

March 2010

**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)

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I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION

I.1 Maximum levels on aflatoxins

Foodstuffs		Maximum levels (µg/kg)		
		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: <i>Capsicum spp</i> (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika) <i>Piper spp</i> (fruits thereof, including white and black pepper) <i>Myristica fragrans</i> (nutmeg) <i>Zingiber officinale</i> (ginger) <i>Curcuma longa</i> (turmeric) Mixtures of spices containing one or more of the abovementioned spices	5.0	10.0	-
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) 669/2009 lays down the rules concerning the increased frequency of controls to be carried out at the point 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 roasting¹. 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*

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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 98

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 be 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 conditions².

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 laboratory³ 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 samples⁴. 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 accompany 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