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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 Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC. Nevertheless, the provisions in this guidance document are also applicable, where relevant, to the control of aflatoxins in food products not subject to Commission Regulation (EC) 1152/2009

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.12 of the guidance document)

参考資料４

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I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION

I.1 Maximum levels on aflatoxins

	Foodstuffs	Maximum levels (µg/kg)		
	Aflatoxins	B_1	Sum of B_1, B_2, G_1 and G_2	M_1
1	Groundnuts (peanuts) and other oilseeds, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs with the exception of - groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production	8.0	15.0	-
2.	Almonds, pistachios and apricot kernels to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	12.0	15.0	-
3.	Hazelnuts and Brazil nuts, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8.0	15.0	
4	Tree nuts, other than the tree nuts listed in 2. and 3, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5.0	10.0	-
5	Groundnuts (peanuts) and other oilseeds and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs, with the exception of - crude vegetable oils destined for refining - refined vegetable oils	2.0	4.0	-
6.	Almonds, pistachios and apricot kernels, intended for direct human consumption or use as an ingredient in foodstuffs	8.0	10.0	-
7.	Hazelnuts and Brazil nuts, intended for direct human consumption or use as an ingredient in foodstuffs[41]	5.0	10.0	
8.	Tree nuts, other than the tree nuts listed in 6. and 7, and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2.0	4.0	-
9	Dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5.0	10.0	-

	Foodstuffs	Maximum levels (µg/kg)		
10	Dried fruit and processed products thereof, intended for direct human consumption or use as an ingredient in foodstuffs	2.0	4.0	-
11	All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs listed in 12, 15 and 17	2.0	4.0	-
12	Maize and rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs	5.0	10.0	-
13	Raw milk, heat-treated milk and milk for the manufacture of milk-based products	-	-	0.050
14	Following species of spices: *Capsicum spp* (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) *Piper spp* (fruits thereof, including white and black pepper) *Myristica fragrans* (nutmeg) *Zingiber officinale* (ginger) *Curcuma longa* (turmeric) Mixtures of spices containing one or more of the abovementioned spices	5.0	10.0	-
15	Processed cereal-based foods and baby foods for infants and young children	0.10	-	-
16	Infant formulae and follow-on formulae, including infant milk and follow-on milk	-	-	0.025
17	Dietary foods for special medical purposes intended specifically for infants	0.10	-	0.025

I.2. The different legislative frameworks related to control on the presence of aflatoxins in commodities

I.2.1. General legislative framework for the official feed and food safety controls

Article 17 of the Regulation (EC) 178/2002 (General Food Law) provides that Member States have the responsibility to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by feed and food business operators at all stages of production, processing and distribution. For that purpose, Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 3 of the Regulation (EC) 882/2004 (Official Feed and Food Control legislation) on the general obligations with regard to the organisation of official controls provides that Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of the Regulation taking into account
- identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;
- feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;
- the reliability of any own checks that have already been carried out; and
- any information that might indicate non-compliance.

Official controls shall be applied, with the same care, to exports outside the Union, to the placing on the market within the Union and to introduction from third countries. Member States shall also take the necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

As regards the control on aflatoxins in imported commodities, in addition to the general control provisions (see above), **three "types" of legislative provisions** have been taken, each with its own control characteristics:

- **safeguard measures**: Regulation (EC) 1152/2009 (see point I.2.2.)
- **increased frequency of controls at import**: Regulation (EC) 669/2009 (see point I.2.3.)
- **reduced frequency of controls at import**: Decision 2008/47/EC (see point I.2.4.)

I.2.2. Safeguard measures

Article 53 of Regulation (EC) 178/2002 (General Food Law) provides that emergency measures for feed and food have to be taken where it is evident that food or feed originating in the Union or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment. Regulation (EC) 1152/2009 is a safeguard measure taken on the basis of article 53 of regulation (EC) 178/2002 because of a serious risk for public health as the consequence of the presence of aflatoxins in certain commodities of certain third countries.

Product/country combinations covered by the provisions of Regulation (EC) 1152/2009.
- pistachios from China
- groundnuts from Egypt
- groundnuts from China
- almonds from United States of America
- dried figs, hazelnuts and pistachios from Turkey
- Brazil nuts in shell from Brazil

Derived products and compound products (containing the abovementioned food for more than 20%) are also covered by the provisions of Regulation (EC) 1152/2009.

Following requirements (as regards Common Entry Document, certificates and frequency of controls) have to be fulfilled at import in accordance with the provisions of Regulation (EC) 1152/2009:
- presence of a Common Entry Document (CED)
- presence of a health certificate, accompanied by the results of sampling and analysis
- physical control by the competent authorities at import at a determined increased frequency.

I.2.3. Increased frequency of controls at import

Article 15(5) of Regulation (EC) 882/2004 (Official Feed and Food Control Regulation) provides that a list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into the EU shall be drawn up. Regulation (EC) 669/2009lays down the rules concerning the increased frequency of controls to be carried out at the point s of entry on imports of feed and food of non-animal origin listed in the Annex to that Regulation. This Regulation contains also a number of product country combinations which have been listed for increased frequency of controls of aflatoxins at import

Product/country combinations for increased frequency of controls on aflatoxins covered by the provisions of Regulation (EC) 1152/2009.
- groundnuts (peanuts) and derived products (feed and food) from Argentina
- groundnuts (peanuts) and derived products (feed and food) from Brazil
- groundnuts (peanuts) and derived products (feed and food) from Ghana
- groundnuts (peanuts) and derived products (feed and food) from India
- groundnuts (peanuts) and derived products (feed and food) from Vietnam
- spices from India
- melon (egusi) seeds and derived products (food) from Nigeria
- Basmati rice for direct human consumption (food) from Pakistan
- Basmati rice for direct human consumption (food) from India.

Following requirements (as regards Common Entry Document, certificates and frequency of controls) have to be fulfilled at import in accordance with the provisions of Regulation (EC) 669/2009:
- presence of a Common Entry Document (CED)
- physical control by the competent authorities at import at a determined increased frequency.

I.2.4. Reduced frequency of controls at import

Article 23 of Regulation (EC) 882/2004 (Official Feed and Food Control Regulation) provides that specific pre-export checks that a third country carries out on feed and food immediately prior to export to the Union with a view to verifying that the exported products satisfy Union requirements may be approved. As these pre-export controls replace effectively and reliably the controls at import this should result in a significant decrease of controls at import. By Commission Decision 2008/47/EC of 20 December 2007, the pre-export checks as regards aflatoxins carried out by the United States Department of Agriculture (USDA) of the United States of America immediately prior to export to the Union were approved for groundnuts and roasted groundnuts.

Product/country combination covered by the provisions of Decision 2008/47/EC.
- peanuts and roasted peanuts from the United States of America

Following requirements (as regards Common Entry Document, certificates and frequency of controls) have to be fulfilled at import in accordance with the provisions of Regulation (EC) 1152/2009:
- presence of a health certificate, accompanied by the results of sampling and analysis
- physical control by the competent authorities at import at a significantly reduced frequency (e.g. < 1 %).

I.3. Groundnuts, other oilseeds, apricot kernels, 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, other oilseeds, apricot kernels, 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 groundnut, other oilseeds, apricot kernels, nuts and dried figs 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, other oilseeds, apricot kernels, 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, other oilseeds, apricot kernels, nuts and dried fruit are not intended for direct human consumption or used as an ingredient in foodstuffs
- the groundnuts, other oilseeds, apricot kernels, 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, other oilseeds, apricot kernels, 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. In case all these conditions are fulfilled the competent authorities control the compliance of the consignment at the "higher levels".

This means that, in order to apply the "higher level" for the groundnuts, other oilseeds, apricot kernels, 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[1] . 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."

[1] There is some evidence that roasting can reduce the aflatoxin content in pistachios. However as the significant reduction only occurs in well defined conditions it is necessary to control compliance with the legislation after roasting and therefore roasting can only be envisaged as a treatment for reducing aflatoxin content under official control with the necessary control measures. Therefore roasting can only be accepted in case of a possible treatment following non-compliance (see II.24)
Information on the reduction aflatoxins by roasting can be found in following publication: Effect of roasting on degradation of Aflatoxins in contaminated pistachio nuts
Hassan Yazdanpanah, Tayyebeh Mohammadi, Giti Abouhossain and A. Majid Cheraghali
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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 and 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 at the moment when the documentation is issued. (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 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

Annex II is not an exhaustive list and establishments can be added to the upon advice of the competent authority where the establishment is physically located

The maximum levels of aflatoxins established in Commission Regulation (EC) 1881/2006, are applicable to all groundnuts, other oilseeds, derived products thereof and cereals placed on the market except for those groundnuts other oilseeds, derived products thereof and cereals which are clearly intended for uses other than human consumption either directly or indirectly and for groundnuts and other oilseeds intended for crushing for refined vegetable oil production (for the latter, see point I.2). 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 and 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, other oilseeds, derived products thereof and cereals placed on the market.

