

CODEX ALIMENTARIUS COMMISSION **E**



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS (AT STEP 3)

INCLUDING THE POSSIBLE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF
MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RECP 51-2003)

Codex Members and Observers wishing to submit comments at Step 3 on the proposed draft maximum level for DON in cereals and cereal-based product and associated sampling plans, including possible implications for their economic interests, should do so in conformity with the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* (Codex Alimentarius Commission Procedural Manual) before **2 March 2012**. Comments should be directed:

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BACKGROUND

1. The 5th session of the CCCF agreed to re-establish an e-WG, led by Canada, to proceed with the elaboration of MLs for DON in cereals and cereal-based foods (REP11/CF, para. 34 – 43). The possible extension of MLs for DON to the acetylated derivatives is to be considered at the 8th session of the Committee. The proposed draft MLs for DON (CX/CF 11/5/6) were returned to Step 2/3 for further development, including the development of associated sampling plans. The Committee also requested that the possibility of revising the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) be explored. A number of Codex members and observers expressed an interest in participating in the e-WG, namely representatives from Argentina, Austria, Belgium (International Special Dietary Foods Industries), Brazil, Canada, China, Dominican Republic, European Union, France, Ghana, India, Italy, Japan, Norway, Tanzania, United Kingdom, United States of America and Uruguay (see Appendix III).

INTRODUCTION

2. This document builds on the previously presented *Proposed Draft Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and Cereal-based Products* (CX/CF 11/5/6). Its objective is to further elaborate the proposed draft MLs for DON in cereals and cereal-based foods in the context of public health and with consideration to achievability. A sampling plan for DON, based largely on the existing European Union sampling plan for DON in cereals has been developed. The possibility of updating and revising the *Codex Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) is also discussed (see Appendix I).

3. An impact assessment of various hypothetical MLs is presented using full occurrence data sets from Austria, Brazil, Canada, China, Japan, South Africa, the United Kingdom and the United States of America, rather than pooled or aggregate data. This provides additional context for the discussion of the proposed MLs from both a health and trade perspective (see Appendix II).

REQUEST FOR COMMENTS

5. Codex Members and Observers are kindly invited to send their comments on the proposed Maximum Levels for DON in cereal and cereal-based products including associated sampling plans as presented in paragraph 12 of Appendix I for consideration by the 6th Session of the Codex Committee on Contaminants in Foods.

6. While considering the proposed MLs and sampling plans, due consideration should be given to the conclusions and recommendations accompanying these proposals.

**PROPOSED DRAFT MAXIMUM LEVELS FOR DON IN CEREALS AND CEREAL-BASED PRODUCTS
AND ASSOCIATED SAMPLING PLANS¹**

(At Step 3)

CONCLUSIONS AND RECOMMENDATIONS

6. The Criteria for the Establishment of Maximum Levels in food and feed of the *Codex General Standard for Contaminants and Toxins in Food and Feed*, suggest that MLs should be set as low as reasonably achievable and at levels that are protective of human health. Based on the information presented in this assessment, it may be difficult to satisfy both of these criteria for DON. For high percentile consumers, especially children, it appears that the PMTDI and in some cases the ARfD has the potential to be exceeded based on current levels of DON contamination.

7. Worldwide consumption patterns of individual cereal grains such as wheat, maize and barley vary significantly which makes it difficult to set MLs that are protective of all consumers globally. The variation in DON contamination of cereal grains and cereal-based foods can also vary significantly from region to region and year to year, adding to the difficulty of setting MLs. The ability to control the occurrence of DON in cereals, and the nature of the occurrence data that are available make it challenging to determine the typical range of DON variation on a global scale and thereby apply the ALARA principle in establishing MLs. As well, it is apparent, based on the available data, that some countries will be better able to meet any proposed MLs than others.

8. The Committee may wish to consider whether DON contamination patterns are sufficiently understood in all areas of the world and whether more surveys are needed in order that the impact, both in terms of health and economic implications, of MLs in those regions can be adequately assessed. Data is lacking from many Central American, South American, Asian, and African countries which are areas of considerable exporting and importing activities of wheat, maize or barley. Multiple year data may also be considered to capture potential climactic effects that may result in temporarily high occurrences of DON. Attempting to set MLs for contaminants on the basis of incomplete global occurrence and exposure data can be problematic, and can lead to lengthy delays and lack of consensus in the finalization of MLs. The setting of an ML for aflatoxin M1 in milk is one example (FAO/WHO, 2002).

9. It may be beneficial to have information on the degree to which recommended practices of the *Codex Code of Practice for the prevention and reduction of mycotoxin contamination in cereals* (CAC/RCP 51-2003) are applied in various countries, given that deficiencies in this area could have a significant influence on the DON content of cereal grains. Good Agricultural Practices and Codes of Practice for the prevention and reduction of mycotoxin contamination of cereals represent the primary line of defence against contamination of cereals with DON, followed by implementation of Good Manufacturing Practice during the handling, storage, processing and distribution of cereals for human food. In this regard, it is important to verify whether occurrence data used for the purposes of proposing MLs reflect the application of these good practices.

10. Many countries have set limits for DON in foods, and these tend to be fairly consistent with one another (Appendix II.A). While several countries have, for example, a general ML for wheat, wheat flour and/or wheat-based foods, the European Union has, in addition to establishing MLs for raw cereal grains, established separate MLs for a variety of finished foods.

11. As noted previously, the possibility of applying processing factors was examined but is currently not considered feasible for the global population. As such, the Committee may give consideration to establishing MLs only for raw cereal grains and semi-processed products such as flour, rather than processed cereal-based foods such as breads and breakfast cereals, with the exception of cereal-based foods intended for infants and young children.

12. The setting and implementation of MLs in conjunction with Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP), which are described in the *Code of Practice for the prevention and reduction of mycotoxin contamination in cereals* (CAC/RCP 51-2003) should contribute to the reduction of mean DON levels by helping to prevent the marketing and consumption of highly contaminated foodstuffs. Setting harmonized maximum levels for raw cereals may provide clear guidance and transparency for international trade. The achievability of, and compliance with, MLs during years of high levels of DON contamination, such as those demonstrated in Tables 9 and 10, as well as the ability to redirect cereals containing elevated levels for other uses, should be further discussed in order to ensure a sufficient food supply and availability of staple foods at all times.

Specific recommendations are provided below:

- The Committee may consider that further data collection as described in the preceding paragraphs is necessary. However, the CCCF may consider the following MLs, which are proposed taking into consideration the following: MLs that were proposed previously (CX/CF 11/5/6); the effects of milling on the DON content of milling fractions; the ML impact assessment conducted in this document; comments from e-WG members; and a comparison to maximum, guidance or reference values that are recognized in various countries (see Appendix II.A):

¹ Supporting information for the above recommendations are be found in Appendix II to this report.

Commodities	Description	Maximum Level (ML)
Raw cereal grains (wheat, maize and barley)	Raw wheat, maize and barley grain to be subject to sorting or other physical treatment before human consumption or before use as an ingredient in other foods	2 mg/kg
Semi-processed products derived from wheat, maize and barley	Flour, semolina, meal, grits, flakes, starch	1 mg/kg
Cereal-based foods for infants (up to 12 months) and young children (12 to 36 months)	Cereal-based foods for infants and young children (e.g., infant cereals, biscuits for infants and young children, pasta for infants and young children)	0.5 mg/kg

- The Committee may wish to consider setting MLs only for those commodities that are important in terms of international trade, such as primary agricultural products (i.e., raw cereal grains and semi-processed products such as flour) as suggested by the 'Criteria for the Establishment of Maximum Levels in Food and Feed' in the *Codex General Standard for Contaminants and Toxins in Food and Feed*, rather than processed products such as bakery wares, breads and breakfast cereals. Since DON occurs at the raw grain level, controlling levels in the raw and semi-processed products would ensure that the levels in processed products are reduced. It is considered that levels in processed products should be lower than what is being proposed for semi-processed products due to the effects of processing in the manufacture of processed products.
- The Committee may consider that a lower ML should be set specifically for cereal-based infant and young children foods since infants and young children may be considered the most vulnerable group in terms of the critical chronic toxicological effect of reduced growth/growth retardation. The extent to which this is achievable should be discussed, as it would involve segregating cereals based on their DON content at an earlier stage to ensure lower levels of DON in these finished products.
- The Committee should consider how to address the enforcement of MLs during periods of increased DON contamination and when higher levels of DON are generally encountered.
- Codex member countries should continue to monitor, or implement monitoring programs, for the occurrence of DON and DON derivatives in wheat, maize and other cereals to allow further characterization of seasonal and regional differences, and to support future consideration of applying any DON MLs to acetylated derivatives of DON.
- When calls for data are made, members should continue to be encouraged to submit complete datasets to JECFA that include individual sample results rather than aggregate data, and that take geographical locations and regional differences into consideration.
- Should there be further work on the elaboration of DON MLs, it would be useful for members, especially those who are primary producers and exporters of cereal grains, to provide information on whether or not they have implemented this COP, whether it or other COPs have succeeded in reducing DON contamination and how the effectiveness and efficiency of the COP in monitored in terms of reducing DON contamination levels. Detailed, concrete information on the impact of the application of the COP on the levels of DON contamination to better enable the setting of MLs at levels that are as low as reasonably achievable (ALARA).

PROPOSED DRAFT SAMPLING PLANS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS

(At Step 3)

DEFINITIONS

Lot - 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.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by a deoxynivalenol test procedure and an accept/reject level. A deoxynivalenol test procedure consists of three steps: sample selection, sample preparation and analysis or deoxynivalenol quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample – the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample – the smallest quantity of cereal/cereal based product comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

Test portion – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the deoxynivalenol for chemical analysis.

Operating Characteristic (OC) Curve – a plot of the probability of a accepting a lot versus lot concentration for a specific sampling plan design. The OC curve provides an estimate of the chances of rejecting a good lot (exporter's risk) and the chances of accepting a bad lot accepted (importer's risk) by a specific deoxynivalenol sampling plan design. A good lot is defined as having a deoxynivalenol concentration below the ML; a bad lot is defined as having a deoxynivalenol concentration above the ML.

SAMPLE SELECTION

Material to be sampled

A) Sampling procedure for cereals and cereal products for lots \geq 50 tonnes

Each lot, which is to be examined for deoxynivalenol must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot has to be subdivided into sublots following table 1

Table 1 Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No incremental samples	Aggregate sample Weight (kg)
Cereals and cereal products	\geq 1 500	500 tonnes	100	10
	> 300 and < 1 500	3 sublots	100	10
	\geq 50 and \leq 300	100 tonnes	100	10
	< 50	--	3-100*	1-10

* Depending on the lot weight - see Table 2

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 subplot may exceed the mentioned weight by a maximum of 20%.

- Each subplot must be sampled separately.

- Number of incremental samples: 100. Weight of the aggregate sample = 10 kg

- If it is not possible to carry out the method of sampling set out in this point because of the commercial consequences resulting from damage to the lot such as packaging forms, means of transport, an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

Sampling procedure for cereals and cereal products for lots < 50 tonnes

For lots of cereals and cereal products less than 50 tonnes, the sampling plan must be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg.

The figures in Table 2 may be used to determine the number of incremental samples to be taken.

Table 2: Number of incremental samples to be taken depending on the weight of the lot of cereals and cereal products

Lot weight (tonnes)	No of incremental samples
≤ 0.05	3
$> 0.05 - \leq 0.5$	5
$> 0.5 - \leq 1$	10
$> 1 - \leq 3$	20
$> 3 - \leq 10$	40
$> 10 - \leq 20$	60
$> 20 - \leq 50$	100

Sampling procedure for cereals and cereal products for lots >>> 500 tonnes

Number of incremental samples (of about 100 g) to be taken:

100 incremental samples + $\sqrt{\text{metric tonnes}}$

Static Lots

A static lot can be defined as a large mass of cereals/cereal-based product contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the cereal /cereal-based product is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot may not be accessible.

Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container.

The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

$$SF = (LT \times IS) / (AS \times IP).$$

The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of cereals/cereal-based product as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and put together at frequent and uniform intervals throughout the entire time the flow past the sampling point.

Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

$$S = (D \times LT) / (T \times V),$$

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed as a function of S, V, D, and MR.

$$SF = (S \times V) / (D \times MR).$$

Packaging and Transportation of Samples

Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

Sealing and Labelling of Samples

Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

Precautions

Sunlight should be excluded as much as possible during sample preparation, since some mycotoxins may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and deoxynivalenol formation.

Homogenization - Grinding

As the distribution of deoxynivalenol is non-homogeneous, laboratory samples should be completely homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent deoxynivalenol cross-contamination.

Test portion

The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 grams.

Procedures for selecting the 25 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 25 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 25 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

Background

A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance Criteria for Methods of Analysis

A list of possible criteria and performance levels are shown in Table 3. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 3 Performance characteristics for deoxynivalenol

Level $\mu\text{g}/\text{kg}$	Deoxynivalenol		
	RSD _r %	RSD _R %	Recovery%
> 100 - \leq 500	\leq 20	\leq 40	60 to 110
> 500	\leq 20	\leq 40	70 to 120

APPENDIX II

**SUPPORTIVE INFORMATION ON THE ELABORATION OF PROPOSED MAXIMUM LEVELS (MLs)
AND ASSOCIATED SAMPLING PLANS INCLUDING AN IMPACT ASSESSMENT OF VARIOUS POTENTIAL MLs
AND THE POSSIBLE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION
OF MYCOTOXIN CONTAMINATION IN CEREALS**

ELABORATION OF PROPOSED MAXIMUM LIMITS (MLs)**Maximum Limits (MLs) for consideration**

13. The following MLs, proposed for consideration at the 5th session of the CCCF, were based on a review of mean occurrence levels (rather than a review of complete datasets, which were not available) and current nationally enforced MLs:

- a) raw wheat, maize and barley, to be subjected to sorting or physical treatment before human consumption or use as an ingredient in foodstuffs: 2 mg/kg
- b) all foods derived from wheat, maize, and/or barley, including those intended for direct human consumption, except cereal-based foods for infants and young children: 1 mg/kg
- c) cereal-based foods for infants (up to 12 months) and young children (12 to 23 months): 0.5 mg/kg

14. An impact assessment of various possible DON ML concentrations, separated by equal increments, is presented herein. The concentrations are based on those that were previously proposed as MLs, as well as levels that are enforced nationally in different countries (see Appendix II.A):

- a) for raw cereal grains, MLs of 2, 1.75, 1.5, and 1.25 mg/kg
- b) for semi-processed products such as cereal flours and similar products (e.g., flour, meal, grits, semolina) intended for direct human consumption and processed foods derived from cereal grains intended for direct human consumption, except cereal-based foods intended for consumption by infants and young children, 1.5, 1.25, 1, 0.75, and 0.5 mg/kg
- c) all cereal-based foods intended for consumption by infants (up to 12 months) and young children (12 to 23 months), 0.5, 0.3, and 0.2 mg/kg

15. The Committee may wish to consider setting MLs only for those commodities that are important in terms of international trade, such as primary agricultural products (i.e., raw cereal grains and semi-processed products such as flour) as suggested by the 'Criteria for the Establishment of Maximum Levels in Food and Feed' in the *Codex General Standard for Contaminants and Toxins in Food and Feed*, rather than processed products such as bakery wares, breads and breakfast cereals. This may also serve to focus enforcement and compliance efforts, where resources are limited, to a more limited number of commodities. Since DON occurs at the raw grain level, controlling levels in the raw and semi-processed products would ensure that the levels in processed products are reduced.

16. The Committee may consider that a lower ML should be set specifically for cereal-based infant and young children foods since infants and young children may be considered the most vulnerable group in terms of the critical chronic toxicological effect of reduced growth/growth retardation. The extent to which this is achievable should be discussed, as it would involve segregating cereals based on their DON content at an earlier stage to ensure lower levels of DON in these finished products.

