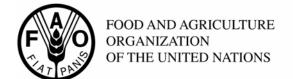
# codex alimentarius commission





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**Agenda Item 8** 

CX/CF 10/4/8 Add.1 April 2010

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS 4<sup>th</sup> Session

4<sup>th</sup> Session Izmir, Turkey, 26 – 30 April 2010

# PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS IN MAIZE AND MAIZE PRODUCTS AND ASSOCIATED SAMPLING PLANS

(N10-2009)

Comments at Step 3 submitted by Egypt, European Union, Ghana, Japan, Kenya, Norway, the Philippines, Thailand, COCERAL and IAEA

#### **EGYPT**

First of all, we would like to thank Germany for the work done on the above mentioned draft.

As the rate of consumption of these products are increasing, So we would like to inform you that Egypt proposals are as follows:

Commodity	Maximum level for fumonisins (FB1+FB2), mg/kg
Unprocessed maize	4
maize flour/meal	1
Maize – based baby food	0.2
Maize – based breakfast cereal, snacks and chips	0.8
Popcorn grain	1

#### **EUROPEAN UNION**

#### **INTRODUCTION**

The European Union (EU) appreciates the work performed by the electronic Working group under the lead of Brazil and provides the following comments on the proposed maximum levels and associated sampling plans for fumonisins in maize and maize products.

# COMMENT ON THE STRUCTURE OF THE DOCUMENT

While Annex II – Proposed draft sampling plan for fumonisins (p. 4) contains some general information as regards the proposed sampling plan, more (background) details on the sampling plans for fumonisins in maize and maize products is provided in Annex III of the document (p. 27 - 39). This section of Annex III of the document contains simultaneously elements which should be part of a Codex sampling plan and background information to the sampling plan (e.g. Operating Characteristic (OC) curves).

Therefore the EU suggests to structure the document for example as follows

- Annex I: proposed maximum levels for fumonisins in maize and maize products with some considerations.
- Annex II: proposed draft Codex sampling plan for fumonisins in maize and maize products thereby integrating certain parts which are currently mentioned in the background information in Annex III but which should be integral part of a Codex sampling plan.
- Annex III: Background information
  - Part A: background information in support of the proposed maximum levels
  - Part B: background information in support of the proposed associated sampling plan

# <u>COMMENTS ON THE PROPOSED DRAFT MAXIMUM LEVELS FOR FUMONISINS (FB1 + FB2)</u> <u>IN MAIZE AND MAIZE PRODUCTS (Annex I of CX/CF 10/4/8)</u>

The European Union (EU) agrees on the establishment of maximum levels of fumonisins as a sum of FB1 and FB2.

The EU is of the opinion that it has to be clarified that the proposed maximum levels concern maize intended for human consumption, given that of the maize and maize products in international trade the largest part is intended for use in animal feed and only a limited part for human consumption.

The EU questions the need of setting a maximum level (ML) for fumonisins in maize based baby food in Codex Alimentarius Commission, given that this kind of foodstuffs are not traded internationally to a significant extent.

The EU cannot agree in general on the setting of a maximum level at a level significantly higher than the highest level observed. This is the case with the proposed ML of 2 mg/kg for popcorn grain, where the highest level observed was 1,6 mg/kg (point (h) on page 3) and with the proposed ML of 0,5 mg/kg for maize based baby food where the highest level observed was 0,32 mg/kg.

The EU is of the opinion that the same ML (the lower level) should apply to "popcorn (grain)" and "maize based breakfast cereals, snacks and chips".

The EU is of the opinion that it should be specified for the (heat) processed foods if the ML refers to free fumonisins or to the sum of bound and free fumonisins.

The EU is of the opinion that it is appropriate to continue the discussion on the ML for fumonisins in maize and maize products in Codex. However, the EU is of the opinion that it is premature to forward any maximum level for fumonisins in maize and maize products for provisional adoption by the Codex Alimentarius Commission at Step 5, whilst the JECFA re-evaluation of fumonisins in maize and maize products, taking into account the available toxicology and occurrence data, is not available and which is expected to be carried out in 2011.

Therefore the EU proposes to (re)-circulate for comments at Step 3 the revised MLs, taking into account the outcome of the discussions at this session of CCCF and eventually further work done in an electronic working group, for consideration at the 5<sup>th</sup> Session of CCCF.

