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DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS (AT STEP 7)

Comments at Step 6 in reply to CL 2013/24-CF submitted by El Salvador, European Union, Nicaragua, Nigeria, Norway, African Union, IFFA

EL SALVADOR

El Salvador apoya los niveles máximos propuestos para el Deoxivalenol (DON), para los siguientes productos:

1. Alimentos a base de cereales para lactantes y niños de corta edad: 0.2 mg/kg;
Se propone que el NM se aplique al producto tal como se comercializa para el consumidor final.
2. Harina, sémola, harina de maíz y hojuelas derivadas de trigo, maíz o cebada: 1 mg/kg;
Apoyamos observación de Japón: **Salvo para los productos destinados a piensos.**
3. Cereales en grano sin elaborar (trigo, maíz y cebada): 2 mg/kg;
El NM es aplicable a cereales en grano sin elaborar antes de la clasificación y la eliminación de granos dañados.
Aclarar la expresión: “grano sin elaborar antes de la clasificación y eliminación de granos dañados”
Apoyamos observación de Japón: **Salvo para los productos destinados a piensos.**

EUROPEAN UNION

The EU would like to provide the following comments:

The proposed maximum level (ML) for raw cereal grains (wheat, maize and barley)

The EU can agree with the proposed maximum level of 2 mg/kg for deoxynivalenol (DON) in raw cereal grains (wheat, maize and barley), with the description that it relates to raw wheat, maize and barley grain prior to sorting and removal of damaged kernels. It is known that cleaning and sorting processes on raw cereal grains can significantly reduce the contamination level of DON in cereals. Therefore, the EU is of the opinion that acceptance of a level for DON in raw cereal grains at Codex level is not in contradiction with the setting of stricter levels by member countries for cereal grains marketed for first-stage processing after possibly cleaning and sorting processes on the raw cereal grains have been applied.

The EU wishes further to indicate that in the EU the maximum level for unprocessed maize is not applicable in case the maize is intended for wet milling as the produced starch does not contain or contains only a very low level of DON.

The proposed ML for flour, semolina, meal and flakes derived from wheat, maize or barley

As regards the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize or barley, the EU asked at the 7th session of the Codex Committee on Contaminants in Food for more time to consult with their risk assessment bodies before agreeing to the proposal¹.

EFSA has adopted on 28 November 2013 a “Statement on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products”².

¹ REP/13/CF, § 65.

² EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2013. Statement on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products. EFSA Journal 2013;11(12):3490, 56 pp. doi:10.2903/j.efsa.2013.3490 Available online: www.efsa.europa.eu/efsajournal

The overall conclusion of the risk assessment is that “The exposure estimations in this statement indicate that the group Health Based Guidance Values (HBGVs) are already exceeded by the parent compound DON in a number of cases. An increase of the DON ML can be expected to be associated with an increase of the levels of DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs.”

Given this conclusion, the EU cannot agree on the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize or barley.

The proposed ML for cereal based foods for infants and young children

The EU cannot agree to the proposed ML of 0.2 mg/kg for cereal based foods for infants and young children in case the ML applies to the commodity as consumed. A maximum level on the commodity as consumed would make the level for the traded products, such as powdered cereal based foods for infants and young children, very difficult as no precise instructions are provided for making these products ready for consumption.

Furthermore a maximum level of 0.2 mg/kg for cereal based foods for infants and young children as consumed would result in a maximum level in the powdered cereal based foods for infants and young children higher than the proposed maximum level of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize and barley. This is unacceptable as the group PMTDI for DON and its acetyl-derivatives is based on a no-observed-effect level for decreased body weight gain in a long term feeding study in mice. This endpoint is of particular relevance for infants, toddlers, children and adolescents, since they are in growing life stages. Exposure above the group PMTDI for these age groups is therefore of concern.

The EU is therefore of the opinion that the ML of 0.2 ppm should apply to the commodity on a dry matter basis.

The proposed sampling procedure

As regards the sampling procedure, the EU maintains its reservation with the proposed aggregate sample weight of 1 kg for raw wheat and barley. The EU is of the opinion that an aggregate sample weight of 10 kg is preferable, but can accept 5 kg. Also for raw maize, 10 kg sample size is preferable, but 5 kg is acceptable by way of compromise.

The EU proposes to consider an aggregate sample weight of 10 kg, which might be reduced to a laboratory sample of 1 kg by making use of a mechanical or automatic divider.

NICARAGUA

Nicaragua apoya los niveles propuestos por el grupo de trabajo para los siguientes grupos:

Producto	Nivel Máximo (mg/kg)	Observaciones
Alimentos a base de cereales para lactantes y niños de corta edad*	0.2	NM aplicable al producto tal y como se consume.
<i>*Todos los alimentos a base de cereales para lactantes (hasta 12 meses) y niños de corta edad (12 a 36 meses)</i>		
Cereales en grano sin elaborar (trigo, maíz, cebada)	2	El NM se aplica a cereales en grano sin elaborar antes de la clasificación y la eliminación de granos dañados.
Harina, sémola y hojuelas derivadas de trigo, maíz o cebada	1	

NIGERIA

Nigeria is requesting for the provision of values for both Ready to eat and Dry Matter.

NORWAY

We appreciate this opportunity to comment upon the Draft maximum level for deoxynivalenol (DON) in cereal-based foods for infants and young children at step 6.

We do not support the MLs for DON in cereal-based foods for infants and young children as proposed in the products as consumed. The reason is that this ML does not give this vulnerable group of the population the intended extra protection.

We would also like to point out that the proposed ML is also very high compared to available occurrence data.

Background

CCCF has proposed that a separate ML should be established for cereal-based foods for infants and young children. The reason for this proposal is that the critical chronic toxicological effect of DON is reduced growth/growth retardation. Infants and young children are considered the most vulnerable group of the population in regard to exposure to DON and the proposed, separate ML was made in order to give extra protection to this special group.

The present proposed draft ML for cereal-based foods for infants and young children is 0,2 mg/kg of the commodity **as consumed**.

In order to compare the ML that is now being proposed for cereal-based foods for infants and young children with the proposed ML for flour, semolina, meal and flakes for the population in general, we have made some calculations. As an example in our calculations we have used instant porridge made from special products for infants and small children, as this type of food constitutes a major part of the baby's diet already from the age of four-six months in Norway and other Nordic countries.

