www.food.gov.uk

Chemical Contaminants Interested Parties Letter May 2008

This Interested Parties Letter contains information about on-going and forthcoming issues relating to agricultural, industrial and environmental contaminants in food.

This letter aims to INFORM YOU of current contaminant issues and SEEKS YOUR VIEWS on these matters.

We welcome all comments from interested parties and submission of data to help inform us on these issues. A list of contacts in the different areas of chemical contaminants is provided for your convenience:

MYCOTOXINS
Gavin Shears
Tel 020 7276 8713
gavin.shears@foodstandards.gsi.gov.uk

PROCESS CONTAMINANTS
Nina Webber
Tel 020 7276 8714
nina.webber@foodstandards.gsi.gov.uk

ENVIRONMENTAL CONTAMINANTS (Inorganic)
Christina Baskaran
Tel 020 7276 8704
christina.baskaran@foodstandards.gsi.gov.uk

ENVIRONMENTAL CONTAMINANTS (Organic – dioxins, PCBs, PAHs)
David Mortimer
Tel 020 7276 8731
david.mortimer@foodstandards.gsi.gov.uk

NITRATE
Valerie McFarlane
Tel 020 7276 8718
valerie.mcfarlane@foodstandards.gsi.gov.uk

FOR GENERAL ENQUIRIES ON CONTAMINANTS

John Bates
Tel 020 7276 8730
john.t.bates@foodstandards.gsi.gov.uk

If you are based in Scotland, Wales or Northern Ireland, you can also contact our colleagues in the devolved administrations directly:

SCOTLAND

Fiona Bruce
Tel 01224 285170
fiona.bruce@foodstandards.gsi.gov.uk

WALES

Deb Morgan
Tel 029 2067 8938
deborah.morgan@foodstandards.gsi.gov.uk

NORTHERN IRELAND

Esther Chartres
Tel 028 90 417737
esther.chartres@foodstandards.gsi.gov.uk

CONTENTS SUMMARY

Click on the main headings for further information

This Interested Parties letter includes information from the following meetings:

22 Feb 2008	Commission Working Group (Industrial and Environmental Contaminants)
10 March 2008	Commission Working Group (Agricultural Contaminants)
31 March – 4 April 2008	Codex Committee on Contaminants in Food (CCCF) (2nd Session)
8 – 9 April 2008	Standing Committee on the Food Chain and Animal Health (SCoFCAH), Zootechnics
11 April 2008	Standing Committee on the Food Chain and Animal Health (SCoFCAH), Toxicology Section

GENERAL INFORMATION

Draft Incident Prevention Strategy Plan Consultation

For further information on the consultation please contact Matthew Cooper: matthew.cooper@foodstandards.gsi.gov.uk; Tel 020 7276 8725.

The Agency is seeking views and comments on it's Draft Incident Prevention Strategy Plan. This sets out a cross-Agency programme of work to help deliver the Agency's Strategic Plan target of developing, by the end of December 2010, effective interventions to tackle food safety problems at source before they become incidents.

Previous incidents have shown that they can require substantial resources to manage, can undermine consumer confidence and can be costly to individual companies and national economies. The Agency believes that building the concept of prevention in from the outset will be more effective than monitoring after production in reducing the number of incidents. This in turn should lead to less food waste, provide greater consumer reassurance on the safety of food sold in the UK, free up resources and result in cost savings.

In developing the strategy, the main focus has been on identifying activities that will have the most impact on preventing food incidents. The Incident Prevention Strategy reflects the various suggestions made by external stakeholders over the past year. The draft strategy was also discussed at a stakeholder workshop on 10 January and those present welcomed the opportunity to help shape the strategy.

The broad aims of the Incident Prevention Strategy Plan are:

- To learn from past incidents to ensure that past mistakes are not repeated;
- To identify and address the main sources of incidents.
- To be as prepared as possible to anticipate and deal with emerging and re-emerging risks.

Further information on the draft strategy and the consultation can be found on the Agency's website at www.food.gov.uk/consultations/ukwideconsults/2008/incprevplan.

Formation of the Food Protection Division at the Food Standards Agency

To facilitate work on incident prevention, the Chemical Safety Division was reorganised in 2007 creating the Incident Prevention Unit from the former contaminants and food contacts materials branches. More recently, recognising the close synergy between incident prevention and response, the Chemical Safety and Incident Prevention (including contaminants) and Emergency Planning Radiological and Incidents Divisions have been combined to form the Food Protection Division.

Appointment of UK National Reference Laboratory (NRL)

For further information on this subject area please contact Karen Barnes: karen.barnes@foodstandards.gsi.gov.uk; Tel. 020 7276 8541.

On the 7th April 2008 the Agency announced that its Food Protection Division has appointed the Central Science Laboratory (CSL) as the UK's National Reference Laboratory (NRL) for contaminants in food.

This work covers the following areas:

- mycotoxins
- heavy metals
- dioxins and polychlorinated biphenyls (PCBs)
- polycyclic aromatic hydrocarbons (PAHs)
- materials and articles in contact with food

The appointment of NRLs is a requirement placed on all EU member states by Regulation (EC) No. 882/2004. Different laboratories may be appointed for different subject areas, although in this case CSL has been appointed for the five food contaminants areas listed. The Agency has already made some other appointments, for example for animal feed additive authorisations and marine biotoxins and is in the process of appointing others. The NRLs work closely with the central Community Reference Laboratories (CRLs) appointed by the European Commission and with Official national Control Laboratories (OCLs) within their country.

The four-year appointment of CSL took effect on 1 April 2008, and will enable it to carry out the functions as described in Article 33 of Commission Regulation (EC) 882/2004. The services provided will include:

- providing a channel for communication between the Agency and other relevant laboratories
- advice and representation within the CRL-NRL network on contaminants within the UK/EU
- production of standard operating procedures, codes of practice and guidance documents (as agreed with the Agency)
- compliance assessment via audits ring trials (as agreed with the Agency)
- co-ordination within the UK of CRL initiatives

The appointment will be reviewed in four years time. Please note this appointment does not mean that the Agency has centralised its research to one laboratory. It will still be tendering as usual for research via the protocols set out in its research requirements document.

Update to the Guidance Note on The Contaminants in Food (England) Regulations

For further information or to submit comments, please contact Jonathan Briggs: jonathan.briggs@foodstandards.gsi.gov.uk; Tel 020 7276 8716.

The Agency is currently in the process of reviewing and updating its Guidance Note on the Contaminants in Food (England) Regulations. It is proposed that the guidance be developed to cover all legislative aspects of contaminants in food, including special legislation governing certain foodstuffs from certain third countries due to contamination risk of these products.

If you have any comments or views on the revision of this guidance, in particular simplifying the document, please submit these to the above contact by **Friday 6 June 2008**. The current guidance document can be found at www.food.gov.uk/foodindustry/guidancenotes/foodguid/contamgn.

▲Contents Summary

MYCOTOXINS

For further information or to submit comments or data on mycotoxins, please contact Gavin Shears: gavin.shears@foodstandards.gsi.gov.uk; Tel. 020 7276 8713.

Outcome of discussions at Codex Committee on Contaminants in Food (CCCF)

Discussed at Codex CCCF 2ND Session, 31 March – 4 April 2008

Draft Maximum Level for Ochratoxin A in Wheat Barley and Rye

It was agreed to forward the draft maximum level of 5 µg/kg to the 31st session of the Codex Alimentarius Commission (CAC) for adoption. It is therefore expected that Codex will adopt this maximum level for Ochratoxin A in wheat, barley and rye in the near future.

Draft Maximum Levels for Total Aflatoxins in Almonds, Hazelnuts and Pistachios

This has also been forwarded to the CAC for adoption (maximum level of 15 µg/kg 'for further processing' and 10 µg/kg for 'ready to eat'). It is therefore expected that Codex will adopt these maximum levels in the near future.

Proposed Draft Sampling Plans for Aflatoxin Contamination in Ready to Eat Tree-nuts and Tree-nuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios

An in session group discussed the draft plan in light of the new draft maximum levels and as a result an amended paper was presented. On the basis of this new draft it was agreed to advance the proposed draft sampling plan for adoption by the CAC. The main points of interest in the plan are:

- 20 – 25 tonnes sampling lot, which is same as in the present EU sampling plan;
- 20 kg sample for 'ready to eat' shelled almonds and hazelnuts but in shell pistachios. This would be divided into 2 x 10 kg sub-samples for analysis, both which must meet the requirement of the new level. For 'for further processing' the 20Kg sample would be analysed as one;
- It will no longer apply to Brazil nuts but may be revised once Codex limits for aflatoxin levels in Brazil nuts are agreed.

Discussion Paper on Aflatoxins Contamination in Brazil nuts

The Committee agreed to start work on draft Maximum Levels for total aflatoxins in Brazil nuts, subject to approval by the 31st session of the CAC. An electronic Working Group, lead by Brazil, will take the work forward.

Proposed Draft Code of Practice (CoP) for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs at Step 4

It was agreed to forward the CoP to CAC for adoption at step 5.

Discussion Paper on Ochratoxin A in Coffee

It was agreed to start work on a CoP on this issue, to assist countries to reduce ochratoxin A contamination of coffee. Brazil will lead the electronic working group.

Discussion Paper on Ochratoxin A in Cocoa
The recommendation was to suspend the work at this time and look again in the near future when more information is available on the occurrence of ochratoxin A contamination in cocoa. If industry has any information on this that they would be willing to share with the Agency then it would be very welcome.

Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA.
This includes various mycotoxins. It was agreed to forward the list to the CAC for adoption with a view to reviewing the list via an in session working group at the next session of the CCCF.

A full report on the 2nd session of CCCF can be found on the Codex website at www.codexalimentarius.net/download/report/700/al31_41e.pdf.

Review of the frequency of controls on commodities covered by Commission Decision 2006/504/EC as amended on aflatoxins

Discussed at Working Group 10 March 2008

Further discussions on revising the frequency of controls for Commission Decisions on aflatoxins took place at this meeting. As in previous meetings, consideration was given to the degree of non-compliance with the Decisions since 2003 and the frequency of controls for each commodity. Data from the Rapid Alert System for Food and Feed (RASFF) were also compiled and analysed.

Taking into account this information, it is intended that the majority of provisions within the Decisions will be kept as they are. The Commission reinforced its proposal to reduce the frequency of controls on peanuts from Egypt and China, However, consideration was given to increasing controls on commodities from Turkey in light of an increase in the frequency and levels of non-compliance.

The Commission expressed its intention to revise the current frequencies and embed them within the consolidated Decision. Further discussion will take place at the next Working Group meeting.

High risk list (Article 15.5 of Regulation 882/2004)

Discussed at Working Group 10 March 2008

Article 15.5 of Regulation (EC) No. 882/2004 makes provision for a list of foods to be subject to increased official controls. These are foods that are considered to have a high known or emerging risk of being unsafe.

A copy of the draft Regulation implementing rules for import controls for these high-risk feed and food products of non-animal origin was made available through an update posted by the Agency on its website in December on Official Controls. An update was published in February and the latest version of this Regulation contains a draft list of high-risk food and feed products of non-animal origin (in appendix 3). The update can be found at www.food.gov.uk/multimedia/pdfs/offcontupdatefeb02.pdf.

The Working Group on 10 March discussed the presence of Basmati rice on the high risk list. The Commission put forward a suggestion to request authorities to update the Commission of compliance with frequency of controls every 3 months for white and brown rice. If a high rate of non-compliance is seen, then it will be kept on the high risk list, however, final discussions on this subject will take place at a later date.

Any comments on the list relating to mycotoxins as well as other chemical contaminants are welcome. Industry and enforcement stakeholders are invited, in particular to comment on the costs and other impacts associated with undertaking the increased controls on these products that will be necessary.

T2 and HT2 Toxins

Held during Working Group 9 – 11 January and 10 March 2008

During discussions at the Fusarium Forum held during the Working Group on 9 – 11 January 2008, issues were raised including the inconsistency of the proposed limits applied to the different fractions, the lack of data on toxicology for T2 and HT2 toxins and the lack of standardised analytical methods for T2 and HT2.

Based on these and further discussions at the Working Group on 10 March 2008, it was decided that the introduction of limits would be postponed until after the next Fusarium Forum; expected to be held in Summer 2009. This will allow collection of more data while continuing with discussions in order to allow for better informed negotiations.

If you would like to submit data on T2 and HT2 toxins that you think will assist during negotiations of setting maximum levels, please send it to Gavin Shears at the address above.

Guidance Document for Competent Authorities for the Control of Compliance with EU Legislation on Aflatoxins

An updated version of the guidance document has been circulated and is available with this letter as an annex. It is intended that the updated version will be placed on the Commission website later this month. We will notify interested parties as and when a published version of the document becomes available. Any comments on the revised document should be sent to the contact above; discussions on the document will continue

on an ad hoc basis at the Commission and amendments and updates will be made as and when is appropriate.

Update with regard to Commission Decision 2007/563/EC on special condition for import of almonds and derived products originating in or consigned from USA due to risk of aflatoxin contamination

A new printed VASP certificate has now been made available, which is easier to read and elaborates on the information contained in the older, hand-written version. Both versions will be valid for the purpose of the Decision. However, regardless of the version used, the certificate must still be hand-signed by a USDA approved analyst (preferably in blue ink to avoid confusion).

