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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 Decision 2006/504/EC. Nevertheless, the provisions in this guidance document are also applicable, where relevant, to the control of aflatoxins in food products not subject to Commission Decision 2006/504/EC.

NOTE

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

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I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION

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

Commission Regulation (EC) No 466/2001 establishes maximum levels for aflatoxin B1 and aflatoxin total in groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs, that are stricter than for groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.

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

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

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

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

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

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

The indication "raw" etc is not sufficient.

The indication "product shall be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs" shall be mentioned on the label of each bag, box individually or on the original accompanying document, which must have a clear link with the consignment by means of mentioning the consignment/batch identification code relating to the consignment in question. The identification code must be indelibly marked on each individual bag, box, etc of the consignment. It is very important that this indication is put on the accompanying documentation at the moment when the documentation is issued. (Where it is evident that this indication has been entered in the accompanying document *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.

The maximum levels of aflatoxins established in Commission Regulation (EC) 466/2001, are applicable to all groundnuts, derived products thereof placed on the market except for those groundnuts, derived products thereof which are clearly intended for uses other than human consumption either directly or indirectly. This has to be demonstrated up to and including the wholesale stage by a clear indication of the intended use on the label of each individual packing or on the accompanying document, which must have a clear link with the consignment by means of mentioning the consignment identification code, which occurs on each individual bag, box, etc. of the consignment. In addition the business activity of the consignee of the consignment given on the accompanying document must be compatible to the intended use.

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

II. APPLICATION OF COMMISSION DECISION 2006/504/EC

II.1. Use of TARIC codes

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

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

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

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

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

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

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

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

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

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

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

Mixtures of nuts or dried fruits: CN 0813 50 (origin Turkey)
Hazelnuts, figs and pistachios, prepared or preserved including mixtures: CN 2008 19 (origin Turkey)
Hazelnut paste and fig paste: CN 2007 99 98 (or traded under CN 1106 30 90) (origin Turley)
Cut, sliced and broken hazelnuts: CN 0802 22200 and 2008 191900 (origin Turkey)

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

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

Commission Decision 2006/504/EC provides that foodstuffs shall be considered as containing the foodstuffs when such foodstuffs are listed as ingredients on the label or packaging in accordance with Article 6 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs[1].

From a practical point of view, **the extension to processed and compound foodstuffs is applicable to processed and compound foodstuffs originating from the third country of origin covered by the Decision or in case the foodstuffs is labelled indicating that it is processed from or containing as ingredient the foodstuffs referred to above.**

In order to facilitate the 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.

II.2. Points of physical entry and designated points of import

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

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

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

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

[1] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC of 10 November 2003 (OJ L 308, 25.11.2003, p. 15).

Designated points of import should fulfil at least the following requirements

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

(b) the availability of detailed instructions regarding sampling and the sending of the samples to the laboratory, in accordance with provisions in Annex I of Commission Regulation (EC) 401/2006;

(c) the possibility to perform the unloading and the sampling in a sheltered place at the designated point of import; it must be possible to place the consignment of the foodstuffs under the official control of the competent authority from the designated point of import onwards in cases where the consignment has to be transported in order to perform the sampling;

(d) the availability of storage rooms, warehouses to store detained consignments of foodstuffs in good conditions during the period of detention awaiting the results of analysis;

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

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

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

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

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

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

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

Every consignment is subjected to a document check to ensure that the requirements for the health certificate and the sampling and analytical results are complied with and that each lot/batch making up the consignment has its own health certificate and sampling and analytical results. **The documentary check must take place at the point of first introduction into the territory of the Community, whether this is a designated point of import or not. Eventually, an identity check can also be performed at the point of physical entry and the appropriate cases have to be ticked off in the second part of the health certificate.**

The competent authorities at the point of physical entry 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

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

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

In particular, controls should ensure that the batch/lot identification code corresponds to the batch mentioned on the health certificate and the results of the official sampling and analysis. For products originating from Turkey and Iran 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.