Our estimations show that the proposed ML of 0.2 mg/kg **product as consumed** will correspond to an ML of approximately 1,0 mg/kg **dry matter**. This means that CCCF is proposing the same ML for both product categories.

We therefore question whether this committee considers that the proposed ML of 0.2 mg/kg product **as consumed** for infants and young children fulfills the aim of this work. We find that by setting such an ML, we would be seriously misleading the consumer to believe that extra protection was given to infants and small children.

Our reservation to the proposed maximum level for DON in cereal-based foods for infants and young children is based on the comprehensive Risk Assessment on Mycotoxins in cereal grain published by The Norwegian Scientific Committee for Food Safety (VKM) 9 April 2013. <http://www.vkm.no/dav/eee04d10c4.pdf> The Scientific Committee found that with concentrations, much lower than the ML now proposed by CCCF, there is reason to be concerned about the intake of DON, in particular the intake among young children.

AFRICAN UNION

AU supports the adoption of the proposed maximum levels (MLs) for deoxynivalenol (DON).

These are ML for raw cereal grains (wheat, maize and barley) of 2 mg/kg, the ML for flour, semolina, meal and flakes derived from wheat, maize and barley of 1 mg/kg and the ML for cereal-based foods for infants and young children of 0.2 mg/kg

However the term "as consumed" requires some clarification with respect to preparation of infant food porridges. Enforcement would be better if applied to commercial dry products.

The proposed MLs are in line with the African position formulated in 2013.

The proposed ML for cereal-based foods for infants and young children of 0.2 mg/kg is in line with the previous suggestion of a limit lower than 0.4 mg/kg. It is a limit currently applied in the EU and one which is achievable by Good Manufacturing Practices. An exposure estimate for African children would indicate that at about 17 months (about 10 kg of body weight) toddlers were consuming about 80 g of maize per day. At a contamination level of 0.2 mg/kg, this equates to an exposure of approximately 1.6 µg/kg body weight per day, marginally above the provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight per day set by JECFA.

AU supports the proposed sampling plan, which requires 5 kg aggregate sample weight for raw maize and 1 kg for raw wheat and barley.

The proposed sampling plan is based on current plans in operation in the EU. Due to its higher kernel mass, a greater mass of maize is required over the smaller grain cereals. Although we previously supported 10 kg for maize and 1 kg for wheat and barley, the higher mass of maize (10 vs 5 kg) achieves only marginally better sampling characteristics, whereas the lower mass is easier to handle in practice.

IFFA

The International Frozen Food Association (IFFA) advocates on behalf of the frozen food sector worldwide. IFFA's membership includes frozen food companies, associations, individuals and suppliers. IFFA members share a common belief in the future of frozen food trade and have a desire to maintain open discussions on trade, technology, legislation and regulation.

IFFA is a non-governmental organization that has observer status in *Codex Alimentarius*. IFFA strongly supports the work of Codex and promotes global harmonization of science-based standards and policies. IFFA also works to ensure equity in the international trade of frozen food products, possible only through the harmonization of global standards.

IFFA welcomes this opportunity to provide the following general and specific comments below in response to CL 2013/24-CF, with additional justification provided in the Appendix.

Proposed CCCF maximum levels (ML) for deoxynivalenol (DON) of 2 ppm in raw grains prior to sorting and cleaning may lead to significant trade disruption of grains in global commerce in bad climatic years without providing additional public health benefits. ^{3/}

MLs for DON in raw grain should be set at levels that are adequately protective of health and are practically achievable so that trade disruptions do not occur or are minimized to the extent possible. Upon re-review of the 2012 CCCF discussion draft on DON, ^{4/} the proposed MLs if increased by *at least* two-fold for wheat and maize will remain adequately protective of health. (*For more details, please see Appendix I.*)

Furthermore, the WHO Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets were recently updated in 2012 ^{5/} employing a new approach to assess diets and consumption patterns. The 2012 CCCF discussion draft on DON analysis (i.e., CX/CF 12/6/9) on the other hand was based on the 13 cluster diets from GEMS/Food 2006.^{6/} To ensure that the most recent food consumption data are leveraged to reflect the 17 cluster diets in GEMS/Food 2012, a re-analysis of the 2012 CCCF discussion draft (i.e., CX/CF 12/6/9) is scientifically warranted.

IFFA specific comments are highlighted below:

- **Any proposed ML should advance public health goals.**

Any risk management measure implemented should provide additional health benefits to current standards.

- **Method for estimating intake of raw grains is based on wrong materials.**

Total grain consumption should not be a surrogate for raw grain consumption when trying to establish an appropriate level of DON in raw grains. This flawed assumption results in a gross overestimate of actual consumption of raw grains thus generating an unrealistically low ML to provide adequate health protections. (*For more details, please see Appendix I.*)

According to CX/CF 12/6/9, total grain consumption (i.e., predicted raw grain consumption + semi-processed grain consumption + finished food consumption) was used as a surrogate for raw grain consumption. However, proposed MLs for raw grains should be inversely proportional to consumption amounts of raw grains and not total grains. CCCF intends to establish MLs for not only raw grains but also for the semi-processed grains (e.g., flour). Thus, instead of total grain consumption, the predicted raw grain consumption amount in GEMS/Food 2006 data (i.e., total grain consumption – semi-processed grain consumption – finished food consumption) would be more representative of actual raw grain consumption.

Nevertheless, to eliminate substantial uncertainties in extent of raw grains actually consumed, it may be prudent to seek actual consumption data for raw grains from impacted nations to serve as the basis for the proposed ML. Risk management decisions should be based on appropriate data when specifying proposed mitigation measures for DON contamination of raw grains.

Moreover, when establishing MLs particularly for raw grains, CCCF should clearly understand at what stage along the harvesting/milling continuum analysis and sampling for DON in raw grains takes place. MLs proposed should correspond to the point at which the grains are analyzed and sampled for DON, to ensure consistency of reporting basis between MLs and occurrence data. Thus, to ascertain that risk management measures proposed are relevant to the grain commodity traded in global commerce, a call-for-data requesting occurrence data for DON in unprocessed hard wheat, soft wheat, maize, and barley after cleaning and sorting (and just prior to first-stage processing) would provide much needed clarity in data interpretation and assessment.

