FOOD STANDARDS AGENCY
SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

To all interested parties

17 November 2004 Reference: SCO/145/Chem/08/02

MYCOTOXINS – EC PERMITTED LEVELS

Dear Sir/Madam,

I am writing to you with information about the progress made with EC discussions on harmonised controls for mycotoxins and with an update of the Standing Committee on the Food Chain and Animal Health (12 October 2004) and the Working Group on Agricultural Contaminants (17 September 2004) meetings. In preparation for the next CCFAC, which will be held in The Hague between the 25th and 29th April 2005, this topic was also discussed at a Commission co-ordination meeting, on the 7th October.

1. **Ochratoxin A**

The Regulation setting maximum limits for ochratoxin A in coffee products, wine and grape juice and musts has been out for WTO consultation, which ended on 31 October. Only two WTO member countries have commented and voiced their concerns that the Regulation will be extended to green coffee, but welcomed the fact that the levels were higher that those currently being applied by one Member State. They also questioned the levels for soluble coffee. If significant comments had been before the end of the consultation period the matter would have to be returned to the Committee. It was agreed to include a requirement that the Commission collate and circulate the results of the monitoring by Member States. The date of application will be 1 April 2005. The draft Regulation was adopted by qualified majority vote.

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The Commission indicated that the project on the toxicology of ochratoxin A was nearing completion and the report will be available by the end of the year. EFSA will then be asked for their opinion. Following minor textural changes to the draft Commission Directive laying down the sampling methods and methods of analysis for the official control of the levels of ochratoxin A, a vote in favour of the draft was obtained from all Member States present.

The Commission indicated that it intends to start discussions on a consolidated text for sampling and analysis for mycotoxins.

2. Aflatoxins

- ***Aflatoxins in tiger nuts (Cyperus esculentus var sativus)***

The Commission informed the Working Group on Agricultural that this issue was raised by the Antifraud Services. Since tiger nuts are not nuts, aflatoxins statutory limits do not apply, although this product may have high aflatoxins levels.

- ***Maximum limits for aflatoxin B_1 in animal feeds***

At this meeting the working group also discussed the new Commission Directive [2003/100/EC (Official Journal of the European Communities, 2003, L285, 1.11.2003, p. 33)] amending the maximum limits for undesirable substances, including aflatoxin B_1, which came into force in November 2003. These new maximum limits are given in **Annex 1.**

- **Iranian pistachios and pistachio products**

The coming into force date of the Commission Decision was set back to 1 January 2005 to take account of the current delays in publication caused by translation difficulties. Details of the Decision are given in **Annex 2.**

- ***Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins***

The draft guidance in **Annex 3** contains details on the taric codes, selection of consignment for sampling and requirements for analysis. It was agreed at the Standing Committee on the Food Chain and Animal Health meeting in October 2004 that this guidance document, would be translated and put on the Commission website for 3 months for consultation, with the understanding that this is a living document and it would be updated on a regular basis. Following this consultation the document will be discussed further at the Working Group.

3. ***Fusarium*-toxins**

The Commission requested Member States to consider that the proposal had been discussed at 16 Working Group meetings and that the text was a compromise, which it hoped Member States could accept. It did not think that any benefit could be derived from further discussion. Details of the proposed maximum limits are given in **Annex 4.** At the request of several Member States, the Commission agreed to produce a Code of Practice aimed at reducing levels of *Fusarium* toxins and publish it as a Recommendation. There was a majority agreement to send the proposal to WTO for member countries' comments.

4. ***Date of implementation***

At the Working Group meeting on Agricultural Contaminants in September some Member States had concerns that delaying implementation would not encourage industry and farmers to adopt good agricultural practices (GAP) and, in terms of consumer perception grounds, January 2005 would be more acceptable. A few Member States reported that, due to the successful use of GAP in their countries, data showed that the proposed limits should be achievable. They were requested to make their GAP documents available to other Member States to enable a discussion of GAP at Working Group level. Some Member States indicated that they were happy to postpone implementation to allow current research work to be published.

5. ***Deoxynivalenol***

At this meeting concerns were raised regarding the achievability of the limits set for products given those set for raw materials. The Commission re-iterated that it would be impossible to set limits throughout the food chain and for all food products and that a pragmatic approach had to be taken.

The UK raised the issue of bran-based products and the importance of these products for a healthy diet. It considered that the limits currently proposed were too low. If limits are generally unattainable in the bran fractions, then targeting of supplies will cause prices to increase thus bran products will become less affordable for consumers. Limited support was received. Some Member States indicated that they could not accept the limit of 1250 ug/kg for deoxynivalenol in raw cereals, preferring 1000 ug/kg. In response to concerns that limits proposed for durum wheat are too low, the Commission will circulate a letter received from the Union of Durum Wheat, stating that the proposed limits could be lived with. After much debate, a compromise limit of 200 ug/kg for baby foods was agreed. The Commission clarified that in case of a dispute, under Article 2 of Regulation 315/93, the limits in the current proposal could be referred to even before they were implemented.

6. ***Zearalenone***

One Member State, although supporting the Commission proposal, considered that the limits for zearalenone and fumonisins in flour were still too high. It was agreed to harmonise category 4 for all fusarium toxins and to remove the term semolina, which could cause confusion for enforcement authorities.

A discussion on the recent proposal for limits for deoxynivalenol and zearalenone in animal feed following EFSA's opinion on animal health followed. Although EFSA could not comment it would seem unlikely that limits in feed would be lower than in food.

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7. **EC legislation on contaminants in food**

A consolidated version of Commission Regulation (EC) No. 466/2001 setting maximum limits for contaminants in foodstuff detailing the amendments made to the Regulation to date is available on the Commission's website at **http://europa.eu.int/eur-lex/en/consleg/index.html**

8. **Codex**

At the CODEX co - ordination meeting in October, there was a request for the Commission to submit data/statistics on rejected consignments of tree nuts with aflatoxin levels between 10 and 15 ug/kg. The Commission will draft a position paper on this and on methods to reduce aflatoxin contamination in tree nuts. The meeting was reminded of the issues raised regarding ALARA at the last CCFAC.

Report on the relationship between analytical results, the measurement uncertainty, recovery factors and the provisions in EU Food and Feed legislation.

The above report has now been placed on the EU website at:
http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf
or
http://europa.eu.int/comm/food/food/animalnutrition/sampling/index_en.htm

Commission comments on various Codex mycotoxin documents, as sent by the Commission Council Secretariat, are given in **Annex 5.** Discussion continues on other areas.

9. **Research Programme Review**

The Food Standards Agency is currently reviewing its research programmes in the areas of mycotoxins, nitrates and process food contaminants. This process will include an opportunity for stakeholders (industry, consumer groups etc.) to meet, discuss current programmes and suggest future directions for research in these areas. These meetings will be held in central London on Monday 18th April 2005 (mycotoxins and nitrate) and Tuesday

19th April 2005 (process contaminants) at venues yet to be decided. Persons interested in receiving further details of these meetings are asked to contact either Ms. Carmen Tudorica (tudorica@campden.co.uk) tel. +44 (0)1386 842144) or Dr. Anton Alldrick (a.alldrick@campden.co.uk) tel 01386 842127).

If you would like to comment or request further information on these issues. Please contact me by email or by postal address, which is provided below by **7 December 2004**.

Yours faithfully

Dr William Munro
Contaminants, Hygiene, Additives & Shellfish Branch
Policy Division
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ANNEXES

Attached:

Annex 1 Maximum limits for Aflatoxins B1 in Animal Feedingstuffs

Annex 2 The Draft Commission Decision of imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran

Annex 3 Draft guidance document for competent authorities for the control of compliance with EU legislation on Aflatoxins

Annex 4 Proposed maximum limits for Fusarium Toxins

Annex 5 EC Comments for the CODEX Committee on General Principles

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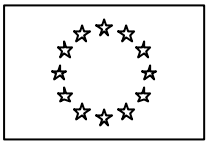
Annex 1

MAXIMUM LIMITS FOR AFLATOXIN B_1 IN ANIMAL FEEDINGSTUFFS

Products intended for animal feed	**Maximum limit in mg/kg (ppm) relating to a feedingstuff with a moisture content of 12%**
All feed materials	0.02
Complete feedingstuffs for cattle, sheep and goats with the exception of:	0.02
- complete feedingstuff for dairy animals	0.005
- complete feedingstuffs for calves and lambs	0.01
Complete feedingstuffs for pigs and poultry (except young animals)	0.02
Other complete feedingstuffs	0.01
Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)	0.02
Complementary feedingstuffs for pigs and poultry (except young animals)	0.02
Other complementary feedingstuffs	0.005

Annex 2



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels
SANCO/0055/2004
TRA: SANCO/2576/2004

Draft

COMMISSION DECISION

of

imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran

(Text with EEA relevance)

COMMISSION DECISION

of

imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[1], and in particular Article 53 (1)(b) thereof,

Whereas:

(1) Commission Decision 97/830/EC of 11 December 1997 repealing Commission Decision 97/613/EC and imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran[2] has been substantially amended several times.

(2) The legal basis for Commission Decision 97/830/EC is Article 10 of the Council Directive 93/43/EC of 14 June 1993 on the hygiene of foodstuffs[3]. Council Directive 93/43/EEC will be repealed as from 1 January 2006 by Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[4]. This Regulation does no longer contain the legal basis for a safeguard measure.

(3) Regulation (EC) No 178/2002 provides that where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health and the environment, measures are to be adopted.

(4) Pistachios originating in, or consigned from Iran have been found, in many cases, to be contaminated with excessive levels of Aflatoxin B1.

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1 OJ L 31, 1.02.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p.4).