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

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

The competent authorities must also fill in the appropriate sections on the second page of the health certificate in order to inform other competent authorities on the controls already performed on the consignment concerned

The second page of the health certificate referred to in Annex I of Commission Decision 2006/504/EC provides in the section for the documentary check two possibilities to be filled:
- Documentary check –consignment released for free circulation
or
- Documentary check – release of the consignment awaits physical check

These two possibilities do cover all situations in case the point of physical entry is also the designated point of import, the same competent authority is responsible for thee point of physical entry and the designated point of import or in case 100 % of the consignments have to undergo a physical check.

However the document does not provide explicitly for the situation where the competent authority for the point of physical entry is not the same as the competent authority for the designated point of import and the physical check is not legally required for all consignments.

Therefore, the document should ideally contain the following third possibility for these situations:
- Documentary check – consignment in transit to the designated point of import (for release for free circulation)

Awaiting a legal modification of the certificate it is appropriate to tick in these cases the box: "Documentary check – release of the consignment awaits physical check", with the understanding that the competent authority of the designated point of import decides upon the necessity of executing a physical check before releasing the consignment for free circulation.

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

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

II.4. Selection of consignment for sampling

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

The Commission Decision 2006/504/EC establishes different frequencies of controls:
- 5% of consignments of hazelnuts and certain products derived thereof from Turkey
- 10 % of consignments of peanuts and products derived thereof from China and dried figs, pistachios and products derived thereof from Turkey)
- 20 % of consignments of peanuts and products derived thereof from Egypt
- 100 % of consignment of pistachios and products derived thereof from Iran and Brazil nuts in shell from Brazil.

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

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

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

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

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[4], provides in Article 4(2)(g) that feed and food business operators (responsible operator) shall be obliged to undergo any inspection carried out in accordance with the Regulation and to assist staff of the competent authority in the accomplishment of their tasks..

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

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.

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

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

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

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

II.5.1. Consignment/lot consisting of several containers

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

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

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

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

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

II.6. General Sampling requirements

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

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

II.6.1 Incremental sample for lots in retail packing

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

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

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

3. Where the retail pack weight is less than the required incremental sample weight and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight.

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

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

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

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

II.7.1 General survey of the method of sampling

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

Commodity	Lot weight (tonne)	Weight or number of sublots	N° of incremental samples	Aggregate sample weight (kg)
Dried figs	≥ 15 < 15	15-30tonnes --	100 10-100 (table 2)	30 ≤ 30
Groundnuts, hazelnuts pistachios, Brazil nuts and other nuts	≥ 500 >125 and <500 ≥ 15 and ≤ 125 < 15	100 tonnes 5 sublots 25 tonnes --	100 100 100 10-100 (table 2)	30 30 30 ≤ 30

II.7.2 Method of sampling for lots ≥ 15 tonnes

- On condition that the sublot can be separated physically, each lot must be subdivided into sublots following **Table 1.** Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may vary from the mentioned weight by a maximum of 20 %. (If, after the division of a lot into sublots, the weight of the sublot exceeds the weight of the sublot as indicated in Table 1 by more than 20 %, the number of sublots has to be increased, even if by so doing the weight of the sublot is lower than the weight indicated in Table 1).

- Each sublot must be sampled separately.

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

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

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

II.7.3 Method of sampling for lots < 15 tonnes

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

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

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

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

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

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

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

II.7.4. Sampling of derived products and compound foods

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

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

Table 3: Number of incremental samples

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

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

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

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

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

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 30 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2 under II.7).

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

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 30 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight is equal to the weight of the sampled lot (see Table 2 under II.7).

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

II.7.5.3. Products derived from nuts, figs and groundnuts with small particle size

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

II.8. Sampling procedure for spices

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

II.8.1. General method of sampling for spices

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

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

* Depending on the lot weight - see table 5

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

- On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following table 4. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

- Each sublot shall be sampled separately.

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

- Weight of the aggregate sample = 10 kg

- If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented as discussed above.

