EFSA Journal 2014;12(5):3699

STATEMENT OF EFSA

Evaluation of the increase of risk for public health related to a possible temporary derogation from the maximum level of deoxynivalenol, zearalenone and fumonisins for maize and maize products[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked to deliver a scientific statement on the increase of risk for public health related to a possible temporary derogation from the maximum level (tML) of deoxynivalenol (DON), fumonisins (FUMO) and zearalenone (ZON) in maize and maize products. EFSA relied on occurrence data reflecting levels of these mycotoxins in the 2013 maize harvest. Depending on the mycotoxin, mean levels estimated considering tMLs were increased by a factor comprised between 7.6 and 27 % in maize and maize milling fractions, and up to 99 % in some processed maize-based products, compared to levels estimated considering current ML. Chronic exposure levels estimated across the population groups – representing different age classes and countries – were increased by a factor up to 17 % for fumonisins, 20 % for deoxynivalenol and 83 % for zearalenone. The tolerable daily intake (TDI) for zearalenone set by EFSA at 0.25 µg/kg body weight (b.w.) per day, and the group provisional tolerable daily intake (PMTDI) of 1 and 2 µg/kg b.w. per day set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for deoxynivalenol and fumonisins, were used as chronic health based guidance values (HBGV). For all three mycotoxins these values were exceeded in at least one age group when considering the current ML, reflecting a health concern. When considering the tMLs, percentages of consumers in the age groups with the highest exposures exceeding chronic HBGVs increased from 9.2 to 9.8 % for zearalenone, from 47 to 48 % for fumonisins and from 52 to 54 % for deoxynivalenol. Acute exposure scenarios resulted in exceedance of the group acute reference dose (ARfD) of 8 µg/kg b.w. established by JECFA for DON, with up to 1.2 % of the consumption days above the group ARfD with the current ML, and up to 8.1 % with the tML. This assessment, mainly based on French data, may lack representativeness for the European situation.

© European Food Safety Authority, 2014

KEY WORDS

maximum level (ML), deoxynivalenol (DON), zearalenone (ZON), fumonisins (FUMO), maize products, occurrence, exposure

[1] On request from the European Commission, Question No EFSA-Q-2014-00321, approved on 21 May 2014.
[2] Correspondence: contam@efsa.europa.eu
[3] Acknowledgement: EFSA wishes to thank Diane Benford, Peter Fürst and Mike DiNovi for reviewing this scientific output and providing valuable comments, and EFSA staff: Davide Arcella, Marco Binaglia, Gina Cioacata, Fanny Héraud and Hans Steinkellner for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), 2014. Evaluation of the increase of risk for public health related to a possible temporary derogation from the maximum level of deoxynivalenol, zearalenone and fumonisins for maize and maize products. EFSA Journal 2014;12(5):3699, 61 pp. doi:10.2903/j.efsa.2014.3699

Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2014

SUMMARY

Following a request from the European Commission (EC), the European Food Safety Authority (EFSA) was asked to deliver a scientific statement on the increase of risk for public health related to a possible temporary derogation from the maximum level (ML) of deoxynivalenol (DON), zearalenone (ZON) and fumonisins (FUMO) for maize and certain maize products.

DON is a plant pathogenic mycotoxin, mainly produced by *Fusarium graminearum* which grows on the crops in the field, and occurs frequently together with its acetyl-derivatives, 3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON). In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a group provisional tolerable daily intake (PMTDI) of 1 µg/kg body weight (b.w.) per day and a group ARfD of 8 µg/kg b.w. for DON, 3-Ac-DON and 15-Ac-DON which are considered in the present assessment.

FUMO are a group of structurally related plant pathogenic mycotoxins produced mainly by *Fusarium verticillioides* and *Fusarium proliferatum* growing on cereals, in particular on maize. The group PMTDI of 2 µg/kg b.w. per day for fumonisins established in 2011 by JECFA was considered in the present assessment.

