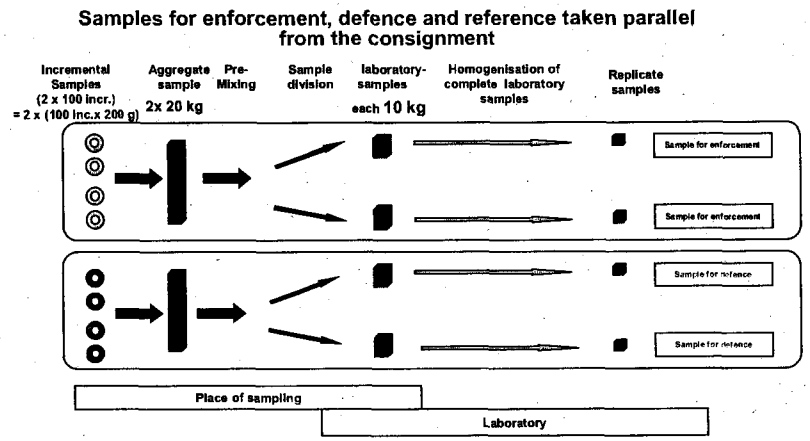
*** Sampling of groundnuts, other oilseeds, apricot kernels and tree nuts for direct human consumption**



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

II.16. Requirements laboratories

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

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

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

- EN ISO/IEC 17011 on "General requirements for accreditation bodies accrediting conformity assessment bodies".

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

As part of the official control, analysis of the enforcement sample and also the analysis of the defence sample when the analytical result of the defence sample supersedes the analytical result of the enforcement sample (see II.21 point 1), must be performed by a laboratory that is accredited and is an official laboratory (belonging to the Competent Authority structure) or a laboratory designated by the competent authority. The Competent Authority should ensure that any such designated laboratories fully meet the criteria established The food business operator has the right to select an official laboratory or a laboratory from the list of laboratories designated by the competent authority for analysis of samples taken during official control for the analysis of the defence sample[10].

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

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

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

II.17. Requirements governing the method of analysis

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

II.17.1. Performance criteria as laid down in Commission Regulation (EC) 401/2006

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

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

Notes:

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

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

where:

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

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

II.17.2. Definitions

The most commonly quoted precision parameters are repeatability and reproducibility.

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

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

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

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

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

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

II.18. Precautions to be taken and calculation of the analytical result with regard to the edible part of the foodstuff

II.18.1. Precautions

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

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

II.18.2. Calculation of proportion of shell/kernel of whole nuts

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

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

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

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

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

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

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

II.19. Reporting of results

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

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

Important information on these items can be found in the document

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

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

- undesirable substances in feed (Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[12])"

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

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

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

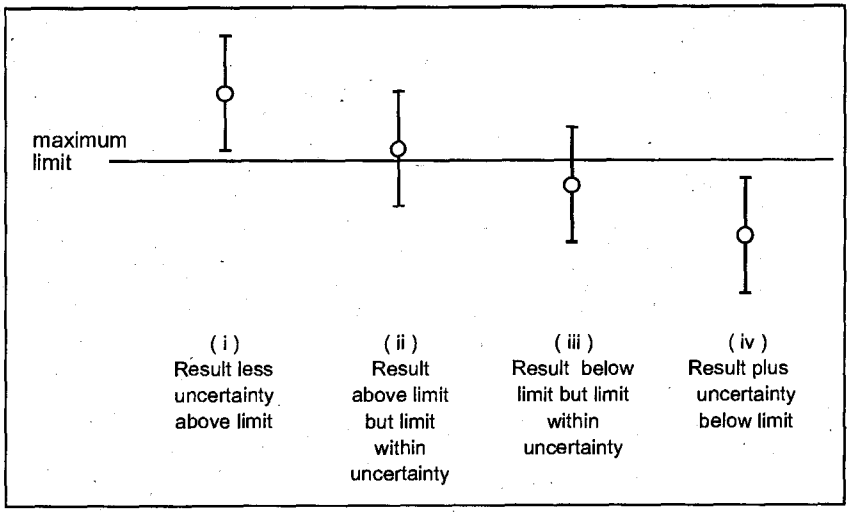
- For dried figs, groundnuts, other oilseeds, apricot kernels and tree nuts subjected to a sorting or other physical treatment and spices:
  - acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum limit, taking into account the expanded measurement uncertainty and the correction for recovery,
  - rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum limit **beyond reasonable doubt taking into account the** expanded **measurement uncertainty and correction for recovery***.
- For dried figs, groundnuts, other oilseeds, apricot kernels and tree nuts intended for direct human consumption :
  - acceptance if none of the laboratory samples exceeds the maximum limit, taking into account the expanded measurement uncertainty and the correction for recovery,
  - rejection if one or more of the laboratory samples exceeds the maximum limit **beyond reasonable doubt taking into account the** expanded **measurement uncertainty and correction for recovery***,
- Where the aggregate sample is equal to or below 10 kg:
  - acceptance if the aggregate sample conforms to the maximum limit, taking into account the expanded measurement uncertainty and the correction for recovery,
  - rejection if the aggregate sample exceeds the maximum limit **beyond reasonable doubt taking into account the** expanded **measurement uncertainty and correction for recovery***.

