

**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 specific Commission Decisions (see Annex: “Specific safeguard measures”). Nevertheless, the provisions in this guidance document are also applicable, where relevant, to the control of aflatoxins in food products not subject to specific Commission Decisions.

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.6 of the guidance document)

TABLE OF CONTENTS

TABLE OF CONTENTS	- 2 -
I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION	- 5 -
I.1. Use of TARIC codes	- 5 -
I.2. Points of entry	- 6 -
I.3. Groundnuts, nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.....	- 7 -
II. APPLICATION OF COMMISSION DECISIONS (LIST IN ANNEX)	- 9 -
II.1. Arrival of consignment at point of entry // for direct human consumption/to be subjected to sorting and/or other physical treatment	- 9 -
II.2. Selection of consignment for sampling	- 10 -
II.3. Clarification of sampling provisions with regard to the definition of a batch/lot/consignment.	- 11 -
Consignment/lot consisting of several containers.....	- 11 -
Two or more consignments/lots in one container/truck	- 11 -
II.4. Sampling procedure for groundnuts, pistachios, Brazil nuts, dried figs and spices	- 12 -
II.5. Sampling procedure for nuts other than pistachios, Brazil nuts, dried fruit other than dried figs	- 14 -
II.6. Sampling procedures other than those described in Directive 98/53/EC which can be used for specific packing/trade forms of the products mentioned under II.4 and II.5	- 15 -
II. 7 Sampling of derived products and compound foods.....	- 17 -
Derived products with a very small particle size, i.e. flour, fig paste, peanut butter (homogeneous distribution of aflatoxin contamination).....	- 17 -
Derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination).....	- 17 -
II.8. Period of detention	- 17 -

II.9. Sample preparation // for direct human consumption // to be subjected to sorting and/or other physical treatment (see above)	- 18 -
* Mixing of the sample	- 18 -
* Treatment of the sample as received in the laboratory	- 18 -
* Homogenisation procedure	- 18 -
* Accreditation – standard operation procedure:	- 18 -
II.10. Samples for defence and reference purposes.....	- 19 -
* Defence and reference samples taken from the homogenised subsample	- 19 -
* Defence and reference samples are taken at the place of sampling	- 20 -
II.11. Requirements laboratories	- 21 -
II.12. Requirements method of analysis.....	- 22 -
Performance criteria as laid down in Commission Directive 1998/53/EC	- 22 -
Definitions.....	- 23 -
II.13. Precautions to be taken and calculation of the analytical result to the edible part.....	- 24 -
* Precautions	- 24 -
* Calculation of proportion of shell/kernel of whole nuts	- 24 -
II.14. Reporting of results	- 25 -
II.15. Acceptance of a lot or subplot and interpretation of results	- 26 -
II.16. Issuing accompanying document in case of compliance.....	- 26 -
II. 17. Right of second opinion for the operator in case of non-compliance.....	- 27 -
II.18. Notification to the Rapid Alert System for Food and Feed (RASFF).....	- 27 -
II.19. Reporting to the Commission of all analytical results.....	- 28 -
II.20 Procedure to be followed for the consignment in case of non-compliance.....	- 28 -
II.20.1. General provision and remark	- 28 -
II.20.2.The specific case: Brazil nuts in shell	- 28 -

II.20.3. In the other cases (other than Brazil nuts in shell from Brazil).....	29 -
* Food produced within the EU (exported) or food that has been put on the EU-market after having been imported (re-exported).....	29 -
* Food rejected at the external border of the EU	30 -
II.21. Costs of official controls	31 -
II.22 Specific issues	32 -
* Procedure for splitting the consignment	32 -
* Finding of non-compliance by sampling at retail stage	32 -
* Control /inspections of establishments	32 -
ANNEX – LEGISLATION.....	33 -
MAXIMUM LEVELS	33 -
SAMPLING AND ANALYSIS	33 -
SPECIFIC SAFEGUARD MEASURES.....	33 -
OTHER FRAMEWORK LEGISLATION OF RELEVANCE	34 -

I. GENERAL ISSUES ON APPLICATION OF AFLATOXIN LEGISLATION

I.1. Use of TARIC codes

Commission decisions¹ refer 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 specific Commission Decisions²

