

30th November 2009

Reference:

Dear Sir or Madam,

Food Contaminants – Update Bulletin November 2009.

This latest issue of our periodical news bulletin provides information on key activities and contacts within the Agency throughout the United Kingdom.

As you may be aware, the Agency is undergoing a restructuring programme. With this letter we are therefore taking the opportunity to update our contacts list for the Food Contaminants area. We shall keep you up to date with any further changes.

The summary of news items overleaf will help you to identify subjects of particular interest to you. Clicking on the bookmark will direct you straight to the section that you are interested in.

In the interim you should expect to see business as usual, although please do contact us if you have any concerns.

Yours faithfully

Terry Donohoe,
Head, Policy and Strategy Unit,
Food Safety: Contaminants Division.

Summary

In this edition we have news on:

Section	Subject	Link
Changes	The first changes to the structure of the Agency in relation to the organisation of work on contaminants in food.	
Food Contact Materials	New Regulations. Regulating food contact plastics in the EU.	
Nitrates	Nitrates	
Environmental Contaminants		
Inorganic	Cadmium Level in various foodstuffs Cadmium Levels in crab Summary of call for data on cadmium	
Organic	Dioxins and dioxin-like PCBS Sheep Liver Review of Dioxin and Dioxin-like PCB limits Non dioxin-like PCBS Non dioxin-like PCB limits on food-current proposals Polycyclic Aromatic Hydrocarbons Summary of calls for data	
Process Contaminants	Experts Committee on Industrial and Environmental contaminants (Acrylamide, Furan, Ethyl carbamate, 3-MCPD esters) Other updates on acrylamide	
Mycotoxins	Commission Regulation (EC) No. 1881/2006 as regards aflatoxins Commission Regulation (EC) No. 1881/2006 as regards ochratoxin A (OTA) Changes to Commission Decision (EC) No. 2006/504 Amendment of Commission Regulation (EC) 401/2006 Deoxynivalenol (DON) in UK Cereal crops Maximum limit for zearalenone (ZON) in high-fibre breakfast cereals	
Pesticides	Commission decision 2009/835/ec – imposing special conditions on the import of pears from turkey due to high residue levels of amitraz	
Declaration on Turkish Pears (Wales)	The Official Feed and Food Control (Wales) Regulations 2007 (SI No.3294 (w.290))	
Declaration on Turkish Pears (Scotland)	The Official Feed and Food Control (Scotland) Regulations 2007	

Key contacts within the teams in London are:

Veterinary Medicines Residues and Food Contact Materials:

Andrew Spencer
Dr Karen Barnes

Mycotoxins & Nitrates

Jonathan Briggs;

Organic Chemical Contaminants

Dr. David Mortimer (including Environmental Permitting Programme)

Inorganic Contaminants

Christina Baskaran

Process Contaminants

Terry Donohoe

Pesticide Residues

Ranulf Barman

Key contact within Northern Ireland

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Food Standards Agency, Northern Ireland
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Key contact within Scotland

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Key contact within Wales

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Food Safety & Enforcement Division / Yr Is-adran Diogelwch Bwyd a Gorfodi
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AGENCY RESTRUCTURING **FOOD CONTAMINANTS WORK.**

The Food Standards Agency is undergoing a restructuring programme.

Food Safety: Contaminants Division will carry forward the work programmes in chemical and radiological contaminants. The Division comprises two Units: the Chemical Risk Assessment Unit and the Strategy and Policy Unit. The Strategy and Policy Unit has responsibility for:

1. Strategy on food defence, horizon scanning and emerging risks;
2. Policy on mycotoxins, pesticides, veterinary medicines and food contact materials;
3. Policy on organic and inorganic contaminants, biocides and process contaminants;
4. Policy on radiological contaminants, food irradiation, radiation monitoring, RIFE and contaminated land.

FOOD CONTACT MATERIALS

Regulation.

The sixth amendment to Commission Directive 2002/72/EC on food contact plastics was published in the Official Journal of the European Communities on 20th October 2009 (ref OJ, 20-10-2009, L274/3) and came into force on 9th November 2009. The amendment is by way of a Commission Regulation and is directly applicable throughout the EU.

Regulation (EC) 975/2009 amends EC Directive 2002/72 by:

- making the Community list of additives a “complete” list in Annex III;
- providing that the Community list of additives will become a closed list from 1st January 2010;
- adding substances to the Community list from the European Commission’s provisional list of additives.

This amendment is already subject to an ambulatory reference in The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 and parallel legislation in force within the devolved territories. There will be no need to take any statutory action for the amendment to have full effect throughout the United Kingdom.

The Materials and Articles in Contact with Food (England) (Amendment) Regulations 2009, have been made and come into force in December 2009. These amending regulations make amendments to The Materials and articles in Contact with Food (England) Regulations 2007 in order to devolve powers to food authorities to enforce the labelling provisions of Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food. The particular provisions that are the subject of these regulations relate to particular labelling and declaration of compliance requirements for such goods placed on the market. They specifically concern the labelling

of parts of the packaging that could be wrongly taken by some consumers to be edible, the written declaration of legal compliance to accompany active and intelligent materials and articles as they pass from business to business prior to retail sale, and the production of supporting documentation to substantiate the declaration of compliance to enforcement authorities on request. Parallel legislation amending Regulations in Scotland, Wales and Northern Ireland are also being put in place. The European provisions take effect from 19th December 2009.

Europe

Discussion continues on a Commission working document to form the basis for a Commission proposal for a European regulation laying down controls for food contact plastics. A new, unrestricted, draft working document has been issued by the Commission and this was sent to interested parties on 6th November. Discussions are now quite advanced and the Commission hopes to make a formal proposal to the Standing Committee on Food and Animal Health for the adoption of a regulation early next year. The next discussions on the working document will take place as this bulletin goes to press at a meeting of the Commission's working group of Member State experts and representative associations from various interested industry sectors have been invited to attend part of that meeting.

Nitrates

Commission proposals for permanent increases to the existing limits for spinach and lettuce laid down in Commission Regulation 1881/2006 emerged at the end of last year, as the temporary derogations (permitting the UK, and some other Northern European countries, to exceed these maximum limits for fresh lettuce and spinach grown and intended for consumption on their own respective territories) came to an end. However, these increased limits for nitrate levels are unlikely to come into force until early 2010 and, in the meantime, UK enforcement authorities have been made aware of the position and are recommended to take a pragmatic and proportionate approach to the enforcement of nitrate limits.

The proposed changes are likely to include:

- relaxing (increasing) the maximum nitrate limits for fresh spinach to 3,500 mg NO₃/Kg (to apply all year, no seasonal differences)
- relaxing (increasing) the existing nitrate limits for fresh lettuce(non-iceberg) to 5,000 mg NO₃/Kg (winter protected), 4000 mg NO₃/Kg (summer protected) & 3,000 mg NO₃/Kg (summer outdoor), with no changes to current level for winter outdoor
- Introducing a maximum nitrate limit for rocket (rucola; *Eruca sativa*) of 5,000 mg NO₃/Kg
- No changes to current nitrate limits for preserved, deep-frozen or frozen spinach or iceberg lettuce

The Commission should submit these proposals to the Standing Committee for adoption in late 2009, once some outstanding minor details have been finalised.

Any comments you may have on the above issues will be welcome.

For further information or to submit comments or data on nitrates, please contact Valerie McFarlane at: valerie.mcfarlane@foodstandards.gsi.gov.uk

Environmental Contaminants (Inorganic and Organic)

ENVIRONMENTAL CONTAMINANTS (INORGANIC)

For further information or to submit comments or data on Inorganic Contaminants, please contact Christina Baskaran Christina.Baskaran@foodstandards.gsi.gov.uk. Tel 020 7276 8704.

Cadmium levels in various foodstuffs

Discussions at the Meeting of the Expert Committee on Industrial and Environmental Contaminants on 26 October 2009.

As we reported in June 2009, EFSA has published its scientific opinion on the risks to human health related to the presence of cadmium in foodstuffs. EFSA's CONTAM panel has concluded that exposure to cadmium at the population level should be reduced. Details of our earlier report can be found on our website at:

<http://www.food.gov.uk/multimedia/pdfs/contaminantsbulletin0609.pdf>

Following this EFSA conclusion, the European Commission has been looking at ways of reducing exposure to cadmium particularly for vulnerable populations (e.g. children and vegetarians). The Commission will also be reviewing the maximum permitted levels for cadmium in food especially those that contribute mostly to exposure (e.g. cereals and cereal products, vegetables nuts and pulses group, edible offals, starchy roots and potatoes).

The following table gives the preliminary draft proposal with amendments of the Annex of Regulation (EC) No. 1881/2006 for cadmium.

	Foodstuffs⁽¹⁾	Current maximum levels (mg/kg wet weight)	Proposed maximum levels (mg/kg wet weight)
3.2	Cadmium		
3.2.1	Meat (excluding offal) of bovine animals, sheep, pig and poultry ⁽⁶⁾	0,050	0,050
3.2.2	Horsemeat, excluding offal ⁽⁶⁾	0,20	0,20
3.2.3	Liver of bovine animals, sheep, pig, poultry and horse ⁽⁶⁾	0,50	
3.2.4	Kidney of bovine animals, sheep, pig, poultry and horse ⁽⁶⁾	1,0	0,50
3.2.5	Muscle meat of fish ⁽²⁴⁾⁽²⁵⁾ , excluding species listed in points 3.2.6, 3.2.7 and 3.2.8	0,050	0,050
3.2.6	Muscle meat of the following fish ⁽²⁴⁾⁽²⁵⁾ : bonito (<i>Sarda sarda</i>) common two-banded seabream (<i>Diplodus vulgaris</i>) eel (<i>Anguilla anguilla</i>) grey mullet (<i>Chelon labrosus</i>) horse mackerel or scad (<i>Trachurus species</i>) louvar or luvar (<i>Luvarus imperialis</i>) mackerel (<i>Scomber species</i>) sardine (<i>Sardina pilchardus</i>) sardinops (<i>Sardinops species</i>) tuna (<i>Thunnus species, Euthynnus species, Katsuwonus pelamis</i>) wedge sole (<i>Dicologlossa cuneata</i>)	0,10	0,10
3.2.7	Muscle meat of the following fish ⁽²⁴⁾⁽²⁵⁾ : bullet tuna (<i>Auxis species</i>)	0,20	0,20
3.2.8	Muscle meat of the following fish ⁽²⁴⁾⁽²⁵⁾ : anchovy (<i>Engraulis species</i>) swordfish (<i>Xiphias gladius</i>)	0,30	0,30
3.2.9	Crustaceans: muscle meat from appendages and abdomen excluding the cephalothorax⁽²⁶⁾	0,50	0,50
3.2.10	Bivalve molluscs ⁽²⁶⁾	1,0	1,0
3.2.11	Cephalopods (without viscera) ⁽²⁶⁾	1,0	1,0
3.2.12	Cereal grains excluding wheat, spelt and rice	0,10	0,05 – 0.10
3.2.13	Wheat, spelt and rice grains	0,20	0,10 – 0.20
	Bread, pasta, breakfast cereals		0,05-0.10
	Bran and germ for direct consumption		0,10- 0.20
	Processed cereal-based foods and baby foods for infants and young children⁽³⁾⁽²⁹⁾		0.05?

