

# Mycotoxins sampling guidance

Reviewed October 2016

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## **Summary**

Intended audience:	<ul><li>Farmers and growers</li><li>Importers</li></ul>	
	Manufacturers and processors	
Which UK nations	·	
does this cover?	England, Scotland, Wales and Northern Ireland.	
Purpose:	Subject areas:	
	<ul> <li>Mycotoxin sampling legislation;</li> </ul>	
	<ul> <li>Sampling of foodstuffs / commodities for mycotoxins.</li> </ul>	
	The guidance:	
	<ul> <li>Provides an overview of EU/UK food safety legislation;</li> </ul>	
	Describes the official sampling methods for commodities/ foodstuffs for which there are EU maximum limits for mycotoxins.	
Legal status:	Regulatory guidance (Information specifying what food business operators need to do to comply with domestic or EU legislation).	
Key words	<ul> <li>Contaminants and food contact materials</li> <li>Food law, monitoring and controls</li> </ul>	
	Hygiene and food safety	
	Imports	
Review date	December 2015	
Sunset date	None	



## **Revision history**

If you have any comments on the guidance itself, please email us using the contact email on page 1.

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
1	22/09/2023	This revision is to update contact details and old links to the FSA website. Information within this document remains unchanged and some links or references may be outdated. A full review of this document will be taken forward in due course.  Update of contact details (Page 1 and page 4)  Replacement of old links to food.gov website. (Paragraph 4, paragraph 11)	C Jones



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#### **Purpose of guidance**

1. The purpose of this document is to provide information to enforcement authorities and food business operators on the legislation regarding mycotoxins in foodstuffs and the official methods of sampling in foods such as cereals, dried fruit, figs, groundnuts, nuts, products derived from nuts, spices, coffee, fruit juice, cider, milk, wine and apple products for mycotoxins.

#### Legal status of guidance

- 2. These guidance notes have been produced to provide best practice advice about sampling for mycotoxin contamination. You are not required by law to follow this advice. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/ environmental health department of the local authority.
- 3. These guidance notes have been produced to explain the legal requirements of Commission Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. They cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law. You are not required by law to follow best practice advice. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.
- 4. This document should be read in conjunction with the relevant legislation, which can be found at https://www.food.gov.uk/business-guidance/mycotoxins

#### **Mycotoxins**

- Mycotoxins are naturally occurring toxins that are produced by moulds growing on food crops during production and subsequent storage.
- Mycotoxins are found in a wide range of foods from around the world, but particularly in foods from countries with climates of high temperature and humidity.
- There are a number of contaminants covered by the class of mycotoxins; these
  include aflatoxins, ochratoxin A, the fusarium toxins, patulin, citrinin, ergot alkaloids
  and alternaria toxins.

#### **Aflatoxins**

- Aflatoxins are produced by the Aspergillus species of mould that grow in warm, humid conditions, principally A. flavus, and A. parasiticus.
- Aflatoxins occur mainly in commodities imported from third countries (i.e. outside the EC), in particular peanuts (groundnuts) and other edible nuts and their products, dried fruit, spices, cereals and cereal products. Milk and milk products may also be contaminated owing to the consumption of aflatoxin contaminated feed by ruminants.
- There are a number of different types of aflatoxin, with aflatoxin B₁ being the most toxic. It is a potent carcinogen in laboratory animals and there is evidence that it is a genotoxic human carcinogen i.e. it can cause cancer by reacting with genetic material.

#### Ochratoxin A

- Ochratoxin A is produced by mould species, including those from the genera Penicillium and Aspergillus that grow in warm humid conditions and by other moulds that generally favour climates with lower temperatures and humidity.
- Ochratoxin A is found as a contaminant in a wide range of commodities, particularly cereals and cereal products and dried vine fruit (currants, raisins and sultanas). Other commodities that can also be affected include coffee and coffee products, wine, grape juice, cocoa and cocoa products and spices. It has also been detected in animal products from non-ruminant animals exposed to ochratoxin A from animal feeding stuffs.

Ochratoxin A has been implicated as a cause of kidney damage in humans.

#### **Patulin**

- The main cause of patulin is the blue mould *Penicillium expansum*. Patulin is
  destroyed by the fermentation process, and so is much less prevalent in apple
  beverages, such as cider.
- Patulin contamination is mainly found in apple products, although it can occur in other mouldy fruits, grains and foods.
- Patulin has been shown to have various toxic effects and can harm the immune system and gastrointestinal tract.

#### **Fusarium Toxins**

- Fusarium moulds produce a number of different mycotoxins, known as fusarium toxins.
- Fusarium toxins include trichothecenes (nivalenol, deoxynivalenol and T-2 and HT-2 toxins), zearalenone, and fumonisins.
- Fusarium toxins are commonly found in cereals grown in temperate regions such as Europe, Asia and America.