ZON is a plant pathogenic mycotoxin produced by different Fusarium species, particularly *Fusarium graminearum* and also *Fusarium culmorum*, *Fusarium equiseti* and *Fusarium verticillioides*, found in cereals on the field (in particular maize) but also as a post-harvest contaminant. A TDI of 0.25 µg/kg b.w. per day set by EFSA in 2011 is used for the present assessment.

Occurrence data from the 2013 harvest originating from three different sources (FranceAgriMer collector survey, IRTAC Cereal Sanitary Monitoring Plan, and Euromaisiers) were provided with the request. Depending on the source, maize samples were taken at the maize collector and/or at maize milling factory. Data were mainly coming from France. DON, ZON and FUMO were analysed with enzyme-linked immunosorbent assays (ELISA) and high performance liquid chromatography (HPLC) (in total 2,637 analytical results). Occurrence data compiled in previous EFSA and JECFA risk assessments were also considered. These were mainly corresponding to results from official monitoring programmes, collected over a 5 - 10 years period between 2000 and 2012, and reported by up to 21 European countries (in total 39,202 analytical results). Mean levels in maize grains and maize milling products estimated from the datasets provided with the request appeared to be 1.3 to 6 times higher compared to mean levels considered in previous assessments.

The impact of a temporary derogation from the maximum levels was assessed considering the data from FranceAgriMer survey which was the most suitable source of information. This represented a total of 663 analytical results, 221 results for each mycotoxin. Transfer rates from grain to grain milling products were assumed to correspond to the ratio between the tML defined in the grain milling products and the tML defined for the unprocessed grains.

Compared to the current MLs, it was estimated that the tMLs would increase mean middle bound (MB) levels of DON, ZON and FUMO in unprocessed maize grains and milling fractions by 16 - 18 %, 25 – 27 % and 7.6 – 23 % respectively. Depending on the kind of maize ingredient and its percentage content in final processed/composite products, the mean MB levels of DON and FUMO in final processed/composite products were increased by 12 – 58 %, whereas mean MB levels of ZON were increased by 25 - 99 %.

Chronic dietary exposure to DON of children age groups estimated with occurrence data reflecting current MLs ranged on average between 0.22 and 1.11 µg/kg b.w. per day (minimum lower bound (LB) to maximum upper bound (UB)) and at 95th percentile between 0.94 and 2.10 µg/kg b.w. per day. Chronic dietary exposure to DON of adult age groups ranged on average between 0.18 and 0.56 µg/kg b.w. per day and at 95th percentile between 0.38 and 1.01 µg/kg b.w. per day.

Depending on the survey and age group, mean and 95th percentile chronic dietary exposure to DON estimated with the occurrence data reflecting tML were up to 20 % higher than the levels estimated with the occurrence data reflecting current ML.

Chronic dietary exposure to ZON of children age groups estimated with occurrence data reflecting current MLs ranged on average between 9.7 and 118 ng/kg b.w. per day (minimum LB-maximum UB) and at the 95th percentile between 47 and 303 ng/kg b.w. per day. The chronic dietary exposure to ZON of the adult age groups ranged on average between 4.4 and 64 ng/kg b.w. per day and at the 95th percentile between 11 and 117 ng/kg b.w. per day.

Depending on the survey and age group, the mean and 95th percentile chronic dietary exposure to ZON estimated with the occurrence data reflecting tML were up to 83 % higher than the levels estimated with the occurrence data reflecting current ML.

Chronic dietary exposure to FUMO of children age groups estimated with occurrence data reflecting current MLs ranged on average between 0.17 and 2.11 µg/kg b.w. per day (minimum LB to maximum UB) and at the 95th percentile between 0.54 and 4.39 µg/kg b.w. per day. Chronic dietary exposure to FUMO of adult age groups ranged on average between 0.03 and 1.19 µg/kg b.w. per day and at the 95th percentile between 0.08 and 2.30 µg/kg b.w. per day.

Depending on survey and age group, mean and 95th percentile chronic dietary exposure to FUMO estimated with the occurrence data reflecting tML were up to 17 % higher than the levels estimated with the occurrence data reflecting current ML.