2 OJ L 343, 13.12.1997, p. 30. Decision last amended by Commission Decision 2004/429/EC of 29 April 2004 (OJ L 154, 30.4.2004, p. 19. Corrigendum published in OJ L 189, 27.5.2004, p. 13)

3 OJ L 175, 19.7.1993, p. 1.

4 OJ L 139, 30.04.2004, p.1. Corrigendum published in OJ L 226, 25.6.2004, p. 3

(5) The Scientific Committee for Food has noted that Aflatoxin B1 is a potent genotoxic carcinogen and, even at extremely low doses, contributes to the risk of liver cancer.

(6) The import of pistachios from Iran therefore constitutes a serious threat to public health within the Community and it is imperative to adopt protective measures at Community level.

(7) An examination of conditions of hygiene in Iran was undertaken by the Commission's Food and Veterinary Office (FVO) for the first time in 1997 and revealed that improvements in hygiene practices and the traceability of pistachios were required. The mission team was unable to check all stages of the handling of pistachios prior to exportation. Commitments were received from the Iranian authorities in particular in relation to improvements in production, handling, sorting, processing, packaging and transport practices. It was therefore appropriate to subject pistachios and certain pistachio products from Iran to special conditions to provide a high level of protection to public health. Follow up missions have been organised in 1998 and 2001. Although during these missions substantial improvements in hygiene practices and the traceability have been observed, there is a continued need imposing special conditions on pistachios and certain pistachio products from Iran to protect public health.

(8) Pistachios and certain pistachio products from Iran may be imported, provided that special conditions are applied.

(9) One of those conditions is that it is necessary to provide that pistachios and products derived from pistachios have been produced, sorted, handled, processed, packaged and transported following good hygienic practices. It is necessary to establish the levels of Aflatoxin B1 and total Aflatoxin in samples taken from the consignment immediately prior to leaving Iran.

(10) It is furthermore necessary for documentary evidence to be provided by the Iranian authorities to accompany each consignment of pistachios originating in, or consigned from Iran, relating to the conditions of production, sorting, handling, processing, packaging and transport and the results of laboratory analysis of the consignment for levels of Aflatoxin B1 and total Aflatoxin.

(11) In the interests of public health, Member States will keep the Commission informed through periodical reports of all analytical results of official controls carried out in respect of consignments of pistachios and certain pistachio products from Iran. Such reports shall be in addition to the notification obligations under the Rapid Alert System for Food and Feed (RASFF) established by Regulation (EC) No 178/2002.

(12) It is important to ensure that the sampling and analysis of consignments of pistachios and pistachio products from Iran are performed in a harmonised manner throughout the Community.

(13) Checks carried out in 2003 and 2004 revealed that a large number of consignments of pistachios from Iran exceeded the maximum level of aflatoxins. It is therefore necessary to restrict the validity of the health certificate in order to limit the duration of transport and storage, when aflatoxins can be formed.

(14) The operation of this Decision should be kept under review in the light of information and guarantees provided by the competent authorities of Iran and of the results of the tests carried out by Member States in order to assess whether the special conditions provide a sufficient level of protection of public health within the Community and whether they are still needed.

(15) The measures provided for in this Decision have a significant impact on the control resources of the Member States. It is therefore appropriate to require that all costs resulting from sampling, analysis, storage and all costs resulting from official measures taken as regards non compliant consignments are to be borne by the importers or food business operators concerned.

(16) Decision 97/830/EC should accordingly be repealed.

(17) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

1. Member States may import
- pistachios falling within CN code 0802 50 00 and
- roasted pistachios falling within CN codes 2008 19 13 and 2008 19 93
originating in, or consigned from Iran, only where the consignment is accompanied by the results of official sampling and analysis, and the health certificate in Annex I, completed, signed and verified by a representative of the Iranian Ministry of Health. The health certificate shall be valid for import carried out no more than 4 months after the issue date of the health certificate.

2. Products covered by paragraph 1 may only be imported into the Community through one of the points of entry listed in Annex II.

3. Each consignment of products covered by paragraph 1 shall be identified with a code which corresponds to the code on the sampling results of the official sampling and analysis and health certificate referred to in paragraph 1.

4. The competent authorities in each Member State shall ensure that products covered by paragraph 1 are subject to documentary checks to ensure that the requirement for the health certificate and sampling results referred to in paragraph 1, are complied with.

5. The competent authorities in each Member State shall take a sample for analysis from each consignment of products covered by paragraph 1 for analysis of aflatoxin B1 and total aflatoxin before release onto the market from the point of entry into the Community.

Member States shall submit to the Commission every three months a report of all analytical results of official controls on consignments of products covered by paragraph 1. This report shall be submitted during the month following each quarter (April, July, October, and January).

6. Any consignment which is to be subjected to sampling and analysis should be held before release onto the market from the point of entry into the Community for a maximum period of 15 working days. The competent authorities of the importing Member State shall issue an accompanying official document establishing that the consignment has been subjected to official sampling and analysis and indicating the result of the analysis.

7. If a consignment is split, copies of the health certificate and accompanying official documents referred to in paragraphs 1 and 6 and certified by the competent authority of the Member State on whose territory the splitting has taken place, shall accompany each part of the split consignment.

Article 2

This Decision shall be kept under review in the light of information and guarantees provided by the competent authorities of Iran and of the results of the tests carried out by Member States in order to assess whether the special conditions set out in Article 1 provide a sufficient level of protection of public health within the Community and whether they are still necessary.

Article 3

All costs resulting from sampling, analysis, storage and issuing of accompanying official document and of copies of health certificate and accompanying documents pursuant to Article 1 (4) to (7) shall be borne by the food business operator responsible for the consignment or its representative.

Also all costs related to official measures taken by the competent authorities as regards non compliant consignments of pistachios and certain products derived from pistachios originating in or consigned from Iran shall be borne by the food business operator responsible for the consignment or its representative.

Article 4

Decision 97/830/EC is repealed.

Article 5

The Decision shall apply from 1 January 2005.

Member States shall take the measures necessary to comply with this Decision. They shall immediately inform the Commission thereof.

Article 6

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
David BYRNE
Member of the Commission

DRAFT GUIDANCE DOCUMENT FOR COMPETENT AUTHORITIES FOR THE CONTROL OF COMPLIANCE WITH EU LEGISLATION ON AFLATOXINS

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I. LEGISLATION (LIST IN ANNEX I)

I.1. Use of TARIC codes

Commission decisions refer to TARIC codes for describing the goods falling under the scope of the Decision. Competent authorities of many Member States do not use TARIC codes in their systems which could create difficulties in control and to demonstrate/report control frequency. Therefore it is recommended to competent authorities to use TARIC codes to enable identification. This will also facilitate the 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 Decisions

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

I.2. Points of entry

It is important that experienced staff to take samples is present at the entry point, as well as the availability experienced laboratories for aflatoxin analysis. In particular the availability of appropriate grinding equipment is very important.

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

Points of entry should fulfil at least following requirements

* presence of trained staff to control the consignments;
* availability of detailed instructions regarding sampling and sending of the samples to the laboratory, in accordance with the provisions provided for in Commission Directive 1998/53/EC;
* possibility to perform the unloading and the sampling in a sheltered place at the point of entry (at least the possibility must exist to put the consignment from the point of entry onwards under official control in case the consignment must be transported for performing the sampling);.
* availability of storage rooms, warehouses to store detained consignments in good conditions during the period of detainment (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 enable to respect the maximum detainment period for consignments of 15 days.

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 stricter 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 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 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 labelled clearly 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 must be complied with for applying the "higher maximum level"

This means that for applying the "higher level", the groundnuts, nuts and dried fruit must be traded in **a packaging form** for which it is **obvious** that these products are **intended further treatment** before consumption or use as an ingredient **AND the destination of the consignment has the possibility/equipment to perform such a 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. Roasting cannot be considered as "physical treatment to reduce aflatoxin contamination" as aflatoxins are thermo stable and are not removed/decreased to a significant extent by roasting.

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 needs to have a clear link with the consignment by means of mentioning the consignment/batch identification code to the consignment concerned. The identification code must be mentioned on each individual bag, box, … of the consignment. It is very important that this indication is put on the accompanying document <u>at the moment of issuing the accompanying document</u>. (In case it is evident that this indication has been put *a posteriori* on the accompanying document, it has of no value).

II. APPLICATION OF COMMISSION DECISIONS (LIST IN ANNEX I)

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 documentary 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 originating in the country concerned. For example the special conditions laid down in Commission Decision 2003/493/EC imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil do also apply to Brazil nuts in shell consigned from the United States but originating in Brazil.

In particular controls should ensure that the batch/lot identification code corresponds to the batch mentioned on the health certificate and the results of the official sampling and analysis. For the products originating from Turkey and Iran (Commission Decisions 2002/80/EC and 97/830/EC) it must be verified if the signature of the official who signed the health certificate occurs 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 Iran) 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 must be marked with the batch identification code.

In case the consignment is labelled clearly 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" (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 (average of 30 kg) applicable to this category is to be used

II.2. Selection of consignment for sampling

The different Commission Decisions establish different frequencies of controls:
- 10 % (Commission Decisions 2002/79/EC – peanuts from China – and 2002/80/EC – hazelnuts, dried figs and pistachios from Turkey-)
- 20 % (Commission Decision 2000/49/EC – peanuts from Egypt-)
- 100 % (Commission Decisions 97/830/EC – pistachios from Iran- and 2003/493/EC – Brazil nuts in shell from Brazil-)

The 10 % or 20 % frequency of controls must be in such a way organised by the competent authorities that within a certain period of time these control frequency percentages are achieved. Care must be taken that the selection of consignments is random ensuring a proportionate treatment of the operators concerned.