Cereals that are significant with respect to their contribution to total dietary DON exposure

17. The proposed MLs focus on wheat, maize and barley because these are the cereals that were found, during JECFA's 2010 evaluation, to contribute significantly to total dietary exposure to DON, as per the criteria described in Section 3 (Identification of Foods/Food Groups that Contribute significantly to the Total Dietary Exposure of the Contaminants or Toxin) of Section IV (Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups) of the Codex Procedural Manual (Codex 2011).

18. Specifically, in 2001 at its 56th meeting, and in 2010 at its 72nd meeting, JECFA assessed the levels and patterns of contamination of cereals by DON on the basis of occurrence data submitted by various members (FAO/WHO, 2001; FAO/WHO, 2010). Wheat was found to be a significant contributor to DON exposure in all cluster diets for which occurrence data was available, contributing from 20 to 89% of total exposure in the clusters where data on multiple commodities were available. Maize was the next highest contributor, although intakes from maize varied considerably between regions, accounting for 2 to 80% of total DON exposure. Barley contributed from 2 to 14% of total DON exposure. Unlike the 2001 assessment, the 2010 assessment found that rice was not a major contributor to total exposure. Oats, rye, and beer had minimal contributions to total DON exposure.

Evaluation of acceptable levels of DON in terms of health protection using the PMTDI and ARfD

19. Table 1 shows the concentrations of DON in various cereal products required for the general world population (using GEMS/Food consumption cluster diets) to reach a DON exposure equivalent to the PMTDI of 1 µg/kg bw. These concentrations were determined by dividing the PMTDI by the consumption of wheat, maize, barley, total cereals or their semi-processed products using the GEMS/Food consumption cluster diets and assuming a body weight of 60 kg.

20. A similar calculation was performed using both the EFSA Concise Food Consumption database and the EFSA Comprehensive Food Consumption database for chronic intakes (see Tables 2 and 3, respectively). While these calculations do not allow for the determination of maximum levels for commodities specifically, they do allow for the determination of maximum average concentrations that would not result in the PMTDI being exceeded in the long term.

21. The calculated concentrations can be compared to average levels of DON that are seen in various surveys. In this regard, if these levels are compared to the mean occurrence values that were used for cereal grains in the JECFA evaluations (Table 2 in CX/CF 11/5/6), it can be observed that for some diets, the actual means are higher than what might be considered appropriate based on GEMS/Food consumption figures. This is not surprising even for the relatively lower, weighted means presented in Table 2 of CX/CF 11/5/6 due to the large variation in consumption of cereal grains between different cluster diets. For example, for wheat, consumption by cluster diet C is 10 times higher than that for cluster diet J (the lowest); for maize, consumption by cluster diet H is 40 times higher than for cluster diet F; and for barley, the highest consumption among the cluster diets is 38 times higher than the diet with the lowest consumption. The variation that is observed in amounts consumed is even greater when comparing the semi-processed products between the various cluster diets. This highlights the difficulty in setting MLs for the global population due to the wide variations in cereal grain consumption patterns that exist between different cluster diets and countries, even before occurrence data is factored in. This also suggests that any proposed MLs may not necessarily be sufficient to protect consumers worldwide. However, less variability exists in total cereal consumption between the various cluster diets (the amount consumed in cluster diet C is 2.3 times higher than that in cluster diet F). Relatively lower levels of DON were detected in processed products: mean levels of DON did not exceed 1.25 µg/g (FAO/WHO, 2011).

Table 1. Maximum average concentrations of DON that the general world population (using GEMS/Food consumption cluster diets) could be exposed to over a long period of time without exceeding the PMTDI of 1 ug/kg bw for DON, or percentage thereof. Calculation based on a 60 kg body weight.

CODE	GEMS - CEREALS		A	B	C	D	E	F	G	H	I	J	K	L	M
<u>RAW COMMODITIES</u>															
GC 654	Wheat	consumption (g/day)	88.4	396.3	426.5	390.2	236.3	216.0	172.9	79.0	68.1	41.9	114.1	103.4	234.2
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	0.68	0.15	0.14	0.15	0.25	0.28	0.35	0.76	0.88	1.43	0.53	0.58	0.26
GC 645	Maize	consumption (g/day)	82.7	148.4	135.9	31.8	33.3	7.5	35.2	298.6	248.1	57.4	63.1	58.6	85.5
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	0.73	0.40	0.44	1.89	1.80	8.00	1.70	0.20	0.24	1.05	0.95	1.02	0.70
GC 640	Barley	consumption (g/day)	40.6	16.8	93.9	13.2	48.6	36.1	5.9	20.5	5.9	2.5	20.2	16.8	43.8
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	1.48	3.57	0.64	4.55	1.23	1.66	10.17	2.93	10.17	24.00	2.97	3.57	1.37
GC 80	Total Cereals	consumption (g/day)	356.9	713.9	763.0	504.5	365.2	328.7	617.0	487.1	389.4	385.7	440.2	567.7	409.9
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	0.17	0.08	0.08	0.12	0.16	0.18	0.10	0.12	0.15	0.16	0.14	0.11	0.15
<u>SEMI-PROCESSED COMMODITIES</u>															
	Maize - flour and germ	consumption (g/day)	69.1	24.3	56.3	17.8	16.7	2.4	29.3	250.0	210.6	47.8	48.4	14.0	25.5
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	0.87	2.47	1.07	3.37	3.59	25.00	2.05	0.24	0.28	1.26	1.24	4.29	2.35
	Wheat - germ, bulgur wholemeal, and flour	consumption (g/day)	68.9	307.8	328.2	301.5	182.6	167.4	133.1	108.2	54.2	32.2	87.7	79.6	180.7
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	0.87	0.19	0.18	0.20	0.33	0.36	0.45	0.55	1.11	1.86	0.68	0.75	0.33
	Barley - pot, pearled, flour and grits	consumption (g/day)	29.0	0.7	50.6	4.7	2.9	14.3	1.6	0.1	0.1	0.7	4.1	4.9	0.1
	Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g)	2.07	85.71	1.19	12.77	20.69	4.20	37.50	600	600	85.71	14.63	12.24	600

Table 2. Concentrations of DON in various cereal products for exposure to reach the PMTDI of 1 µg/kg bw using the EFSA Concise Food Consumption Database

		mean	median	95th	97.5th	99th
Cereals & cereal products	consumption (g/day) range	153.5 - 372.4	140.1 - 300	283.4 - 760	330.5 - 1360	374.5 - 2792.0
Assuming exp. @ PMTDI (1µg/kg bw)	concentration (µg/g) range	0.16 - 0.39	0.2 - 0.43	0.08 - 0.21	0.04 - 0.18	0.02 - 0.16

Table 3. Concentrations of DON in various cereal grains and grain-based products for exposure to reach the PMTDI of 1 µg/kg bw using the EFSA Comprehensive Food Consumption Database for chronic intakes

	Cereals & cereal products	mean (range)	median (range)	95th (range)	97.5th (range)	99th (range)
Very Elderly	consumption (g/kg bw/day)	2.65 - 3.71	2.39 - 3.55	4.95 - 6.46	5.55 - 7.00	5.63 - 8.24
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.27 - 0.38	0.28 - 0.42	0.15 - 0.20	0.14 - 0.18	0.12 - 0.18
Elderly	consumption (g/kg bw/day)	2.01 - 3.44	1.86 - 3.33	3.75 - 6.01	4.20 - 6.64	5.15 - 7.91
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.29 - 0.50	0.30 - 0.54	0.17 - 0.27	0.15 - 0.24	0.13 - 0.19
Adults	consumption (g/kg bw/day)	2.04 - 3.71	1.90 - 3.52	3.78 - 6.99	4.22 - 8.00	4.96 - 9.46
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.27 - 0.49	0.28 - 0.53	0.14 - 0.26	0.13 - 0.24	0.11 - 0.20
Adolescents	consumption (g/kg bw/day)	3.24 - 6.14	2.96 - 5.59	6.16 - 12.01	7.56 - 12.95	8.45 - 15.70
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.16 - 0.31	0.18 - 0.34	0.08 - 0.16	0.08 - 0.13	0.06 - 0.12
Other children	consumption (g/kg bw/day)	5.13 - 10.65	4.84 - 10.35	8.64 - 23.26	9.70 - 31.06	11.78 - 36.58
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.09 - 0.20	0.10 - 0.21	0.04 - 0.12	0.03 - 0.10	0.03 - 0.08
Toddlers	consumption (g/kg bw/day)	5.92 - 10.51	5.29 - 10.45	10.47 - 18.84	10.47 - 19.92	10.47 - 21.03
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.10 - 0.17	0.10 - 0.19	0.05 - 0.10	0.05 - 0.10	0.05 - 0.10
Infants	consumption (g/kg bw/day)	5.75 - 5.82	5.28 - 5.97	12.71 - 14.42	12.71 - 15.77	12.71 - 17.47
Assuming exp. @ TDI (1µg/kg bw)	concentration (µg/g)	0.17	0.17 - 0.19	0.07 - 0.08	0.06 - 0.08	0.06 - 0.08

22. The acute reference dose (ARfD) for DON of 8 µg/kg bw, derived by JECFA (FAO/WHO, 2011), can also be used as an aid in the determination of acceptable MLs in the context of public health. Ideally, an ML should not be set at a level that could result in exposure exceeding the ARfD. Tables 4 through 7 demonstrate, based on various sources of food consumption data, acceptable levels of DON that would result in the ARfD for DON not being exceeded.

23. For Table 4, these levels were determined by dividing the ARfD by the consumption of wheat, maize, barley, total cereals or their semi-processed products using the GEMS/Food consumption cluster diets and assuming a body weight of 60 kg. A similar calculation was performed using the GEMS/Food Programme database of International Estimates of Short Term Intakes (IESTI) and Large Portion diets for acute dietary intake assessments, the EFSA Concise Food Consumption database and the EFSA Comprehensive Food Consumption database for acute intakes (Tables 5, 6 and 7).

24. In general, an ML of 1 µg/g would not result in DON exposure, based on mean consumption, exceeding the ARfD. However, it may not be protective for all high percentile consumers, especially children at the higher percentiles. Estimates made using the GEMS/Food IESTI and Large Portion database for acute intakes (Table 5) suggest that an ML of 1 µg/g is protective of most high percentile consumers with the exception of wheat and wheat flour.

25. If however, MLs are set for raw cereals that would be subject to further processing, such as cleaning and milling, prior to human consumption; and for semi-processed products such as flour, meal, grits and semolina intended for human consumption or for use as an ingredient in products to be further processed for human consumption, the proposed ML of 1 µg/g for semi-processed products may be considered more protective in that the effects of processing from semi-processed products to processed products would be expected to reduce DON further.

Table 4. Estimation of the maximum levels of DON in cereal grains and their semi-processed products that the general population could be exposed to without exceeding the ARfD of 8 µg/kg bw for DON using the GEMS/Food consumption cluster diets. Calculations assume a 60 kg body weight.

CODE	GEMS - CEREALS		A	B	C	D	E	F	G	H	I	J	K	L	M
<u>RAW COMMODITIES</u>															
GC 654	Wheat	consumption (g/day):	88.4	396.3	426.5	390.2	236.3	216.0	172.9	79.0	68.1	41.9	114.1	103.4	234.2
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	5.4	1.2	1.1	1.2	2.0	2.2	2.8	6.1	7.0	11.5	4.2	4.6	2.0
GC 645	Maize	consumption (g/day):	82.7	148.4	135.9	31.8	33.3	7.5	35.2	298.6	248.1	57.4	63.1	58.6	85.5
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	5.8	3.2	3.5	15.1	14.4	64.0	13.6	1.6	1.9	8.4	7.6	8.2	5.6
GC 640	Barley	consumption (g/day):	40.6	16.8	93.9	13.2	48.6	36.1	5.9	20.5	5.9	2.5	20.2	16.8	43.8
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	11.8	28.6	5.1	36.4	9.9	13.3	81.4	23.4	81.4	192.0	23.8	28.6	11.0
GC 80	Total Cereals	consumption (g/day):	356.9	713.9	763.0	504.5	365.2	328.7	617.0	487.1	389.4	385.7	440.2	567.7	409.9
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	1.34	0.67	0.63	0.95	1.31	1.46	0.78	0.99	1.23	1.24	1.09	0.85	1.17
<u>SEMI-PROCESSED COMMODITIES</u>															
Maize - flour and germ		consumption (g/day):	69.1	24.3	56.3	17.8	16.7	2.4	29.3	250.0	210.6	47.8	48.4	14.0	25.5
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	6.9	19.8	8.5	27.0	28.7	200.0	16.4	1.9	2.3	10.0	9.9	34.3	18.8
		Assume cons 2 x per cap cluster & exp at ARfD*													
		concentration (µg/g)	3.5	9.9	4.3	13.5	14.4	100.0	8.2	1.0	1.1	5.0	5.0	17.1	9.4
Wheat - germ, bulgur wholemeal, and flour		consumption (g/day):	68.9	307.8	328.2	301.5	182.6	167.4	133.1	108.2	54.2	32.2	87.7	79.6	180.7
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	7.0	1.6	1.5	1.6	2.6	2.9	3.6	4.4	8.9	14.9	5.5	6.0	2.7
		Assume cons 2 x per cap cluster & exp at ARfD*													
		concentration (µg/g)	3.5	0.8	0.7	0.8	1.3	1.4	1.8	2.2	4.4	7.5	2.7	3.0	1.3
Barley - pot, pearled, flour and grits		consumption (g/day):	29.0	0.7	50.6	4.7	2.9	14.3	1.6	0.1	0.1	0.7	4.1	4.9	0.1
		Assuming exp.@ ARfD (8 µg/kg bw)													
		concentration (µg/g)	16.6	685.7	9.5	102.1	165.5	33.6	300.0	4800	4800	685.7	117.1	98.0	4800
		Assume cons 2 x per cap cluster & exp at ARfD*													
		concentration (µg/g)	8.3	342.9	4.7	51.1	82.8	16.8	150.0	2400	2400	342.9	58.5	49.0	2400

*High percentiles of consumption and subsequent maximum concentrations are estimated by assuming 2 times the consumption of the GEMS/Food cluster diets.