Acute exposure scenarios were carried out for people who consume maize grains, maize milling products, maize-based breakfast cereals, maize-based snacks and maize-based pastries containing DON equal to the ML and resulted in a very low percentage of consumption days above the group ARfD (acute reference dose) (< 1 %) for all products except maize-based pastries, whatever the ML (current, tML) considered. For maize-based pastries, percentage of consumption days above the group ARfD estimated up to 1.2 % with current ML was increased up to 8.1 % considering the tML, with a maximum acute exposure level estimated at 20.8 µg/kg b.w.

Exceedance of the group PMTDI (provisional maximum tolerable daily intake**)** for DON is higher in the children than in the adults age groups, ranging between 2.7 and 52 % (minimum LB to maximum UB) considering the current MLs. Considering the tMLs, this is slightly increased and estimated to range between 4.2 and 54 %.

The results suggest a low impact of tMLs for chronic exposure levels of DON in all age groups owing to the fact that DON exposure is mainly driven by non maize-based foods. However, both application of current and increased MLs lead to exposures in the region of the group PMTDI of 1 µg/kg b.w. per day especially in the 'toddlers' age group.

Percentage of consumption days above the group ARfD of 8 µg/kg b.w. estimated up to 1.2 and 8.1 % with the current MLs and tMLs, respectively, indicates a potential concern resulting from the consumption of maize-based pastries containing high DON level for the children age groups.

Although the mandate concerns FB_1 and FB_2, based on the occurrence data available the assessment was based on total fumonisin occurrence. Based on the fact that toxicological assessments and also the group PMTDI are derived mainly from data with FB_1 and the structural similarities of the different fumonisin derivatives of relevance, this is considered acceptable.

The exceedance of the group PMTDI defined for FUMO is higher in the children than in the adults age groups, ranging between 0 and 47 % (minimum LB to maximum UB) when considering current ML. When considering tML, this is slightly increased and estimated to range between less than 0.1 % and 48 %.

Results show that a temporary increase in MLs has only a very minor impact on exposure levels of FUMO and consequently on any risk estimates. However, when applying the current MLs, the exposure levels of FUMO are already in the region of the group PMTDI of 2 µg/kg b.w. per day in several age groups, being highest in 'other children' age group.

Exceedance of the TDI for ZON is the higher in the children than in the adults age groups, ranging between 0 and 9.2 % (minimum LB to maximum UB) when considering the current MLs. With tMLs, this is slightly increased and estimated to range between 0 and 9.8 %.

Exposure levels for ZON both with current and tML levels are around or above the TDI of 0.25 µg/kg b.w. per day for the age groups of infants, toddlers and other children and thus might be considered as being of health concern. It is important to add here that although no acute reference value has been derived for ZON in a previous EFSA assessment, it was pointed out there that is possible that elevated circulating levels of oestrogens could lead to adverse effects also from short-term exposure during a sensitive stage of development. The impact of the increased ML for ZON need to be considered also in the light of these conclusions.

It was assumed that increased exposure of individuals suffering from celiac disease due to a temporary increase of MLs for DON, FUMO and ZON for maize and maize products were reflected in the high exposure levels (95^{th} percentile) estimated for the general population.

