codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 16 J **CX/FAC 03/35-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
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DISCUSSION PAPER ON DEOXYNIVALENOL, INCLUDING INFORMATION AND DATA SUBMITTED ON THE OCCURRENCE OF DEOXYNIVALENOL IN CEREALS IN RESPONSE TO CL 2002/10-FAC

COMMENTS

The following comments have been received from Australia, Canada, Uruguay, ISDI:

AUSTRALIA:

Australia appreciates the opportunity to comment on CX/FAC 03/35 – Discussion Paper on Deoxynivalenol prepared by the Belgium Delegation, with the assistance of Canada, Denmark, Germany, the Netherlands, Switzerland, the US and the EC.

Australia believes that the discussion paper presents a very good summary of the occurrence, screening and analytical methods, prevention, decontamination and effects of processing for Deoxynivalenol (DON). Australia congratulates the drafting group on these aspects of the discussion paper and agrees that it is desirable to reduce the levels of DON to levels as low as is reasonable achievable using good agricultural practices. We note that no information on levels is available in the paper but that data from Europe, Canada and the USA is quoted.

However, whilst Australia would agree that the appropriateness of setting of maximum levels on DON in foodstuffs should be discussed by CCFAC, Australia would have some concerns regarding the assumptions made to develop the proposed maximum levels of DON in foodstuffs. Australia has also made several comments in relation to the good agricultural practice issues. Our comments are as follows:

1. Receival and Other Marketing Issues

1. Text Document

1.1 Australian experience supports the statements relating to the sampling of bulk product and the difficulty in obtaining representative samples.

1.2 Australia also agrees that looking at damaged kernels cannot be used to predict DON levels. The draft Code of Practice previously supplied and referred to in the document will assist in this regard.

1.3 We agree with statements in paragraph 33 relating to "developing ways to reduce, eliminate and control Mycotoxin concentrations in commercial shipments and end-products". This must leave the option open for marketers to actively alter the concentration of any Mycotoxin in a product, ensuring that the final commercial parcel of grain meets relevant regulations. The level of Mycotoxin contamination in small parcels such as a truckload of grain is generally not homogeneous, thus it is difficult to set an appropriate standard and ensure the sampling and testing procedure is adequate. When marketers purchase a load of grain, having the option to actively mix that grain via a number of movements during the storage and transport phase is vital to our ability to purchase the grain. This is especially so in Australia which relies on the accumulation of grain from a number of sources, in order to meet stringent standards for a range of quality parameters on outturn.

1.4 Paragraph 34 states various cleaning and downstream processes may reduce the level of DON in grain. However, as a marketer of grain, Australia must market to an appropriate standard at the point of sale. We cannot rely on a buyer to process the commodity to meet a standard. A further reason why processing to a standard is not relevant in Australia is that the common ownership and storage of grain results in frequent stock swaps and transfer of grain from one owner to another. Thus we may purchase a parcel of grain at a particular standard intended for one market, but eventually ship an entirely different unrelated parcel from another storage site.

1.5 We agree that trade disruption due to DON or head scab limits is a concern.

1.6 Prevention of contamination in all grower loads tendered for delivery is not practicably achievable at present and maximum levels must be set for consumer products as a preference, followed by raw cereal grains. In either case, separate levels for food and feed, including offal, should be set once all relevant information on global dietary exposure is obtained.

1.7 Referring to paragraph 69, the setting of harmonised maximum levels may provide transparency for international trade, but not necessarily be reflected in importing country or buyer requirements.

1.8 Australia strongly believes that the option of the ability to mix grain to meet standards must be available, as the process of storage and handling of grain in Australia reflects such a practice. In the absence of an economic, practical and accurate test at receival, marketers will not consider setting a Receival Standard limit. In reality, the infrequent nature of DON contamination would cause Receival Agents to question the need for a Mycotoxin test on every load tendered for delivery due to the costs and time required to conduct the testing. Thus any isolated parcels or incidents of DON contamination must be able to be addressed by such means as mixing of parcels of wheat.