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

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

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

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

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

II.8.4. Sampling of spices traded in vacuum packings

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 5 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 5).

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

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

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

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

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

* Depending on the lot weight - see table 7

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

- On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 6. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

- Each sublot shall be sampled separately.

- Number of incremental samples: 100.

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

- Weight of the aggregate sample = 10 kg

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

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

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

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

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

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

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

II.10. Sampling procedure for vegetable oil

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

- The weight of the incremental sample shall be at least about 100 grams (ml), resulting in an aggregate sample of at least 1 kg (litre).

- The minimum number of incremental samples to be taken from the lot shall be as given in Table 8. The lot shall be thoroughly mixed insofar possible by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of aflatoxin can be assumed within a given lot, it is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

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

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

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

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

RECOMMENDATION

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

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

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

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

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

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

II.12. Period of detention

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

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

II.13.1 Mixing of the sample

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

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

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

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

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

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

II.13.3. Homogenisation procedure

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

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

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

II.13.4.Accreditation – standard operation procedure:

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

II.14. Samples for defence and reference purposes

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

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

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

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

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

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

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

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

The following papers, the first of which was produced in the context of the European Standardisation Programme (CEN), provide further information:

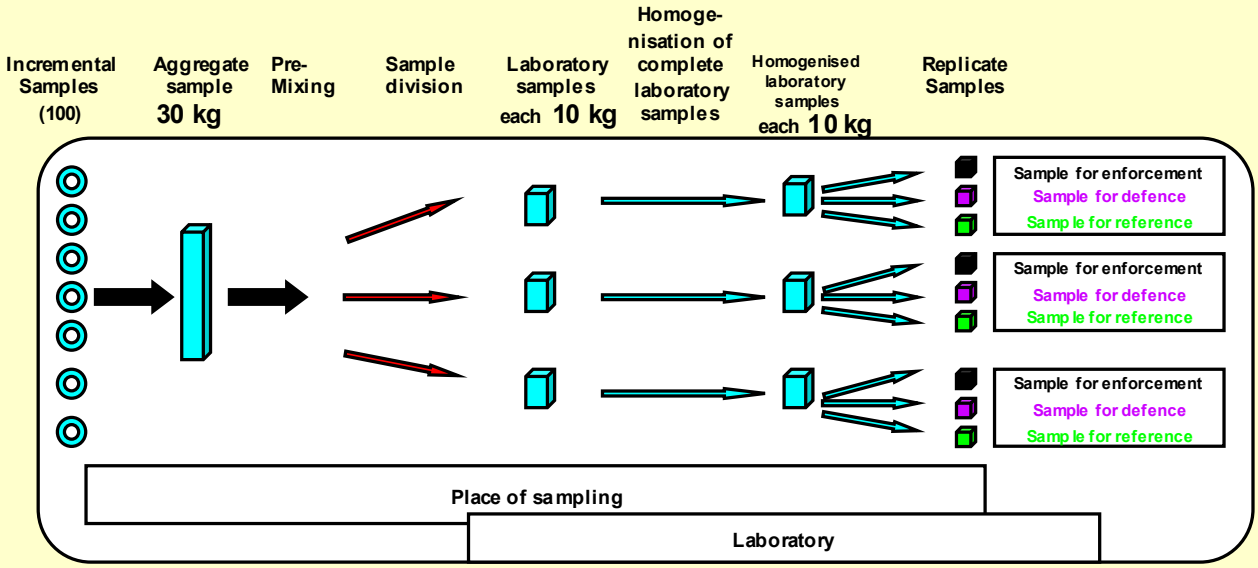
- "Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?"