There is a need to better assess the DON, ZON and FUMO levels in maize grains and maize milling products from the 2013 harvest coming from other countries than France and used for food processing at the European level.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 5
Background as provided by the European Commission 7
Terms of reference as provided by the European Commission 9
Assessment 10
1. Introduction and previous assessments 10
1.1. Deoxynivalenol 10
1.2. Fumonisins 11
1.3. Zearalenone 13
2. Legislation on fumonisins, deoxynivalenol and zearalenone in food 14
3. Occurrence data 16
3.1. Overview of the data available for the analysis 16
3.1.1. Data provided with the request 16
3.1.2. Data used in previous risk assessments 18
3.2. Description of occurrence levels 18
3.2.1. Levels of DON, ZON and FUMO in maize grains and maize milling products 18
3.2.2. Levels of DON, ZON and FUMO in other foods 20
4. Consumption data 20
4.1. EFSA's Comprehensive European Food Consumption Database 20
4.2. Consumption patterns of maize-based products in European countries 23
4.2.1. Maize grain for consumption 23
4.2.2. Maize milling fractions ≤ 500 µm 24
4.2.3. Maize milling fractions > 500 µm 24
5. Impact of temporary maximum levels (tMLs) 24
5.1. Impact on the mean DON, ZON and FUMO levels in maize-based products 24
5.1.1. Methodology 24
5.1.2. Results of the impact on occurrence levels 26
5.2. Impact on chronic exposure levels to DON, FUMO and ZON 29
5.2.1. Methodology 29
5.2.2. Results of the impact on chronic exposure levels 30
5.3. Impact on acute exposure levels to DON 36
5.3.1. Methodology 36
5.3.2. Results of the impact on acute DON exposure levels 36
6. Risk characterization 40
6.1. Deoxynivalenol 40
6.1.1. Chronic risk characterisation 40
6.1.2. Acute risk characterisation 40
6.2. Fumonisins 41
6.3. Zearalenone 42
6.4. Risk consideration of individuals suffering from celiac disease 42
7. Uncertainty analysis 43
7.1. Assessment objectives 43
7.2. Model input (parameters) 43
7.3. Exposure model/exposure scenarios 44
7.4. Other uncertainties 45
7.5. Summary of uncertainties 45
Conclusions and recommendations 46
References 49
Appendix A: Mean levels of DON, ZON and FUMO reported in previous assessments in other foods than maize-based ones 51

Appendix B: Maize consumption habits in the European population 55
Appendix C: Contribution of maize-based products to the total exposure to DON, FUMO and ZON . 58
Abbreviations 61

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Commission Regulation (EC) No 1881/2006 of 19 December 2006[4] lays down maximum levels for certain contaminants in foodstuffs, including maximum levels for deoxynivalenol, zearalenone and fumonisins.

On 29 April 2014, the French authorities informed the European Commission that exceptional climatic conditions resulted in very high levels of mycotoxins (deoxynivalenol, zearalenone and fumonisins) on maize harvested in 2013 in Europe. Furthermore the growing conditions in the year 2013 resulted into a higher carry-over of these mycotoxins into the maize flours (while in other years the contamination is more in the outer parts of the maize grain). This results in a serious risk of disruption in the maize milling supply chain for the rest of the season (until end of 2014).

In order to avoid such disruption in the maize milling chain with serious economic consequences, a request for a temporary derogation to the mycotoxin regulatory limits has been introduced by the French authorities to the Commission. The derogation requested is temporary until the availability of the next maize harvest at the end of 2014.

The requested "derogation values" compared to the current maximum levels of deoxynivalenol, zearalenone and fumonisins for maize and relevant maize products are provided in the table hereafter. Important to note is that no derogation is requested for processed maize-based foods for infants and young children and baby foods.

	Foodstuffs	**Maximum level (µg/kg) Regulation (EC) 1881/2006**	**Requested temporary "derogation value" (µg/kg) for products produced before 31/12/2014**
	Deoxynivalenol		
1	Unprocessed maize, with the exception of unprocessed maize intended to be processed by wet milling	1750	**2250**
2	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 1010	750	**1000**
3	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 1010	1250	**1500**
4	Maize and maize milling products intended for direct human consumption	750	**1000**
5	Maize-based breakfast cereals and maize-based snacks, maize based foods for direct human consumption	500	**750**

[4] OJ L 364, 20.12.2006, p. 5-17.