# <u>COMMENTS ON THE PROPOSED DRAFT SAMPLING PLAN FOR FUMONISINS (FB1 + FB2)</u> (<u>Annex II of CX/CF 10/4/8)</u>

The EU is of the opinion that no justification is given in the document CX/CF 10/4/8 for requiring 2 laboratory samples in the case of sampling of maize grain and popcorn for the control of the presence of fumonisins and whereby both laboratory samples have to comply with the proposed ML. Therefore the EU questions the need of the requirement of two laboratory samples, both having to comply with the ML.

The Decision rule foreseen for maize flour and meal is not correct, as it is a copy of the decision rule foreseen for maize grain, while for maize flour and meal only one laboratory sample is proposed and the suggested ML is 2 mg/kg instead of 5 mg/kg.

The EU is of the opinion that the option of 100 incremental samples of 100 g resulting in an aggregate sample size of 10 kg should be foreseen in the relevant OC curves in order to be able to take into consideration this option for the proposed draft sampling plan for fumonisins.

Therefore, the EU proposes to (re)-circulate for comments at Step 3 the proposed associated sampling plan, taking into account the outcome of the discussions at this session of CCCF and eventually further work done in an electronic working group, for consideration at the 5<sup>th</sup> Session of CCCF.

# EDITORIAL AND OTHER SPECIFIC COMMMENTS TO THE BACKGROUND INFORMATION (mainly Annex III of CX/CF 10/4/8)

Page 2, paragraph (c) line 3: "perform" instead of "performed".

**Page 2, paragraph (e) last sentence:** The correctness of this sentence needs to be verified (see the comments on page 20, table 10 at the end of this position paper).

Page 3, paragraph (k) and (l): The issue of free versus bound residues is raised. It is not mentioned if the reported on fumonisins in (heat) processed maize based foods such as breakfast cereal, chips, snacks, tortillas refer to only free fumonisins or do also include bound fumonisins. Furthermore it is not specified if the proposed maximum levels refer to free fumonisin only or to free and bound fumonisins.

**Page 5, paragraph 2:** Alternaria alternate f. sp. Lycopersici should be deleted from the list of fumonisin producers, as this species do not produce fumonisins but Alternaria alternate lycopersici toxins (AAL toxins) which are structurally similar and have similar effects but these toxins are not called fumonisins.

**Page 8, paragraph 23, 1**<sup>st</sup> **sentence**: ELISA methods are certainly quick and cheap, but are potentially subject to interferences that render them less accurate than LC/MS or LC/fluorescence. Some comment as to the accuracy of these ELISA methods would be appropriate.

Page 8, paragraph 28, line 3: "market" instead of "marked"

**Page 9, Table 2**: There is a problem with the FB2 data from Croatia. The maximum is given as 3.08 mg/kg. However in the mean/SD box, 3 figures are given which are presumably the values of the 3 positive samples. One of these figures (68.4 mg/kg) considerably exceeds the "maximum" figure of 3.08 mg/kg.

**Page 9, table 2**: The footnote to Table 2 mentions PHC (primary hepatocellular carcinoma), but this doesn't appear to be cited anywhere in the main body of the table.

There is a footnote a, c and d but not b.

Page 9, paragraph 29, line 2: "world" instead of "word".

Page 10-11, paragraphs 30 and 31 and figure 2 and table 4: For the understanding of the text it would be better to put paragraph 31 and table 4 before paragraph 30 and figure 2.

Page 10, paragraph 30, before last line: "countries" instead of "country".

#### Page 11, paragraph 31:

- It is stated here that the sample numbers ranged from 36 (UK) to 1123 (Brazil). However, this does not take into account the 12 samples from Norway (table 4).
- Additionally, it is not clear to what type of raw data the paragraph is referred to and therefore as it are the same data as referred to in paragraph 30 it is appropriate to mention that it concerns raw data on FB1+FB2 levels in corn/maize (grains).

Page 11, table 4: The heading of this table should state the units and the fact that the samples are corn/maize.

**Page 11, table 4**: There is something wrong with the reporting of the data from Belgium: if 40 out of the 41 samples are positive, this constitutes 97.5 %. It is unclear how 98.9 % has been derived. Furthermore if, 98.9% of the 41 Belgian samples were positive then the minimum, 25<sup>th</sup> percentile and median cannot all have the same (0.075 mg/kg) value.

Page 12, table 5: The "NR" entry in the middle of the last row of the table is not defined. 'Not Reported'?