#### Deoxynivalenol

- Deoxynivalenol (DON) is a mycotoxin produced by various Fusarium species, which
  can co-occur in cereal based food and feed together with its acetyl derivatives and
  glucoside-conjugate.
- It can be acutely toxic to humans, causing sickness and diarrhoea, but at much higher levels than those typically seen in the UK. Reported chronic effects in animals include suppression of the immune system.

#### T-2 and HT-2 toxins

T-2 toxin and HT-2 toxin are also mycotoxins produced by various *Fusarium* species.
 Generally, the *Fusarium* species grow and invade crops under moist cool conditions.
 T-2 toxin and HT-2 toxin are found in cereal grains and products thereof.

 These toxins are known to produce immunological or haematological effects, and impair protein and DNA synthesis.

#### Zearalenone

- Zearalenone is also produced by various Fusarium species and occurs in cereals and cereal products.
- It is oestrogenic and has been shown to exhibit hormonal effects, such as infertility, particularly in pigs.

#### **Fumonisins**

- Fumonisins are made up of about 15 closely related chemicals; the most common are B1 and B2. They are also produced by *Fusarium* species and occur mostly in hot continental climates. Maize is the crop that is most commonly affected.
- Fumonisins have been related to oesophageal cancer in humans, and to liver and kidney toxicity in animals.

#### **Ergot Alkaloids**

- These mycotoxins are produced by fungi of all species of the *Claviceps* genus, most notably by *C. purpurea*, which parasitises the seed heads of living plants (mostly cereals and grasses) at the time of flowering. Ergot is ubiquitous, but is more common in seasons with heavy rainfall and wet soils. Rye and triticale are the most susceptible species because they have open florets.
- The sclerotia are harvested together with the cereals or grass and can lead to contamination of cereal-based food and feed products with ergot alkaloids, particularly when they break apart. Normally, ergot is easily visible as intact sclerotia. The six most prevalent ergot alkaloids are ergotamine, ergocornine, ergocristine, ergocryptine, ergosine and ergometrine along with their nine stereoisomers.
- Typical symptoms of ergotism are gangrene and/or hallucinations and convulsions. At lower levels of contamination, they can cause vasoconstriction and reproductive effects.

#### **Alternaria Toxins**

- Alternaria is a genus of fungi that can contaminate crops such as fruits, vegetables, nuts and grains, and produce a range of mycotoxins, the alternaria toxins, including alternariol (AOH), alternariol methyl ether (AME), tentoxin (TEN) and tenuazonic acids (TeA).
- AOH and AME are considered as carcinogens, whereas AME, TeA and altertoxins
   (ATX) are fetotoxic and teratogenic in rats. In addition, it has been suggested that in
   certain areas in China alternaria toxins might be responsible for oesophageal cancer.

#### Citrinin

- Citrinin is produced by several species of Aspergillus, Penicillium and Monascus.
   Citrinin is generally formed after harvest and occurs mainly in stored grains, but also in other plant products such as beans, fruits, fruit and vegetable juices, herbs and spices, and also in spoiled dairy products.
- Citrinin is known to occur also as an undesirable contaminant in *Monascus* fermentation products (generally described as red mould rice (RMR)), which have been used in Asia for centuries for meat preservation and food colouring.
- Citrinin is nephrotoxic (affects the kidneys) but there is uncertainty regarding its potential carcinogenicity.

### **Sterigmatocystin**

- Sterigmatocystin is a polyketide mycotoxin that is produced by more than 50 fungal species, including Aspergillus flavus, A. parasiticus, A. versicolor and A. nidulans, of which A. versicolor is the most common source. It is found in cereals and cerealbased products
- Sterigmatocystin is genotoxic and carcinogenic i.e. it can cause cancer.

### **Other Mycotoxins**

 There are some other mycotoxins that may potentially be of relevance to consumer safety, such as cyclopiazonic acid, Moniliformin, Neosolaniol, Fusarenone X, Diacetoxyscirpenol and masked forms of mycotoxins.

#### Legislation

5. The Food Safety Act 1990 (<a href="http://www.legislation.gov.uk/ukpga/1990/16/contents">http://www.legislation.gov.uk/ukpga/1990/16/contents</a>) provides the framework for much of the legislation concerning food in the UK and covers all types of food business, there is also subsequent legislation for Northern Ireland referred to as the Food Safety (Northern Ireland) Order 1991. It is an offence under the Act for anyone to sell food which is not of the nature, substance or quality demanded by the customer. It is the responsibility of a food business to ensure that they have adequate food hygiene standards within their business.

#### **European and UK Legislation**

- 6. European Community Regulations are directly applicable in the UK and other members of the European Union. These pieces of legislation set limits for certain contaminants in foodstuffs, as well as detailing the official methods of control and requirements for complying with food laws. In addition to EC Regulations made by the Council and the European Parliament, and by the European Commission, Commission Decisions are also used to provide additional commodity specific safeguard measures.
- 7. European Legislation is given effect in England via the use of Statutory Instruments; these are used in the case of EC Regulations to specify the offences and related penalties that are applicable in the enforcement of the European legislation.