	Foodstuffs	Maximum level (µg/kg) Regulation (EC) 1881/2006	Requested temporary "derogation value" (µg/kg) for products produced before 31/12/2014
	Zearalenone		
1	Unprocessed maize, with the exception of unprocessed maize intended to be processed by wet milling	350	**500**
2	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 1010	200	**300**
3	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 1010	300	**400**
4	Maize intended for direct human consumption and maize-based snacks and maize based breakfast cereals	100	**200**
5	Maize milling products and maize based foods for direct human consumption	100	**200**
	Fumonisins B_1 + B_2		
1	Unprocessed maize, with the exception of unprocessed maize intended to be processed by wet milling	4000	**4500**
2	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 1010	1400	**1900**
3	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 1010	2000	**3500**
4	Maize intended for direct human consumption, maize based foods for direct human consumption with the exception of maize-based breakfast cereals and maize-based snacks	1000	**1500**
5	Maize-based breakfast cereals and maize-based snacks	800	**1300**
6	Maize milling products intended for direct human consumption	1000	**1500**

The request for derogation and the annexes containing information on the extreme weather conditions, the difficult harvest conditions and the findings of deoxynivalenol, zearalenone and fumonisins in maize of the harvest 2013 are transmitted separately to EFSA.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Art. 31 (1) of Regulation (EC) No 178/2002 the Commission asks EFSA for a scientific statement assessing the possible increase of risk to human health related to a possible temporary derogation of the maximum level of deoxynivalenol, zearalenone and fumonisins for maize and maize based products taking into account:

- the occurrence data provided;
- the requested derogation values;
- the specific consumption patterns of maize and maize based foods in the different Member States;
- the limited time period (until end of 2014) for which the temporary derogation is requested.

ASSESSMENT

1. Introduction and previous assessments

1.1. Deoxynivalenol

Deoxynivalenol (DON) is mainly produced by *Fusarium graminearum* and *Fusarium culmorum,* plant pathogens growing on cereals (wheat, maize, rye, barley, oats, and rice) in temperate climates. It frequently occurs together with its acetyl-derivatives (3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON) at levels of typically less than 10 % of those for DON (FAO/WHO, 2011; Berthiller et al., 2013; Marin et al., 2013; Varga et al., 2013). DON belongs to the type B trichothecenes, characterised by a carbonyl group at the C8 position (Döll and Dänicke, 2011). The chemical structure of DON (12,13-epoxy-3α,7α,15-trihydroxytrichothec-9-en-8-one, $C_{15}H_{20}O_6$, molecular weight: 296.32 g/mol, CAS: 51481-10-8) is shown in Figure 1. DON is usually detected with immunoassays, liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS). Among the immunoassays, enzyme-linked immunosorbent assays (ELISA) are widely used but have the disadvantage of cross-reactivity and false-positive results, thus, positive results are usually confirmed by other analytical methods (Ran et al., 2013).

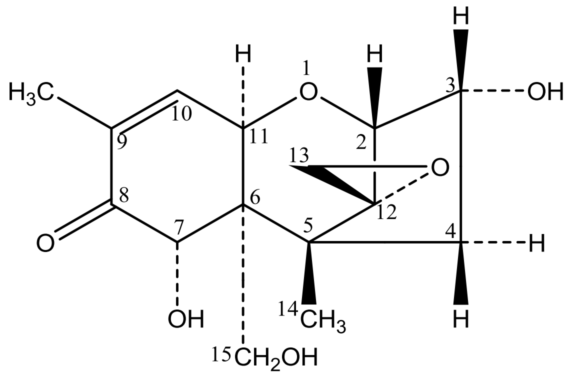

Figure 1: Chemical structure of deoxynivalenol

Earlier risk assessments for DON are available from the Scientific Committee on Food (SCF, 1999) in which a temporary tolerable daily intake (tTDI) of 1 µg/kg body weight (b.w.) per day has been set based on a no-observed-adverse-effect level (NOAEL) for reduced growth in a chronic mouse study (UF 100) which was confirmed as a tolerable daily intake (TDI) in a later opinion SCF (2002). JECFA (FAO/WHO, 2002) further confirmed this health based guidance value (HBGV) by setting a provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg b.w. per day.