Groundnuts, not roasted or otherwise cooked, whether or not shelled or broken

- in shell – other than for sowing: CN 1202 10 90

- shelled – whether or not broken: CN 1202 20 00

Groundnuts roasted

- 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

- 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

Pistachios roasted

- 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*)

- in shell: CN 0802 21 00

- shelled: CN 0802 22 00

Brazil nuts

- in shell: CN 0801 21 00

(- shelled: CN 0801 22 00 – not subject to a specific Commission Decision)

Figs

(- 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

Mixtures of nuts or dried fruits: CN 0813 50

Hazelnuts, figs and pistachios, prepared or preserved including mixtures: CN 2008 19

Hazelnut paste and fig paste: CN 2007 99 98 (or traded under CN 1106 30 90)

¹ See Annex : Specific safeguard measures

² Composite products containing products falling within the customs/TARIC codes specified in the Commission Decisions are also subject to the provisions contained in the Commission Decisions.

I.2. Points of entry

It is important that experienced staff are present at the point of entry 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 entry points and ensure that the controls at all entry points can be performed efficiently and under good conditions.

Points of entry should fulfil at least the following requirements

- * presence of trained staff to perform controls on consignments;
- * availability of detailed instructions regarding sampling and sending of the samples to the laboratory, in accordance with the provisions of Commission Directive 1998/53/EC;
- * possibility to perform the unloading and the sampling in a sheltered place at the point of entry (it must at least be possible to place the consignment under official control from the point of entry onwards in cases where the consignment has to be transported in order to perform the sampling);
- * availability of storage rooms, warehouses to store detained consignments in good conditions during the period of detention (awaiting the result of analysis)
- * availability of unloading equipment and appropriate sampling equipment;
- * availability of an accredited official laboratory 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. The laboratory must be able to analyse the sample within a reasonable period of time in order to comply with the 15-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.2).

I.3. 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.

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 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”

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”, 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** before consumption or use as an ingredient **AND the destination of the consignment has the possibility/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”**

“Physical treatment to reduce aflatoxin contamination” means any treatment, not involving chemical substances, by which aflatoxins are removed. 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 can be mentioned on the label of each bag individually or can be mentioned 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 mentioned on each individual bag, box, etc of the consignment. It is very important that this indication is put on the accompanying document at the moment when the accompanying document 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.

II. APPLICATION OF COMMISSION DECISIONS (LIST IN ANNEX)

II.1. Arrival of consignment at point of entry // for direct human consumption/to be subjected to sorting and/or other physical treatment

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.

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, Commission Decision 2003/493/EC imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil also applies 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 (Commission Decisions 2002/80/EC and 2005/85/EC) it must be verified that the signature of the official who signed the health certificate is on the list of authorised officials as updated in the RASFF system.

Additionally, where the certificate has a date of validity (as in the case of pistachios from Iran) the validity of the certificate should not exceed four months and the certificate must be 'in date' at the moment of import.

In the case of Brazil nuts in shell from Brazil (Commission Decision 2003/493/EC), 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 individual bags, packages etc must be 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 applicable as well the sampling procedure (average of 30 kg) applicable to this category are to be used (see II.4)

II.2. Selection of consignment for sampling

The different Commission Decisions establish different frequencies of controls:

- 10 % (Commission Decisions 2002/79/EC – peanuts and products derived thereof from China – and 2002/80/EC – hazelnuts, dried figs and pistachios and products derived thereof from Turkey)
- 20 % (Commission Decision 2000/49/EC – peanuts and products derived thereof from Egypt)
- 100 % (Commission Decisions 2005/85/EC – pistachios and products derived thereof from Iran – and 2003/493/EC – Brazil nuts in shell from Brazil)

The 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 so 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.

Article 11 of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs³ provides that the natural and legal persons concerned (responsible operator) shall be obliged to undergo any inspection carried out in accordance with that directive and to assist inspectors in the accomplishment of their tasks. The same provision is set out in Article 4(2)(g) of 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 rules⁴, applicable from 1 January 2006.

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

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.