  Scotland, Wales and Northern Ireland have equivalent procedures in place for the enforcement of European legislation.
- 8. General food law is enforced by the following European and domestic legislation:
  - EC Regulation 178/2002 lays down the general principles and requirements of food law and describes procedures in matters of food safety and traceability, including those for imported foods. This is given effect in Great Britain by The General Food Regulations 2004, which creates the offence of placing unsafe food on the market.
  - The principal piece of EU legislation regarding mycotoxins is Commission Regulation (EC) No. 1881/2006, as amended. This Regulation sets out specific rules in relation to mycotoxins and other contaminants. It includes specific maximum levels for certain mycotoxins in individual foodstuffs, which

are laid down in Section 2 to the annex of the Regulation. Those mycotoxins for which there are currently specific maximum levels include aflatoxins, ochratoxin A, patulin, the Fusarium toxins including deoxynivalenol, zearalenone and fumonisins and citrinin. In addition to the maximum levels laid down in Commission Regulation (EC) No. 1881/2006, as amended, foodstuffs containing mycotoxins for which there are no specific maximum levels may, under certain circumstances, also be considered non-compliant with more general food safety requirements, for example those requirements laid down in Regulation (EC) No. 178/2002.

- EC Regulation 669/2009: Since 25 January 2010, imports of certain feed and food of non-animal origin, from certain non-EU countries, that are considered to be 'high-risk' can only enter the UK through specific ports and airports approved as designated points of entry (DPEs) where official controls will be carried out. A 'high-risk' product is feed or food that is either a known, or an emerging, risk to public health. This may be due to the presence of contaminants and/or undesirable substances such as aflatoxins, *Salmonella* or pesticides.
- EC Regulation 884/2014: There are special import conditions for some foods such as nuts and dried fruit that present an increased risk of mycotoxin contamination. The regulation imposes special conditions on the import of certain feed and food from certain third countries (outside of the EU) where mycotoxins can be an increased risk.
- EC Regulation 882/2004 describes how official controls (checks) should be performed by the enforcement authorities to ensure that food business operators comply with food laws. Such controls may be carried out at all stages of production, processing and distribution to ensure that requirements are met. It also contains specific provisions concerning controls on imports from countries outside the European Community. This regulation is implemented in England by The Official Feed and Food Controls (England) Regulations 2009 and by equivalent regulations in the devolved countries.
- 9. Further details of maximum levels set for individual commodities are given in the following pages; however, these should be read in conjunction with the full Regulation.

#### Where to Find Copies of the Legislation

- 10. The European legislation listed is available on the internet:
  - EC Regulation 178/2002, which lays down the general principles and requirements of food law, and procedures relating to food safety. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF</a>
  - Commission Regulation 1881/2006, as amended this Regulation sets the maximum levels for certain contaminants in foodstuffs, including levels for mycotoxins. Maximum levels have been set for mycotoxins in cereals and cereal products, groundnuts and nuts, dried fruit, figs, spices, coffee and coffee products, drinks and apple products and food supplements based on rice fermented with red yeast *Monascus purpureus*. Details can be found by referring to the attached link. <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20140701&rid=1">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20140701&rid=1</a>. This Commission Regulation is enforced by The Contaminants in Food (England) Regulations 2013 and by equivalent regulations in the devolved countries <a href="http://www.legislation.gov.uk/uksi/2013/2196/pdfs/uksi">http://www.legislation.gov.uk/uksi/2013/2196/pdfs/uksi</a> 20132196 en.pdf
  - EC Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0882:EN:NOT">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0882:EN:NOT</a>
  - EC Regulation 669/2009 (as amended), as regards the increased level of official controls on imports of certain feed and food of non-animal origin <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R0669-20140701&rid=1">http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R0669-20140701&rid=1</a>
  - EC Regulation 884/2014 which amends regulation 1152/2009, which imposes special conditions on the import of certain foods from certain third countries due to contamination risk by aflatoxin <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0884&rid=1">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0884&rid=1</a>
  - EC Regulation 401/2006, for methods of analysis for sampling of mycotoxins <u>http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R0401</u> and EC Regulation 519/2004 which amends EC Regulations 401/2006 with regards to sampling of large lots and T2 and HT2 toxins <a href="http://eur-brown.net/brown.net/">http://eur-brown.net/prown.net/prown.net/</a>