The most recent comprehensive risk assessment on deoxynivalenol in food has been carried out by JECFA (FAO/WHO, 2011). The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) has issued a statement (EFSA CONTAM Panel, 2013) in regard to the risks related to a possible increased of the maximum levels for DON in certain cereal products which was based on the toxicological assessment carried out by JECFA earlier on. In July 2013, EFSA received a request from the European Commission to deliver a scientific opinion on the risks for animal and public health related to the presence of DON, metabolites of DON and masked DON in food and feed. As the deadline for finalisation of this risk assessment is later than that for the present request, EFSA used the HBGVs as established by JECFA (FAO/WHO, 2011) also for the present assessment. It needs to be pointed out here that since the present assessment is triggered by an urgent request from the European Commission for a temporary derogation from the legally binding MLs for some certain foodstuffs and does not constitute a comprehensive risk assessment it cannot anticipate or overrule any outcome of the risk assessment of DON in food and feed to be issued at a later point in time.

In their evaluation JECFA (FAO/WHO, 2011) reported that DON and its acetyl derivatives are rapidly and extensively absorbed from the gastrointestinal tract and the main part is also rapidly excreted mainly via the urine. Adverse effects of DON occurring already after single dose application are decreased feed consumption and emesis. DON does not exert mutagenic potential in bacteria while there is ambiguous evidence for its clastogenicity. DON is considered as being devoid of carcinogenic potential. A NOAEL for developmental effects of 2.5 mg/kg b.w. per day based on an increase in misaligned and fused sternaebrae at 5 mg/kg b.w. per day in pups was derived from a rat developmental study (Collins et al., 2006). In a reproductive study with male rats a NOAEL of 1 mg/kg b.w. per day was derived based on reduced epididymal and seminal vesicle and increased sperm motility (Sprando et al., 2005). Low doses of DON have immunological effects (i.e. they increased immunoglobuline A levels in blood of mice and pigs). And the mechanistic evidence obtained from these species indicate that immunological effects and the reduced weight gain from which the PMTDI was derived were mainly due to suppression of cytokine signalling and interference with pituitary growth hormone (GH) axis. Changes in these parameters occurred early in studies and were rapidly reversible and it was concluded that at dietary exposure levels only continuous exposure would lead to the observed effects on the immune system and growth.

Taking into account the overall toxicological evidence a PMTDI of 1 µg/kg b.w. per day was derived on basis of a no-observed-effect level (NOEL) of 100 µg/kg b.w. per day for reduced growth observed in a 2- year feeding study in mice applying an uncertainty factor (UF) of 100 for inter- and intra-species differences. Since 3-Ac-DON is transformed to DON and thus contributing also to its toxicity, the Committee concluded further to convert the PMTDI to a group PMTDI for DON, and its acetylated derivatives 3-Ac-DON and 15-Ac-DON.

A group acute reference dose (ARfD) for the sum of DON, 3-Ac-DON and 15-Ac-DON of 8 µg/kg b.w. was established in addition as an acute reference point based the lower 95 % confidence limit for a benchmark response of 10 % extra risk ($BMDL_{10}$) of 0.21 mg/kg b.w. per day was derived for emesis observed in pigs and applying an uncertainty factor of 25.

1.2. Fumonisins

Fumonisins are a group of structurally related mycotoxins produced mainly by *Fusarium verticillioides and F. proliferatum*, plant pathogens growing on cereals in particular on maize. The B series of fumonisins, including FB_1, FB_2, FB_3 and FB_4, is the most frequently occurring form in food, the FB_1 derivative being the form for which most biological and occurrence data is available. The toxicological properties of the FB_2 and FB_3 derivatives are very similar (FAO/WHO, 2002, 2012). The chemical structure of Fumonisin B_1 (the diester of propane-1,2,3-tricarboxylic acid and 2*S*-amino-12*S*,16*R*-dimethyl-3*S*,5*R*,10*R*,14*S*,15*R*-pentahydroxyeicosane in which the C-14 and C-15 hydroxy groups are esterified with the terminal carboxy group of propane-1,2,3-tricarboxylic acid, CAS: 116355-83-0) is shown in Figure 2. Fumonisins (FB_1, FB_2, FB_3) are usually determined in food via liquid chromatography with fluorescence detection. Other methods are liquid chromatography coupled with mass spectrometry. Immunoassays are also employed but results have to be confirmed with quantitative methods (FAO/WHO, 2012).