³ OJ L 186, 30.6.1989, p. 23

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

II.3. Clarification of sampling provisions with regard to the definition of a batch/lot/consignment.

Commission Directive 1998/53/EC 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.

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 apply only to the two containers sampled. If there is suspicion that the other containers from the consignment are also non-compliant, then a representative sampling of all containers per two containers has to be performed before deciding on the official measures applicable to all containers. Consequently, if it is decided to sample the whole consignment (10 containers), then five samples of 30 kg must be taken.

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.

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 Directive 98/53/EC, even if the product is identical (in this particular case from the 8 tonnes, 80 incremental samples of 300g 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.4. Sampling procedure for groundnuts, pistachios, Brazil nuts, dried figs and spices

As mentioned above, sampling must be representative and therefore it is necessary that the incremental samples are taken throughout the batch. It is therefore necessary in almost every case to unload the truck or container for the sampling. Unloading should not expose the product to adverse weather conditions or excessive moisture

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

- On condition that the subplot 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 subplot may vary from the mentioned weight by a maximum of 20 %. (If, after the division of a lot into sublots, the weight of the subplot exceeds the weight of the subplot 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 subplot is lower than the weight indicated in Table 1).
- Each subplot must be sampled separately.
- Number of incremental samples: **100**. Each incremental sample weighs 300 grams except in the case of spices where the incremental sample weight is 100 grams (N.B. retail packs – *see note hereafter*). 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**).

Note: In the case of retail packs the weight of the incremental sample is determined by the weight of a single retail pack. In the case of retail packs of > 300 grams or >100 grams for spices, this will result in aggregate samples weighing more than 30 kg and 10 kg respectively. If the weight of a single retail pack is >> 300 grams or 100 grams in the case of spices, then 300 grams or 100 grams are taken respectively from each individual retail pack as an incremental sample. This can be done either when the sample is taken or in the laboratory.

However, in cases where such sampling procedure would lead to unacceptable commercial consequences resulting from damage to the lot, then alternative sampling procedures can be applied. This is the case, for example, with dried figs marketed in retail packs of 500 grams or 1 kg. In such a case, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in table 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2.

Where the retail pack is less than 300 grams or 100 grams respectively and if the difference is not very large, one retail pack is to be considered as one incremental sample, resulting in an aggregate sample of less than 30 kg and 10 kg respectively. If the weight of the retail pack is much less than 300 grams or 100 grams respectively, one incremental sample consists of two or more retail packs, whereby the 300 grams or 100 grams respectively are approximated as closely as possible.

- **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 subsamples of 10 kg before grinding and homogenisation. This division into three subsamples is not necessary in the case of groundnuts, nuts and dried fruit intended for further sorting or other physical treatment (and where clearly labelled and treated as such – see point I 3) of the guidance).

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

- * < 10 kg: no division into subsamples
- * 12/18 kg: division into two subsamples
- * 24 kg: division into three subsamples

. In the case of spices the aggregate sample weighs not more than 10 kg and therefore no division into subsamples is necessary.

- Laboratory sample: a subsample of 10 kg. **Each subsample must be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Commission Directive 1998/53/EC.**

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

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

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

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

Lot weight (tonnes)	N° of incremental samples	Aggregate sample Weight (kg)
≤ 0.1	10	3
> 0.1 - ≤ 0.2	15	4.5
> 0.2 - ≤ 0.5	20	6
> 0.5 - ≤ 1.0	30	9
> 1.0 - ≤ 2.0	40	12
> 2.0 - ≤ 5.0	60	18
> 5.0 - ≤ 10.0	80	24
> 10.0 - ≤ 15.0	100	30

II.5. Sampling procedure for nuts other than pistachios, Brazil nuts, dried fruit other than dried figs

For nuts other than pistachios and Brazil nuts and dried fruit other than dried figs, it is preferable to apply the sampling procedure laid down for groundnuts, pistachios, Brazil nuts and dried figs (see above). However, taking into account the low incidence of contamination for these products and/or the newer forms of packaging in which products can be traded, simpler sampling methods may be applied.

A simpler sampling method might be the sampling procedure set out in Commission Directive 2002/26/EC of 13 March 2002 laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs⁵ for the control of OTA in dried vine fruit. Under this procedure 100 incremental samples of 100 grams are taken, resulting in an aggregate sample of 10 kg.