	Foodstuffs⁽¹⁾	Current maximum levels (mg/kg wet weight)	Proposed maximum levels (mg/kg wet weight)
3.2.14	Soybeans (dry)	0,20	0,20
3.2.15	Vegetables and fruit, excluding leaf vegetables and fresh herbs, leafy brassica , fungi, stem vegetables, root and tuber vegetables and potatoes⁽²⁷⁾	0,050	0,050
3.2.16	Stem vegetables, root and tuber vegetables and potatoes , excluding celeriac ⁽²⁷⁾ . For potatoes the maximum level applies to peeled potatoes.	0,10	0,05 - 0,10
3.2.17	Leaf vegetables and fresh herbs, leafy brassica , celeriac and the following fungi ⁽²⁷⁾ : <i>Agaricus bisporus</i> (common mushroom), <i>Pleurotus ostreatus</i> (Oyster mushroom), <i>Lentinula edodes</i> (Shiitake mushroom)	0,20	0,20
3.2.18	Fungi, excluding those listed in point 3.2.17 ⁽²⁷⁾	1,0	1,0
	Oilseeds, excl. poppy seeds, peanuts, soybeans (dry)	---	0,50
	Poppy seeds	---	1,0
3.2.19	Food supplements ⁽³⁹⁾ excl. food supplements listed in point 3.2.20	1,0	1,0
3.2.20	Food supplements ⁽³⁹⁾ consisting exclusively or mainly of dried seaweed, products derived from seaweed, or of dried bivalve molluscs	3,0	3,0
	Cocoa and chocolate products (as defined in Directive 2000/36/EC)	---	0,30

Please send any data on the levels of cadmium in the above foodstuffs. **The closing date for the data submissions on cadmium is 31 December 2009.**

We request your assistance in ensuring that the new limits will be set proportionately so that consumers are protected without placing an unnecessary burden on industry.

Cadmium levels in crab

This issue was also highlighted in the June 2009 letter. The maximum level of 0.5 mg/kg for crustaceans applies to the white meat of crab and excludes brown meat of crab and head and thorax meat of lobster and similar large crustaceans. The maximum limit does not apply to the brown meat as it is known that it has higher levels of cadmium compared to the white meat. However, there is concern that the safety limit for cadmium could be exceeded if the brown meat is also consumed particularly in the case of certain high-risk consumers.

Discussions are ongoing within the Commission regarding this. With a view to finding a solution in the longer term, the Commission has informed Member States that more data on different parts of crabs (white and brown meat) would be needed in order to complete the picture. The Commission therefore requested all the Member States to collect data on the different parts of the crabs separately. The percentage of the weight of different parts in relation to the weight of the total edible portion should be given. If analyses were already carried out in the past on the basis of composite samples (mixture of white and brown meat of crab), these results should be provided as well, but should clearly specify the sample portion that was used to establish the result. Results should be provided to the Commission by 1 February 2010 at the latest.

Please send data on the following **before 15 January 2010**.

- Cadmium levels in crabs (white meat, brown meat or mixed)
- Consumption data on crab

The **closing date for submission of data is 1 February 2010**. These data will be compiled and assessed to carry out refined exposure assessments and formulate the UK's position.

Summary of call for data on cadmium

Please send data on the levels of cadmium in the following foodstuffs:

- Offal
- Various fish species
- Crab (white, brown and mixed meat)
- Cereal grains
- Cereal products – bread, pasta, breakfast cereal, bran, germ
- Cereal-based foods for babies and young children
- Vegetables – particularly roots and tubers
- Oilseeds and nuts
- Cocoa, chocolate and chocolate products

Please send the data to Christina Baskaran Christina.Baskaran@foodstandards.gsi.gov.uk **before 31 December 2009**.

Data on cadmium levels in crab and consumption data on crab can be sent before **15 January 2010**.

ENVIRONMENTAL CONTAMINANTS (ORGANIC)

Discussions from the Expert Committee on POPs, 21 September and 16 November 2009.

Dioxins and dioxin-like PCBS

Guar gum from India

Other than a single border rejection by the Czech Republic in October 2008, there have been no reports of non-compliance with the provisions of Decision 2008/352/EC, and the Commission had expected to be in a position to repeal the Decision. However, during a recent FVO mission to India to check that the recommendations from the previous mission had been applied, significant concerns were found to remain. In particular, a legal framework for the use of pentachlorophenol and sodium pentachlorophenate had not been introduced, there was no system for matching test certificates to batches and the test laboratory in India was not reporting non-compliances to the Indian authorities, who were thus unable to investigate. The FVO found PCP test results of up to 1.5 mg/kg, compared with a limit of 0.01 mg/kg. If a batch contaminated at the higher level were to enter the food chain as a result of inadequate controls, it could cause a repeat of the original incident. Consequently, the Commission now intends to replace Decision 2008/352 with a new Regulation. Key provisions will include all test certificates from India being checked and certified by the Indian authorities and an increase in random testing of incoming consignments from 5% to 10%. The Regulation is expected to apply from April 2010.

Sheep Liver

Sheep liver is now subject to a temporary ban in several German Länder due to high rates of non-compliance with the current dioxin limit. The Commission is due to ask EFSA for a risk assessment. Negotiations to have the limit for dioxins in liver re-expressed on a whole weight basis are continuing and the Agency has commissioned further testing to provide additional supporting data.

Review of Dioxin and Dioxin-like PCB limits

New limits will be set on the basis of the 2005 WHO-TEFs. Applying these TEFs to existing data has the effect of reducing calculated TEQs by an average of about 15%, although any new limits will be established using actual data and probably targeting around the 97.5th percentile level for each food group.

The initial dataset to be used as the basis for deriving new limits for dioxins and total TEQ has been presented by EFSA. It indicates a number of food groups where a reduction of the existing limit appears feasible. The process is likely to be lengthy as all of the data will be examined in detail to ensure that no specific food sub-groups (such as individual species of fish) are inadvertently excluded. The Commission has stated that any additional data can be submitted during the negotiations so it is essential to have any new data as soon as possible, especially where a potential problem is indicated. It will be easier to make changes during negotiation rather than once new values have been finalised.

Non dioxin-like PCBs

The Commission has presented the outcome of its stakeholder consultation on the introduction of limits for non dioxin-like PCBs. Industry stakeholders had raised concerns, some of which had already been mentioned by committee delegates during previous

discussions. The industry responses also referred to data which was not, however, supplied. The Commission has asked to see it.

Issues still of concern include whether the milk limit will be achievable for individual farms and, if a separate limit is to be applied to freshwater fish, how it should be expressed. There is still concern about method performance criteria and analytical capabilities, particularly in relation to the ability of laboratories to achieve the necessary limit of quantification for pork, vegetable fat and infant foods. The Community Reference Laboratory has asked National Reference Laboratories to determine the capability and capacity of official control laboratories within their networks.

Despite the number of aspects that are yet to be resolved, the Commission has stated its intention to limit further debate to one more working group before putting a formal proposal to Standing Committee early in 2010.

The limits put forward for the stakeholder consultation are as follows:

Non dioxin-like PCB limits on food – current proposals

FOOD	MAXIMUM LEVELS SUM OF PCBs 28, 52, 101, 138, 153, 180
1. Meat and meat products (excluding edible offal) of the following animals — bovine animals and sheep — poultry — pigs	<i>30 ng/g fat 30 ng/g fat 15 ng/g fat</i>
2. Liver of terrestrial animals, referred to in 1 and derived products	<i>50 ng/g fat OR 2.0 ng/g fresh weight</i>
3a. Muscle meat of fish and fishery products except eel, excluding brown crab meat and head/thorax of lobster etc.	<i>75 ng/g fresh weight</i>
3b. Muscle meat of river fish	<i>200 ng/g fresh weight</i>
3c. Muscle meat and products of eel (<i>Anguilla anguilla</i>)	<i>300 ng/g fresh weight</i>
3d. Fish liver	<i>200 ng/g fresh weight</i>
4. Raw milk and dairy products, including butter fat	<i>25 ng/g fat</i>
5. Hen eggs and egg products	<i>75 ng/g fat</i>
6. Oils and fats - Fat of the following animals -- bovine animals and sheep -- poultry -- pigs - mixed animal fats - vegetable oil and fats - marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	<i>30 ng/g fat 30 ng/g fat 15 ng/g fat 30 ng/g fat 15 ng/g fat 200 ng/g fat</i>
7. Foods for infants and young children	<i>1.0 ng/g fresh weight</i>

Discussions from the Expert Committee on Environmental and Industrial Contaminants, 26 October 2009.

Emerging contaminants

Some brominated flame retardants (BFRs) and perfluorooctane sulphonate (PFOS) have been added to the list of chemicals of concern under the Stockholm Convention. The Commission has repeated its previous informal call for data on BFR levels in food and is considering a Recommendation for monitoring levels of PFOS and related compounds, which it hopes to have endorsed at a Standing Committee early in 2010.

Polycyclic Aromatic Hydrocarbons

Future regulations will be formulated around four PAHs: benzo(a)pyrene as at present, together with benz(a)anthracene, benzo(b)fluoranthene and chrysene. Discussions covered four separate issues. The first concerns how the limits should be expressed. The Commission favours maintaining individual limits for BaP, together with limits for the sum of the four, an approach that received some support but is not finalised. Secondly, the analytical criteria for official control methods need to be agreed for the three new compounds and will probably be the same as for BaP currently. Thirdly, there is the question of whether any new food groups should be added, in particular cereals and vegetables (which EFSA had identified as significant dietary sources), dried fruit, food supplements and beverages. Finally, there was a very brief discussion about possible changes to existing limits although progress will be limited until the basis for limits is agreed. The Commission is also considering a request for a permanent derogation for cocoa butter from the limit for vegetable oil.

Summary of calls for data

- Dioxins and PCBs in all currently-regulated food groups, particularly ovine and bovine liver
- Non-dioxin like PCBs, particularly in freshwater fish
- Brominated flame retardants, notably polybrominated diphenyl ethers (PBDEs) in any foods
- PFOS and related compounds in any foods
- PAHs, particularly in cocoa butter, cereals and cereal products, vegetables and vegetable products, directly smoked fish, dried fruit and supplements.

For further information or to submit comments or data relating to dioxins, PCBs and PAHs, please contact David Mortimer (020 72768731 / david.mortimer@foodstandards.gsi.gov.uk)

Process Contaminants

Experts Committee on Industrial and Environmental contaminants

At the meeting of the Expert Committee on the 26th October 2009 the following issues were raised.

- EFSA presented their findings on the acrylamide and furan monitoring carried out as a result of commission recommendation 2007/331/EC and 2007/196/EC on the monitoring of acrylamide and furan respectively for 2007

Acrylamide

EFSA concluded that there was no consistent trend to lower acrylamide levels across food groups. It was therefore not clear at this stage if the acrylamide CIAA toolbox had achieved its desired effect.

The Commission was considering risk management measures for acrylamide. Guidance levels, which will not be legal limits, are being considered. Further investigations including obtaining additional information about the production process, in cases where acrylamide levels exceed these guidance levels would be carried out. The 2008 report from EFSA is expected in February 2010. The Agency would welcome feedback from Industry on this issue.