I.4. Groundnuts and other oilseeds intended for crushing for refined vegetable oil production

The maximum levels of aflatoxins are not applicable to groundnuts and other oilseeds intended for crushing for refined vegetable oil production. The exemption only applies to consignments which are clearly labelled showing their use and bearing the indication "product to be subject to crushing for the production of refined vegetable oil". The indication shall be included on the label of each individual bag, box etc. and on the accompanying document(s). The final destination must be a crushing plant.

II. APPLICATION OF COMMISSION REGULATION (EC) 1152/2009

II.1. Use of TARIC codes

Commission Regulation (EC) No 1152/2009 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 Regulation (EC) 1152/2009:

GENERAL NOTE: if the below mentioned food products are traded under a different CN code than the ones mentioned in Regulation (EC) 1152/2009, the provisions of Regulation (EC)- 1152/EC also apply to these food products.

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 91
- 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 91
- 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 the Commission Regulation (EC) 1152/2009)

Figs (origin Turkey)
(- fresh: CN 0804 20 10 – not subject to the Commission Regulation (EC) 1152/2009)
- 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) and containing figs, hazelnuts or pistachios
Hazelnuts, figs and pistachios, prepared or preserved including mixtures: CN 2008 19 (origin Turkey)
Hazelnut paste, pistachio paste and fig paste: CN 2007 10, 2007 99 and CN 1106 30 90) (origin Turkey). It can also happen that fig paste is traded under CN 2008 19 11 20 and the provisions of Regulation (EC) 1152/2009 are also applicable to this fig paste.

Cut, sliced and broken hazelnuts: CN 0802 22 00 and 2008 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 Regulation 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 Regulation (EC) 1152/2009

Commission Regulation (EC) 1152/2009 provides that compound foodstuffs shall be considered as containing the foodstuffs to a significant amount when such foodstuffs are present in a quantity of 20 % 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 Regulation).

Consignments with a gross weight of less than 20 kg are exempted from the application of the provisions provided for in this Regulation, which means that they have not to be accompanied by a health certificate. However, enforcement authorities can test consignments of less than 20 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 Regulation 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 >20 % and imported from the countries covered by the Regulation 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 is not equipped to do sampling and analysis and has therefore not been designated as point of import by the competent authority of the country concerned. . A consignment received by such a point of first introduction must be forwarded to a designated point of import in order to undertake the further checks required.

There is no requirement as regards the points of first introduction. However some Member States might determine for a list of points of first introduction for facilitating the organisation of the controls. A compilation of links to the list of points of first introduction of those Member States which have determined such a list is provided in annex IV to this guidance document

Designated points of import' means the points, designated by the competent authority through which the foodstuffs covered by the Regulation may only be imported into the Union. The list of designated points of import is made publicly available on the internet and updated by the competent authority. The list of the national links to those lists is provided in Annex V to this guidance document.
List of designated points of import – list with links to lists of Member States (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 in case the grinding takes place in the laboratory.

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[2].

[2] 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[3] 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[4]. 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 – prior notification

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

For that purpose, they shall complete Part I of the common entry document (CED) (see Annex VI) and transmit that document to the competent authority at the first point of introduction, at least one working day prior to the physical arrival of the consignment. Competent authorities might allow some flexibility as regards the requirement of one working day and flexibility is even recommended in some particular cases such as in the case of a very short transport time between the place of departure of the consignment at the exporters place and the first point of introduction.

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

[4] The grinding step for homogenization 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 homogenization.

In case the CED has not been received as prior notification at the first point of introduction and the CED is not accompanying the consignment, the competent authority shall not allow the introduction of the consignment entering the EU territory and reject the consignment or eventually block the consignment during one working day as from the day they receive the CED, in case a commitment is made to deliver as yet the CED.

Each consignment (batch) has to be accompanied with a separate CED even if the different consignments/batches are transported in the same truck/ship.

In case part I is not completely filled in by the food business operator, the consignment/batch cannot enter the EU until the CED has been completed by the food business operator. In case no fully completed CED is received in a reasonable time after arrival of the consignment, the consignment should be rejected.

It is authorized to email or to fax as prior notification the CED. Although faxing is possible it should be avoided because it might decrease the readability.
The original CED must accompany in these cases the consignment.

In case the designated point of import selected by the food business operator is different from the first point of introduction, it has been advised to the food business operators to send a copy of the CED also to the competent authorities at the designated point of import when they transmit as prior notification the CED to the authorities at the first point of introduction.

For the completion of the CED in application of Regulation (EC) 1152/2009, food business operators shall take into account the notes for guidance laid down in Annex VII.

Every consignment is to be subjected to a documentary 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 common entry document (CED), its own health certificate and sampling and analytical results (as regards the 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 Union in case the foodstuffs are intended for import into the EU, whether this is a designated point of import or not. Consignments in transit to another third country fall outside the scope are not subject to the provisions of Regulation (EC) 1152/2009.**

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 is provided in Annex VIII to this Guidance Document.

At the occasion of the documentary control, it should also be verified if the sampling and analysis have been performed in accordance with Regulation (EC) 401/2006 or equivalent.
In the case of almonds from US, the aflatoxin analysis must be performed by an USDA approved laboratory. A list of these laboratories is provided in Annex X.

(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.

The validity of the certificate should not exceed four months and the certificate must be 'in date' at the moment of offering the consignment at the designated point of import for possible identity and physical checks.

By way of derogation from the point (a) above, Member States shall authorise the import of consignments of foodstuffs covered by Regulation (EC) 1152/2009 which left the country of origin prior to 1 July 2010 accompanied by a health certificate as provided for by Decision 2006/504/EC.

Particular attention must be paid to consignments of nuts consigned from a country which is not a producer country, as the special conditions of the safeguard Regulation 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 Regulation. For example, the Commission Regulation 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 the case that foodstuffs covered by Regulation (EC) 1152/2009 have been first exported to another third country and has been processed in that other third country prior to export to the EU, the provisions of Regulation (EC) 1152/2009 apply for import into the EU. However in such cases, the country of origin has in many cases not issued a health certificate (as it was not exported to the EU) as the health certificate is not required for export to a country outside the EU or the European Economic Area (EEA). In that case the competent authority of the other third country where the processing/transformation has taken place should issue the required health certificate after having performed the official sampling and analysis in accordance with Regulation (EC) 401/2006 (as substitute for the health certificate to accompanied by the results of sampling and analysis as required by article 4(1) of Regulation (EC) 1152/2009) and the food business operator a CED.

For example, in the case almonds in shell originating in the US are exported to Tunisia and these almonds are shelled and blanched in Tunisia for export to the EU, the competent authorities from Tunisia have to sample and analyse the shelled and blanched almonds in accordance with Regulation (EC) 401/2006 and to issue the certificate as provided for in Annex I to Regulation (EC) 1152/2009. and the food business operator has to present a CED at the point of first introduction.

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).

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.

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.

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 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 and II.8)

The competent authorities shall after completion of the checks, for checks carried out by them, fill in the appropriate sections on the common entry document (CED) on the checks performed in order to inform other competent authorities on the controls already performed on the consignment concerned

Part II as regards the identity and physical checks can only be filled in by the competent authority of the designated point of import mentioned in box I.20 of the CED. In case this is not complied with, the consignment cannot be accepted for import.

This means the competent authority shall

(a) complete the relevant part of Part II of the common entry document (CED);

(b) join the results of sampling and analysis;

(c) stamp and sign the original of the CED;

(d) make and retain a copy of the signed and stamped CED.

For the completion of the CED in application of this Regulation, the competent authority shall take into account the notes for guidance laid down in Annex II to Regulation (EC) 1152/2009 and provided here in Annex VII to this guidance note. .

The original of the CED, together with the original of the accompanying documents (results of sampling and analysis and health certificate), shall accompany the consignment during its transfer until it is released for free circulation.

The release for free circulation of consignments shall be subject to the presentation by the food business operator or their representative to the custom authorities of a common entry document (CED) or its electronic equivalent duly completed by the competent authority once all official controls have been carried out and favourable results from physical checks, where such checks are required, are known. Besides the presentation of the CED, also the health certificate and the results of sampling and analysis as referred to in Article 4(1) of the Regulation (EC) 1152/2009 shall be presented. **Part II as regards the identity and physical checks can only be filled in by the competent authority of the designated point of import mentioned in box I.20 of the CED. In case this is not complied with, the consignment cannot be accepted for import.**

The completed CED, health certificate and results of sampling and analysis can be presented at any custom office for release for free circulation.

II.4. Selection of consignment for sampling

To note that the Commission Regulation (EC) No 1152/2009 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.

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 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 and II.8)

The Commission Regulation (EC) No 1152/2009 establishes different frequencies of controls:
- 10 % of consignments of hazelnuts and certain products derived thereof from Turkey
- 20 % of consignments of dried figs and products derived thereof from Turkey
- 50 % of consignments of pistachios and products derived thereof from Turkey
- 20 % of consignments of peanuts and products derived thereof from China
and)
- 20 % of consignments of peanuts and products derived thereof from Egypt
- 50 % of consignment of pistachios and products derived thereof from Iran
- 100 % of consignments of Brazil nuts in shell from Brazil.
- a random check (< 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 10 %, 20 or 50 % 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 when **frequent** non-compliance is found and indicates that an increase of frequency of controls is necessary in order to safeguard public health. Such an increase of controls is not necessary and appropriate in case of isolated/few findings of non-compliance.