#### **Page 13, table 7**:

- The units need to be given in the title.
- The same superscript, c, has been used twice once for the Mean column heading and once for the USA Cornmeal sample, each with a different meaning.
- Some of the concentrations for the Belgian corn chip samples use a comma rather than a full stop to designate the decimal point.
- For the (heat) processed foodstuffs, it should be specified if the reported levels refer to free fumonisins or to free and bound fumonisins.

# Page 14, table 7:

- For the sake of consistency an entry of 0.30 needs to be made for the Maximum of the Finnish Taco sample.

Pages 13 – 14, table 7: not all the UK data are correct. The data that the UK submitted (in total 482) are the following

• Baby food: 47 instead of 46

• Popcorn: 9

• Breakfast cereals: 76 instead of 64

• Sweet/baby corn: 32

Cornmeal/polenta: 41 instead of 22

• Corn/maize flour: 62 instead of 69

Tortilla/tortilla chips/taco: 58 instead of 56

Corn/maize snacks: 48 instead of 46

• Corn oil: 19

• Pasta/bread: 15 instead of 11

• Corn/corn on the cob: 33

Raw maize: 36

• Other: 6

Page 15, paragraph 35, line 2: The fungus can *happily* (?) grow (...)

Page 15, paragraph 37, line 2: "scientific" instead of "scientifically".

**Page 15, paragraph 38-48:** it would be appropriate to include information from a study performed in the UK as regards the fate of fumonisins during processing. This information can be found in:

Scudamore K.A. and Patel, S. (2008) The fate of deoxynivalenol and fumonisins in wheat and maize during commercial breakfast cereal production. World Mycotoxin Journal, Volume 1, number 4, p. 437-448.

# Page 17 – 18, table 8 - 9:

The first cell of these tables needs to be labelled Cluster.

Additionally, the way that the exposure data are presented in these tables is not clear. More explanation needs to be given of the 13 GEMS/FOOD Consumption Cluster Diets. It would also be helpful for the country composition of these 13 Cluster Diets to be more explicitly stated.

Table 8 gives daily intake estimates for fumonisins in maize (excluding flour, oil and beer), while Table 9 provides daily intake estimates for fumonisins in maize flour. The data in these two tables seem only to be considered separately, i.e. in terms of assessing which Cluster Diet as a function of fumonisin intake exceeds

the PMTDI. It seems that the results of these two tables should be considered together as well. What is of particular relevance is the extent to which the PMTDI is exceeded as a function of the combined consumption of maize (Table 8) and maize flour (Table 9).

Page 19, paragraph 70, line 2: Cluster diet C should read "Africa and Middle East".

# Page 20, table 10:

Only cluster C was selected for the calculation on this table with the fumonisin distribution for maize grain from South Africa and Nigeria. Although this choice is justified in the text, it would have been informative to have run this calculation separately for all 13 Cluster Diets; and also to have looked at the impact of using the fumonisin/maize distribution supplied by other national governments – i.e. rather than just that of South Africa and Nigeria.

Furthermore, the impact of all maize and maize products contributing to the human fumonisin exposure at the different proposed maximum levels on the estimated human exposure compared with the PMTDI should be included in the assessment.

In addition, table 10 is potentially misleading. It is assumed that at a limit of 5 mg/kg, all 95<sup>th</sup> percentile consumers will exceed the PMTDI and that their consumption will be 1.3 time the PMTDI. However, the last sentence of paragraph (e) of Annex I (page 2), possibly resulting from the table 10, indicates that "a limit of 5 mg/kg would mean that 30 % of the 95<sup>th</sup> percentile consumers will exceed the PMTDI" which seems not to be correct.

In general table 10 should be better elaborated and extended (see comments above) and more discussion on these better elaborated tables should be provided in the text.

#### **GHANA**

#### **GENERAL COMMENTS**

We wish to congratulate Brazil and other members of the Working group for the efforts put into the development of this document.

Ghana is pleased to offer these comments:

#### ANNEX II,

#### PROPOSED DRAFT SAMPLING PLANS FOR FUMONISINS

Page 4

Maize Flour/Meal

The number of laboratory samples should be 2 but not same as laboratory sample.

Change 5mg/kg to 2mg/kg under decision rule.

# **Popcorn**

The subtitle '**Popcorn'** for the third table or category should be changed to '**Popcorn Grain'** for uniformity in document; also in page 2 we have popcorn grain not popcorn.