Furan

From the data collected so far, the main exposure to furan for infants was from jarred baby foods and for adults it was from coffee. The majority of the data submitted was from products tested as sold rather than as prepared. More data is needed on furan in prepared products. EFSA has funded research on furan levels in cooked foods and a final report is due soon. Due to the lack of data and mitigation measures risk management for furan is presently not being considered. The Agency is inviting submission of data on furan levels in prepared foods to help inform risk assessments.

Ethyl carbamate

A draft recommendation for monitoring stone fruit spirits and fruit marc spirits for ethyl carbamate starting in 2010 for 3 years, has been agreed by EU member states and will go forward to the next standing committee for endorsement. The monitoring is being proposed to ensure that member states take the necessary measures to ensure that the code of practice on the prevention and reduction of ethyl carbamate in stone fruit and stone fruit marc spirits is implemented. The code of practice would be disseminated in the annex to the recommendation. It is proposed that levels of ethyl carbamate in these spirits should be as low as possible with the aim to achieve a level of 1mg/l as target. The Agency is inviting the submission of data on these products or on any other alcoholic beverage which might help inform risk assessments.

3-MCPD esters

EFSA has set up a database of on-going projects relating to 3-MCPD esters. The Agency has conducted monitoring of 3-MCPD esters in some of the samples purchased for the 2008 survey of process contaminants in food and a report would be published soon.

Other updates on acrylamide

ECHA (the European Chemicals Agency) in September 2009, issued a proposal to classify acrylamide as a substance of very high concern because of its potentially serious effect on human health as a category 2 carcinogen and mutagen.

The Canadian government after its assessment of acrylamide in February 2009 decided in August 2009 to add acrylamide to a list of toxic substances. Health Canada confirmed it had placed the substance onto Schedule 1 of the Canadian Environmental Protection Act, 1999 in order to minimise the public's exposure to the chemical which "*may pose a risk to human health*".

The US Food and Drug administration (FDA) is considering issuing guidelines on acrylamide content in food and is seeking comments from industry on the issue because of new emerging toxicological evidence about its potential health impacts from carcinogenicity studies in laboratory animals which could help form the basis of the new guidelines.

The current Food Standards Agency (FSA) policy, as previously, is that exposure to acrylamide should be as low as reasonably practicable (ALARP), since acrylamide is considered to be a genotoxic carcinogen in animals and probably carcinogenic in humans based on independent expert scientific advice, and guidance given by the risk assessment advice provided by JECFA (the Joint FAO/WHO Expert Committee on Food Additives) following their evaluation of acrylamide in 2005

Since acrylamide forms naturally in a wide variety of cooked foods, it is not possible to have a healthy balanced diet that avoids acrylamide. Therefore, the FSA advise remains the same i.e that people should not change their diets because of concern about acrylamide but should continue to eat a healthy balanced diet, including plenty of fresh fruits and vegetables, bread, rice, potatoes, pasta and other starchy foods, some meat, fish, eggs, beans, milk and dairy foods, and just a small amount of foods and drinks high in salt, fat and/or sugar (including chips and crisps)

For further information or to submit comments or data relating to acrylamide, furan and ethyl carbamate please contact Terry Donohoe (020 7276 8709 email: [@terry.donohoe@foodstandards.gsi.gov.uk](mailto:terry.donohoe@foodstandards.gsi.gov.uk))

Mycotoxins

Commission Regulation (EC) No. 1881/2006 as regards aflatoxins

The draft legal text amending Commission Regulation 1881/2006 was agreed and adopted at the Standing Committee meeting held on 15/16th October. As previously reported via our Interested Parties' letters, maximum limits for oilseeds are now incorporated in the text with limits of 2 ppb for aflatoxin B1 and 4 ppb for total aflatoxin. Oilseeds for further processing are also included with limits of 8 ppb and 15 ppb for aflatoxin B1 and total aflatoxin respectively. The limits for further processing do not apply for oilseeds and groundnuts for crushing for refined vegetable oil production; similarly the limits for direct human consumption for do not apply to crude vegetable oils destined for refining or refined vegetable oils.

The amendment to the Regulation also includes the revision of maximum limits for aflatoxin in hazelnuts, almonds and pistachios as agreed at Codex, (please note that separate maximum limits for B1 additionally apply in the EU and which the Commission has indicated will be subject to future review). The amendment also contains the updated limits for Brazil nuts, which are the same as for hazelnuts and the new limits for apricot kernels, which are the same as for almonds and pistachios.

New limits for rice intended for further processing are also included

It is anticipated that the amendment will come into force and apply early in the new year, 10 days after publication in the official journal of the EU although this is not likely to be before the end of January at the earliest. This Regulation shall not apply to apricot kernels,

oilseeds, other than groundnuts (peanuts) and processed products thereof, which were placed on the market at a date prior to the date of application of the amendment.

Commission Regulation (EC) No. 1881/2006 as regards ochratoxin A (OTA)

The draft text amending Commission Regulation (EC) No. 1881/2006 was agreed and adopted at the Standing Committee on the 28th September. The amendment includes a maximum limit for OTA in spices of 30 ppb, which will be applicable from 1 July 2010. In addition, from 1 July 2012, a level of 15 ppb will apply subject to a review by Member States of data supplied by interested parties in the interim as detailed in a new article (article 2) of the text.

Maximum limits for OTA in liquorice root (20 ppb) and liquorice extract (80ppb) are also included.

Transitional measures included in the Regulation mean that that the Regulation and new limits shall not apply to products which were placed on the market at a date prior to 1 July 2010.

Changes to Commission Decision No. 2006/504/EC

A new Regulation to replace Commission Decision No. 2006/504/EC was agreed and adopted at the Standing Committee on the 28th September. It is expected to come into force on the 1st of January 2010.

The new Regulation includes measures to align it with Commission Regulation (EC) No. 669/2009, as well as other changes that have been agreed. These include:

- Food business operators or their representatives must complete Part I of the common entry document (CED) referred to in Article 3 (a) of Commission Regulation (EC) 669/2009 at least one working day prior to the physical arrival of the consignment to give prior notification of the estimated date and time of physical arrival of the consignment at the first point of introduction and of the nature of the consignment;
- All costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the food business operator;
- Processed and compound foodstuffs are to be excluded below 20% inclusion rather than 10%;
- Consignments of foodstuffs not exceeding 20kg to be excluded, as opposed to the current 5kg.

The frequency of controls for some of the products have also been amended and are as follows:

- 100 % of consignments of in-shell Brazil nuts from Brazil;
- approximately 20 % of consignments of groundnuts from China;
- approximately 20 % of consignments of groundnuts from Egypt;
- approximately 50 % of consignments of pistachios from Iran;
- approximately 10 % of the consignments for each category of hazelnuts and derived products from Turkey, approximately 20 % of the consignments for each category of dried figs and derived products from Turkey and approximately 50 % of

- a random basis for consignments of almonds from the United States of America covered by the VASP, but each consignment of almonds from the United States of America not covered by the VASP

Measures for increased control for peanuts from Brazil have been moved to the annex to Commission Regulation (EC) No. 669/2009.

Amendment of Commission Regulation (EC) No. 401/2006

A draft Regulation amending Commission Regulation 401/2006 was agreed and adopted at Standing Committee on the 15/16th October. It includes new provisions for groundnuts/oilseeds, apricot kernels, liquorice and liquorice extract and vegetable oil as well as the agreed sampling plans agreed at Codex for hazelnuts, almonds and pistachios, which will be applicable to all nuts. The Regulation will come into force on the tenth day following that of its publication in the Official Journal of the European Union, which should be at the same time as both the amendments to 1881/2006.

The details in this letter are not exhaustive and interested parties are advised to familiarise themselves with the changes to the legislation by reading the adopted texts.

Deoxynivalenol (DON) in UK Cereal crops

The Agency has published an update on DON in UK wheat which can be found at www.food.gov.uk/foodindustry/farmingfood/fusarium/ and www.food.gov.uk/foodindustry/farmingfood/fusarium/don09.

Maximum limit for zearalenone (ZON) in high-fibre breakfast cereals

The temporary increase in the maximum limit for ZON for high-fibre breakfast cereals that was agreed at the Standing Committee meeting on 19th June due to high levels in the 2008 harvest expired on the 31st October. The background to this change can be found at www.food.gov.uk/multimedia/pdfs/enforcement/enfs09032.pdf.

Commission Decision 2009/835/EC Imposing Special Conditions On The Import Of Pears From Turkey.

This is to inform you that the Commission has published Commission Decision 2009/835/EC on emergency measures imposing special conditions on official controls governing the import of pears originating in or consigned from Turkey due to high residue levels of amitraz. The following URL will take you to the Decision: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:299:0015:0016:EN:PDF>

Decision 2009/835/EC has been implemented by means of Declaration OFFC/REG/2009/E/001 issued under Regulation 33 of the Official Feed and Food Controls (England) Regulations 2007 and this is attached as a pdf file. This took effect from 17 November 2009.

Decision 2009/835/EC requires Member States to carry out documentary, identity and physical checks, including laboratory analysis, on at least 10% of consignments of fresh pears falling, originating in or consigned from Turkey. Consignments shall be detained pending the availability of laboratory analysis results. These checks will take place on import at ports and airports.

Furthermore, the Decision requires that these products which are already on the market in Member States are also subject to the appropriate level of controls to ensure the maximum residue level (MRL) is not exceeded. Therefore inland Authorities are being asked to check the origin of pears already on the market at relevant businesses within their jurisdiction and, if necessary, submit samples for analysis as outlined below. This is particularly relevant for products already imported before these measures in Decision 2009/835/EC took effect.

These checks and controls shall ascertain that levels of amitraz do not exceed the Community MRL established under Regulation (EC) No 396/2005. The Decision is based on information received via the RASFF system which has indicated that high levels of amitraz have been found in consignments entering the EU on repeated occasions. The MRL for amitraz is 0.05 mg/kg and is equivalent to the Limit of Determination.

FSA support these emergency measures taken in order to safeguard the UK food supply. Based on the distribution information provided on RASFF notifications, none of the affected pears have been distributed to the UK market. However, we are aware that 2% of Turkish pear imports into the EU come to the UK. Given the severity of exceedances seen recently in certain samples of Turkish pear, we consider this action is warranted and proportionate.

Decision 2009/835/EC shall apply until 24 January 2010 whereupon the measures applying to the high-risk products listed in Annex I of Regulation (EC) No 669/2009 will come into effect. It is therefore important that action is taken before this end date.

If you require further information please contact Ranulf Barman by email (Ranulf.barman@foodstandards.gsi.gov.uk) or telephone 020 7276 8586.

Parallel declarations have been issued in Scotland and Wales under, respectively, the The Official Feed and Food Controls (Scotland) Regulations 2007 and under The Official Feed and Food Controls (Wales) Regulations 2007.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
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SANCO/06326/2009 – rev. 4
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Draft

COMMISSION REGULATION

of

**amending Regulation (EC) No 1881/2006 setting maximum levels for certain
contaminants in foodstuffs as regards aflatoxins**

(Text with EEA relevance)

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food¹, and in particular Article 2 (3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs² sets maximum levels for aflatoxin B1 and aflatoxin total (aflatoxin B1 + G1 + B2 + G2) in a range of foodstuffs.
- (2) It is necessary to amend certain maximum levels for aflatoxins in certain foodstuffs to take into account developments in Codex Alimentarius and new information contained in recent scientific advice.
- (3) Codex Alimentarius established a level of 15 µg/kg aflatoxin total in almonds, hazelnuts and pistachios intended for further processing and a level of 10 µg/kg aflatoxin total in almonds, hazelnuts and pistachios "ready-to-eat"³.
- (4) The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) adopted on 25 January 2007 an opinion on the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products⁴. The CONTAM Panel concluded that changing the maximum levels for total aflatoxins from 4 to 8 or 10 µg/kg in almonds, hazelnuts and pistachios would have minor effects on the estimates of dietary exposure, cancer risk and the calculated Margins of Exposure (MOEs). The Panel furthermore concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic. The data indicate that reduction of total

¹ OJ L 37, 13.2.1993, p. 1.