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

Also in 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 the sampling cannot be representatively performed with the usual sampling equipment.

Article 11 of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs[1] foresees that the natural and legal persons concerned (responsible operator) shall be obliged to undergo any inspection carried out in accordance with this directive and to assist inspectors in the accomplishment of their tasks. The same provision is foreseen 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 rules[2], applicable from 1 January 2006.
This means that the food business operator must make available sufficient human resources and logistics to unload the consignment enabling a representative sampling;

[1] OJ L 186, 30.6.1989, p. 23
[2] OJ, L 165, 30.04.2004, 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 every lot much 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 of each 22 ton resulting in a consignment of 220 ton with the same batch identification code, legislation provides that the consignment has to be split into 5 sublots of 44 tons (2 containers). Representative sampling must be performed on two containers each. However if the inspector decides to control only 2 containers out of the 10, the analytical result is only valid for the two containers sampled and in case of non compliance eventual 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 per two containers has to be performed before deciding on official measures applicable to all consignments. Consequently in case it is decided to sample the whole consignment (10 containers) then 5 samples of 30 kg must be taken.
To be noted is that where the Commission Decision requires a 100 % control at import, all consignments and all containers 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 one 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 it concerns an identical product (in this particular case from the 8 tonnes, 80 incremental samples of 300 gram resulting in a sample of 24 kg and from the batch of 15 tonnes 100 incremental samples of 300 gram 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 a 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 in almost all cases necessary to unload the truck or container for the sampling. Unloading should not expose the product to adverse weather conditions or excessive moisture!!!

- On condition that the sublot can be separated physically, each lot must be subdivided into sublots following **table 1.** Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may vary from the mentioned weight by a maximum of 20 %.

- Each sublot 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 (attention: 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 case of retail packs the weight of the incremental sample is determined by the weight of a single retail pack. In case retail packs > 300 grams or more than 100 grams in the cases of spices this will result in aggregate samples weighing more than 30 kg and 10 kg respectively. In case the weight of single retail pack is >> 300 gram or 100 gram in case of spices then 300 grams or 100 gram are taken respectively from each individual retail pack taken as incremental sample. This can be done when the sample is taken or in the laboratory.
  In case the retail pack is less than 300 grams or 100 grams respectively in case 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. In case the retail pack is << than 300 grams or 100 grams respectively one incremental sample consist of 2 or more retail packs whereby the 300 grams or 100 grams respectively is as close as possible approximated.

- **Weight of the aggregate sample = 30 kg** which has to **be <u>mixed thoroughly</u>** (*to avoid that e.g. the samples taken from the front side of the consignment are at the bottom of the sample and the samples of the backside of the consignment at the top)* and **<u>only afterwards</u> 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, dried fruit and maize 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 following guidance:

* < 10 kg: no division into subsamples
* 12/18 kg: division into two subsamples
* 24 kg: division into 3 subsamples

. In the case of spices the aggregate sample weighs not more than 10 kg and therefore no division in 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	15-30tonnes --	100 10-100 (table 2)	30 ≤ 30
Groundnuts, pistachios, Brazil nuts and other nuts	≥ 500 >125 and <500 ≥ 15 and ≤ 125 < 15	100 tonnes 5 sublots 25 tonnes --	100 100 100 10-100 (table 2)	30 30 30 ≤ 30
Spices	≥ 15 < 15	25 tonnes --	100 10-100 (table 2)	10 ≤ 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 less than 15 tonnes and for spices

Lot weight (tonnes)	N° of incremental samples
≤ 0.1	10
> 0.1 - ≤ 0.2	15
> 0.2 - ≤ 0.5	20
> 0.5 - ≤ 1.0	30
> 1.0 - ≤ 2.0	40
> 2.0 - ≤ 5.0	60
> 5.0 - ≤ 10.0	80
> 10.0 - ≤ 15.0	100

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, the sampling procedure laid down for groundnuts, pistachios, Brazil nuts and dried figs may be applied (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.

Such a simpler sampling method to be applied might be the sampling procedure as laid down 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 foodstuffs[3] for the control of OTA in dried vine fruit whereby the sampling procedure consists of the taking of 100 incremental samples of 100 gram resulting in an aggregate sample of 10 kg.

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

For example, a consignment of 20 tonnes hazelnut paste traded in 100 barrels of each 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).

[3] 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)

Competent authorities are encouraged to exchange via the Commission services information on sampling procedures applied on these specific forms of packing eventually accompanied by reporting experiences in applying this sampling procedure. Competent authorities are also encouraged to exchange information on sampling equipment.

ATTENTION:

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

In the case of hazelnuts traded in vacuum packs, for lots equal 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.

RECOMMENDATION

- To apply where possible also the sampling procedure as established for groundnuts, pistachios, Brazil nuts, dried figs also to other nuts and other dried fruit.

- For groundnuts and nuts other than hazelnuts, traded in vacuum packs:

* **for pistachios, groundnuts, Brazil nuts and dried figs (whole kernels): for lots equal or more than 15 tonnes at least 50 incremental samples resulting in a 30 kg aggregate sample have to be taken and for lots 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 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 (as the one outlined for vacuum packs) is appropriate (see also above).

II.6. Period for detainment

Any consignment to be subjected to sampling and analysis should be detained from the moment of sampling before 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 period of maximum of 15 days is only applicable to the official sampling and does not include the additional time required when a second analysis is required by the operator.

II.7. 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 case of products intended for direct human consumption) (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 sample 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 a sorting and/or physical treatment before human consumption.

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

II.8. 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 98/53/EC – Annex II, point 3.

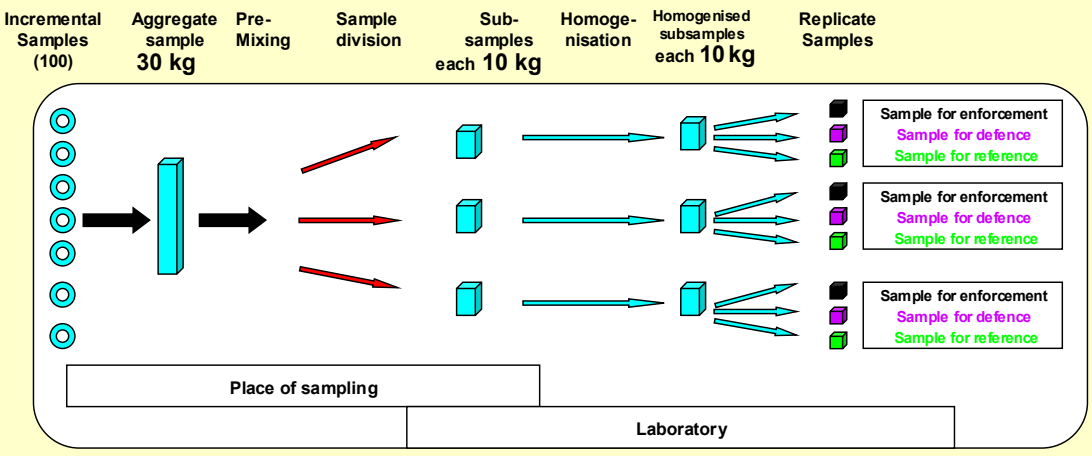
In case of products intended for direct human consumption of each subsample (laboratory sample) is taken one analytical sample, one defence sample and one reference sample (in quantities needed according to GLP).

So for every aggregate sample taken from a batch of nuts intended for direct human consumption, 9 samples in total are obtained from the homogenised subsamples (laboratory samples) (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

