Discussions on ochratoxin A (OTA) within the Codex Committee on Food Additives and Contaminants (CCFAC) began in 1991 (see: 'Overview of the work of Codex Committee on Food Additives and Contaminants (CCFAC)' [.pdf], found in the Support Documentation area of this Section). At its 27th Session in 1995, CCFAC requested the delegation of Sweden to prepare a position paper on OTA.

The paper was introduced at the 28th Session of the Committee. It reviewed toxicological evaluations and intake data as well as maximum limits currently applied and made specific recommendations, especially for establishing a maximum level for ochratoxins in cereals and the development of a code of practice to minimise exposure to OTA. Discussions on the issue during that session focussed on methods of analysis and sampling, potential problems in trade if a level of 5 µg/kg was established and the possible development of a code of practice. It was noted that the carcinogenicity of ochratoxin A had been evaluated twice by JECFA in 1991 and 1995 (37th and 44th meetings respectively) (see: 'Overview of JECFA and its role in establishing international standards and guidelines on contaminants in foods and feed' [.pdf], found in the Support Documentation area of this Section).

Discussions of the topic continued in the Committee during its 29th Session and the Delegation of Sweden was to revise the position paper according to the comments of the Committee. The revised position paper was introduced at the 30th Session in 1998. Special attention was focused on the fact that a number of Aspergillus species were able to produce OTA. Possible genotoxic carcinogenic and nephrotoxic properties were mentioned. Dietary exposure from sources other than cereals (e.g. wine, fruit juices, pig meat and coffee) was also highlighted. The main recommendations were the need for a code of practice for the reduction of OTA levels in cereals, and the establishment of a maximum level of 5 µg/kg for cereals and cereal products intended for direct human consumption.

Many delegates agreed that standards for commodities other than cereals needed to be considered. Several countries referred to JECFAs most recent toxicological evaluation, and stated that JECFA needed to clarify its position on the carcinogenicity of ochratoxin A, and noted that an updated risk assessment might be necessary. At the end of the session, the Committee concluded that it would be premature to set a maximum OTA level for cereals and accepted the offer of Sweden to prepare an updated version of the position paper for circulation, comment and discussion at its next meeting.

At its 31st Session in 1999 the Committee considered an updated version of the position paper was presented. Many countries supported the proposal to develop a code of practice for prevention of contamination by ochratoxin A in cereals. The Committee asked the Delegation of Sweden to develop this code, assisted by the United States, Canada, the United Kingdom, the Netherlands and Argentina. The Committee agreed to propose the elaboration of the code as new work to the CAC.
The Committee also discussed the proposal for a maximum level of 5 µg/kg for ochratoxin A for cereals and cereal products. Many delegations supported this proposal, including the Observer from Consumers International who stressed the need for immediate action to protect consumers. However, some delegations were in favour of obtaining more information about contamination levels and distribution, problems in trade and a risk assessment from JECFA, before initiating the process for establishing a maximum level. The Committee requested JECFA to perform a risk assessment of the consequences of establishing a maximum level of 5 µg/kg or 20 µg/kg for ochratoxin A in cereal and cereal products.

The Codex Alimentarius Commission approved the elaboration of the proposed draft 'Code of Practice for the Prevention of Contamination by Ochratoxin A in Cereals' as new work in 1999. At its 32nd Session in 2000, the Committee decided to create a single general proposed draft 'Code of Practice for the Prevention of Mycotoxin Contamination in Cereals', with an Annex related to the prevention of ochratoxin A contamination.

In 2001, JECFA performed the risk assessment requested by CCFAC and concluded that the mechanism of carcinogenicity was unknown. The JECFA Secretariat noted that further studies were underway on this issue and that ochratoxin A should be evaluated in 2004. The JECFA meeting therefore retained the previously established PTWI of 100 µg/kg body weight per week. The 95th percentile of cereal consumers would have an intake close to the PTWI, regardless of which limit (5 µg/kg or 20 µg/kg) of ochratoxin A was employed in intake calculations for cereals and cereal products. The JECFA Secretariat noted that the difference in exposure at these two levels, on the basis of available data, were not significant.

The 33rd Session of the CCFAC in 2001 decided to return the proposed draft maximum level of 5 µg/kg ochratoxin A in Cereals and Cereal Products to Step 3 for additional comments, noting the findings of the JECFA risk assessment.

Several delegations indicated that because the difference in health risk between the two proposed limits was negligible, a level of 20 µg/kg could be adequate in terms of food safety. Moreover, it was noted that the contribution of some cereals to total intake was not highly significant and did not justify the establishment of a maximum level applicable to all cereals. Other delegations stressed that insofar as intake due to cereal consumption was close to the PTWI, and because many other foodstuffs contributed to total ochratoxin A intake, the level should be kept as low as possible. Some delegations indicated that the levels found in cereals in Europe would justify setting an even lower level in cereal products such as 3 µg/kg.

After an extensive discussion, the Committee agreed that it would be generally acceptable and practically achievable to establish a maximum level of 5 µg/kg for ochratoxin A in the cereals wheat, barley and rye and derived products.

At its 34th Session in 2002, CCFAC agreed to forward the revised proposed draft 'Code of Practice for the Prevention (Reduction) of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes', to the Executive Committee for preliminary adoption at Step 5.
The Committee also agreed to forward the draft maximum level of 5 µg/kg for ochratoxin in raw wheat, barley and rye and derived products to CAC for adoption.

The CAC adopted the Code of Practice at its 26th Session in 2003, but noted that there was no consensus over the draft maximum level and decided to send the draft maximum level back to Step 6 of the Codex process for further consideration by CCFAC.

At its 36th Session in 2004, CCFAC agreed to limit the draft standard to raw wheat, barley and rye and not to include derived products, since many of them were of little significance to international trade. The delegation of the EC stated that occurrence data from EU countries indicated that a level of 5 µg/kg was technologically achievable and that the ALARA principle should apply. Other delegations argued that a maximum level of 20 µg/kg was appropriate since the 2001 JECFA evaluation showed no difference in public health impact when possible maximum levels of 5 µg/kg or 20 µg/kg were considered, on the basis of occurrence data made available to the Committee for evaluation.

CCFAC concluded that it would hold the draft maximum level at Step 7 and request that JECFA give priority to a re-evaluation of OTA in 2006 depending on the availability of new data on occurrence of contamination, dietary exposure to OTA, and toxicology.