² OJ L 364, 20.12.2006, p. 5.

³ Codex General Standard for Contaminants and toxins in foods (CODEX STAN 193-1995) http://www.codexalimentarius.net/download/standards/17/CXS_193e.pdf

⁴ *The EFSA Journal* (2007) 446, 1-127. http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/CONTAM%20_op_ej446_aflatoxins_en.3.pdf?ssbinary=true

dietary exposure to aflatoxins could be achieved by reducing the number of highly contaminated foods reaching the market through more effective enforcement and reducing exposure from food sources other than almonds, hazelnuts and pistachios.

- (5) The CONTAM Panel adopted on 16 June 2009 a statement on the effects on public health of an increase of the levels for aflatoxin total from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios⁵. The Panel concluded that based on the information which was available in 2007 public health would not be adversely affected by increasing the levels for total aflatoxins from 4 µg/kg to 10 µg/kg for other tree nuts, including Brazil nuts. Given the current discussions in Codex Alimentarius on the maximum levels for aflatoxins in Brazil nuts, it is appropriate to align the level for aflatoxins in Brazil nuts with the Codex level for almonds, hazelnuts and pistachios.
- (6) Codex Alimentarius established only a maximum level for aflatoxin total. The corresponding aflatoxin B1 level was determined by making use of the database on occurrence of aflatoxins in food used by EFSA for the exposure assessment.
- (7) In the EFSA opinion on aflatoxins it is observed that oilseeds and derived products are an important contributor to the human aflatoxin exposure. EFSA concluded that exposure to aflatoxins from all sources should be as low as reasonably achievable. Furthermore, notifications in the Rapid Alert System for Food and Feed (RASFF) indicate high levels of aflatoxins in oilseeds such as sunflower seeds, melon seeds etc. It is therefore proposed to also set a maximum level for oilseeds other than groundnuts (peanuts), in line with the existing maximum levels for groundnuts (peanuts). However, as aflatoxins are nearly completely removed by the process for producing refined vegetable oils, it is appropriate to exclude oilseeds, including groundnuts (peanuts), intended for crushing for refined vegetable oil and refined vegetable oil.
- (8) A maximum level of 2 µg/kg for aflatoxin B1 and 4 µg/kg aflatoxin total has been established in all cereals and all products derived from cereals with the exception of maize to be subjected to sorting or other physical treatment before human consumption for which a maximum level of 5 µg/kg for aflatoxin B1 and 10 µg/kg for aflatoxin total has been established. Rice in husk regularly contains levels of aflatoxins slightly above the maximum levels. After milling, a process which removes the husk, the levels of aflatoxins in the white milled rice are below the maximum levels. It is therefore appropriate to apply the same approach for rice as the existing approach for maize, and to set a higher maximum level of aflatoxin B1 and aflatoxin total for rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs.
- (9) The maximum levels refer to the edible part of the tree nuts. However, recent scientific evidence has demonstrated that a part of the aflatoxin contamination can be found on the shell of Brazil nuts. Therefore, it is appropriate to modify the footnote in

⁵ Statement of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on the effects on public health of an increase of the levels for aflatoxin total from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios. *The EFSA Journal* (2009) 1168, 1-11. http://www.efsa.europa.eu/cs/BlobServer/Statement/contam_statement_ej1168_aflatoxin_other_treenuts_en.pdf?ssbinary=true

the Annex, indicating the procedure to be followed in case tree nuts "in shell" are analysed, to take into account this recent scientific information.

- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1881/2006 is amended as follows:

- (1) Article 4 is replaced by the following:

*"Article 4
Specific provisions for groundnut, other oilseeds, tree nuts, dried fruit, rice and
maize*

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

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

- (2) Article 5 is replaced by the following:

"Article 5

Specific provisions for groundnuts (peanuts), other oilseeds, derived products thereof and cereals

A clear indication of the intended use must appear on the label of each individual bag, box, etc. and on the original accompanying document. This accompanying document must have a clear link with the consignment by means of mentioning the consignment identification code, which is on each individual bag, box, etc. of the consignment. In addition the business activity of the consignee of the consignment given on the accompanying document must be compatible with the intended use.

In the absence of a clear indication that their intended use is not for human consumption, the maximum levels laid down in points 2.1.5 and 2.1.11 of the Annex shall apply to all groundnuts (peanuts), other oilseeds and derived products thereof and cereals placed on the market.

As regards the exception of groundnuts (peanuts) and other oilseeds for crushing and the application of the maximum levels laid down in point 2.1.1. of the Annex, the exception only applies to consignments which are clearly labelled showing their use and bearing the indication "product to be subject to crushing for the production of refined vegetable oil". The indication shall be included on the label of each individual bag, box etc. or on the accompanying document(s). The final destination must be a crushing plant."

- (3) The Annex is amended as follows:

(a) subsection 2.1 (Aflatoxins) is replaced by the text in the Annex to this Regulation.

(b) footnote 5 is replaced by the following:

"(5) The maximum levels refer to the edible part of groundnuts (peanuts) and tree nuts. If groundnuts (peanuts) and tree nuts "in shell" are analysed, it is assumed when calculating the aflatoxin content all the contamination is on the edible part, except in the case of Brazil nuts."

(c) the following footnotes are added:

(40) Oilseeds falling under codes CN 1201, 1202, 1203, 1204, 1205, 1206, 1207 and derived products CN 1208 - melon seeds fall under code ex 1207 99

(41) In case derived/ processed products thereof are derived/processed solely or almost solely from the tree nuts concerned, the maximum levels as established for the corresponding tree nuts apply also to the derived/processed products.

In other cases, Article 2 (1) and 2(2) apply for the derived/processed products."

Article 2

This Regulation shall not apply to apricot kernels, oilseeds, other than groundnuts (peanuts) and processed products thereof, which were placed on the market at a date prior to the date of application in conformity with the provisions applicable at such date.

The burden of proving when the products were placed on the market shall be borne by the food business operator.

Article 3

This Regulation shall enter into force on the tenth day following that of its publication in the Official Journal of the European Union.

It shall apply from the date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Foodstuffs ¹		Maximum levels (µg/kg)		
"2.1	Aflatoxins	B ₁	Sum of B ₁ , B ₂ , G ₁ and G ₂	M ₁
2.1.1	Groundnuts (peanuts) and other oilseeds ⁽⁴⁰⁾ , to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs with the exception of - groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production	8.0 ⁵	15.0 ⁵	-
2.1.2.	Almonds, pistachios and apricot kernels to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	12.0 ⁵	15.0 ⁵	-
2.1.3.	Hazelnuts and Brazil nuts, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8.0 ⁵	15.0 ⁵	
2.1.4	Tree nuts, other than the tree nuts listed in 2.1.2. and 2.1.3, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5.0 ⁵	10.0 ⁵	-
2.1.5	Groundnuts (peanuts) and other oilseeds ⁴⁰ and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of - crude vegetable oils destined for refining - refined vegetable oils	2.0 ⁵	4.0 ⁵	-
2.1.6.	Almonds, pistachios and apricot kernels, intended for direct human consumption or use as an ingredient in foodstuffs ⁴¹	8.0 ⁵	10.0 ⁵	-
2.1.7.	Hazelnuts and Brazil nuts, intended for direct human consumption or use as an ingredient in foodstuffs ⁴¹	5.0 ⁵	10.0 ⁵	
2.1.8.	Tree nuts, other than the tree nuts listed in 2.1.6. and 2.1.7, and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2.0 ⁵	4.0 ⁵	-
2.1.9	Dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5.0	10.0	-
2.1.10	Dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2.0	4.0	-
2.1.11	All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs listed in 2.1.12, 2.1.15 and 2.1.17	2.0	4.0	-

2.1.12	Maize and rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs	5.0	10.0	-
2.1.13	Raw milk ⁶ , heat-treated milk and milk for the manufacture of milk-based products	-	-	0.050
2.1.14	Following species of spices: <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) Mixtures of spices containing one or more of the abovementioned spices	5.0	10.0	-
2.1.15	Processed cereal-based foods and baby foods for infants and young children ^{3,7}	0.10	-	-
2.1.16	Infant formulae and follow-on formulae, including infant milk and follow-on milk ^{4,8}	-	-	0.025
2.1.17	Dietary foods for special medical purposes ^{9,10} intended specifically for infants	0.10	-	0.025"

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
SANCO/00875/2007 –rev 6
28/09/2009

Draft

COMMISSION REGULATION

of

**amending Regulation (EC) No 1881/2006 setting maximum levels for certain
contaminants in foodstuffs as regards ochratoxin A.**

(Text with EEA relevance)

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A.

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006² sets maximum levels for certain contaminants in foodstuffs.
- (2) The Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) has, on a request from the Commission, adopted on 4 April 2006 an updated scientific opinion relating to ochratoxin A (OTA) in food³, taking into account new scientific information and derived a tolerable weekly intake (TWI) of 120 ng/kg b.w.
- (3) It is foreseen in Regulation (EC) No 1881/2006 that the appropriateness of setting a maximum level for OTA in foodstuffs such as dried fruit other than dried vine fruit, cocoa and cocoa products, spices, meat products, green coffee, beer and liquorice, as well as a review of the existing maximum levels, in particular for OTA in dried vine fruit and grape juice, has to be considered in the light of the recent EFSA scientific opinion.

¹ OJ L 37, 13.2.1993, p. 1.

² OJ L 364, 20.12.2006, p. 5.