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

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

Additional explanatory information

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



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

Example on the Use of expanded Measurement Uncertainty (MU)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[13] established a Rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed as a network.

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

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

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

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

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

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

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

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

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

II.24.1. General provision and remark

In the event of a non-compliant consignment, the health certificate and any other relevant accompanying document (specifically relevant for import into the EU) should be made invalid in every case, by a large red stamp **"REFUSED FOR ENTRY INTO THE EU"** (or a similar marking) The accompanying document can be rendered null and void by putting on the health certificate, and on any other relevant accompanying document (specifically relevant for import into the EU) including the commercial invoice, one of the endorsements provided for in Article 29(1) and (2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93[14].

Products covered by Commission Regulation (EC) 1152/2009 can be deemed non-compliant solely on the grounds of incorrect documentation.

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

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

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

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

[14] OJ L218, 13.8.2008, p. 30

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

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety authority and laying down procedures in matters of food safety[16] provides as a general rule in Article 12 that non-compliant consignments **already in free circulation in the internal market can only be re-exported if they comply with EU food legislation, unless otherwise required by the authorities, legislation or administrative procedures of the importing country.**

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

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

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

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

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

[15] Reference is made to document « Guidance on the implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal – 26 January 2010» -available on the website of the Directorate-General Health and Consumers at http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_8_en.pdf
[16] OJ L 31, 1.2.2002, p. 1

II.24.3. Food rejected at the external border of the EU

For **food rejected at the external border of the EU, Regulation (EC) No 882/2004** of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[17] applies from 1 January 2006 and provides in its Articles 19, 20 and 21 the following measures as regards non-compliant consignments.

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

- order that such food be destroyed

- subjected to special treatment

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

- treatment or processing[18] to bring the food into line with the requirements of Union law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution – IMPORTANT NOTE: in the case of food contaminated with aflatoxin, detoxification by chemical treatment is prohibited;
- processing in any other suitable manner for purposes other than animal or human consumption.

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

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

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

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

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

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

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

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

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

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

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

In other cases, given that worldwide the highest level established for aflatoxin B1 is 20 µg/kg and for aflatoxin total 35 µg/kg[19], these levels are considered as being upper limits above which consignments must be rejected and cannot be re-dispatched without any control and appropriate measures have to be taken to protect human or animal health.

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

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

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

These appropriate measures could be

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

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

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

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

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

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

(c) a specific indication of:
  (i) the destination of the returned consignment;
  (ii) the intended treatment of the returned consignment; and
  (iii) the intended sampling and analysis to be performed on the returned consignment."