#### <u>lex.europa.eu/legal-</u> <u>content/EN/TXT/PDF/?uri=OJ:JOL 2014 147 R 0002&from=EN</u>

- 11. Copies of UK Statutory Instruments are also available online,
  - The Official Feed and Food Controls (England) Regulations 2011
     http://www.legislation.gov.uk/uksi/2011/136/pdfs/uksi 20110136 en.pdf
  - The official Feed and Food Controls Regulations (Northern Ireland) 2009
     <a href="http://legislation.data.gov.uk/nisr/2009/427/made/data.htm?wrap=true">http://legislation.data.gov.uk/nisr/2009/427/made/data.htm?wrap=true</a>
  - The Official Feed and Food Controls (Scotland) Regulations 2009
     <a href="http://www.legislation.gov.uk/ssi/2009/446/made/data.pdf">http://www.legislation.gov.uk/ssi/2009/446/made/data.pdf</a>
  - The Official Feed and Food Controls (Wales)(Amendment) Regulations 2011
     <a href="http://www.legislation.gov.uk/wsi/2011/626/pdfs/wsi">http://www.legislation.gov.uk/wsi/2011/626/pdfs/wsi</a> 20110626 mi.pdf
  - The General Food Regulations 2004
     <a href="https://www.legislation.gov.uk/uksi/2004/3279/made/data.pdf">https://www.legislation.gov.uk/uksi/2004/3279/made/data.pdf</a>

## Information for Food Business Operators. The Responsibilities of Food Business Operators (FBOs)

- 12. The responsibilities of a food business, derived from EU food safety legislation, are described in a guidance document from the European Commission. This document is available from the European Commission website:
  <a href="http://ec.europa.eu/food/food/foodlaw/responsibilities/obligations\_en.pdf">http://ec.europa.eu/food/food/foodlaw/responsibilities/obligations\_en.pdf</a>
- 13. There is also domestic food safety legislation for food business operators, please refer to the guidance on our food.gov website.
- 14. This requires businesses to ensure the food they place on the market is safe and places an onus on processors to identify critical control points and carry out quality controls on their products before they are put on sale in order to ensure that their products meet legal requirements

- 15. There are additional responsibilities placed on FBOs for certain products being imported into the EU. Safeguard measures have been introduced where a food safety problem has been identified related to a product from a certain third country and control measures are necessary to protect public health. This list is updated quarterly and relates to commission regulation No 884/2014 as well as commission regulation 669/2009 which is updated quarterly. Please refer to the link which gives you more information on the regulation as well as the updates <a href="http://food.gov.uk/business-industry/imports/banned">http://food.gov.uk/business-industry/imports/banned</a> restricted/highrisknonpoao.
- 16. The Commission has produced guidance on the application of safeguard measures which can be found at the following link:

  <a href="http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-2010.pdf">http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-2010.pdf</a>
- 17. In the UK, regular checks are carried out to ensure products comply with legislation. These checks are carried out by port health authorities (PHAs) or local authorities at the point of import and by trading standards officers and environmental health officers throughout the food chain, including manufacturer's premises and at retail level. For information on how checks are carried out in Northern Ireland please refer to the link: <a href="http://www.legislation.gov.uk/nisr/2004/505/contents/made">http://www.legislation.gov.uk/nisr/2004/505/contents/made</a>
- 18. The Food Standards Agency undertakes its own surveys of contaminants in food. FSA surveys are not intended to be official controls, but instead a snap-shot of what is available on the market for UK consumers, in order to monitor consumer exposure and the effectiveness of controls throughout the food chain. However, in such instances where surveys reveal non-compliance with food law or other risks to food safety, the Agency will take action to ensure consumer protection such as product recall or withdrawal. There are also domestic contaminants in food legislation in each UK country which specify enforcement powers.
- 19. Additionally, depending on the severity of the contamination and the distribution of the product, the Agency may put out food alerts (either a Product Withdrawal Information Notice (PWIN) or Product Recall Information Notice (PRIN)) which alerts Local Authorities across the UK of a potential problem with the product and any action that is required from enforcement authorities.

#### **Due Diligence**

- 20. Although the testing of imported consignments for mycotoxins is not a compulsory requirement, importers and food business operators have a responsibility to ensure the food they trade is safe for human consumption. If a food business operator is found to have placed on the market food that is injurious to health or unfit for human consumption they can be prosecuted under the General Food Regulations 2004. These Regulations are enforced by local authorities and port health authorities.
- 'Due diligence' is a defence to certain offences under the Food Safety Act 1990, the General Food Regulations 2004 and the Contaminants in Food (England) Regulations 2013 (and equivalent regulations in the devolved countries). This balances the proper protection of the consumer against contaminated food with the right of food business operators not to be convicted of an offence they have taken all reasonable care to avoid committing. If it can be proved that an operator "took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control" then it can enable that person to be acquitted of the offence.