⁵ OJ L 75, 16.3.2002, p. 38. Last amended by Commission Directive 2004/43/EC of 13 April 2004 (OJ L 113, 20.4.2004, p. 14)

II.6. Sampling procedures other than those described in Directive 98/53/EC which can be used for specific packing/trade forms of the products mentioned under II.4 and II.5

Several specific packing/trading forms have been identified for which the normal sampling procedure is not applicable:

- vacuum packing (see below)
- large bags, large boxes
- wrapped pallets
- paste (hazelnut paste, ...)
- packing under CO₂
-

ATTENTION:

Hazelnuts from Turkey: Commission Decision 2002/80/EC provides that, for the control of hazelnuts originating from Turkey, sampling shall be performed according to the sampling procedure laid down for groundnuts, pistachios and Brazil nuts.

In the case of hazelnuts traded in vacuum packs, for lots equal to or more than 15 tonnes, at least 25 incremental samples resulting in a 30 kg aggregate sample have to be taken and, for lots of less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 are to be taken.

RECOMMENDATION

- **To apply where possible the sampling procedure as established for groundnuts, pistachios, Brazil nuts, dried figs also to other nuts and other dried fruit (see above).**
- **For groundnuts and nuts other than hazelnuts, traded in vacuum packs:**
 - * **for pistachios, groundnuts, Brazil nuts and dried figs (whole kernels): for lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 30 kg aggregate sample have to be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in table 2 are to be taken.**
 - * **for other nuts or for nut/fig products with small particle size: for lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 30 kg aggregate sample have to be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in table 2 are to be taken.**
- **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@cec.eu.int) or by fax (+32-2 299.18.56), or by mail (European Commission – Office B232 04/67 – 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. 7 Sampling of derived products and compound foods

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

- Number of incremental samples: 100. For lots of under 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. The weight of the incremental sample depends on the weight of the retail packing
- 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

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

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

II.8. Period of detention

Any consignment of a commodity covered by the safeguard measure that is to be subjected to sampling and analysis should be detained from the moment of sampling until release onto the market from the point of entry 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.9. Sample preparation // for direct human consumption // to be subjected to sorting and/or other physical treatment (see above)

*** Mixing of the sample**

The sample must be thoroughly mixed (not ground!!!) before dividing the sample into three subsamples in the case of products intended for direct human consumption. (This can be done when the sample is taken or in the laboratory).

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

*** Treatment of the sample as received in the laboratory**

The aggregate sample or the three subsamples 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 in three subsamples: proceed with homogenisation procedure;
- sample arrived at the laboratory as aggregate sample: aggregate sample must be first divided into three separate subsamples before proceeding with the homogenisation procedure

*** Homogenisation procedure**

Finely grind and mix thoroughly each subsample / laboratory sample completely (and **not** only a part of it) using a process that has been demonstrated to achieve complete homogenisation (see below).

The wet grinding and homogenisation process, which results in most cases in a more homogeneous slurry 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 subsamples as well the analytical samples taken from the homogenised sample are stored in such conditions that microbial contamination and growth is excluded.

*** 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/subsample and analyse for the aflatoxin content. The levels of aflatoxins analysed in the different analytical samples from one homogenised subsample should be within the range of the variability of the method.