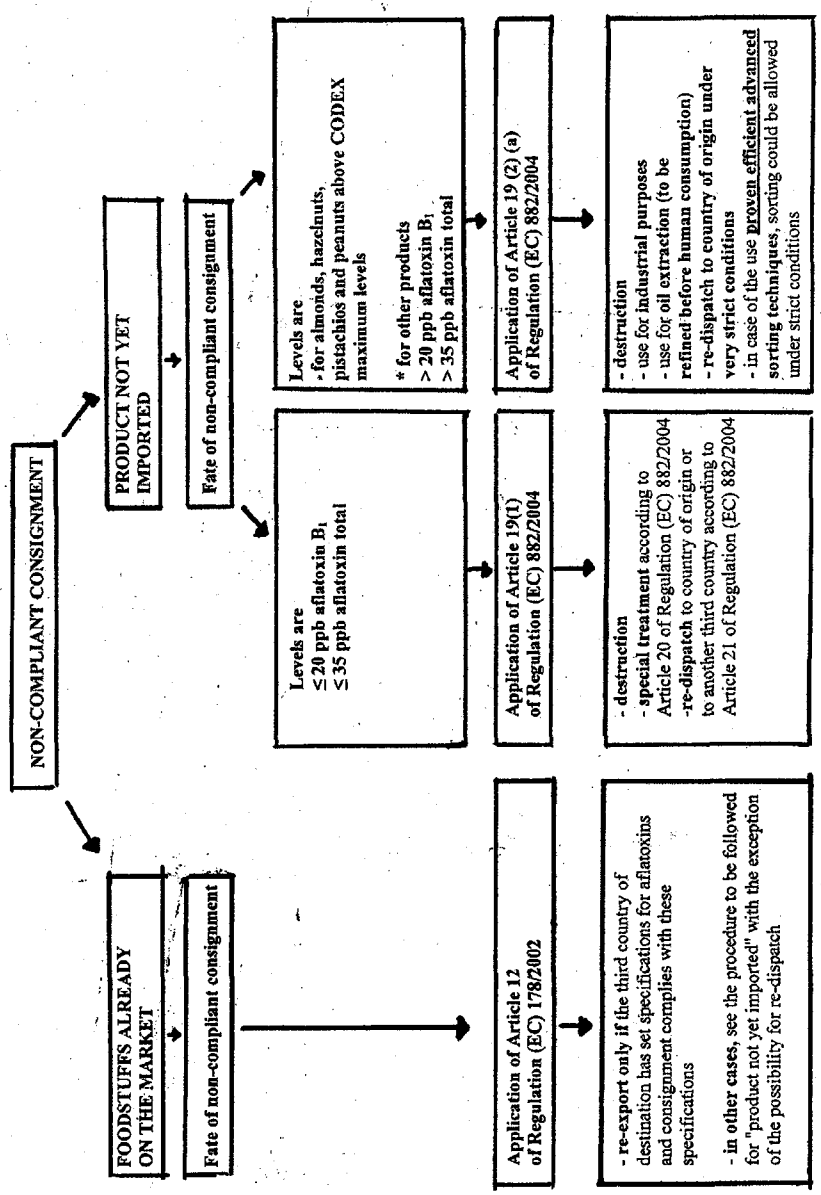
e) The possibility for sorting and physical treatment in case of non-compliance is as a general rule limited to the cases of consignments, not complying with EU legislation but containing levels below the worldwide highest level established for aflatoxin B1 and total.

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

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

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

II.24.4. Schematic overview



II.25. Costs of official controls

Article 10 of Commission Regulation (EC) 1152/2009 **provides that all costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the food business operator.** issuing of accompanying official documents and of copies of health certificate and accompanying documents for consignments Brazil nuts in shell from Brazil, pistachios and derived products thereof from Iran and almonds and derived products from US not accompanied by a certificate demonstrating that it is covered under the VASP, shall be borne by the food business operator responsible for the consignment or its representative.

No specific provisions are provided as regards the calculation of these costs.

For the calculation of the costs resulting from sampling and analysis, the provisions in Regulation (EC) 882/2004 could be used as guidance, in particular the criteria mentioned in Annex VI to the mentioned Regulation:

- salaries of the staff involved in the controls of pistachios and certain products derived from pistachios originating in or consigned from Iran
- costs for these staff, including facilities, tools, equipment, training, travel and associated costs
- laboratory analysis and sampling costs

II.26 Specific issues

II.26.1. Procedure for splitting the consignment

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

If a consignment is split, copies of the report and health certificate and the accompanying document shall accompany each part of the split consignment. These copies must be certified by the competent authority of the Member State on whose territory the splitting has taken place. These certified copies must accompany the split consignment until it is released for free circulation.