#### **Analysis of Foodstuffs for Mycotoxins**

- 22. If a food business operator wishes to have samples analysed for mycotoxins in the UK it is recommended that a laboratory accredited for mycotoxin analysis is used. Further information on accredited laboratories can be found on the UKAS (United Kingdom Accreditation Services) website (<a href="www.ukas.org">www.ukas.org</a>). Official samples must be analysed at an Official Control Laboratory (OCL). A list of OCLs can be found on the FSA website (<a href="http://www.food.gov.uk/enforcement/monitoring/foodlabs/">http://www.food.gov.uk/enforcement/monitoring/foodlabs/</a>).
- 23. A sample which is taken and analysed according to all the relevant legislation is considered to be a formal sample. Formal or Official samples are split at the laboratory into three samples, known as enforcement, defence, and referee samples. When the sample is taken, the enforcement officer advises the food business operator that they can have the defence sample for their analysis if they wish. In the case of the enforcement sample being non-compliant and the food business operator wishing to challenge this they have the right to a second expert opinion. Thus they can request that the referee sample is analysed at the LGC (<a href="http://www.lgc.co.uk/">http://www.lgc.co.uk/</a>). It is for the enforcement officer and the owner to agree who is responsible for the fee for the analysis of the referee sample

24. The contaminants legislation states that the measurement uncertainty and the recovery must be taken into consideration when enforcement authorities are interpreting analytical results. All analytical results have variability known as the measurement uncertainty; this is the range of values that the analyst believes could be reasonably attributed to the measurement value. The analytical result should be reported as "x ± 2u" or "x ± U", where x is the analytical result and u is the standard measurement uncertainty. The expanded measurement uncertainty (2u = U) gives a confidence level of approximately 95%.

#### **Example of the Use of Measurement Uncertainty**

 The EU sets a maximum limit of 5 μg/kg for aflatoxin B1 in spices (Commission Regulation 1881/2006)

The analysis of three different batches of paprika gave the following results for aflatoxin B1:

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1. 3.0 \mug/kg (44% MU) = 3.0 \pm 1.3 \mug/kg \rightarrow range 1.7 – 4.3 \mug/kg
2. 6.0 \mug/kg (44% MU) = 6.0 \pm 2.6 \mug/kg \rightarrow range 3.4 – 8.6 \mug/kg
3. 9.0 \mug/kg (44% MU) = 9.0 \pm 4.0 \mug/kg \rightarrow range 5.0 – 13.0 \mug/kg
```

The result for batch 1 is below the limit both with and without measurement uncertainty being taken into account. This sample is therefore <u>compliant</u> with the limits.

The reported result for batch 2 is above the statutory limit, but the true value for this analysis lies in the range  $3.4-8.6~\mu g/kg$ . In the EU this sample is considered <u>compliant</u>, as it is not beyond reasonable doubt that the maximum limit has actually been exceeded.

The reported result for batch 3 is once again above the statutory limit and the acceptable range of values obtained are also above the limit. This sample is therefore non-compliant.

#### Sampling

- 25. This section describes the methods of sampling commodities for which there are EU maximum limits set. Mycotoxins are known to be unevenly distributed in foods and so it is important to be able to detect isolated 'hot spots' of contamination. It is therefore necessary to take a large number of small incremental samples at various places distributed throughout the consignment in order to obtain a representative sample. This applies regardless of whether the sample is taken formally or informally, as it is impossible to confidently assess what further action should be taken based on the analysis of an unrepresentative sample
- 26. The European Commission have laid down the official procedures for sampling foodstuffs for mycotoxin analysis for enforcement purposes, these procedures are described in Commission Regulation 401/2006, as amended by Commission Regulations 178/2010 and 519/2014. The web links to Commission Regulation 401/2006 and its' amendments are given below:
  - Commission Regulation 401/2006, is available at the link below:

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:070:0012:0034:EN: PDF

 Commission Regulation 178/2010, as regards groundnuts, other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil:

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0178:EN:NOT

- Commission Regulation 516/2014. This includes methods for sampling of large lots, spices and food supplements, performance criteria of T2 and HT2 toxins and citrinin, and screening methods of analysis. <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0519&from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0519&from=EN</a>
- 27. The Commission has provided additional information to officers carrying out sampling official controls for aflatoxins in a specific guidance document.

  <a href="http://ec.europa.eu/food/food/chemicalsafety/contaminants/aflatoxin guidance en.pd">http://ec.europa.eu/food/food/chemicalsafety/contaminants/aflatoxin guidance en.pd</a>
  f. This document provides information on sampling of lot weights of <15 tonnes for</p>

dried fruit, nuts, groundnuts, spices and coffee and sampling of lot weights of <50 tonnes for cereals and products derived from nuts, groundnuts and dried figs. For lot weights above these amounts please refer to Commission Regulation 401/2006 for sampling guidance.

The following sections describe the best practices for carrying out sampling of commodities for mycotoxins and sending these samples for analysis. It is advised that these practices are followed; however, you may wish to use your own discretion when collecting samples within the limits allowed by EC legislation and guidance.

### **General Information on Sampling**

- 28. Ensure that samples are taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date.
- 29. When collecting samples avoid any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative (e.g. do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby).
- 30. Take incremental samples of the appropriate weight at various places distributed throughout the lot.
- 31. Place samples collected in a clean, dry, leak-proof container (such as food quality plastic jars or bags) that can be securely sealed.
- 32. Combine incremental samples together into one container to make up the aggregate sample to be sent to the analyst. It is important that the samples are stored in opaque containers to reduce exposure to light which can affect the analytical results.
- 33. When sampling from retail outlets the number of packs that may be available to you could be limiting. Always ensure that enough packs have been taken to give an aggregate sample representative of a batch, i.e. do not take just one pack. We recommend that you take at least 8 retail packs if possible, picked at random from the same batch. If this number of packs is not available then take as many packs as will make up one kg. For foods such as spices and crisps it may not be possible to obtain the necessary 500g to 1kg. In these cases take at least the minimum required

by the analytical laboratory. This amount depends on the nature of the sample. In general, at least 50g of sample are required for each replicate, i.e. at least 150g for the three samples. It should be noted that some laboratories require 1kg of sample for the preparation of solid samples by homogenisation. It is advisable to contact the analytical laboratory prior to sampling.

34. General guidance on sampling foods can be found in the Food Law Code of Practice and Practical Sampling Guidance for Food Standards and Feeding Stuffs. The procedures outlined here are in addition to the provisions of these documents.

http://www.food.gov.uk/multimedia/pdfs/samplingguidancepart1.pdf

http://www.food.gov.uk/multimedia/pdfs/samplingguidancepart2.pdf

#### **Recording Sample Information**

35. Record as much information as possible about the lots from which samples have been taken to provide as much traceability data as possible.

### **Sending the Sample for Analysis**

- 36. Store samples in a cool dark place.
- 37. Do not remove pre-packed retail samples from their packaging. Seal the entire pack in a plastic bag after purchase, and put the sample code on the outside of the bag.
- 38. Send the **entire aggregate sample** to the analytical contractor; the sampler is not required to split the sample.
- 39. Dispatch samples to the laboratory as soon as possible after collection, ensuring that they are in a good condition.

## **Method of sampling for Cereals and Cereal Products**

40. Aflatoxins in cereals and processed cereal products, baby foods and processed cereal products for infants and young children