Table 5. Concentrations of DON in various cereal products for exposure to reach the ARfD of 8 µg/kg bw using entries from the GEMS/Food Programme database of International Estimates of Short Term Intakes (IESTI) and Large Portion diets for acute dietary intake assessments

Codex Code	Commodity		Adults	Reporting Country	Children ≤ 6 years	Reporting Country
Raw Commodities						
GC 654	Wheat (total)	consumption (g/kg bw/day)	13.46	France (gen pop, 3+ yrs)	20.33	France (3-6 yrs)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	0.59		0.39	
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	1.55		2.63	
GC 645	Maize (total)	consumption (g/kg bw/day)	4.06	France (gen pop, 3+ yrs)	6.17	France (3-6 yrs)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	1.97		1.30	
GC 640	Barley (total)	consumption (g/kg bw/day)	5.99	Australia (general pop, 2+yrs)	0.90	Australia (2-6 yrs)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	1.34		8.92	
Semi-processed commodities						
CF1211	Wheat flour	consumption (g/kg bw/day)	9.17	France (gen pop, 3+)	12.95	France (3-6 yrs)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	0.87		0.62	
CF 1212	Wheat wholemeal	consumption (g/kg bw/day)	2.39	USA (general pop)	5.31	Netherlands (babies, 8-20 mos)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	3.35		1.51	
CF 1255	Maize flour	consumption (g/kg bw/day)	2.04	France (gen pop, 3+ yrs)	4.30	Germany (2-4 yrs)
	Assuming exp. not exceed ARfD (8 µg/kg bw)	concentration (µg/g)	3.92		1.86	

Note: Since data were available on so many different population groups, the highest large portion (based on g/kg bw/d) for each commodity from all population groups has been chosen for calculation purposes. Where that value was significantly higher than other estimates for that same commodity, the next highest consumption value is also listed (i.e., wheat)

Table 6. Concentrations of DON in various cereal products for exposure to reach the ARfD of 8 µg/kg bw using the EFSA Concise Food Consumption Database

		mean	median	95th	97.5th	99th
Cereals & cereal products	consumption (g/day) range	153.5 - 372.4	140.1 - 300	283.4 - 760	330.5 - 1360	374.5 - 2792.0
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g) range	1.29 - 3.13	1.6 - 3.43	0.63 - 1.69	0.35 - 1.45	0.17 - 1.28

Table 7. Concentrations of DON in various cereal products for exposure to reach the ARfD of 8 µg/kg bw using the EFSA Comprehensive Food Consumption Database for acute intakes

	Cereals & cereal products	mean (range)	median (range)	95th (range)	97.5th (range)	99th (range)
Very Elderly	consumption (g/kg bw/day)	2.66 - 3.72	2.27 - 3.52	4.95 - 7.19	5.64 - 9.31	7.40 - 10.47
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	2.15 - 3.00	2.27 - 3.52	1.11 - 1.62	0.86 - 1.42	0.76 - 1.08
Elderly	consumption (g/kg bw/day)	2.01 - 3.64	1.87 - 3.35	3.81 - 7.13	4.32 - 8.35	5.17 - 9.52
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	2.20 - 3.97	2.39 - 4.29	1.12 - 2.10	0.96 - 1.85	0.84 - 1.55
Adults	consumption (g/kg bw/day)	2.05 - 4.37	1.90 - 3.99	3.98 - 8.75	4.50 - 10.08	5.25 - 12.6
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	1.83 - 3.91	2.01 - 4.21	0.91 - 2.01	0.79 - 1.78	0.64 - 1.53
Adolescents	consumption (g/kg bw/day)	3.41 - 6.95	2.88 - 6.17	7.61 - 13.81	8.91 - 16.42	10.19 - 21.33
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	1.15 - 2.35	1.30 - 2.78	0.58 - 1.05	0.49 - 0.90	0.38 - 0.78
Other children	consumption (g/kg bw/day)	5.13 - 10.67	4.74 - 10.25	9.73 - 26.21	11.38 - 32.22	13.62 - 38.94
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	0.75 - 1.56	0.78 - 1.69	0.31 - 0.82	0.25 - 0.70	0.21 - 0.59
Toddlers	consumption (g/kg bw/day)	5.91 - 10.54	5.24 - 10.17	12.64 - 23.39	14.38 - 24.52	14.38 - 25.05
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	0.76 - 1.35	0.79 - 1.53	0.34 - 0.63	0.33 - 0.56	0.32 - 0.56
Infants	consumption (g/kg bw/day)	6.22 - 7.84	5.43 - 6.45	14.76 - 18.75	18.65 - 18.75	18.75 - 20.09
Assuming exp. @ ARfD (8 µg/kg bw)	concentration (µg/g)	1.02 - 1.29	1.24 - 1.47	0.43 - 0.54	0.43 - 0.43	0.40 - 0.43

Assessment of the impact of various potential MLs based on DON occurrence

26. Individual occurrence data was either provided by or available from Austria, Brazil, Canada, China, Japan, South Africa, United Kingdom and the United States of America (Austrian Agency for Health and Food Safety, 2011; Brazilian Health Surveillance Agency, 2012; Canadian Grain Commission, 2011; Canadian Food Inspection Agency, 2011; Health Canada, 2011; China National Center of Food Safety Risk Assessment, 2011; Japanese Ministry of Agriculture, Forestry and Fisheries, 2011; South African Grain Laboratory, 2011; United Kingdom Food Standards Agency, 2012; and U.S. FDA, 2011).

27. Between 2005 and 2009, the United States of America, Canada, and the United Kingdom were among the top ten exporting nations for wheat; the United States of America, Brazil, China, and South Africa were among the top ten exporting nations for maize; and Canada and the United Kingdom were among the top ten exporting nations for barley. As a result, full distributions of DON occurrence data from these countries make for a useful starting point in determining the impact of various potential MLs for wheat, maize and barley grains.

28. Table 8 details the impact of various potential MLs (3.0, 2.0, 1.75, 1.5, and 1.25 mg/kg) for DON on the statistical distribution of DON in Brazilian, Canadian, Chinese, Japanese, South African, United Kingdom and United States of America wheat and/or maize grain and/or barley grain, including the predicted proportion of rejected samples. In comparing the data between countries, it is apparent that contamination levels differ between different regions, making it difficult to propose an ML that is both achievable by all countries and protective of health. For example, from the individual occurrence data available for this document, DON concentrations in wheat grain tend to be higher in Brazil and the U.S. than in other countries. Extremes in year-to-year variation may also present challenges in meeting MLs. Tables 9 and 10 show single year data for Canadian and South African maize grain, where a single year of data exceeded the potential MLs in relation to other years. For the single year in which higher levels of DON were found, a 2.0 mg/kg ML would have resulted in 68% of Canadian maize being rejected from the market, while for the elevated year in South Africa, 69% of maize would have been rejected. When this elevated year was removed from each of the datasets, percentages of rejected samples were only 0.7% in Canadian maize, and 3.1% in South African maize, compared to 10.3% and 11.1% when each of the high years are included in the datasets. In Appendix II.B, Tables B1 to B7, and B10 to B13, detail the impact of various potential MLs for DON by country for all the cereal-grain data provided by each country (includes grains other than wheat, maize and barley).

29. The impact of various potential MLs on semi-processed cereal-based foods are detailed in Table 11; on cereal-based foods intended for consumption by infants and young children in Table 12; and on all other processed cereal-based foods in Table 15. MLs of 1.5, 1.25, 1.0, 0.75 and 0.5 mg/kg for DON were applied to semi-processed and processed cereal-based foods, while MLs of 0.5, 0.3, 0.2 mg/kg were applied to cereal-based foods for infants and young children (e.g., infant cereals). From these tables it is apparent that levels in processed cereal-based products are lower than that of the grain or milling products, as is to be expected. In Appendix II.B, Tables B6 to B13 detail, by country, the impact of various potential MLs on semi-processed, processed cereal-based foods, and cereal-based foods for infants and young children for those data sets in which these commodities were present.

Impact of various potential MLs on mean estimates of dietary exposure to DON from wheat, maize and barley

30. The impact of different hypothetical MLs on mean estimates of dietary exposure to DON from wheat, maize and barley, using the GEMS/Food Consumption Cluster Diets and each of the Canadian, South African, Brazilian, Chinese, Japanese, United Kingdom and United States of America raw cereal grain datasets are shown in Table 14. Each country's occurrence data are used for each of the 13 GEMS/Food Consumption Cluster Diets.

31. Results from Table 14 also demonstrate the effects of varying occurrence levels. For instance, for Cluster diet M (Argentina, Australia, Canada, Chile, New Zealand, United States of America, and Uruguay), the 2010 JECFA assessment estimated a mean exposure of 11.04 µg/kg bw/day using occurrence data originating mostly from outside of the Americas. In contrast, when using the multi-year Canadian occurrence data for wheat, maize and barley, the results presented here suggest a combined exposure from these three cereals of 1.88-2.09 µg/kg bw/day (Table 14). This highlights the importance of estimating dietary exposure using occurrence data that is most representative of levels in the region from which populations within cluster diets are obtaining grain-based foods for consumption. For example, if a country mostly imports grain products, occurrence data from the exporting countries is likely to be more representative for exposure estimates for that country. Alternatively, if a population consumes more domestic grain-based foods, domestic occurrence data would provide a more accurate estimate of DON exposure.

Table 8. Summary of the impact of different MLs (no MLs, 3.0, 2.0, 1.75, 1.5, and 1.25 µg/g for raw cereal grains; µg/g = mg/kg) for DON on the statistical distribution of DON in raw cereal grains from countries for which individual occurrence data were available, including the predicted proportion of rejected samples from the world market.

Country	RAW CEREAL GRAINS	Scenario	No. of samples	DON content (µg/g)						% of rejected samples
				Mean	Median (P50)	P75	P90	P95	Max	
Brazil	Wheat	All data	187	0.893 - 0.910	0.723	1.162	2.000	2.988	4.000	0.0
		ML 3.0 µg/g	180	0.795 - 0.813	0.692	1.133	1.816	2.048	3.000	3.7
		ML 2.0 µg/g	170	0.688 - 0.706	0.614	1.069	1.520	1.790	2.000	9.1
		ML 1.75 µg/g	159	0.605 - 0.624	0.546	1.000	1.237	1.457	1.676	15.0
		ML 1.5 µg/g	152	0.558 - 0.579	0.518	0.927	1.142	1.279	1.486	18.7
		ML 1.25 µg/g	143	0.507 - 0.529	0.496 - 0.500	0.852	1.072	1.140	1.232	23.5
	Maize	All data	96	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.0
		ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	96	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.0
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Canada	Wheat	All data	2272	0.208 - 0.248	0.000 - 0.100	0.240	0.669	1.030	2.790	0.0
		ML 3.0 µg/g	2272	0.208 - 0.248	0.000 - 0.100	0.240	0.669	1.030	2.790	0.0
		ML 2.0 µg/g	2254	0.192 - 0.232	0.000 - 0.100	0.230	0.627	0.930	2.000	0.8
		ML 1.75 µg/g	2239	0.181 - 0.221	0.000 - 0.100	0.220	0.610	0.870	1.750	1.5
		ML 1.5 µg/g	2225	0.172 - 0.212	0.000 - 0.100	0.220	0.590	0.840	1.500	2.1
		ML 1.25 µg/g	2202	0.159 - 0.200	0.000 - 0.100	0.210	0.560	0.779	1.240	3.1
	Maize	All data	156	0.720 - 0.725	0.425	0.723	2.030	2.730	4.460	0.0
		ML 3.0 µg/g	151	0.627 - 0.632	0.420	0.680	1.220	2.315	3.040	3.8
		ML 2.0 µg/g	140	0.478 - 0.483	0.410	0.600	0.822	1.143	2.000	10.3
		ML 1.75, 1.5 µg/g	138	0.456 - 0.461	0.410	0.580	0.786	0.997	1.390	11.5
		ML 1.25 µg/g	136	0.443 - 0.448	0.410	0.573	0.765	0.920	1.220	12.8
		All data	302	0.048 - 0.116	0.000 - 0.100	0.000 - 0.100	0.099 - 0.100	0.239	3.150	0.0
	Barley	ML 3.0, 2.0 µg/g	301	0.038 - 0.106	0.000 - 0.100	0.000 - 0.100	0.090 - 0.100	0.220	1.900	0.3
		ML 1.75 µg/g	300	0.032 - 0.100	0.000 - 0.100	0.000 - 0.100	0.081 - 0.100	0.220	1.510	0.7
ML 1.5, 1.25 µg/g		299	0.027 - 0.095	0.000 - 0.100	0.000 - 0.100	0.080 - 0.100	0.211	0.840	1.0	
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China	Wheat	All data	166	0.104	0.024	0.069	0.195	0.341	4.280	0.0
		ML 3.0 µg/g	165	0.078	0.024	0.065	0.186	0.279	2.534	0.6
		ML 2.0, 1.75, 1.5, 1.25 µg/g	164	0.063	0.024	0.065	0.178	0.272	0.591	1.2
	Maize	All data	203	0.144	0.002	0.098	0.394	0.624	4.374	0.0
		ML 3.0 µg/g	202	0.123	0.002	0.094	0.389	0.518	2.717	0.5
		ML 2.0, 1.75, 1.5 µg/g	200	0.100	0.001	0.082	0.340	0.488	1.272	1.5
		ML 1.25 µg/g	199	0.094	0.000	0.079	0.335	0.485	1.064	2.0
	Barley	All data	2	0.004 - 0.024	0.004 - 0.024	0.006 - 0.032	0.008 - 0.037	0.008 - 0.038	0.008 - 0.040	0.0
		ML 3.0, 2.0, 1.75, 1.5, 1.25 µg/g	2	0.004 - 0.024	0.004 - 0.024	0.006 - 0.032	0.008 - 0.037	0.008 - 0.038	0.008 - 0.040	0.0
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Japan	Wheat	All data	240	0.052	0.017	0.055	0.160	0.240	0.540	0.0
		ML 3.0, 2.0, 1.75, 1.5, 1.25 µg/g	240	0.052	0.017	0.055	0.160	0.240	0.540	0.0
	Barley	All data	200	0.049	0.017	0.061	0.130	0.201	0.500	0.0
		ML 3.0, 2.0, 1.75, 1.5, 1.25 µg/g	200	0.049	0.017	0.061	0.130	0.201	0.500	0.0
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South Africa	Wheat	All data	240	0.67 - 0.79	0.59	1.20	1.60	1.80	3.00	0.0
		ML 3.0 µg/g	240	0.67 - 0.79	0.59	1.20	1.60	1.80	3.00	0.0
		ML 2.0 µg/g	235	0.63 - 0.75	0.56	1.20	1.60	1.70	2.00	2.1
		ML 1.75 µg/g	225	0.57 - 0.70	0.50	1.10	1.50	1.60	1.70	6.3
		ML 1.5 µg/g	207	0.48 - 0.62	0.00 - 0.50	0.94	1.30	1.40	1.50	13.8
		ML 1.25 µg/g	184	0.36 - 0.52	0.00 - 0.50	0.78	1.10	1.19	1.20	23.3
	Maize	All data	740	0.65 - 0.86	0.00 - 0.50	0.80	2.20	3.00	13.00	0.0
		ML 2.0 µg/g	658	0.31 - 0.55	0.00 - 0.50	0.56	1.07	1.31	2.00	11.1
		ML 1.75 µg/g	650	0.29 - 0.53	0.00 - 0.50	0.54	1.00	1.30	1.70	12.2
		ML 1.5 µg/g	636	0.26 - 0.51	0.00 - 0.50	0.50	0.92	1.20	1.50	14.1
		ML 1.25 µg/g	611	0.22 - 0.47	0.00 - 0.50	0.40 - 0.50	0.77	0.99	1.20	17.4
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United Kingdom	Wheat	All data	328	0.217 - 0.219	0.038	0.102	0.346	0.594	10.626	0.0
		ML 3.0 µg/g	324	0.124 - 0.126	0.037	0.100	0.320	0.509	2.954	1.2
		ML 2.0, 1.75, 1.5 µg/g	322	0.109 - 0.110	0.037	0.096	0.312	0.442	1.487	1.8
		ML 1.25 µg/g	320	0.100 - 0.101	0.037	0.090	0.300	0.432	1.103	2.4
	Maize	All data	115	0.186 - 0.189	0.097	0.273	0.461	0.631	1.325	0.0
		ML 3.0, 2.0, 1.75, 1.5 µg/g	115	0.186 - 0.189	0.097	0.273	0.461	0.631	1.325	0.0
		ML 1.25 µg/g	114	0.176 - 0.179	0.095	0.272	0.443	0.613	1.000	0.9
	Barley	All data	128	0.016 - 0.020	0.012	0.024	0.035	0.045	0.207	0.0
		ML 3.0, 2.0, 1.75, 1.5, 1.25 µg/g	128	0.016 - 0.020	0.012	0.024	0.035	0.045	0.207	0.0
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United States of America	Wheat	All data	97	0.821 - 0.832	0.000 - 0.020	0.790	2.740	3.408	17.600	0.0
		ML 3.0 µg/g	88	0.378 - 0.389	0.000 - 0.020	0.545	1.204	1.730	2.800	9.3
		ML 2.0 µg/g	84	0.279 - 0.291	0.000 - 0.020	0.428	0.889	1.358	1.800	13.4
		ML 1.75 µg/g	83	0.261 - 0.273	0.000 - 0.020	0.405	0.850	1.099	1.600	14.4
		ML 1.5 µg/g	82	0.244 - 0.257	0.000 - 0.020	0.400	0.799	0.910	1.400	15.5
		ML 1.25 µg/g	79	0.200 - 0.213	0.000 - 0.020	0.380	0.746	0.866	1.120	18.6
	Maize	All data	2	2.715 - 2.725	2.715 - 2.725	4.073	4.887 - 4.889	5.159 - 5.160	5.430	0.0
		ML 3.0, 2.0, 1.75, 1.5, 1.25 µg/g	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	50.0
	Barley	All data	4	0.065 - 0.080	0.000 - 0.020	0.065 - 0.080	0.182 - 0.188	0.221 - 0.224	0.260	0.0
		ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	4	0.065 - 0.080	0.000 - 0.020	0.065 - 0.080	0.182 - 0.188	0.221 - 0.224	0.260	0.0
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Max., maximum; Px, xth percentile; ML, maximum limit; LOD, limit of detection; LOQ, limit of quantification; LOR, limit of reporting. Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOD, LOQ or LOR, whereas upper bound values were calculated by assuming concentrations less than the LOD, LOQ or LOR were equal to the LOD, LOQ or LOR. LOD, LOQ and LOR values ranged from 0.0001 to 0.5 µg/g.