2. Exposure and Risk Characterisation

As acknowledged in the draft discussion paper, JECFA estimated the dietary intake of DON on the basis of the single weighted mean concentrations for each commodity and the GEMS/Food regional diets. JECFA noted that there was considerable uncertainty in the intake estimates, and also possible reductions in levels of DON as a result of processing were not taken into consideration in the assessment.
It is stated in the Discussion Paper that there was incomplete coverage for regions outside of the European region and data from the European region "was used to estimate concentrations in other regions". It is admitted that the use of European data "could have led to either an over- or under-estimate of exposure in regions other than the European region".
Based on the use of the European data, it was shown that the PMTDI of 1 μg/kg bw/day may be exceeded in 4 of 5 GEMS/Food regional diets. There is an underlying assumption that concentration data collected in Europe and used in the modelling matched the consumption data. The GEMS/Food regional diets are a representation of European countries plus North America, but are not a true representation of the potential dietary exposure in the different regions. Therefore, the suggestion that it is quite likely that the PMTDI is exceeded by a substantial percentage of the world's population cannot be substantiated on the basis of the limited, current available data on global exposure to DON using only the GEMS/Food regional diets. Australia considers that it is therefore premature to propose maximum levels for DON until such time as data is made available from member countries that is more representative of global exposure.

Moreover, the maximum level suggested for all products derived from cereals (500 μg/kg) under Paragraph 70 (b) is at least two times lower than guideline levels used in some countries (e.g. 1000 μg/kg in USA and 1200 μg/kg in Canada), and ten times lower than most other maximum levels in place in any other country in relation to the new suggested maximum level of 100 μg/kg for cereal-based infant food. The scientific basis for such recommended levels is not elaborated in the discussion paper, other than the speculation that the PMTDI might be exceeded on the basis of limited exposure data available from the GEMS/Food regional diets. For example, there is no evidence offered as to why the level of 100 μg/kg recommended for cereal-based infant food is warranted or scientifically justified, or that it is possible to segregate cereals used for such purposes from other uses.

In relation to the lack of complete information on global exposure for DON, it might be worthwhile to note the recent report of the **Evaluation of the Codex Alimentarius and other FAO and WHO Food Standards Work.** On page 49 of this report, an example is given on the problems encountered with the elaboration of the maximum level for Aflatoxin M1 in milk, which took almost a decade to finalise. In this example, it is pointed out that attempting to set maximum levels for contaminants on the basis of incomplete global exposure data is highly problematic, and leads to lengthy delays and lack of consensus on the finalisation of the maximum level. The example for Aflatoxin M1 in Milk has many similarities with the current situation for DON, and it will be important not to repeat the same mistakes in relation to DON made previously for Aflatoxin M1 in milk.

<u>Recommendation:</u> Australia recommends that MLs for DON should not be elaborated until such time as data is made available to CCFAC on levels for DON in a significant number of countries that are more representative of global exposure.

CANADA:

Background

The 34th CCFAC agreed that a drafting group led by Belgium would revise the Discussion Paper on Deoxynivalenol for circulation, comments and consideration at its next session. The 34th CCFAC also agreed to request additional information and data on the occurrence of deoxynivalenol in cereals, as well as the results of any studies on the effect of processing, for consideration at its next session (ALINORM 03/12, para. 163).

Canadian Position

Canada has actively participated as a member of the working group, led by Belgium, that drafted the discussion paper on deoxynivalenol (DON). Canada would like to congratulate Belgium for the work that it has conducted, and supports the presentation of this document for consideration at the 35th Session of CCFAC.

The Discussion Paper proposes that the appropriateness of establishing maximum levels (ML's) for DON in raw cereal grains and foodstuffs derived from cereals be discussed. It further suggests ML values for three food groupings. The proposed 2000 µg/kg ML for DON in raw cereal grains is in line with Canada's 2.0 ppm (2000 µg/kg) guideline level for DON in uncleaned soft wheat for use in non-staple foods. DON is generally found at only very low levels in Canadian hard wheat. Hence, Canada does not have guidelines for deoxynivalenol in hard wheat. Rather, the human intake of DON from hard wheats has been calculated on a case-by-case basis and it has been demonstrated that DON intake from hard wheat is generally very low, with the exception of wheats grown in a few specific areas and under certain climatic conditions.