Page 6, para 15,

The letter 'p' should be introduced in the word shingosine in last line of phrase of para 15:

"......sphinganine:shingosine ratio (Sa:So) with increase risk of NTD in the offspring."

for sentence to read as follows:

"......sphinganine:sphingosine ratio (Sa:So) with increase risk of NTD in the offspring."

#### ANNEX III

Page 9, Table 2: The incidence of Fumonisin in Maize /Corn reported in the literature

Column 1, Row 1 with Fandohan et al., 2005 as reference:

'West Africa' should be changed to 'Benin' since work was carried out in Benin and not the West African Region. Secondly West Africa refers to a region or group of countries as heading for column is titled Country. The title of the publication reads as follows: the Natural occurrence of Fusarium and subsequent fumonisins contamination in Pre-harvest maize and stored maize in Benin

Page 15 para 35 line 2

We propose that the replacement of the word 'happily' with 'readily' in the sentence:

"Hence, fungus can happily grow......' for sentence to read as follows:

"Hence, fungus can readily grow......"

Page 15, para 37, line 2

We propose that the replacement of the word 'scientifically' with 'scientific' in the sentence:

- "....there is no scientifically evidence......' for sentence to read as follows:
- ".....there is no scientific evidence......"

#### SPECIFIC COMMENTS

Page 2 (b), second sentence

We suggest the insertion of the phrase' and some fermented maize products' into sentence below:

It is important to point out that bound fumonisins found in extruded maize products such as breakfast cereal, are not detected by the usual extraction procedure and the exposure to fumonisins cannot be fully assessed.

for sentence to read as follows:

It is important to point out that bound fumonisins found in extruded maize products (breakfast cereal) **and some fermented maize products** are not detected by the usual extraction procedure and the exposure to fumonisins cannot be fully assessed.

Rationale: The normal procedure was not able to detect fumonisins in fermented products such as kenkey and banku which are indigenous food products for Ghana when analyzed.

# Maize consumption in Africa

Due to the high maize consumption in Africa, MTL for fumonisins should not be set above 1 mg/kg. Maize consumption can be as high as 500g/person/day in Bukina Faso (Nikiema et al. 2004), 469g/person/day in Malawi (FAO 1992), 456g/person/day in South Africa, 400g/person/day in Kenya (Shephard et al. 2007) and 385g/person/day in Tanzania (Kimanya et al. 2008).

Due to these high maize consumptions the PMTDI of  $2\mu g/kg$  bw/day is exceeded in Africa when maize containing more than 0.2 mg/kg is consumed (Marasas 1997, Kimanya et al. 2008; 2009).

Shephard showed by calculation that, consumption of maize containing 2 mg/kg (the MTL recommended by Brazil for maize meal/flour etc), by an individual who consumes 400g of maize per day, leads to fumonisins exposure of 13 µg/kg body weight /day or 650% of the PMTDI (Van Egmond et al. 2007).

However, in Europe maize containing as high as 12 mg/kg can be consumed without exceeding the PMTDI. According to Shephard et al. 2007 and Van Egmond et al. 2007, maize consumption in Europe is low (about 10g/person/day).

#### Recommendation for MTLs for maize based foods

	Food	MTL	MTL (mg/kg):
		(mg/kg):	Proposal by
		Proposed by	Ghana
		the EWG led	
		by Brazil	
1	Maize grain for processing (eg	5	3

	sorting, cleaning, dehulling etc )		
2	Maize grains, maize grits, cracked maize, maize meal/flour	2	1
3	Maize foods*, maize based breakfast cereals, snacks and chips.	2	0.5
4	Popcorn grain	1	1
5	Maize based foods for infants and young children	0.5	0.3

<sup>\*,</sup> Foods made solely from maize eg. Kenkey, Ugali and Nshima.

With application of good agricultural practices combined with proper sorting, it is possible to reduce the current high contamination in maize to below 3 mg/kg for maize destined for processing (Fandohan et al. 2005; Kimanya et al. 2009). Also, in processing maize (eg. dehulling or soaking in water) it is possible to reduce contamination in maize grains from the levels above 2 mg/kg to levels below 1 mg/kg (Fandohan *et al.*, 2005; Kpodo et al. 2006).

#### PROPOSED LIMIT

Considering the technological difficulties to reduce fumonisins contamination in maize to levels below 2 mg/kg, we suggest an MTL not exceeding 1mg/kg for maize based foods for direct human consumption.