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

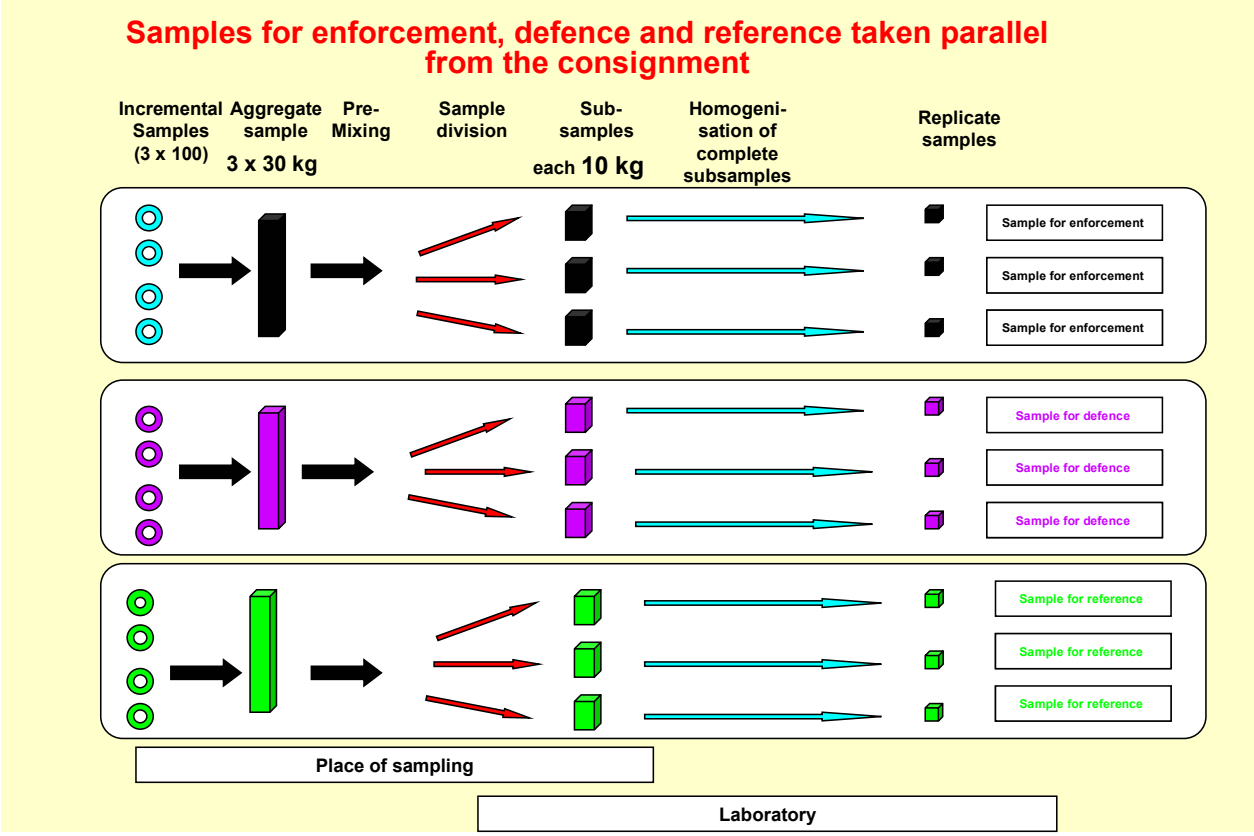


*** Defence and reference samples are taken at the place of sampling**

In some Member States, it is foreseen that the defence and reference samples have to be taken from the consignment in the presence of the operator, also in the case of sampling for aflatoxin analysis. Commission Directive 98/53 provides for that possibility.

If this is the case then the sampling procedure as outlined in II.4 and II.5. must be applied with that understanding that e.g. 2 x 100 (in case of official + defence sample) or 3 x 100 (in case of official + defence + reference sample) incremental samples must be taken resulting in 2 or 3 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 is excluded



II.9. Requirements laboratories

Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs[4] 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.

Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs[5] foresees 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.

In order to perform an analysis for the official control, including the analysis of the defence sample, the laboratory must be accredited and has to be or an official laboratory (belonging to the Competent Authority structure) or an laboratory designated by the competent authority. The Competent Authority should ensure any such private laboratories fully meet the criteria established above and should be maintained on a list of official laboratories notified to the Commission under Art 15 of Council Directive 89/397/EC.

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

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 treatment and extraction/clean-up procedures.

[4] OJ L 186, 30.6.1989, p. 23
[5] OJ L 290, 24.11.1993, p. 14

II.10. Requirements 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 98/53/EC. The laboratory must be able to provide the evidence that the used method of analysis does comply with the established performance criteria.

Performance criteria as laid down in Commission Directive 98/53/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 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 sum of individual aflatoxins $B_1 + B_2 + G_1 + G_2$ are to be reported, then response of each to the analytical system must be either known or equivalent.
- The detection limits of the methods used are not stated as 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 = 1,000 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.

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II.11. Precautions to be taken and calculation of the analytical result 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 ultra-violet 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 by:

- 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 to be non compliant 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: In case the nuts in shell are gone through the sample preparation procedure and the ratio nut shell/nut kernel is 50/50 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.12. 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

Acceptable method(s) for measuring the recovery rate are outlined in Annex II.

The analytical result has to be reported as x +/- U whereby 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 that item can be found in the document

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

- contaminants in food (Council Regulation (EEC) No 315/93 of 8 February 1993 laying down community procedures for contaminants in food[6])

- 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[7])"

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

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

II.13. Interpretation of results

Acceptance of a lot or sublot

– 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 to be subjected to a sorting or other physical treatment:

  – 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 under 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.14. Issuing accompanying document in case of compliance

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 (eventually with analysis report enclosed).

In case 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 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 be made on the accompanying document.

II. 15. 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 must be performed in an official laboratory or a laboratory designated by the competent authority. In both cases the laboratory must be accredited (see point II.9).

The taking of the defence and reference samples is addressed in point II.8

Three approaches can be identified within the Member States in case the defence sample generates a compliant result:

1) the consignment is considered compliant and released (the result of the defence samples supersedes the result of the official result)

2) the reference sample is analysed in the national reference laboratory. In case 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 Court.

II.16. 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[8] 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 alerts 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.

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

II.17. Reporting to the Commission of all analytical results

Member States shall submit to the Commission every three months a report of all nalytical 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.18 Procedure to be followed for the consignment in case of non-compliance

*** General provision**

In case of a non-compliant consignment, in any case the health certificate and any other relevant accompanying document should be made invalid. The rendering null and void, invalidation of the accompanying document can be done by putting on the health certificate and any other relevant accompanying document including the commercial invoice one of the endorsements provided for in Article 6 (1) and (2) of Council regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[9]

*** 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 individual concerned non-conforming consignment the Ministério da Agricultura, Pecuária e Abastecimento – (MAPA), provides the following in writing:

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

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

(c) a concrete 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.

[9] OJ L40, 17.2.1993, p. 1

*** In the other cases**

No specific provisions in current legislation. Possible option(s) are return 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, in any case the health certificate should be made invalid (see general provision above).

However following provisions concerning the non-compliant consignments are foreseen in Community legislation and which will become applicable within the near future (1 January 2005 or 1 January 2006).

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety authority and laying down procedures in matters of food safety[10] foresees in its Article 12, which becomes applicable in the EU from 1 January 2005 onwards, that non complying consignments already in free circulation in the internal market can only be re-exported if the competent authorities of the country expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food –or feed concerned could not be placed in the market. This is applicable except in the cases where foods are injurious to health or feeds are unsafe.

Translating these measures to the case of aflatoxins, this means that a non-complying consignment can be re-exported to a third country that is not the country of origin only after explicit agreement and on the condition that the consignment complies with the maximum levels established by the country of destination. In case the consignment contains levels of aflatoxins above the maximum levels of the country of origin, the consignment is to be considered as injurious to health.
Therefore, in case the consignment is not complying with the maximum level of the third country of destination (not being the country of origin) the consignment can only be re-exported to the country of origin or destroyed at the expense of the operator.

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

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 foresees in its Articles 19, 20 and 21 the following measures as regards non complying consignments:

- order that such feed or food be destroyed

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

- subjected to a special treatment

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

- treatment or processing to bring the feed and 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 the 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 control. The food business operator has first to inform 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. In case 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.

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

II.19 Specific issues

*** Procedure for splitting the consignment**

In case 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**

Important in such situation is to consider how representative is the sample taken at retail on a very minor part of the consignment, where the retail product originates from, for the whole original consignment? What are the consequences for the recall procedure?

Procedure proposed:

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

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

In case of an observed non-compliance at 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 complying analytical result.

*** Control /inspections of establishments**

Inspections of premises who use nuts/groundnuts/dried fruit (for further processing, as ingredient) should cover autocontrols (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 I – LEGISLATION

MAXIMUM LEVELS

Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs[11] as last amended by Commission Regulation (EC) 684/2004 of 13 April 2004[12]

SAMPLING AND ANALYSIS

Commission Directive 98/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of foodstuffs[13] as last amended by Commission Directive 2004/43/EC of 13 April 2004[14]

SPECIFIC SAFEGUARD MEASURES

Commission Decision 97/830/EC of 11 December 1997 repealing Decision 97/613/EC and imposing special conditions on the import of pistachios and certain products derived from pistachios originating in or consigned from Iran[15] as last amended by Commission Decision 2004/429/EC of 29 April 2004[16]

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 Egypt[17] as last amended by Commission Decision 2004/429/EC of 29 April 2004

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 China[18] 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 Turkey[19] as last amended by Commission Decision 2004/429/EC of 29 April 2004

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 Brazil[20] as last amended by Commission Decision 2004/428/EC of 29 April 2004[21]

[11] OJ L 77, 16.3.2001, p.1
[12] OJ L 106, 15.4.2004, p.6
[13] OJ L 201, 17.7.1998, p. 93
[14] OJ L 113, 20.4.2004, p. 14
[15] OJ L343, 13.12.1997, p.30
[16] OJ L 154, 30.4.2004, p. 20
[17] OJ L19, 25.1.2000, p.46
[18] OJ L34, 5.2.2002, p.21
[19] OJ L34, 5.2.2002, p.26
[20] OJ L168, 5.7.2003, p.33
[21] OJ L 154, 30.4.2004, p. 14

FRAMEWORK LEGISLATION OF RELEVANCE

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[22]

Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs[23]

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 consumption[24]

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs[25]

Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs[26]

Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[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] (Provisions with regard to export and re-export of non-complying consignments – Article 12 – applicable from 1 January 2005)

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[29] (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 rules[30] (applicable from 1 January 2006)

[22] OJ L 37, 13.2.1993, p. 1
[23] OJ L 175, 19.7.1993, p. 1
[24] OJ L 372, 31.12.1985, p. 50
[25] OJ L 186, 30.6.1989, p. 23
[26] OJ L 290, 24.11.1993, p. 14
[27] OJ L 40, 17.2.1993, p. 1
[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 PROCEDURES FOR ASSESSING RECOVERY[31]

It is foreseen to include the information contained in this Annex on procedures for assessing recovery in the "Report on the relationship between analytical results, the measurement uncertainty, recovery factors and the provisions in EU Food and Feed legislation with particular focus on the community legislation concerning

- contaminants in food (Council Regulation (EEC) No 315/93 of 8 February 1993 laying down community procedures for contaminants in food[32])

- 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[33])"

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

INTRODUCTION

The estimation and use of recovery is an area where practice differs among analytical chemists. The variations in practice are most obvious in the determination of analytes such as veterinary drug residues and pesticide residues in complex matrices, such as foodstuffs and in environmental analysis. Typically, such methods of analysis rely on transferring the analyte from the complex matrix into a much simpler solution that is used to present the analyte for instrumental determination. However, the transfer procedure results in loss of analyte. Quite commonly in such procedures a substantial proportion of the analyte remains in the matrix after extraction, so that the transfer is incomplete, and the subsequent measurement gives a value lower than the true concentration in the original test material. If no compensation for these losses is made, significantly discrepant results may be obtained by different laboratories. Even greater discrepancies arise if some laboratories compensate for losses and others do not.