In case of a consignment consists of a mixture of nuts and dried fruits, the frequency of control is the frequency of the ingredient with the highest frequency of control.

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[5], 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.

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.

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

NB: The Commission Regulation (EC) 1152/2009 specifies that, for example 20 % of consignments of Chinese peanuts must be sampled, and not 20 % 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 200 g resulting in a sample of 16 kg and, from the batch of 15 tonnes, 100 incremental samples of 200g resulting in a sample of 20 kg). It is important that for each batch/lot a separate Common Entry Document (CED) and 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 10/20/30 kg, an incremental sample shall be taken from each individual retail pack to make up the 10/20/30 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.12) may also be applied in case the individual vacuum packings are larger than 10 kg.**

II.7. Sampling procedure for dried figs

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	15-30tonnes	100	30
	< 15	--	10-100 (table 2)	≤ 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 dried figs 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) and in case the equipment to homogenise 30 kg samples is available.

- **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 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 diverge)	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 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 dried figs 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) and in case the equipment to homogenise 30 kg samples is available.

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 (homogeneous distribution of aflatoxin contamination)

- Attention! the aflatoxin contamination in fig paste is in many cases not homogeneously distributed. Therefore the sampling procedure as mentioned in this point is not applicable in fig paste and the sampling procedure as described for dried figs in II.7.1, II.7.2. and II.7.3. applies.

- 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 dried figs. (II.7.1, II.7.2. and II.7.3). This applies also to fig paste in which the aflatoxin contamination is in many cases not homogeneously distributed.

II.7.5. Sampling of dried figs and derived products in vacuum packings[6]

II.7.5.1. Dried figs

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

[6] 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.7.5.2. Products derived from or containing figs with small particle size

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

II.8. Sampling procedure for groundnuts, other oilseeds, apricot kernels and tree nuts (e.g. hazelnuts, pistachios, Brazil nuts and almonds)

II.8.1 General survey of the method of sampling

Table 4 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)
Groundnuts, other oilseeds, apricot kernels and tree nuts	≥ 500	100 tonnes	100	20
	>125 and <500	5 sublots	100	20
	≥ 15 and ≤ 125	25 tonnes	100	20
	< 15	--	10-100 (table 5)	≤ 20

II.8.2 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 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 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 4 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 4).

- Each sublot must be sampled separately.

- Number of incremental samples: **100.** Each incremental sample weighs 200 grams.

- **Weight of the aggregate sample = 20 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 two equal laboratory samples of 10 kg before grinding and homogenisation.** This division into two laboratory samples is not necessary in the case of groundnuts, other oilseeds, apricot kernels and tree nuts 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) and in case the equipment to homogenise 20 kg samples is available.

- **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.8.3 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 5).**

Table 5: Number of incremental samples to be taken from groundnuts, other oilseeds, apricot kernels and tree 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 diverge)	No of laboratory samples from aggregate sample
≤ 0.1	10	2	1 (no division)
> 0.1 - ≤ 0.2	15	3	1 (no division)
> 0.2 - ≤ 0.5	20	4	1 (no division)
> 0.5 - ≤ 1.0	30	6	1 (no division)
> 1.0 - ≤ 2.0	40	8(- < 12 kg)	1 (no division)
> 2.0 - ≤ 5.0	60	12	2
> 5.0 - ≤ 10.0	80	16	2
> 10.0 - ≤ 15.0	100	20	2

- **Weight of the aggregate sample = 20 kg** which 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 two equal laboratory samples of 10 kg before grinding and homogenisation.** This division into two laboratory samples is not necessary in the case of groundnuts, other oilseeds, apricot kernels and tree nuts 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) and in case the equipment to homogenise 20 kg samples is available.

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

* < 12 kg: no division into laboratory samples
* ≥12 kg: division into two 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.8.4. Sampling of derived products and compound foods

II.8.4.1. Compound and derived products (other than vegetable oils) 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 6)**
- 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 6: 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.8.4.2. 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.8.5. Sampling of groundnuts, other oilseeds, apricot kernels, tree nuts and derived products in vacuum packs[7]

II.8.5.1.Pistachios, groundnuts and Brazil nuts

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in Table 5 shall be taken resulting in an aggregate sample of which the weight is the weight of the aggregate sample as foreseen in function of the size of the sampled lot (see Table 5).

II.8.5.2. Apricot kernels, tree nuts other than pistachios and Brazil nuts, oilseeds other than peanuts

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental

[7] 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.

samples mentioned in Table 5 shall be taken resulting in an aggregate sample of which the weight is the weight of the aggregate sample as foreseen in function of the size of the sampled lot (see Table 5).

II.8.5.3. Products derived from or containing tree nuts, apricot kernels, groundnuts and other oilseeds with small particle size

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in Table 6 shall be taken resulting in an aggregate sample of which the weight is the weight of the aggregate sample as foreseen in function of the size of the sampled lot (see Table 6).

II.9. Sampling procedure for spices

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

II.9.1. General method of sampling for spices

Table 7 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 8

II.9.2 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 7. 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.9.3. 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 8 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.9.4. 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 8 shall be taken resulting in an aggregate sample of which the weight is the weight of the aggregate sample as foreseen in function of the size of the sampled lot (see Table 8).

II. 10. 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.10.1. General method of sampling dried fruit, with the exception of figs

Table 9: 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 10

II.10.2. Method of sampling for dried fruit (lots ≥ 15 tonnes), with the exception of dried figs

- On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 9. 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.10.3.Method of sampling for dried fruit (lots < 15 tonnes), with the exception of dried figs

For dried fruit lots, with the exception of dried 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 10 can be used to determine the number of incremental samples to be taken.

Table 10: 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.10.4 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 10 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see table 10).

II.11. Sampling procedure for vegetable oil

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

- 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 11. 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/mycotoxin 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 11: 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

* On condition that the sublot can be separated physically, large bulk consignments/lots of vegetable oils shall be subdivided into sublots as foreseen in table 12.

Table 12: Subdivision of lots into sublots depending on lot weight

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

Method of sampling for vegetable oils at retail stage : Where the procedure of sampling as described above is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg[8].

II.12. Sampling procedures other than those described in Regulation (EC) 401/2006 as referred to in II.6.2., which can be used for specific packing/trade forms of the products mentioned under II.7, II.8, II.9 II.10 and II.11

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 Consumers 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)

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

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

II.13. 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 Union 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.

In the Member States where the procedure for right for second opinion includes the possibility of analysing a reference sample (see point II.21.(2), the analysis of this reference sample should be performed within 15 working days after the favourable result of the defence sample is known by the competent authority.
During the period of detention, necessary guarantees are to be taken to ensure that consignments are kept in appropriate storage conditions (low humidity and temperatures), preventing thereby a secondary aflatoxin formation and quality deterioration.

For some specific derived and compound foodstuffs covered by the provisions of Commission Regulation (EC) 1152/2009 **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 XI of this Guidance document

II.14. Sample preparation // for direct human consumption // to be subjected to sorting and/or other physical treatment (see above)

II.14.1 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.14.2. 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.14.3. 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[9] (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 and transported in such conditions that microbial contamination and growth is excluded.

II.14.4.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.15. Samples for defence and reference purposes

II.15.1.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.

[9] The grinding step for homogenization 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 homogenization.

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.

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.

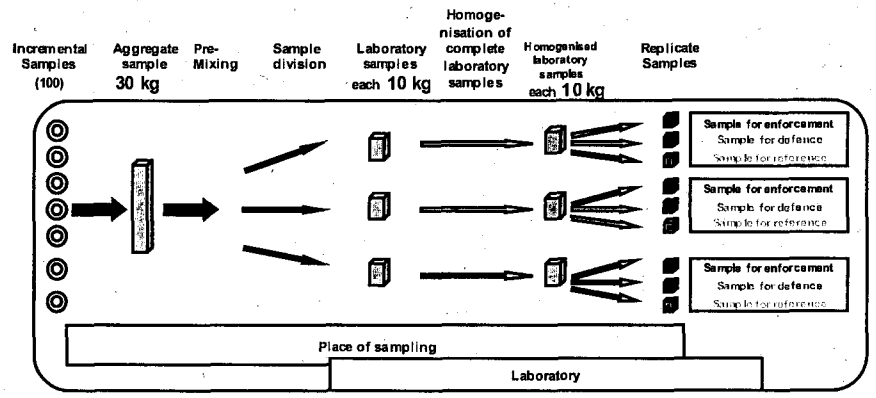
The following papers, the first of which was produced by the European Committee for Standardisation (CEN) provide further information:

- "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.