#### References

- 1. Fandohan, P., Zoumenou, D., Hounhouigan, D. J., Marasas, W. F. O., Wingfield, M. J. and Hell, K. (2005). Fate of aflatoxins and fumonisins during the processing of maize into food products in Benin. *International Journal of Food Microbiology*; 98:249-259
- 2. FAO (1992). Comparison of Nutritive value of common maize and quality protein maize. *Maize in human nutrition. Food and Agriculture Organization, Rome Italy*
- 3. Kimanya ME, De Meulenaer B, Tiisekwa B, Ugullum C, Van Camp J, Devlieghere F, Kolsteren P. (2009). Fumonisins exposure from freshly harvested and stored maize and its relationship with traditional agronomic practices in Rombo district, Tanzania. *Food Additives and Contaminants Part A-Chemistry Analysis Control Exposure & Risk Assessment, Part A, 26 (8), 1199 1208*
- 4. Kimanya ME, Meulenaer BD, Baert K, Tiisekwa B Van Camp J, Samapundo S, Lachat C and Kolsteren P. (2009). Exposure of infants to fumonisins in maize-based complementary foods in rural Tanzania. *Molecular Nutrition and Food Research*. 53, 667 674
- 5. Kimanya, M., De Meulenaer, B., Tiisekwa, B., Ndomondo-Sigonda, M. and Kolsteren, P. (2008). Human exposure to fumonisins from home grown maize in Tanzania. *World Mycotoxin Journal*; *1*(*3*):307-313
- 6. Kpodo, K.A., Ayernor, G.S., Shephard, G.S. and Jacobsen, M. (2006). Exposure to fumonisins through Kenkey- a Ghanaian fermented maize product. In: Mycotoxins and Phycotoxins; Adavnces in determination, toxicology and exposure management. Proceedings of the Xith International IUPAC Symposium on Mycotoxins and Phycotoxins, May 17-21, 2004, Bethesda, Maryland, USA. Wageningen Academic Publishers, The Netherlands. p 209 216.
- 7. Marasas, W.F.O. (1997). Risk assessment of fumonsins produced by Fusarium moniliforme in corn. *Cereal Research Communications*; 25: 399-406
- 8. Nikiema, P. N., Worrilow, L., Troure, A. S., Wild, C. P. and Turner, P. C. (2004). Fumonisin contamination of maize in Burkina Faso, West Africa. *Food Additives and Contaminants*;, 21: 865–870

9. Shephard, G.S., Van der Westhuizen, L. and Sewram, V. (2007). Biomarkers of exposure to fumonisin mycotoxins: A review. *Food Additives and Contaminants*; 24: 1196 – 1201

10. Van Egmond, H. P., Schothorst, R. C. and Jonker, M. A., (2007). Regulations relating to mycotoxins in food. *Analytical and Bioanalytical Chemistry 389: 147-157* 

#### **JAPAN**

#### 1. Inclusion of fumonisin B3

First Japan proposes that the committee should consider the inclusion of fumonisin B3 (FB3) as object of ML establishment.

Referring to the principle that risk management decisions should be based on risk assessment, Japan believes that the JECFA's risk assessment constitutes a basis for consideration on risk management options. From this point of view, Japan is of the opinion that the Committee should consider establishing a maximum level of total fumonisins (FB1+FB2+FB3), rather than addressing FB1 and FB2 only.

Given that the occurrence of FB3 is also well documented (e.g. JECFA in 2001 estimated the ratio FB1:FB2:FB3 as 10:3:1) and that JECFA in 2001 allocated the provisional maximum tolerable daily intake (PMTDI) of 2  $\mu$ g/kgBW/day to FB1, FB2 and FB3 alone or in combination, total ML for FB1, FB2 and FB3 should be established to control fumonisin contamination in maize and maize products. Otherwise, the reason for not including FB3 should be clearly presented.

#### 2. Need for further information on the occurrence of fumonisins

Second, Japan is of the view that, at this stage, with limited availability of information on intake estimates, it might be premature to decide for which commodities MLs should be established.

Taking into consideration the CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED (CODEX STAN 193-1995 ANNEX I), which stipulates that *MLs should be set only for food that is significant for the total exposure of the consumer to the contaminant*, proposal for MLs for fumonisins in several commodities should be accompanied by the data showing that the contribution to total fumonisins dietary exposure is high for each proposed commodity in GEMS/Food Regional diets.