- **The proposed ML should represent the international/global perspective. Limited or no data from most countries.**

Should an ML be set for raw grains, it should be relevant on an international scale to avoid significant trade disruptions. Limited occurrence data from most countries in Latin America, Africa, and Asia precludes a full understanding of the impact that such low MLs would have on global trade. The proposed MLs are neither practical nor reasonably achievable in bad years and do not provide any additional health protections. (*For more details, please see Appendix II.*)

A call-for-data is warranted and should encourage data submission from different regions globally to assess impact of proposed ML to global trade.

- **CCCF should clearly define what raw means.**

Clarification on what raw means when considering MLs for raw grains (e.g., after cleaning and sorting or “first-stage processing” as per the [European Commission Regulation](#)) ^{7/} may facilitate discussions on what an appropriate ML should be. (*For more details, please see Appendix III.*)

^{3/} REP13/CF (http://www.codexalimentarius.org/download/report/797/REP13_CFe.pdf)

^{4/} CX/CF 12/6/9 “PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS” (ftp://ftp.fao.org/codex/meetings/cccf/cccf6/cf06_09e.pdf)

^{5/} GEMS 2012 Cluster Diets (http://www.who.int/foodsafety/chem/Cluster_diets_2012_consumption.xls)

^{6/} GEMS 2006 Cluster Diets (<http://www.who.int/foodsafety/chem/ClusterDietsAug06.xls>)

^{7/} COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:EN:PDF>)

Additionally, CCCF should differentiate between unprocessed grains slated for first-stage processing and those intended for sale for direct human consumption that will not undergo further processing. Since DON levels can be mitigated in unprocessed grains slated for further downstream processing by a number of process-related activities such as cleaning, sorting, removal of bran, scouring, tempering, etc., CCCF proposed MLs should be limited to unprocessed grains that will not undergo further processing slated strictly for direct human consumption.

- **CCCF should consider setting different MLs for different grains.**

Due to the differences in susceptibility of cultivars and grains, climatic differences among the geographic regions in which the different grains are grown, and differences in food consumption patterns among cereal grains (i.e., hard wheat, soft wheat, maize, barley), it may be more appropriate to differentiate among the grains setting a more appropriate ML for the specific grains.

Conclusion

In conclusion, a more reasonable risk management approach would assist CCCF in achieving its stated goals of protecting public health while facilitating trade. Considering the uncertainties associated with the available data as stated above, IFFA is of the view that finalizing the proposed MLs on raw grain is premature and will not further CCCF goals and objectives. Should the proposed MLs be endorsed for adoption, unnecessary trade barriers are likely to be erected. IFFA suggests that:

- Actual raw grain consumption data from relevant regions is necessary before an ML is established, to assure adequate health protections while promoting equity in trade;
- A clear understanding of what the ML would apply to is critical to ensure minimal disruption to trade – i.e., at harvest, at country elevator, at first-stage processing after sorting and cleaning as suggested in EU directives;
- More occurrence data (at the specified stage along the harvesting/milling continuum once CCCF has reached consensus) should be collected from different regions globally to adequately assess impact of proposed ML to global trade; and
- Different MLs should be established for different raw grains due to differences in consumption pattern and susceptibility to *Fusariumgraminearum* contamination.

IFFA thanks CCCF for taking these comments into consideration.

Appendix I. GEMS/Food 2006 Consumption Data and Appropriate MLs that would be adequately protective of health for the global population.

The GEMS/Food Consumption Cluster Diets are built with the FAO Stats data but are expressed on the 1993 Codex Classification basis. A + in front of a Codex Code means there is no direct match between the two classifications. A * means the code and/or the name used are not defined in the Codex Classification. Please refer to specific notes for further details.

CODE	GEMS	NOTES	A	B	C	D	E	F	G	H	I	J	K	L	M
CEREALS															
GC 640	BARLEY	(1)	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
	* POT BARLEY		29.0	0.0	11.9	4.7	2.0	2.5	0.7	0.0	0.0	0.7	2.4	4.1	0.0
	* BARLEY, PEARLED		0.0	0.4	27.9	0.1	0.4	0.9	0.5	0.1	0.0	0.0	0.7	0.0	0.1
	* BARLEY FLOUR AND GRITS		0.0	0.3	10.8	0.3	0.5	0.9	0.4	0.0	0.1	0.0	1.0	0.8	0.0
GC 645	MAIZE	(3)	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
CF 1255	MAIZE FLOUR		68.9	15.4	51.3	10.6	14.7	2.0	28.8	248.8	206.7	47.8	46.2	10.5	21.5
	* GERM MAIZE	(4)	0.2	8.9	0.0	2.2	2.0	0.4	0.5	1.2	3.9	0.0	2.2	3.5	4.0
GC 654	WHEAT	(12)	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
CF 1210	WHEAT GERM		0.0	1.3	0.0	1.3	0.9	1.2	0.1	48.1	1.8	0.0	0.0	0.0	0.6
* CF 1211bu	* WHEAT BULGUR WHOLEMEAL		5.0	10.2	0.7	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CF 1211	WHEAT FLOUR		63.4	296.3	327.5	300.0	181.6	166.2	133.0	60.1	52.4	32.2	87.7	79.6	180.1
* CF 1211ma	* WHEAT MACARONI		0.8	1.1	0.8	1.8	4.6	7.6	1.7	3.6	0.5	0.2	0.3	1.7	2.0
* CF 1211pa	* WHEAT PASTRY		0.4	1.1	0.7	2.6	1.7	5.4	0.3	0.6	0.7	0.2	0.3	0.6	1.7
CP 1211	WHITE BREAD		0.0	0.1	0.0	0.1	0.1	1.0	0.0	2.2	0.1	0.0	0.0	0.0	0.0
CP 1212	WHOLEMEAL BREAD		0.0	0.1	0.0	0.1	0.1	1.0	0.0	2.2	0.1	0.0	0.0	0.0	0.0
	* CEREAL PREPARATIONS NES		0.0	0.5	0.6	0.3	0.7	1.5	0.4	2.8	1.2	0.2	0.2	0.3	0.3
GC 80	TOTAL CEREALS	(13)	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

Note 1: BARLEY (GC 640) is the maximum of (a) BARLEY (FAO 44, not indicated), (b) 1.1xPOT BARLEY (FAO 45), (c) 1.4x2.4xBARLEY PEARLED (FAO 46), (d) 1.4x2.9xBARLEY FLOUR AND GRITS (FAO 48) and (e) 0.2xBARLEY BEER (FAO 51) to be consistent with FAO FBS definitions.