* Sampling of dried figs for direct human consumption

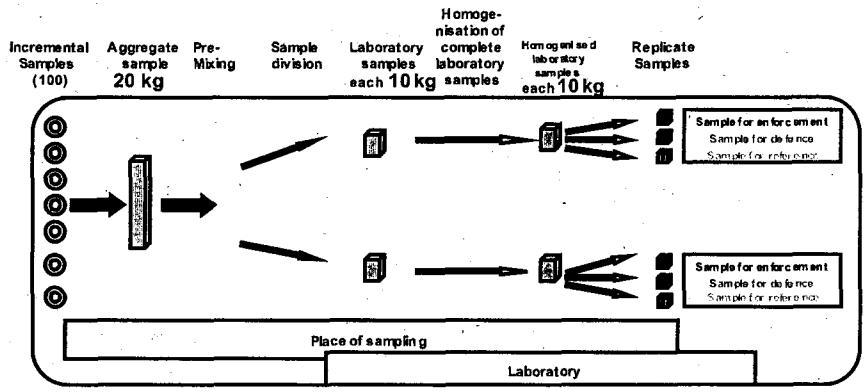
Samples for enforcement, defence and reference taken from homogenised laboratory or subsamples



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

*** Sampling of groundnuts, other oilseeds, apricot kernels and tree nuts for direct human consumption**

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



Each of the 2 enforcement samples has to be compliant for a consignment to be accepted

II.15.2. Defence and reference samples are taken at the place of sampling

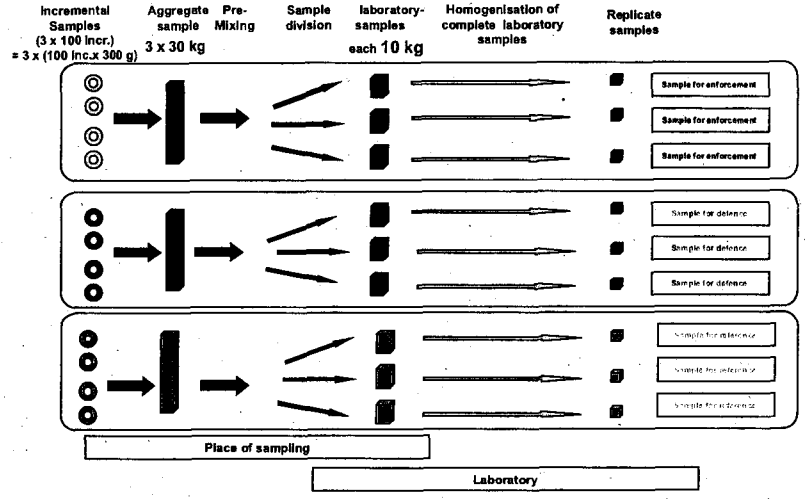
In **two** Member States (Spain and Germany because of their additional national legislation as regards the rights of the operator which is not overruled by Commission Regulation (EC) 401/2006), it is stipulated that the defence and reference samples have to be taken from the consignment in the presence 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 and II.8 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 20 or 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

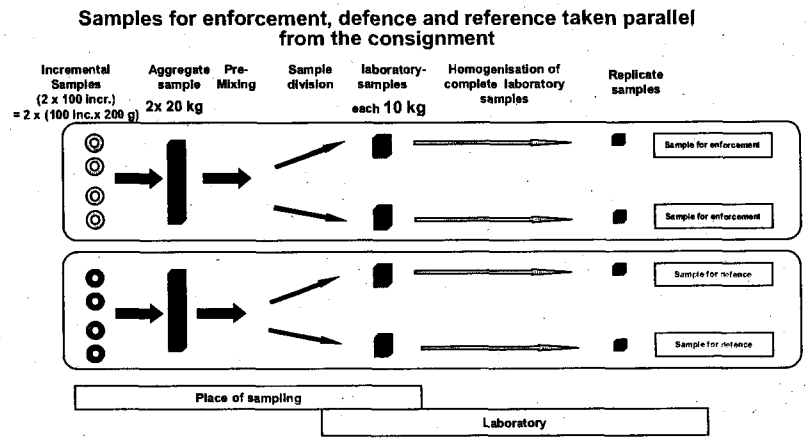
* Sampling of dried figs for direct human consumption

Samples for enforcement, defence and reference taken parallel from the consignment



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

*** Sampling of groundnuts, other oilseeds, apricot kernels and tree nuts for direct human consumption**



NB: Each of the 2 enforcement samples has to be compliant for a consignment to be accepted

II.16. 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 ISO/IEC 17011 on "General requirements for accreditation bodies accrediting conformity assessment bodies".

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[10].

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.

[10] 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.17. 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.17.1. 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.17.2. 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.18. Precautions to be taken and calculation of the analytical result with regard to the edible part of the foodstuff

II.18.1. 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.18.2. 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: Where 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 .

ATTENTION: Recent scientific evidence has demonstrated that a part of the aflatoxin contamination can be found on the shell of Brazil nuts. Therefore, it is appropriate to take into account this recent scientific information.
Therefore in case Brazil nuts in shell are to be controlled, and as the maximum level for aflatoxins is applicable on the edible part (kernels), the nuts should be shelled and the aflatoxin analysis should be performed on the kernels (good and bad). The extra costs for shelling the sample of Brazil nuts in shell shall be borne by the food business operator.

II.19. 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 Union legislation concerning

- contaminants in food (Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[11])

- 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[12])"

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

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

II.20. Acceptance of a lot or sublot and interpretation of results

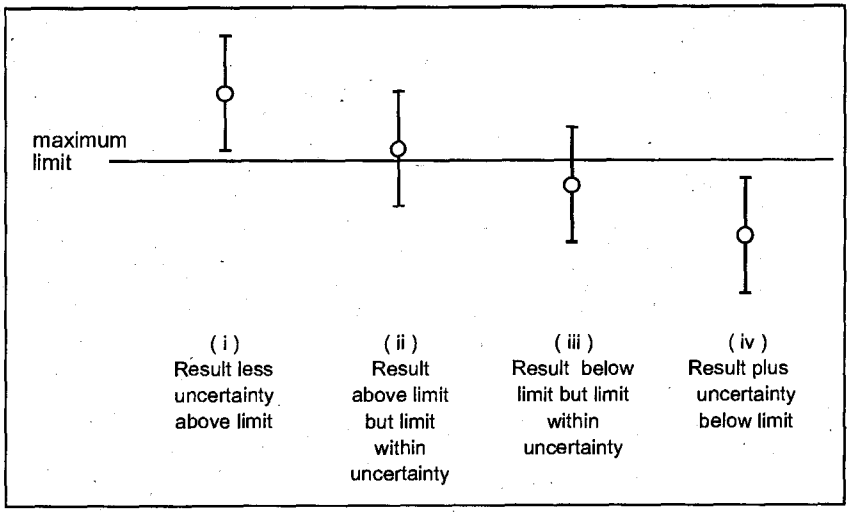
- For dried figs, groundnuts, other oilseeds, apricot kernels and tree nuts subjected to a sorting or other physical treatment and spices:
  - acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the expanded measurement uncertainty 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 dried figs, groundnuts, other oilseeds, apricot kernels and tree nuts intended for direct human consumption :
  - acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the 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 lays 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. 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, and 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, and Latvia

3) the operator must challenge the analytical result of the official sample before a Court. This approach is followed in Denmark, Slovenia, Germany, Luxembourg, and 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[13] 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;

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

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

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 29(1) and (2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93[14].

Products covered by Commission Regulation (EC) 1152/2009 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.

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

[14] OJ L218, 13.8.2008, p. 30

II.24.2.Food produced within the EU (exported) or food that has been put on the EU-market after having been imported (re-exported)[15]

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[16] provides as a general rule in Article 12 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 Union food law.

In all other cases, i.e. if there is no relevant Union 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.

[15] Reference is made to document « Guidance on the implementation of articles 11, 12, 14, 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 – 26 January 2010» -available on the website of the Directorate-General Health and Consumers at http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_8_en.pdf
[16] OJ L 31, 1.2.2002, p. 1

II.24.3. 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[17] 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[18] to bring the food into line with the requirements of Union 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 Union. 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 Union; 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 Union.

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

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

[18] In the case of pistachios, roasting under well defined conditions can eventually be considered as a treatment to reduce aflatoxin content.

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.

However, Article 19 (2) (a) of Regulation (EC) 882/2004 provides that if the official control indicates 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

In case maximum levels established by Codex Alimentarius Commission have been exceeded, rejected consignments cannot be re-dispatched without any control and appropriate measures have to be taken to protect human or animal health.

In other cases, given that worldwide the highest level established for aflatoxin B1 is 20 µg/kg and for aflatoxin total 35 µg/kg[19], 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.

This might include the sorting of the consignments in view of bringing the consignment in compliance with EU legislation by eliminating the contaminated parts of the consignment. These levels do also apply to other foodstuffs imported into the EU e.g. spices, melon seeds, sesame seeds ...

Therefore it is in accordance with Union law, to authorise under official control the transport of a non-complaint consignment to an authorised sorting plant (see Annex II) under the condition that the competent authorities of the country where the sorting plant is located accept the consignment and accept to take over control over the non-compliant consignment. The competent authorities of the country where the sorting plant is located have to ensure that the consignment is effectively transported to the sorting plant, that the consignment effectively undergoes the sorting treatment and have to officially sample and analyse the consignment after the treatment (sorting) in order to verify that the consignment is brought in compliance with the provisions in EU legislation. And only if the analytical result shows compliance after official control, the consignment can be released for free circulation.

[19] 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."

