JFCO 587
DISK / 13/2/02

ARTICLE IN PRESS

No. of pages: 6
DTD 4.3.1/ SPS

ELSEVIER

Food Control xxx (2002) xxx–xxx

FOOD CONTROL

www.elsevier.com/locate/foodcont

How to establish international limits for mycotoxins in food and feed? ☆

Abstract

In 1961/62 the FAO and WHO established Codex Alimentarius to elaborate international food legislation, including provisions for mycotoxins in foods and feeds. Chemical contaminants and toxins are handled in the Codex Committee for Food Additives and Contaminants, CCFAC. The Codex Alimentarius system for developing legislation concerning contaminants including mycotoxins in food is based upon the Codex General Standard for Contaminants and Toxins in Food, GSCTF. The GSCTF covers also feeds and raw commodities.

The Codex Alimentarius Risk Analysis system comprises a scientifically based Risk Assessment by the FAO/WHO Joint Expert Committee on Food Additives, JECFA, a committee also dealing with contaminants and natural toxins such as mycotoxins, and a Risk Management part by CCFAC.

The principles for laying down Maximum Limits (MLs) for contaminants and toxins in foods and feeds within Codex Alimentarius are agreed, and work is in progress to establish MLs for some mycotoxins, in particular in cereals. In the European Union, a similar process is in progress. The legal basis for European Commission regulations concerning specific contaminants such as mycotoxins became available with the framework Council Regulation EEC 315/93 laying down Community procedures for contaminants in foods. © 2002 Published by Elsevier Science Ltd.

1. Introduction

Mycotoxins may be present in many foods, feeds and commodities as a result of growth of mould on crops and foods, albeit sometimes in quantities below the limit of detection of the analytical methods of today. Mycotoxins may be pathogenic in animals and humans as they may cause damage to e.g., liver, kidney or the nervous system. Some are carcinogenic in laboratory animals and a few are considered possibly to have corresponding effects in humans. As foods, feeds and raw materials and ingredients for food production are to an increasing extent traded across borders, there is an evident need for international legislation on mycotoxins in foods and feeds in order to avoid trade barriers and to protect the health of the consumer.

International legislation on foods and feeds is established by Codex Alimentarius (CAC). The Codex Alimentarius system for development of legislation concerning contaminants, including mycotoxins in foods and feeds, is laid down in considerable detail (Berg, 2000; Codex Alimentarius Commission, 2000). The Codex Committee on Food Additives (CCFAC) serves as the body responsible for the risk management component of the Codex Alimentarius risk analysis process in relation to contaminants in general and mycotoxins in foods and feeds in particular.

The body responsible for the risk assessment component of the Codex Alimentarius risk analysis process is JECFA. It is the role and privilege of JECFA to provide Codex Alimentarius with scientifically based assessment of the toxicity of food additives and contaminants, such as mycotoxins, and to establish safe levels for human consumption. Hence, the 56th JECFA in February 2001 assessed several mycotoxins (FAO/WHO, 2001).

The Codex General Standards for Contaminants and Toxins in Food (GSCTF) covers also feeds and raw commodities. The GSCTF contains the most important principles for laying down Codex Maximum Limits (MLs) for contaminants and toxins in foods and feeds (FAO, 2000). The General Standard, however, does not yet contain figures pertaining to the MLs for all contaminants and toxins in all food groups. Development of MLs as well as sampling plans and Codes of Practice to reduce the contamination of food by certain mycotoxins are presently in progress in the CCFAC (Berg, 2001; Codex Alimentarius Commission, 2001).

In the European Union, a similar process takes place. The legal basis for European Commission regulations concerning specific contaminants such as mycotoxins became available with the framework Council Regula-

☆ Lecture at the First World Mycotoxin Forum, Noordwijk aan Zee, The Netherlands, 14 May 2001.

0956-7135/02/$ - see front matter © 2002 Published by Elsevier Science Ltd.
PII: S0956-7135(02)00021-X

tion (EEC) No. 315/93 laying down Community procedures for contaminants in foods (Council Regulation, 1993). The EU regulations and proposals are roughly similar to the worldwide Codex legislation, but contain more detail (Commission Regulation, 2001).

2. Maximum limits for mycotoxins in Codex Alimentarius

2.1. The Codex Alimentarius

The Joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission (CAC) elaborate international food standards and codes of practice related to food. The purpose of the Joint FAO/WHO Food Standards Programme, as laid down in the statutes of the Codex Alimentarius (FAO, 2000), includes:

- protecting the health of the consumers and ensuring fair practices in the food trade;
- promoting co-ordination of all food standards work undertaken by international governmental and non governmental organisations; and
- determining priorities and initiating and guiding the preparation of draft standards, etc.