Table 9. Impact of different MLs for DON when DON occurrences for one year are much higher than other years using data from Canadian corn grain destined for export from 1994-2008.

MAIZE	Scenario ^a	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95	Max	
All years									
	All data	156	0.72	0.43	0.72	2.03	2.73	4.46	0.0
	ML 2.0 µg/g	140	0.48	0.41	0.60	0.82	1.14	2.00	10.3
	ML 1.75, 1.5 µg/g	138	0.46	0.41	0.58	0.79	1.00	1.39	11.5
	ML 1.25 µg/g	136	0.44 - 0.45	0.41	0.57	0.77	0.92	1.22	12.8
All years (exclu. 2006)									
	All data	134	0.46 - 0.47	0.41	0.58	0.77	1.02	2.42	0.0
	ML 2.0 µg/g	133	0.45	0.41	0.57	0.75	0.94	2.00	0.7
	ML 1.75, 1.5 µg/g	132	0.44	0.41	0.56	0.75	0.92	1.33	1.5
	ML 1.25 µg/g	131	0.43 - 0.44	0.41	0.55	0.74	0.88	1.22	2.2
year 2006									
	All data	22	2.28	2.51	3.01	3.39	3.42	4.46	0.0
	ML 2.0 µg/g	7	1.01	0.91	1.30	1.61	1.77	1.93	68.2
	ML 1.75, 1.5 µg/g	6	0.86	0.87	1.14	1.30	1.35	1.39	72.7
	ML 1.25 µg/g	5	0.76	0.82	0.91	1.09	1.15	1.21	77.3

Max., maximum; Px, xth percentile; ML, maximum limit; LOQ, limit of quantification

Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOQ (0.05-0.1 µg/g) whereas upper bound values were calculated by assuming concentrations less than the LOQ were equal to the LOQ.

Table 10. Impact of different MLs for DON when DON occurrences for one year are much higher than other years using data from South African maize from 2003/04 to -2010/11.

MAIZE	Scenario ^a	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95	Max	
All years									
	All data	740	0.65 - 0.86	0.00 - 0.50	0.80	2.20	3.00	13.00	0.0
	ML 2.0 µg/g	658	0.31 - 0.55	0.00 - 0.50	0.56	1.07	1.31	2.00	11.1
	ML 1.75 µg/g	650	0.29 - 0.53	0.00 - 0.50	0.54	1.00	1.30	1.70	12.2
	ML 1.5 µg/g	636	0.26 - 0.51	0.00 - 0.50	0.50	0.92	1.20	1.50	14.1
	ML 1.25 µg/g	611	0.22 - 0.47	0.00 - 0.50	0.40 - 0.50	0.77	0.99	1.20	17.4
All years excluding 2005/2006 crop year where higher concentrations of DON encountered									
	All data	650	0.36 - 0.60	0.00 - 0.50	0.54	1.01	1.43	13.00	0.0
	ML 2.0 µg/g	630	0.26 - 0.51	0.00 - 0.50	0.49 - 0.50	0.92	1.20	1.90	3.1
	ML 1.75 µg/g	626	0.25 - 0.50	0.00 - 0.50	0.47 - 0.50	0.87	1.10	1.70	3.7
	ML 1.5 µg/g	620	0.24 - 0.49	0.00 - 0.50	0.45 - 0.50	0.85	1.10	1.50	4.6
	ML 1.25 µg/g	602	0.21 - 0.47	0.00 - 0.50	0.40 - 0.50	0.75	0.96	1.20	7.4
2005/2006 crop year									
	All data	90	2.74 - 2.75	2.55	3.60	4.52	5.21	6.20	0.0
	ML 2.0 µg/g	28	1.36 - 1.40	1.45	1.70	1.93	2.00	2.00	68.9
	ML 1.75 µg/g	24	1.26 - 1.30	1.30	1.60	1.70	1.70	1.70	73.3
	ML 1.5 µg/g	16	1.06 - 1.12	1.20	1.30	1.45	1.50	1.50	82.2
	ML 1.25 µg/g	9	0.82 - 0.93	1.00	1.20	1.20	1.20	1.20	90.0

Max., maximum; Px, xth percentile; ML, maximum limit; LOD, limit of detection

Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOD (0.1-0.5 µg/g) whereas upper bound values were calculated by assuming concentrations less than the LOD were equal to the LOD.

China	Wheat milling products (wheat flour, germ and whole meal)										
	All data	811	8.250 - 8.252	0.049 - 0.048	0.176	0.494	1.008	919.000	0.0		
	ML 1.5 µg/g	784	0.133 - 0.135	0.045 - 0.044	0.150	0.372	0.590	1.440	3.3		
	ML 1.25 µg/g	777	0.122 - 0.124	0.044 - 0.043	0.142	0.349	0.554	1.241	4.2		
	ML 1.0 µg/g	770	0.113 - 0.115	0.043	0.137	0.328	0.527	1.000	5.1		
	ML 0.75 µg/g	760	0.102 - 0.105	0.042	0.129	0.301	0.441	0.708	6.3		
	ML 0.5 µg/g	730	0.082 - 0.084	0.039 - 0.040	0.110	0.239	0.330	0.494	10.0		
	Wheat bran, processed										
	All data	1	0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.0	
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.010	0.010	0.010	0.010	0.010	0.010	0.010	0.0	
United Kingdom	Wheat milling products (wheat flour, germ, bulgar wheat, semolina, couscous)										
	All data	62	0.103 - 0.104	0.040	0.097	0.253	0.480	0.707	0.0		
	ML 1.5, 1.25, 1.0, 0.75 µg/g	62	0.103 - 0.104	0.040	0.097	0.253	0.480	0.707	0.0		
	ML 0.5 µg/g	59	0.076 - 0.077	0.038	0.073	0.207	0.266	0.482	4.8		
	Wheat bran										
	All data	10	0.268	0.262	0.363	0.496	0.501	0.505	0.0		
	ML 1.5, 1.25, 1.0, 0.75 µg/g	10	0.268	0.262	0.363	0.496	0.501	0.505	0.0		
	ML 0.5 µg/g	9	0.241	0.239	0.343	0.394	0.445	0.495	10.0		
	Corn milling products (corn flakes, flour & dry mixes, cornmeal and polenta)										
	All data	103	0.092 - 0.105	0.020 - 0.050	0.119	0.233	0.447	1.035	0.0		
	ML 1.5, 1.25 µg/g	103	0.092 - 0.105	0.020 - 0.050	0.119	0.233	0.447	1.035	0.0		
	ML 1.0 µg/g	102	0.082 - 0.096	0.020 - 0.050	0.110	0.223	0.279	0.890	1.0		
	ML 0.75 µg/g	101	0.074 - 0.088	0.019 - 0.050	0.091	0.205	0.275	0.683	1.9		
	ML 0.5 µg/g	99	0.062 - 0.076	0.018 - 0.050	0.084	0.194	0.250	0.492	3.9		
	Corn bran										
	All data	8	0.683	0.605	1.154	1.261	1.296	1.332	0.0		
	ML 2.0, 1.75, 1.5 µg/g	8	0.683	0.605	1.154	1.261	1.296	1.332	0.0		
	ML 1.25 µg/g	7	0.590	0.382	0.979	1.169	1.200	1.230	12.5		
	Corn oil										
	All data	18	0.000 - 0.041	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.0	
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	18	0.000 - 0.041	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.000 - 0.050	0.0	
	Barley products (pearl barley, flakes, malt extract)										
	All data	10	0.020 - 0.027	0.000 - 0.010	0.009 - 0.012	0.029	0.100	0.171	0.0		
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	10	0.020 - 0.027	0.000 - 0.010	0.009 - 0.012	0.029	0.100	0.171	0.0		
	United States of America	Wheat milled products (incl. wheat flour, wheat starch)									
		All data	1310	0.150 - 0.163	0.000 - 0.020	0.137	0.440	0.687	10.970	0.0	
		ML 1.5 µg/g	1297	0.116 - 0.129	0.000 - 0.020	0.125	0.400	0.615	1.470	1.0	
		ML 1.25 µg/g	1289	0.108 - 0.121	0.000 - 0.020	0.111	0.400	0.596	1.250	1.6	
ML 1.0 µg/g		1277	0.098 - 0.112	0.000 - 0.020	0.100	0.375	0.540	1.000	2.5		
ML 0.75 µg/g		1249	0.081 - 0.095	0.000 - 0.020	0.076	0.318	0.470	0.740	4.7		
ML 0.5 µg/g		1197	0.059 - 0.073	0.000 - 0.020	0.042	0.270	0.342	0.500	8.6		
Wheat bran											
All data		68	0.509 - 0.519	0.000 - 0.020	0.545	1.016	2.774	6.100	0.0		
ML 1.5, 1.25 µg/g		63	0.243 - 0.254	0.000 - 0.020	0.424	0.823	0.955	1.100	7.4		
ML 1.0 µg/g		61	0.214 - 0.226	0.000 - 0.020	0.400	0.764	0.900	0.980	10.3		
ML 0.75 µg/g		54	0.129 - 0.142	0.000 - 0.020	0.215	0.442	0.559	0.733	20.6		
ML 0.5 µg/g		50	0.087 - 0.101	0.000 - 0.020	0.176	0.337	0.424	0.457	26.5		
Corn milling products (flour, starch, milled corn and corn meal milled products)											
All data		13	0.266 - 0.275	0.146	0.423	0.637	0.846	1.080	0.0		
ML 1.5, 1.25 µg/g		13	0.266 - 0.275	0.146	0.423	0.637	0.846	1.080	0.0		
ML 1.0, 0.75 µg/g		12	0.198 - 0.208	0.073 - 0.083	0.406	0.425	0.544	0.690	7.7		
ML 0.5 µg/g		11	0.153 - 0.164	0.000 - 0.020	0.345	0.423	0.424	0.425	15.4		
Barley products (ground malt, malted barley)											
All data		2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0	
ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g		2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0	
Milled Grain Products											
All data		4	0.048 - 0.063	0.000 - 0.020	0.048 - 0.063	0.133 - 0.139	0.162 - 0.165	0.190	0.0		
ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g		4	0.048 - 0.063	0.000 - 0.020	0.048 - 0.063	0.133 - 0.139	0.162 - 0.165	0.190	0.0		

Max., maximum; Px, xth percentile; ML, maximum limit; LOD limit of detection; LOQ, limit of quantification; LOR, limit of reporting Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOD, LOQ or LOR, whereas upper bound values were calculated by assuming concentrations less than the LOD, LOQ or LOR were equal to the LOD, LOQ or LOR.
 LOD, LOQ and LOR values ranged from 0.005 to 0.15 ug/g.

Table 12. Summary of the impact of different potential MLs (no ML, 0.5, 0.3, and 0.2 ug/g) for DON in foods intended for consumption by infants and young children on the statistical distribution of DON in those foods from countries for which individual occurrence data were available.

Country	Foods intended for infants and young children	Scenario	No. of samples	DON content ($\mu\text{g/g}$)						% of rejected samples
				Mean	Median (P50)	P75	P90	P95	Max	
Austria	Cereal-based food for infants and young children	All data	68	0.003 - 0.027	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.025 - 0.050	0.073	0.0
		ML 0.5, 0.3, 0.2 μg	68	0.003 - 0.027	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.025 - 0.050	0.073	0.0
Canada	Infant Cereal	All data	527	0.047 - 0.052	0.007 - 0.020	0.040	0.110	0.220	1.000	0.0
		ML 0.5 $\mu\text{g/g}$	518	0.034 - 0.040	0.006 - 0.020	0.039	0.090	0.162	0.500	1.7
		ML 0.3 $\mu\text{g/g}$	508	0.027 - 0.033	0.005 - 0.020	0.035	0.080	0.130	0.290	3.6
		ML 0.2 $\mu\text{g/g}$	500	0.024 - 0.029	0.005 - 0.020	0.032	0.070	0.110	0.200	5.1
United Kingdom	Foods for infants and young children (includes cereal-based foods; biscuits, rusks, and cookies; pasta)	All data	180	0.014 - 0.030	0.000 - 0.014	0.016 - 0.050	0.037 - 0.050	0.058	0.217	0.0
		ML 0.5, 0.4 $\mu\text{g/g}$	180	0.014 - 0.030	0.000 - 0.014	0.016 - 0.050	0.037 - 0.050	0.058	0.217	0.0
		ML 0.3 $\mu\text{g/g}$	179	0.013 - 0.029	0.000 - 0.014	0.016 - 0.050	0.036 - 0.050	0.058	0.180	0.6

Max., maximum; Px, xth percentile; ML, maximum limit; LOD limit of detection; LOQ, limit of quantification

Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOD, or LOQ whereas upper bound values were calculated by assuming concentrations less than the LOD or LOQ were equal to the LOD or LOQ.

LOD and LOQ values ranged from 0.005 to 0.05 $\mu\text{g/g}$.

Table 13. Summary of the impact of different potential MLs (No MLs, 1.5, 1.25, 1.0, 0.75, and 0.5 µg/g) for DON in processed cereal grain-based products on the statistical distribution of DON in those products from countries for which individual occurrence data were available, including the predicted proportion of rejected samples from the world market.

Country	Processed cereal grain-based products	Scenario†	No. of samples	DON content (µg/g)					% of rejected samples	
				Mean	Median (P50)	P75	P90	P95		Max
Austria	Cereal-based processed food (Breads & rolls, pasta, biscuits & cookies, crackers, crisp bread and rusks, fine bakery wares, cakes & pastries, pretzels, waffles, muesli, and popped cereals)									
		All data	326	0.065 - 0.078	0.025 - 0.050	0.095	0.150	0.227	1.115	0.0
		ML 1.5, 1.25 µg/g	326	0.065 - 0.078	0.025 - 0.050	0.095	0.150	0.227	1.115	0.0
		ML 1.0 µg/g	325	0.061 - 0.075	0.025 - 0.050	0.095	0.147	0.224	0.800	0.3
		ML 0.75 µg/g	324	0.059 - 0.073	0.025 - 0.050	0.094	0.145	0.214	0.634	0.6
		ML 0.5 µg/g	323	0.057 - 0.071	0.025 - 0.050	0.093	0.143	0.214	0.412	0.9
Brazil	Cereal-based processed food (bread, cookies, cream crackers, cakes, wafers, pasta)									
		All data	87	0.382 - 0.397	0.289	0.597	0.802	1.005	1.248	0.0
		ML 1.5, 1.25 µg/g	87	0.382 - 0.397	0.289	0.597	0.802	1.005	1.248	0.0
		ML 1.0 µg/g	80	0.320 - 0.336	0.252	0.532	0.718	0.778	0.948	8.0
		ML 0.75 µg/g	75	0.287 - 0.304	0.243	0.463	0.620	0.698	0.748	13.8
		ML 0.5 µg/g	58	0.188 - 0.210	0.180	0.286	0.402	0.462	0.477	33.3
Canada	Cereal-based processed food (breakfast cereals, bread, baked goods, other wheat products and corn & tortilla chips)									
		All data	577	0.109 - 0.110	0.040	0.153	0.308	0.412	1.610	0.0
		ML 1.5 µg/g	576	0.106 - 0.108	0.040	0.152	0.304	0.406	1.440	0.0
		ML 1.25, 1.0 µg/g	575	0.104 - 0.105	0.040	0.151	0.297	0.404	0.940	0.3
		ML 0.75 µg/g	568	0.095 - 0.097	0.039	0.140	0.276	0.396	0.690	1.6
		ML 0.5 µg/g	557	0.086 - 0.087	0.036	0.132	0.255	0.346	0.473	3.5
United Kingdom	Cereal-based processed food (pasta, bread and rolls, breakfast cereals & cereal bars, pancakes, biscuits and crackers†, cakes & pastries, snack food, corn-based snacks, corn pasta, sweet corn, grain-based products)									
		All data	586	0.053 - 0.061	0.013 - 0.020	0.045 - 0.050	0.142	0.229	2.082	0.0
		ML 1.5, 1.25, 1.0 µg/g	585	0.049 - 0.057	0.013 - 0.020	0.044 - 0.050	0.142	0.227	0.879	0.2
		ML 0.75 µg/g	584	0.048 - 0.056	0.013 - 0.020	0.044 - 0.050	0.141	0.223	0.714	0.3
		ML 0.5 µg/g	575	0.039 - 0.047	0.013 - 0.019	0.041 - 0.050	0.126	0.195	0.492	1.9
United States of America	Cereal-based processed food (bakery products, breakfast cereals, cereal preparatons, cookies & crackers, tortillas, pasta, snack food, dinner/sauces/gravy, canned beans/corn)									
		All data	194	0.161 - 0.177	0.000 - 0.020	0.000 - 0.020	0.299	0.453	14.040	0.0
		ML 1.5, 1.25, 1.0, 0.75 µg/g	190	0.049 - 0.066	0.000 - 0.020	0.000 - 0.020	0.281	0.322	0.733	2.1
	ML 0.5 µg/g	185	0.033 - 0.050	0.000 - 0.020	0.000 - 0.020	0.103	0.300	0.493	4.6	

Max., maximum; Px, xth percentile; ML, maximum limit; LOD limit of detection; LOQ, limit of quantification

Lower bound values were calculated assuming a concentration of zero for concentrations less than the LOD, or LOQ whereas upper bound values were calculated by assuming concentrations less than the LOD or LOQ were equal to the LOD or LOQ.