Furthermore, the Criteria states that proposals for MLs in products should be based on data from various countries and sources and that MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group. In the light of these conditions, the current discussion paper seems to point out limits of available information: firstly the incidence data on certain commodities (e.g. corn/maize flour/meal and maize based baby food) are from only limited countries; secondly the intake estimates shown in the paper (cf. Tables 8 and 9) seem rough because its calculation is using mean levels, not the distribution of contamination levels.

Japan is of the opinion that, for the purposes of more accurate assessment of human exposure to fumonisins, more data on the occurrence in maize and maize products as well as data on the dairy intake of these commodities should be obtained at this stage, before discussing further the establishment of Codex MLs for total fumonisins. Given that re-evaluation of fumonisins (fumonisin exposure assessment) by JECFA is supposed to be scheduled in or after 2011, it needs now to encourage Member countries to collect relevant data with a view to ensuring more refined intake estimates.

#### 3. Suggestion of a text to be inserted in the document

For the reasons mentioned above, Japan would like to propose a new text to be inserted in Annex I as an item to be considered, as follows:

More data on occurrence of fumonisins in maize and maize products should be obtained at this stage, with a view to contributing to the JECFA re-evaluation as well as establishing MLs based on refined intake estimates.

# **KENYA**

#### **General comment**

1. Kenya supports the setting of standard and it was important to consider determining the quantity consumed per person per day. It was also important to know the risks associated with other cereals such as sorghum, in order to advice consumers appropriately. There should be data indicating compliance with good agricultural practices in the area, for example, levels of fertilizer used and choice of seed planted.

2. The proposed draft should set Maximum Limit of fumonisins in maize and maize products for animal feed and human and the contamination data from any country should serve the purpose of setting the maximum safe level for both consumer and animals.

# **NORWAY**

Norway wishes to congratulate Brazil and the electronic working group with their extensive work on "Proposed draft maximum levels for fumonisins (FB1 + FB2) in maize and maize products and associated sampling plans". The document provides a good background for discussions on the forthcoming CCCF meeting.

We would like to draw the attention to the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals, including annexes on Ochratoxin A, Zearalenon, Fumonisins and Tricothecenes (CAC/RCP 51-2003)*. In addition to discussing maximum levels and sampling plans for Fumonisins, we support an assessment of the compliance and efficiency of this Code of practice on the Fumonisins.

Norway generally supports the ongoing work in Codex on maximum levels for Fumonisins (FB1 + FB2) in maize and maize products for human consumption. We do, however, have certain reservations as regards progressing the draft levels and food commodities further at the upcoming CCCF meeting, as we wish to await the scheduled JECFA evaluation in 2011. Norway therefore propose that the draft maximum levels should be held at step 3 pending the outcome of the JECFA evaluation.

#### THE PHILIPPINES

The Philippines would like to submit the following data superceding previously submitted data at the 3<sup>rd</sup> CCCF as reflected (CRD 13) on the levels of fumonisins in maize and maize products.

Table 1. Levels of fumonisins (FB1 and FB2) in maize and maize products used as feeds in the Philippines

Sample		Positive Samples/	Range of Total	
		Analyzed Samples	Fumonisins mg kg <sup>-1</sup>	
			nig kg	
1.	Maize bran	2/2	2.5-3.4	
2.	Maize By-Product (High Fat)	4/6	ND-0.40	
3.	Maize flour (white)	1/1	0.1	
4.	Maize flour (yellow)	1/2	ND-2.1	
5.	Maize germ	1/1	210	
6.	Maize germ meal	1/1	3.3	
7.	Yellow maize	5/11	ND-300	

ND- None Detected

Reference: Begino, Edna. Unpublished Report. Bureau of Animal Industry Mycotoxin Laboratory, Philippines. (Accessed last 18 February 2009).

Table 2. Levels of fumonisins (FB1 and FB2) in maize and maize products used as raw material for

processed foods in the Philippines

	Sample	Positive Samples/ Analyzed samples	Range of FB <sub>1</sub> mg kg <sup>-1</sup>	Mean FB <sub>1</sub> mg kg <sup>-1</sup>	Range of FB <sub>2</sub> mg kg <sup>-1</sup>	Mean FB <sub>2</sub> mg kg <sup>-1</sup>
1	Yellow maize (semolina grits)	0/3	ND <sup>a</sup>	N/A	$ND^b$	N/A

ND- None Detected

N/A- Not Applicable

#### Reference:

Philippine Chamber of Food Manufacturers, Inc. (PCFMI). Unpublished Report (Accessed last 19 February 2010).