An updated list of USDA approved laboratories and analysts permitted to perform the analysis has been released. Details of these and of the new certificate can be obtained from the Agency on request.

▲Contents Summary

PROCESS CONTAMINANTS

For further information or to submit comments or data on process contaminants, please contact Nina Webber at: nina.webber@foodstandards.gsi.gov.uk; Tel. 020 7276 8714.

Ethyl carbamate

Discussed at Working Group (Ind & Env), 22 Feb 2008 and CCCF 2ND session, 31 March – 4 April 2008

Discussions around setting maximum limits for ethyl carbamate were initially discussed at the SCOFAH meeting in December 2007. Some Member States had supported limits at this meeting while others preferred reduction measures as a code of practice. At the working group, The Commission favoured an approach whereby a target level could be agreed. This might become the maximum limit in the future but at present would be used to encourage good practice in industry. There was still a need to agree a level and the products to which it would apply. The Commission appeared to suggest a level of 100 mg/kg, which was supported by the UK.

At CCCF, Germany agreed to prepare discussion paper on ethyl carbamate in alcoholic beverages for consideration by the next session.

Acrylamide Code of Practice

Discussed at Codex CCCF 2ND session, 31 March – 4 April 2008

The Codex proposed draft code of practice for acrylamide in food was discussed at CCCF and will be forwarded to the 31st session of CAC in June for adoption at step five. This decision was supported by the UK, EC and Member States. Revisions in the COP were agreed for the next meeting including a new section to be included detailing the scope of the code of practice.

3-MCPD Code of Practice

Discussed at Codex CCCF 2ND session, 31 March – 4 April 2008

The Codex proposed draft code of practice for the reduction of 3-MCPD was agreed to be forwarded to the CAC meeting in June for adoption at step eight. All scientific references contained in the code of practice have been deleted to try to keep the finalised CODEX document up to date and as relevant as possible. A new scope section will be incorporated into the document before adoption. This will incorporate text from other paragraphs from the document.

Draft Maximum Level for 3-MCPD in Liquid Condiments containing acid-HVPs, (excluding naturally fermented soy sauce)

Discussed at Codex CCCF 2ND Session, 31 March – 4 April 2008

The Codex Committee discussed maximum levels for 3-MCPD in liquid condiments. A number of Codex members expressed the view that they were willing to accept a level of 0.4 micrograms/kg. However the EC raised concerns over the limited amount of information available regarding 3-MCPD esters in the diet and proposed to postpone discussions until the next meeting in order to obtain more scientific data on 3-MCPD esters.

The Chair of the Codex Committee concluded that the majority of delegations were in favour of advancing the level of 0.4 micrograms/kg and so the proposed limit was advanced to step eight for adoption. Reservations on this decision were entered by the EC, Norway and Switzerland.

Survey of Process Contaminants in UK Retail Products: 1st Year of Survey Now Completed

The first year of results obtained from the FSA survey on process contaminants in foods will shortly be published in a Food Surveillance Information Sheet (FSIS) which will be available on the FSA website.

The FSIS will contain analytical results from the products sampled for various process contaminants monitored i.e. – acrylamide, ethyl carbamate, furan and 3-MCPD (please note not all contaminants were analysed for in every product).

The data obtained will be sent to EFSA as part of the European Recommendation for acrylamide monitoring in food.

If you have any comments on any of the above issues then please forward them to Nina Webber at the e-mail above by the 23rd May 2008 at the very latest.

▲Contents Summary

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.

Heavy metals in certain species of fish and mushrooms

Discussed at SCoFCAH (Tox), 11 April 2008

Amendments to Commission Regulation 1881/2006 to revise maximum limits for cadmium and lead limits in fungi and some minor changes to cadmium and mercury limits in fish were proposed.

- Following ongoing discussions on setting limits for cultivated and wild species of mushrooms, limits of 0.2 mg/kg for three common species - *Agaricus bisporus* (common mushroom), *Pleurotus ostreatus* (Oyster mushroom), *Lentinula edodes* (Shiitake mushroom) - and a 1 mg/kg limit for all other species were proposed.

- The cadmium limits for certain species of fish to be changed as follows: Mackerel 0.1 mg/kg (old limit 0.05 mg/kg), bullet tuna 0.2 mg/kg (old limit 0.05 mg/kg) and anchovy 0.3 mg/kg (old limit 0.1 mg/kg). Two species of fish to have higher limits for mercury - kingklip and pink cusk eel (old limits 0.5 mg/kg) to have maximum levels of 1.0 mg/kg for mercury.

- A footnote to be added stating that tree nuts are not covered by the maximum level for cadmium in fruit (0.05 mg/kg).

On a vote, the amendment was approved by qualified majority. These changes will go through the Commission adoption procedures and will enter into force 20 days following its publication.

Heavy metals in food supplements

Discussed at SCoFCAH (Tox), 11 April 2008

There was a consensus that limits are needed for lead and cadmium in food supplements because some very high levels had been reported. Discussions took place at Working Group meetings and the UK wanted to ensure that the new limits were set at proportionate levels so that consumers are protected without placing an unnecessary burden on the industry.

Some Member States already have National legislations in place which were much tighter than the levels proposed by the UK. From a consideration of the data available and as a compromise between levels suggested by different Member States, limits for lead, cadmium and mercury were proposed and agreed upon.

The maximum limits for food supplements as defined in Article 2 of Directive 2002/46/EC will be: Lead - 3 mg/kg, cadmium - 1 mg/kg (non-seaweed based) and 3 mg/kg (supplements consisting exclusively or mainly of dried seaweed or of products derived from seaweed) and mercury - 0.1 mg/kg. These levels will be applicable to the products as sold and the Commission has agreed that this legislation will apply from 1 July 2009 to allow more time for implementation.

Testing of fishery products from Gabon

Discussed at SCoFCAH (Zoo), 8 – 9 April 2008

A Community inspection carried out in Gabon in 2007 has revealed serious deficiencies with regard to certain fishery products exported to the EU particularly with regards to heavy metals and sulphites. A Commission Regulation will be put in place which will require Member States to carry out appropriate checks on certain fishery products from Gabon intended for human consumption on arrival at the Community border to ensure compliance with Regulation (EC) No. 1881/2006 and Directive 95/2/EC as regards heavy metals and sulphites respectively. The Regulation will be reviewed after one year.

EFSA Working group on Cadmium

Discussed at Working Group (Ind & Env), 22 Feb 2008

The Committee was informed about the state of play of the EFSA Working Group on cadmium. The draft opinion is still being discussed within the EFSA WG and a first discussion in the CONTAM Panel is expected for June 2008. Approximately 150,000 occurrence data were submitted by the Member States to EFSA. These data are currently being compiled and assessed to be used in the exposure assessment of the opinion.

▲Contents Summary

ENVIRONMENTAL CONTAMINANTS (Organic – dioxins, PCBs, PAHs)

For further information or to submit comments or data on organic Contaminants, please contact David Mortimer: david.mortimer@foodstandards.gsi.gov.uk; Tel 020 7276 8731.

Commission Decision 2008/352/EC on guar gum from India

Commission Decision 2008/352/EC of 29 April 2008 imposing special conditions governing guar gum originating in or consigned from India due to contamination risks of those products by pentachlorophenol and dioxins **applied from 5 May 2008**. The Decision can be found on the Commission's website at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:117:0042:0044:EN:PDF.

This new Decision requires that consignments of guar gum, falling within CN code 1302 32 90, and products containing at least 10% guar gum, originating in or consigned from India will need to be accompanied by an original analytical report stating that the consignment does not contain more than 0.01 mg/kg of PCP.

The analytical report must be issued by a laboratory accredited according to EN ISO/IEC 17025 for the analysis of PCP in food and feed or by a laboratory pursuing the necessary accreditation procedures – see Article 2(1) of the Decision. The analytical report must also be endorsed by a representative of the competent authority from the country where the laboratory is based – see Article 2(2) of the Decision. In order to facilitate this process, the Commission has produced a list of approved laboratories within the EU for which this endorsement by the Competent Authority can be assumed. The list is available on the SANCO website at http://ec.europa.eu/food/food/chemicalsafety/contaminants/new_measures_guar_gum_india.pdf.

In the absence of an analytical report the consignment will be detained until the feed or food business operator arranges and pays for the consignment to be tested by an accredited laboratory. In this event samples will be taken by, or under the supervision of the relevant authority. Consignments may be detained for up to 60 days pending the report being provided. If the consignment is found to be non-compliant or if the report is not provided within the 60 days then appropriate enforcement action will be taken – see Article 2(5) of the Decision.

The Decision also provides for random sampling and analysis to take place with a frequency of 5% of consignments. Consignments may be detained for up to 15 working days (Article 3). Any costs from sampling, analysis, storage or measures following non-compliance are borne by the importer (Article 6).

Consignments originating or consigned from India which left India before the Decision comes into force on 5 May 2008 are not required to be accompanied by an analytical report (Article 7).

Decision 2008/352/EC is implemented into UK law by means of Declaration OFFC 2008/E/001 under regulation 33 of the Official Feed and Food Controls (England) Regulations 2007. For instances where guar gum is an ingredient of a Product of Animal Origin (POAO) compound product above the specified percentage, a Declaration (Declaration POAO REG 61/019) has been made under regulation 61 of the Products of Animal Origin (Third Country Imports) (England) Regulations 2006. To view a copy of the Declarations go to www.food.gov.uk/foodindustry/imports/legislation/legislation.

▲Contents Summary

SANCO/1218/2005-rev. 2
Version 30/01/2008

GUIDANCE DOCUMENT FOR COMPETENT AUTHORITIES FOR THE CONTROL OF COMPLIANCE WITH EU LEGISLATION ON AFLATOXINS

IMPORTANT DISCLAIMER

"This document has no formal legal status and, in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice"

SCOPE

This guidance document focuses mainly on the official control of aflatoxin contamination in food products which are subject to Commission Decision 2006/504/EC. Nevertheless, the provisions in this guidance document are also applicable, where relevant, to the control of aflatoxins in food products not subject to Commission Decision 2006/504/EC.

NOTE

This document is an evolving document and will be updated to take account of the experience of the competent authorities or of information provided (see in particular point II.11 of the guidance document)

TABLE OF CONTENTS

I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION

I.1. Groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs

Commission Regulation (EC) No 1881/2006 establishes maximum levels for aflatoxin B1 and aflatoxin total in groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs, that are stricter than for groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.

Although nuts for further processing are permitted to have a higher level of aflatoxins, this does not exclude food operators throughout the food chain taking all necessary precautions to reduce aflatoxin contamination as much as possible.

The application of the higher maximum levels for the groundnuts, nuts and dried fruit to be subjected to sorting or other physical treatment is only allowed when the following strict conditions are complied with:

- the groundnuts, nuts and dried fruit are not intended for direct human consumption or used as an ingredient in foodstuffs
- the groundnuts, nuts and dried fruit are subjected to a secondary treatment involving sorting or other physical treatment and after this treatment the products comply with the stricter levels laid down for the products intended for direct human consumption or use as an ingredient in foodstuffs
- the groundnuts, nuts and dried fruit are clearly labelled showing their use, and bearing the indication "product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs".

Each of the three conditions for applying the "higher maximum level" must be complied with and should be supervised by the competent authority.

This means that, in order to apply the "higher level" for the groundnuts, nuts and dried fruit ALL of the following conditions apply and must be complied with : the products must be traded in **a packaging form** for which it is **obvious** that these products are **intended for further treatment to reduce aflatoxin contamination** before consumption or use as an ingredient **AND the destination of the consignment has the capability/equipment to perform such treatment AND must be labelled to the letter with the following indication** "**product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs" This form of labelling is not required for any other form of further processing such as salting and roasting ,which is not intended to reduce the level of aflatoxin contamination. Such nuts and groundnuts must, however, comply with the lower regulatory limits for direct human consumption.**

"Physical treatment to reduce aflatoxin contamination" means any treatment, not involving chemical substances, which has been proven to reduce the levels of aflatoxins. An example of such treatment is blanching combined with sorting. Roasting cannot be considered as "physical treatment to reduce aflatoxin contamination" as aflatoxins are thermo-stable and are not removed/reduced to a significant extent by roasting. Sorting by hand of nuts cannot be considered as a reliable method to reduce aflatoxin contamination. On the other hand, the use of active carbon for the purification of oils obtained from nuts can be considered as a "physical treatment to reduce aflatoxin contamination."

The indication "raw" etc is not sufficient.

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" shall be mentioned on the label of each bag, box individually or on the original accompanying document, which must have a clear link with the consignment by means of mentioning the consignment/batch identification code relating to the consignment in question. The identification code must be indelibly marked on each individual bag, box, etc of the consignment. It is very important that this indication is put on the accompanying documentation <u>at the moment when the documentation is issued</u>. (Where it is evident that this indication has been entered in the accompanying documents *a posteriori*, the indication is invalid).