II.10. Samples for defence and reference purposes

* Defence and reference samples taken from the homogenised subsample

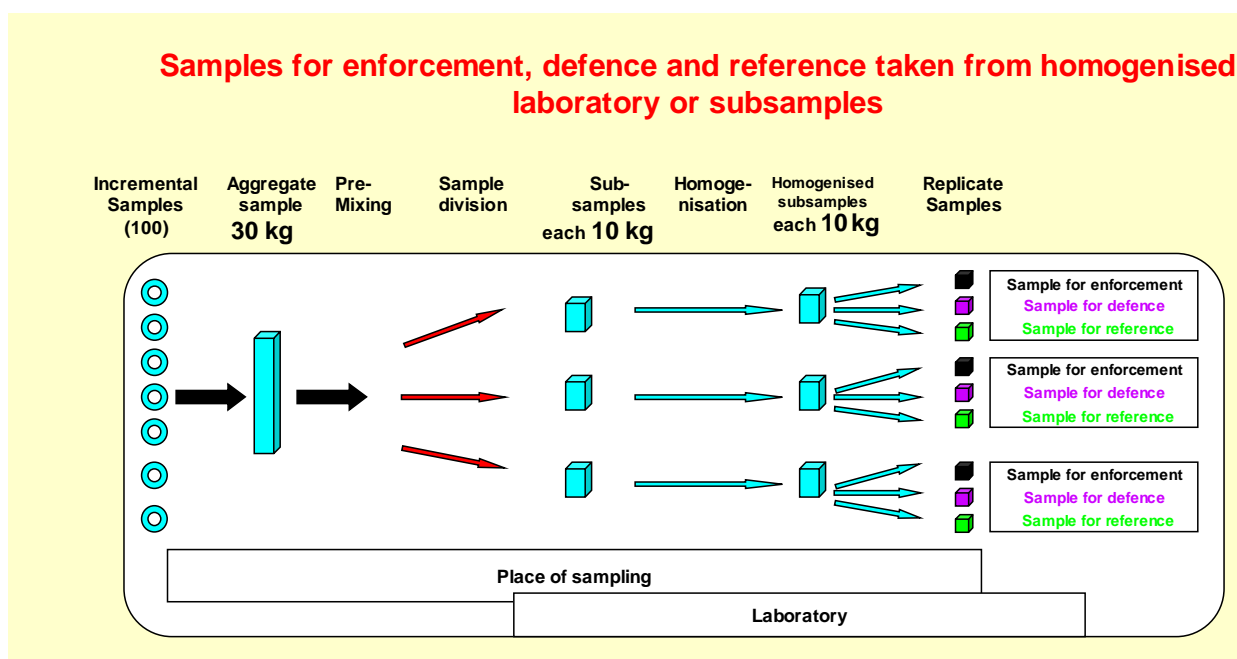
Samples for defence and reference purposes are taken from the homogenised subsamples (laboratory samples) – see provisions in Commission Directive 1998/53/EC – Annex II, point 3.

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 subsample (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 subsamples (laboratory samples) that is three analytical samples, three defence samples, three reference samples.