³

http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_opinions/1521.Par.0001.File.dat/contam_op_ej365_ochratoxin_a_food_en1.pdf

- (4) On the basis of the opinion adopted by EFSA, the existing maximum levels appear appropriate to protect public health and have to be retained. As regards the foodstuffs not yet covered by Regulation (EC) 1881/2006, it was considered necessary and appropriate for the protection of public health to establish maximum levels for ochratoxin A in those foodstuffs that are a significant contributor to the exposure of OTA (for the whole population, or for vulnerable group of the population, or for significant part of the population) or for those foodstuffs that are not necessarily a significant contributor to the exposure of OTA, but there is evidence that there can be found a very high levels of OTA in these commodities. A maximum level is appropriate to be set in these cases to avoid that those very highly contaminated commodities could enter the food chain.
- (5) On the basis of the information available, it does not appear necessary for the protection of public health to set a maximum level of OTA in dried fruit other than dried vine fruit, cocoa and cocoa products, meat products, including edible offal and blood products and liqueur wines as they are not a significant contributor to OTA exposure or no very high levels of OTA has been found in those commodities to a significant extent. In the case of green coffee and beer, the presence of OTA is already controlled at another more appropriate stage of the production chain (respectively roasted coffee and malt).
- (6) Very high levels of OTA have been observed at several occasions in spices and liquorice. It is therefore appropriate to set a maximum level for spices and liquorice.
- (7) There is recent evidence that in some main producing countries of spices exporting to the Community no prevention measures and official controls are in place to control the presence of ochratoxin A in spices. In order to protect public health, it is appropriate to establish without delay a maximum level for ochratoxin A in spices. To enable the producing countries to put prevention measures in place and not to disrupt trade to an unacceptable extent, a higher maximum level, applicable within short notice, is established for a limited period of time, before the maximum level reflecting the level achievable by applying good practices enters into application. It is appropriate that an assessment of the achievability in the different producing regions in the world of the levels for ochratoxin A by applying good practices takes place before the stricter level applies.
- (8) It is appropriate to continue the monitoring of OTA in foodstuffs for which no maximum level has been set and in the case of regular findings of unusually high levels of OTA, setting of a maximum level for OTA in those foodstuffs might be considered as appropriate.
- (9) Regulation (EC) 1881/2001 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended as follows:

(1) point 2.2.11 is replaced by the following points:

<p>"2.2.11 Spices</p> <p><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)</p> <p>Mixtures of spices containing one or more of the abovementioned spices</p>	<p>30 µg/kg as from 01.07.2010 until 30.06.2012</p> <p>15 µg/kg as from 01.07.2012</p>
<p>2.2.12. Liquorice (<i>Glycyrrhiza glabra</i>, <i>Glycyrrhiza inflata</i> and other species)</p> <p>2.2.12.1 Liquorice root, ingredient for herbal infusion</p> <p>2.2.12.2 Liquorice extract (*), for use in food in particular beverages and confectionary</p>	<p>20 µg/kg</p> <p>80 µg/kg "</p>

(2) The following footnote is added :

"(42) The maximum level applies to the pure and undiluted extract, obtained whereby 1 kg of extract is obtained from 3 to 4 kg liquorice root)."

Article 2

Interested parties shall communicate to the Commission the results of investigations undertaken including occurrence data and the progress with regard to the application of prevention measures to avoid contamination by ochratoxin A in spices.

Member States should report to the Commission findings on ochratoxin A in spices on a regular basis.

The Commission will make this information available to the Member States in view of an assessment, before the stricter level applies, of the achievability in the different producing regions in the world of the stricter level for ochratoxin A in spices by applying good practices.

Article 3

This Regulation shall not apply to products which were placed on the market at a date prior to 1 July 2010 in conformity with the provisions applicable at such date.

The maximum level for ochratoxin A established in point 2.2.11 of the Annex which is applicable as from 1 July 2012 shall not apply to products which were placed on the market at a date prior to 1 July 2012 in conformity with the provisions applicable at such date.

The burden of proving when the products were placed on the market shall be borne by the food business operator.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission
Androulla VASSILIOU
Member of the Commission

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SANCO/06370/2009 –R1

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
SANCO/06370/2009 –R1
28-09-2009

Draft

COMMISSION REGULATION

of

imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC

(Text with EEA relevance)

Draft

COMMISSION REGULATION

of [...]

imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 safety¹, and in particular Article 53(1)(b)(ii) thereof,

Whereas:

- (1) Commission Decision 2006/504/EC of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins², has been amended substantially several times. It is necessary to amend again certain provisions substantially to take into account particularly developments as regards aflatoxin contamination of certain products covered by that Decision. At the same time, the provisions have a direct application and are binding in their entirety, therefore Decision 2006/504/EC should be replaced by this Regulation.
- (2) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs³ lays down permitted maximum levels of aflatoxins in foodstuffs for the protection of public health. It can be observed that these maximum levels of aflatoxins are frequently exceeded in certain foodstuffs from certain countries. Such contamination constitutes a serious threat to public health within the Community and it is therefore appropriate to adopt special conditions at the Community level.

¹ OJ L 31, 1.2.2002, p. 1.

² OJ L 199, 21.7.2006, p. 21.

³ OJ L 364, 20.12.2006, p. 5.

- (3) For the protection of public health it is important that compound foodstuffs containing to a significant amount the foodstuffs covered by this Regulation are also within the scope of this Regulation. To facilitate the enforcement of controls of processed and compound foodstuffs whilst maintaining a high level of effectiveness of controls, it is appropriate to increase the threshold for control of compound products. For the same reason, the limit of 5 kg for consignments falling out of scope should be increased to 20 kg. Competent authorities may control at random for the presence of aflatoxins the compound foodstuffs containing less than 20 % of foodstuffs covered by this Regulation. When monitoring data indicate that compound foodstuffs containing less than 20 % of foodstuffs covered by this Regulation have been found in several cases to be non-compliant with the Community legislation on maximum levels for aflatoxins, these thresholds should be reviewed.
- (4) The Combined Nomenclature (CN) code has changed for certain food categories covered by this Regulation. It is appropriate to change the CN codes in this Regulation accordingly.
- (5) Experience has shown that the additional conditions for non compliant shipments of unshelled Brazil nuts imported from Brazil are no longer necessary, since such shipments can be handled in accordance with the general provisions for non compliant shipments and those additional conditions should therefore be repealed. As regards the imports of foodstuffs from the United States of America, since the transitional provisions for non-USDA approved laboratories for aflatoxin analysis are no longer needed, those transitional provisions should be repealed. .
- (6) Commission Regulation (EC) 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC⁴ provides for the use of a Common Entry Document for prior notification of arrival of consignments and information on the official checks performed. It is appropriate to provide for the use of that document and to lay down specific guidance notes for the completion thereof in application of this Regulation.
- (7) In the light of the number and nature of notifications in the Rapid Alert System for Food and Feed, trade volumes, the outcome of inspections of the Food and Veterinary Office and the outcome of controls, the existing control frequencies should be reviewed.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁴ OJ L 194, 25.7.2009, p. 11.

HAS ADOPTED THIS REGULATION:

Article 1
Scope

1. This Regulation shall apply to the import of the following foodstuffs and of the foodstuffs processed and compound thereof:
 - (a) The following foodstuffs originating in or consigned from Brazil:
 - (i) Brazil nuts in shell falling within category CN code 0801 21 00;
 - (ii) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing Brazil nuts in shell;
 - (b) The following foodstuffs originating in or consigned from China:
 - (i) groundnuts falling within CN code 1202 10 90 or 1202 20 00;
 - (ii) groundnuts falling within CN code 2008 11 91 (in immediate packings of a net content exceeding 1 kg) or 2008 11 98 (in immediate packings of a net content not exceeding 1 kg);
 - (iii) roasted groundnuts falling within CN codes 2008 11 91 (in immediate packings of a net content exceeding 1 kg) or 2008 11 96 (in immediate packings of a net content not exceeding 1 kg);
 - (c) The following foodstuffs originating in or consigned from Egypt:
 - (i) groundnuts falling within CN code 1202 10 90 or 1202 20 00;
 - (ii) groundnuts falling within CN code 2008 11 91 (in immediate packings of a net content exceeding 1 kg) or 2008 11 98 (in immediate packings of a net content not exceeding 1 kg);
 - (iii) roasted groundnuts falling within CN codes 2008 11 91 (in immediate packings of a net content exceeding 1 kg) or 2008 11 96 (in immediate packings of a net content not exceeding 1 kg);
 - (d) The following foodstuffs originating in or consigned from Iran:
 - (i) pistachios falling within CN code 0802 50 00;
 - (ii) roasted pistachios falling within CN codes 2008 19 13 (in immediate packings of a net content exceeding 1 kg) and 2008 19 93 (in immediate packings of a net content not exceeding 1 kg);
 - (e) The following foodstuffs originating in or consigned from Turkey:
 - (i) dried figs falling within CN code 0804 20 90;

- (ii) hazelnuts (*Corylus* spp.) in shell or shelled falling within CN code 0802 21 00 or 0802 22 00;
 - (iii) pistachios falling within CN code 0802 50 00;
 - (iv) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing figs, hazelnuts or pistachios;
 - (v) fig paste, pistachio paste and hazelnut paste falling within CN codes 1106 30 90, 2007 10 or 2007 99;
 - (vi) hazelnuts, figs and pistachios, prepared or preserved, including mixtures falling within CN code 2008 19;
 - (vii) flour, meal and powder of hazelnuts, figs and pistachios falling within CN code 1106 30 90;
 - (viii) cut, sliced and broken hazelnuts falling within CN 0802 22 00 and 2008 19;
- (f) The following foodstuffs originating in or consigned from the United States of America, which are covered by the Voluntary Aflatoxin Sampling Plan set up by the Almond Board of California in May 2006 (the Voluntary Aflatoxin Sampling Plan):
- (i) almonds in shell or shelled falling within CN code 0802 11 or 0802 12;
 - (ii) roasted almonds falling within CN codes 2008 19 13 (in immediate packings of a net content exceeding 1 kg) and 2008 19 93 (in immediate packings of a net content not exceeding 1 kg);
 - (iii) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing almonds;
- (g) The following foodstuffs imported from the United States of America, which are not covered by the Voluntary Aflatoxin Sampling Plan:
- (i) almonds in shell or shelled falling within CN code 0802 11 or 0802 12;
 - (ii) roasted almonds falling within CN codes 2008 19 13 (in immediate packings of a net content exceeding 1 kg) and 2008 19 93 (in immediate packings of a net content not exceeding 1 kg);
 - (iii) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing almonds.
2. Paragraph 1 shall not apply to consignments of foodstuffs of a gross weight not exceeding 20 kg, or to processed or compound foodstuffs containing the foodstuffs referred to in points (b) to (g) of paragraph 1 in a quantity below 20 %.

Article 2
Definitions

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 and in Article 2 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004⁵ shall apply.

In addition, the following definitions shall apply:

- (a) 'designated points of import' means any point designated by the competent authority, through which the foodstuffs referred to in Article 1 may be imported into the Community;
- (b) 'first point of introduction' means the point of first physical introduction of a consignment into the Community.

Article 3
Import into the Community

Consignments of foodstuffs referred to in Article 1 (hereafter referred to as foodstuffs), may only be imported into the Community in accordance with the procedures laid down in this Regulation.

Article 4
Health certificate and results of sampling and analysis

1. Foodstuffs presented for import into the Community shall be accompanied by the results of sampling and analysis and a health certificate in accordance with the model set out in Annex I, completed, signed and verified by an authorised representative of:
 - (a) the Ministério da Agricultura, Pecuária e Abastecimento (MAPA) for foodstuffs from Brazil;
 - (b) the State Administration for Entry-Exit inspection and Quarantine of the People's Republic of China for foodstuffs from China;
 - (c) the Egyptian Ministry of Agriculture for foodstuffs from Egypt;
 - (d) the Iranian Ministry of Health for foodstuffs from Iran;
 - (e) the General Directorate of protection and Control of the Ministry of Agriculture and Rural Affairs of the Republic of Turkey for foodstuffs from Turkey;
 - (f) the United States Department of Agriculture (USDA) for foodstuffs from the United States of America.

⁵ OJ L 165, 30.4.2004, p. 1.

2. The health certificates shall be drawn up in an official language of the exporting country and in an official language of the importing Member State.

The competent authorities concerned may decide to use any other language understandable for certifying officers or control officials concerned.