If all the abovementioned conditions are complied with and the levels of aflatoxins are below the maximum levels applicable to products to "be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs", the consignment/batch can be put on the market. It is the responsibility of the food business operator, under the supervision of the competent authority, to ensure that the necessary authorised treatments are applied to the product in order to ensure that the products intended for direct human consumption or use as an ingredient in foodstuffs derived from that consignment do comply with the stricter maximum levels of aflatoxins applicable to these products.
For the situation when the consignment is transported in transit to the designated point of import (for release for free circulation), the competent authority for the designated point of import is responsible for physical check and supervision of the abovementioned authorised treatment. However, in case the consignment with the indication "to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs" is destined for a designated point of import in a Member State, which does not have the premises to sort or physical treatment (see list of premises/establishments which can perform the sorting and/or physical treatment), then the consignment should, after having consulted the competent authority from the designated point of import, not be authorised for transportation in transit to the designated point en import.

The maximum levels of aflatoxins established in Commission Regulation (EC) 1881/2006, are applicable to all groundnuts, derived products thereof placed on the market except for those groundnuts, derived products thereof which are clearly intended for uses other than human consumption either directly or indirectly. This has to be demonstrated up to and including the wholesale stage by a clear indication of the intended use on the label of each individual packing or on the accompanying document, which must have a clear link with the consignment by means of mentioning the consignment identification code, which occurs on each individual bag, box, etc. of the consignment. In addition the business activity of the consignee of the consignment given on the accompanying documents must be compatible to the intended use.

In the absence of a clear indication that their intended use is not for human consumption, the maximum levels of aflatoxins for foodstuffs shall apply to all groundnuts and derived products thereof placed on the market.

The higher levels for products to be subjected to sorting or other physical treatment or only allowed if the business activity of the consignee of the consignment given on the accompanying documents is compatible to the intended use. In order to facilitate the enforcement, establishments able to perform sorting or physical treatment are listed in Annex II

II. APPLICATION OF COMMISSION DECISION 2006/504/EC

II.1. Use of TARIC codes

Commission Decision 2006/504/EC refers to TARIC codes to describe the goods falling under their scope. The fact that in many Member States the competent authorities do not use TARIC codes in their systems could create difficulties both for control and for demonstrating/reporting control frequency. It is therefore recommended that the competent authorities use TARIC codes to enable identification. This will also facilitate communication with the Customs authorities.
Information on TARIC codes can be found on the DG TAXUD website: http://europa.eu.int/comm/taxation_customs/dds/en/tarhome.htm

TARIC codes for products subject to Commission Decision 2006/504/EC:

Groundnuts, not roasted or otherwise cooked, whether or not shelled or broken (origin China and Egypt)
- in shell – other than for sowing: CN 1202 10 90
- shelled – whether or not broken: CN 1202 20 00

Groundnuts roasted (origin China and Egypt)
- in immediate packings of a net content exceeding 1 kg: CN 2008 11 92
- in immediate packings of a net content not exceeding 1 kg: CN 2008 11 96

Groundnuts – other (origin China and Egypt)
- in immediate packings of a net content exceeding 1 kg: CN 2008 11 94
- in immediate packings of a net content not exceeding 1 kg: CN 2008 11 98

Pistachios: CN 0802 50 00 (origin Iran and Turkey)

Pistachios roasted (origin Iran and Turkey)
- in immediate packings of a net content exceeding 1 kg: CN 2008 19 13
- in immediate packings of a net content not exceeding 1 kg: CN 2008 19 93

Hazelnuts or filberts (*Corylus spp)* (origin Turkey)
- in shell: CN 0802 21 00
- shelled: CN 0802 22 00

Brazil nuts (origin Brazil)
- in shell: CN 0801 21 00
(- shelled: CN 0801 22 00 – not subject to a specific Commission Decision)

Figs (origin Turkey)
(- fresh: CN 0804 20 10 – not subject to a specific Commission Decision)
- dried: CN 0804 20 90

Flour, meal and powder of hazelnuts, figs and pistachios: CN 1106 30 90 (origin Turkey)

Mixtures of nuts or dried fruits: CN 0813 50 (origin Turkey)
Hazelnuts, figs and pistachios, prepared or preserved including mixtures: CN 2008 19 (origin Turkey)
Hazelnut paste and fig paste: CN 2007 99 98 (or traded under CN 1106 30 90) (origin Turkey)
Cut, sliced and broken hazelnuts: CN 0802 22 00 and 2008 19 19 (origin Turkey)

Almonds (origin US)

- almonds in shell or shelled: CN code 0802 11 or 0802 12;

- roasted almonds
-- in immediate packings of a net content exceeding 1 kg: CN code 2008 19 13
-- in immediate packings of a net content not exceeding 1 kg: CN code 2008 19 93

- mixtures of nuts or dried fruits and containing almonds: CN code 0813 50;

The Decision applies also to processed and compound foodstuffs derived from or containing the foodstuffs referred to above.

No specific TARIC codes are provided for these products in the Commission Decision

Commission Decision 2006/504/EC amended by Commission Decision 2007/459/EC provides that compound foodstuffs shall be considered as containing the foodstuffs to a significant amount when such foodstuffs are present in a quantity of 10 % and more (the controls carried out on derived and compound foodstuffs are done in principle at the frequency established for the main foodstuffs covered by the Decision).

Consignments with a gross weight of less than 5 kg are exempted from the application of the provisions provided for in this Decision, which means that they have not to be accompanied by a health certificate. However, enforcement authorities can test consignments of less than 5 kg in cases there are concerns.

From a practical point of view, **the extension to processed and compound foodstuffs is applicable to processed and compound foodstuffs originating from the third country of origin covered by the Decision or foodstuffs labelled with an indication that they have been processed from or contain as ingredient the foodstuffs referred to above.**

In order to facilitate effective control, competent authorities of the Member States are requested to report to the Commission the (regular) import of such products as well the TARIC Code under which these products are traded. These foodstuffs will be listed hereafter as a regular update of this guidance document.

List of compound and derived foodstuffs usually containing >10 % and imported from the countries covered by the Decision and for which consignments have to accompanied by a health certificate (Annex III)

II.2. Points of first introduction and designated points of import

'Point of first introduction' means the point of first physical introduction of a consignment into the EU. In some cases the point of first introduction can only carry out documentary checks and not sampling and analysis. A consignment received by such a point of first introduction but must be forwarded to a designated point of import in order to undertake the further checks required in order for the consignment to be officially imported.

List of points of first introduction with contact points (in annex IV to this guidance document)

Designated points of import' means the points through which the foodstuffs covered by the Decision may only be imported into the Community. A list of these points is annexed to Commission Decision 2006/504/EC[1].

List of designated points of import with contact details (in annex V to this guidance document)

It is important that experienced staff is present at the designated point of import to take samples and that there are laboratories with the requisite experience available to undertake the aflatoxin analyses. The availability of appropriate grinding equipment, in particular, is very important.

Competent authorities of Member States should therefore examine the list of designated points of import and ensure that the controls at all designated points of import can be performed efficiently and under good conditions.

[1] The requirements apply to the designated points of import or to the place where the sampling effectively takes place in case where the consignment is transported from the point of import under official control to that place to perform the sampling.

Designated points of import should fulfil at least the following requirements

(a) the presence of trained staff to perform official controls on consignments of foodstuffs;

(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 Commission Regulation (EC) 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 during the period of detention awaiting the results of analysis;

(e) the availability of unloading equipment and appropriate sampling equipment;

(f) the availability of an accredited official laboratory[2] for aflatoxin analysis, situated at a place to which the samples can be transported within a short period of time; the laboratory must have the appropriate grinding equipment for homogenising 10-30 kg samples[3]. The laboratory must be able to analyse the sample within a reasonable period of time in order to comply with the 15 working day maximum period of detention for consignments.

In addition, food business operators must make available sufficient human resources and logistics to unload the consignment, thus enabling representative sampling to take place.

Also, in the case of special transport and/or specific packaging forms, the operator/responsible food business operator must make available to the official inspector the appropriate sampling equipment insofar as representative sample cannot be obtained with the usual sampling equipment (see also point II.4).

II.3. Arrival of consignment for direct human consumption/to be subjected to sorting and/or other physical treatment at the first point of introduction/designated point of import

Every consignment to be subjected to a document check to ensure that the requirements for the health certificate and the sampling and analytical results are complied with and that each lot/batch making up the consignment has its own health certificate and sampling and analytical results (exception for almonds and derived products originating in or consigned from the US and not covered by VASP). **The documentary check must take place at the point of first introduction into the territory of the Community in case the foodstuffs are intended for import into the EU, whether this is a designated point of import or not. Eventually, an identity check can also be performed at the point of introduction (if this does not require an unloading of the consignment) and the appropriate boxes have to be ticked off in the common document for checks.**

---

[2] Laboratory that is accredited and is an official laboratory (belonging to the Competent Authority structure) or a laboratory designated by the competent authority

[3] The grinding step for homogenisation as part of sample preparation, can be performed outside the laboratory, but the premise where the grinding is performed must have the appropriate grinding equipment, environment and protocol for homogenisation.

The competent authorities at the point of introduction should ensure that:

(a) the consignment is accompanied by the results of sampling and analysis and a health certificate completed, signed and verified by the authorised representative (exception for almonds and derived products originating in or consigned from the US and not covered by VASP). A specimen of the health certificate from each third country covered by this Decision (Brazil, Egypt, Iran, China, Turkey and US) is provided in Annex VI to this Guidance Document

(b) the health certificate referred to above is valid for import and is within four months from the date of issue of the health certificate (for foodstuffs originating from Iran, applicable with immediate effect; for foodstuffs originating from the other third countries concerned, the requirement of validity of the health certificate is not applicable to consignments which left the country of origin before 1 October 2006).

Particular attention must be paid to consignments of nuts consigned from a country which is not a producer country, as the special conditions of a safeguard Decision are also applicable to the nuts consigned from another third country not concerned by the safeguard Decision but which are originating in the country concerned by the safeguard Decision. For example, the Commission Decision imposes special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil but these conditions also apply to Brazil nuts in shell consigned from the United States but originating in Brazil.

In particular, controls should ensure that the batch/lot identification code corresponds to the batch mentioned on the health certificate and the results of the official sampling and analysis. For products originating from Turkey, Iran and United States of America it must be verified that the signature of the official who signed the health certificate is on the list of authorised officials which is updated by the RASFF system (or eventually referring to the Annex VII of this guidance document).

Additionally, the validity of the certificate should not exceed four months and the certificate must be 'in date' at the moment of import. If the documentary check is carried out at a point other than the designated point of import, the designated point of import should ensure that all the documentation is still in date before authorising import.

The originals of the accompanying documents (results of sampling and analysis and health certificate) shall be forwarded to the competent authority at the designated point of import

In the case of Brazil nuts in shell from Brazil, the aflatoxin analysis must be performed by the official control laboratory for the analysis of aflatoxins in Brazil nuts in Belo Horizonte, Brazil, the Laboratório de Controle de Qualidade de Segurança Alimentar – (LACQSA*)*

In the case of almonds from US, the aflatoxin analysis must be performed by an USDA approved laboratory or a laboratory that has initiated the USDA approval process). A list of these laboratories is provided in Annex.

Identity check:

1. Certificates and other documents accompanying the consignment tally with the labelling of the consignment: physical check on the means of transport and on the packaging necessary to verify the compliance of consignment code, description of consignments, product and type of packaging with the information stated in certificates and other documents. Unloading of the consignment is not necessary.

2. Certificates and other documents accompanying the consignment tally with the content of the consignments: physical check on the means of transport and on the packaging necessary to verify the compliance of consignment code, description of consignments, product and type of packaging, gross or net weight of the consignment and the number of packaging with the information stated in certificates and other documents. Unloading of the consignment may be necessary.

3. Identification codes on the certificates and other documents accompanying the consignment correspond to the identification of individual entities of the consignment: physical check on the packaging necessary to verify whether identification codes on the certificates and other documents accompanying the consignment correspond to the identification of individual entities of the consignment. Unloading of the consignment may be necessary.

The competent authorities must also fill in the appropriate sections on the common document on the checks performed in order to inform other competent authorities on the controls already performed on the consignment concerned

All individual bags, packages etc must be indelibly marked with the batch identification code.

Where the consignment is labelled clearly showing its destination and bearing the indication "product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs" (on the labels on the bag and/or on the accompanying document with a clear link to the consignment coding labelled on the bags), the levels as well the sampling procedure applicable to this category are to be used (see II.7)

II.4. Selection of consignment for sampling

To note that the Commission Decision applies to the foodstuffs covered by the TARIC codes referred to at point II.1 and to processed and compound foodstuffs derived from or containing these foodstuffs.

The Commission Decision 2006/504/EC establishes different frequencies of controls:
- 5% of consignments of hazelnuts and certain products derived thereof from Turkey
- 10 % of consignments of peanuts and products derived thereof from China and dried figs, pistachios and products derived thereof from Turkey)
- 20 % of consignments of peanuts and products derived thereof from Egypt
- 100 % of consignment of pistachios and products derived thereof from Iran and Brazil nuts in shell from Brazil.
- 5 % of consignments of almonds and products derived thereof from the US and accompanied by a certificate demonstrating that the consignment is falling under the VASP
- 100 % of consignments of almonds and products derived thereof from the US and not accompanied by a certificate demonstrating that the consignment is falling under the VASP or accompanied by an invalid certificate

It should be noted that these percentages are applicable to each product category under specific TARIC codes.