[31] Extract from « Harmonised guidelines for the use of recovery information in analytical measurement (Technical report)» by *M. Thompson, S.L.R. Ellison, A. Fajgelj, P. Willetts and R. Wood.*

Resulting from the Symposium on Harmonisation of Quality Assurance Systems for Analytical Laboratories, Orlando, USA, 4–5 September 1996 held under the sponsorship of IUPAC, ISO and AOAC INTERNATIONAL.. Published in *Pure and Applied Chemistry,* Volume 71, No 2, pp. 337-348, 1999.

Codex Alimentarius Commission adopted at its 24th session held in Geneva from 2 to 7 July 2001, the adopted the IUPAC Guidelines for the use of recovery information in Analytical Measurement by reference ofr the purposes of Codex (ALINORM 01/41, § 196.

[32] Official Journal of the European Communities, L37, 13.2.1993, p. 1

[33] Official Journal of the European Communities, L 140, 30.5.2002, p. 10

Recovery studies are clearly an essential component of the validation and use of all analytical methods. It is important that all concerned with the production and interpretation of analytical results are aware of the problems and the basis on which the result is being reported. At present, however, there is no single well-defined approach to estimating, expressing and applying recovery information. The most important inconsistency in analytical practice concerns the correction of a raw measurement, which can (in principle) eliminate the low bias due to loss of analyte. The difficulties involved in reliably estimating the correction factor deter practitioners in some sectors of analysis from applying such corrections.

In the absence of consistent strategies for the estimation and use of recovery information, it is difficult to make valid comparisons between results produced in different laboratories or to verify the suitability of those data for the intended purpose. This lack of transparency can have important consequences in the interpretation of data. For example in the context of enforcement analysis, the difference between applying or not applying a correction factor to analytical data can mean, respectively, that a legislative limit is exceeded or that a result is in compliance with the limit. Thus, where an estimate of the *true concentration* is required, there is a compelling case for compensation for losses in the calculation of reported analytical result.

DEFINITIONS AND TERMINOLOGY USED IN THE GUIDELINES

General analytical terminology is assumed to be accepted when these Guidelines are read, but specific definitions of the terms most pertinent to the Guidelines are given below:

Recovery: Proportion of the amount of analyte, present in or added to the analytical portion of the test material, which is extracted and presented for measurement.

Surrogate: Pure compound or element added to the test material, the chemical and physical behaviour of which is taken to be representative of the native analyte.

Surrogate recovery: Recovery of a pure compound or element specifically added to the test portion or test material as a spike. (Sometimes called ‘marginal recovery’.)

Native analyte: Analyte incorporated into the test material by natural processes and manufacturing procedures (sometimes called ‘incurred analyte’). Native analyte includes ‘incurred analyte’ and ‘incurred residue’ as recognised in some sectors of the Analytical Community. It is so defined to distinguish it from analyte added during the analytical procedure.

Empirical method of analysis: A method that determines a value which can be arrived at only in terms of the method *per se* and serves by definition as the only method for establishing the measurand. (Sometimes called ‘defining method of analysis’.)

Rational method of analysis: A method that determines an identifiable chemical(s) or analytes(s) for which there may be several equivalent methods of analysis available.

PROCEDURES FOR ASSESSING RECOVERY

Recovery information from matrix reference materials

In principle, recoveries could be estimated by the analysis of matrix reference materials. The recovery is the ratio of the concentration of analyte found to that stated to be present. Results obtained on test materials of the same matrix could, in principle, be corrected for recovery on the basis of the recovery found for the reference material. However, several problems potentially beset this use of the reference materials, namely: (a) the validity of any such recovery estimate depends on the premise that the analytical method is otherwise unbiased; (b) the range of appropriate matrix reference materials available is limited; and (c) there may be a matrix mismatch between the test material and the most appropriate reference material available.

In the last instance the recovery value obtained from the reference material would not be strictly applicable to the test material. The shortfall applies especially in sectors such as foodstuffs analysis where reference materials have to be finely powdered and dried to ensure homogeneity and stability. Such treatment is likely to affect the recovery in comparison with that pertaining to fresh foods of the same kind. However, matrix mismatch is a general problem in the application of recovery information and is treated separately..

Recovery information from surrogates

Where (certified) reference materials are unavailable, the recovery of analyte can be estimated by studying the recovery of an added compound or element that is regarded as a surrogate for the native analyte. The degree to which this surrogate is transferred into the measurement phase is estimated separately and this recovery can, if appropriate, be attributed also to the native analyte. This procedure in principle allows the loss of analyte to be corrected, and an unbiased estimate of the concentration of the native analyte in the original matrix to be made. Such a 'correction-for-recovery' methodology is implicit or explicit in several distinct methods of analysis and must be regarded as a valid procedure if it can be shown to be properly executed.

In order for this procedure to be valid the surrogate must behave quantitatively in the same way as analyte that is native in the matrix, especially in regard to its partition between the various phases. In practice that equivalence is often difficult to demonstrate and certain assumptions have to be made. The nature of these assumptions can be seen by considering the various types of surrogate that are used.

Isotope dilution

The best type of surrogate is an isotopically modified version of the analyte which is used in an isotope dilution approach. The chemical properties of the surrogate are identical with, or very close to, those of the native analyte and, so long as the added analyte and the native analyte come to effective equilibrium, its recovery will be the same as that of the analyte. In isotope dilution methods the recovery of the surrogate can be estimated separately by mass spectrometry, or by radiometric measurement if a radioisotope has been used, and validly applied to the native analyte. The achievement of effective equilibrium is not always easy, however.

In some chemical systems, for example in the determination of trace metals in organic matter, the native analyte and the surrogate can be readily converted into the same chemical form by the application of vigorous reagents that destroy the matrix. This treatment converts organically bound metal into simple ions that are in effective equilibrium with the surrogate. Such a simple procedure is usually effective in the determination of trace elements, but might not apply to a pesticide residue. In the latter instance the analyte may be in part chemically bound to the matrix. Vigorous chemical reagents could not be used to release the analyte without the danger of

destroying it. The native analyte and surrogate cannot come into effective equilibrium. The recovery of the surrogate is therefore likely to be greater than that of the native analyte. Thus even for this best type of surrogate, a bias in an estimated recovery may arise. Moreover, the application of the isotope dilution approach is limited by the availability and cost of isotopically enriched analytes.

Spiking

A less costly expedient, and one very commonly applied, is to estimate in a separate experiment the recovery of the analyte added as a spike. If a matrix blank (a specimen of the matrix containing effectively none of the analyte) is available the analyte can be spiked into that and its recovery determined after application of the normal analytical procedure. If no matrix blank is available, the spike can be added to an ordinary test portion that is analysed alongside an unspiked test portion. The difference between these two results is the recovered part of the added analyte, which can be compared with the known amount added. This type of recovery estimate is called here the 'surrogate recovery' (the added analyte acts as a surrogate for the native analyte). It is analogous to the method of standard additions. It suffers from the same problem as that encountered with isotopically modified analyte, namely that added analyte may not come to effective equilibrium with the native analyte. If the added analyte is not so firmly bound to the matrix as the native analyte, the surrogate recovery will tend to be high in relation to that of the native analyte. That circumstance would lead to a negative bias in a corrected analytical result.

Internal standards

A third type of surrogate used for recovery estimation is the internal standard. When internal standardisation is used in recovery experiments the surrogate is an entity chemically distinct from the analytes, and therefore will not have identical chemical properties. However, it will normally be selected so as to be closely related chemically to the analytes, thus representing their chemical behaviour to the highest degree practicable. The internal standard would be used, for example, in recovery estimation where numerous analytes are to be determined in the same matrix and marginal recovery experiments would be impracticable for each of them individually. The question of practicability goes beyond the costs of handling numerous analytes: some analytes (for example, new veterinary residues, or metabolites) may not be available as pure substances. While it may be the most cost-effective expedient in some circumstances, the internal standard at best is technically less satisfactory than the spike as a surrogate, because its chemical properties are not identical with those of the analytes. Biases in both directions could result from the use of a recovery estimate based on an internal standard. Internal standards may also be used for other purposes.

Matrix mismatch

Matrix mismatch occurs when a recovery value is estimated for one matrix and applied to another. The effect of matrix mismatch would be manifested as a bias in the recovery in addition to those considered above. The effect is likely to be most serious when the two matrices differ considerably in their chemical nature. However, even when the matrices are reasonably well matched (say two different species of vegetable) or nominally identical (for example, two

different specimens of bovine liver), the analytical chemist may be forced to make the unsubstantiated assumption that the recovery is still appropriate. This would clearly increase the uncertainty in the recovery and in a recovery-corrected result. Matrix mismatch can be avoided in principle by a recovery experiment (for example, by spiking) for each separate test material analysed. However, such an approach will often be impracticable on a cost-benefit basis so a representative test material in each analytical run is used to determine the recovery.