Note 3: MAIZE (GC 645) is the maximum of (a) MAIZE (FAO 56, not indicated), (b) 1.2xMAIZE FLOUR (CF 1255), (c) 16.7xMAIZE GERM (FAO 57) and (d) 0.2xMAIZE BEER (FAO 66) to be consistent with FAO FS definitions.

Note 4: *GERM MAIZE is the maximum of (a) GERM MAIZE (FAO 57, not indicated) and (b) 2.2xMAIZE OIL (FAO 60) to be consistent with FAO FBS definitions.

Note 12: WHEAT (GC 654) is the maximum of (a) WHEAT (FAO 15, not indicated) and (b) 1.1xWHEAT BULGUR WHOLEMEAL (CF 1211bu) + 1.3xWHEAT FLOUR (CF 1211) to be consistent with FAO FBS definitions.

The acute reference dose for DON is 8 ug/kg bw. For an average individual weighing 60 kg, maximum dietary intake of DON-contaminated grain should not exceed 480 ug/d (= 0.48 mg/d).

In reference to the table above containing 2006 GEMS/Food data, cluster diets that contribute most to potential DON exposure in the general population were selected to calculate proposed MLs that would adequately protect public health for the global population based on predicted consumption of raw (unprocessed) wheat, maize and barley. These are compared with MLs that are proposed in CF/CX 12/6/9, as explained below.

As shown above, for wheat consumption in Cluster C diets, a contribution from wheat flour is around 327.5 g/d while total wheat consumption is ~ 426.5 g/d. Thus, predicted raw wheat consumption would be 426.5 g/d – 327.5 g/d = 99 g/d. As such, a proposed ML that would be adequately protective of health in this case would be: 0.48 mg/d ÷ 0.099 kg raw wheat/d ≈ 5 mg/kg DON in raw wheat.

Likewise for maize consumption in Cluster B diets, a contribution from maize flour is 15.4 g/d and from maize germ is 8.9 g/d while total maize consumption is anticipated to be 148.4 g/d. Thus, predicted raw maize consumption would be 148.4 g/d – 15.4 g/d – 8.9 g/d = 124.1 g/d. As such, a proposed ML that would be adequately protective of health in this case would be: 0.48 mg/d ÷ 0.124 kg raw maize/d ≈ 4 mg/kg DON in raw maize.

Similarly for barley consumption in Cluster E diets, contributions from barley flour is ~0.5 g/d while total barley consumption is anticipated to be ~48.6 g/d. Thus, predicted raw barley consumption would be 48.6 g/d – 0.5 g/d = 48.1 g/d. As such, a proposed ML that would be adequately protective of health in this instance would be: 0.48 mg/d ÷ 0.0481 kg/d raw barley ≈ 10 mg/kg DON in raw barley.

However, in CX/CF 12/6/9, using total grain consumption (table 4 below) was used as the surrogate for raw grain consumption leading to proposed MLs that are grossly below levels that would be protective of human health, especially for raw wheat.

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
RAW COMMODITIES															
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)	5.4	4.2	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)	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)	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)	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

Comparison between corrected MLs and those based on CX/CF 12/6/9 data analysis.

Raw Grain (Highest exposure cluster diet from GEMS/Food 2006)	Corrected proposed ML based on predicted raw grain consumption (ppm)	Proposed ML based on total grain consumption as reflected in CX/CF 12/6/9 (ppm)
Wheat (Cluster C diet)	5 ppm	1.1 ppm
Maize (Cluster B diet)	4 ppm	3.2 ppm
Barley (Cluster E diet)	10 ppm	9.9 ppm

In summary, the proposed ML for unprocessed grain could be increased to 4 or 5 ppm and still be adequately health protective.

In view of the variations noted above in adequately protective MLs dependent on the type of unprocessed grain, CCCF should consider setting different MLs for different grains.

Appendix II. Probable trade impact of proposed ML of 2 ppm for raw maize. (CX/CF 12/6/9, Tables 9 and 10)

CX/CF 12/6/9

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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*	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 (excl. 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 BAD YEAR!	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*	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
All years excluding 2005/2006 crop year where higher concentrations of DON encountered	All data	611	0.22 - 0.47	0.00 - 0.50	0.40 - 0.50	0.77	0.99	1.20	17.4
	ML 2.0 µg/g	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
2005/2006 crop year BAD YEAR!	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
	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
2005/2006 crop year BAD YEAR!	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.

Based on limited data, it is clear that a proposed ML of 2 ppm will have significant impacts on global trade of raw maize in Canada and South Africa, with over 65% lot rejection in bad years.

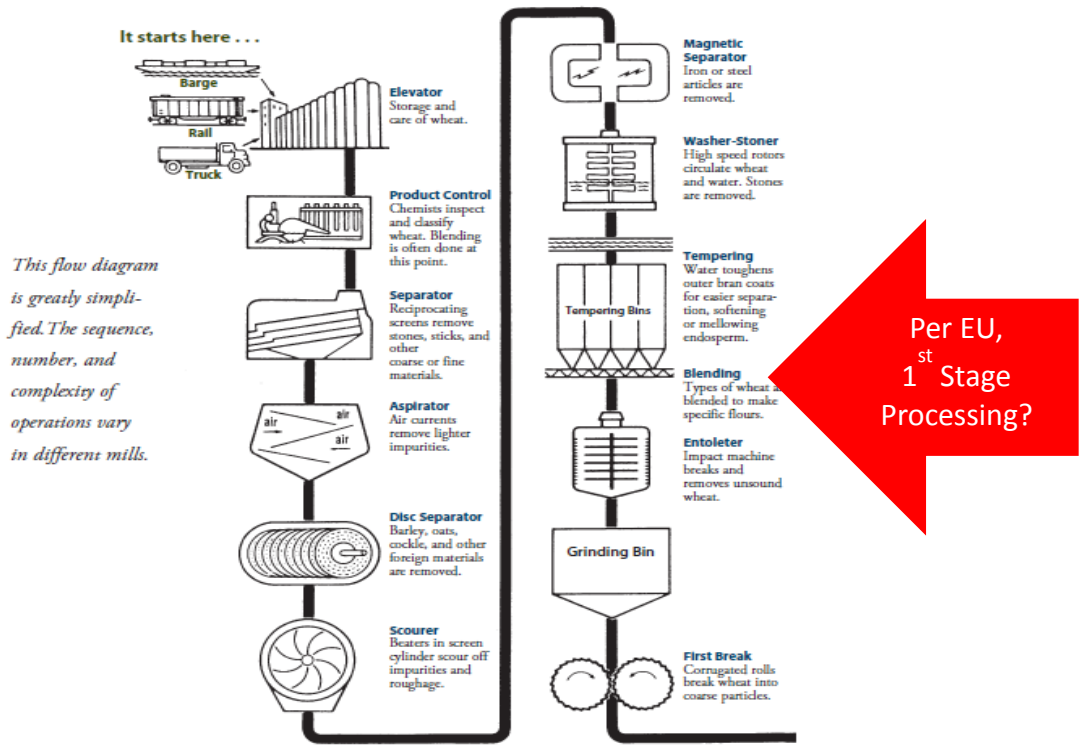
Appendix III.EU “First-stage processing” after cleaning and sorting of raw grains.