LOD and LOQ values ranged from 0.005 to 0.15 µg/g.

Table 14. Mean estimates of dietary exposure to DON from wheat, maize and barley for the 13 GEMS/Food Consumption Cluster Diets, taking into consideration the impact of different hypothetical ML scenarios for DON (no MLs; MLs of 2, 1.75, 1.5, 1.25 µg/g; µg/g = mg/kg) in those cereals contributing most to dietary DON exposure, using each of the Canadian, South African, Brazilian, Chinese, Japanese, United Kingdom and United States of America raw cereal grain occurrence data sets for DON

Table with columns for Scenario, Country, Cereal Type, ML Scenario, and Dietary exposure to DON (µg/kg bw per day) for 13 GEMS/Food Consumption Cluster Diets (A-M). Rows include Canada, South Africa, and Brazil with various ML scenarios (No ML, 2.0, 1.75, 1.5, 1.25 µg/g) and cereal types (All 3 cereals, Wheat, Maize, Barley, Wheat and Maize).

China	No ML	Wheat and Maize	0.35	0.35	1.04	1.04	1.07	1.07	0.75	0.75	0.49	0.49	0.39	0.39	0.38	0.38	0.85	0.85	0.71	0.71	0.21	0.21	0.35	0.35	0.32	0.32	0.61	0.61
		Wheat	0.15	0.15	0.69	0.69	0.74	0.74	0.68	0.68	0.41	0.41	0.37	0.37	0.30	0.30	0.14	0.14	0.12	0.12	0.07	0.07	0.20	0.20	0.18	0.18	0.41	0.41
		Maize	0.20	0.20	0.36	0.36	0.33	0.33	0.08	0.08	0.08	0.08	0.02	0.02	0.08	0.08	0.72	0.72	0.60	0.60	0.14	0.14	0.15	0.15	0.14	0.14	0.21	0.21
	ML 2.0, 1.75, 1.5 µg/g	Wheat and Maize	0.23	0.23	0.66	0.66	0.67	0.67	0.46	0.46	0.30	0.30	0.24	0.24	0.24	0.24	0.58	0.58	0.49	0.49	0.14	0.14	0.22	0.22	0.21	0.21	0.39	0.39
		Wheat	0.09	0.09	0.42	0.42	0.45	0.45	0.41	0.41	0.25	0.25	0.23	0.23	0.18	0.18	0.08	0.08	0.07	0.07	0.04	0.04	0.12	0.12	0.11	0.11	0.25	0.25
		Maize	0.14	0.14	0.25	0.25	0.23	0.23	0.05	0.05	0.06	0.06	0.01	0.01	0.06	0.06	0.50	0.50	0.41	0.41	0.10	0.10	0.11	0.11	0.10	0.10	0.14	0.14
	ML 1.25 µg/g	Wheat and Maize	0.22	0.22	0.65	0.65	0.66	0.66	0.46	0.46	0.30	0.30	0.24	0.24	0.24	0.24	0.55	0.55	0.46	0.46	0.13	0.13	0.22	0.22	0.20	0.20	0.38	0.38
		Wheat	0.09	0.09	0.42	0.42	0.45	0.45	0.41	0.41	0.25	0.25	0.23	0.23	0.18	0.18	0.08	0.08	0.07	0.07	0.04	0.04	0.12	0.12	0.11	0.11	0.25	0.25
		Maize	0.13	0.13	0.23	0.23	0.21	0.21	0.05	0.05	0.05	0.05	0.01	0.01	0.06	0.06	0.47	0.47	0.39	0.39	0.09	0.09	0.10	0.10	0.09	0.09	0.13	0.13
Japan	No ML	Wheat and Barley	0.11	0.11	0.36	0.36	0.45	0.45	0.35	0.35	0.24	0.24	0.22	0.22	0.15	0.15	0.09	0.09	0.06	0.06	0.04	0.04	0.12	0.12	0.10	0.10	0.24	0.24
		Wheat	0.08	0.08	0.34	0.34	0.37	0.37	0.34	0.34	0.20	0.20	0.19	0.19	0.15	0.15	0.07	0.07	0.06	0.06	0.04	0.04	0.10	0.10	0.09	0.09	0.20	0.20
		Barley	0.03	0.03	0.01	0.01	0.08	0.08	0.01	0.01	0.04	0.04	0.03	0.03	0.00	0.00	0.02	0.02	0.00	0.00	0.00	0.00	0.02	0.02	0.01	0.01	0.04	0.04
	ML 2.0, 1.75, 1.5, 1.25 µg/g	Wheat and Maize	0.11	0.11	0.36	0.36	0.45	0.45	0.35	0.35	0.24	0.24	0.22	0.22	0.15	0.15	0.09	0.09	0.06	0.06	0.04	0.04	0.12	0.12	0.10	0.10	0.24	0.24
		Wheat	0.08	0.08	0.34	0.34	0.37	0.37	0.34	0.34	0.20	0.20	0.19	0.19	0.15	0.15	0.07	0.07	0.06	0.06	0.04	0.04	0.10	0.10	0.09	0.09	0.20	0.20
		Barley	0.03	0.03	0.01	0.01	0.08	0.08	0.01	0.01	0.04	0.04	0.03	0.03	0.00	0.00	0.02	0.02	0.00	0.00	0.00	0.00	0.02	0.02	0.01	0.01	0.04	0.04
United Kingdom	No ML	All 3 cereals	0.59	0.60	1.90	1.92	1.99	2.02	1.51	1.53	0.97	0.98	0.81	0.82	0.74	0.74	1.22	1.24	1.02	1.03	0.33	0.33	0.61	0.62	0.56	0.57	1.12	1.14
		Wheat	0.32	0.32	1.43	1.45	1.54	1.56	1.41	1.42	0.85	0.86	0.78	0.79	0.63	0.63	0.29	0.29	0.25	0.25	0.15	0.15	0.41	0.42	0.37	0.38	0.85	0.85
		Maize	0.26	0.26	0.46	0.47	0.42	0.43	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.02	0.02	0.11	0.11	0.93	0.94	0.77	0.78	0.18	0.18	0.20	0.20
		Barley	0.01	0.01	0.00	0.01	0.03	0.03	0.00	0.00	0.01	0.02	0.01	0.01	0.00	0.00	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.00	0.01	0.01	0.01
	ML 2.0, 1.75, 1.5 µg/g	All 3 cereals	0.43	0.44	1.18	1.20	1.22	1.24	0.81	0.82	0.55	0.55	0.43	0.43	0.42	0.43	1.07	1.09	0.89	0.91	0.25	0.26	0.41	0.41	0.37	0.38	0.70	0.71
		Wheat	0.16	0.16	0.72	0.73	0.77	0.78	0.71	0.72	0.43	0.43	0.39	0.40	0.31	0.32	0.14	0.14	0.12	0.12	0.08	0.08	0.21	0.21	0.19	0.19	0.43	0.43
		Maize	0.26	0.26	0.46	0.47	0.42	0.43	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.02	0.02	0.11	0.11	0.93	0.94	0.77	0.78	0.18	0.18	0.20	0.20
		Barley	0.01	0.01	0.00	0.01	0.03	0.03	0.00	0.00	0.01	0.02	0.01	0.01	0.00	0.00	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.00	0.01	0.01	0.01
	ML 1.25 µg/g	All 3 cereals	0.40	0.41	1.10	1.12	1.13	1.15	0.75	0.76	0.50	0.51	0.39	0.40	0.39	0.40	1.01	1.03	0.84	0.86	0.24	0.24	0.38	0.39	0.35	0.35	0.65	0.66
		Wheat	0.15	0.15	0.66	0.67	0.71	0.72	0.65	0.66	0.39	0.40	0.36	0.36	0.29	0.29	0.13	0.13	0.11	0.11	0.07	0.07	0.19	0.19	0.17	0.17	0.39	0.39
		Maize	0.24	0.25	0.44	0.44	0.40	0.41	0.09	0.09	0.10	0.10	0.02	0.02	0.10	0.11	0.88	0.89	0.73	0.74	0.17	0.17	0.19	0.19	0.17	0.17	0.25	0.26
		Barley	0.01	0.01	0.00	0.01	0.03	0.03	0.00	0.00	0.01	0.02	0.01	0.01	0.00	0.00	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.00	0.01	0.01	0.01
United States of America	No ML	Wheat	1.21	1.23	5.42	5.50	5.84	5.91	5.34	5.41	3.23	3.28	2.96	3.00	2.37	2.40	1.08	1.10	0.93	0.94	0.57	0.58	1.56	1.58	1.41	1.43	3.20	3.25
	ML 2.0 µg/g	Wheat	0.41	0.43	1.84	1.92	1.98	2.07	1.81	1.89	1.10	1.15	1.00	1.05	0.80	0.84	0.37	0.38	0.32	0.33	0.19	0.20	0.53	0.55	0.48	0.50	1.09	1.14
	ML 1.75 µg/g	Wheat	0.38	0.40	1.72	1.80	1.86	1.94	1.70	1.78	1.03	1.08	0.94	0.98	0.75	0.79	0.34	0.36	0.30	0.31	0.18	0.19	0.50	0.52	0.45	0.47	1.02	1.07
	ML 1.5 µg/g	Wheat	0.36	0.38	1.61	1.70	1.73	1.83	1.59	1.67	0.96	1.01	0.88	0.93	0.70	0.74	0.32	0.34	0.28	0.29	0.17	0.18	0.46	0.49	0.42	0.44	0.95	1.00
	ML 1.25 µg/g	Wheat	0.29	0.31	1.32	1.41	1.42	1.51	1.30	1.39	0.79	0.84	0.72	0.77	0.58	0.61	0.26	0.28	0.23	0.24	0.14	0.15	0.38	0.41	0.34	0.37	0.78	0.83

LB, lower bound; UB, upper bound; ML, Maximum Limit; LOD, Limit of Detection; LOQ, Limit of Quantification; LOR, Limit of Reporting
 Lower and upper bound calculations have been undertaken for each scenario. The lower bound was calculated for the occurrence data by using zero for concentrations less than the LOD, LOQ or LOR and calculating the upper bound estimates assuming concentrations less than the LOD, LOQ or LOR are equal to the LOD, LOQ or LOR.
 LOD, LOQ and LOR values ranged from 0.0001 to 0.5 ug/g. Calculated mean occurrence values were then multiplied by the GEMS/Food Cluster diet consumption values.

Processing Factors and the Elaboration of MLs

32. In elaborating MLs for DON, the possibility of applying processing factors was considered. Processing studies have shown that concentration reductions of up to 50%, moving from raw cereal grains to semi-processed products such as flour and semolina, are possible during the cleaning and milling of grain. However, physical procedures for removing DON from contaminated grains and the effectiveness of milling practices on reducing the concentration of DON products derived from those grains depends on the distribution of the toxin throughout the kernels and the degree of fungal penetration of the endosperm, as well as the level of contamination. While it is well known that processing reductions do occur, there is a wide variety of processed cereal-based foods, a broad range of food processing and preparation methods that are employed worldwide, and there is variability in the results of studies examining processing factors. The apparent variability may stem from the manner in which reductions or increases are reported (i.e., reductions due to dilution with other ingredients or reporting on an “as is basis” due to processing), variability in baking conditions (i.e., time, temperature and inclusion of additives), the commercial applicability of parameters used in pilot studies, differences in extraction efficiency between studies, and unwanted degradation products that may be generated from detoxification procedures (Scudamore et al., 2009; Pacin et al., 2010; JECFA 2010). For these reasons, the use of processing factors in elaborating MLs is currently not considered feasible for application at a global level. As such, the Committee may give consideration to establishing MLs only for raw cereal grains and semi-processed products such as flour, rather than processed cereal-based foods such as breads and breakfast cereals, with the exception of cereal-based foods intended for infants and young children.

SAMPLING PLAN FOR DON IN CEREAL AND CEREAL-BASED PRODUCTS

33. Sampling is an essential element in the establishment of MLs for chemical contaminants and natural toxicants, particularly if these substances may be heterogeneously distributed within a lot, which is the case for most mycotoxins in cereals. While DON is not as heterogeneously distributed as ochratoxin A or the aflatoxins, it is still considered important that a sampling procedure be proposed simultaneously with the ML. The need for a sampling plan at this stage of ML development was generally supported by the e-WG although one member commented that a sampling plan should not be considered until an ML is elaborated. Nonetheless, a sampling plan for DON, based largely on the existing European Union sampling plan for DON in cereals is presented in Appendix I for consideration as a Codex sampling plan.

CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS

34. Very few comments were received regarding whether or not the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003) should be updated and revised. While some considered that for the time being, there were no issues with the Code of Practice (COP) as it currently stands with regards to the prevention of DON in cereals, that it is still valid at the “world” level and would not require updating, one e-WG member felt that it was not fully relevant to the North American situation. While no comments were received on a request for information concerning the compliance with and efficiency of the COP in reducing DON contamination in cereals, one e-WG member suggested that countries who have implemented any of the procedures recommended within the COP be asked to comment on its effectiveness in reducing DON in order to help determine whether the existing COP should be revised and/or updated.