Concentration of analyte

The recovery of the surrogate or the native analyte has up to this point been treated as if it were independent of its concentration. This is unlikely to be strictly true at low concentrations. For instance a proportion of the analyte may be unrecoverable by virtue of irreversible adsorption on surfaces. However, once the adsorption sites are all occupied, which would occur at a particular concentration of analyte, no further loss is likely at higher concentrations. Hence the recovery would not be proportional to concentration. Circumstances like this should be investigated during the validation of an analytical method, but a complete study may be too time-consuming for *ad hoc* use.

ESTIMATION OF RECOVERY

There is no generally applicable procedure for estimating recovery that is free from shortcomings. However, it is possible to conduct a 'thought experiment' in which an ideal procedure is used. This provides a reference point for real procedures. In this ideal procedure a definitive analytical method is available: the analyte can be determined by a method that is completely unbiased with no recovery losses. The method is too resource-intensive for use in routine analysis, but there is an alternative routine method with imperfect recovery. The recovery obtained in the routine method is estimated by using both methods to analyse a large set of typical test materials, a set that covers the required range of matrices and analyte concentrations. This gives the recovery (and its uncertainty) for the routine method for any conceivable situation.

In practice there may be no such definitive method available for reference, so reference materials or surrogate studies have to be used for the estimation of recovery. However, reference materials are few, and lack of resources restricts the range of test materials that can be used to estimate recovery by using surrogates. Additionally, the use of surrogates in itself adds an uncertainty to a recovery estimate because it may not be possible to determine whether some proportion of the native analyte is covalently or otherwise strongly bound to the matrix and hence not recoverable.

A strategy commonly employed to handle this problem is to estimate recovery during the process of method validation. Recoveries are determined over as wide a range of pertinent matrices and analyte concentrations as resources allow. These values are then held to apply during subsequent use of the analytical method. To justify that assumption, all routine runs of the method must contain a reference material (or spiked samples) to act as internal quality control. This helps to ensure that the analytical system does not change in any significant way that would invalidate the original estimates of the recovery. The following points are therefore suggested as requiring consideration, even if lack of resources prevents their complete execution in practice.

Representative recovery studies

The entire range of matrix types for which the method will be applied should be available for the method validation. Moreover, several examples of each type should be used to estimate normal range of recoveries (the uncertainty) for that matrix type. If it is likely that the history of the material will affect the recovery of the analyte (for example, the technical processing or cooking of foodstuffs), then examples at different stages of the processing should be procured. If this range cannot be encompassed in the validation, there will be an extra uncertainty associated with the matrix mismatch in the use of the recovery. That uncertainty may have to be estimated from experience.

An appropriate range of analyte concentrations should be investigated where that is technically and financially possible, because the recovery of the analyte may be concentration-dependent. Consider adding an analyte to a matrix at several different levels. At very low levels the analyte may be largely chemisorbed at a limited number of sites on the matrix, or irreversible adsorbed onto surfaces of the analytical vessels. Recovery at this concentration level might be close to zero. At a somewhat higher level, where the analyte is in excess of that so adsorbed, the recovery will be partial. At considerably higher concentrations, where the adsorbed analyte is only a small fraction of the total analyte, the recovery may be effectively complete. The analytical chemist may need to have information about recovery over all of these concentration ranges. In default of complete coverage, it may be suitable to estimate recovery at some critical level of analyte concentration, for example at a regulatory limit. Values at other levels would have to be estimated by experience, again with an additional uncertainty.

When spiking is applied to a matrix blank then the whole range of concentrations can be conveniently considered. When the concentration of the native analyte is appreciable the spike added should be at least as great, to avoid incurring a relatively large uncertainty in the surrogate recovery.

Internal quality control

The principles and application of internal quality control (IQC) are described. The purpose of IQC is to ensure that the performance of the analytical system remains effectively unchanged during its use. The concept of statistical control is crucial in IQC applied to routine analysis (as opposed to *ad hoc* analysis). When applied to recovery, IQC has some special features that have to be taken into account. This IQC of recovery can be addressed in two distinct ways, depending on the type of control material that is used.

(a) A matrix-matched reference material can be used as a control material. The recovery for this material and an initial estimate of its between-run variability are determined at the time of method validation. In subsequent routine runs the material is analysed exactly as if it were a normal test material, and its value plotted on a control chart (or the mathematical equivalent). If the result for a run is in control, then the validation-time estimate of the recovery is taken as valid for the run. If the result is out of control, further investigation is required, which may entail the rejection of the results of the run or possibly a re-investigation of the recovery. It may be necessary to use several control materials, depending on the length of the run, the analyte concentration range, etc.

(b) Spiked materials can also be used for quality control. As usual, initial estimates of the average recovery and its between-run variability are made during method validation, and are used to set up a control chart. Either of two variant approaches can be used in routine analysis, depending on

the stability of the material: (a) a single long-term control material (or several such materials) can be prepared for use in each routine run, or (b) all, or a random selection, of the test materials for the run can be spiked. In either instance the surrogate recovery is plotted on a control chart. While the recovery remains in control it can be deemed to apply to the test materials generally. Of the two alternative methods, the latter (involving the actual test materials) is probably the more representative, but also the more demanding.

There is a tendency for the role of IQC to be confused with the simple estimation of recovery (where deemed appropriate). It is better to regard IQC results solely as a means of checking that the analytical process remains in control. The recovery estimated at method validation time are usually more accurate for application to subsequent in-control runs, because more time can be spent on studying their typical levels and variability. If real-time spiking is used to correct for recovery, this is more like a species of calibration by standard additions.

ANNEX III: ACTION POINTS / POINTS OF ATTENTION FOR THE COMMISSION

*** Date of application of Decisions**

Decisions are in principle immediately applicable. This can create a problem for countries where a national publication is necessary for application → ensure whenever possible a uniform starting date for the application of special measures (a reasonable period depending on the urgency of the measures but should in any case not exceed 1 month). Even if there is a national requirement for publication, it is appropriate that the competent authority communicates the required controls to the port of entry as soon as possible.

*** Problems identified with the use of TARIC codes**

The same TARIC code is used for nuts and dried fruit for animal feed as for food. In the absence of clear indication of destination, goods should be considered as being intended for human consumption.
In case problems are observed in applying the TARIC codes for identifying goods, it is important that this is communicated. TAXUD will then be informed of this problem/observation for clarification or for possible amendment to the TARIC classification system.

*** Establishment of a list of officials authorised for signing the health certificates**

The establishment of a list of officials authorised for signing the health certificate for peanuts from Egypt, peanuts from China and Brazil nuts in shell from Brazil (Commission Decisions 2000/49/EC, 2002/79/EC, and 2003/493/EC) should be considered.

*** Further harmonisation of sample procedure**

Further harmonisation on sampling procedures for situations for which no specific, concrete and detailed sampling provisions are foreseen, especially sample procedures in the case of special forms of packing. Examine the legal possibilities for harmonising the approach to be followed in case a defence sample generates a compliant result

Annex 4

PROPOSED MAXIMUM LIMITS FOR *FUSARIUM* TOXINS

Deoxynivalenol

Product[1]	**Maximum level**
1. Unprocessed cereals[2] other than durum wheat, oats and maize	1250
2. Unprocessed durum wheat and	1750
3 Unprocessed maize	- [3]
4. Cereal flour, including maize flour, semolina, maize grits, maize	750
5. Bread, pastries, biscuits, cereal snacks and breakfast cereals	500
6. Pasta (dry)	750
7. Processed cereal-based food for infants and young children and baby	200

[1] For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B1 and B2, T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products”

[2] The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing.

“First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain.

Cleaning and sorting procedures are not considered being “first stage processing” insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.

[3] If no specific level is fixed before 1 July 2007, the level of 1750 µg/kg will apply thereafter to maize referred to in this point.

[4] This category includes also similar products otherwise denominated such as semolina.

[5] Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14..02.2003, p. 33).

The maximum level for processed cereal-based foods for infants and young children and baby food refers to the dry matter.

Zearalenone

Product[1]	**Maximum level**
1. Unprocessed cereals[2] other than maize	100
2. Unprocessed maize	- [3]
3. Cereal flour except maize flour	75
4. Maize flour, maize meal, maize grits and refined maize oil[4]	- [3]
5. - Bread, pastries, biscuits - maize snacks and cornflakes - other cereal snacks and breakfast	50 - [3] 50
6. – Processed maize-based foods for infants and young children - Other processed cereal-based foods for infants and young children	- [3] 20

[1] For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B1 and B2, T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products”

[2] The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing.
“First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain.

Cleaning and sorting procedures are not considered being “first stage processing” insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.

[3] If no specific level is fixed before 1 July 2007, the level of
- 200 µg/kg will apply thereafter to unprocessed maize
- 200 µg/kg will apply thereafter to maize flour, maize meal, maize grits and refined maize oil
- 50 µg/kg will apply thereafter to maize snacks and cornflakes
- 20 µg/kg will apply thereafter to processed maize-based foods for infants and young children

[4] This category includes also similar products otherwise denominated such as semolina.

[5] Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14..02.2003, p. 33).
The maximum level for processed cereal-based foods for infants and young children and baby food refers to the dry matter.

Fumonisins[1]

Product	Maximum level
1. Unprocessed maize[2]	- [3]
2. Maize grits, maize meal, maize flour and maize semolina[4]	- [3]
3. Maize-based foods for direct human consumption with the	- [3]
4. Processed maize-based food for infants and young children and baby [5]	- [3]

[1] The maximum level applies to the sum of fumonisin B1 (FB1) and fumonisin B2 (FB2)

[2] The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing.

“First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain.

Cleaning and sorting procedures are not considered being “first stage processing” insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.