The CAC is the superior body of the Codex system, meeting regularly every two years, alternating between the FAO headquarters in Rome and the WHO in Geneva. There are more than 165 Member Nations of the CAC. The CAC meetings as well as those of the subsidiary bodies such as the CCFAC are attended both by government representatives and international professional organisations and consumer fora, sometimes as members of the government delegations and sometimes as observers in their own right.

Contaminants were originally partly dealt with by the many Commodity Committees and partly by the CCFAC; now CCFAC is the appropriate forum in Codex for discussions concerning contaminants. CCFAC meets every year, normally in The Hague, The Netherlands.

The 1995 WTO Agreement on the Application of Sanitary and Phytosanitary Measures (World Trade Organization, 1995) recognises as the international standards, guidelines and recommendations for food safety those standards, guidelines and recommendations that are established by Codex Alimentarius. This decision meant that the work of Codex Alimentarius immediately gained importance and momentum, as the Codex documents will be those that a WTO panel will use as the basis for settling disputes in international trade.

2.2. The General Standard for Contaminants and Toxins in Food

The GSCTF was accepted in 1997 by the CAC, in the form of a Preamble with five Annexes (FAO, 2000). The five annexes cover, respectively:

1. Criteria for the Establishment of Maximum Limits in Food.
2. Procedure for Risk Management Decisions.
3. Format of the Standard.
4. Annotated List of Contaminants and Toxins.
5. Food Categorisation System to be used in the GSCTF.

The Food Categorisation System is consistent with the systems used for food additives and pesticide residues. Additional classes and product descriptions may, however, be needed in the GSCTF.

The GSCTF does not yet contain figures pertaining to the MLs for contaminants and toxins in the various food groups. The MLs are presently under development by the CCFAC for the contaminants included in the GSCTF.

The philosophy of the GSCTF is that it shall be based upon a horizontal approach, i.e., covering the important contaminants in all relevant foods, and that the MLs should be set as low as reasonably achievable the ALARA principle (Bal & Berg, 1991). A decision on whether international action shall be taken on a contaminant in food shall be based upon the following criteria:

- the substance is demonstrated to be present in the foodstuff at a certain level, which is determined by reliable analysis;
- the substance is of toxicological concern at this level;
- the foodstuff for which action is to be taken plays a sufficiently important role in the intake of the substance concerned;
- the foodstuff appears in international trade.

The need for a Codex Standard for a contaminant in foods will be recognised by the CCFAC as a result of a discussion in the Committee. Such a discussion will normally be based on a Discussion Paper or a more formal Position Paper produced by one or more Member States that can provide particular experience or expertise on the problem. The Position Paper shall include a risk assessment, preferably by JECFA, the official scientific advisory body of the Codex Alimentarius system. The JECFA evaluation will cover the toxicological properties of – in this case – the mycotoxin – and an assessment of the exposure of the consumer to this mycotoxin.

2.3. The JECFA risk assessment

The FAO/WHO Joint Expert Committee on Food Additives, JECFA, was established in 1956 as the sci-

entific advisory body the FAO, WHO and Codex Alimentarius. JECFA is a group of independent scientific experts, convened on a meeting-by-meeting basis depending on expertise related to the agenda of the particular meeting. JECFA meets once or twice every year and deals with evaluation of food additives, contaminants, toxins and residues of veterinary drugs in food and feed. JECFA is responsible for providing risk assessment advice to CCFAC and other Codex Committees.

Risk assessment is the scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of hazard identification, hazard characterisation, exposure assessment and risk characterisation (FAO, 1997; WHO, 1995).

Said briefly, JECFA is responsible for assessment of the scientific data available on the toxicity of a food additive or a contaminant e.g., a mycotoxin – and exposure data for human consumption for this contaminant, both on a worldwide and a regional basis. This risk assessment will often briefly be expressed as figure representing the Acceptable Daily Intake (ADI), normally in mg/kg bodyweight, of a food additive, or representing the Tolerable Daily Intake (TDI) of a contaminant, or TWI if it is expressed on a weekly basis. In accordance with its role and privilege, the 56th JECFA in February 2001 evaluated several mycotoxins (FAO/WHO, 2001).