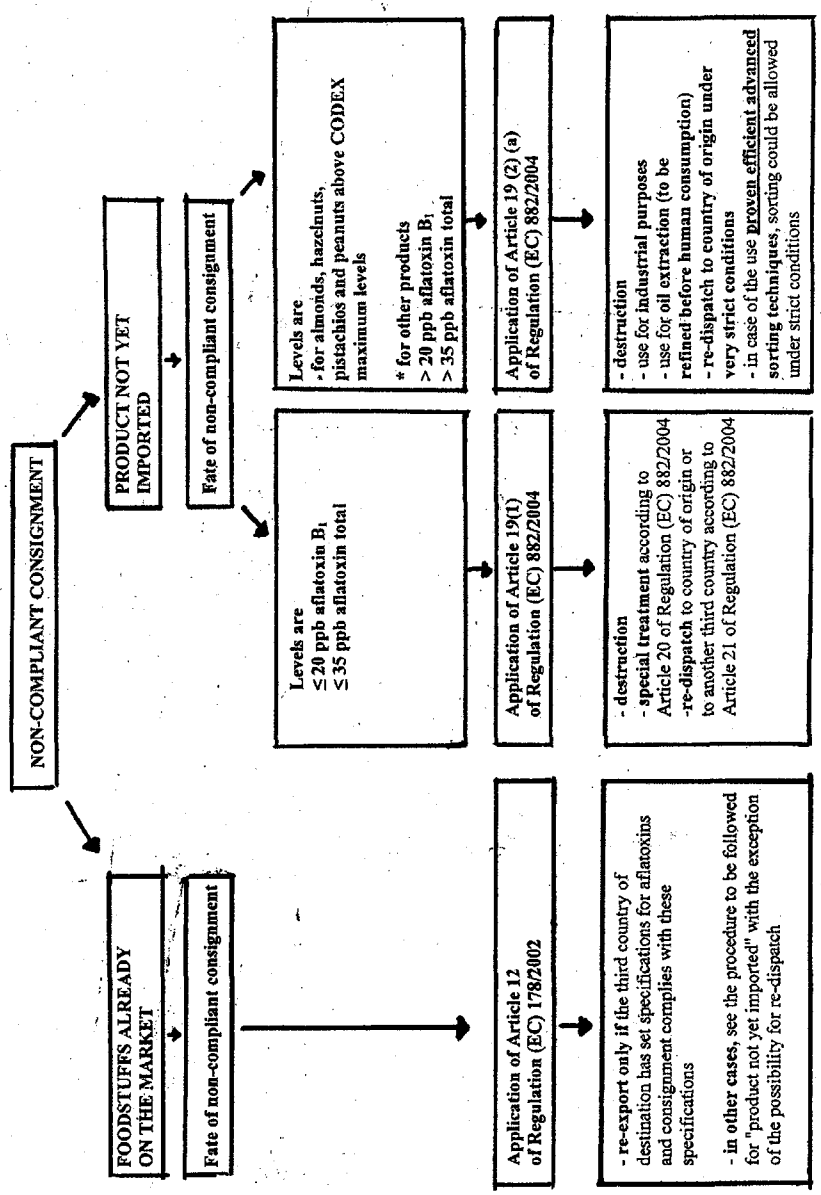
e) The possibility for sorting and physical treatment in case of non-compliance is as a general rule limited to the cases of consignments, not complying with EU legislation but containing levels below the worldwide highest level established for aflatoxin B1 and total.

However, in case it can be demonstrated that with advanced sorting techniques, levels below the maximum levels established for groundnuts, nuts and other food products for direct human consumption are achieved in a consistent manner, this could be taken into account to allow sorting on consignments with higher levels of aflatoxins.

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.24.4. Schematic overview



II.25. Costs of official controls

Article 10 of Commission Regulation (EC) 1152/2009 **provides that all costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the food business operator.** 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

II.26 Specific issues

II.26.1. Procedure for splitting the consignment

Consignments shall not be split until all official controls have been completed, and the Common Entry Document (CED) has been fully completed by the competent authorities

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 until it is released for free circulation.

In case the operator has the intention to split over a certain period of time the consignment for different consignees, he might request the competent authority to deliver a number of certified copies at the time of import.

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 on the recipe. In such a case, it seems appropriate to apply to the compound food the levels applicable to the major ingredient(s) if a major ingredient can be identified without discussion

II.26.5.2. Mixture of nuts and mixtures of nuts and dried fruit

In the case of mixture of nuts or mixture of nuts and dried fruit, it is proposed to divide the sample of the mixture or a representative part of the sample into nuts and dried fruits to which the same levels of aflatoxin B1 and aflatoxin total applies. Each part is weighted to determine its proportion in the sample (representative for the sampled lot) and the maximum level of aflatoxin B1 and aflatoxin total applicable is calculated. Another possibility is that the food business operator provides a verifiable recipe of the mixture

Example: sample of 20 kg from a mixture with hazelnuts, cashews, walnuts, shelled Brazil nuts, pistachios (kernels), almonds, peanuts and dried raisins.

After grouping of the nuts and dried fruits with the same levels following result was obtained:

- pistachios and almonds: 5,3 kg
- shelled Brazil nuts and hazelnuts: 4.8 kg
- peanuts, cashews, walnuts and raisins: 9.9 kg

The maximum level aflatoxin B1 applicable is: [(5.3 x 8) + (4.8 x 5) + (9.9 x 2)]/20 = (42.4 + 24 + 19.8) / 20 = 4.31 µg/kg

The maximum level aflatoxin total applicable is: [(5.3 x 10) + (4.8 x 10) + (9.9 x 4)]/20 = (53 + 48 + 39.6) / 20 = 7.03 µg/kg

Thereafter the 20 kg sample is completely mixed and then afterwards subdivided into two laboratory samples and both laboratory samples have to comply with the abovementioned calculated maximum levels.

II.26.5.3. Composition of compound food is not exactly known and/or a maximum level does not exist for all individual ingredients

In this case and in case the food business operator is not in a position to provide a verifiable recipe for the compound food, it seems appropriate to apply to the compound food the levels applicable to the major ingredient(s).

In case 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[20]

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[21]

* Commission Regulation (EU) No 165/2010 of 26 February 2010 amending Regulation (EC) N0 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins [22]

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[23]

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[24]

* Commission Regulation (EU) No 178/2010 of 2 March 2010 amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil[25]

SPECIFIC SAFEGUARD MEASURE

Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC[26]

[20] OJ L 37, 13.2.1993, p. 1
[21] OJ L 364, 20.12.2006, p.5
[22] OJ L 30, 27.2.2010, p. 8
[23] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6:2004, p. 83
[24] OJ L 70, 9.3.2006, p. 12
[25] OJ L 52, 3.3.2010, p. 32
[26] OJ L 313, 28.11.2009, p. 40

OTHER FRAMEWORK LEGISLATION OF RELEVANCE

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93[27]

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[28]

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

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[30]

[27] OJ L218, 13.8.2008, p. 30
[28] OJ L 31, 1.2.2002, p. 1
[29] OJ L 139, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 3
[30] 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: none
- 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: 5 companies C. Steinweg Handelsveen BV Rotterdam; Giesko BV Giessen; Tybex Warehousing BV – Rotterdam; Vebero BV Oosterhout; Synergie Food Ingredients and Processing (Rotterdam)
- 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, 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: New Factor, S.P.A. Cerasolo Ausa Di Coriano; V. Besana 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 (to follow)

ANNEX IV: list of links to lists of points of first introduction with full contact details (in case they have been determined by the Member States) (to follow)

ANNEX V list of links to lists of designated points of import with full contact details

ANNEX VI: Common entry document

ANNEX VII: Guidance notes to common entry document

ANNEX VIII: specimen of health certificate (general and if appropriate country specific)

ANNEX IX: specimen of signatures of officials, authorised to sign health certificates on behalf of the competent authority (to follow)

* Turkey
* Iran
* United States of America

ANNEX X: list of USDA approved laboratories performing the aflatoxin analysis in almonds in the frame of VASP

ANNEX XI: list of compound and derived foodstuffs with a short shelf life (to follow)

ANNEX XII: contact points in third countries (information from RASFF) (to follow)

ANNEX V list of links to lists of designated points of import with full contact details

First points of introduction or DPI for the products falling under Regulation (EC) 1152/2009 (update 10/03/2010)

BELGIUM

Dutch:
http://www.afsca.be/invoerderdelanden/_documents/2010-03-16_aangewezenpuntenvaninvoer_Ver.1152_2009_NL.pdf

French:
http://www.afsca.be/importationpaystiers/_documents/2010-03-16_aangewezenpuntenvaninvoer_Ver.1152_2009_FR.pdf

BULGARIA
http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=390

1. Burgas Port Center
2. Varna Port
3. Varna Port — West
4. Svilengrad — railway station
5. Kapitan Andreevo
6. Sofia air port
7. Customs House — Sofia
8. Customs House — Plovdiv

CZECH REPUBLIC
http://www.szpi.gov.cz/docDetail.aspx?docid=1020860&doctype=ART

DENMARK
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

GERMANY:
http://www.bvl.bund.de/cln_027/nn_491402/DE/01_Lebensmittel/00_doks_download/Eingangszollstellen_LM_Art6_VO_EG1152_2009,templateId=raw,property=publicationFile.pdf/Eingangszollstellen_LM_Art6_VO_EG1152_2009.pdf