According to EU Directives, ^{5/} the ML for DON in COMMISSION REGULATION (EC) No 1881/2006 applies to unprocessed cereals placed on the market for first-stage processing.

‘First-stage processing’ shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be ‘first-stage processing’ insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting. *[Is tempering phase to be considered as first-stage processing?]*

In integrated production and processing systems, the maximum level applies to the unprocessed cereals in case they are intended for first-stage processing.

Thus, in a generic milling diagram (shown below), unprocessed cereals placed on the market for first-stage processing may correspond to the tempering stage. Thus, occurrence data should be collected at this stage. The proposed ML should be applicable at this stage as well.



Courtesy of Wheat Foods Council, 10841 S. Crossroads Drive, Suite 105, Parker, Colorado 80138.

IFFA – SPANISH

La Asociación Internacional de Alimentos Congelados (IFFA) representa al sector de alimentos congelados en todo el mundo. Nuestra asociación incluye industrias de alimentos congelados, asociaciones, individuos y proveedores. Los miembros de IFFA creen en el futuro del comercio de alimentos congelados y tienen el deseo de mantener discusiones abiertas sobre el comercio, la tecnología, la legislación y la regulación.

IFFA es una organización no gubernamental que tiene el rol de observador en el Codex Alimentarius. IFFA apoya firmemente la labor del Codex y promueve la armonización mundial de las normas y directrices basadas en la ciencia. IFFA también trabaja para asegurar la equidad en el comercio internacional de productos alimenticios congelados, posible sólo a través de la armonización de las normas mundiales.

IFFA agradece esta oportunidad de presentar las siguientes observaciones generales y específicas en respuesta a la CL 2013/24-CF, con una justificación adicional proporcionada en el Apéndice.

Niveles máximos propuestos (NM) por el CCCF para el deoxinivalenol (DON) de 2 ppm en granos crudos antes de la clasificación y limpieza pueden dar lugar a una alteración importante en el comercio de granos en el comercio global en los próximos años debido a los cambios climáticos sin proporcionar beneficios adicionales de salud pública.^{8/}

NM para el DON en los cereales crudos deben establecerse de tal forma que protejan adecuadamente la salud, que sean alcanzables en la práctica y que no produzcan interrupciones al comercio o éstas sean minimizadas en la medida posible. Tras la nueva revisión del proyecto de discusión CCCF 2012 en DON,^{9/} los NM propuestos, si éste aumenta en al menos dos veces para el trigo y el maíz, se garantiza un nivel adecuado de protección a la salud. *(Para más detalles, ver el Apéndice I.)*

Además, el Sistema de Monitoreo Ambiental Global de la OMS/Programa de Evaluación y Monitoreo de Contaminación de Alimentos por grupos de dietas (GEMS/Food), ha sido actualizado recientemente en 2012^{10/} empleando un nuevo enfoque para evaluar las dietas y los hábitos de consumo. El borrador de discusión CCCF 2012 sobre el análisis de DON (es decir, CX/CF 12/6/9) en cambio se basó en los 13 grupos de dietas de GEMS/Food 2006.^{11/} Para asegurarse de que los datos más recientes de consumo de alimentos se aprovechan para reflejar los 17 grupos de dietas de GEMS/Food 2012, un re-análisis del proyecto de discusión CCCF 2012 (es decir, CX/CF 12/6/9) está científicamente garantizado.

Comentarios específicos IFFA se destacan a continuación:

- ***Cualquier propuesta NM debe avanzar en los objetivos de salud pública.***

Cualquier medida de gestión de riesgos que sea implantada debería proporcionar beneficios de salud adicionales a los estándares actuales.

- ***El método para la estimación de la ingesta de granos crudos se basa en información incorrecta.***

El consumo total de granos no debe ser una referencia para un adecuado nivel de DON en los cereales crudos. Esta suposición errónea resulta en una sobreestimación bruta de consumo real de los granos crudos generando un bajo NM para la protección de la salud. *(Para más detalles, ver el Apéndice I.)*

De acuerdo con el documento CX/CF 12/6/9, el consumo total de granos (por ejemplo, el consumo en crudo de grano + el consumo de productos semielaborados de grano + el consumo de alimentos terminados) fue utilizado como referencia en vez del consumo de grano crudo. Sin embargo, los NM propuestos para granos crudos deben ser inversamente proporcionales a la cantidad de consumo de los granos crudos y no granos totales. CCCF propone establecer NM no sólo para los granos crudos, sino también para los granos semi-procesados (por ejemplo, harina). Así, en lugar del consumo total de cereales, la cantidad de consumo de grano crudo pronosticado en GEMS/Food datos de 2006 (es decir, el consumo total de granos - Consumo de semielaborados de grano - el consumo de producto terminado) sería más representativo del consumo actual de grano crudo.

Sin embargo, para eliminar incertidumbres de los datos referentes a los granos crudos que realmente se consumen, puede ser prudente buscar datos de consumo reales de los cereales crudos de las naciones afectadas para que sirvan de base para el NM propuesto. Las decisiones de gestión de riesgos deben basarse en datos apropiados cuando se especifican las medidas de mitigación propuestas para la contaminación de DON de los cereales crudos.