[3] If no specific level is fixed before 1 July 2007, the level of

- 2000 µg/kg will apply thereafter to unprocessed maize
- 1000 µg/kg will apply thereafter to maize flour, maize meal, maize grits and maize semolina
- 400 µg/kg will apply thereafter to maize-based foods for direct human consumption
- 200 µg/kg will apply thereafter to processed maize-based foods for infants and young children and baby food

[4] This category includes also similar products otherwise denominated such as semolina.

[5] Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.02.2003, p. 33).

The maximum level for processed cereal-based foods for infants and young children and baby food refers to the dry matter.

T-2 and HT-2 toxins[1]

Product[2]	**Maximum level**
1. Unprocessed cereals [3] and cereal products	- [4]

[1] The maximum level refers to the sum of T-2 and HT-2 toxin

[2] For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B1 and B2, T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products”

[3] The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing.

“First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain.

Cleaning and sorting procedures are not considered being “first stage processing” insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.

[4] A maximum level will be fixed, if appropriate, before 1 July 2007.

Data on the presence of T-2 and HT-2 toxin are for the time being limited. However intake estimates indicate clearly that the presence of T-2 and HT-2 can be of concern for public health. Therefore, the development of a sensitive method, collection of more occurrence data and more investigations/research in the factors involved in the presence of T-2 and HT-2 in cereal and cereal products particular in oats and oat products is necessary and of high priority”

Annex 5

European Community Comments for the

CODEX COMMITTEE ON GENERAL PRINCIPLES
21st Session, 08-12 November 2004, Paris, France
Agenda Item 2 Matters referred by the Codex Alimentarius Commission and other Codex Committees

CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

INTRODUCTION

At its 36th session held in Rotterdam, The Netherlands, 22-26 March 2004, The Codex Committee on Food Additives and Contaminants forwarded the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups to the Codex Alimentarius Commission through the Codex Committee on General Principles, for final adoption at Step 8 and inclusion in the Procedural Manual (ALINORM 04/27/12 § 129)

At this session, the following paragraph 8 was included in the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups:

"JECFA performs exposure assessments if requested by CCFAC using the GEMS/Food Regional Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCFAC about these risk management options". The delegation of Belgium expressed its reservation on this decision. (ALINORM 04/27/12 § 128 c).

COMMENTS

The European Community wishes to make following observations as regards the paragraph 8.

The exposure assessments performed by JECFA to estimate the impact on dietary exposure of proposed alternative maximum levels will provide only very limited useful information to CCFAC about these risk management options and will result in many cases in an unnecessary delay in the standard setting process within CODEX. A significant impact on dietary exposure if different alternative maximum levels can only be expected if these are (significantly) lower than the 97.5 percentile of the frequency distribution of the occurrence data. Alternative maximum levels proposed at levels (much) higher than the 97.5 percentile will have no or very limited impact on the exposure.

Codex Alimentarius Commission has already adopted several Codes of Practice to prevent or to reduce the presence of contaminants in food[1]. The effective application of these Codes of practice will ensure that the presence of contaminants in food is

prevented as much as possible and will consequently result in an overall decrease of contamination levels in the food chain. This overall decrease of the contamination level of the food chain is of major importance to ensure the protection of the health of the consumers. By fixing maximum levels at the higher end of the frequency distribution of the occurrence data, the effective application of Codes of practice is stimulated.

This positive effect of setting a maximum level at the higher end of the frequency distribution of occurrence data is not taken into account in the JECFA assessment on the impact on dietary exposure of proposed maximum levels as such an assessment takes only into account existing occurrence data. The indisputable positive effect of a maximum level established at a level, stimulating the effective application of codes of practice, resulting in an overall decrease of the contamination level of the food chain is not taken into account in such comparative exposure assessment.

CODEX POLICY FOR THE PREVENTION AND REDUCTION OF CONTAMINANTS IN THE FOOD CHAIN

The main purposes of the Codex Alimentarius are protecting health of the consumers and ensuring fair trade practices. In the field of contaminants these objectives are pursued through a policy of elaborating of codes of practice on the one hand and standards on the other hand.

The adoption of codes of practice for the prevention and reduction of contaminants in the food chain is the first important pillar. The adoption of standards, maximum levels at a level, achievable and stimulating the effective application of these codes of practice are the second important pillar. Such maximum levels further provide a bench-mark against the effectiveness of application of codes of practice to prevent contamination and provide a tool for the authorities to control the correct application by each operator in the chain of these codes of a practice.

1 Code of Practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk producing animals (CAC/RCP 45-1997).

Code of Practice for source directed measures to reduce contamination of food with chemicals
(CAC/RCP 49-2001).
Code of Practice for the prevention and reduction of patulin contamination in apple juice and apple
juice ingredients in other beverages (CAC/RCP 50-2003).

Code of Practice for the prevention and reduction of mycotoxin contamination in cereals, including
annexes on ochratoxin A, zearalenone, fumonisins and trichothecenes (CAC/RCP 51-2003).

Code of Practice for the prevention and reduction of aflatoxin contamination in peanuts
(ALINORM 04/27/41, § 30).

Code of Practice for the prevention and reduction of lead contamination in food (ALINORM
04/27/41, § 30).

It is major importance for the achievement of the objectives that Codex Alimentarius follows a consistent policy on the prevention and reduction of contaminants in the food chain. The setting of maximum levels, standards must provide a strong incentive for the application of the Codes of practice.

CONCLUSION AND POSITION OF THE EUROPEAN COMMUNITY

While not opposing the inclusion of paragraph 8 in the draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, the European Community is of the opinion that such comparative exposure assessments of proposed maximum levels do provide only very limited useful information enabling CCFAC to perform a consistent policy on the prevention and reduction of the contamination of the food chain by contaminants.

European Community Comments for the
CODEX COMMITTEE ON GENERAL PRINCIPLES

21st Session, 08-12 November 2004, Paris, France

Agenda Item 2 Matters referred by the Codex Alimentarius

Commission and other Codex Committees

Draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants

At its 36th session held in Rotterdam, The Netherlands, 22-26 March 2004, The Codex Committee on Food Additives and Contaminants (CCFAC) forwarded the draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants to the Codex Alimentarius Commission through the Codex Committee on General principles, for final adoption at Step 8 and inclusion in the procedural Manual (ALINORM 04/27/12 § 39).

At this 36th session of the CCFAC as at its previous sessions, the draft Risk Analysis Principles were discussed in extenso and agreed upon.

The European Community has therefore no further comments to make and **agrees on the final adoption and the inclusion in the Procedural Manual** of these Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants.

European Community Comments for the

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

37th Session, 25-29 April 2005, The Hague, The Netherlands

Proposed Draft Maximum Level for Total Aflatoxins in Processed and Unprocessed Almonds, Hazelnuts and Pistachios at Step 3

The European Community welcomes the discussion on maximum levels for aflatoxins in almonds, hazelnuts and pistachios.

At the 36th session of the CCFAC, Rotterdam, The Netherlands, 22-26 March 2004, the Committee agreed to set up a proposed draft maximum level of 15 µg/kg total aflatoxins for unprocessed and processed almonds , hazelnuts and pistachios and to circulate it for comments at Step 3 and consideration at its next Session (ALINORM 04/27/12, § 155).

Aflatoxins are amongst the most potent mutagenic and carcinogenic substances known and are genotoxic carcinogens, therefore possible maximum levels must be set at a level as low as reasonable achievable (= ALARA principle).

The four main aflatoxins (B1, B2, G1, and G2) usually occur together in varying ratios but normally aflatoxin B1 is the major component.

The Codex Alimentarius Commission adopted at its 23rd session, Rome, July 1999, a maximum level of 15 µg/kg for total aflatoxins in peanuts intended for further processing. No level was adopted for aflatoxin B1 separately.

Because aflatoxin B1 is the most toxic compound of all aflatoxins, setting a separate (lower) level for aflatoxin B1 offers an extra guarantee for public health. The EC is therefore in favour of setting a maximum level for total aflatoxins and a lower maximum level for aflatoxin B1 separately. In accordance with the ALARA principle the EC proposes a maximum level of 10 µg total aflatoxin/kg and 5 µg aflatoxin B1/kg for almonds, hazelnuts and pistachios intended for further processing.

It is known that sorting techniques and other physical treatments, carried out on unprocessed almonds, hazelnuts and pistachios to obtain the final consumer product can considerably decrease the aflatoxin content.

Therefore significantly lower maximum levels should be set for processed almonds, hazelnuts and pistachios for direct human consumption or use as food ingredient. The EC proposes for these food products a maximum level of 2 µg aflatoxin B1/kg and 4 µg total aflatoxin/kg and **opposes the setting of a maximum level of 15 µg/kg total aflatoxin especially for processed almonds, hazelnuts and pistachios**.

European Community Comments for the

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

37th Session, 25-29 April 2005, The Hague, The Netherlands

on deoxynivalenol (DON) contamination in cereals

The European Community welcomes also the discussion on deoxynivalenol in cereals and cereal products.

JECFA performed a risk assessment on DON in 2001 and established a provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight and concluded that intake at this level would not result in effects of DON on the immune system, growth or reproduction. Estimations of the dietary intake of deoxynivalenol on the basis of the single weighted mean concentrations and the GEMS/food regional diets resulted in values that exceed the PMTDI for four of the five regional diets. JECFA noted that there was considerable uncertainty in these intake estimates and that it can be expected that food processing would reduce the levels of deoxynivalenol to varying extents, resulting in lower estimates of dietary intake.

A study in the framework of the scientific co-operation between Member States (SCOOP) of the EU has been performed to evaluate the dietary intake of trichothecenes (in particular deoxynivalenol and T-2 and HT-2 toxin), zearalenone and fumonisins of the general European population and of high risk sub-groups of the population, in particular children.