The 5 %, 10 % or 20 % frequency of controls must be organised by the competent authorities in such a way that these control frequency percentages are achieved within a given period of time. The frequency of controls is to be considered as a minimum in the sense that competent authorities can decide to increase the frequency of controls if the analytical results indicate that this is necessary in order to safeguard public health.

Care must be taken that the selection of consignments is random, ensuring a proportionate treatment of the operators concerned. Nevertheless, the frequency of control can depend on the food business operator taking into account the history of compliance/non-compliance in conjunction with the requirements of the products placed on the market by a food business operator.

Sampling must be representative and incremental samples must be taken throughout the batch. It is therefore necessary in almost all cases to unload the truck or container for the sampling. Unloading should not expose the product to adverse weather conditions or excessive moisture.

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 rules[4], provides in Article 4(2)(g) that feed and food business operators (responsible operator) shall be obliged to undergo any inspection carried out in accordance with the Regulation and to assist staff of the competent authority in the accomplishment of their tasks..

This means that the food business operator must make available sufficient human resources and logistics to unload the consignment so as to enable representative sampling to be undertaken.

[4] OJ, L 165, 30.04.2004, p. 1. Corrigendum published in OJ L191, 28.5.2004, p. 1

Also in the case of special transport and/or specific packaging forms the operator/ responsible food business operator must make available to the official inspector the appropriate sampling equipment insofar as the sampling cannot be representatively performed with the usual sampling equipment.

II.5. Sampling provisions for a batch/lot/consignment.

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

NB: The Commission Decision specifies that, for example 10 % of consignments of Chinese peanuts must be sampled, and not 10 % of containers within a consignment

II.5.1. Consignment/lot consisting of several containers

If a consignment of peanuts (for example) consists of 10 containers, each of 22 tonnes, resulting in a consignment of 220 tonnes with the same batch identification code, the legislation provides that the consignment has to be split into five sublots of 44 tonnes (two containers). Representative sampling must be performed on sublots of two containers each. However, if the inspector decides to control only two containers out of the 10, the analytical result is only valid for the two containers sampled and, in the event of non-compliance, any official measures can only applied immediately (with respect of the right of the operator for a second opinion) to the two containers sampled.

However, Article 14(6) of Regulation (EC) 178/2002 provides that "*where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description,, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe*". However this article is not detrimental to the right of a second opinion for the operator as provided for in Article 11(5) of Regulation (EC) 882/2004.
This means that when on the basis of an official control, and after the operator has been given the right for a second opinion as foreseen in Article 11(5) of Regulation 882/2004, the controlled part of a consignment has been found to be non-compliant, accordingly the other containers from the consignment/lot/batch should be presumed to be also non-compliant unless the food business operator can demonstrate following a detailed assessment that the other parts of the consignment are safe (i.e. compliant with EU legislation as regards aflatoxins). This can be done e.g. by performing a representative sampling of all containers, in accordance with Regulation (EC) 401/2006.

It should be noted that where the safeguard measure requires a 100 % control on import, all consignments and all containers (sublots) of a consignment must be sampled.

II.5.2. Two or more consignments/lots in one container/truck

If a container or truck contains two lots of peanuts (for example), one lot of 8 tonnes and another of 15 tonnes, each with a separate batch/lot identification code, then the two batches/lots must be sampled separately, in accordance with the provisions of Regulation (EC) 401/2006 even if the product is identical (in this particular case from the 8 tonnes, 80 incremental samples of 300 g resulting in a sample of 24 kg and, from the batch of 15 tonnes, 100 incremental samples of 300g resulting in a sample of 30 kg). It is important that for each batch/lot a separate health certificate is issued and that each batch/lot has undergone sampling and analysis in the country of origin.

II.6. General Sampling requirements

As mentioned above, sampling must be representative and therefore it is necessary that the incremental samples are taken throughout the batch. In almost every case the truck or container will have to be unloaded for the sampling. Unloading should not expose the product to adverse weather conditions or excessive moisture. The area designated for sampling and storage of a consignment should not expose it to any risk of contamination or degradation. Food hygiene provisions are applicable.

Care should be taken to use clean sampling equipment and sample bags and containers free of contamination to avoid any cross-contamination.

II.6.1 Incremental sample for lots in retail packing

For lots in retail packing, the weight of the incremental sample may depend on the weight of the retail packing. Therefore, an element of judgement has to be employed. For example:

1. If retail packs, each weighing more than the required incremental sample, are to be sampled and individual packs are taken as incremental samples so that the aggregate sample sent to the laboratory weighs more than 10 kg or 30 kg, an incremental sample shall be taken from each individual retail pack to make up the 10 or 30 kg aggregate sample in the laboratory.

2. If the retail packs are large and option 1 would cause an unacceptable economic damage, then a number of individual samples should be collected to correspond to the required weight of the aggregate sample referred to in the respective tables in the sections below.

3. Where the retail pack weight is less than the required incremental sample weight 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 the required weight.

4. If the weight of the retail pack is much less than the required incremental sample, one incremental sample shall consist of two or more retail packs, whereby the required incremental sample weight is approximated as closely as possible.

II.6.2 Impossibility to carry out the prescribed method of sampling

If it is not possible to carry out the method of sampling set in legislation because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, or the number of retail packs is unavailable etc.), an alternative method of sampling may be applied, provided that it is as representative as possible and is fully described and documented. **An alternative method other than the one described in legislation (see II.9) may also be applied in case the individual vacuum packings are larger than 10 kg.**

II.7. Sampling procedure for dried figs, groundnuts, hazelnuts, pistachios, Brazil nuts, almonds and other nuts

II.7.1 General survey of the method of sampling

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	15-30tonnes --	100 10-100 (table 2)	30 ≤ 30
Groundnuts, hazelnuts pistachios, Brazil nuts, almonds and other nuts	≥ 500 >125 and <500 ≥ 15 and ≤ 125 < 15	100 tonnes 5 sublots 25 tonnes --	100 100 100 10-100 (table 2)	30 30 30 ≤ 30

II.7.2 Method of sampling for lots ≥ 15 tonnes

- On condition that the sublot can be separated physically, each lot must 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 sublot may vary from the mentioned weight by a maximum of 20 %. (If, after the division of a lot into sublots, the weight of the sublot exceeds the weight of the sublot as indicated in Table 1 by more than 20 %, the number of sublots has to be increased, even if by so doing the weight of the sublot is lower than the weight indicated in Table 1).

- Each sublot must be sampled separately.

- Number of incremental samples: **100.** Each incremental sample weighs 300 grams.

- **Weight of the aggregate sample = 30 kg** which has to **be mixed thoroughly** (*to avoid e.g. the incremental samples taken from the front of the consignment being at the bottom of the aggregate sample and the samples taken from the back of the consignment being at the top)* and **only afterwards to be divided into three equal laboratory samples of 10 kg before grinding and homogenisation.** This division into three laboratory samples is not necessary in the case of groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment before human consumption or use as an ingredient in foodstuffs (and where clearly labelled and treated as such – see point I 1) of the guidance).

- **Each laboratory sample must be separately ground finely to achieve complete homogenisation, in accordance with the provisions laid down in Commission Regulation (EC) 401/2006.**

II.7.3 Method of sampling for lots < 15 tonnes

- In the case of lots less than 15 tonnes, the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100 **(see table 2).**

Table 2: Number of incremental samples to be taken from dried figs, groundnuts, pistachios, Brazil nuts, almonds and other nuts for consignments of less than 15 tonnes

Lot weight (tonnes)	**N° of incremental samples**	**Aggregate sample weight (kg) (in case of retail packages, weight of aggregate sample can change)**	**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 has to **be <u>mixed thoroughly</u>** (*to avoid e.g. the incremental samples taken from the front of the consignment being at the bottom of the aggregate sample and the samples taken from the back of the consignment being at the top)* and **<u>only afterwards</u> to be divided into three equal laboratory samples of 10 kg before grinding and homogenisation.** This division into three laboratory samples is not necessary in the case of groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment before human consumption or use as an ingredient in foodstuffs (and where clearly labelled and treated as such – see point I 1) of the guidance).

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

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

- **Each laboratory sample must be separately ground finely to achieve complete homogenisation, in accordance with the provisions laid down in Commission Regulation (EC) 401/2006.**

II.7.4. Sampling of derived products and compound foods

II.7.4.1. Compound and derived products with very small particle size, i.e. flour, peanut butter (homogeneous distribution of aflatoxin contamination

- Number of incremental samples: 100. For lots of less than 50 tonnes the number of incremental samples should be 10 to 100, depending on the lot weight: **see table 3**)
- The weight of the incremental sample is about 100 grams.
- Weight of the aggregate sample = 1-10 kg sufficiently mixed
- For very large consignments the consignment has to be divided into sublots of 100 tonnes for consignments between 50 and 300 tonnes, into three sublots for consignments between 300 and 1500 tonnes and into sublots of 500 tonnes for consignments more than 1500 tonnes.

Table 3: Number of incremental samples

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

II.7.4.2. Compound and derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)

Sampling procedure and acceptance as laid down for the raw agricultural product.

II.7.5. Sampling of groundnuts, nuts, dried figs and derived products in vacuum packings[5]

II.7.5.1.Groundnuts and the edible nuts, pistachios and Brazil nuts, and dried figs

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 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 under II.7).

II.7.5.2. Edible nuts other than pistachios and Brazil nuts

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 30 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 under II.7).

[5] Because of the possible significant economic damage, an alternative method other than the one described in this section may be applied in case the individual vacuum packings are larger than 10 kg.

II.7.5.3. Products derived from or containing nuts, figs and groundnuts 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)..

II.8. Sampling procedure for spices

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in spices. The weight of the incremental sample shall be about 100 grams

II.8.1. General method of sampling for spices

Table 4 Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	N° incremental samples	Aggregate sample weight (kg)
Spices	≥ 15 <15	25 tonnes -	100 5 -100*	10 0.5-10

* Depending on the lot weight - see table 5

II.8.2 Method of sampling for spices (lots ≥ 15 tonnes)

- On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 4. 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 sublot may exceed the mentioned weight by a maximum of 20 %.

- Each sublot shall be sampled separately.

- Number of incremental samples: 100. Weight of the incremental sample: 100 g

- 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 as discussed above.

II.8.3. Method of sampling for spices (lots < 15 tonnes)

For lots of spices less than 15 tonnes the sampling plan shall be 5 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0.5 to 10 kg

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

Table 5 Number of incremental samples to be taken depending on the weight of the lot of spices

Lot weight (tonnes)	N° of incremental samples	Aggregate sample weight (kg)
≤ 0.01	5	0.5
> 0.01 - ≤ 0.1	10	1
> 0.1 - ≤ 0.2	15	1.5
> 0.2 - ≤ 0.5	20	2
> 0.5 - ≤ 1.0	30	3
> 1.0 - ≤ 2.0	40	4
> 2.0 - ≤ 5.0	60	6
> 5.0 - ≤ 10.0	80	8
> 10.0 - ≤ 15.0	100	10

II.8.4. Sampling of spices traded in vacuum packings

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 5 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 5).

II. 9 Sampling procedure for dried fruit other than 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 fruit other than dried figs

II.9.1. General method of sampling dried fruit, with the exception of figs

Table 6: Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	N° of incremental samples	Aggregate sample weight (kg)
Dried fruit other than dried figs	≥ 15 <15	15-30 tonnes -	100 10-100*	10 1-10

* Depending on the lot weight - see table 7

II.9.2. Method of sampling for dried fruit (lots ≥ 15 tonnes), with the exception of figs

- On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 6. 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 sublot may exceed the mentioned weight by a maximum of 20 %.

- Each sublot shall be sampled separately.

- Number of incremental samples: 100.

- The weight of the incremental sample shall be about 100 grams

- Weight of the aggregate sample = 10 kg

II.9.3.Method of sampling for dried fruit (lots < 15 tonnes), with the exception of figs

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

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

Table 7: Number of incremental samples to be taken depending on the weight of the lot of dried fruit other than dried figs

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

II.9.4 Sampling of dried fruit other than dried figs traded in vacuum packs

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 7 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 7).

II.10. Sampling procedure for vegetable oil

Although there is no prescribed sampling regime for vegetable oil, the sampling method for fruit juices including grape juice, grape must, wine and cider, as set out in Regulation (EC) 401/2006, can be applied.

- 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 8. 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 8: Minimum number of incremental samples to be taken from the lot

Form of commer-cialisation	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

II.11. Sampling procedures other than those described in Regulation (EC) 401/2006 which can be used for specific packing/trade forms of the products mentioned under II.7, II.8, II.9 and II.10

Several specific packing/trading forms have been identified for which the normal sampling procedure is not applicable:
- large bags, large boxes
- wrapped pallets
- paste (hazelnut paste, …)
- packing under CO_2
- ….

RECOMMENDATION

- To identify other common special forms of packing to which the normal sampling procedure appears not to be applicable and for which the establishment of a common specific sampling procedure (such as the one outlined for vacuum packs) is appropriate.

For example, a consignment of 20 tonnes of hazelnut paste traded in 100 barrels, each of 200 kg. A sampling procedure applied by a Member State consists of taking incremental samples from 10 barrels (different layers within a barrel) resulting in an aggregate sample of 6 kg (10 x 600 g).