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Appendix II.A. Maximum, guidance, or reference levels for deoxynivalenol (DON) for various countries around the world; either established in the countries respective legislation, or developed as guidance for further risk assessment and risk management purposes

Country	Regulatory Authorities	Maximum Level
Argentina†		<ul style="list-style-type: none"> • 2 ppm in wheat • 1 ppm in wheat flour and sub-products (these are reference values not regulatory limits)
Armenia*	Supervision Service of Haypetstandard and Authorities of Health Sphere	<ul style="list-style-type: none"> • 0.7 ppm in wheat • 1 ppm in barley
Belarus*	Ministry of Public Health	<ul style="list-style-type: none"> • 1 ppm in barley • 0.7 ppm in wheat • in infant food not allowed
Brazil	Brazilian Health Surveillance Agency (Anvisa)	<ul style="list-style-type: none"> • 0.75 ppm in processed rice and sub-products • 0.2 ppm in processed cereal-based foods and baby foods for infants and young children • 2 ppm whole wheat, wheat kebab, whole wheat flour, wheat bran, rice bran, barley grain • 1.75 ppm wheat flour, pasta, crackers, biscuits and salt water, and bakery products, cereals and cereal products except wheat and malted barley To be adopted in 2014: <ul style="list-style-type: none"> • 3 ppm wheat and maize for further processing • 1.5 ppm whole wheat, wheat kebab, whole wheat flour, wheat bran, rice bran, barley grain • 1.25 ppm wheat flour, pasta, crackers, biscuits and salt water, and bakery products, cereals and cereal products except wheat and malted barley To be adopted in 2016: <ul style="list-style-type: none"> • 1 ppm whole wheat, wheat kebab, whole wheat flour, wheat bran, rice bran, barley grain • 0.75 ppm wheat flour, pasta, crackers, biscuits and salt water, and bakery products, cereals and cereal products except wheat and malted barley (Resolution RDC Anvisa n°. 7/2011)
Canada	Health Canada and Canadian Food Inspection Agency	<ul style="list-style-type: none"> • 2 ppm uncleaned soft wheat intended for use in non-staple foods (under review) • 1 ppm in uncleaned soft wheat for use in baby foods (under review)
China	Ministry of Health	<ul style="list-style-type: none"> • 1 ppm in cereals and their products, maize, maize flour (pulp and pieces), barley, wheat, oatmeal and wheatmeal
Cuba*	Ministry of Public Health/ Instituto de Nutricion e Higiene de los Alimentos	<ul style="list-style-type: none"> • 0.3 ppm in imported cereals
European Union	European Commission	<ul style="list-style-type: none"> • 1.25 ppm in unprocessed cereals other than durum wheat, oats and maize • 1.75 ppm in unprocessed durum wheat, oats and maize, except unprocessed maize intended to be processed by wet milling • 0.75 ppm in cereals intended for direct human consumption, cereal flour (including maize flour, maize meal and maize grits, semolina), bran as end product marketed for direct human consumption and germ

Country	Regulatory Authorities	Maximum Level
		<ul style="list-style-type: none"> • 0.75 ppm in pasta (dry) • 0.5 ppm in bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals • 0.2 ppm in processed cereal-based foods and baby foods for infants and young children • Milling fractions of maize with particle size > 500 micron falling within CN code 1103 13 or 1103 20 40 and other maize milling products with particle size > 500 micron not used for direct human consumption falling within CN code 1904 10 10 • Milling fractions of maize with particle size ≤ 500 micron falling within CN code 1102 20 and other maize milling products with particle size ≤ 500 micron not used for direct human consumption falling within CN code 1904 10 10
Iran, Islamic Republic of*	Institute of Standard and Industrial Research of the Islamic Republic of Iran; Ministry of Health and Medical Evaluation	<ul style="list-style-type: none"> • 1 ppm in barley, maize, rice and wheat
Japan*	Ministry of Health, Labour and Welfare	<ul style="list-style-type: none"> • 1.1 ppm in husked wheat
Russian Federation, The*	Ministry of Health	<ul style="list-style-type: none"> • 0.7 ppm in wheat • 1 ppm in barley
Singapore*	Agri-Food and Veterinary Authority	<ul style="list-style-type: none"> • Cereal and grain products (specific ML not given)
Switzerland*		<ul style="list-style-type: none"> • 1 ppm in cereal grains (cereal products and cereals as sold to consumer†)
Ukraine*	Ministry of Health Protection; State Department of Veterinary Medicine (Ministry of Agricultural Policy)	<ul style="list-style-type: none"> • 0.2 ppm grain-based baby food products; fruit-vegetable –dairy mixes for baby food • 0.5 ppm in wheat of other than hard strong varieties, flour, bread • 1 ppm in wheat of hard strong varieties; all seeds to be used for immediate human consumption and for processing into the products for human consumption; wheat middlings
United States of America	U.S. Food and Drug Administration (U.S. FDA)	<ul style="list-style-type: none"> • 1 ppm in finished wheat products (e.g. flour, bran and germ) for human consumption
Uruguay*	Ministerio de Salud Pública; Technological Laboratory of Uruguay; Ministerio de Ganadería Agricultura y Pesca	<ul style="list-style-type: none"> • 1 ppm in wheat flour and by-products

* As reported in Worldwide regulations for mycotoxins in food and feed in 2003 (FAO, 2004)

† As reported in CX/FAC 05/37/25, November 2004 (Agenda Item 16(e)) in response to CL 2004/9-FAC. Indicated that levels based on US FDA levels and the 2001 JECFA assessment

‡ As reported in Discussion Paper on Deoxynivalenol (CX/FAC 03/35), November 2002, Agenda Item 16(j)

Appendix II.B. DON Maximum Limit (ML) Impact Assessment Tables, showing the impact of different potential MLs for DON on the statistical distribution of DON in various cereal-based foods by country (i.e., those countries who submitted raw occurrence data)

Table B1. Summary of the impact of different potential MLs (2.0, 1.75, 1.5, and 1.25 ug/g) for DON on the statistical distribution of DON in Canadian hard wheat grain from harvest survey between 1999-2009.

WHEAT	Scenario ^a	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
All years	All data	251	0.18 - 0.22	0.00 - 0.10	0.18	0.56	0.95	2.10	0.0
	ML 2.0 µg/g	248	0.15 - 0.20	0.00 - 0.10	0.15	0.54	0.77	1.90	1.2
	ML 1.75, 1.5 µg/g	245	0.13 - 0.18	0.00 - 0.10	0.13	0.51	0.65	1.30	2.4
	ML 1.25 µg/g	244	0.13 - 0.18	0.00 - 0.10	0.12	0.50	0.64	1.20	2.8

Canadian Grain Commission data

Table B2. Summary of the impact of different potential MLs (2.0, 1.75, 1.5, and 1.25 ug/g) for DON on the statistical distribution of DON in Canadian wheat grains destined for export from 1994-2008.

WHEAT	Scenario ^a	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
All years	All data	2021	0.21 - 0.25	0.05 - 0.10	0.25	0.68	1.04	2.79	0.0
	ML 2.0 µg/g	2006	0.20 - 0.24	0.00 - 0.10	0.24	0.65	0.94	2.00	0.7
	ML 1.75 µg/g	1994	0.19 - 0.23	0.00 - 0.10	0.23	0.62	0.88	1.75	1.3
	ML 1.5 µg/g	1980	0.18 - 0.22	0.00 - 0.10	0.22	0.60	0.85	1.50	2.0
	ML 1.25 µg/g	1958	0.16 - 0.20	0.00 - 0.10	0.21	0.56	0.80	1.24	3.1
Hard Wheat	All data	1291	0.25 - 0.29	0.05 - 0.10	0.31	0.81	1.20	2.79	0.0
	ML 2.0 µg/g	1277	0.23 - 0.27	0.05 - 0.10	0.30	0.75	1.10	2.00	1.1
	ML 1.75 µg/g	1266	0.21 - 0.25	0.00 - 0.10	0.29	0.71	1.00	1.75	1.9
	ML 1.5 µg/g	1254	0.20 - 0.24	0.00 - 0.10	0.29	0.68	0.91	1.50	2.9
	ML 1.25 µg/g	1234	0.18 - 0.22	0.00 - 0.10	0.26	0.62	0.83	1.24	4.4
Soft Wheat	All data	192	0.34 - 0.36	0.21	0.49	0.85	1.11	2.15	0.0
	ML 2.0 µg/g	191	0.33 - 0.35	0.21	0.49	0.85	1.11	1.89	0.5
	ML 1.75 µg/g	190	0.32 - 0.34	0.20	0.49	0.85	1.10	1.60	1.0
	ML 1.5 µg/g	189	0.32 - 0.34	0.19	0.49	0.84	1.10	1.30	1.6
	ML 1.25 µg/g	188	0.31 - 0.33	0.19	0.48	0.83	1.10	1.20	2.1
Durum Wheat	All data	538	0.08 - 0.12	0.00 - 0.10	0.10	0.20	0.32	1.30	0.0
	ML 2.0, 1.75 µg/g	538	0.08 - 0.12	0.00 - 0.10	0.10	0.20	0.32	1.30	0.0
	ML 1.5 µg/g	537	0.07 - 0.12	0.00 - 0.10	0.10	0.20	0.30	1.30	0.2
	ML 1.25 µg/g	536	0.07 - 0.12	0.00 - 0.10	0.10	0.20	0.29	0.94	0.4

Canadian Grain Commission data

Table B3. Summary of the impact of different potential MLs (2.0, 1.75, 1.5, and 1.25 µg/g) for DON on the statistical distribution of DON in Canadian barley grain destined for export from 1994-2008.

BARLEY	Scenario ^a	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
All years	All data	302	0.05 - 0.12	0.00 - 0.10	0.00 - 0.10	0.10	0.24	3.15	0.0
	ML 2.0 µg/g	301	0.04 - 0.11	0.00 - 0.10	0.00 - 0.10	0.09 - 0.10	0.22	1.90	0.3
	ML 1.75 µg/g	300	0.03 - 0.10	0.00 - 0.10	0.00 - 0.10	0.08 - 0.10	0.22	1.51	0.7
	ML 1.5, 1.25 µg/g	299	0.03 - 0.09	0.00 - 0.10	0.00 - 0.10	0.08 - 0.10	0.21	0.84	1.0

Canadian Grain Commission data

Table B4. Summary of the impact of different potential MLs (2.0, 1.75, 1.5, and 1.25 µg/g) for DON on the statistical distribution of DON in domestic raw cereal grains from 2009-2010 in Japan.

RAW CEREAL GRAINS	Scenario	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
Wheat grain	All data	240	0.052	0.017	0.055	0.160	0.240	0.540	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	240	0.052	0.017	0.055	0.160	0.240	0.540	0.0
Barley grain	All data	200	0.049	0.017	0.061	0.130	0.201	0.500	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	200	0.049	0.017	0.061	0.130	0.201	0.500	0.0

Data provided by the Japanese Ministry of Agriculture, Forestry and Fisheries

Table B5. Summary of the impact of different potential MLs (2.0, 1.75, 1.5, and 1.25 µg/g) for DON on the statistical distribution of DON in South African wheat grains from 2003/2004 – 2010/2011.

WHEAT	Scenario ^a	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
All years	All data	240	0.67 - 0.79	0.59	1.20	1.60	1.80	3.00	0.0
	ML 2.0 µg/g	235	0.63 - 0.75	0.56	1.20	1.60	1.70	2.00	2.1
	ML 1.75 µg/g	225	0.57 - 0.70	0.50	1.10	1.50	1.60	1.70	6.3
	ML 1.5 µg/g	207	0.48 - 0.62	0.00 - 0.50	0.94	1.30	1.40	1.50	13.8
	ML 1.25 µg/g	184	0.36 - 0.52	0.00 - 0.50	0.78	1.10	1.19	1.20	23.3

South African Grain Laboratory data

Table B6. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in raw cereal grains, semi-processed and processed cereal-based foods from 2007-2010 in Austria.

RAW CEREAL GRAINS AND PROCESSED CEREAL GRAIN PRODUCTS	Scenario	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
RAW CEREAL GRAINS									
Wheat grain	All data	1	0.084	0.084	0.084	0.084	0.084	0.084	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	1	0.084	0.084	0.084	0.084	0.084	0.084	0.0
Corn grain	All data	1	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	1	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.0
Barley grain	All data	1	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	1	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.015 - 0.050	0.0
Oat grain	All data	2	0.008 - 0.038	0.008 - 0.038	0.011 - 0.044	0.014 - 0.048	0.014 - 0.049	0.015 - 0.050	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	2	0.008 - 0.038	0.008 - 0.038	0.011 - 0.044	0.014 - 0.048	0.014 - 0.049	0.015 - 0.050	0.0
Rye grain	All data	1	0.110	0.110	0.110	0.110	0.110	0.110	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	1	0.110	0.110	0.110	0.110	0.110	0.110	0.0
Spelt grain	All data	5	0.041 - 0.047	0.051	0.054	0.081	0.089	0.098	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	5	0.041 - 0.047	0.051	0.054	0.081	0.089	0.098	0.0
Millet grain	All data	1	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	1	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.0
Grains for human consumption	All data	2	0.119 - 0.131	0.119 - 0.131	0.178 - 0.184	0.213 - 0.216	0.225 - 0.226	0.237	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	2	0.119 - 0.131	0.119 - 0.131	0.178 - 0.184	0.213 - 0.216	0.225 - 0.226	0.237	0.0
PROCESSED CEREAL GRAIN PRODUCTS									
Wheat flour and flour mixtures									
Wheat milling products	All data	55	0.080 - 0.089	0.066	0.111	0.205	0.278	0.315	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	55	0.080 - 0.089	0.066	0.111	0.205	0.278	0.315	0.0
Breads and rolls	All data	3	0.105 - 0.114	0.044	0.151	0.214	0.236	0.257	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	3	0.105 - 0.114	0.044	0.151	0.214	0.236	0.257	0.0
Pasta	All data	114	0.059 - 0.070	0.060	0.096	0.124	0.166	0.259	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	114	0.059 - 0.070	0.060	0.096	0.124	0.166	0.259	0.0
Biscuits (cookies, sweet)	All data	24	0.155 - 0.164	0.077	0.214	0.304	0.586	0.800	0.0
	ML 1.5, 1.25, 1.0 µg/g	24	0.155 - 0.164	0.077	0.214	0.304	0.586	0.800	0.0
	ML 0.75 µg/g	23	0.127 - 0.137	0.070	0.214	0.277	0.309	0.634	4.2
	ML 0.5 µg/g	22	0.104 - 0.114	0.067	0.213	0.230	0.285	0.311	8.3
Crackers (salt biscuits, unleavened bread, crisp bread and rusks)	All data	30	0.034 - 0.051	0.013 - 0.038	0.055	0.090	0.109	0.227	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	30	0.034 - 0.051	0.013 - 0.038	0.055	0.090	0.109	0.227	0.0
Fine bakery wares, cakes and pastries, and pretzels	All data	36	0.093 - 0.103	0.078	0.140	0.213	0.275	0.412	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	36	0.093 - 0.103	0.078	0.140	0.213	0.275	0.412	0.0
Waffles	All data	37	0.066 - 0.077	0.056	0.097	0.145	0.190	0.376	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	37	0.066 - 0.077	0.056	0.097	0.145	0.190	0.376	0.0
Corn milling products (includes corn semolina, flakes and starch)	All data	9	0.077 - 0.082	0.081	0.113	0.122	0.133	0.145	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	9	0.077 - 0.082	0.081	0.113	0.122	0.133	0.145	0.0
Popped cereals	All data	76	0.142 - 0.152	0.083	0.171	0.277	0.384	2.110	0.0
	ML 1.5, 1.25 µg/g	75	0.116 - 0.126	0.082	0.165	0.265	0.345	1.120	1.3
	ML 1.0, 0.75, 0.5 µg/g	74	0.103 - 0.113	0.078	0.160	0.264	0.326	0.433	2.6
Barley flakes	All data	12	0.138 - 0.153	0.013 - 0.033	0.086	0.271	0.661	1.115	0.0
	ML 1.5, 1.25 µg/g	12	0.138 - 0.153	0.013 - 0.033	0.086	0.271	0.661	1.115	0.0
	ML 1.0, 0.75, 0.5 µg/g	11	0.049 - 0.065	0.000 - 0.025	0.058 - 0.063	0.113	0.201	0.289	8.3
Grain milling products	All data	1	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.0
Muesli	All data	16	0.090 - 0.100	0.056	0.113	0.288	0.313	0.338	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	16	0.090 - 0.100	0.056	0.113	0.288	0.313	0.338	0.0
Oat flakes	All data	64	0.023 - 0.045	0.000 - 0.025	0.025 - 0.050	0.058	0.099	0.270	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	64	0.023 - 0.045	0.000 - 0.025	0.025 - 0.050	0.058	0.099	0.270	0.0
Rye milling products	All data	10	0.020 - 0.038	0.000 - 0.020	0.000 - 0.025	0.020 - 0.043	0.112 - 0.123	0.204	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	10	0.020 - 0.038	0.000 - 0.020	0.000 - 0.025	0.020 - 0.043	0.112 - 0.123	0.204	0.0
Spelt milling products	All data	13	0.008 - 0.030	0.000 - 0.025	0.015 - 0.040	0.025 - 0.050	0.025 - 0.050	0.025 - 0.050	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	13	0.008 - 0.030	0.000 - 0.025	0.015 - 0.040	0.025 - 0.050	0.025 - 0.050	0.025 - 0.050	0.0
Millet flour	All data	8	0.049 - 0.067	0.015 - 0.040	0.052 - 0.070	0.164	0.168	0.171	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	8	0.049 - 0.067	0.015 - 0.040	0.052 - 0.070	0.164	0.168	0.171	0.0
Rice and rice products	All data	1	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.000 - 0.015	0.0
Cereal-based food for infants and young children	All data	9	0.008 - 0.029	0.000 - 0.025	0.000 - 0.025	0.014 - 0.034	0.042 - 0.052	0.071	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	9	0.008 - 0.029	0.000 - 0.025	0.000 - 0.025	0.014 - 0.034	0.042 - 0.052	0.071	0.0
Cereal-based food for infants and young children	All data	68	0.003 - 0.027	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.025 - 0.050	0.073	0.0
	ML 0.5, 0.3, 0.2 µg/g	68	0.003 - 0.027	0.000 - 0.025	0.000 - 0.025	0.000 - 0.025	0.025 - 0.050	0.073	0.0

Data provided by the Austrian Agency for Health and Food Safety

Table B7. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in raw cereal grains, semi-processed and processed cereal-based foods from 1998 and 2007-2011 in Brazil.