The SCOOP report "Collection of Occurrence data of *Fusarium*-toxin in Food and Assessment of the Dietary Intake by the Population of EU Member States" has been finalised and has been made publicly available on the website of the DG Health and Consumer protection of the European Commission.
(http://europa.eu.int/comm/food/fs/scoop/task3210.pdf)

This study (see table below) indicates that the average level intake of deoxynivalenol do not exceed the PMTDI for the entire population as well as for the group adults. However for the group of young children the intake might approach TDI.

The intake of high level consumers, especially young children, might exceed the PMTDI.

Table: Range of average dietary intakes* calculated as percentage of the PMTDI-value

Mycotoxin	PMTDI µg/kg bw/day	Population	Adults	Infants
Deoxynivalenol	1	1% - 34%	14% - 46%	11% - 96%

* **Average** food consumption and **average** occurrence data whereby the mean is calculated using
LOD/2 for results lower than the LOD (LOD = limit of determination).

These exposure assessments indicate clearly the need to limit the presence of deoxynivalenol in cereals and cereal products in order to protect public health. It is therefore important that all prevention measures as outlined in the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Trichothecenes (CAC/RCP 51-2003), as adopted by the Codex Alimentarius Commission at its 26th session in Rome, July 2003 are put in place.

The aforementioned SCOOP report contains also a compilation of occurrence data of deoxynivalenol in cereals and cereal products provided by the EU Member States. The analytical results of about 9350 samples were provided and 57 % of the samples had levels of deoxynivalenol above the LOD.

In the Annex to this document a summary of occurrence data in cereals and cereal products is provided. Twelve countries provided data on deoxynivalenol from the period 1996 until 2002. It should be noted that detailed information on the analytical method, quality assurance, sampling method, sample size etc was not made available for all provided data.

The EC is currently discussing maximum levels for DON in cereals and cereal products. Also the associated sampling procedure for official control and performance requirements for the methods of analysis are discussed.

It is expected to finalise these discussions in the beginning of 2005 and the EC will be able to provide in advance of the meeting information on maximum levels, sampling procedures and methods of analysis for consideration at the 37th session of CCFAC

Summary of occurrence of DON in cereals and cereal products in various EU Member States

Food product	N° samples	Max. value (µg/kg)	Mean (1)[1] µg/kg	Mean (2)[1] µg/kg	Median µg/kg
Wheat	265	764	175	258	143
Wheat	2250	5000	239	399	?30
Wheat	3	744	256	744	
Wheat	159	2153	60	90	17
Wheat	30	2125	132	325	3
Wheat	22	170	11	170	3
Wheat	1	0	50		50
Wheat	1	85	105	85	40
Wheat	3	120	100	95	50
Wheat	955	1723	145	258	40
Soft wheat	31	230	22	149	3
Soft wheat	82	1500	270	319	190
Soft wheat	72	700	62	201	15
Soft wheat	71	1900	216	313	100
Soft wheat	276	1520	283		190
Soft wheat	252	1038	95		25
Wheat grains	47	504	63	343	<LOQ
Durum wheat	16	1000	263	412	170
Durum wheat	16	1600	372	649	175
Durum wheat	13	730	169	238	110
Durum wheat	52	3600	689	891	470
Durum wheat flour	33	2591	1155	1155	1233
Buckwheat	1		30		30
Buckwheat	5		30		30
Buckwheat	3		33		33
Buckwheat	15		33		33
Buckwheat	1		16		16
Buckwheat	3	70	35	70	16

[1] Mean 1 accounts for all the individual provided values according to the following criteria:
a) If LOD and LOQ are available, participants were requested to calculate mean level using LOD/2 for results lower than the LOD. For results between LOD and LOQ, numerical values, if available, were used.
b) If only LOQ is available, or if numerical values between LOD and LOQ are not available, LOQ/6 for values below the LOQ was used.

Mean 2 accounts for all positives above LOD values and it accounts for the distribution and level of positive results.

Food product	N° samples	Max. value (µg/kg)	Mean (1) µg/kg	Mean (2) µg/kg	Median µg/kg
Barley	9	35	6	35	3
Barley	40	510	75	284	<50
Barley	20	60	26	47	15
Rye	64	61	43	46	15
Rye	37	220	106	164	<220

Rye	47	351	15	51	20
Oats	23	-	34	-	-
Oats	36	174	16	38	18
Oats	204	1300	93	157	46
Corn	29	8850	494	841	50
Corn	25	4800	1056	1140	
Corn	59	3390	475		300
Corn	107	5400	903		650
Corn	115	3920	653	668	510
Sweet corn	4	222	33	222	33
Sweet corn	9	224	57	142	33
Cereal grains	549	690	216	485,8	<LOQ
Malting barley	30		15		15
Malting barley	52	200	10	200	5
Malting barley	44	500	5	173	5
Malting barley	68	310	21	156	5
Malting barley	59	550	50		10
Malting barley	47	350	61		35
Malting barley	50	550	46		10
Malting barley	64	350	65		37
Wheat bran	1		17		17
Wheat bran	6		33	33	33
Wheat bran	3		33		33
Wheat bran	39	3600	205	352	50
Wheat bran	8	650	166	189	86
Wheat bran	9	2000	526	526	240
Wheat bran	8	170	59	64	13
Wheat bran	13	915	222	310	140
Wheat bran	20	2050	711	830	543
Wheat bran	4	1821	761	1510	
Wheat bran	20	360	75	169	<50

Food product	**N° samples**	**Max. value µg/kg**	**Mean (1) µg/kg**	**Mean (2) µg/kg**	**Median µg/kg**
Wheat products	3		30		30
Wheat products	5		33		33
Wheat products	75	1826	286	538	235
Wheat products	2		33		33
Wheat products	8	502	348	902	33
Wheat products	10	800	67	450	50
Wheat products	2	160	66	103	41
Wheat products	1	289	289	289	289
Wheat products	15	250	105	235	40
Wheat products	7	220	100	220	50
Wheat products	24	600	67	208	50
Wheat products	1		66		66

Wheat products	12	1000	993	410	45
Wheat products	15	410	105	236	40
Wheat products	3	220	100	220	50
Wheat flour	409	2650	109	232	<50
Wheat flour	88	527	114	135	87
White wheat flour	15	500	156	316	125
White wheat flour	1		125	125	125
White wheat flour	170	1213	143	324	33
White wheat flour	11	136	46	101	33
White wheat flour	46	595	63	322	17
White wheat flour	308	300	67	123	50
White wheat flour	57	330	66	91	41
White wheat flour	55	50000	993	1183	45
White wheat flour	38	400	105	174	40
White wheat flour	33	330	100	184	50
White wheat flour	14	200	67	127	50
White wheat flour	4	130	66	97	41
White wheat flour	10	300	153	993	45
White wheat flour	4	280	105	220	40
White wheat flour	3	0	50		50
White wheat flour	37	2100	304		220
White wheat flour	101	328	53		25
White wheat flour	29		30		30
White wheat flour	3	333	119	333	
Rice flour	1		33		33
Rice flour	1		17		17
Food product	**N° samples**	**Max. value µg/kg**	**Mean (1) µg/kg**	**Mean (2) µg/kg**	**Median µg/kg**
Rye flour	69	257	43	55	14
Rye flour	1	120	120	120	120
Rye flour	2		33		33
Rye flour	1		33		33
Rye flour	3	595	174	595	33
Rye flour	11	350	104	292	33
Corn fractions	1		50		50
Corn fractions	1		50		50
Corn fractions	1		50		50
Corn fractions	17	1400	105	559	40
Corn fractions	7	825	100	271	50
Corn fractions	1	340	340	340	340
Corn fractions	1	620	620	620	620
Corn meal	2	450	435	435	435
Corn meal	3	1400	331	480	340
Corn meal	1	245	245	245	245
Corn products	2	611	33	33	33
Corn products	1		33		33
Corn products	8	320	238	92	226

Barley products	1		30		30
Barley products	9		33		33
Oat products	1		30		30
Oat products	11		33		33
Oat products	3		33		33
Oat products	5		8		8
Rice products	1		30		30
Rice products	7		33		33
Rice products	1		17		17
Rice products	3		33		33
Breakfast cereals	14	235	63	243	33
Breakfast cereals	1		33		33
Breakfast cereals	24	100	67	50	50
Breakfast cereals	8	25700	66	3229	41
Breakfast cereals	9	250	993	42	45
Breakfast cereals	1	0	105		40
Breakfast cereals	4	80	100	80	50
Breakfast cereals	10	426	162	162	161

Food product	**N° samples**	**Max. value µg/kg**	**Mean (1) µg/kg**	**Mean (2) µg/kg**	**Median µg/kg**
Pasta	29	716	126	430	<LOQ
Pasta	1		33		33
Pasta	110	3200	219	227	150
Pasta	163	840	92	231	<10
Pizza	1	150	150	150	150
Pizza	1	216	216	216	216
Polenta	1		33		33
Polenta	3		64	88	25
Bread	38	560	70	394	<LOQ
Bread	51	557	103	192	<50
Biscuits	80	420	60	147	<50
Biscuits including babyfood	15	<LOQ	31	0	<LOQ
Bran	5	475	128	475	<LOQ
Composite grain product	19	86	25	39	21
Muesli	46	390	56	185	<50
Muësli bars	5	<LOQ	42	0	<LOQ
Starch	24	320	97	199	<50
Oat baby porridge	28		10	0	10
Infant food	21	270	81	99	70
Maize baby porridge	19	1022	451	475	609
Baby food	164	1075	102	120	74
Rice baby porridge	16		10	0	10
Wheat baby porridge	39	183	28	63	10