3. The health certificate provided for in paragraph 1 shall only be valid for imports of foodstuffs into the Community not later than four months from the date of issue.
4. The sampling and the analysis referred to in paragraph 1 must be performed in accordance with Commission Regulation (EC) No 401/2006 of 23 February 2006⁶ or equivalent.
5. Each consignment of foodstuffs shall be identified with a code which corresponds to the code on the results of the sampling and analysis and the health certificate referred to in paragraph 1. Each individual bag, or other packaging form, of the consignment shall be identified with that code.
6. By way of derogation from paragraphs 1, consignments of foodstuffs referred to in Article 1(1)(g) may be imported into the Community without being accompanied by the results of sampling and analysis and a health certificate.

Article 5

Prior notification of consignments

Food business operators or their representatives shall give prior notification of the estimated date and time of physical arrival of the consignment at the first point of introduction and of the nature of the consignment.

For that purpose, they shall complete Part I of the common entry document (CED) referred to in Article 3 (a) of Commission Regulation (EC) 669/2009 of 24 July 2009⁷ and transmit that document to the competent authority at the first point of introduction, at least one working day prior to the physical arrival of the consignment.

For the completion of the CED in application of this Regulation, food business operators shall take into account the notes for guidance laid down in Annex II .

Article 6

Designated points of import

1. The competent authorities in Member States shall ensure that the designated point of import comply with following requirements:
 - (a) the presence of trained staff to perform official controls on consignments of foodstuffs;

⁶ OJ L 70, 9.3.2006, p. 12.

⁷ OJ L 194, 25.7.2009, p. 11.

- (b) the availability of detailed instructions regarding sampling and the sending of the samples to the laboratory, in accordance with provisions in Annex I of Regulation (EC) No 401/2006;
 - (c) the possibility to perform the unloading and the sampling in a sheltered place at the designated point of import; it must be possible to place the consignment of the foodstuffs under the official control of the competent authority from the designated point of import onwards in cases where the consignment has to be transported in order to perform the sampling;
 - (d) the availability of storage rooms, warehouses to store detained consignments of foodstuffs in good conditions while awaiting the results of analysis;
 - (e) the availability of unloading equipment and appropriate sampling equipment;
 - (f) the availability of an official laboratory for aflatoxin analysis, situated at a place to which the samples can be transported within a short period of time and which is able to perform the analysis within a due time-limit.
2. The Member States shall maintain and make publicly available an up-to-date list of the designated points of import. The Member States shall communicate them to the Commission.
 3. Food business operators shall ensure the unloading of the consignment of foodstuffs necessary for representative sampling to take place.

In the case of special transport or specific packaging forms, the operator shall make available to the official inspector the appropriate sampling equipment insofar as the sampling cannot be representatively performed with the usual sampling equipment.

Article 7 *Official controls*

1. All official controls before the acceptance for release for free circulation into the Community and completion of the common entry document shall be performed within 15 working days from the moment the consignment is offered for import and physically available for sampling at the designated point of import.
2. The competent authority at the first point of introduction shall ensure that the foodstuffs intended for import into the Community are subject to documentary checks to ensure that the requirements for the results of sampling and analysis and the health certificate provided for in Article 4 are complied with.

Where a consignment of foodstuffs is not accompanied by the results of sampling and analysis and the health certificate provided for in Article 4 (1), the consignment may not enter the Community for import into the Community and must be re-dispatched to the country of origin or destroyed.

3. The competent authority at the first point of introduction shall authorise transfer of the consignment to a designated point of import after favourable completion of the

checks referred to in paragraph 2. The original certificate shall accompany the consignment during transfer.

4. The competent authority at the designated point of import shall take a sample for analysis of aflatoxin B1 and total aflatoxin contamination on certain consignments with a frequency indicated in paragraph 5 and in accordance with Annex I of Regulation (EC) No 401/2006 before release for free circulation into the Community.
5. The sampling for analysis referred to in paragraph 4 shall be carried out on:
 - (a) 100 % of the consignments of foodstuffs from Brazil;
 - (b) approximately 20 % of the consignments of foodstuffs from China;
 - (c) approximately 20 % of the consignments of foodstuffs from Egypt;
 - (d) approximately 50 % of the consignments of foodstuffs from Iran;
 - (e) approximately 10 % of the consignments for each category of hazelnuts and derived products from Turkey referred to in Article 1(1) (e)(ii) and (iv) to (viii), approximately 20 % of the consignments for each category of dried figs and derived products from Turkey referred to in Article 1(1) (e)(i) and (iv) to (vii) and approximately 50 % of the consignments for each category of pistachios and derived products from Turkey referred to in Article 1(1) (e)(iii) to (vii);
 - (f) a random basis for consignments of foodstuffs from the United States of America, referred to in Article 1(1)(f);
 - (g) each consignment of foodstuffs from the United States of America referred to in Article 1(1)(g).
6. After completion of the checks, the competent authorities shall, for checks carried out by them,
 - (a) complete the relevant part of Part II of the common entry document (CED);
 - (b) join the results of sampling and analysis;
 - (c) stamp and sign the original of the CED;
 - (d) make and retain a copy of the signed and stamped CED.

For the completion of the CED in application of this Regulation, the competent authority shall take into account the notes for guidance laid down in Annex II.

7. The original of the CED shall accompany the consignment during its transfer until it is released for free circulation.
8. The release for free circulation of consignments shall be subject to the presentation by the feed and food business operator or their representative to the custom authorities of a common entry document or its electronic equivalent duly completed

by the competent authority once all official controls have been carried out and favourable results from physical checks, where such checks are required, are known.

9. Member States shall submit to the Commission every three months a report of all analytical results of official controls on consignments of foodstuffs. That report shall be submitted during the month following each quarter.

Article 8
Splitting of a consignment

Consignments shall not be split until all official controls have been completed, and the CED has been fully completed by the competent authorities as provided for in Article 7.

In the case of subsequent spitting of the consignment, an authenticated copy of the CED shall accompany each part of the consignment until it is released for free circulation.

Article 9
Additional conditions as regards imports of foodstuffs from the United States of America

1. As regards imports from the United States of America, the analysis referred to in Article 4(1) must be performed by an USDA approved laboratory for aflatoxin analysis.
2. The health certificate referred to in Article 4(1) accompanying consignments of foodstuffs referred to in Article 1(1)(f) shall make a reference to the Voluntary Aflatoxin Sampling Plan.

Article 10
Costs

All costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the food business operator.

Article 11
Repeal

Decision 2006/504/EC is hereby repealed.

References to the repealed Decision shall be construed as references to this Regulation.

Article 12
Transitional provisions

By way of derogation from Article 4 (1), Member States shall authorise the imports of consignments of foodstuffs referred to in Article 1(1) which left the country of origin prior to [1 July 2010] accompanied by a health certificate as provided for by Decision 2006/504/EC.

Article 13
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from [1 January 2010].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission
[...]
Member of the Commission

ANNEX I

Health Certificate for the importation into the European Community of

.....*

Consignment Code **Certificate Number**

According to the provisions of Commission Regulation (EC) NNN/2009 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins and repealing Commission Decision 2006/504/EC, the

.....

..... (competent authority referred to in Article 4 (1))

CERTIFIES that the

..... (insert foodstuffs referred to in Article 1)

of this consignment composed of:

.....

..... (description of consignment, product, number and type of packages, gross or net weight)

embarked at (embarkation place)

by (identification of transporter)

going to (place and country of destination)

which comes from the establishment

..... (name and address of establishment)

have been produced, sorted, handled, processed, packaged and transported in line with good hygiene practices.

From this consignment, samples were taken in accordance with Commission Regulation (EC) No 401/2006 on (date), subjected to laboratory analysis on

(date) in the

(name of laboratory), to determine the level of aflatoxin B1 and level of total aflatoxin contamination.

The details of sampling, methods of analysis used and all results are attached.

This certificate is valid until

Done at on.....

Stamp and signature of
authorised representative of competent authority referred to in Article 4 (1)

.....
* Product and country of origin.

Annex II

Notes for guidance for the CED in case of foodstuffs imported from certain third countries due to contamination of these products by aflatoxins in application of this Regulation.

General: For the use of the CED in application of this Regulation, whenever "DPE" is mentioned, this should be read as "first point of entry" or "designated point of import" as stipulated in the specific notes for each box. Whenever "control point" is mentioned, this should be read as "designated point of import".

Complete the document in capital letters. Notes are shown against the relevant box number.

Part I **This section is to be completed by the food business operator or their representative, unless otherwise indicated.**

Box I.1. Consignor: name and full address of the natural or legal person (food business operator) dispatching the consignment. Information on telephone and fax numbers or email address is recommended.

Box I.2. All three fields in this box are to be filled in by the authorities of the designated point of import as defined in Article 2. Attribute a CED reference number in the first box. Indicate the name of the designated point of import and its number respectively in the second and third box.

Box I.3. Consignee: indicate name and full address of the natural or legal person (food business operator) to whom the consignment is destined. Information on telephone and fax numbers or email address is recommended.

Box I.4. Person responsible for the consignment: (also agent, declarant or food business operator) indicate name and full address of the person who is in charge of the consignment when presented to the first point of introduction and makes the necessary declarations to the competent authorities on behalf of the importer. Information on telephone and fax numbers or email address is recommended.

Box I.5. Country of origin: indicate the country where the commodity is originating from, grown, harvested or produced.

Box I.6. Country from where consigned: indicate the country where the consignment was placed aboard the means of final transport for the journey to the Community.

Box I.7. Importer: indicate name and full address. Information on telephone and fax numbers or email address is recommended.

Box I.8. Place of destination: indicate delivery address in the Community. Information on telephone and fax numbers or email address is recommended.

Box I.9. Arrival at the DPE (estimated date): give the estimated date on which the consignment is expected to arrive at the first point of introduction.

- Box I.10. Documents: indicate the date of issue and the number of official documents accompanying the consignment, as appropriate.
- Box I.11. Means of transport: tick the box to indicate the means of arrival transport.
- Identification: give full details of the means of transport. For aircraft, indicate the flight number. For vessels, indicate the ship's name. For road vehicles: indicate the registration number plate with trailer number if appropriate. For railway transport: indicate the train identity and wagon number.
- Documentary references: number of airway bill, bill of lading or commercial number for railway or truck.
- Box I.12. Description of the commodity: provide a detailed description of the commodity using the terminology in Article 1.
- Box I.13. Commodity code (HS code): use the Harmonized System of the World Customs Organization.
- Box I.14. Gross weight: specify overall weight in kg or tonnes. This is defined as the aggregate mass of the products and of the immediate containers and all their packaging, but excluding transport containers and other transport equipment.
- Net weight: specify weight of actual product in kg or tonnes, excluding packaging. This is defined as the mass of the products themselves without immediate containers or any packaging.
- Box I.15. Number of packages: specify the number of packages in the consignment.
- Box I.16. Temperature: tick the appropriate mode of transport/storage temperature.
- Box I.17. Type of packaging: identify the type of packaging of products.
- Box I.18. Commodity intended for: tick the appropriate box depending on whether the commodity is destined for human consumption without prior sorting or other physical treatment (in this case tick "human consumption") or is intended for human consumption after such treatment (tick "further process" in this case), or is intended for use as "feedingstuff" (in this case tick "feedingstuffs"). In the latter case the provisions of this Regulation do not apply.
- Box I.19. Seal number and container number: give all seal and container identification numbers where relevant.
- Box I.20. For transfer to Control Point: in case the consignment is intended for import (cf. Box I.22), tick the box and identify the designated point of import.
- Box I.21. Not applicable.
- Box I.22. For import: tick the box in case the consignment is intended for import.
- Box I.23. Not applicable.