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

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

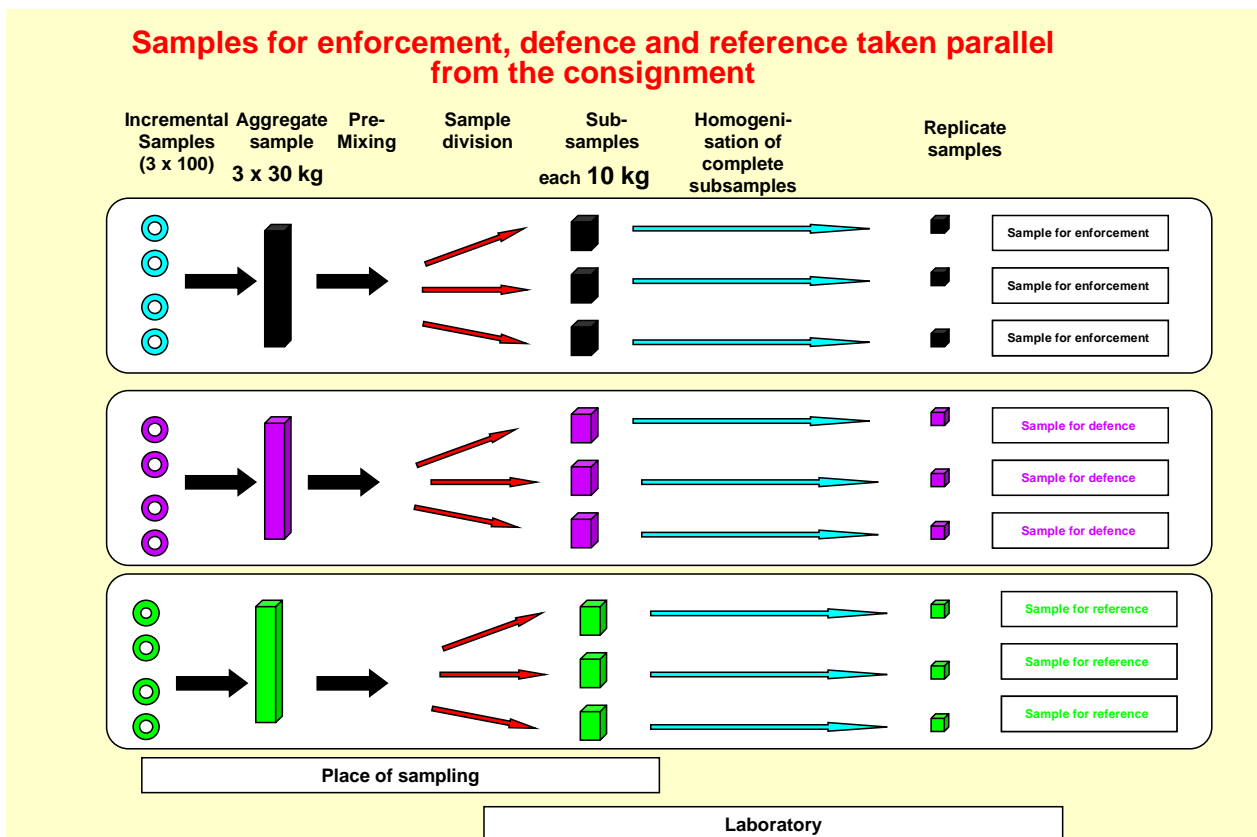


*** Defence and reference samples are taken at the place of sampling**

In **very few** Member States, 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 Directive 98/53 allows that possibility.

If this is the case then the sampling procedure as outlined in II.4 and II.5. 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 subsamples as well the analytical samples taken from the homogenised sample are stored and transported in such conditions that microbial contamination and growth are excluded



II.11. Requirements laboratories

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs⁶ provides that the analysis, including the counter-analysis, shall be carried out by official laboratories and that Member States may also empower other laboratories to carry out these analyses. The enforcement sample and defence sample should be preferably analysed in different laboratories.

Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs⁷ provides that the above-mentioned laboratories must comply with the general criteria for the operation of testing laboratories laid down in European Standard EN 45001 (currently replaced by EN ISO/IEC 17025 on “General requirements for the competence of testing and calibration laboratories”) supplemented by standard operating procedures and the random audit of their compliance by quality assurance personnel.

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 and extraction/clean-up 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.17 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 above and should be maintained on a list of official laboratories notified to the Commission under Article 15 of Council Directive 89/397/EC. 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.

In other cases (see point II.17. 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

These requirements are also provided for in Regulation 882/2004 applicable from 1 January 2006 onwards.

However, it has to be noted that when a judicial procedure has been initiated following a finding of non-compliance, the judicial authorities decide upon the procedure to be followed and the analyses to be performed.

⁶ OJ L 186, 30.6.1989, p. 23

⁷ OJ L 290, 24.11.1993, p. 14

II.12. 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 Directive 1998/53/EC. The laboratory must be able to provide the evidence that the method of analysis used does comply with the established performance criteria.

Performance criteria as laid down in Commission Directive 1998/53/EC

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 mg/kg	60 to 120 %	
	> 0.05 mg/kg	70 to 110 %	
Recovery-Aflatoxins B ₁ , B ₂ , G ₁ , G ₂	< 1.0 mg/kg	50 to 120 %	
	1 - 10 mg/kg	70 to 110 %	
	> 10 mg/kg	80 to 110 %	
Precision RSD _R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD _T may be calculated as 0.66 times Precision RSD _R at the concentration of interest			

Notes:

- Values to apply to both B₁ and sum of B₁ + B₂ + G₁ + G₂.
- If sums of individual aflatoxins B₁ + B₂ + G₁ + G₂ 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.

Definitions

The most commonly quoted precision parameters are repeatability and reproducibility.