RAW CEREAL GRAINS AND PROCESSED CEREAL GRAIN	Scenario	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
RAW CEREAL GRAINS									
Wheat grain									
	All data	187	0.893 - 0.910	0.723	1.162	2.000	2.988	4.000	0.0
	ML 2.0 µg/g	170	0.688 - 0.706	0.614	1.069	1.520	1.790	2.000	9.1
	ML 1.75 µg/g	159	0.605 - 0.624	0.546	1.000	1.237	1.457	1.676	15.0
	ML 1.5 µg/g	152	0.558 - 0.579	0.518	0.927	1.142	1.279	1.486	18.7
	ML 1.25 µg/g	143	0.507 - 0.529	0.496 - 0.500	0.852	1.072	1.140	1.232	23.5
Maize									
	All data	96	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	96	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.000 - 0.070	0.0
PROCESSED CEREAL GRAIN PRODUCTS									
Wheat flour									
	All data	409	0.428 - 0.450	0.327	0.685	0.987	1.125	1.695	0.0
	ML 1.5 µg/g	404	0.413 - 0.436	0.317	0.652	0.963	1.106	1.494	1.2
	ML 1.25 µg/g	395	0.390 - 0.413	0.310	0.614	0.906	1.042	1.206	3.4
	ML 1.0 µg/g	369	0.340 - 0.365	0.272	0.541	0.795	0.871	0.991	9.8
	ML 0.75 µg/g	324	0.267 - 0.296	0.239 - 0.250	0.430	0.599	0.685	0.743	20.8
	ML 0.5 µg/g	267	0.191 - 0.225	0.161 - 0.200	0.311	0.423	0.468	0.500	34.7
Wheat bran									
	All data	65	1.571 - 1.574	1.220	2.299	3.050	3.173	5.336	0.0
	ML 1.5 µg/g	35	0.610 - 0.616	0.732	0.929	0.982	1.238	1.451	46.2
	ML 1.25 µg/g	33	0.564 - 0.570	0.716	0.914	0.954	0.973	1.220	49.2
	ML 1.0 µg/g	32	0.544 - 0.550	0.584	0.902	0.948	0.955	1.000	50.8
	ML 0.75 µg/g	18	0.255 - 0.266	0.169	0.311	0.531	0.718	0.732	72.3
	ML 0.5 µg/g	16	0.196 - 0.209	0.168	0.299	0.332	0.377	0.451	75.4
Bread (includes toast)									
	All data	38	0.449 - 0.468	0.462	0.677	1.003	1.039	1.248	0.0
	ML 1.5, 1.25 µg/g	38	0.449 - 0.468	0.462	0.677	1.003	1.039	1.248	0.0
	ML 1.0 µg/g	33	0.352 - 0.373	0.400	0.577	0.712	0.734	0.780	13.2
	ML 0.75 µg/g	32	0.338 - 0.360	0.373	0.566	0.685	0.720	0.748	15.8
	ML 0.5 µg/g	21	0.184 - 0.218	0.115	0.346	0.462	0.462	0.477	44.7
Cookies, cream crackers and cakes									
	All data	21	0.453 - 0.465	0.309	0.734	0.948	1.004	1.139	0.0
	ML 1.5, 1.25 µg/g	21	0.453 - 0.465	0.309	0.734	0.948	1.004	1.139	0.0
	ML 1.0 µg/g	19	0.388 - 0.401	0.308	0.607	0.782	0.811	0.948	9.5
	ML 0.75 µg/g	16	0.303 - 0.319	0.262	0.383	0.607	0.648	0.734	23.8
	ML 0.5 µg/g	12	0.198 - 0.219	0.235	0.279	0.309	0.320	0.334	42.9
Wafer									
	All data	10	0.177 - 0.187	0.185	0.222	0.254	0.297	0.339	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	10	0.177 - 0.187	0.185	0.222	0.254	0.297	0.339	0.0
Pasta									
	All data	18	0.270 - 0.284	0.189	0.386	0.562	0.651	0.812	0.0
	ML 1.5, 1.25, 1.0 µg/g	18	0.270 - 0.284	0.189	0.386	0.562	0.651	0.812	0.0
	ML 0.75 µg/g	17	0.238 - 0.253	0.185	0.328	0.492	0.553	0.622	5.6
	ML 0.5 µg/g	15	0.193 - 0.210	0.174	0.271	0.374	0.422	0.463	16.7
Semolina									
	All data	1	0.469	0.469	0.469	0.469	0.469	0.469	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.469	0.469	0.469	0.469	0.469	0.469	0.0
Maize grits									
	All data	18	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	18	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.0
Bran and Husk									
	All data	6	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	6	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.0
Rice (includes parboiled, polished, rice paddy)									
	All data	171	0.008 - 0.036	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.045	0.244	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	171	0.008 - 0.036	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.045	0.244	0.0
Rice bran and rice husks									
	All data	42	0.007 - 0.036	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.300	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	42	0.007 - 0.036	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.000 - 0.030	0.300	0.0
Rice flour									
	All data	1	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.000 - 0.100	0.0

Data provided by the Brazilian Health Surveillance Agency

Table B8. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in cereal grain-based foods available on the Canadian retail market.

PROCESSED CEREAL GRAIN PRODUCTS	Scenario ^a	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
3 yr breakfast cereal survey (1999/00 - 2001/02)									
	All data	156	0.05	0.00 - 0.01	0.04	0.11	0.22	0.94	0.0
	ML 1.5, 1.25, 1.0 µg/g	156	0.05	0.00 - 0.01	0.04	0.11	0.22	0.94	0.0
	ML 0.75 µg/g	154	0.04	0.00 - 0.01	0.04	0.09	0.21	0.53	1.3
	ML 0.5 µg/g	153	0.03 - 0.04	0.00 - 0.01	0.04	0.08	0.19	0.47	1.9
3yr Infant cereal survey (1997/98 - 1999/00)									
	All data	206	0.08 - 0.09	0.04	0.08	0.23	0.39	1.00	0.0
	ML 0.5 µg/g	199	0.06 - 0.07	0.03	0.07	0.16	0.27	0.50	3.4
	ML 0.3 µg/g	190	0.04 - 0.05	0.03	0.06	0.12	0.17	0.29	7.8
	ML 0.2 µg/g	184	0.04 - 0.05	0.03	0.05	0.09	0.14	0.18	10.7
DON infant Cereal Survey (2000/2001)									
	All data	105	0.04	0.00 - 0.01	0.03	0.10	0.15	0.90	0.0
	ML 0.5, 0.3, 0.2 µg/g	103	0.02 - 0.03	0.00 - 0.01	0.03	0.08	0.12	0.20	1.9
DON infant Cereal Survey (2005/2006)									
	All data	107	0.02	0.00 - 0.01	0.02	0.03	0.06	0.44	0.0
	ML 0.5 µg/g	107	0.02	0.00 - 0.01	0.02	0.03	0.06	0.44	0.0
	ML 0.3 µg/g	106	0.01 - 0.02	0.00 - 0.01	0.02	0.03	0.05	0.29	0.9
	ML 0.2 µg/g	105	0.01 - 0.02	0.00 - 0.01	0.02	0.03	0.04	0.19	1.9
DON Oat-based products survey (2008/2009)									
	All data	95	0.01	0.00	0.01	0.03	0.04	0.10	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	95	0.01	0.00	0.01	0.03	0.04	0.10	0.0

Health Canada data

Table B9. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in semi-processed and processed cereal-based foods available on the Canadian retail market from 2009 – 2011.

PROCESSED CEREAL GRAIN PRODUCTS	Scenario	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
Infant Cereal									
	All data	109	0.014	0.005	0.015	0.029	0.047	0.255	0.0
	ML 0.5, 0.3, 0.2 µg/g	109	0.014	0.005	0.015	0.029	0.047	0.255	0.0
Breakfast cereal									
	All data	277	0.124	0.058	0.178	0.329	0.441	1.610	0.0
	ML 1.5, 1.25, 1.0 µg/g	276	0.118	0.058	0.177	0.321	0.429	0.850	0.4
	ML 0.75 µg/g	271	0.106	0.057	0.159	0.277	0.400	0.690	2.2
	ML 0.5 µg/g	264	0.094	0.054	0.154	0.245	0.343	0.462	4.7
Wheat flour									
	All data	121	0.209 - 0.211	0.050	0.165	0.472	0.860	6.010	0.0
	ML 1.5 µg/g	120	0.161 - 0.163	0.050	0.161	0.445	0.860	1.430	0.8
	ML 1.25, 1 µg/g	117	0.129 - 0.131	0.050	0.152	0.349	0.612	0.979	3.3
	ML 0.75 µg/g	112	0.096 - 0.098	0.044	0.125	0.279	0.590	0.720	7.4
	ML 0.5 µg/g	109	0.082 - 0.084	0.043	0.112	0.226	0.325	0.472	9.9
Wheat bran									
	All data	46	0.213 - 0.215	0.041	0.314	0.755	0.874	1.500	0.0
	ML 1.5 µg/g	46	0.213 - 0.215	0.041	0.314	0.755	0.874	1.500	0.0
	ML 1.25, 1.0 µg/g	45	0.185 - 0.186	0.038	0.204	0.724	0.794	0.920	2.2
	ML 0.75 µg/g	41	0.120 - 0.122	0.033	0.081	0.380	0.590	0.740	10.9
	ML 0.5 µg/g	38	0.076 - 0.078	0.030	0.071	0.248	0.376	0.500	17.4
Wheat germ									
	All data	35	0.143	0.098	0.197	0.324	0.443	0.740	0.0
	ML 1.5, 1.25, 1, 0.75 µg/g	35	0.143	0.098	0.197	0.324	0.443	0.740	0.0
	ML 0.5 µg/g	34	0.125	0.093	0.184	0.314	0.360	0.492	2.9
Bread									
	All data	61	0.184	0.174	0.281	0.361	0.410	0.473	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	61	0.184	0.174	0.281	0.361	0.410	0.473	0.0
Other wheat products									
	All data	14	0.179 - 0.180	0.081	0.313	0.361	0.410	0.473	0.0
	ML 1.5, 1.25, 1, 0.75 µg/g	14	0.179 - 0.180	0.081	0.313	0.361	0.410	0.473	0.0
	ML 0.5 µg/g	12	0.107 - 0.108	0.049	0.134	0.347	0.384	0.400	14.3
Baked goods									
	All data	5	0.165	0.190	0.205	0.296	0.327	0.357	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	5	0.165	0.190	0.205	0.296	0.327	0.357	0.0
Specialty grain flours and breads (e.g., gluten free, quinoa, kamut, spelt, arrowroot)									
	All data	51	0.031	0.001	0.018	0.074	0.141	0.484	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	51	0.031	0.001	0.018	0.074	0.141	0.484	0.0
Barley									
	All data	1	0.005	0.005	0.005	0.005	0.005	0.005	0.0
Corn bran									
	All data	2	1.106	1.106	1.583	1.869	1.965	2.060	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	1	0.152	0.152	0.152	0.152	0.152	0.152	50.0
Corn flour/meal/grits/masa									
	All data	95	0.178 - 0.180	0.050	0.173	0.505	0.726	2.460	0.0
	ML 1.5 µg/g	94	0.154 - 0.156	0.050	0.172	0.433	0.684	1.380	1.1
	ML 1.25, 1 µg/g	93	0.141 - 0.143	0.049	0.170	0.419	0.614	0.856	2.1
	ML 0.75 µg/g	91	0.126 - 0.127	0.040	0.165	0.381	0.555	0.740	4.2
	ML 0.5 µg/g	85	0.090 - 0.092	0.040	0.140	0.271	0.328	0.438	10.5
Corn and tortillas chips									
	All data	64	0.101	0.041	0.106	0.218	0.302	1.440	0.0
	ML 1.5 µg/g	64	0.101	0.041	0.106	0.218	0.302	1.440	0.0
	ML 1.25, 1, 0.75 µg/g	63	0.080	0.036	0.104	0.188	0.270	0.623	1.6
	ML 0.5 µg/g	62	0.071	0.035	0.100	0.185	0.259	0.369	3.1
Oat-based products									
	All data	67	0.028 - 0.031	0.004 - 0.010	0.040	0.080	0.123	0.244	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	67	0.028 - 0.031	0.004 - 0.010	0.040	0.080	0.123	0.244	0.0
Rice									
	All data	3	0.001	0.000 - 0.001	0.001	0.002	0.002	0.002	0.0
	ML 1.5, 1.25, 1, 0.75, 0.5 µg/g	3	0.001	0.000 - 0.001	0.001	0.002	0.002	0.002	0.0

Canadian Food Inspection Agency data

Table B10. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in raw cereal grains and semi-processed cereal grain-based foods from 2008 – 2011 in China.

RAW CEREAL GRAINS AND PROCESSED CEREAL GRAIN PRODUCTS	Scenario	No. of samples	DON content (µg/g)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
RAW CEREAL GRAINS									
Wheat									
	All data	166	0.104	0.024	0.069	0.195	0.341	4.280	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	164	0.063	0.024	0.065	0.178	0.272	0.591	1.2
Maize									
	All data	203	0.144	0.002	0.098	0.394	0.624	4.374	0.0
	ML 2.0, 1.75, 1.5 µg/g	200	0.100	0.001	0.082	0.340	0.488	1.272	1.5
	ML 1.25 µg/g	199	0.094	0.000	0.079	0.335	0.485	1.064	2.0
Barley									
	All data	2	0.004 - 0.024	0.004 - 0.024	0.006 - 0.032	0.008 - 0.037	0.008 - 0.038	0.008 - 0.040	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	2	0.004 - 0.024	0.004 - 0.024	0.006 - 0.032	0.008 - 0.037	0.008 - 0.038	0.008 - 0.040	0.0
Oats									
	All data	2	0.007 - 0.008	0.007 - 0.008	0.011	0.013	0.014	0.014	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	2	0.007 - 0.008	0.007 - 0.008	0.011	0.013	0.014	0.014	0.0
Buckwheat									
	All data	2	0.005 - 0.006	0.005 - 0.006	0.007 - 0.008	0.009	0.009	0.010	0.0
	ML 2.0, 1.75, 1.5, 1.25 µg/g	2	0.005 - 0.006	0.005 - 0.006	0.007 - 0.008	0.009	0.009	0.010	0.0
PROCESSED CEREAL GRAIN PRODUCTS									
Wheat flour									
	All data	804	8.321 - 8.323	0.049	0.176	0.512	1.014	919.000	0.0
	ML 1.5 µg/g	777	0.133 - 0.136	0.045	0.150	0.373	0.591	1.440	3.4
	ML 1.25 µg/g	770	0.122 - 0.124	0.044 - 0.043	0.142	0.352	0.558	1.241	4.2
	ML 1.0 µg/g	763	0.113 - 0.115	0.043	0.137	0.330	0.531	1.000	5.1
	ML 0.75 µg/g	753	0.103 - 0.105	0.042	0.129	0.300	0.444	0.708	6.3
	ML 0.5 µg/g	723	0.082 - 0.084	0.039 - 0.040	0.110	0.238	0.330	0.494	10.1
Wheat bran, processed									
	All data	1	0.010	0.010	0.010	0.010	0.010	0.010	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.010	0.010	0.010	0.010	0.010	0.010	0.0
Wheat germ									
	All data	1	0.053	0.053	0.053	0.053	0.053	0.053	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.053	0.053	0.053	0.053	0.053	0.053	0.0
Wheat wholemeal									
	All data	6	0.082 - 0.083	0.004 - 0.007	0.125	0.240	0.278	0.316	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	6	0.082 - 0.083	0.004 - 0.007	0.125	0.240	0.278	0.316	0.0
Rye flour									
	All data	13	0.022	0.003	0.006	0.087	0.105	0.119	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	13	0.022	0.003	0.006	0.087	0.105	0.119	0.0

Data provided by the China National Center of Food Safety Risk Assessment

Table B12. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in domestic raw cereal grains, semi-processed and processed cereal-based foods from 2004 – 2010 in the United States of America.