2.4. The CCFAC risk management process drafting codex standards, sampling plans and codes of practice

Risk assessment, as a part of the framework of the risk analysis process applied in the Codex Alimentarius, is defined as a scientifically based process. Whereas the JECFA is responsible for the risk assessment, it is the CAC or in practical terms in the case of mycotoxins the CCFAC which is responsible for the risk management. Risk management is defined as the process of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practises, and, if needed, selecting appropriate prevention and control options (Codex Alimentarius Commission, 2000). It is based upon adequate risk assessment and on information about policy options and strategies to deal with contamination problems, and it includes risk communication. Risk management involves, in a consistent way, a decision of what is acceptable and what is not in a given situation, and a decision of what should be done to achieve sufficient protection of public health as well as control of the contamination.

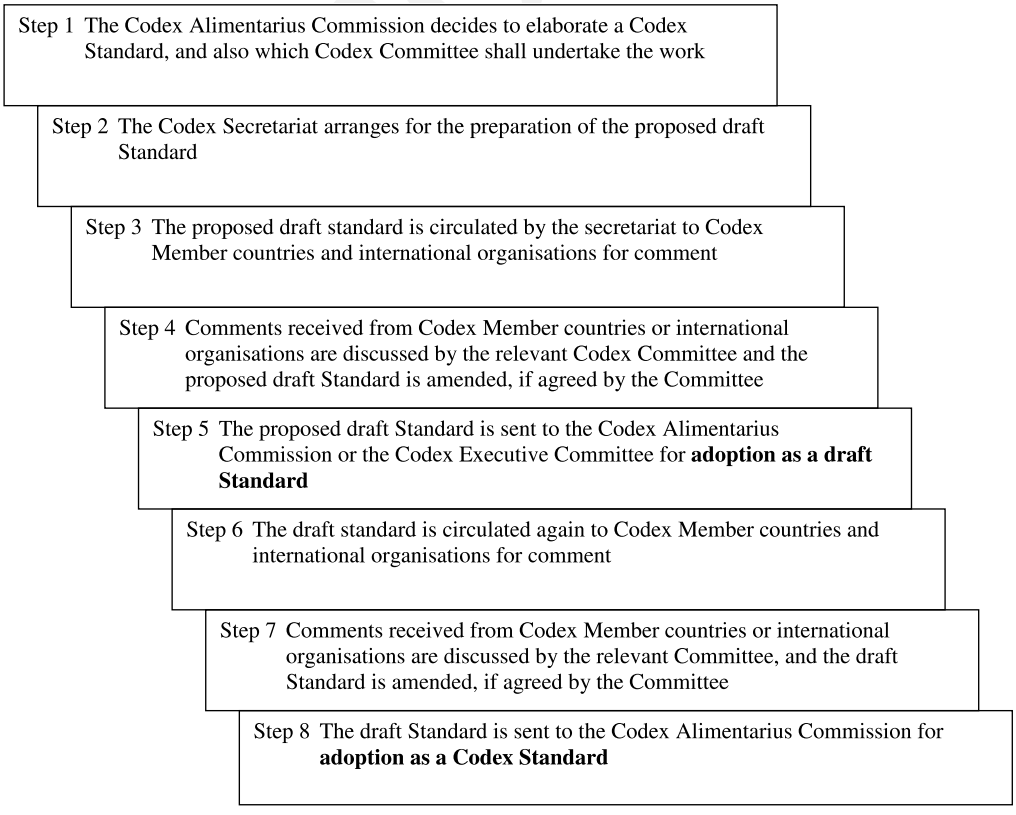

Fig. 1. A brief overview of the stepwise procedure for the elaboration of Codex Standards and related texts.

It is currently discussed what these 'other factors' appearing in the definition of risk management, or 'other legitimate factors' as they are often called can be. Among those 'other legitimate factors' that are under discussion can be mentioned:

- economic costs associated with the establishment of MLs and methods of analysis;
- technical need and feasibility;
- consumer concerns related to the safety of contaminants;
- enforceability of MLs;
- traditional, cultural, national and regional differences in food consumption.

Elaboration of Codex Standards follows a stepwise procedure to ensure that all relevant parties, including governments, professional and consumer organisations and other Codex Committees that may have an interest in the content of a Standard, have several opportunities to express their opinion (Fig. 1).

When general agreement has been reached in CCFAC, the proposed Draft Standard goes for adoption to the CAC or the Executive Committee on step 5. Member states may again comment at this stage. Following adoption by the CAC as a Codex Draft Standard at step 5, a second round of discussions in CCFAC takes place at step 7. This may again lead to general agreement, perhaps a few Member States may express reservations, and the CCFAC decides to send the Draft Standard again to the Commission, now for final adoption by the CAC on step 8. The procedure appears to be designed to give ample time for consideration of any draft standard, given the frequency of the meetings of CCFAC and CAC. If there are problems in finding agreement, a draft standard may well be kept at a certain step of the procedure for years.