Furthermore, the sampling procedure should also take into account other legitimate factors such as hygiene. For example, the sampling of a paste carried out in tanker lorries with openings at the bottom and the top. Sampling from the bottom opening could cause hygiene problems due to plug-building, and therefore it is preferable in such cases to take samples from the top opening at three levels in the tank (bottom, middle and top).

Competent authorities and other bodies and organisations concerned are encouraged to provide Commission services with information on best practices of sampling procedures currently applied or applicable on these specific forms of packing accompanied where appropriate by reports of experience in applying this sampling procedure. Competent authorities and other bodies and organisations concerned are also encouraged to provide information and description of available sampling equipment.

The information should be provided to Frans Verstraete, European Commission, Health and Consumer Protection DG, **preferably** by @mail (Frans.Verstraete@ec.europa.eu) or by fax (+32-2 299.18.56), or by mail (European Commission – Office F101 04/56 – B-1049 Brussels)

After discussion of the information supplied in the competent Expert Committee, that information will be included in the guidance document under this chapter.

II.12. Period of detention

Any consignment of a commodity covered by the safeguard measure that is to be subjected to sampling and analysis may be detained from the moment the consignment is offered for import and physically available for sampling (**physically available for sampling means that the consignment is physically available and can be sampled without danger for the sampling official**. **In case the consignment has been fumigated, then the consignment is considered as being physically available for sampling only after it has been aired/ventilated and officially found safe for sampling)** until release onto the market from the designated point of import into the Community for a maximum of **15 working days (3 weeks of calendar days).** This maximum period of 15 days is only applicable to the official sampling and does not include the additional time needed when a second analysis is required by the operator.

For some specific derived and compound foodstuffs covered by the provisions of Commission Decision 2006/504/EC the shelf life is so short that the maximum detention period should be shortened. Member States take the necessary measures to ensure that the control on foodstuffs with a short expiry date is performed in such a way that the consignment needs only to be blocked for a very limited period so that the foodstuff remains marketable after control and having been found compliant (expiry date not passed)

It concerns in particular the derived and compound foodstuffs, mentioned in Annex VIII of this Guidance document

II.13. Sample preparation // for direct human consumption // to be subjected to sorting and/or other physical treatment (see above)

II.13.1 Mixing of the sample

The sample must be thoroughly mixed **but not ground** before dividing the sample into laboratory sample(s) in the case of products intended for direct human consumption. (This can be done when the sample is collected or in the laboratory).

At the place of sampling the sample is clearly labelled and the aggregate sample or the laboratory sample(s) are sealed. This subdivision into laboratory sample(s) can also be performed in the laboratory.

II.13.2. Treatment of the sample as received in the laboratory

The aggregate sample or the laboratory sample(s) must arrive **sealed** at the laboratory in an opaque bag/container (as aflatoxins break down under the influence of ultra-violet light/daylight).

It must be clearly mentioned on the document accompanying the sample if the consignment is intended for direct human consumption or to be subjected to sorting and/or other physical treatment before human consumption.

Where the consignment is intended for direct human consumption:
- sample arrived at the laboratory as laboratory sample(s): proceed with homogenisation procedure;
- sample arrived at the laboratory as aggregate sample: aggregate sample must be first divided into separate laboratory sample(s) before proceeding with the homogenisation procedure

II.13.3. Homogenisation procedure

Finely grind each entire laboratory sample completely (and **not** only a part of it) using a process that has been demonstrated to achieve complete homogenisation[6] (see below).

The wet grinding and homogenisation process, which results in most cases in slurry, which is more homogeneous than can be obtained by a dry grinding and homogenisation process, is recommended.

As the homogenisation procedure might result in a slurry which is subject to microbial degradation, it is appropriate that the homogenised laboratory samples as well the analytical samples taken from the homogenised sample are stored in such conditions that microbial contamination and growth is excluded.

II.13.4.Accreditation – standard operation procedure:

The sample preparation must be available at the laboratory as a Standard Operation Procedure (SOP) and must be covered by the accreditation. The laboratory must be able to demonstrate that the homogenisation procedure used achieves complete homogenisation. This can be demonstrated by taking different analytical samples at different locations in the homogenised laboratory sample and analyse for the aflatoxin content. The levels of aflatoxins analysed in the different analytical samples from one homogenised laboratory sample should be within the range of the variability of the method.

II.14. Samples for defence and reference purposes

II.14.1.Defence and reference samples taken from the homogenised laboratory sample

Samples for defence and reference purposes are taken from the homogenised laboratory samples– see provisions in Commission Regulation (EC) 401/2006 – Annex I, point A.3.6.

In the case of products intended for direct human consumption, one analytical sample, one defence sample and one reference sample (in quantities needed according to GLP) are taken of each laboratory sample.

So, for every aggregate sample taken from a batch of nuts intended for direct human consumption, nine samples in total are obtained from the homogenised laboratory samples, that are three analytical samples, three defence samples, three reference samples.

Since the defence and the reference samples are obtained from the homogenised sub-samples they can only be obtained from the laboratory.

Different rules are applicable in the Member States regarding the obligatory presence in the laboratory of an official inspector and the food business operator when the defence and reference samples are taken.

---

[6] The grinding step for homogenisation as part of sample preparation, can be performed outside the laboratory, but the premise where the grinding is performed must have the appropriate grinding equipment, environment and protocol for homogenisation.

As the homogenisation procedure might result in a slurry, which is subject to microbial degradation, it is appropriate that the homogenised laboratory samples as well the replicate samples taken from the homogenised sample are stored and transported in such conditions that microbial contamination and growth is excluded.

The following papers, the first of which was produced by the European Committee for Standardisation (CEN) provide further information:

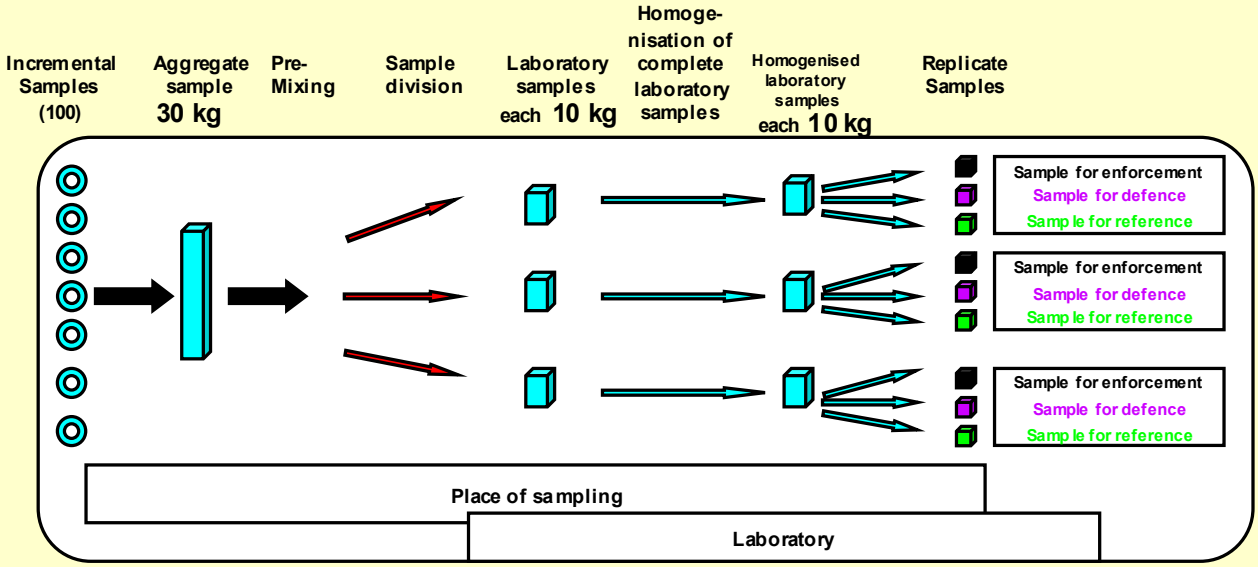
- "Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?"

M.C. Spanjer *et al.* (2006) Food Additives and Contaminants, **23**, 73 – 83.

- "Use of water slurries in aflatoxin analysis"

J. Velsaco and S. L. Morris (1976) J. Agric. Food Chem., **24**, 86 – 88.

Samples for enforcement, defence and reference taken from homogenised laboratory or subsamples



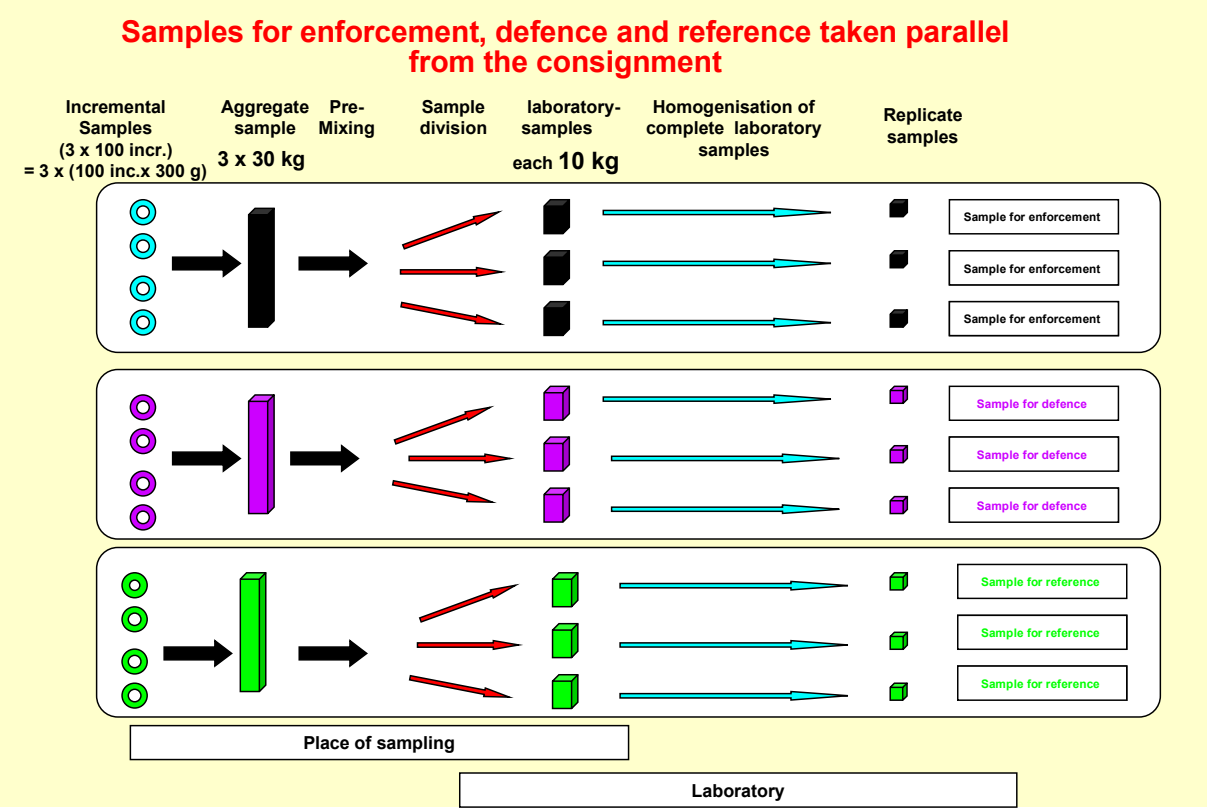
NB: Each of the 3 enforcement samples have to be compliant for a consignment to be accepted

II.14.2. Defence and reference samples are taken at the place of sampling

In **two** Member States (Spain and Germany because of their additional national legislation as regards the rights of the operator which is not overruled by Commission Regulation (EC) 401/2006), it is stipulated that the defence and reference samples have to be taken from the consignment in the presence of the operator, including in the case of sampling for aflatoxin analysis. Commission Regulation (EC) 401/2006 provides for that possibility.

If this is the case then the sampling procedure as outlined in II.7 must be applied, on the understanding that, for example, 2 x 100 (for official + defence sample) or 3 x 100 (for official + defence + reference sample) incremental samples must be taken, resulting in two or three aggregate samples of 30 kg. Each aggregate sample must be further processed as outlined above.

As the homogenisation procedure might result in a slurry, which is subject to microbial degradation, it is appropriate that the homogenised laboratory samples as well the analytical samples taken from the homogenised sample are stored and transported in such conditions that microbial contamination and growth are excluded



NB: Each of the 3 enforcement samples has to be compliant for a consignment to be accepted

II.15. Requirements laboratories

Regulation (EC) 882/2004 provides in article 12 that the competent authority designate laboratories that may carry out the analysis of samples taking during official controls.

However competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European Standards

- EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories"

- EN 45002 on "General criteria for the assessment of testing laboratories"

- EN 45003 on "Calibration and testing laboratory accreditation system – General requirements for operation and recognition".

It is also of major importance that the laboratories have Standard Operating Procedures (SOP), not only for the analysis itself but also for the sample preparation, extraction/clean-up and quantification procedures.

As part of the official control, analysis of the enforcement sample and also the analysis of the defence sample when the analytical result of the defence sample supersedes the analytical result of the enforcement sample (see II.21 point 1), must be performed by a laboratory that is accredited and is an official laboratory (belonging to the Competent Authority structure) or a laboratory designated by the competent authority. The Competent Authority should ensure that any such designated laboratories fully meet the criteria established The food business operator has the right to select an official laboratory or a laboratory from the list of laboratories designated by the competent authority for analysis of samples taken during official control for the analysis of the defence sample[7].

