | 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 |

### 4.3 Specific Provisions for the Sampling of Lots Containing Whole Fishes of Comparable Size and Weight

Fishes 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 are defined in Table 3. The aggregate sample uniting all incremental samples should be at least 1kg (see point 3.5.)

- In case the lot to be sampled contains small fishes (individual fishes 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 fishes 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 the gill opening and the anus.

- In case the lot to be sampled contains larger fishes (individual fishes weighing more than about 1kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams.

For fishes of intermediate size (about 1-6 kg) 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 fishes, 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 a 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.

<sup>17</sup> OJ L 303, 6.11.1997, p. 12.

#### 4.4 Sampling of Lots of Fish Containing Whole Fishes of Different Size and/or Weight

- The provisions of point 4.3. 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 fishes 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 fishes 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 fishes of different size and/or weight<sup>18</sup>.”

#### 4.5 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 4.2 of this Annex.

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 subplot.

### 5. Compliance of the Lot or Sublot with the Specification

The lot is accepted if the analytical result of a single analysis does not exceed the respective maximum level of dioxins and the sum of dioxins and dioxin-like PCBs as laid down in Regulation (EC) No1881/2006 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<sup>19</sup> analytical result, confirmed by duplicate analysis<sup>20</sup>, exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.

The taking into account of the measurement uncertainty may be done 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 subplot is non-compliant if the measured value minus U is above the established permitted level. In case of a separate determination of dioxins and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of dioxins and dioxin-like PCBs has to be used for the sum of dioxins and dioxin-like PCBs
- by establishing the decision limit (CC $\alpha$ ) according to the provisions of Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results<sup>21</sup> (point 3.1.2.5. of the Annex - the case of substances with established permitted level) A Lot or subplot is non-compliant if the measured value is equal to or above the CC $\alpha$ .

The present interpretation rules apply for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.

<sup>18</sup> [http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/dioxins\\_en.htm](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/dioxins_en.htm)

<sup>19</sup> 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.

<sup>20</sup> 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.

<sup>21</sup> OJ L 221, 17.8.2002, p. 8.





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