2.5. Status for the Codex Alimentarius Standards and proposals for mycotoxins in food

After the 33rd CCFAC in March 2001, and before the 24th CAC in Geneva in July 2001, status for the Codex Alimentarius Standards and proposals concerning mycotoxins are as follows.

For Total Aflatoxins in peanuts intended for further processing, the 23rd CAC adopted a ML of 15 μg/kg and a draft sampling plan, on an interim basis. A revised draft sampling plan was agreed both by the Codex Committee on Methods of Analysis and Sampling an by the CCFAC in early 2001 and this draft sampling plan will now be discussed in the CAC on step 5, with a proposal to use an accelerated procedure, so that steps 6 and 7 will be omitted.

After a long discussion, a draft ML of 0.5 μg/kg for Aflatoxin M1 in milk was forwarded by the 33rd CCFAC to the CAC for adoption on step 8. The recent JECFA evaluation appeared to be pivotal for this decision, against which there were many reservations, in particular from European countries, Korea and South Africa.

The GSCTF covers also feeds and raw commodities. A 'Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplementing Feedingstuffs for Milk Producing Animals', prepared by Canada, was adopted by the 22nd CAC in 1997. This Code of Practice should assist Member States to comply with the proposed Maximum Limits for Aflatoxin M in milk.

For Ochratoxin A in wheat, barley, rye and derived products, the CCFAC agreed to forward a draft ML of 5 μg/kg to the CAC for adoption on step 5. A 'Proposed Draft Code of Practice for the Prevention of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Trichotecenes' is in an early stage of preparation and will, following revision, come back to the 34th CCFAC in 2002 on step 3.

Zearalenone in cereals has been discussed in the CCFAC based on a Position Paper by Norway (Codex Alimentarius Commission, 1999a). The CCFAC agreed in 2000 to finalise this item without recommending MLs. There will be an Annex on Zearalenone in the Proposed Draft Code of Practice for the Prevention of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Trichotecenes'.

The situation for Fumonisins in cereals is similar to Zearalenone. A Position Paper prepared by the USA was finalised by the 32nd CCFAC in 2000 (Codex Alimentarius Commission, 1999b). No MLs were proposed, and the Proposed Draft Code of Practice for the Prevention of Mycotoxin Contamination in Cereals, will also include an Annex on Fumonisins.

For Trichotecenes, a first discussion took place in the 33rd CCFAC, following the recent JECFA evaluation (FAO/WHO, 2001). A Position Paper should be developed, and the 33rd CCFAC asked the USA to include a new Annex in the revised 'Proposed Draft Code of Practice for the Prevention of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Trichotecenes'.

For Patulin in apple juice and apple juice ingredients in ready made soft drinks, the 32nd CCFAC in 2000 forwarded the Draft ML of 50 μg/l to the CAC on step 8. The 33rd CCFAC agreed that a 'Proposed Draft Code of Practice for the Prevention of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages', prepared by the UK delegation, would be revised and circulated again for comments on step 3.

2.6. Maximum limits for mycotoxins in the European Union

In the EU the legal basis is the Council Regulation (EEC) 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, which:

- provides a legal framework for establishing regulations for contaminants in foodstuffs in EU,
- includes a general clause, and
- includes the legal basis for setting MLs for contaminants in different foodstuffs.

Specific EU MLs for mycotoxins and other contaminants in food are based on proposals from the European Commission, which, in a Standing Committee procedure, shall be agreed by the Commission and the Member States, after the Scientific Committee for Food (SCF) has been heard. The SCF plays a similar expert advisory role in EU as JECFA does for Codex Alimentarius.

The specific EU legislation is now in Commission Regulation (EC) 466/2001 of 8 March 2001. This new regulation enters into force on 5 April 2002 and replaces Commission Regulation 194/97 of 31 January 1997. Regulation 466/2001 is setting MLs for certain contaminants in foodstuffs:

- nitrite and nitrate in spinach and lettuce,
- aflatoxins in nuts and dried fruits, cereals and milk,
- lead, cadmium and mercury in certain foods, and
- monochloropropanediol, 3-MCPD, in Hydrolysed Vegetable Protein and soy sauce.

European Union Member States, and other countries, appear to have few problems complying with the lower limit of 0.05 μg/kg Aflatoxin M in milk, probably because a Council Directive on Maximum Levels for Aflatoxin B1 in Feedingstuffs for Lactating Cows lays down a rather restrictive ML of 0.005 μg/kg, leading to levels well below 0.05 μg/kg Aflatoxin M in milk (Commission Directive, 1999).