- 41. Ochratoxin A in cereals and processed cereal products, baby foods and processed cereal products for infants and young children
- 42. Fusarium toxins in cereals and processed cereal products, baby foods and processed cereal products for infants and young children

Lot Weight	No. of Incremental Samples	Aggregate Sample Weight (kg)
< 50 kg	3	1
> 50 kg - ≤ 500 kg	5	1
> 500 kg - ≤ 1 tonne	10	1
> 1 tonne - ≤ 3 tonnes	20	2
> 3 tonnes - ≤ 10	40	4
tonnes		
> 10 tonnes - ≤ 20	60	6
tonnes		
> 20 tonnes - ≤ 50	100	10
tonnes		

- 43. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a **representative** sample is obtained and that a minimum of 1kg aggregate sample is collected.
- 44. The method of sampling for cereals and cereals products for lots ≥ 50 tonnes, please refer to EC regulation 401/2006, Annex 1, section B4.

## Method of sampling for Dried Fruit including dried vine fruit and derived products but with the exception of dried figs

- Aflatoxins in dried fruit (excluding dried figs)
- Ochratoxin A in dried vine fruit (currants, raisins and sultanas)

Lot Weight	No. of Incremental	Aggregate Sample
	Samples	Weight (kg)
≤ 100 kg	10	1
> 100 kg - ≤ 200 kg	15	1.5
> 200 kg - ≤ 500 kg	20	2
> 500 kg - ≤ 1000 kg (1 tonne)	30	3
> 1 tonne - ≤ 2 tonnes	40	4
> 2 tonnes - ≤ 5 tonnes	60	6
> 5 tonnes - ≤ 10 tonnes	80	8
> 10 tonnes ≤ 15 tones	100	10

- 45. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a <u>representative</u> sample is obtained and that a minimum of 1kg aggregate sample is collected.
- 46. The method of sampling for Dried Fruit including dried vine fruit and derived products but with the exception of dried figs for lots ≥ 50 tonnes, please refer to EC regulation 401/2006, Annex 1, section C4.

#### Method of sampling for Dried Figs, Groundnuts and nuts

 Aflatoxins in groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts

Total Lot Weight	No. of Incremental Samples	Aggregate Sample Weight (kg)
≤ 100 kg	10	3
> 100 kg - ≤ 200 kg	15	4,5
> 200 kg - ≤ 500 kg	20	6
> 500 kg - ≤ 1000 kg (1 tonne)	30	9 (- < 12kg)
> 1 tonne - ≤ 2 tonnes	40	12
> 2 tonnes - ≤ 5 tonnes	60	18 (- < 24kg)
> 5 tonnes - ≤ 10 tonnes	80	24
> 10 tonnes - ≤ 15 tonnes	100	30

- 47. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a **representative** sample is obtained and that a minimum of 1kg aggregate sample is collected.
- 48. The method of sampling for Groundnuts (peanuts) other oilseeds, apricot kernels and tree nuts for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section D.2.4.

### **Method of sampling for Spices**

- Aflatoxins in spices
- OTA in spices

Total Lot Weight	No. of Incremental	Aggregate Sample Weight (kg)
≤ 10 kg	5	0.5
> 10 kg - ≤ 100 kg	10	1
> 100 kg - ≤ 200 kg	15	1.5
> 200 kg - ≤ 500 kg	20	2
> 500 kg - ≤ 1000 kg (1 tonne)	30	3
> 1 tonne - ≤ 2 tonnes	40	4
> 2 tonnes - ≤ 5 tonnes	60	6
> 5 tonnes - ≤ 10 tonnes	80	8
> 10 tonnes - ≤ 15 tonnes	100	10

- 49. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a **representative** sample is obtained and that a minimum of 0.5 kg aggregate sample is collected.
- 50. The method of sampling for spices for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section E.4.

## Method of sampling for Milk and Milk Products Infant Formula and Follow on Formula Including infant milk and follow on milk

 Aflatoxin M1 in Milk and Milk Products, Infant Formula and Follow-on-Formula Including infant milk and follow on milk

#### Minimum number of incremental samples to be taken from the lot

Form of commercialisation	No. of Incremental Samples	Aggregate Sample Weight (kg)
Bulk	3 – 5	1
Bottles / packages	3	1
Bottles / packages	5	1
Bottles / packages	10	1

- 51. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a <u>representative</u> sample is obtained and that a minimum of 1 kg aggregate sample is collected.
- 52. The method of sampling for Milk and Milk Products Infant Formula and Follow on Formula Including infant milk and follow on milk for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section F.1

#### **Method of sampling for Coffee & Coffee Products**

 Ochratoxin A in roasted coffee beans, ground roasted coffee and soluble coffee, liquorice root and liquorice extract.

Total Lot Weight	No. of Incremental	Aggregate Sample Weight (kg)
≤ 100 kg	10	1
> 100 kg - ≤ 200 kg	15	1.5
> 200 kg - ≤ 500 kg	20	2
> 500 kg - ≤ 1000 kg (1 tonne)	30	3
> 1 tonne - ≤ 2 tonnes	40	4
> 2 tonnes - ≤ 5 tonnes	60	6
> 5 tonnes - ≤ 10 tonnes	80	8
>10 tonnes - ≤ 15tonnes	100	10

- 53. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a <u>representative</u> sample is obtained and that a minimum of 1kg aggregate sample is collected.
- 54. The method of sampling for Coffee & Coffee Products, Liquorice Root and Liquorice Extract for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section G.4.

## Method of sampling for Fruit Juices including Grape Juice, Grape Must, Cider & Wine

- Ochratoxin A in wine, grape juice and grape.
- Patulin in fruit juices, spirit drinks, cider and other apple derived drinks

#### Minimum number of incremental samples to be taken:

Packaging Form	Volume of Lot (litres)	No. of Incremental	Aggregate Sample Volume
Bulk	-	3	1
Bottles/packages (excluding wine)	≤ 50	3	1
Bottles/packages (excluding wine)	50 – 500	5	1
Bottles/packages (excluding wine)	> 500	10	1
Bottles/packages (wine only)	≤ 50	1	1
Bottles/packages (wine only)	50 – 500	2	1
Bottles/packages (wine only)	> 500	3	1

- 55. If you are sampling fruit juice, wine or cider which is packaged in ≥1 litre volumes, you must take the minimum number of incremental samples as stated in the table above. Please note that this is a different strategy to sampling of non-liquid goods, where the minimum number of incremental samples to take is that which gives the aggregate sample weight.
- 56. The method of sampling for Fruit Juice, Grape Juice, Grape Must, Wine & Cider for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section H.1

## Method of sampling for Solid Apple Products & Apple Juice and Solid Apple Products for Infants and Young Children.

 Patulin in solid apple products and apple juice and apple products for infants and young children

#### Number of incremental samples to be taken from a bulk lot

Total Lot Weight	No. of Incremental	Aggregate Sample Weight (kg)
< 50 kg	3	1
50 kg – 500 kg	5	1
> 500 kg	10	1

57. Number of packages (incremental samples) which shall 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 weight(kg)
1 to 25	1 package or unit	1
26 to 100	about 5 %, at least two packages or units	1
> 100	about 5 %, at maximum 10 packages or units	1

- 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 (1).