In other cases (see point II.21. point 2 and 3) than the one mentioned above, the analysis of the defence sample must be performed by a laboratory that is accredited. The food business operator has the right to select a laboratory that is accredited for the analysis of the defence sample.

However, it has to be noted that when a judicial procedure has been initiated following a dispute, the judicial authorities decide upon the procedure to be followed.

[7] In Portugal and Greece, in case the food business operator requests the analysis of the defence sample, the analysis is performed in the official laboratory in the presence of an analytical expert, appointed by the food business operator.

II.16. Requirements governing the method of analysis

The method of analysis used by the laboratory must comply with the performance criteria laid down in point 4 of Annex II to Regulation (EC) 401/2006. The laboratory must be able to provide the evidence that the method of analysis used does comply with the established performance criteria.

II.16.1. Performance criteria as laid down in Commission Regulation (EC) 401/2006

Laboratories may select any method, provided the selected method meets the following criteria:

Criterion	Concentration Range	Recommended Value	Maximum permitted Value
Blanks	All	Negligible	-
Recovery - Aflatoxin M1	0.01-0.05 µg/kg	60 to 120 %	
	> 0.05 µg/kg	70 to 110 %	
Recovery - Aflatoxins B_1, B_2, G_1, G_2	< 1.0 µg/kg	50 to 120 %	
	1 - 10 µg/kg	70 to 110 %	
	> 10 µg/kg	80 to 110 %	
Precision RSD_R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD_r may be calculated as 0.66 times Precision RSD_R at the concentration of interest			

Notes:

- Values to apply to both B_1 and sum of $B_1 + B_2 + G_1 + G_2$.
- If sums of individual aflatoxins $B_1 + B_2 + G_1 + G_2$ are to be reported, then the response of each to the analytical system must be either known or equivalent.
- The detection limits of the methods used are not stated since the precision values are given at the concentrations of interest
- The precision values are calculated from the Horwitz equation, i.e.:

$$RSD_R = 2^{(1-0.5\log C)}$$

where:

* RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [$(s_R / \bar{x}) \times 100$]
* C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1000 mg/kg)

This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

II.16.2. Definitions

The most commonly quoted precision parameters are repeatability and reproducibility.

r = Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2.8 \times s_r$.

s_r = Standard deviation, calculated from results generated under repeatability conditions.

RSD_r = Relative standard deviation, calculated from results generated under repeatability conditions [$(s_r / \bar{x}) \times 100$], where $\bar{x}$ is the average of results over all samples analysed under the same conditions within one laboratory.

R = Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e. on identical material obtained by operators in different laboratories, using the standardised test method) may be expected to lie within a certain probability (typically 95%); $R = 2.8 \times s_R$.

s_R = Standard deviation, calculated from results under reproducibility conditions.

RSD_R = Relative standard deviation calculated from results generated under reproducibility conditions [$(s_R / \bar{x}) \times 100$] where $\bar{x}$ is the average of results over all laboratories and samples.

.

II.17. Precautions to be taken and calculation of the analytical result with regard to the edible part of the foodstuff

II.17.1. Precautions

Daylight should be excluded as much as possible during the whole procedure of transport of sample, sample preparation and analysis, since aflatoxin gradually breaks down under the influence of ultraviolet light. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared - and especially homogenised - with extreme care.

All the material received by the laboratory is to be used for the preparation of the homogenised sample.

II.17.2. Calculation of proportion of shell/kernel of whole nuts

The limits established for aflatoxins in Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs **apply to the edible part**.

The level of aflatoxins in the edible part can be determined as follows:

- samples of nuts "in shell" can be shelled and the level of aflatoxins is determined in the edible part.

- the nuts "in shell" can be taken through the sample preparation procedure. The sampling and analytical procedure must estimate the weight of nut kernel in the aggregate sample. The weight of nut kernel in the aggregate sample is estimated after establishing a suitable factor for the proportion of nut shell to nut kernel in whole nuts. This proportion is used to ascertain the amount of kernel in the bulk sample taken through the sample preparation and analysis procedure.

  Approximately 100 whole nuts are taken at random separately from the lot or are to be put aside from each aggregate sample. The ratio may, for each laboratory sample, be obtained by weighing the whole nuts, shelling and re-weighing the shell and kernel portions.
  However, the proportion of shell to kernel may be established by the laboratory from a number of samples and so can be assumed for future analytical work. But if a particular laboratory sample is found not to comply with the maximum level, only slightly exceeding the maximum level, the proportion should be determined for that sample using the approx. 100 nuts that have been set aside.

Example: <u>Where</u> the nuts in shell have gone through the sample preparation procedure and the ratio nut shell/nut kernel is 50/50 and if the analytical result in the test material is 1.5 µg/kg of aflatoxin B1, recalculation of this amount of aflatoxin B1 to the edible part is 1.5 µg x 2 = 3 µg/kg .

II.18. Reporting of results

The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery is used for checking compliance.

The analytical result has to be reported as x +/- U, where x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

Important information on these items can be found in the document

"Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions in EU Food and Feed legislation with particular focus on the community legislation concerning

- contaminants in food (Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[8])

- undesirable substances in feed (Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[9])"

The document is available at the SANCO Food Safety website: http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

[8] Official Journal of the European Communities, L37, 13.2.1993, p. 1
[9] Official Journal of the European Communities, L 140, 30.5.2002, p. 10

II.19. Acceptance of a lot or sublot and interpretation of results

– For groundnuts, nuts and dried fruit subjected to a sorting or other physical treatment and spices:

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

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

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

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

  – rejection if one or more of the laboratory samples exceeds the maximum limit **beyond reasonable doubt taking into account the** expanded **measurement uncertainty and correction for recovery***,

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

  – acceptance if the aggregate sample conforms to the maximum limit, taking into account the expanded measurement uncertainty and the correction for recovery,

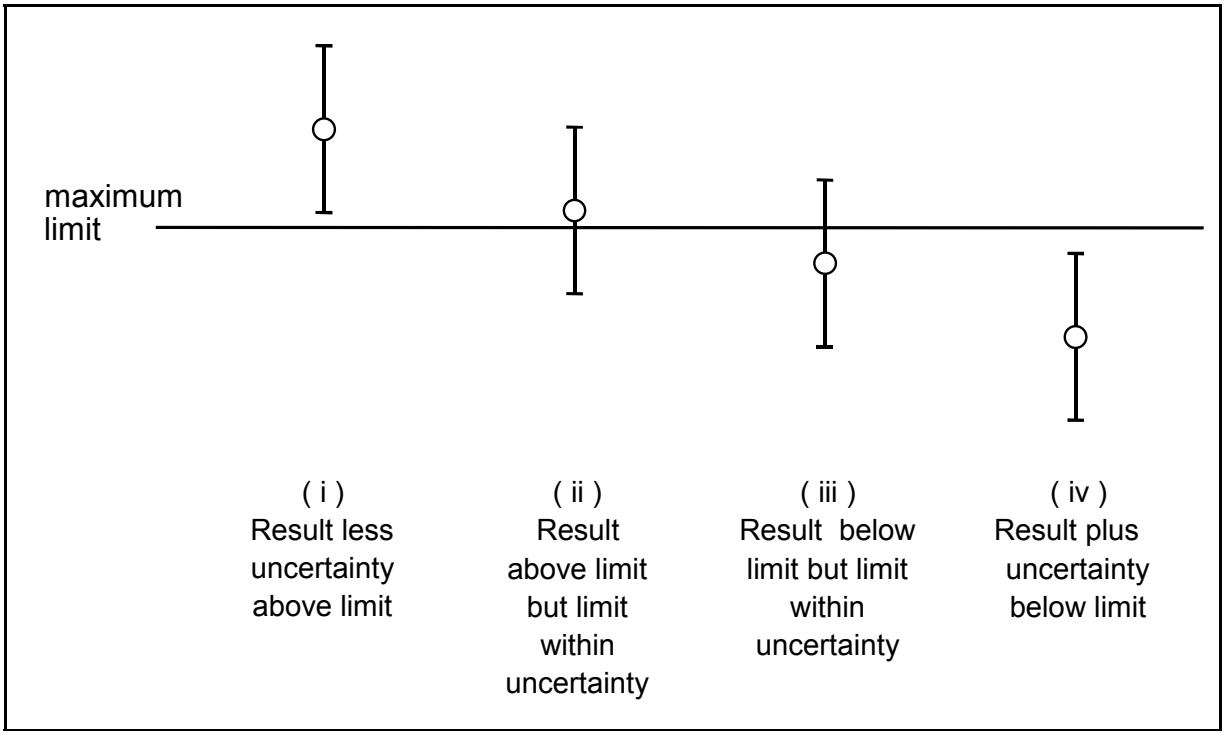
  – rejection if the aggregate sample exceeds the maximum limit **beyond reasonable doubt taking into account the** expanded **measurement uncertainty and correction for recovery***.

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

The present interpretation rules of the analytical result in view of acceptance or rejection of the lot apply to the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

Additional explanatory information

Interpretation of the expanded measurement uncertainty when considering compliance with a statutory limit, where the circle is the analytical result.



Action:	**reject**	**accept**	**accept**	**accept**

Example on the Use of expanded Measurement Uncertainty (MU)

The analysis of three different batches of paprika gave the following results for aflatoxin B1 (analytical results already corrected for recovery):

1. 3.0 µg/kg (40% MU) = 3.0 ± 1.2 µg/kg i.e. range 1.8 – 4.2 µg/kg
2. 6.0 µg/kg (40% MU) = 6.0 ± 2.4 µg/kg i.e. range 3.6 – 8.4 µg/kg
3. 9.0 µg/kg (40% MU) = 9.0 ± 3.6 µg/kg i.e. range 5.4 – 12.6 µg/kg

The result for batch 1 is below the limit (5 µg/kg aflatoxin B1) both with and without expanded measurement uncertainty being taken into account. This sample is therefore compliant with the maximum limit.

The reported result for batch 2 is above the statutory limit, but the true value for this analysis lies in the range 3.6 – 8.4 µg/kg. This sample is considered compliant, as it is not beyond reasonable doubt that the maximum limit has actually been exceeded.

The reported result for batch 3 is once again above the statutory limit and the range of values obtained, taking into account the expanded measurement uncertainty is also above the limit. This sample is therefore non-compliant.

Example on the Use of expanded Measurement Uncertainty (MU) and correction for recovery

The analysis of different batches of paprika gave the following results for aflatoxin B1 (analytical results still to be corrected for recovery):

1. 3.0 µg/kg (40% MU, 75 % recovery) = 4.0 ± 1.6 µg/kg i.e. range 2.4 – 5.6 µg/kg
2. 3.0 µg/kg (40% MU, 110 % recovery) = 2.7 ± 1.1 µg/kg i.e. range 1.6 – 3.8 µg/kg
3 6.0 µg/kg (40% MU, 75 % recovery) = 8.0 ± 3.2 µg/kg i.e. range 4.8 – 11.2 µg/kg
4. 6.0 µg/kg (40% MU, 110 % recovery) = 5.5 ± 2.2 µg/kg i.e. range 3.3 – 7.7 µg/kg.
5. 9.0 µg/kg (40% MU, 75 % recovery) = 12.0 ± 4.8 µg/kg i.e. range 7.2 – 16.8 µg/kg
6. 9.0 µg/kg (40% MU, 110 % recovery) = 8.2 ± 3.3 µg/kg i.e. range 4.9 – 11.5 µg/kg

Following samples are considered to be compliant with the maximum levels: 1, 2, 3, 4, 6. Following samples are considered to be non-compliant with the maximum levels: 5

II.20. Completion of common document for checks performed on foodstuffs covered by Commission Decision 2006/504/EC

The common document for checks performed on foodstuffs covered by Commission Decision 2006/504/EC has to be completed by the competent authority when the consignment is compliant, stating that the consignment has been officially sampled on (date) and analysed in accordance with Regulation (EC) 401/2006 and was found to be compliant, indicating the analytical results (possibly with analysis report enclosed). **These documents must accompany the consignment up to and including the initial wholesale stage.**

Where only part of the consignment was found compliant with EU legislation, the original certificate (or certified copies), without modifications, has to accompany the part of the consignment allowed for free circulation. As the quantity allowed for free circulation does not correspond to the quantity mentioned on the original health certificate, an official explanatory statement should appear in the common document for checks performed on foodstuffs covered by Commisson decision 2006/504/EC. .

II. 21. Right of second opinion for the operator in case of non-compliance

The right of a second opinion for operators in the case of the official sample being found non-compliant is provided for in Article 11(5) of Regulation (EC) 882/2004. The analysis of the defence sample must be performed in an official laboratory or a laboratory designated by the competent authority, or it is sufficient that the laboratory is accredited according to the case. In all cases the laboratory must be accredited or must have adequate quality control procedures in place (see point II.15).

The taking of the defence and reference samples is addressed in point II.14.