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

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

When an instance of non-compliance is found by taking only a small quantity of sample at the retail stage it is important to consider how representative the sample taken was of batch available at the retail level and also the batch/lot as a whole and therefore the implications for a product recall. Due to the non-homogeneous distribution of aflatoxins in most commodities generally

samples taken at the retail stage will not be representative of the original batch/lot from which the product at retail stage originates from.

Procedure proposed:

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

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

II.26.3. Control /inspections of establishments

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

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

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

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

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

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

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

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

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

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

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

- for food products produced after knowledge of the contamination

* The food operator has committed an infraction on purpose against Article 3 (1) and (2) of Regulation (EC) 1881/2006 as the food operator has in that case on purpose mixed complying products with non -complying products and on purpose used non –complying ingredients for the production of foodstuffs and has therefore to be penalised according to the provisions provided for in criminal law

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

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

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

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

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

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

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

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

It is obvious from the abovementioned provisions that in some cases (compound food with several processed/dried ingredients) it might be very difficult to calculate what level is applicable to the compound food in case the food business operator is not in a position to provide detailed information on the recipe. In such a case, it seems appropriate to apply to the compound food the levels applicable to the major ingredient(s) if a major ingredient can be identified without discussion

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

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

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

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

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

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

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

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

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

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

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

ANNEX I – LEGISLATION

MAXIMUM LEVELS

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[20]

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

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

SAMPLING AND ANALYSIS

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[23]

Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in food[24]

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

SPECIFIC SAFEGUARD MEASURE

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

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

OTHER FRAMEWORK LEGISLATION OF RELEVANCE

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

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[28]

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

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[30]

[27] OJ L218, 13.8.2008, p. 30
[28] OJ L 31, 1.2.2002, p. 1
[29] OJ L 139, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 3
[30] OJ L 165, 30.4.2004, p. 1. Corrigendum published in OJ L 226, 25.6.2004, p. 83

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

- Cyprus: none
- Czech Republic: none
- Belgium: none known at this stage – further investigations ongoing
- Slovak Republic: one company:Topco Internacional, Budimír
- Poland: three companies: DOMAT sp Bydgoszcz, ATLANTA Gdansk and Aromat Snack, Trzebielino
- Spain: five companies: Almendras LLopis, Alicante; Juan Escoda Reus-Tarragona; Borges SA Reus-Tarragona; Importaco, SA Valencia; Frit Ravich SL, Gerona
- Lithuania: no establishments
- The Netherlands: 5 companies C. Steinweg Handelsveen BV Rotterdam; Giesko BV Giessen; Tybex Warehousing BV – Rotterdam; Vebero BV Oosterhout; Synergie Food Ingredients and Processing (Rotterdam)
- Portugal: no establishments
- Estonia: no establishments
- Slovenia: no establishments
- Bulgaria: no establishments
- Ireland: no establishments
- Germany: no establishments known at this stage
- UK: 3 companies: Conversion Services Ltd, South Yorkshire, KP Foods;, Rotherham and Trigon Snacks, Liverpool.
- Greece: following companies perform physical treatment
  * almonds: Georgitsopoulos, Aspropyrgos Attikis; Nutissimo Ltd, Messini; Kardassilaris Kon. & Sons Ltd, Shimatari Viotias; Theodoropoulos sa, Egion; Vamvalis N; sa, Kalohori, Thessalonikis; Menexopouloi D. Bros Ltd, Thessaloniki
  * peanuts s: Kardassilaris Kon. & Sons Ltd, Shimatari Viotias Kardassilari N;Bros Ltd, Moshato Athens; Hatezigeorgiou sa, Adriani Drama; Moraiti Bros sa, Volos; Fotou Ekaterini, Volos,;Tsik Ltd Ptolemaida; Theodoropoulos sa, Egion;
- Italy: New Factor, S.P.A. Cerasolo Ausa Di Coriano; V. Besana SPA, S. Gennaro Vesuviano NA – list not complete yet
- Romania: no establishments
- Sweden: no establishments
- Denmark: no establishments known at this stage
- Latvia: no establishments
- Norway: no establishments known at this stage
- France: SOPREX, Arles
- Hungary: no establishments known at this stage;
- Finland: no establishments
- Luxembourg: no establishments known at this stage
- Malta: no establishments known at this stage
- Austria: no establishments known at this stage
- Iceland: no establishments known at this stage