Box I.24. Means of transport to Control Point: tick the appropriate means of transport used for transfer to the designated point of import.

Part II **This section is to be completed by the competent authority.**

General: Box II.1 is to be completed by the competent authority of the designated point of import. Boxes II.2 till II.9 are to be completed by the authorities responsible for the documentary control. Boxes II.10. till II.21 are to be completed by the competent authorities of the designated point of import.

Box II.1. CED Reference number: use the same CED reference number as in Box I.2.

Box II.2. Customs Document Reference: for use by customs services if necessary.

Box II.3. Documentary Check: to be completed for all consignments.

Box II.4. Consignments selected for physical checks: not applicable in the framework of this Regulation.

Box II.5. ACCEPTABLE for transfer: in case the consignment is acceptable for transfer to a designated point of import following a satisfactory documentary check, the competent authority at the first point of introduction shall tick the box and indicate to which designated point of import the consignment shall be transferred for a possible physical check (following information given in Box I.20).

Box II.6. NOT ACCEPTABLE: in case the consignment is not acceptable for transfer to a designated point of import due to the unsatisfactory outcome of the documentary checks, the competent authority at the first point of introduction shall tick the box and indicate clearly the action to be carried out in case of rejection of the consignment. The address of the destination establishment in case of 'Re-dispatching', 'Destruction', 'Transformation' and 'Use for other purpose' should be entered in Box II.7.

Box II.7. Details of Controlled Destinations (II.6): indicate as appropriate approval number and address (or ship's name and port) for all destinations where further control of the consignment is required, for example for Box II.6, 'Re-dispatching', 'Destruction', 'Transformation' or 'Use for other purpose'.

Box II.8. Full identification of DPE and official stamp: indicate here the full identification of the first point of introduction and the official stamp of the competent authority at this point.

Box II.9. Official inspector: signature of the official responsible of the competent authority at the first point of introduction.

Box II.10. Not applicable.

Box II.11. Identity Check: tick the boxes to indicate whether the identity checks have been performed and with which results.

Box II.12. Physical Check: indicate here the results of the physical checks.

Box II.13. Laboratory tests: tick the box to indicate whether the consignment has been selected for sampling and analysis

Tested for: indicate for which (aflatoxin B1 and/or total) and by which analytical method a laboratory test is carried out.

Results: indicate the results of the laboratory test and tick the appropriate box.

Box II.14. ACCEPTABLE for release for free circulation: tick the box in case the consignment is to be released for free circulation within the Community.

Tick one of the boxes ("Human consumption", "Further process", "Feedingstuff" or "Other") to indicate the further use.

Box II.15. Not applicable.

Box II.16. NOT ACCEPTABLE: tick the box in case of rejection of the consignment due to the unsatisfactory outcome of the identity or physical checks.

Indicate clearly the action to be carried out in such case by ticking one of the boxes ("Re-dispatching", "Destruction", "Transformation" or "Use for other purpose"). The address of the establishment of destination shall be entered in Box II.18.

Box II.17. Reasons for refusal: tick the appropriate box. Use as appropriate to add relevant information.

Box II.18. Details of controlled destinations (II.16): give as appropriate approval number and address (or ship's name and port) for all destinations where further control of the consignment is required following information indicated in Box II.16.

Box II.19. Consignment resealed: use this box when the original seal recorded on a consignment is destroyed on opening the container. A consolidated list of all seals that have been used for this purpose must be kept.

Box II.20. Full identification of DPE/Control Point and official stamp: put here the full identification of the designated point of import and the official stamp of the competent authority at the designated point of import.

Box II.21. Official Inspector: put name (in capital letters), date of issuing and signature of the official responsible of the competent authority at the designated point of import.

Part III **This section is to be completed by the competent authority.**

Box III.1. Details on re-dispatching: the competent authority at the first point of entry or at the designated point of import indicates the means of transport used, its identification, the country of destination and the date of re-dispatching, as soon as they are known.

Box III.2. Follow-up: indicate the local competent authority unit responsible, as appropriate, for the supervision in case of "Destruction", "Transformation" or

"Use for other purpose" of the consignment. This competent authority shall report here the result of the arrival of the consignment and the correspondence.

Box III.3. Official Inspector: signature of the official responsible for the competent authority at the DPI in case of "Re-dispatching". Signature of the official responsible for the local competent authority in case of "Destruction", "Transformation" or "Use for other purpose".

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

SANCO/06327/2009 – rev. 3
version clean 15-10-2009

Draft

COMMISSION REGULATION (EC)

of [...]

**amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds,
tree nuts, apricot kernels, liquorice and vegetable oil.**

(Text with EEA relevance)

Draft

COMMISSION REGULATION (EC) of [...]

amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil.

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹, in particular Article 11 (4)

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs² provides for maximum limits for certain mycotoxins in certain foodstuffs.
- (2) Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are very heterogeneously distributed in a lot. It is therefore necessary to fix general criteria which the sampling method should comply with.
- (3) 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 foodstuffs³ establishes the criteria for the sampling for the control of the levels of mycotoxins.
- (4) It is necessary to amend certain provisions for sampling aflatoxins in certain foodstuffs to take into account developments in Codex Alimentarius and to take into account recently established maximum levels of mycotoxins for new categories of foodstuffs.
- (5) Codex Alimentarius established a new sampling plan for groundnuts (peanuts), almonds, hazelnuts and pistachios intended for further processing and a new sampling plan for almonds, hazelnuts and pistachios "ready-to-eat"⁴.
- (6) To facilitate the enforcement of the maximum levels of aflatoxins, it is appropriate to apply the sampling provisions as provided for by Codex Alimentarius for peanuts, almonds, hazelnuts and pistachios intended for further processing as well as to other tree nuts which are intended for further processing and the sampling provisions as provided for by Codex for almonds, hazelnuts and pistachios "ready-to-eat" to other tree nuts and groundnuts (peanuts) "ready-to-eat". The sampling procedure for tree

¹ OJ L 165, 30.4.2004, p. 1.

² OJ L 364, 20.12.2006, p. 5.

³ OJ L 70, 9.3.2006, p. 12

⁴ Codex General Standard for Contaminants and toxins in foods (CODEX STAN 193-1995) http://www.codexalimentarius.net/download/standards/17/CXS_193e.pdf

nuts should also be applied to apricot kernels. Part D of the Annex should therefore be amended accordingly to provide only for the sampling procedure for dried figs which should remain unchanged and the new sampling procedure for groundnuts (peanuts), other oilseeds, apricot kernels, tree nuts should be provided in a separate Part of the Annex.

- (7) Maximum levels have been established for aflatoxins in oilseeds other than groundnuts (peanuts) and for ochratoxin A in spices, liquorice root and liquorice extract [reference to the two relevant new regulations]. It is appropriate to provide for specific sampling provisions for these new categories of foodstuffs and to refer to existing provisions where applicable.
- (8) The sampling of vegetable oils for the control of mycotoxins has specific characteristics and it is therefore appropriate to provide for specific sampling rules.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 401/2006 is amended as follows:

- (1) Part D is replaced by the text set out in Annex I to this Regulation.
- (2) In Part E, the first sentence is replaced by the following:
"This method of sampling is of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices."
- (3) Part G is replaced by the text set out in Annex II to this Regulation.
- (4) A Part K, as set out in Annex III to this Regulation, is added.

Article 2

This Regulation shall enter into force on the tenth day following that of its publication in the Official Journal of the European Union.

It shall apply from the date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

"D.1. METHOD OF SAMPLING FOR DRIED FIGS

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in dried figs.

D.1. Weight of the incremental sample

The weight of the incremental sample shall be about 300 grams, unless otherwise defined in part D.1 of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 300 grams, this will result in aggregate samples weighing more than 30 kg. If the weight of a single retail pack is much more than 300 grams, then 300 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail pack is less than 300 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 30 kg. If the weight of the retail pack is much less than 300 grams, one incremental sample shall consist of two or more retail packs, whereby the 300 grams are approximated as closely as possible.

D.1.2. General survey of the method of sampling for dried figs

Table 1: Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	N° of incremental samples	Aggregate sample weight (kg)
Dried figs	≥ 15	15-30tonnes	100	30
	< 15	--	10-100*	≤ 30

* Depending on the lot weight - see table 2 of this part of this Annex

D.1.3. Method of sampling for dried figs (lots ≥ 15 tonnes)

- On condition that the subplot can be separated physically, each lot shall be subdivided into sublots following table 1. 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.

- Number of incremental samples: 100.

- Weight of the aggregate sample = 30 kg which shall be mixed and to be divided into three equal laboratory samples of 10 kg before grinding (this division into three laboratory samples is not necessary in case of groundnuts (peanuts) and tree nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 30 kg sample).
- Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II
- If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, 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.

D.1.4. Method of sampling for dried figs (lots < 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.

The figures in the following table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2: Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	N° of incremental samples	Aggregate sample Weight (kg) (in case of retail packings, weight of aggregate sample can diverge – see point D.1)	No of laboratory samples from aggregate sample
≤ 0.1	10	3	1 (no division)
> 0.1 - ≤ 0.2	15	4.5	1 (no division)
> 0.2 - ≤ 0.5	20	6	1 (no division)
> 0.5 - ≤ 1.0	30	9 (- < 12 kg)	1 (no division)
> 1.0 - ≤ 2.0	40	12	2
> 2.0 - ≤ 5.0	60	18 (- < 24 kg)	2
> 5.0 - ≤ 10.0	80	24	3
> 10.0 - ≤ 15.0	100	30	3

- Weight of the aggregate sample ≤ 30 kg which shall be mixed and divided into two or three equal laboratory samples of ≤ 10 kg before grinding (this division into two or three laboratory samples is not necessary in case of dried figs, subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise up to 30 kg samples).

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

- * < 12 kg: no division into laboratory samples
- * $\geq 12 - < 24$ kg: division into two laboratory samples
- * ≥ 24 kg: division into 3 laboratory samples

- Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.

- 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 packaging forms, 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.

D.1.5. Method of sampling for derived products and compound foods

D.1.5.1. Derived products with very small particle weight (homogeneous distribution of aflatoxin contamination)

- Number of incremental samples: 100; for lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see table 3)

Table 3: Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	N° of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
$> 1 - \leq 3$	20	2
$> 3 - \leq 10$	40	4
$> 10 - \leq 20$	60	6
$> 20 - \leq 50$	100	10

- 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 depends on the weight of the retail packing.

- Weight of aggregate sample = 1-10 kg sufficiently mixed

D.1.5.2. Other derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)

Method of sampling and acceptance as for dried figs ((D.1.3 and D.1.4)

D.1.6. Sampling at retail stage

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg⁵.

D.1.7. Specific method of sampling figs and derived products traded in vacuum packs

D.1.7.1 dried figs

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 30 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

D.1.7.2. Products derived from figs with small particle size

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 3)..