- r = Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2.8 \times s_r$.
- s_r = Standard deviation, calculated from results generated under repeatability conditions.
- RSD_r = Relative standard deviation, calculated from results generated under repeatability conditions $[(s_r / \bar{x}) \times 100]$, where \bar{x} is the average of results over all samples analysed under the same conditions within one laboratory.
- R = Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e. on identical material obtained by operators in different laboratories, using the standardised test method) may be expected to lie within a certain probability (typically 95%); $R = 2.8 \times s_R$.
- s_R = Standard deviation, calculated from results under reproducibility conditions.
- RSD_R = Relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$ where \bar{x} is the average of results over all laboratories and samples.

II.13. Precautions to be taken and calculation of the analytical result with regard to the edible part

*** 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 test material.

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

II.14. 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 $x \pm U$, 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 food⁸)

- 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 feed⁹)”

The document is available at the SANCO Food Safety website:
http://europa.eu.int/comm/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.15. Acceptance of a lot or subplot 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 subsamples conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
 - rejection if the aggregate sample or the average of the subsamples exceeds the maximum limit **beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.**
- For groundnuts, nuts and dried fruit intended for direct human consumption :
 - acceptance if none of the subsamples exceeds the maximum limit, taking into account the measurement uncertainty and correction for recovery,
 - rejection if one or more of the subsamples 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 correction for recovery,
 - rejection if the aggregate sample exceeds the maximum limit **beyond reasonable doubt taking into account analytical uncertainty and correction for recovery.”**

II.16. 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 Directive 98/53 and was found to be compliant, indicating the analytical results (possibly with analysis report enclosed).

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

Operators have the right of a second opinion in the case of the official sample being found non-compliant as required by the provisions of Council Directive 89/397/EEC.

This right is also provided for in Article 11(5) of Regulation 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 (see point II.11).

The taking of the defence and reference samples is addressed in point II.10.

Three 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)
- 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.
- 3) the operator must challenge the analytical result of the official sample before a court.

II.18. 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 safety¹⁰ 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 entry point within the European Union, aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food in order to protect public health.

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

¹⁰ OJ L 31, 1.2.2002, p. 1

II.19. 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 a specific Commission Decision. This report shall be submitted during the month following each quarter (April, July; October, January).

II.20 Procedure to be followed for the consignment in case of non-compliance

II.20.1. 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 countries¹¹.

It has to be noted that when a judicial procedure has been initiated following a finding of non-compliance, it is the prerogative of the judicial authorities to decide on the fate of the non-compliant consignment.

II.20.2.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.

¹¹ OJ L40, 17.2.1993, p. 1

II.20.3. In the other cases (other than Brazil nuts in shell from Brazil)

There are no specific provisions in the current legislation. Possible options are: returning to the country of origin, use for non-food uses (in the case of use for feed – must comply with the relevant legislation) and destruction.

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 set down in Community legislation which is already applicable or will become applicable in the near future (1 January 2005 or 1 January 2006).

*** 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 safety¹³ provides as a general rule in its 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.

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 and the third country has not set any specific requirements applicable to imports, paragraph 2 of this Article 12 provides that food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons why the feed and food could not be put or remain on the market within the EU.

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

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

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

¹³ OJ L 31, 1.2.2002, p. 1

*** 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 rules¹⁴ applies from 1 January 2006 and provides in its Articles 19, 20 and 21 the following measures as regards non-compliant consignments.

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

- order that such food be destroyed

- subjected to special treatment

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

- treatment or processing to bring the food into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution – **IMPORTANT NOTE:** in the case of food contaminated with aflatoxin, detoxification by chemical treatment is prohibited;

- processing in any other suitable manner for purposes other than animal or human consumption.

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

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

* the food business operator has first informed 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.

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

Competent authorities shall co-operate to take any further measures necessary (in addition to the notification to RASFF – see II. 18) to ensure that it is not possible for the rejected consignments to be reintroduced into the Community.

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.

These provisions in Regulation 882/2004 are applicable from 1 January 2006 onwards.

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

II.21. Costs of official controls

Article 3 of Commission Decision 2005/85/EC of 26 January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in or consigned from Iran provides that all costs resulting from sampling, analysis, storage and issuing of accompanying official documents and of copies of health certificate and accompanying documents shall be borne by the food business operator responsible for the consignment or its representative.