Canada continues to support the application of strict codes of practice to minimise DON exposure from cereal-based foods, particularly foods consumed by infants. Indeed, there is a Canadian guideline of 1.0 ppm (1000 µg/kg) DON in uncleaned soft wheat for use in infant foods. However, a maximum level of 100 µg/kg DON in cereal-based infant foods, as proposed in the Discussion Paper, may have a significant global impact on the availability of cereal-based foods, particularly in certain years when climatic conditions are such that high *Fusarium* incidence and damage are unavoidable. For example, a comparative review of recent (1997-2000) Canadian infant cereal monitoring data in relation to the proposed Codex ML's has revealed that 20% of barley-based cereals exceeded the proposed ML for infant cereals. Of multi-grain cereals, 29% were above this proposed ML. Limited monitoring of soy-based cereals revealed a similar trend and recent published data suggest that such excursions above the proposed ML's are not unique to Canada.

This highlights the potential difficulties associated with the establishment of ML's for mycotoxins in food commodities as consumed. Mycotoxins are natural toxins, the occurrence of which is influenced by local growing conditions and, in turn, general climatic conditions. As a result, some degree of flexibility is necessary with respect to regulating the level of DON in foods. Consider a hypothetical scenario, where climate conditions in a particular growing season cause increased incidence of *Fusarium* head blight in many countries. The effect of firmly enforcing ML's based on DON background levels in such a hypothetical case could have a wide-reaching impact.

The discussion document also alludes to the determination of an "ALARA level" based on scientific information and data contributed by interested countries. The factors mentioned above may confound the determination of an "ALARA level", which is, in a sense, a "moving target." This level could be expected to have temporal (based on annual growing conditions) and geographic variability, rather than having a static value.

For the reasons cited above, it is Canada's view that further global monitoring of DON levels in cereals and other foods should be conducted and it is premature for the Committee to set maximum levels for DON at this time.

In response to Circular Letter 2002/10-FAC (April 2002), Canada is pleased to provide the following data and information in connection with Item 16, Part C:

(1) A table summarising recent Health Canada monitoring data for infant and adult cereals sampled in Canada, and representing both domestic and imported products (see next page).

(2) Hard-copies of four journal publications (attached) relating to the occurrence of deoxynivalenol in Canadian cereal samples:

- Stratton, G.W., *et al*., Levels of Five Mycotoxins in Grains Harvested in Atlantic Canada as Measured by High Performance Liquid Chromatography, *Archives of Environmental Contamination and Toxicology*, 24: 399-409, 1993.

- Scott, P.M., Multi-year monitoring of Canadian grains and grain-based foods for trichothecenes and zearalenone, *Food Additives and Contaminants*, 14(4): 333-339, 1997.

- Campbell, H., *et al.,* Mycotoxins in barley and oat samples from eastern Canada, *Canadian Journal of Plant Science*, 80(4): 977-980, 2000.

- Campbell, H., *et al.*, Comparison of mycotoxin profiles among cereal samples from eastern Canada, *Can. J. Bot.*, 80: 526-532, 2002.

- Scott, P.M., Mycotoxins transmitted into beer fro contaminated grains during brewing, Journal of AOAC International, 79(4): 875-882, 1996.

Canadian Monitoring Data on Deoxynivalenol - Compiled September 2002

Concentration means are determined after setting non-detects[1] to zero. DL or QL is either the Detection Limit (DL) or the Quantification Limit (QL).