^{8/} REP13/CF (http://www.codexalimentarius.org/download/report/797/REP13_CFe.pdf)

^{9/} CX/CF 12/6/9 "PROPOSED DRAFT MAXIMUM LEVELS FOR DEOXYNIVALENOL (DON) IN CEREALS AND CEREAL-BASED PRODUCTS AND ASSOCIATED SAMPLING PLANS" (ftp://ftp.fao.org/codex/meetings/cccf/cccf6/cf06_09e.pdf)

^{10/} GEMS 2012 Cluster Diets (http://www.who.int/foodsafety/chem/Cluster_diets_2012_consumption.xls)

^{11/} GEMS 2006 Cluster Diets (<http://www.who.int/foodsafety/chem/ClusterDietsAug06.xls>)

Por otra parte, al establecer niveles máximos de DON en particular para los granos crudos, CCCF debe entender claramente en qué momento de la cosecha/molienda debe realizarse el análisis continuo y la toma de muestra. Los NMs propuestos deberán corresponder en el punto en el que se tomaron las muestras para el DON de los granos, para garantizar la coherencia de la base reportada entre los NMs y los datos de ocurrencia. Por lo tanto, para comprobar si las medidas de gestión del riesgo propuestas son relevantes para el producto que se cotiza en el comercio mundial, se deben solicitar datos sobre la presencia de DON en trigo duro, el trigo blando sin procesar, maíz y cebada después de la limpieza y la clasificación (y justo antes de la primera transformación) esto proporcionaría la claridad necesaria en la interpretación de datos y la evaluación.

- ***El NM propuesto debe representar el punto de vista internacional/global. Los datos son limitados o nulos por parte de la mayoría de los países.***

En caso de que un NM pueda establecerse para los granos crudos, debe ser relevante a escala internacional para evitar perturbaciones significativas del mercado. Datos limitados sobre la presencia de DON de la mayoría de los países de América Latina, África y Asia no permite una interpretación más completa del impacto que tales niveles máximos tan restrictivos tendrían sobre el comercio mundial. Los NM propuestos no son ni prácticos ni razonablemente posibles de alcanzar en los años malos y no proporcionan ninguna protección de salud adicional. *(Para más detalles, ver el Apéndice II.)*

Se justifica la necesidad de hacer la solicitud de recolección de información de diferentes regiones a nivel mundial para evaluar el impacto de la propuesta de NM para el comercio global.

- ***CCCF deberá definir claramente lo que significa “crudo”.***

Aclaración sobre lo que significa “crudo” al considerar NM para granos crudos (por ejemplo, después de la limpieza y la clasificación o “primera transformación” de acuerdo con el [European Commission Regulation](#))^{12/} puede facilitar el debate sobre cuál debe ser el modelo NM apropiado. *(Para más detalles, ver el Apéndice III).*

Además, CCCF deberá diferenciar entre los granos sin procesar antes de la primera transformación y los destinados a la venta para el consumo humano directo que no van a someterse a una transformación. Dado que los niveles de DON pueden ser mitigados en granos sin procesar para posterior transformación mediante una serie de operaciones relacionadas con el proceso, tales como la limpieza, la clasificación, la eliminación de salvado, desengrasado, revenido, etc, los NM propuestos por CCCF deben limitarse a los granos no procesados que no se someten a una transformación posterior y que son estrictamente para el consumo humano directo.

- ***CCCF debería considerar el establecimiento de distintos NM para diferentes granos.***

Debido a las diferencias en la susceptibilidad de los cultivos y los granos, las diferencias climáticas entre las regiones geográficas en las que se cultivan los distintos granos, y las diferencias en los patrones de consumo de alimentos entre los granos de cereales (por ejemplo, el trigo duro, el trigo blando, maíz, cebada), es posible que sea más conveniente diferenciar el NM más apropiado para los granos específicos.

Conclusión

En conclusión, un enfoque más razonable de gestión del riesgo ayudaría al CCCF en el logro de sus objetivos de protección de la salud pública, y la facilitación del comercio. Teniendo en cuenta las incertidumbres asociadas a los datos disponibles como se indica más arriba, IFFA es de la opinión de que el establecimiento de los NM propuestos en grano crudo es prematuro y no va de acuerdo con otras metas y objetivos del CCCF. En caso de que los NM propuestos sean adoptados, se crearían barreras al comercio.

IFFA sugiere que:

- Los datos de consumo de grano crudo reales de las regiones pertinentes deben ser considerados antes de establecer un NM, para asegurar la protección de la salud adecuada, y la equidad en el comercio;
- Una comprensión clara de cuál sería el producto al que se le aplicaría el NM es fundamental para asegurar la mínima interrupción al comercio - es decir, en la cosecha, en el ascensor del país, en una primera fase después de la clasificación y limpieza como se sugiere en las directivas de la UE;
- Más datos de ocurrencia (en la etapa específica a lo largo de la cosecha/molienda una vez que CCCF haya llegado a un consenso) deben ser recolectados de diferentes regiones a nivel mundial para evaluar adecuadamente el impacto de la propuesta de NM para el comercio mundial, y
- Diferentes niveles máximos deben ser establecidos para los diferentes granos crudos debido a las diferencias en el patrón de consumo y la susceptibilidad a la contaminación por *graminearium Fusarium*.

^{12/} COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:EN:PDF>)

IFFA agradece al CCCF por tomar en cuenta estos comentarios.

Apéndice I. GEMS/Food 2006 Consumo de Datos y NM apropiados que protegerían adecuadamente la salud de la población mundial.