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

- "Use of water slurries in aflatoxin analysis"

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

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



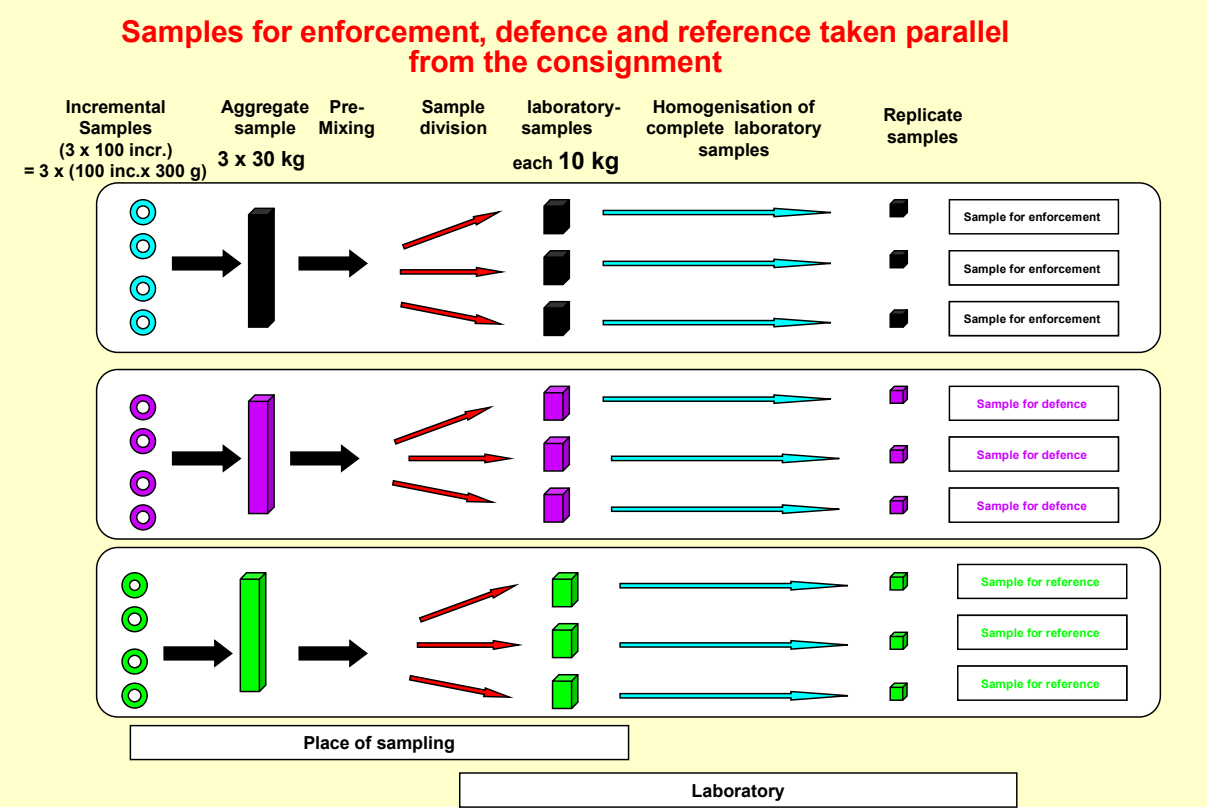
NB: Each of the 3 enforcement samples have to be compliant for a consignment to be accepted

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

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

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

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



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

II.15. Requirements laboratories

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

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

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

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

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

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

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

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

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

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

II.16. Requirements governing the method of analysis

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

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

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

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

Notes:

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

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

where:

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

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

II.16.2. Definitions

The most commonly quoted precision parameters are repeatability and reproducibility.

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

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

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

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

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

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

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

II.17.1. Precautions

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

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

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

The limits established for aflatoxins in Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs **apply to the edible part**.