Four approaches can be identified within the Member States if the defence sample generates a compliant result

1) the consignment is considered compliant and released (the result of the defence samples supersedes the outcome of the official result). This approach is followed in France, Greece, Sweden, Belgium, Finland

2) the reference sample is analysed in the national reference laboratory. If the analytical result is compliant with the legislation, the consignment is considered compliant and released. This approach is followed in UK, Estonia, Hungary, Spain, Poland**,** Czech Republic, The Netherlands, Portugal, Ireland, Slovak Republic, Romania, Italy

3) the operator must challenge the analytical result of the official sample before a Court. This approach is followed in Denmark, Slovenia, Germany, Luxembourg, Lithuania

4) the operator must demonstrate that the consignment is compliant by organising at least an additional sampling of the lot and analysis of these samples by an accredited laboratory, associated with an expert approved by the competent authority to carry out expertise on such samples taken during official controls. If the analytical result is compliant with the legislation, the rest of the consignment is considered compliant and released. This approach is followed in Austria.

II.22. Notification to the Rapid Alert System for Food and Feed (RASFF)

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[10] established a Rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed as a network.

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

[10] OJ L 31, 1.2.2002, p. 1

Notification to the RASFF of failures on documentary check
* minor issues: failures have to be notified to the RASFF but will not necessarily be circulated within the RASFF system
* failures indicating a possible fraud or possible recurrent problems: failures have to be notified to the RASFF and these notifications will in principle be circulated for information within the RASFF system

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

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

II.23. Reporting to the Commission of all analytical results

Member States shall submit to the Commission every three months a report of all analytical results of official controls on consignments of products, subject to the Commission Decision. This report shall be submitted during the month following each quarter (April, July; October, January).

The results should be provided per product/product category – country of origin combination and will contain per product/product category – country of origin combination at least following information
- number of batches imported (if available)
- number of batches sampled and analysed
- number of batches found to be compliant with EU legislation
- number of batches found to be non-compliant with EU legislation

II.24 Procedure to be followed for the consignment in case of non-compliance

II.24.1. General provision and remark

In the event of a non-compliant consignment, the health certificate and any other relevant accompanying document (specifically relevant for import into the EU) should be made invalid in every case, by a large red stamp "**REFUSED FOR ENTRY INTO THE EU**" (or a similar marking) The accompanying document can be rendered null and void by putting on the health certificate, and on any other relevant accompanying document (specifically relevant for import into the EU) including the commercial invoice, one of the endorsements provided for in Article 6(1) and (2) of Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[11].

[11] OJ L40, 17.2.1993, p. 1

Products covered by Commission Decision 2006/504/EC can be deemed non-compliant solely on the grounds of incorrect documentation.

However, it has to be noted that when a judicial procedure has been initiated following a dispute, it is the prerogative of the judicial authorities to decide upon the fate of the non-compliant consignment.

'Re-dispatch' means the return of a consignment, which has not been imported into EU territory, to the country of origin or another third country, which has agreed to accept it.

'Re-export' means the exportation of a consignment, which has been imported into EU territory and subsequently been found to be non-compliant, to the country of origin or another third country, which has agreed to accept it.

II.24.2.The specific case: Brazil nuts in shell

Consignments of Brazil nuts not complying with the maximum levels for aflatoxin B1 and aflatoxin total established by Regulation (EC) No 1881/2006 may be returned to the country of origin only where, for each such individual non-conforming consignment, the Ministério da Agricultura, Pecuária e Abastecimento – (MAPA) provides the following in writing:

(a) explicit agreement for the return of the relevant consignment, and indicating the consignment code;

(b) a commitment to put the returned consignment under official control from the date of arrival;

(c) a specific indication of:

  (i) the destination of the returned consignment;

  (ii) the intended treatment of the returned consignment; and

  (iii) the intended sampling and analysis to be performed on the returned consignment.

However, if the conditions provided for in points (a), (b) and (c) are not complied with by the Ministério da Agricultura, Pecuária e Abastecimento – (MAPA), all subsequent consignments that do not comply with the maximum levels for aflatoxin B1 and aflatoxin, established by Regulation (EC) No 1881/2006 shall be destroyed by the importing Member State.

II.24.3. In all the other cases (other than Brazil nuts in shell from Brazil)

There are no specific provisions provided in Commission Decision 2006/504/EC.

However, the health certificate should be made invalid in every case (see general provision above).

However, the following provisions concerning the non-compliant consignments are laid down in general Community legislation as regards general principles and requirements of food law and official controls to ensure verification of compliance with feed and food law.

II.24.3.1.Food produced within the EU (exported) or food that has been put on the EU-market after having been imported (re-exported) [12]

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety authority and laying down procedures in matters of food safety[13] provides as a general rule in Article 12, which became applicable in the EU from 1 January 2005 onwards, that non-compliant consignments **already in free circulation in the internal market can only be re-exported if they comply with EU food legislation, unless otherwise required by the authorities, legislation or administrative procedures of the importing country.**

The situation referred to is that third countries have set their own level of protection for a particular food or feed, and exporting and re-exporting operators must then comply with the requirements set up by importing countries.

In this case the exporting and re-exporting operators shall submit written affirmation or confirmation of the competent authority of an importing country indicating the following information:
1. exact and unambiguous identification of the food (name, lot number etc.)
2. specification of the shortcoming (e.g. exceeding the limit established by EC legislation for the particular contaminant, declaration of the contaminant content)
3. reference to the relevant laws, regulations, standards, and other legal and administrative procedures of the importing country and the maximum level or requirement being in force in the importing country.

Where no requirements are set by the authorities of the importing countries (legislation or administrative procedures), the food and feed intended for export or re-export must comply with the relevant requirements of Community food law.

In all other cases, i.e. if there is no relevant Community food law requirement e.g. there is no regulatory limit for aflatoxin in the particular commodity and the third country has not set any specific requirements applicable to imports, paragraph 2 of Article 12 provides that food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons why the feed and food could not be put or remain on the market within the EU.
However, if the food and feed does not comply with the provisions of food/feed safety legislation ("where foods are injurious to health or feeds are unsafe"), such food and feed cannot be exported or re-exported and safe disposal must be ensured.

Applying these measures by analogy to the case of aflatoxins, this means that a non-compliant consignment can only be re-exported if the third country of destination has set specific requirements and the consignment complies with these specific requirements of the importing country. In all other cases, the consignments cannot be exported or re-exported and they must be disposed of safely.

[12] Reference is made to document « Guidance on the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health - 20 December 2004 » -available on the website of the Health and Consumer protection Directorate-General at http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf
[13] OJ L 31, 1.2.2002, p. 1

II.24.3.2. Food rejected at the external border of the EU

For **food rejected at the external border of the EU**, **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 rules[14] applies from 1 January 2006 and provides in its Articles 19, 20 and 21 the following measures as regards non-compliant consignments.

The non-compliant consignment originating in or consigned from a third country is placed under official detention by the competent authority and, after having heard the food business operator responsible for the consignment, the following measures in respect of that consignment are taken:

- order that such food be destroyed

- subjected to special treatment

The special treatment must take place in establishments under the control of the competent authority and may include

- treatment or processing to bring the food into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution – IMPORTANT NOTE: in the case of food contaminated with aflatoxin, detoxification by chemical treatment is prohibited;
- processing in any other suitable manner for purposes other than animal or human consumption.

- re-dispatched outside the Community. Pending re-dispatch of consignments, the competent authority shall place the consignments under official detention. The re-dispatch of the consignment is allowed by the competent authority only if

* the destination has been agreed with the food business operator responsible for the consignment; and

* the food business operator has first informed -and provided proof to- the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the feed or food concerned within the Community; and

* where the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

Competent authorities shall co-operate to take any further measures necessary (in addition to the notification to RASFF – see II. 22) to ensure that it is not possible for the rejected consignments to be reintroduced into the Community.

- other appropriate measures such as the use of the feed or food for purposes other than those for which they were originally intended

The food business operator responsible for the consignment or its representative shall be liable for the costs incurred by the competent authorities for the above-mentioned activities.

[14] OJ L 165, 30.04.2004, p.1. Corrigendum published on OJ L191, 28.5.2004, p. 1

However, Article 19 (2) (a) of Regulation (EC) 882/2004 provides that if the official control indicate that a consignment is injurious to human or animal health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure necessary to protect human and animal health

Given that worldwide the highest level established for aflatoxin B1 is 20 µg/kg and for aflatoxin total 35 µg/kg[15], these levels are considered as being upper limits above which consignments must be rejected and cannot be re-dispatched without any control and appropriate measures have to be taken to protect human or animal health.

These levels do also apply to other foodstuffs imported into the EU e.g. spices, melon seeds, sesame seeds …

[15] Worldwide regulations for mycotoxins in food and feed in 2003, FAO FOOD AND NUTRITION PAPER 81, available in English, French and Spanish on http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/007/y5499e/y5499e00.htm

These appropriate measures could be

a) destruction of the goods under official control and the costs are borne by the food business operator

b) use under official control for industrial purposes (non feed /non food uses)

c) use under official control for oil extraction provided the resulting oil is refined to reduce any aflatoxin which may be present to acceptable levels and use under official control of the residual cake/meal for animal feeding after an appropriate treatment (detoxification).

d) re-dispatch to the country of origin under following strict conditions
"For each such individual non-conforming consignment, the competent authority of the country of origin (the authority responsible for issuing the health certificate) provides the following in writing:

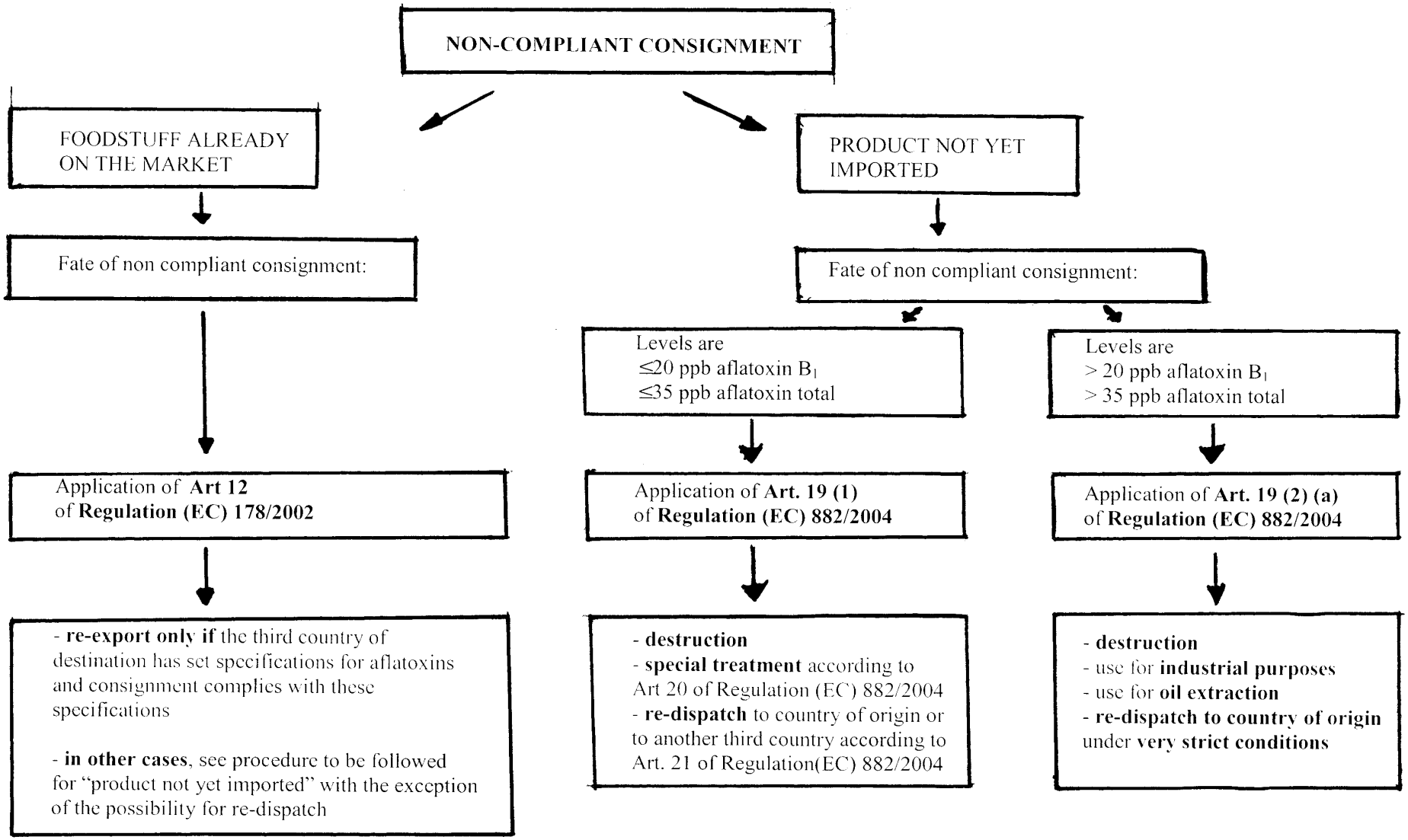
(a) explicit agreement for the return of the relevant consignment, and indicating the consignment code;
(b) a commitment to put the returned consignment under official control from the date of arrival;
(c) a specific indication of:
    (i) the destination of the returned consignment;
    (ii) the intended treatment of the returned consignment; and
    (iii) the intended sampling and analysis to be performed on the returned consignment."