The GEMS/Food Consumption Cluster Diets are built with the FAO Stats data but are expressed on the 1993 Codex Classification basis. A + in front of a Codex Code means there is no direct match between the two classifications. A * means the code and/or the name used are not defined in the Codex Classification. Please refer to specific notes for further details.															
CODE	GEMS	NOTES	A	B	C	D	E	F	G	H	I	J	K	L	M
CEREALS															
GC 640	BARLEY	(1)	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
	* POT BARLEY		29.0	0.0	11.9	4.0	2.0	2.5	0.7	0.0	0.0	0.7	2.4	4.1	0.0
	* BARLEY, PEARLED		0.0	0.4	27.9	0.0	0.4	0.9	0.5	0.1	0.0	0.0	0.7	0.0	0.1
	* BARLEY FLOUR AND GRITS		0.0	0.3	10.8	0.3	0.5	0.9	0.4	0.0	0.1	0.0	1.0	0.8	0.0
GC 645	MAIZE	(3)	82.7	148.4	135.9	11.0	33.3	7.5	35.2	298.6	248.1	57.4	63.1	58.6	85.5
CF 1255	MAIZE FLOUR		68.6	15.4	51.3	10.5	14.7	2.0	28.8	248.8	206.7	47.8	46.2	10.5	21.5
	* GERM MAIZE	(4)	0.2	8.9	5.0	2.0	0.4	0.5	1.2	3.9	0.0	2.2	3.5	4.0	
GC 654	WHEAT	(12)	88.4	396.3	426.5	390.0	236.3	216.0	172.9	79.0	68.1	41.9	114.1	103.4	234.2
CF 1210	WHEAT GERM		0.0	1.3	0.0	1.3	0.9	1.2	0.1	48.1	1.8	0.0	0.0	0.0	0.6
* CF 1211bu	* WHEAT BULGUR WHOLEMEAL		5.0	10.2	0.7	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CF 1211	WHEAT FLOUR		63.4	296.3	327.5	300.0	181.6	166.2	133.0	60.1	52.4	32.2	87.7	79.6	180.1
* CF 1211ma	* WHEAT MACARONI		0.8	1.1	0.8	1.8	4.6	7.6	1.7	3.6	0.5	0.2	0.3	1.7	2.0
* CF 1211pa	* WHEAT PASTRY		0.4	1.1	0.7	2.6	1.7	5.4	0.3	0.6	0.7	0.2	0.3	0.6	1.7
CP 1211	WHITE BREAD		0.0	0.1	0.0	0.1	0.1	1.0	0.0	2.2	0.1	0.0	0.0	0.0	0.0
CP 1212	WHOLEMEAL BREAD		0.0	0.1	0.0	0.1	0.1	1.0	0.0	2.2	0.1	0.0	0.0	0.0	0.0
	* CEREAL PREPARATIONS NES		0.0	0.5	0.6	0.3	0.7	1.5	0.4	2.8	1.2	0.2	0.2	0.3	0.3
GC 80	TOTAL CEREALS	(13)	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

Note 1: BARLEY (GC 640) is the maximum of (a) BARLEY (FAO 44, not indicated), (b) 1.4xPOT BARLEY (FAO 45), (c) 1.4x2.4xBARLEY PEARLED (FAO 46), (d) 1.4x2.9xBARLEY FLOUR AND GRITS (FAO 48) and (e) 0.2xBARLEY BEER (FAO 51) to be consistent with FAO FBS definitions.

Note 3: MAIZE (GC 645) is the maximum of (a) MAIZE (FAO 56, not indicated), (b) 1.2xMAIZE FLOUR (CF 1255), (c) 16.7xMAIZE GERM (FAO 57) and (d) 0.2xMAIZE BEER (FAO 66) to be consistent with FAO FS definitions.

Note 4: *GERM MAIZE is the maximum of (a) GERM MAIZE (FAO 57, not indicated) and (b) 2.2xMAIZE OIL (FAO 60) to be consistent with FAO FBS definitions.

Note 12: WHEAT (GC 654) is the maximum of (a) WHEAT (FAO 15, not indicated) and (b) 1.1xWHEAT BULGUR WHOLEMEAL (CF 1211bu) + 1.3xWHEAT FLOUR (CF 1211) to be consistent with FAO FBS definitions.

La dosis aguda de referencia para el DON es de 8 ug/kg de peso corporal. Para una persona promedio que pesa 60 kg, la ingesta máxima dietética de cereales contaminados por DON no debe exceder de 480 ug/d (= 0,48 mg/d).

En referencia a la tabla de arriba que contiene datos de 2006 GEMS/Food, dietas de grupos que más contribuyen a la exposición potencial de DON en la población general fueron seleccionados para el cálculo de los NM propuestos de tal forma que protejan adecuadamente la salud pública a nivel mundial basándose en el consumo previsto de grano crudo (sin procesar) de trigo, maíz y cebada. Estos se comparan con los niveles máximos que se proponen en CF/CX 12/6/9, como se explica más adelante.

Como puede observarse, para el consumo de trigo en las dietas del grupo C, una contribución de la harina de trigo es de alrededor de 327,5 g/d, mientras que el consumo total de trigo es de ~ 426.5 g/d. Por lo tanto, el consumo de trigo crudo estimado sería 426.5 g/d - 327.5 g/d = 99 g/d. Como tal, una propuesta de NM que sería adecuada para la protección de la salud en este caso sería: 0.48 mg/d ÷ 0.099 kg de trigo crudo/d ≈ 5 mg/kg de DON en el trigo.

Lo mismo sucede con el consumo de maíz en la dieta de la Categoría B, una contribución de la harina de maíz es de 15,4 g/d y del germen de maíz es de 8,9 g/d, mientras que se prevé que el consumo total de maíz podría ser 148,4 g/d. Por lo tanto, el consumo de maíz crudo estimado sería 148.4 g/d - 15,4 g / d - 8,9 g/d = 124.1 g/d. Como tal, una propuesta de NM que sería adecuada para la protección de la salud en este caso sería: 0.48 mg/d ÷ 0.124 kgde maíz crudo /d ≈ 4 mg/kg de DON en el maíz sin procesar.

Del mismo modo para el consumo de cebada en las dietas de la Categoría E, las contribuciones de la harina de cebada es ~ 0,5 g/d, mientras que se prevé que el consumo total de cebada sea ~ 48,6 g/d. Así, para la cebada cruda el consumo estimado sería 48,6 g/d - 0,5 g/d = 48,1 g/d. Como tal, una propuesta de NM que sería adecuada para la protección de la salud en este caso sería: 0.48 mg/d ÷ 0,0481 kg/d cebada cruda ≈ 10 mg/kg de DON.

Sin embargo, en el documento CX/CF 12/6/9, se utiliza el consumo total de granos (cuadro 4) en lugar del dato de consumo en crudo de grano con losNM propuestos, los cuales se encuentran por debajo de los niveles que protegen la salud humana, especialmente para trigo crudo.

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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
RAW COMMODITIES															
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
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
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
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

Comparación entre los NM corregidos y los basados en CX/CF 12/6/9.

Grano crudo (Mayor dieta exposición de GEMS/Food 2006)	Propuesta corregida NM basado en el consumo pronosticado grano crudo (ppm)	Propuesta NM basada en el consumo total de granos como se refleja en el documento CX/CF 12/6/9 (ppm)
trigo(CategoríaC)	5 ppm	1.1 ppm
maíz(CategoríaB)	4 ppm	3.2 ppm
cebada(CategoríaE)	10 ppm	9.9 ppm

En resumen, el NM propuesto para el grano sin procesar se podría aumentar a 4 o 5 ppm y aún así son adecuados para la protección de la salud de la población.

En vista de las variaciones arriba citadas en los NM para la protección de la salud dependiendo del tipo de grano sin procesar, CCCF debería considerar el establecimiento de distintos NM para diferentes granos.