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

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

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

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

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

II.18. Reporting of results

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

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

Important information on these items can be found in the document

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

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

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

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

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

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

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

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

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

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

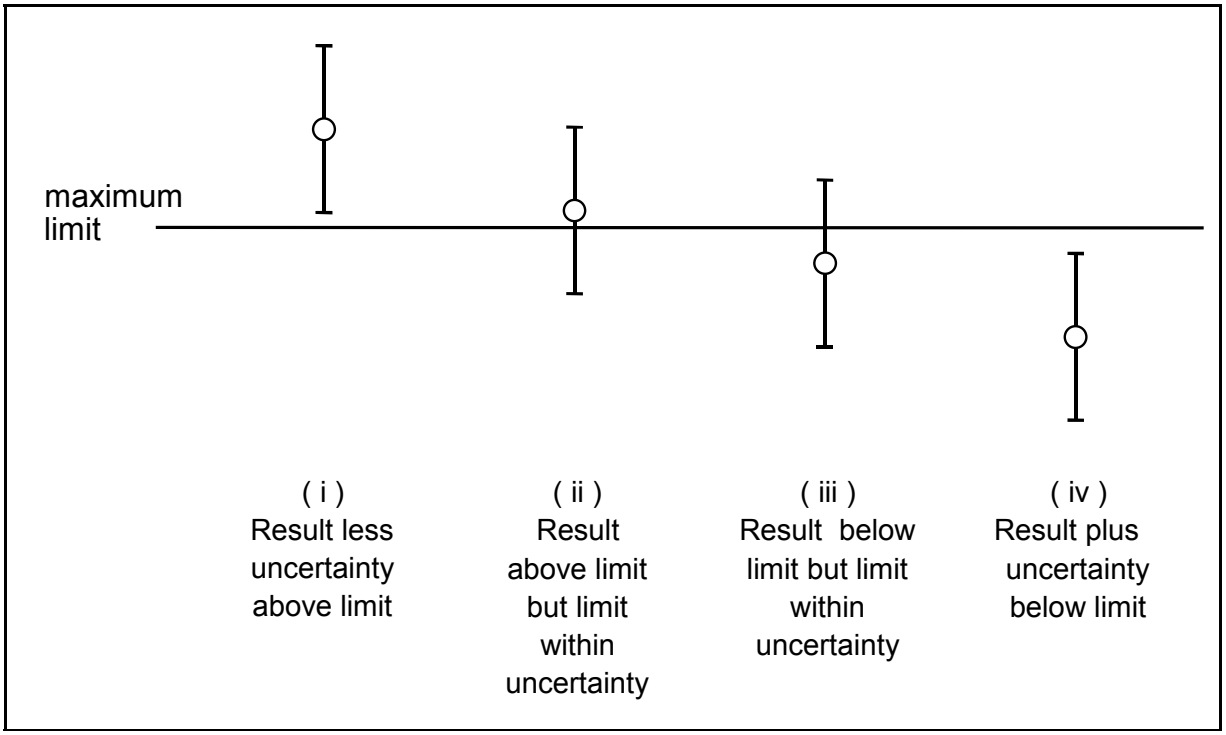
  – rejection if the aggregate sample exceeds the maximum limit **beyond reasonable doubt taking into account analytical uncertainty and correction for recovery***."

***** The measurement of 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 measurement of 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 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 measurement uncertainty being taken into account. This sample is therefore compliant with the maximum limit.

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

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

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

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

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

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

II.20. Issuing accompanying document in case of compliance

An accompanying document (official document) has to be issued by the competent authority when the consignment is compliant, stating that the consignment has been officially sampled on (date) and analysed in accordance with Regulation (EC) 401/2006 and was found to be compliant, indicating the analytical results (possibly with analysis report enclosed). Also the relevant parts of the second page of the health certificate have to be completed by the competent authority of the importing Member State (see II.3). **These documents must accompany the consignment up to and including the wholesale stage.**

Where only part of the consignment was found compliant with EU legislation, the original certificate (or certified copies), without modifications, has to accompany the part of the consignment allowed for free circulation. As the quantity allowed for free circulation does not correspond to the quantity mentioned on the original health certificate, an official explanatory statement should appear in the accompanying document.

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

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

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

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

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

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

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

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

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

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

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

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.