Moreover, the European Commission is finalising proposals on:

- aflatoxins in certain spices (chillies, peppers, ginger, etc.) of 5 μg/kg for Aflatoxin B1 and 10 μg/kg for total Aflatoxins, and
- ochratoxin A of 5 μg/kg in cereals, 3 μg/kg in cereal products and 10 μg/kg in dried vine fruit (currants, raisins, sultanas).

These proposals and proposals concerning other contaminants than mycotoxins were adopted by the Standing Committee for Foodstuffs in 2001, and they are expected to be officially issued soon. They will in due course become amendments to Commission Regulation 466/2001.

2.7. Future development

In Codex Alimentarius, the draft Standards and Codes of Practice concerning mycotoxins, which are discussed above, will be finalised within the next few years. There will be further discussion on whether there is a basis for international regulation of other mycotoxins, such as Trichotecenes.

In the EU the amendment to Commission Regulation 466/2001 concerning Aflatoxins in certain spices and Ochratoxin A in cereals and cereal products as well as in dried vine fruit, including methods of sampling and criteria for methods of analysis, shall soon be formally adopted by the Commission.

There will come further discussion, probably both in Codex Alimentarius and in the European Union, on subjects including:

- ochratoxin A in coffee, wine, beer, grape juice, cocoa and spices;
- patulin in apple juice, etc.;
- trichotecenes in cereals, etc.;
- other mycotoxins so far disregarded.

In future, more reliable data for the content of mycotoxins in foods and feeds will become available. Legislators in Codex Alimentarius and in the EU and other international bodies will have to discuss how to use these data effectively as risk management tools in order to protect public health and promote international trade. The establishment of detailed and specific Codes of Practice and sampling plans are going to be an important aspect of this discussion (Berg, 2001; Berg, Rasmussen, & Thorup, 1995; FAO, 1993).

References

Bal, A., & Berg, T. (1991). *Contaminants in food. Towards a Codex Approach, CX/FAC 92/10*. Rome: Codex Alimentarius Commission.

Berg, T. (2000). Development of the codex standard for contaminants and toxins in food. In N. Rees, & D. Watson (Eds.), *International standards for food safety*. Gaithersburg, MD: Aspen Publishers.

Berg, T. (2001). The international regulation of chemical contaminants in food. In D. H. Watson (Ed.), *Food chemical safety*. Cambridge: Woodhead Publishing.

Berg, T., Rasmussen, G., & Thorup, I. (1995). *Mycotoxins in Danish foods*. Publication nr. 225, National Food Agency of Denmark.

Codex Alimentarius Commission. (1999a). Position paper on zearalenone. CX/FAC 00/19, Rome: Codex Alimentarius Commission.

Codex Alimentarius Commission. (1999b). Position paper on fumonisins. CX/FAC 00/22, Rome: Codex Alimentarius Commission.

Codex Alimentarius Commission. (2000). *Procedural manual* (11th ed.) Rome: Joint FAO/WHO Food Standards Programme, FAO.

Codex Alimentarius Commission. (2001). Report of the 33rd session of the codex alimentarius committee on food additives and contaminants. ALINORM 01/12A.

Commission Directive. (1999). Commission directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition. *Official Journal, 50*(115), 4 May 1999, pp. 32–46.

Commission Regulation. (2001). Commission regulation (EC) 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs. *Official Journal, 50*(77), 16 March 2001, pp. 1–13.

Council Regulation. (1993). Council Regulation (EEC) 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. *Official Journal, 50*(37), 13 February 1993, pp. 1–3.

FAO. (1993). Sampling plans for aflatoxin analysis in peanuts and corn. Food and nutrition paper No. 55, Rome.

FAO. (1997). Application of risk management to food safety matters. Report of the joint FAO/WHO consultation, FAO Food and Nutrition paper no. 65, Rome: FAO.

FAO. (2000). Preamble and annexes. Codex general standard for contaminants and toxins in food. CODEX-STAN 193-1995 (Rev. 1-1997). Rome: Joint FAO/WHO Food Standards Programme, FAO.

FAO/WHO. (2001). Summary and conclusions. In *56th joint FAO/WHO expert committee on food additives, Geneva, 6–15 February 2001*.

WHO. (1995). *Application of risk analysis to food standards issues*. Report of the joint FAO/WHO expert consultation, Geneva 13–17 March 1995, Geneva.

World Trade Organization. (1995). *Agreement on the application of sanitary and phytosanitary measures, legal texts, Uruguay round of multilateral trade negotiations*. Geneva: World Trade Organization.

Torsten Berg
Danish Veterinary and Food Administration
Mørkhøj Bygade 19, DK-2860
Søborg, Denmark
E-mail address: tb@fdir.dk
9 November 2001