Apéndice II. Impacto probable en el comercio con NM de 2 ppm para el maíz crudo. (CX/CF 12/6/9, Tablas 9 y 10)

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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*	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 (excl. 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 BAD YEAR!	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*	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
All years excluding 2005/2006 crop year where higher concentrations of DON encountered	All data	611	0.22 - 0.47	0.00 - 0.50	0.40 - 0.50	0.77	0.99	1.20	17.4
	ML 2.0 µg/g	650	0.36 - 0.60	0.00 - 0.50	0.54	1.01	1.43	13.00	0.0
	ML 1.75 µg/g	630	0.26 - 0.51	0.00 - 0.50	0.49 - 0.50	0.92	1.20	1.90	3.1
	ML 1.5 µg/g	626	0.25 - 0.50	0.00 - 0.50	0.47 - 0.50	0.87	1.10	1.70	3.7
2005/2006 crop year BAD YEAR!	All data	620	0.24 - 0.49	0.00 - 0.50	0.45 - 0.50	0.85	1.10	1.50	4.6
	ML 2.0 µg/g	602	0.21 - 0.47	0.00 - 0.50	0.40 - 0.50	0.75	0.96	1.20	7.4
	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.

Con base en datos limitados, está claro que una propuesta de NM de 2 ppm tendrá un impacto significativo en el comercio mundial de maíz crudo en Canadá y Sudáfrica, con más del 65% de rechazo en los años malos.

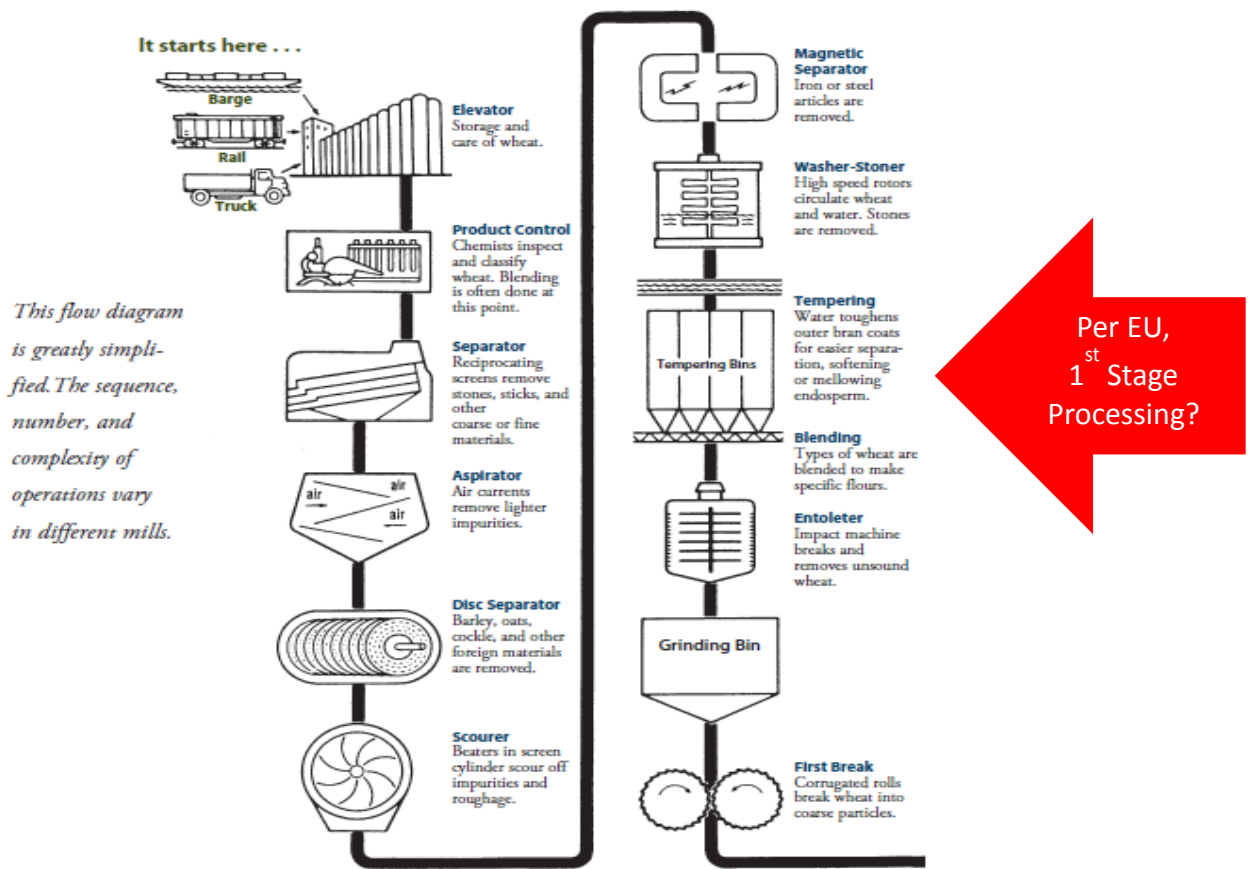
Apéndice III. UE “primera fase de procesamiento” después de la limpieza y clasificación de granos crudos.

De acuerdo con las Directivas de la UE, ^{5/} el NM para el DON en REGLAMENTO (CE) n ° 1881/2006 se aplica a los cereales no procesados comercializados en una primera fase de procesamiento.

“Primera fase de procesamiento” se entenderá cualquier tratamiento físico o térmico, distinto al secado, de o en el grano. Limpieza, clasificación y secado no se consideran incluidos en la «primera fase de procesamiento» en la medida en que ninguna acción física se ejerce sobre el grano en sí y el grano entero permanece intacto tras la limpieza y la clasificación. [Fase de temperado puede ser considerada como la primera etapa de procesamiento?]

En los sistemas de producción y procesamiento integrados, el NM se aplica a los cereales no procesados en caso de que estén destinados a una primera fase de procesamiento.

Así, en un diagrama de molinero genérico (que se muestra más abajo), los cereales no procesados comercializados para una primera fase de procesamiento pueden corresponder a la etapa de temperado. Por lo tanto, los datos sobre presencia se deben recoger en esta etapa. El NM propuesto debe ser así aplicable en esta etapa.



Courtesy of Wheat Foods Council, 10841 S. Crossroads Drive, Suite 105, Parker, Colorado 80138.