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

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 consignments imported (if available)
- number of consignments sampled and analysed
- number of consignments found to be compliant with EU legislation
- number of consignments found to be non-compliant with EU legislation

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

II.24.1. General provision and remark

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

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

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

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

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

[11] OJ L40, 17.2.1993, p. 1

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

Consignments of Brazil nuts not complying with the maximum levels for aflatoxin B1 and aflatoxin total established by Regulation (EC) No 466/2001 may be returned to the country of origin only where, for each such individual non-conforming consignment, the Ministério da Agricultura, Pecuária e Abastecimento – (MAPA) provides the following in writing:

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

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

(c) a specific indication of:

  (i) the destination of the returned consignment;

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

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

However, if the conditions provided for in points (a), (b) and (c) are not complied with by the Ministério da Agricultura, Pecuária e Abastecimento – (MAPA), all subsequent consignments that do not comply with the maximum levels for aflatoxin B1 and aflatoxin, established by Regulation (EC) No 466/2001 shall be destroyed by the importing Member State.

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

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

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

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

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

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

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

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

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

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

In all other cases, i.e. if there is no relevant Community food law requirement e.g. there is no regulatory limit for aflatoxin in the particular commodity and the third country has not set any specific requirements applicable to imports, paragraph 2 of Article 12 provides that food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons why the feed and food could not be put or remain on the market within the EU.

However, if the food and feed does not comply with the provisions of food/feed safety legislation ("where foods are injurious to health or feeds are unsafe"), such food and feed cannot be exported or re-exported and safe disposal must be ensured.

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

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

For **food rejected at the external border of the EU**, **Regulation (EC) No 882/2004** of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[14] applies from 1 January 2006 and provides in its Articles 19, 20 and 21 the following measures as regards non-compliant consignments.

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

- order that such food be destroyed

- subjected to special treatment

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

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

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

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

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

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

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

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

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

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

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

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

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

These appropriate measures could be

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

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

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

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

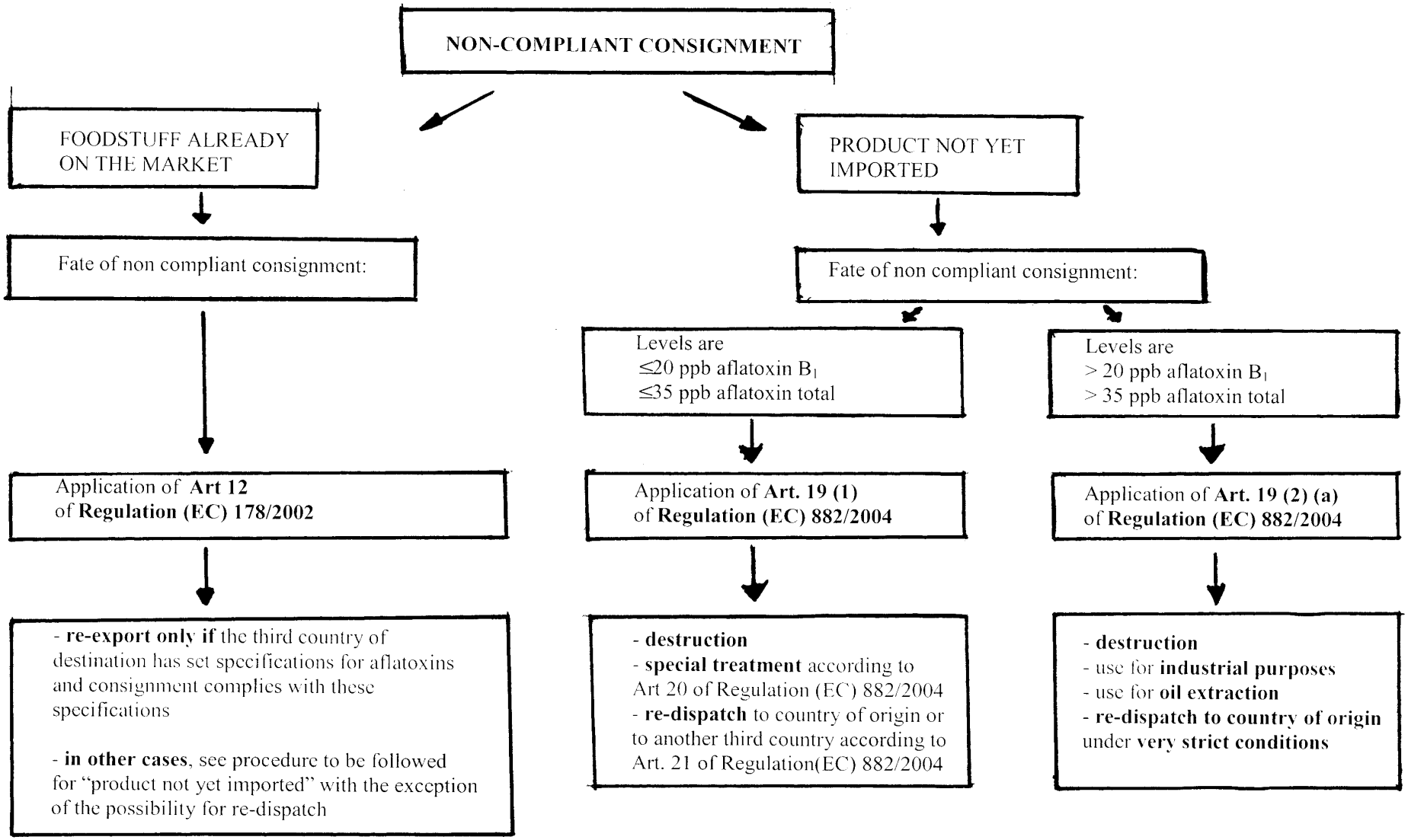
(a) explicit agreement for the return of the relevant consignment, and indicating the consignment code;
(b) a commitment to put the returned consignment under official control from the date of arrival;
(c) a specific indication of:
    (i) the destination of the returned consignment;
    (ii) the intended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