#### **THAILAND**

Thailand would like to express our appreciation to Brazil on the attempts of the development of the Proposed Draft Maximum Levels for Fumonisins in Maize and Maize-Products and associated Sampling Plans. The calculated dietary intake of fumonisin through the consumption data of Thailand is estimated. The result shows that the intake did not exceed the PMTDI. Also, monitoring data of maize grain in Thailand showed compliance with the proposed ML. Therefore, we appreciate the proposed ML of fumonisins at 5 mg/kg for unprocessed corn/maize grain, 2 mg/kg for corn/maize flour/meal, 2 mg/kg for popcorn grain, 0.5 mg/kg for maize-based baby food and 1 mg/kg for maize-based breakfast cereals, snacks and chips.

For sampling plans for fumonisins in maize and maize products, we also agree with this procedure. It is useful information for stakeholder.

#### **COCERAL**

Whilst, in principle, COCERAL welcomes the introduction of guidance levels by the Codex Alimentarius, we are concerned that distribution of fumonisin in products of the dry-milling process does not make it possible to comply with a guidance level of maximum  $2000\mu g/kg$  in maize flour, milling maize that contains  $5000 \mu g/kg$ .

According to COCERAL experience, a limit of 2000  $\mu$ g/kg fumonisins is feasible for maize grits and other larger products of the milling process, coming from the hardest part of the grain. A large part of the fumonisin in maize is however concentrated in the soft/powdery part of the grain, the part that constitutes the flour made in the dry-milling process.

Thus compliance with a maximum of 2000  $\mu$ g/kg fumonisins in maize flour is doubtful, starting from the raw material that would be accepted by the proposed Codex levels.

The variation in fumonisin levels in various products of the dry-milling industry was recognised by the European Commission, which lead to different EU limits for products of the milling industry depending on the particle size of these products, which is a direct result of the part of the grain they originate from.

The following EU limits have been set for products of the dry-milling industry (Commission Regulation 1881/2006 and amendments):

- Unprocessed maize : max 4000 μg/kg

- Milling fractions of maize with particle size > 500 micron : max 1400 µg/kg

<sup>&</sup>lt;sup>a</sup> Less than level of detection of 0.02

<sup>&</sup>lt;sup>b</sup> Less than level of detection of 0.05

- Milling fractions of maize with particle size  $\leq 500$  micron: max 2000 µg/kg

A higher limit on unprocessed maize would benefit farmers, but without an equivalent adaptation of the limits on milling products the dry milling industry would be placed in a difficult situation.

In our opinion it would be more feasible to fix the CODEX maximum limits as follows:

- Unprocessed Maize : max 5000 μg/kg
- Maize grits (milling fractions >500 μm): max 2000 μg/kg
- Maize flour (milling fraction ≤ 500 μm): max 3000 μg/kg
   Should you have any questions do not hesitate to contact us.

Thank you for the opportunity to submit the present suggestions and remarks, and appreciating your availability in this respect.

#### **IAEA**

1. The International Atomic Energy Agency (IAEA) is pleased to note that the scientific publication on Evaluating the Performance of Sampling Plans to Detect Fumonisin B1 in Maize Lots Marketed in Nigeria¹ has been referenced and used throughout the text (Annex III – Sampling Plans for Fumonisins in Maize and Maize Products, paragraphs 1, 2 and 46). The publication was based on the results of an IAEA Technical Cooperation Project in Nigeria (NIR/5/030) on Regulatory Control and Monitoring of Contaminants and Residues in Fresh Produce.

- 2. The IAEA is also pleased to report that the manual on *Sampling Procedures to Detect Mycotoxins in Agricultural Commodities* (T.B. Whitaker, A.B. Slate. M.B. Doko, B.M. Maestroni and A. Cannavan, 2009) is currently in press with the Springer Publishing Company.
- 3. The IAEA looks forward to the further consideration of the proposed draft Maximum Levels for Fumonisins in Maize and Maize Products and Associated Sampling Plans.

<sup>&</sup>lt;sup>1</sup> Whitaker, T.B.; Doko, M.B.; Maestroni, B.M.; Slate, A.B.; Ogunbanwo, B.F.; Evaluating the Performance of Sampling Plans to Detect Fumonisin B1 in Maize Lots Marketed in Nigeria. J AOAC Intl. 90(4): 1050-1059, 2007.