- 59. The method of sampling for Apple Products & Apple Based Baby Foods for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section I.1

## Method of sampling for baby foods and processed cereal based foods for infants and young children

- 60. The method of sampling for cereals and cereal products as set out in point B.4 of Annex I shall apply to food intended for infants and young children. Accordingly the number of incremental samples to be taken shall depend on the weight of the lot, with a minimum of 10 and a maximum of 100, in accordance with Table 2 at point B.4 of Annex I. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg.
- 61. The weight of the incremental sample shall be about 100 grams. In the case of lots in retail packing, the weight of the incremental sample shall depend on the weight of the retail packing and in case of very small lots (≤0.5 tonnes) the incremental samples shall have a weight as such that uniting the incremental samples results in an aggregate sample of at least 1 kg. Departure from this method shall be recorded in the record provided for under A.3.8.
- 62. Weight of aggregate sampling = 1-10 kg sufficiently mixed.
- 63. The method of sampling for Apple Products & Apple Based Baby Foods for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section J.1

### **Method of sampling for Vegetable oils**

• Aflatoxin B1, aflatoxin total and zearalenone in vegetable oils.

Total Lot Weight	No. of Incremental Samples	Aggregate Sample Weight (kg)
Bulk	-	3
Package	<50kg	3
Package	>50kg 500kg	5
Package	> 500Kg	10

- 64. If you are sampling at the retail stage and it is not possible to follow the above sampling plan, an alternative method of sampling may be used provided that it ensures a representative sample is obtained and that a minimum of 1 kg aggregate sample is collected.
- 65. The method of sampling for vegetable oils for lots of <15 tonnes, please refer to EC regulation 401/2006, Annex 1, section K.1

## Method of sampling of very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible - *General Principles*

- 66. In case the way of transport or storage of a lot does not enable to take incremental samples throughout the whole lot, sampling of such lots should preferably be done when the lot is in flow (dynamic sampling).
- 67. In the case of large warehouses destined to store food, operators should be encouraged to install equipment in the warehouse enabling (automatic) sampling across the whole stored lot.
- 68. When the sampling procedures as provided for in part L of EC Regulation No 519/2014 amending Regulation (EC) No 401/2006 are applied, the food business operator or his representative should be informed of the sampling procedure. If the sampling procedure is questioned by the food business operator or his representative, the food business operator or his representative shall enable the competent authority to sample throughout the whole lot at his/her own cost.
- 69. Sampling of a part of the lot is allowed, on the condition that the quantity of the sampled part is at least 10% of the lot to be sampled. If a part of a lot of food of the same class or description has been sampled and identified as not satisfying EU requirements, it shall be presumed that the entire lot is also affected, unless further detailed assessment shows no evidence that the rest of the lot is unsatisfactory.
- 70. The relevant provisions, such as weight of the incremental sample, provided for in the other parts of the Annex to the Regulation are applicable for the sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible.

## Number of incremental samples to be taken in the case of very large lots

71. In the case of large sampled portions (sampled portions > 500 tonnes), the number of incremental samples to be taken = 100 incremental samples + √tonnes. However in case the lot is less than 1 500 tonnes and can be subdivided into sublots in accordance with the table 1 of part B and on the condition that the sublots can be separated physically, the number of incremental samples as provided for in part B have to be taken.

## Method of sampling for food supplements based on rice fermented with red yeast *Monascus purpureus*

Lot size (number of retail packages)	Number of retail packages to be taken for sample	Sample size
1 - 50	1	All capsules
51 - 250	2	All capsules
251- 1000	4	From each retail package taken for sample, half of the capsules
> 10000	4 + 1 retail package per 1000 retail packages with a maximum of 25 retail packages	≤ 10 retail packages: from each retail package, half of the capsules > 10 retail packages: from each retail package, an equal number of capsules is taken to result in a sample with the equivalent of the content of retail 5 packages'

#### **Vacuum Packed Goods**

#### **Dried Fruit (not including dried figs)**

72. For dried fruit traded in vacuum packs in lots of <15 tonnes, 25% of the number of incremental samples shown in the table on page 22 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.

#### **Dried Figs, Groundnuts and Nuts**

- 73. For pistachios, groundnuts, Brazil nuts and dried figs traded in vacuum packs in lots of <15 tonnes, 50% of the number of incremental samples shown in the table on page 23 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.
- 74. For other nut types traded in vacuum packs in lots of <15 tonnes, 25% of the number of incremental samples shown in the table on page 20 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.

#### **Nut Derived Products and Compound Foods**

75. For other products derived from nuts, groundnuts and dried fruit traded in vacuum packs in lots of <50 tonnes, 25% of the number of incremental samples shown in the table on page 23 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.

#### **Spices**

76. For spices traded in vacuum packs in lots of <15 tonnes, 25% of the number of incremental samples shown in the table on page 24 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.

#### **Coffee and Coffee Products**

77. For coffee beans, ground coffee and soluble coffee traded in vacuum packs in lots of <15 tonnes, 25% of the number of incremental samples shown in the table on page

26 should be taken. The appropriate aggregate sample weight for the total batch weight given in the table should be maintained.

#### **Sampling Advice Flow Chart**

**78.** This flow chart outlines possible scenarios when sampling at a wholesalers. Please familiarise yourself with this figure **before** sampling. The flow chart should be used as a guide to determine which consignments you should sample.