ESTONIA:
The common entry document (CED) must be transmitted to the competent authority at the first point introduction; the contact details can be found:
http://www.vet.agri.ee/static/files/362.Piiripunktid_17.12.09.pdf

GREECE:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

SPAIN:
http://www.msps.es/profesionales/saludPublica/sanidadExterior/controlesSanitarios/instaAlmacen/pdf/PDI.pdf

FRANCE:
http://www.dgccrf.bercy.gouv.fr/securite/produits_alimentaires/controles_importation/index.htm

IRELAND:

http://www.fsai.ie/food_businesses/imports_non_animal_origin/imports_non_animal.html

http://www.fsai.ie/uploadedFiles/Food_Businesses/Imports_Non_Animal/DPIs%20to%20Cion%2026%20Jan%2010%20for%20Regulation%201152%202009.pdf

ITALY:

http://www.salute.gov.it/imgs/C_17_pagineAree_1251_listaFile_itemName_1_file.pdf:

Ufficio di Sanità Marittima Aerea e di Frontiera di Pescara, Unità Territoriale di Ancona
Ufficio di Sanità Marittima Aerea e di Frontiera di Bari, Unità Territoriale di Bari
Ufficio di Sanità Marittima Aerea e di Frontiera di Brindisi, Unità Territoriale di Brindisi
Ufficio di Sanità Marittima Aerea e di Frontiera di Genova, Unità Territoriale di Genova
Ufficio di Sanità Marittima Aerea e di Frontiera di Genova, Unità Territoriale di La Spezia
Ufficio di Sanità Marittima Aerea e di Frontiera di Genova, Unità Territoriale di Savona
Ufficio di Sanità Marittima Aerea e di Frontiera di Genova, Unità Territoriale di Imperia
Ufficio di Sanità Marittima Aerea e di Frontiera di Livorno, Unità Territoriale di Livorno
Ufficio di Sanità Marittima Aerea e di Frontiera di Napoli, Unità Territoriale di Napoli
Ufficio di Sanità Marittima Aerea e di Frontiera di Napoli, Unità Territoriale di Salerno
Ufficio di Sanità Marittima Aerea e di Frontiera di Napoli, Unità Territoriale di Cagliari
Ufficio di Sanità Marittima Aerea e di Frontiera di Trieste, Unità Territoriale di Trieste, compresa dogana di Fernetti-Interporto Monrupino
Ufficio di Sanità Marittima Aerea e di Frontiera di Trieste, Unità Territoriale di Venezia
Ufficio di Sanità Marittima Aerea e di Frontiera di Bologna, Unità Territoriale di Ravenna
Ufficio di Sanità Marittima Aerea e di Frontiera di Catania, Unità Territoriale di Reggio Calabria
Ufficio di Sanità Marittima Aerea e di Frontiera di Catania, Unità Territoriale di Gioia Tauro
Ufficio di Sanità Marittima Aerea e di Frontiera di Catania, Unità Territoriale di Siracusa, Porto di Pozzallo.

http://www.ministerosalute.it/sicurezzaAlimentare/paginaInternaMenuSicurezzaAlimentare.jsp?id=1251&lingua=italiano&menu=controlli

CYPRUS:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

LATVIA:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

LITHUANIA:
http://vmvt.lt/en/top/contacts/designated.points.of.entry.regulation.ec.no.6692009/

http://vmvt.lt/uploads/file/List%20of%20DPEs%20and%20DPIs_Lithuania.doc

LUXEMBOURG:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

HUNGARY:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

MALTA:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

NETHERLANDS:
- port of Rotterdam
- port of Amsterdam
- Schiphol airport
http://www.vwa.nl/portal/page?_pageid=119,1667803&_dad=portal&_schema=portal

AUSTRIA:
http://www.bmg.gv.at/cms/site/standard.html?channel=CH0758&doc=CMS1260804905529

POLAND:
http://www.pis.gov.pl/?dep=628

PORTUGAL:
http://www.gpp.pt/RegAlimentar/Lista_Pontos_Entrada_Designados.pdf

ROMANIA:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

SLOVENIA:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

SLOVAKIA:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

FINLAND:
The list of designated points of import mentioned in Annex II to Commission Decision 2006/504/EC can be provisionally used, awaiting the publication of the designated points of import/introduction in accordance with Article 6(2) of Regulation (EC) 1152/2009

SWEDEN:

http://www.slv.se/upload/nfa/documents/international_trade/import/Adresser-gks-webb-vegetabilier-eng-dec2009.pdf

http://www.slv.se/upload/dokument/import_export/import/Vegetabilier/Adresser_gks_webb_vegetabilier_dec2009.pdf

UNITED KINGDOM:
http://www.food.gov.uk/foodindustry/imports/banned_restricted/aflatoxinreg11522009

ANNEX VI: Common entry document

COMMON ENTRY DOCUMENT (CED)

EUROPEAN COMMUNITY — Common Entry Document, CED

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Country + ISO code

I.2. CED reference number
DPE
DPE Unit N°

I.3. Consignee
Name
Address
Postal code
Country + ISO code

I.4. Person responsible for the consignment
Name
Address

I.5. Country of origin + ISO code

I.6 Country from where consigned + ISO code

I.7. Importer
Name
Address
Postal code
Country + ISO code

I.8. Place of destination
Name
Address
Postal code
Country + ISO code

I.9. Arrival at DPE (estimated date)
Date

I.10. Documents
Number
Date of issue

I.11. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐
Identification:
Documentary references:

I.12. Description of commodity

I.13. Commodity code (HS code)

I.14. Gross weight/Net weight

I.15. Number of packages

I.16. Temperature
Ambient ☐ Chilled ☐ Frozen ☐

I.17. Type of packages

I.18. Commodity intended for
Human consumption ☐ Further process ☐ Feedingstuff ☐

I.19. Seal number and container number

I.20. For transfer to ☐
Control Point Control Point Unit N°

I.21.

I.22. For import ☐

I.23.

I.24. Means of transport to Control Point
Railway wagon ☐ Registered No.
Aeroplane ☐ Flight No.
Ship ☐ Name
Road vehicle ☐ Plate No.

I.25. Declaration
I, the undersigned person responsible for the consignment detailed above, certify that to the best of my knowledge and belief the statements made in Part I of this document are true and complete and I agree to comply with the legal requirements of Regulation (EC) N° 882/2004, including payment for official controls, and consequent official measures in case of non compliance with the feed and food law.

Place and date of declaration
Name of signatory
Signature

EUROPEAN COMMUNITY — Common Entry Document, CED

Part II: Decision on consignment

II.1. CED Reference Number

II.2. Customs Document Reference

II.3. Documentary Check
Satisfactory ☐ Not satisfactory ☐

II.4. Consignment selected for physical checks
Yes ☐ No ☐

II.5. ACCEPTABLE for transfer ☐
Control Point Control Point Unit N°

II.6. NOT ACCEPTABLE ☐
1. Re-dispatching ☐
2. Destruction ☐
3. Transformation ☐
4. Use for other purpose ☐

II.7. Details of Controlled Destinations (II.6)
Approval no (where relevant)
Address
Postal code

II.8. Full identification of DPE and official stamp ☐
DPE Stamp
DPE Unit N°

II.9. Official inspector
I the undersigned official inspector of the DPE, certify that the checks on the consignment have been carried out in accordance with Community requirements.

II.10.

II.11. Identity check Yes ☐ No ☐
Satisfactory ☐ Not satisfactory ☐

II.12. Physical Check
Satisfactory ☐ Not satisfactory ☐

II.13. Laboratory Tests Yes ☐ No ☐
Tested for
Results: Satisfactory ☐ Not satisfactory ☐

II.14. ACCEPTABLE for release for free circulation ☐
Human consumption ☐
Further process ☐
Feedingstuff ☐
Other ☐

II.15.

II.16. NOT ACCEPTABLE ☐
1. Re-dispatching ☐
2. Destruction ☐
3. Transformation ☐
4. Use for other purpose ☐

II.17. Reason for Refusal
1. Absence/invalid certificate (if applicable) ☐
2. ID: Mis-match with documents ☐
3. Physical hygiene failure ☐
4. Chemical contamination ☐
5. Microbiological contamination ☐
6. Other ☐

II.18. Details of Controlled Destinations (II.16)
Approval no (where relevant)
Address
Postal code

II.19. Consignment resealed
New seal no

II.20. Full identification of DPE/Control Point and official stamp
Stamp

II.21. Official Inspector
I the undersigned official inspector of the DPE/Control Point, certify that the checks on the consignment have been carried out in accordance with Community requirements.
Name (in capital)
Date Signature

Part III: Control

III.1. Details on re-dispatching:
Means of transport n°
Railway wagon ☐ Aeroplane ☐ Ship ☐ Road vehicle ☐
Country of destination: + ISO code
Date

III.2. Follow up
Local Competent Authority Unit ☐
Arrival of the consignment Yes ☐ No ☐ Correspondence of the consignement Yes ☐ No ☐

III.3. Official Inspector
Name (in capital) Unit N°
Address Signature
Date Stamp

ANNEX VII: Guidance notes to common entry document

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

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

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

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

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

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

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

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

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

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

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

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

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

Box I.10. Documents: indicate the date of issue and the number of official documents accompanying the consignment, as appropriate.