D.1.8. Acceptance of a lot or subplot

- For dried figs subjected to a sorting or other physical treatment:
 - acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;
 - rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.
- For dried figs intended for direct human consumption
 - acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty;
 - rejection if one or more of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.
- In cases where the aggregate sample is 12 kg or less:
 - acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;
 - rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty;

D.2. METHOD OF SAMPLING FOR GROUNDNUTS (PEANUTS), OTHER OILSEEDS, APRICOT KERNELS AND TREE NUTS

⁵ In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts.

D.2.1. Weight of the incremental sample

The weight of the incremental sample shall be about 200 grams, unless otherwise defined in part D.2. of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 200 grams, this will result in aggregate samples weighing more than 20 kg. If the weight of a single retail pack is much more than 200 grams, then 200 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail pack is less than 200 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 20 kg. If the weight of the retail pack is much less than 200 grams, one incremental sample shall consist of two or more retail packs, whereby the 200 grams are approximated as closely as possible.

D.2.2. General survey of the method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts

Table 1: Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	N° incremental samples	Aggregate sample weight (kg)
Groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts	≥ 500	100 tonnes	100	20
	>125 and <500	5 sublots	100	20
	≥ 15 and ≤ 125	25 tonnes	100	20
	< 15	--	10-100*	≤ 20

* Depending on the lot weight - see table 2 of this part of this Annex

D.2.3. Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (lots ≥ 15 tonnes)

- On condition that the subplot can be separated physically, each lot shall be subdivided into sublots following table 1. 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.
- Number of incremental samples: 100.
- Weight of the aggregate sample = 20 kg which shall be mixed and to be divided into two equal laboratory samples of 10 kg before grinding (this division into two laboratory samples is not necessary in case of groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 20 kg sample).
- Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II
- If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, 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.

D.2.4. Method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (lots < 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.

The figures in the following table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2: Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	N° of incremental samples	Aggregate sample Weight (kg) (in case of retail packings, weight of aggregate sample can diverge – see point D.2.1)	No of laboratory samples from aggregate sample
≤ 0.1	10	2	1 (no division)
> 0.1 - ≤ 0.2	15	3	1 (no division)
> 0.2 - ≤ 0.5	20	4	1 (no division)
> 0.5 - ≤ 1.0	30	6	1 (no division)
> 1.0 - ≤ 2.0	40	8 (- < 12 kg)	1 (no division)
> 2.0 - ≤ 5.0	60	12	2
> 5.0 - ≤ 10.0	80	16	2
> 10.0 - ≤ 15.0	100	20	2

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

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

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

- Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.
- 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 packaging forms, 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.

D.2.5. Method of sampling for derived products, with the exception of vegetable oil, and compound foods

D.2.5.1. Derived products (other than vegetable oil) with small particle size, i.e. flour, peanut butter (homogeneous distribution of aflatoxin contamination)

- Number of incremental samples: 100; for lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see table 3)

Table 3: Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	N° of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
> 1 - ≤ 3	20	2
> 3 - ≤ 10	40	4
> 10 - ≤ 20	60	6
> 20 - ≤ 50	100	10

- 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 depends on the weight of the retail packing.

- Weight of aggregate sample = 1-10 kg sufficiently mixed

D.2.5.2. Derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)

Method of sampling and acceptance as for groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts (D.2.3 and D.2.4)

D.2.6. Sampling at retail stage

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg⁶.

D.2.7. Specific method of sampling for groundnuts (peanuts), other oilseeds, apricot kernels, tree nuts and derived products traded in vacuum packs

D.2.7.1. Pistachios, groundnuts (peanuts), Brazil nuts For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

⁶ In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

D.2.7.2. Apricot kernels, tree nuts other than pistachios and Brazil nuts, other oilseeds

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight is equal to the weight of the sampled lot (see table 2).

D.2.7.3. Products derived from tree nuts, apricot kernels and groundnuts (peanuts) with small particle size

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 3)..

D.2.8. Acceptance of a lot or subplot

- For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts subjected to a sorting or other physical treatment:

- acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;

- rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

- For groundnuts (peanuts), other oilseeds, apricot kernels and tree nuts intended for direct human consumption

- acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the correction for recovery and measurement uncertainty;

- rejection if one or both of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

- In cases where the aggregate sample is 12 kg or less:

- acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;

- rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty;"

ANNEX II

"G. METHOD OF SAMPLING FOR COFFEE, COFFEE PRODUCTS, LIQUORICE ROOT AND LIQUORICE EXTRACT

This method of sampling is of application for the official control of the maximum levels established for ochratoxin A in roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract

G.1. Weight of the incremental sample

The weight of the incremental sample shall be about 100 grams, unless otherwise defined in this part G of Annex I.

In the case of lots in retail packings, the weight of the incremental sample shall depend on the weight of the retail packing.

In the case of retail packs of more than 100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is much more than 100 grams, then 100 grams shall be taken from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail packs of 500 grams or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2.

Where the retail pack is less than 100 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample shall consist of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

G.2. General survey of the method of sampling for roasted coffee, ground roasted coffee, soluble coffee, liquorice root and liquorice extract

Table 1 Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight number or of sublots	N° incremental samples	Aggregate sample Weight (kg)
Roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract	≥ 15	15-30 tonnes	100	10
	<15	-	10-100*	1-10

* Depending on the lot weight - see table 2 of this Annex

G.3. Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee liquorice root and liquorice extract (lots \geq 15 tonnes)

- On condition that the subplot can be separated physically, each lot shall be subdivided into sublots following table 1. 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 %.
- Each subplot shall be sampled separately.
- Number of incremental samples: 100.
- Weight of the aggregate sample = 10 kg
- 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 packaging forms, 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.

G.4. Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee liquorice root and liquorice extract (lots $<$ 15 tonnes)

For roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract under 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 10 kg.

The figures in the following table can be used to determine the number of incremental samples to be taken.

Table 2: Number of incremental samples to be taken depending on the weight of the lot of roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract.

Lot weight (tonnes)	N° of incremental samples	Aggregate sample weight (kg)
≤ 0.1	10	1
$> 0.1 - \leq 0.2$	15	1.5
$> 0.2 - \leq 0.5$	20	2
$> 0.5 - \leq 1.0$	30	3
$> 1.0 - \leq 2.0$	40	4
$> 2.0 - \leq 5.0$	60	6
$> 5.0 - \leq 10.0$	80	8
$> 10.0 - \leq 15.0$	100	10

G.5 Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee, liquorice root and liquorice extract traded in vacuum packs

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 2).

G. 6. Sampling at retail stage

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part of Annex I.

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. In any case, the aggregate sample shall be at least 1 kg⁷.

G.7. Acceptance of a lot or subplot

- acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;
- rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty."

⁷ In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

ANNEX III

"K. METHOD OF SAMPLING VEGETABLE OILS

This method of sampling is of application for the official control of the maximum levels established for mycotoxins, in particular aflatoxin B1, aflatoxin total and zearalenone, in vegetable oils.

K.1. Method of sampling for vegetable oils

- The weight of the incremental sample shall be at least about 100 grams (ml) (depending of the nature of the consignment e.g. vegetable oil in bulk, at least 3 incremental samples of about 350 ml have to be taken), resulting in an aggregate sample of at least 1 kg (litre).

- The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The lot shall be thoroughly mixed insofar possible by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of aflatoxin can be assumed within a given lot, it is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

Table 1: Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Weight of lot (in kg) Volume of lot (in litres)	Minimum number of incremental samples to be taken
Bulk *	-	3
packages	≤ 50	3
packages	> 50 to 500	5
packages	> 500	10

* On condition that the subplot can be separated physically, large bulk consignments/lots of vegetable oils shall be subdivided into sublots as foreseen in table 2 of this part.

Table 2: Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	Minimum N° of incremental samples	Minimum aggregate sample weight (kg)
Vegetable oils	≥ 1500	500 tonnes	3	1
	>300 and <1500	3 sublots	3	1
	≥ 50 and ≤ 300	100 tonnes	3	1
	< 50	--	3	1

K.2. Method of sampling for vegetable oils at retail stage

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the provisions set out in this part of Annex I.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the

sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg⁸.

K.3. Acceptance of a lot or subplot

- acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty;
- rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty."

⁸ In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

Reference: OFFC 2009/W/001

**THE OFFICIAL FEED AND FOOD CONTROLS (WALES) REGULATIONS
2007 (S.I. 3294 (W.290)) ("the Regulations")**

DECLARATION UNDER REGULATION 33

Whereas the Food Standards Agency has reasonable grounds to suspect that pears originating in or consigned from Turkey may contain levels of amitraz exceeding the acute reference dose as defined in Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ No. L70, 16.3.2005, p.1);

Whereas this is likely to constitute a serious risk to public health;

Whereas on 12 November 2009 the Commission of the European Communities adopted Commission Decision 2009/835/EC on emergency measures imposing special conditions on official controls governing the import of pears originating in or consigned from Turkey due to high residue levels of amitraz (OJ No. L299, 14.11.2009, p.15);

The Food Standards Agency declares in accordance with regulation 33 of the Regulations that with effect from 18 November 2009 the introduction into Wales of fresh pears falling within CN codes 0808 20 10 and 0808 20 50 originating in or consigned from Turkey is permitted subject to the conditions specified in Article 1.1, 1.3, 1.6 and 1.7 of Commission Decision 2009/835/EC.

Signed by  on 18 November 2009

Print nameSTEVE WEARNE

Give details of post heldDirector

For and on behalf of the Food Standards Agency

NOTES

(1) Any expression used both in this declaration and Commission Decision 2009/835/EC has the meaning it bears in that Decision.

(2) Introduction into Wales of fresh pears falling within CN codes 0808 20 10 and 0808 20 50 originating in or consigned from Turkey in contravention of this declaration is an offence, punishable by a fine or imprisonment or both.

**THE OFFICIAL FEED AND FOOD CONTROLS (SCOTLAND) REGULATIONS 2007
("the Regulations")**

DECLARATION UNDER REGULATION 33

Whereas the Food Standards Agency has reasonable grounds to suspect that pears originating in or consigned from Turkey may contain levels of amitraz exceeding the acute reference dose as defined in Regulation (EC) No. 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ No. L70, 16.3.2005, p.1);

Whereas this is likely to constitute a serious risk to public health;

Whereas on 12 November 2009 the Commission of the European Communities adopted Commission Decision 2009/835/EC on emergency measures imposing special conditions on official controls governing the import of pears originating in or consigned from Turkey due to high residue levels of amitraz (OJ No. L299, 14.11.2009, p.15);

The Food Standards Agency declares in accordance with regulation 33 of the Regulations that with effect from 19 November 2009 the introduction into Scotland of fresh pears falling within CN codes 0808 20 10 and 0808 20 50 originating in or consigned from Turkey is permitted subject to the conditions specified in Article 1.1, 1.3, 1.6 and 1.7 of Commission Decision 2009/835/EC.

Signed by  at 11-00AA on 19 November 2009

Print name JAMES A THOMSON

Give details of post held.....Assistant Director.....

For and on behalf of the Food Standards Agency in Scotland

NOTES

(1) Any expression used both in this declaration and Commission Decision 2009/835/EC has the meaning it bears in that Decision.

(2) Introduction into Scotland of fresh pears falling within CN codes 0808 20 10 and 0808 20 50 originating in or consigned from Turkey in contravention of this declaration is an offence, punishable by a fine or imprisonment or both.

Declaration OFFC Turkey Pears 19.11.09