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

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

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

II.24.3.3. Schematic overview


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

II.25. Costs of official controls

Article 8 of Commission Decision 2006/504/EC of provides that all costs resulting from sampling, analysis, storage and issuing of accompanying official documents and of copies of health certificate and accompanying documents for consignments Brazil nuts in shell from Brazil and pistachios and derived products thereof from Iran shall be borne by the food business operator responsible for the consignment or its representative.

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

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

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

- laboratory analysis and sampling costs

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

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

As regards the products other than pistachios from Iran and Brazil nuts in shell from Brazil, Article 22 of the Regulation (EC) 882/2004 provides that all costs related to official measures taken by the competent authorities as regards non-compliant consignments shall be borne by the food business operator responsible for the consignment or its representative.

II.26 Specific issues

II.26.1. Procedure for splitting the consignment

If a consignment is split, copies of the report and health certificate and the accompanying document shall accompany each part of the split consignment. These copies must be certified by the competent authority of the Member State on whose territory the splitting has taken place. These certified copies must accompany the split consignment up to and including the wholesale stage.

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).

ANNEX – LEGISLATION

MAXIMUM LEVELS

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

Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs[17] as last amended by Commission Regulation (EC) 199/2006 of 3 February 2006[18]

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[19]

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[20]

SPECIFIC SAFEGUARD MEASURE

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

OTHER FRAMEWORK LEGISLATION OF RELEVANCE

Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[22]

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[23] (Provisions with regard to export and re-export of non-complying consignments – Article 12 – applicable from 1 January 2005)

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[24]

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[25]

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[16] OJ L 37, 13.2.1993, p. 1
[17] OJ L 77, 16.3.2001, p.1
[18] OJ L 32, 4.2.2006, p.34
[19] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83
[20] OJ L 70, 9.3.2006, p. 12
[21] OJ L 199, 21.7.2006, p. 21
[22] OJ L 40, 17.2.1993, p. 1
[23] OJ L 31, 1.2.2002, p. 1
[24] OJ L 139, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 3
[25] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83