Box I.11. Means of transport: tick the box to indicate the means of arrival transport.

Identification: give full details of the means of transport. For aircraft, indicate the flight number. For vessels, indicate the ship's name. For road vehicles: indicate the registration number plate with trailer number if appropriate. For railway transport: indicate the train identity and wagon number.

Documentary references: number of airway bill, bill of lading or commercial number for railway or truck.

Box I.12. Description of the commodity: provide a detailed description of the commodity using the terminology in Article 1. **In this box, also the batch identification number has to be mentioned.**

Box I.13. Commodity code (HS code): use the Harmonized System of the World Customs Organization.

Box I.14. Gross weight: specify overall weight in kg or tonnes. This is defined as the aggregate mass of the products and of the immediate containers and all their packaging, but excluding transport containers and other transport equipment.

Net weight: specify weight of actual product in kg or tonnes, excluding packaging. This is defined as the mass of the products themselves without immediate containers or any packaging.

Box I.15. Number of packages: specify the number of packages in the consignment.

Box I.16. Temperature: tick the appropriate mode of transport/storage temperature.

Box I.17. Type of packaging: identify the type of packaging of products.

Box I.18. Commodity intended for: tick the appropriate box depending on whether the commodity is destined for human consumption *without* prior sorting or other physical treatment (in this case tick "human consumption") or is intended for human consumption after such treatment (tick "further process" in this case), or is intended for use as "feedingstuff" (in this case tick "feedingstuffs"). In the latter case the provisions of this Regulation do not apply.

Box I.19. Seal number and container number: give all seal and container identification numbers where relevant.

Box I.20. For transfer to Control Point: in case the consignment is intended for import (cf. Box I.22), tick the box and identify the designated point of import.

Box I.21. Not applicable.

Box I.22. For import: tick the box in case the consignment is intended for import.

Box I.23. Not applicable.

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

Part II **<u>This section is to be completed by the competent authority.</u>**

General: Box II.1 is to be completed by the competent authority of the designated point of import. Boxes II.2 till II.9 are to be completed by the authorities responsible for the documentary control. **Boxes II.10. till II.21 are to be completed by the competent authorities of the designated point of import, mentioned inbox I 20 of the CED.**

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

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

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

Box II.4. Consignments selected for physical checks: **not applicable in the framework of this Regulation and therefore this box has not be completed at the first point of introduction.**

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

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

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

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

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

Box II.10. Not applicable.

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

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

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

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

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

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

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

Box II.15. Not applicable.

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

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

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

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

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

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

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

Part III **<u>This section is to be completed by the competent authority.</u>**

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

Box III.2. Follow-up: indicate the local competent authority unit responsible, as appropriate, for the supervision in case of "Destruction", "Transformation" or "Use for other purpose" of the consignment. This competent authority shall report here the result of the arrival of the consignment and the correspondence.

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

ANNEX VIII: specimen of health certificate (general and if appropriate country specific)

A) GENERAL

ANNEX I

Health Certificate for the importation into the European Union of

.....*

Consignment Code ..... **Certificate Number** .....

According to the provisions of Commission Regulation (EC) 1152/2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC, the .....

.....

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

CERTIFIES that the .....

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

of this consignment composed of:.....

.....

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

embarked at ..... (embarkation place)

by.....(identification of transporter)

going to..... (place and country of destination)

which comes from the establishment .....

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

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

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

(name of laboratory), to determine the level of aflatoxin B1 and level of total aflatoxin contamination. The details of sampling, methods of analysis used and all results are attached.

This certificate is valid until.....

Done at ..... on.....

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

* Product and country of origin.

B) SPECIFIC – IMPORT OF ALMONDS FROM US

EXPLANATORY NOTE AS REGARDS THE VASP CERTIFICATE

* Consignments of almonds and derived products which are accompanied by a health certificate are to be **sampled and analysed at a random (< 5 %) frequency at import. A specimen of the health certificate is provided hereafter.** Although this VASP/health certificate has an deviating appearance to the health certificate as provided for in Annex I to Commission Regulation (EC) 1152/2009, it was agreed that this is acceptable as it contains all elements which the health certificate has to contain (with the exception of the stamp).

* **the USDA, being the competent authority** as referred to in Article 4(1)(f) **has confirmed** that the list of laboratories listed in **Annex X** to this guidance document are the laboratories (USDA Approved) authorised to do the analysis in view of official certification.

* **the USDA, being the competent authority** as referred to in Article 4(1)(f) **has confirmed** that the signatories mentioned in Annex XI to this guidance document are authorised to sign the health certificates on behalf of the USDA, being the competent authority.

* The certificate foresees for the possibility of a 3 x 5 kg sample (instead of the 3 x 10 kg sample as foreseen in Regulation (EC) 401/2006) for the control on the aflatoxins content in view of obtaining the VASP certificate. The 3 x 5 kg sample with a rejection limit of 2 ppb aflatoxin total, i.e. half of the EU maximum level, **has been accepted to be comparable with the 3 x 10 kg sample as provided for in Regulation (EC) 401/2006 for the issuing of the certificate** . This equivalence was acknowledged by the FVO during their inspection mission (see mission report DG SANCO 8300/2006, p.14) and underpinned by scientific research (see the Article: Sampling Almonds for Aflatoxins, Part II: Estimating Risks Associated with Various Sampling Plan Designs. Whitaker et al (2007), Journal of AOAC International Vol. 90, No 3, 2007, p 778-785). It goes without saying that for the 5 % official control at import the sampling of 3 x 10 kg as provided for in Commission Regulation (EC) 401/2006 has to be carried out.

*** However as from 13 March 2010, the sampling under the VASP is performed on the basis of a 2 x 10 kg sample, in accordance with the EU legislation. In the period between 13 March 2010 and 13 July 2010, VASP certificates based on the sampling 3 x 5 kg (see previous bullet) and VASP certificates based on the sampling 2 x 10 kg will be in circulation. Both VSP certificates are acceptable in the period between 13 March 2010 and 13 July 2010. Specimen of both VASP certificates are hereafter provided.**
As from 13 July 2010 onwards, only VASP certificates based on the sampling 2 x10 kg are acceptable.

* Consignments of almonds and derived products which are not accompanied by a health certificate are to be **sampled and analysed at a frequency of 100 % at import and the costs resulting from sampling, analysis, storage and issuing of accompanying official documents shall be borne by the food business operator responsible for the consignment or its representative.** This procedure might also be applied also to consignments which are covered by a non valid certificate (instead of e.g. rejection).

* The certificate might refer to the control on aflatoxins of whole almonds, while the consignment concerns sliced almonds (or otherwise processed such chopped, blanched)). As slicing (and chopping, blanching, ...) does not generate aflatoxins, this is an acceptable procedure **only on the condition that there is a clear correspondence** of the consignment of sliced almonds with the sampled consignment of sliced almonds.

CERTIFICATE OF AFLATOXIN
SAMPLING & ANALYSIS FOR CALIFORNIA ALMONDS
VOLUNTARY AFLATOXIN SAMPLING PLAN
USDA/AMS APPROVED LABORATORY

CERTIFICATE NO.: _____

SAMPLE NO.: _____

To Be Filled Out By Handler

APPLICANT:

Company Name: _____
Contact: _____
Address: _____
_____
Telephone: _____
Fax: _____

PRODUCT DESCRIPTION:

Crop Year: _____
Size & Grade: _____
# of Cartons, Bins, etc.: _____
Lot No./ID Marks: _____
_____
Total Lot Size (lbs): _____

SAMPLING AGENCY:

In House ☐ Third Party ☐ Third Party Name and Address:

_____
_____
_____

Shipping Notes:

SAMPLING INFORMATION:

The California almond lot described above was sampled by the listed sampling agency. The collected sample was submitted to the USDA AMS-Approved Laboratory noted below. Representative incremental samples have been collected from throughout the lot to equal the aggregate weight of 15 kg minimum or a maximum of 30 kg

Date/Time Sampled: _____
Destination (Country): _____
By: _____
Sampling Agency Representative
_____
Printed Name

To Be Filled Out By Laboratory

USDA/AMS-APPROVED LABORATORY:

Lab Location: In House ☐ Third Party ☐ Third Party Name and Address:

_____
_____

The representative incremental samples collected from the lot must all be mixed together to be sure that each sub-sample contains portions of the whole lot. Grinding should be accomplished by a method which not only reduces the particle size but also is effective in thoroughly mixing the particles to a homogenous grind and conforms to the USDA/AMS Laboratory Approval Program procedures.

☐ Sample has been divided into 3x5kg subsamples. Each of the sub-samples has been individually ground and presented for analytical analysis. **This sampling and analytical protocol are comparable to the parameters of Regulation (EC) 401/2006.**

☐ Sample has been divided into 3x10kg subsamples. Each of the sub-samples has been individually ground and presented for analytical analysis. **This sampling and analytical protocol are comparable to the parameters of Regulation (EC) 401/2006.**

☐ Sample has been analyzed using HPLC with a limit of quantification (LOQ) of _____ppb for total Aflatoxin.