Commodity	**N**	**DL or QL µg/g**	**Mean / µg/g**	**Range positives/ µg/g**	**No. < D/QL**
Infant cereals, general (00/01)	105	0.01	0.04	0.01-0.9	60 (57%)
Infant cereals, oatmeal-based (97/98 - 99/00)	53	0.02	0.032	0.028-0.094	20 (40%)
Infant cereals, barley-based (97/98 - 99/00)	50	0.02	0.15	0.02-1.0	21 (42%)
Infant cereal, multi-grain (97/98 - 99/00)	86	0.02	0.084	0.02-0.398	24 (28%)
Infant cereal, soy-based (97/98 - 99/00)	8	0.02	0.12	0.02-0.24	0 (0%)
Infant cereal, rice-based (97/98 - 99/00)	9	0.02	<0.02	All below 0.02	9 (100%)
Adult Breakfast Cereals (00/01)	60	0.01	0.07	0.01-0.94	27 (45%)
Adult Breakfast Cereals (99/00)	51	0.01	0.01	0.01-0.14	30 (59%)
Wheat-based foods [2] (96/97)	100	0.1	0.39	0.1 - 3.2 [3]	33 (33%)
Infant cereals, cookies, biscuits, containing wheat (96/97)	11	0.1	<0.07	0.12 - 0.22	6 (55%)

[1] "Non-detects" are samples in which deoxynivalenol was not detected above the limit of quantification or limit of detection (depending on the laboratory reporting procedure).

[2] Flour, bread, cookies, crackers, cake and pancake mixes, and adult cereals.

[3] The highest sample was a white flour sample. The next highest samples were a whole wheat flour sample containing 2.6 µg/g and a cracker containing 1.35 µg/g deoxynivalenol.

URUGUAY:

Uruguay has suffered two consecutive years of very favorable climatological conditions for the infection of its crops with Fusarium. This has caused an extensive contamination by Deoxynivalenol (DON) of the cultivated cereals and the foodstuffs derived from them. Therefore, Uruguay is now updating its national legislation for the prevention and control of mycotoxins in cereals, with special emphasis on the control and prevention of DON.

FAO is collaborating in this work through de Project TCP/URU/2801 (A) 'Support for the Prevention and Control of Fusarium and Mycotoxins in Cereals'. In the framework of this project the undersigned are

taking part as legal advisers. Our work consists of compiling the international regulations and the relevant national legislation, and developing a legal and regulatory framework project for mycotoxins in Uruguay.

We have reviewed the documents of the Codex Committee on Food Additives and Contaminants (CCFAC) applying to these subjects, in particular CX/FAC 03/05 'Discussion Paper on Deoxynivalenol' and ALINORM 03/12, Appendix XII.

We are writing to you because we would like to have access to the members' answers to the specific questions of document CX/FAC 03/35, Para. 1, for which the period for sending in comments expired on December the 31st 2002.

We should also like to know whether after the 34th Session of the CCFAC the governments were asked to send in comments on ALINORM 03/12, Appendix XII, and if so, whether we could have access to those comments as well.

If necessary we could ask the Codex Contact Point for Uruguay to make an official request.

We would be very grateful for any information that you could give us concerning this.

ISDI:

ISDI is in favor of having separate limits for baby food if it justified from a toxicological point of view, but the limits should be achievable throughout the years. 100 ppb is not an achievable limit over several years.

ISDI welcomes the discussion paper prepared by the Belgium delegation especially the acknowledgment that if CCFAC opts for the setting of maximum levels for DON, complementary to the development of the Code of Practice for the prevention of mycotoxins contamination in cereals, this has to be based on the ALARA principle (para 69.)

Nevertheless, ISDI disagrees with the level proposed for discussion for cereal-based infant food which is 5 times lower compared to the level proposed for all other products derived from cereals intended for direct human consumption (100 and 500 µg/kg respectively).

ISDI believes a level of 100 µg/kg for processed cereal-based foods intended for infants and children (as defined in Codex Standard 74-1981) does not correspond to an ALARA level considering that such a low level may be achievable one year, but not over a longer period of time due to the existing year to year variation. Indeed, as described in the discussion paper, the level of DON is very much dependent of the climatic conditions. Moreover data from the baby food industry shows that the level of 100 ppb is not achievable throughout a period of years.