The possibility for sorting and physical treatment in case of non-compliance is limited to the cases of consignments, not complying with EU legislation but containing levels below the worldwide highest level established for aflatoxin B1 and total:

Nuts labelled for direct human consumption found with levels of total aflatoxins above those for direct human consumption or as an ingredient and below the worldwide highest level established for aflatoxin B1 is 20 µg/kg and/or for aflatoxin total 35 µg/kg, can be re-labelled and sorted or undergo a physical treatment to reduce aflatoxin content under official control. This requires that the transfer to the processing plant, the process and the sampling and analysis have to be performed under the official control of the competent authority. After sorting and/or physical treatment, an official sampling and analysis must be performed to demonstrate that the nuts should be compliant with the limits set for direct human consumption or use as an ingredient.

Similarly, nuts labelled for further processing found with levels above those set in legislation but below the worldwide highest level established for aflatoxin B1 is 20 µg/kg and/or for aflatoxin total 35 µg/kg, can be re-labelled and also be further sorted or undergo a physical treatment under official control as above.

II.24.3.3. Schematic overview


NON-COMPLIANT CONSIGNMENT
FOODSTUFF ALREADY ON THE MARKET
PRODUCT NOT YET IMPORTED
Fate of non compliant consignment:
Fate of non compliant consignment:
Levels are
≤20 ppb aflatoxin B1
≤35 ppb aflatoxin total
Levels are
> 20 ppb aflatoxin B1
> 35 ppb aflatoxin total
Application of Art 12 of Regulation (EC) 178/2002
Application of Art. 19 (1) of Regulation (EC) 882/2004
Application of Art. 19 (2) (a) of Regulation (EC) 882/2004
- re-export only if the third country of destination has set specifications for aflatoxins and consignment complies with these specifications
- in other cases, see procedure to be followed for "product not yet imported" with the exception of the possibility for re-dispatch
- destruction
- special treatment according to Art 20 of Regulation (EC) 882/2004
- re-dispatch to country of origin or to another third country according to Art. 21 of Regulation(EC) 882/2004
- destruction
- use for industrial purposes
- use for oil extraction
- re-dispatch to country of origin under very strict conditions

II.25. Costs of official controls

Article 8 of Commission Decision 2006/504/EC of provides that all costs resulting from sampling, analysis, storage and issuing of accompanying official documents and of copies of health certificate and accompanying documents for consignments Brazil nuts in shell from Brazil, pistachios and derived products thereof from Iran and almonds and derived products from US not accompanied by a certificate demonstrating that it is covered under the VASP, shall be borne by the food business operator responsible for the consignment or its representative.

No specific provisions are provided as regards the calculation of these costs. For the calculation of the costs resulting from sampling and analysis, the provisions in Regulation (EC) 882/2004 could be used as guidance, in particular the criteria mentioned in Annex VI to the mentioned Regulation:

- salaries of the staff involved in the controls of pistachios and certain products derived from pistachios originating in or consigned from Iran

- costs for these staff, including facilities, tools, equipment, training, travel and associated costs

- laboratory analysis and sampling costs

In addition, also the costs related to the storage and the issuing of official documents have to be taken into account.

Article 8 (2) of Commission Decision 2006/504/EC provides that, in accordance with Article 22 of the Regulation (EC) 882/2004 all costs related to official measures taken by the competent authorities as regards non-compliant consignments shall be borne by the food business operator responsible for the consignment or its representative.

II.26 Specific issues

II.26.1. Procedure for splitting the consignment

If a consignment is split, copies of the report and health certificate and the accompanying document shall accompany each part of the split consignment. These copies must be certified by the competent authority of the Member State on whose territory the splitting has taken place. These certified copies must accompany the split consignment up to and including the wholesale stage.
At the wholesale stage, the products are not yet offered for sale to the final consumer and the split consignment is generally still a significant part of the original consignment e.g. > 1 tonne or > 10 % of the weight of the original consignment.

II.26.2. Finding of non-compliance at retail stage

When an instance of non-compliance is found by taking only a small quantity of sample at the retail stage it is important to consider how representative the sample taken was of batch available at the retail level and also the batch/lot as a whole and therefore the implications for a product recall. Due to the non-homogeneous distribution of aflatoxins in most commodities generally samples taken at the retail stage will not be representative of the original batch/lot from which the product at retail stage originates from.

Procedure proposed:

When non-compliance is found at the retail level it is only an indication of possible problems with other parts of the batch/lot.

Article 14(6) of Regulation (EC) 178/2002 provides that "*where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description,, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe*".
Therefore, unless there is a serious level of contamination, the competent authorities should take into account the results of testing carried out further back in the manufacturing/processing chain before any action is taken. In case no evidence by the operator can be provided that the other parts of the consignment are not affected by the contamination, it will be necessary for enforcement authorities to trace the other parts of the batch/lot, assuming that these are still available. Further action to protect consumer's health may include detention of the batch/lot so that it can be representatively sampled and tested to ascertain whether it is compliant or not.

II.26.3. Control /inspections of establishments

Inspections of premises who use nuts/groundnuts/dried fruit/maize (for further processing, as an ingredient) should cover self-checking (such as sampling, private analysis, storage conditions etc) related to identification of aflatoxins as a hazard in the permanent procedure based on the HACCP principles which has been put in place, implemented and maintained by the food business operator (Regulation (EC) 852/2004, Regulation (EC) 882/2004).

II.26.4. Finding of non-compliance in food ingredient – Action as regards compound food produced from contaminated food ingredient

The information provided for under this heading is not only applicable to the provisions as regards aflatoxins but is applicable to all provisions provided for in Commission Regulation (EC) 1881/2006

Reference is made to the application of Article 3 (1) and (2) of Regulation (EC) 1881/2006, which provide that
- Foodstuffs not complying with the established maximum levels shall not be used as food ingredients
- Foodstuffs complying with the established maximum levels shall not be mixed with foodstuffs which exceed these maximum levels

On the basis of Article 3 (1) and (2) of Regulation (EC) 1881/2006, **the food ingredient, non compliant with the legislation, can no longer be used for the production of foodstuffs and must be recalled and measures in accordance with Article 19 (1) (a) have to be taken (e.g. redirection of use for animal feed)**

As regards the food products produced from the contaminated food ingredient:

- for food products produced before knowledge of the contamination and the food business operator has acted in accordance with the provisions of the Regulation (EC) 178/2002 (the General Food Law). :

**** A maximum level has been established for the compound food/ food product produced from the food ingredient***

In case the produced foodstuffs do comply with the maximum level established for that compound food, a recall is not necessary as the food operator was not aware of using non-compliant product and has in that sense not committed an infraction towards Article 3 (1) and (2) of Regulation (EC) 1881/2006 and the food products produced are compliant with the EU-legislation

**** No specific maximum level has been established for the compound food / food product produced from the food ingredient***

A risk assessment has to be performed to determine the risk for public health. In case there is a potential risk for public health, then the compound foods have to be recalled. In case the risk assessment does not indicate a risk for public health, then a recall is not necessary as the food operator was not aware of using non-compliant product and has in that sense not committed an infraction towards Article 3 (1) and (2) of Regulation (EC) 1881/2006 and the food products produced are compliant with the EU-legislation

- for food products produced after knowledge of the contamination

* The food operator has committed an infraction on purpose against Article 3 (1) and (2) of Regulation (EC) 1881/2006 as the food operator has in that case on purpose mixed complying products with non -complying products and on purpose used non –complying

ingredients for the production of foodstuffs and has therefore to be penalised according to the provisions provided for in criminal law

* As regards the recall of food products produced from the food products produced from the contaminated food ingredient, in principle the same approach applies as provided for the case where food products have been produced before knowledge of the contamination incident. However it might be appropriate in this case to take a stricter approach as regards the recall in case no maximum level has been established for the food products produced from the food ingredient.

II.26.5. Application of a maximum level to compound food for which no specific maximum level has been established

II.26.5.1. Composition of compound food is known and a maximum level exists for all individual ingredients

-Article 2 1) (a) , (b) (c) and (d) and Article 2 2) of Regulation (EC) 1881/2006 apply:

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

a) changes of the concentration of the contaminant caused by drying or dilution processes (of the individual ingredients)
b) changes of the concentration of the contaminant caused by processing (of the individual ingredients)
c) the relative proportions of the ingredients in the product.

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

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

It is obvious from the abovementioned provisions that in some cases (compound food with several processed/dried ingredients) it might be very difficult to calculate what level is applicable to the compound food in case the food business operator is not in a position to provide detailed information. In such a case, it seems appropriate to apply to the compound food the levels applicable to the major ingredient(s) and in case of aflatoxins this will mean in most cases 2 ppb aflatoxin B1 and 4 ppb aflatoxin total.

II.26.5.2. Composition of compound food is not exactly known and/or a maximum level does not exist for all individual ingredients

In this case it seems appropriate to apply to the compound food the levels applicable to the major ingredient(s) and in case of aflatoxins this will mean in most cases 2 ppb aflatoxin B1 and 4 ppb aflatoxin total.

In cast the food business operator questions this approach, the food business operator should be able to provide the detailed information as provided for in Article 2 2)

ANNEX I – LEGISLATION

MAXIMUM LEVELS

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[16]

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[17]

SAMPLING AND ANALYSIS

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 rules[18]

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 food[19]

SPECIFIC SAFEGUARD MEASURE

Commission Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins[20]

Commission Decision 2007/459/EC of 25 June 2007 amending Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins[21]

Commission Decision 2007/…/EC of 2007 amending Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins as regards almonds and derived products originating in or consigned from the United States of America[22]

[16] OJ L 37, 13.2.1993, p. 1
[17] OJ L 364, 20.12.2006, p.5
[18] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83
[19] OJ L 70, 9.3.2006, p. 12
[20] OJ L 199, 21.7.2006, p. 21
[21] OJ L 174, 4.7.2007, p. 8
[22] OJ L , .8.2007, p.

OTHER FRAMEWORK LEGISLATION OF RELEVANCE

Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[23]

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[24] (Provisions with regard to export and re-export of non-complying consignments – Article 12 – applicable from 1 January 2005)

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[25]

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 rules[26]

[23] OJ L 40, 17.2.1993, p. 1
[24] OJ L 31, 1.2.2002, p. 1
[25] OJ L 139, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 3
[26] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83

ANNEX II : list of establishments able to perform sorting and/or physical treatment to reduce aflatoxin content

- Cyprus: none
- Czech Republic: one company: CANTO s.r.o. in Hradec Králové
- Belgium: none known at this stage – further investigations ongoing
- Slovak Republic: one company:Topco Internacional, Budimír
- Poland: three companies: DOMAT sp Bydgoszcz, ATLANTA Gdansk and Aromat Snack, Trzebielino
- Spain: five companies: Almendras LLopis, Alicante; Juan Escoda Reus-Tarragona; Borges SA Reus-Tarragona; Importaco, SA Valencia; Frit Ravich SL, Gerona
- Lithuania: no establishments
- The Netherlands: 4 companies C. Steinweg Handelsveen BV Rotterdam; Giesko BV Giessen; Tybex Warehousing BV – Rotterdam; Vebero BV Oosterhout
- Portugal: no establishments
- Estonia: no establishments
- Slovenia: no establishments
- Bulgaria: no establishments
- Ireland: no establishments
- Germany: no establishments known at this stage
- UK: 3 companies: Conversion Services Ltd, South Yorkshire, and KP Foods;, Rotherham and Trigon Snacks, Liverpool.
- Greece: following companies perform physical treatment
    * almonds: Georgitsopoulos, Aspropyrgos Attikis; Nutissimo Ltd, Messini; Kardassilaris Kon. & Sons Ltd, Shimatari Viotias; Theodoropoulos sa, Egion; Vamvalis N; sa, Kalohori, Thessalonikis; Menexopouloi D. Bros Ltd, Thessaloniki
    * peanuts s: Kardassilaris Kon. & Sons Ltd, Shimatari Viotias Kardassilari N;Bros Ltd, Moshato Athens; Hatezigeorgiou sa, Adriani Drama; Moraiti Bros sa, Volos; Fotou Ekaterini, Volos,;Tsik Ltd Ptolemaida; Theodoropoulos sa, Egion;
-Italy: Murano S.P.A, Pomigliano d'Arco NA; New Factor, S.P.A. Cerasolo Ausa Di Coriano; V. Befana SPA, S. Gennaro Vesuviano NA – list not complete yet
- Romania: no establishments
- Sweden: no establishments
- Denmark: no establishments known at this stage
- Latvia: no establishments
- Norway: no establishments known at this stage
- France: SOPREX, Arles
- Hungary: no establishments known at this stage;
- Finland: no establishments
- Luxembourg: no establishments known at this stage
- Malta: no establishments known at this stage
- Austria: no establishments known at this stage
- Iceland: no establishments known at this stage

ANNEX III: list of derived and compound foodstuffs for which following their usual composition the consignments have to be accompanied by a health certificate

ANNEX IV: list of points of first introduction with full contact details

ANNEX V list of designated points of import with full contact details

ANNEX VI: specimen of health certificate

* Brazil
* Egypt
* Iran
* China
* Turkey
* United States of America

ANNEX VII: specimen of signatures of officials, authorised to sign health certificates on behalf of the competent authority.

* Turkey
* Iran
* United States of America

ANNEX VIII: list of compound and derived foodstuffs with a short shelf life

ANNEX IX: contact points in third countries (information from RASFF)