☐ Sample has been analyzed using the _____ methodology with a detection limit of _____ppb.

RESULTS	SUBSAMPLE 1 (ppb)	SUBSAMPLE 2 (ppb)	SUBSAMPLE 3 (ppb)
B1			
B2			
G1			
G2			
Total			

Date Sample Received: _____

Date Sample Analyzed: _____

This is a USDA AMS-Approved Laboratory for Aflatoxin Analysis in almonds. Official methods of the AOAC as approved by the USDA/AMS are used in all analyses unless otherwise stated. Reported results are not corrected for recovery or expanded measurement of uncertainty. Reports are for the exclusive use of the applicant. We certify to the truth and accuracy of this report as applying to the samples tested only.

BY _____
Signature, Authorized Lab Representative

_____
Printed Name

CERTIFICATE DATE _____ *(Certificate valid for 4 months from this date)*

CERTIFICATE OF AFLATOXIN
SAMPLING AND ANALYSIS FOR CALIFORNIA ALMONDS
VOLUNTARY AFLATOXIN SAMPLING PLAN
USDA/AMS APPROVED LABORATORY

CERTIFICATE NO.: e14498

SAMPLE NO.: _____

APPLICANT:

Company Name: ABC - Handler TEST
Contact: Sue Olson
Address: 1150 9th Street
Modesto CA 95354
Telephone: 847-875-5253
Fax: 252-795-9972

PRODUCT DESCRIPTION:

Crop Year: 2009
Product Type: Blanchable Std 5%
# of Cartons, Bins, etc.: 20x2200 lbs.
Lot No./ID Marks: YTR567
Total Lot Size (lbs): 44000

SAMPLING AGENCY:

In House ☒ Third Party ☐ Third Party Name and Address:

Shipping Notes:

SAMPLING INFORMATION:

As a VASP participant, the memorandum of understanding (MOU) with the Almond Board of California has been signed, declaring that the almonds have been produced, handled, processed, packaged, and transported in line with good hygiene practices. From this consignment, representative incremental samples have been collected from throughout the lot to equal the aggregate weight of 20 kg., in accordance with the Commission Regulation (EC) No. 401/2006. The collected samples were submitted to the USDA/AMS-Approved Laboratory noted below.

Date/Time Sampled: 02-04-2010
Destination (Country): European Union
By: Sue Olson
Sampling Agency Representative

To Be Filled Out By Laboratory

USDA/AMS-APPROVED LABORATORY

Lab Location

Third Party Name and Address:

Test Lab
123 test street
Sacramento CA 95812

The representative incremental samples collected from the lot must all be mixed together to be sure that each sub-sample contains portions of the whole lot. Grinding should be accomplished by a method which not only reduces the particle size but also is effective in thoroughly mixing the particles to a homogenous grind and conforms to the USDA/AMS Laboratory Approval Program procedures.

Sample has been divided into 3x10kg subsamples. Each of the sub-samples has been individually ground and presented for analytical analysis. **This sampling and analytical protocol are comparable to the parameters of Regulation (EC) 401/2006.**

☐ Sample has been analyzed using HPLC with a limit of quantification (LOQ) of _____ ppb for total Aflatoxin.

RESULTS:(ppb)	SUBSAMPLE 1	SUBSAMPLE 2
B1		
B2		
G1		
G2		
Total		

Date Sample Received: ~~(mm-dd-yyyy)~~ 00-00-0000

Date Sample Analyzed: ~~(mm-dd-yyyy)~~ 00-00-0000

This is a USDA/AMS-Approved Laboratory for Aflatoxin Analysis in almonds. Official methods of the AOAC as approved by the USDA/AMS are used in all analyses unless previous in-laboratory validation studies shows minor modifications can be made to the analytical procedures as approved by the USDA/AMS to provide consistent equivalent aflatoxin results. Reported results are not corrected for recovery or expanded measurement of uncertainty. Reports are for the exclusive use of the applicant. We certify to the truth and accuracy of this report as applying to the samples tested only.

BY: _____
Signature, Authorized Lab Representative

_____
Printed Name

CERTIFICATE DATE: 00-00-0000 *(Certificate valid four months from issue)*

ANNEX X: list of USDA approved laboratories performing the aflatoxin analysis in almonds in the frame of VASP

USDA Approved Labs
Voluntary Aflatoxin Sampling Program
(VASP) Certificate Labs

March 03, 2010

Aflatoxin in Almonds Approved Laboratory Program

Advance Mycotoxin Lab
16070 Wildwood Road
Wasco, CA 93280
Dona Stanfield
Phone: 661-758-7790 ext. 807
Email: aflalab@primexfarms.com
Status: Approved
Signatories: Dona Stanfield
Blanca Rios
Adriana Gonzalez
Tiffany Weldin
Mayra Castelo

AmCal Analytical Laboratories,
6914 Road 160
Earlimart, CA 93219
Lizzette Medina
Phone: 559-757-1085
Email: amcalb@aol.com
Status: Approved
Signatories: Lizzette A. Medina
Natacia Fleming
Claudia Rivas

American Council for Food Safety & Quality / DFA of California
1855 South Van Ness
Fresno, CA 93721
J. Michael Hurley
Phone: 559-233-0604
Email: mikehurley@dfaofca.com
Status: Approved
Signatories: J. Michael Hurley
Thomas Jones
Joni Bunnell
Jim Kutschinski
Kevin Willet
Kasey Harper-Ferreria

Blue Diamond Growers
P.O. Box 1768
Sacramento, CA 95812
Steven Phillips
Phone: 916-329-3354
Email: sphillips@bdgrowers.com
Status: Approved
Signatories: Steven Phillips
Donna Dean-Zavala
Jeffrey Vidanes
Linda Quan
Margaret Smith
Adriana Moyo

BSK Analytical Laboratories
1414 Stanislaus Street
Fresno, CA 93706
Alicia Del Carlo
Phone: 559-497-2888
Email: adelcarlo@bskinc.com
Status: Approved
Signatories: Maria Manuel
Jeff Koelewyn
Juli Adams
Alicia Del Carlo
Jason Botwright

Certified Laboratories, Inc.
240 Riggs Avenue
Merced, CA 95340
Gordon Brock
Phone: 866-915-5223
Email: gbrock@800certlab.com
Status: Approved
Signatories: Martin Mitchell
Gordon Brock
Jaspreet Walia
Tina Carrasco
Shankar Bhattacharyya
Desiree Lopez
Steven Mitchell

USDA Approved Labs
Voluntary Aflatoxin Sampling Program
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Aflatoxin in Almonds Approved Laboratory Program

Denele Analytical Inc.
1232 South Ave.
Turlock, CA 95380
Scott Foster
Phone: 209-634-9055
Email: deneleanalytical@yahoo.com
Status: Approved
Signatories: Scott Foster
Brenda Hayes
Joe Mullinax

Food Safety & Process Technology
5043 North Montpelier Road
Denair, CA 95316-9608
Rick Falkenberg
Phone: 209-874-1971
Email: rickf@fs-pt.com
Status: Approved
Signatories: Rick Falkenberg
Humberto Vega
Rebecca Schuller
William Hawes
Donna Yadron
Richard Villegas
Peyman Fatemi

Food Safety Net Services (FSNS)
186 S. West Ave., Suite 104
Fresno, CA 93706
Paul Browning
Phone: 559-443-1046
Email: pbrowning@Food-SafetyNet.com
Status: Approved
Signatories: Paul Browning
Mayra Gomez

IEH Laboratories and Consulting Group
13646 Highway 33
Lost Hills, CA 93249-9719
Jorge Reprieto
Phone: 661-797-6482
Email: jorge@iehinc.com
Status: Approved
Signatories: Nora Enriquez
Jorge Reprieto
Michael Wolf
Paul Slevkoff III

J.L. Analytical Services, Inc.
217 Primo Way
Modesto, CA 95358
Michael Wolf
Phone: 209-538-8111
Email: mike@jlanalytical.com
Status: Approved
Signatories: Michael Wolf
Pete Mostoufi
Ernesto Madueno
Amy Ballinger
Amos Snider

Kerman Almond Lab / American Council for Food Safety & Quality / DFA of California
1221 S. Madera Avenue
Kerman, CA 93630
Kevin Willet
Phone: 559-842-8803
Email: kevinw@agfoodsafety.org
Status: Approved
Signatories: J. Michael Hurley
Thomas Jones
Joni Bunnell
Jim Kutschinski
Kevin Willet
Kasey Harper-Ferreria

USDA Approved Labs
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Aflatoxin in Almonds Approved Laboratory Program

Ntegra
1795 Cortina School Road
Arbuckle, CA 95912
Saul Aguilar
Phone: 530-473-2446
Email: ntegra@jlaglobal.com
Status: Approved
Signatories: Mike Jackson
Pam Smith
Saul Aguilar
Guadalupe Ibarra
John Waters

Silliker, Inc.
5262 Pirrone Court
Salida, CA 95368
Matt Dewitt
Phone: 209-549-7508
Email: Matt.Dewitt@silliker.com
Status: Approved
Signatories: Matt DeWitt
Terry Buchanan
Heather Fullmer