No specific provisions are provided in Commission Decision 2005/85/EC 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 3 of Commission Decision 2005/85/EC also 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 shall be borne by the food business operator responsible for the consignment or its representative.

II.22 Specific issues

*** 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 only up to and including the wholesale stage.

*** Finding of non-compliance by sampling at retail stage**

It is important in such a situation to consider the following: How representative of the whole original consignment is the sample taken at retail on a very minor part of the consignment where the retail product originates from? What are the implications for the recall procedure?

Procedure proposed:

In the case of a sample taken at retail: the sample is representative for the remaining part **of the sampled portion** at retail.

However, the sample **is not representative for the whole original consignment of which the sampled portion is only a (minor) part.**

In a case of observed non-compliance at the retail stage on a part of the consignment, this is only an indication of possible problems with other parts of the consignment → tracing back of different parts of consignment → blocking of different parts of consignment → representative sampling of different parts of the consignment → destruction/re-export/ ... of the parts from which the sample taken had a non-compliant analytical result.

*** Control /inspections of establishments**

Inspections of premises who use nuts/groundnuts/dried fruit (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 (Directive 93/43/EC, Regulation 852/2004, Regulation 882/2004).

ANNEX – LEGISLATION

MAXIMUM LEVELS

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food¹⁵

Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs¹⁶ as last amended by Commission Regulation (EC) 684/2004 of 13 April 2004¹⁷

SAMPLING AND ANALYSIS

Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption¹⁸

Commission Directive 1998/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of foodstuffs¹⁹ as last amended by Commission Directive 2004/43/EC of 13 April 2004²⁰

SPECIFIC SAFEGUARD MEASURES

Commission Decision 2000/49/EC of 6 December 1999 repealing Decision 1999/356/EC and imposing special conditions on the import of peanuts and certain products derived from peanuts originating in or consigned from Egypt²¹ as last amended by Commission Decision 2004/429/EC of 29 April 2004²²

Commission Decision 2002/79/EC of 4 February 2002 imposing special conditions on the import of peanuts and certain products derived from peanuts originating in or consigned from China²³ as last amended by Commission Decision 2004/429/EC of 29 April 2004

Commission Decision 2002/80/EC of 4 February 2002 imposing special conditions on the import of figs, hazelnuts and pistachios and certain products derived thereof originating in or consigned from Turkey²⁴ as last amended by Commission Decision 2004/429/EC of 29 April 2004

¹⁵ OJ L 37, 13.2.1993, p. 1

¹⁶ OJ L 77, 16.3.2001, p.1

¹⁷ OJ L 106, 15.4.2004, p.6

¹⁸ OJ L 372, 31.12.1985, p. 50

¹⁹ OJ L 201, 17.7.1998, p. 93

²⁰ OJ L 113, 20.4.2004, p. 14

²¹ OJ L19, 25.1.2000, p.46

²² OJ L154, 30.04.2004, p. 20

²³ OJ L34, 5.2.2002, p.21

²⁴ OJ L34, 5.2.2002, p.26

Commission Decision 2003/493/EC of 4 July 2003 imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil²⁵ as last amended by Commission Decision 2004/428/EC of 29 April 2004²⁶

Commission Decision 2005/85/EC of 26 January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in or consigned from Iran²⁷

OTHER FRAMEWORK LEGISLATION OF RELEVANCE

Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs (end of validity: 31.12.2005)²⁸

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (end of validity: 31.12.2005)²⁹

Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (end of validity: 31.12.2005)³⁰

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 countries³¹

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 safety³² (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 foodstuffs³³ (applicable from 1 January 2006)

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 rules³⁴ (applicable from 1 January 2006)

²⁵ OJ L168, 5.7.2003, p.33

²⁶ OJ L 154, 30.4.2004, p. 14

²⁷ OJ L 30, 3.2.2005, p.12

²⁸ OJ L 175, 19.7.1993, p. 1

²⁹ OJ L 186, 30.6.1989, p. 23

³⁰ OJ L 290, 24.11.1993, p. 14

³¹ OJ L 40, 17.2.1993, p. 1

³² OJ L 31, 1.2.2002, p. 1

³³ OJ L 139, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 3

³⁴ OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83