RAW CEREAL GRAINS AND PROCESSED CEREAL GRAIN PRODUCTS	Scenario	No. of samples	DON content ($\mu\text{g/g}$)					% of rejected samples	
			Mean	Median (P50)	P75	P90	P95		Max
RAW CEREAL GRAINS									
Wheat grain	All data	73	1.004 - 1.015	0.000 - 0.020	0.910	3.126	3.528	17.600	0.0
	ML 2.0 $\mu\text{g/g}$	60	0.285 - 0.298	0.000 - 0.020	0.403	0.901	1.400	1.800	17.8
	ML 1.75 $\mu\text{g/g}$	59	0.260 - 0.272	0.000 - 0.020	0.400	0.900	1.148	1.600	19.2
	ML 1.5 $\mu\text{g/g}$	58	0.237 - 0.249	0.000 - 0.020	0.395	0.873	0.942	1.400	20.5
	ML 1.25 $\mu\text{g/g}$	56	0.195 - 0.208	0.000 - 0.020	0.379	0.774	0.900	1.400	23.3
Whole grain corn	All data	2	2.715 - 2.725	2.715 - 2.725	4.073	4.887 - 4.889	5.159 - 5.160	5.430	0.0
	ML 2.0, 1.75, 1.5, 1.25 $\mu\text{g/g}$	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	50.0
Whole grain oats	All data	6	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	5.159	5.430	0.0
	ML 2.0, 1.75, 1.5, 1.25 $\mu\text{g/g}$	6	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	5.159	5.430	0.0
PROCESSED CEREAL GRAIN PRODUCTS									
Wheat flour	All data	847	0.157 - 0.170	0.000 - 0.020	0.210	0.518	0.782	3.157	0.0
	ML 1.5 $\mu\text{g/g}$	838	0.137 - 0.149	0.000 - 0.020	0.200	0.500	0.679	1.470	1.1
	ML 1.25 $\mu\text{g/g}$	832	0.128 - 0.141	0.000 - 0.020	0.190	0.470	0.622	1.250	1.8
	ML 1.0 $\mu\text{g/g}$	823	0.116 - 0.130	0.000 - 0.020	0.180	0.419	0.591	1.000	2.8
	ML 0.75 $\mu\text{g/g}$	801	0.097 - 0.110	0.000 - 0.020	0.140	0.370	0.510	0.730	5.4
	ML 0.5 $\mu\text{g/g}$	758	0.069 - 0.083	0.000 - 0.020	0.077	0.300	0.370	0.500	10.5
Wheat bran	All data	59	0.581 - 0.590	0.188	0.717	1.100	2.930	6.100	0.0
	ML 1.5, 1.25 $\mu\text{g/g}$	54	0.277 - 0.287	0.025 - 0.035	0.455	0.880	0.967	1.100	8.5
	ML 1.0 $\mu\text{g/g}$	52	0.245 - 0.256	0.000 - 0.020	0.435	0.786	0.904	0.980	11.9
	ML 0.75 $\mu\text{g/g}$	45	0.147 - 0.159	0.000 - 0.020	0.280	0.453	0.618	0.733	23.7
	ML 0.5 $\mu\text{g/g}$	41	0.098 - 0.111	0.000 - 0.020	0.197	0.400	0.431	0.457	30.5
Bakery Products	All data	20	0.072 - 0.087	0.000 - 0.020	0.025 - 0.040	0.300	0.315	0.600	0.0
	ML 1.5, 1.25, 1.0, 0.75 $\mu\text{g/g}$	20	0.072 - 0.087	0.000 - 0.020	0.025 - 0.040	0.300	0.315	0.600	0.0
	ML 0.5 $\mu\text{g/g}$	19	0.044 - 0.060	0.000 - 0.020	0.000 - 0.020	0.172	0.300	0.300	5.0
Breakfast Cereals - RTE	All data	8	0.236 - 0.249	0.000 - 0.020	0.123	0.613	1.107	0.600	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	7	0.041 - 0.056	0.000 - 0.020	0.050 - 0.060	0.136	0.163	0.190	12.5
Cookies & Crackers	All data	4	0.148 - 0.158	0.145 - 0.155	0.293	0.297	0.299	0.300	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	4	0.148 - 0.158	0.145 - 0.155	0.293	0.297	0.299	0.300	0.0
Other Wheat Milled Products	All data	94	0.114 - 0.129	0.000 - 0.020	0.052	0.494	0.789	1.050	0.0
	ML 1.5, 1.25 $\mu\text{g/g}$	94	0.114 - 0.129	0.000 - 0.020	0.052	0.494	0.789	1.050	0.0
	ML 1.0 $\mu\text{g/g}$	93	0.104 - 0.119	0.000 - 0.020	0.026	0.472	0.686	0.940	1.1
	ML 0.75 $\mu\text{g/g}$	89	0.068 - 0.083	0.000 - 0.020	0.000 - 0.020	0.220	0.492	0.740	5.3
	ML 0.5 $\mu\text{g/g}$	85	0.040 - 0.056	0.000 - 0.020	0.000 - 0.020	0.143	0.280	0.500	9.6
Corn Flour	All data	4	0.376 - 0.386	0.213 - 0.223	0.589	0.884	0.982	1.080	0.0
	ML 1.5, 1.25 $\mu\text{g/g}$	4	0.376 - 0.386	0.213 - 0.223	0.589	0.884	0.982	1.080	0.0
	ML 1.0, 0.75, 0.5 $\mu\text{g/g}$	3	0.142 - 0.155	0.000 - 0.020	0.213 - 0.223	0.340	0.383	0.425	25.0
Milled Corn	All data	2	0.200 - 0.210	0.200 - 0.210	0.300 - 0.305	0.360 - 0.362	0.380 - 0.381	0.400	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	2	0.200 - 0.210	0.200 - 0.210	0.300 - 0.305	0.360 - 0.362	0.380 - 0.381	0.400	0.0
Corn Meal Milled Products	All data	4	0.315 - 0.320	0.285	0.490	0.610	0.650	0.690	0.0
	ML 1.5, 1.25, 1.0, 0.75 $\mu\text{g/g}$	4	0.315 - 0.320	0.285	0.490	0.610	0.650	0.690	0.0
	ML 0.5 $\mu\text{g/g}$	3	0.190 - 0.196	0.146	0.285	0.368	0.395	0.423	25.0
Corn Starch	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Tortillas	All data	6	0.050 - 0.067	0.000 - 0.020	0.000 - 0.020	0.150 - 0.160	0.225 - 0.230	0.300	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	6	0.050 - 0.067	0.000 - 0.020	0.000 - 0.020	0.150 - 0.160	0.225 - 0.230	0.300	0.0
Ground Malt	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Milled Grain Products	All data	4	0.048 - 0.063	0.000 - 0.020	0.048 - 0.063	0.133 - 0.139	0.162 - 0.165	0.190	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	4	0.048 - 0.063	0.000 - 0.020	0.048 - 0.063	0.133 - 0.139	0.162 - 0.165	0.190	0.0
Other Flours	All data	89	0.236 - 0.248	0.000 - 0.020	0.300	0.446	0.740	5.200	0.0
	ML 1.5 $\mu\text{g/g}$	86	0.136 - 0.148	0.000 - 0.020	0.295	0.415	0.478	1.390	3.4
	ML 1.25, 1.0 $\mu\text{g/g}$	85	0.121 - 0.133	0.000 - 0.020	0.278	0.400	0.464	0.900	4.5
	ML 0.75, 0.5 $\mu\text{g/g}$	84	0.112 - 0.124	0.000 - 0.020	0.271	0.400	0.439	0.500	5.6
Soybean	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 $\mu\text{g/g}$	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0

Data provided by U.S. Food and Drug Administration

Table B13. Summary of the impact of different potential MLs for DON on the statistical distribution of DON in imported raw cereal grains, semi-processed and processed cereal-based foods imported into the United States of America in samples from 2004 – 2010.

RAW CEREAL GRAINS AND PROCESSED CEREAL GRAIN PRODUCTS	Scenario	No. of samples	DON content (µg/g)						% of rejected samples
			Mean	Median (P50)	P75	P90	P95	Max	
RAW CEREAL GRAINS									
Wheat grain	All data	24	0.263 - 0.275	0.000 - 0.020	0.520	0.735	0.783	1.400	0.0
	ML 2.0, 1.75, 1.5 µg/g	24	0.263 - 0.275	0.000 - 0.020	0.520	0.735	0.783	1.400	0.0
	ML 1.25 µg/g	23	0.213 - 0.226	0.000 - 0.020	0.435	0.708	0.742	0.790	4.2
Whole Grain Barley	All data	4	0.065 - 0.080	0.000 - 0.020	0.065 - 0.080	0.182 - 0.188	0.221 - 0.224	0.260	0.0
	ML 2.0, 1.75, 1.5 µg/g	4	0.065 - 0.080	0.000 - 0.020	0.065 - 0.080	0.182 - 0.188	0.221 - 0.224	0.260	0.0
Whole Grain	All data	2	0.065 - 0.075	0.065 - 0.075	0.098 - 0.103	0.117 - 0.119	0.124 - 0.125	0.130	0.0
	ML 2.0, 1.75, 1.5 µg/g	2	0.065 - 0.075	0.065 - 0.075	0.098 - 0.103	0.117 - 0.119	0.124 - 0.125	0.130	0.0
PROCESSED CEREAL GRAIN PRODUCTS									
Wheat flour	All data	294	0.148 - 0.162	0.000 - 0.020	0.040	0.277	0.400	10.970	0.0
	ML 1.5 µg/g	291	0.065 - 0.079	0.000 - 0.020	0.040	0.270	0.330	1.440	1.0
	ML 1.25 µg/g	290	0.060 - 0.074	0.000 - 0.020	0.040	0.263	0.327	1.240	1.4
	ML 1.0 µg/g	289	0.056 - 0.070	0.000 - 0.020	0.039	0.252	0.322	0.955	1.7
	ML 0.75 µg/g	287	0.051 - 0.065	0.000 - 0.020	0.034	0.226	0.317	0.680	2.4
	ML 0.5 µg/g	283	0.043 - 0.057	0.000 - 0.020	0.030	0.185	0.290	0.460	3.7
Wheat bran	All data	9	0.037 - 0.054	0.000 - 0.020	0.000 - 0.020	0.066 - 0.082	0.198 - 0.206	0.330	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	9	0.037 - 0.054	0.000 - 0.020	0.000 - 0.020	0.066 - 0.082	0.198 - 0.206	0.330	0.0
Wheat starch	All data	2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Bakery Products	All data	30	0.514 - 0.530	0.000 - 0.020	0.000 - 0.020	0.144	0.625	14.040	0.0
	ML 1.5, 1.25, 1.0, 0.75 µg/g	29	0.047 - 0.065	0.000 - 0.020	0.000 - 0.020	0.054	0.338	0.733	3.3
	ML 0.5 µg/g	28	0.023 - 0.041	0.000 - 0.020	0.000 - 0.020	0.012 - 0.026	0.083	0.493	6.7
Breakfast Cereal Ready to Eat (including RTE breakfast meal)	All data	15	0.559 - 0.570	0.000 - 0.020	0.502	2.035	3.057	3.400	0.0
	ML 1.5, 1.25, 1.0, 0.75 µg/g	13	0.160 - 0.172	0.000 - 0.020	0.295	0.551	0.640	0.723	13.3
	ML 0.5 µg/g	11	0.070 - 0.085	0.000 - 0.020	0.030 - 0.040	0.295	0.358	0.420	26.7
Breakfast Cereal (quick cook)	All data	7	0.040 - 0.057	0.000 - 0.020	0.000 - 0.020	0.112 - 0.124	0.196 - 0.202	0.280	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	7	0.040 - 0.057	0.000 - 0.020	0.000 - 0.020	0.112 - 0.124	0.196 - 0.202	0.280	0.0
Cereal Preparations	All data	2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	2	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Macaroni/Noodle Products	All data	46	0.018 - 0.037	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.508	0.0
	ML 1.5, 1.25, 1.0, 0.75 µg/g	46	0.018 - 0.037	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.508	0.0
	ML 0.5 µg/g	45	0.007 - 0.027	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.332	2.2
Cookies & Crackers	All data	32	0.046 - 0.063	0.000 - 0.020	0.000 - 0.020	0.262	0.345	0.432	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	32	0.046 - 0.063	0.000 - 0.020	0.000 - 0.020	0.262	0.345	0.432	0.0
Other Wheat Milled Products	All data	73	0.117 - 0.132	0.000 - 0.020	0.009 - 0.020	0.297	0.488	2.473	0.0
	ML 1.5 µg/g	72	0.085 - 0.099	0.000 - 0.020	0.002 - 0.020	0.279	0.437	1.400	1.4
	ML 1.25 µg/g	71	0.066 - 0.081	0.000 - 0.020	0.000 - 0.020	0.216	0.417	1.100	2.7
	ML 1.0, 0.75 µg/g	70	0.051 - 0.067	0.000 - 0.020	0.000 - 0.020	0.202	0.355	0.560	4.1
	ML 0.5 µg/g	69	0.044 - 0.059	0.000 - 0.020	0.000 - 0.020	0.178	0.294	0.440	5.5
Snack food (includes fired snack foods, tortillas and shelled peanuts)	All data	21	0.015 - 0.034	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.310	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	21	0.015 - 0.034	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.310	0.0
Corn Meal Milled Products	All data	2	0.145 - 0.155	0.145 - 0.155	0.218 - 0.223	0.261 - 0.263	0.276 - 0.277	0.290	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	2	0.145 - 0.155	0.145 - 0.155	0.218 - 0.223	0.261 - 0.263	0.276 - 0.277	0.290	0.0
Malted Barley	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Other Flours	All data	30	0.145 - 0.159	0.000 - 0.020	0.015 - 0.020	0.550	1.050	1.200	0.0
	ML 1.5, 1.25 µg/g	30	0.145 - 0.159	0.000 - 0.020	0.015 - 0.020	0.550	1.050	1.200	0.0
	ML 1.0 µg/g	28	0.073 - 0.089	0.000 - 0.020	0.000 - 0.020	0.179	0.455	1.000	6.7
	ML 0.75, 0.5 µg/g	27	0.039 - 0.055	0.000 - 0.020	0.000 - 0.020	0.075	0.288	0.500	10.0
Dinner/Sauces/Gravy	All data	3	0.086 - 0.100	0.000 - 0.020	0.130 - 0.140	0.207 - 0.211	0.233 - 0.235	0.259	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	3	0.086 - 0.100	0.000 - 0.020	0.130 - 0.140	0.207 - 0.211	0.233 - 0.235	0.259	0.0
Beans/Peas/Corn (Canned)	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
Candy	All data	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0
	ML 1.5, 1.25, 1.0, 0.75, 0.5 µg/g	1	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.000 - 0.020	0.0

Data provided by U.S. Food and Drug Administration

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