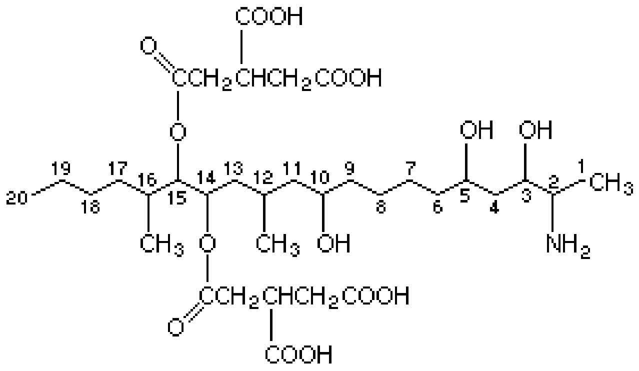

Figure 2: Chemical structure of fumonisin B_1

Earlier assessments for FUMO are available from the SCF (2000a) where a TDI of 2 µg/kg b.w. per day for FB_1 based on kidney effects was derived. In an updated opinion (SCF, 2003) they concluded that the TDI for FB_1 could be extended to a group TDI for the total fumonisin B_1, B_2 and B_3 alone or combined. Likewise the JECFA (FAO/WHO, 2002) derived a group PMTDI for fumonisins B_1, B_2 and B_3 alone or in combination.

The most recent comprehensive risk assessment related to the presence of fumonisins in food has been presented by the JECFA (FAO/WHO, 2012) and the health based guidance value (HBGV) established therein are consequently also used as a basis for the present assessment. As for DON it has to be noted here that the present assessment is based on an urgent request from the Commission and thus does not constitute a comprehensive risk assessment and likewise cannot anticipate any future in depth analyses on fumonisins that might be carried out by EFSA.

As the previous assessments the JECFA evaluation (FAO/WHO, 2012), owing to the scarcity of information on the other fumonisin derivatives, is essentially based on data generated with FB_1. Fumonisins are poorly absorbed from the digestive tract (main residues are found in liver and kidney), rapidly distributed and eliminated mainly unchanged. Fumonisins do not exert appreciable acute toxicity. Kidney and liver are the organs most sensitive towards fumonisin mediated toxicity in rats and mice. Early signs of fumonisin nephrotoxicity are increased free sphingoid bases in plasma and urine, apoptosis and cell regeneration in renal tubule cells, while early hepatotoxicity manifests as apoptotic and oncotic necrosis, cell proliferation, hyperplasia and bile duct regeneration. Mechanistic studies suggest disruption of lipid metabolism as being the mode of action for FB_1 mediated toxicity. FB_1 is not mutagenic but is capable of inducing reactive oxygen species that could lead to DNA damage. FB_1 caused effects in some developmental and reproductive studies (induction of neural tube defects in mice and decreased reproductive performance in rabbits and pigs respectively). However, JECFA concluded not to consider these studies as their significance and validity were considered as being doubtful.

NOAELs for FB_1 of 0.67 mg/kg b.w. per day and 0.8 mg/kg b.w. day for induction of kidney tumours in rats and liver tumours in mice have been reported. It was noted by JECFA that taking into account mechanistic information, together with the overall toxicological data, it could be hypothesized that the perturbation of lipid metabolism induced by FB_1 causes cell death possibly via oxidative damage, regenerative cell proliferation, which could lead to the increase in kidney and liver tumours.

Taking into account the overall evidence available, a group PMTDI of 2 µg/kg b.w. per day based on a $BMDL_{10}$ of 165 µg/kg b.w. per day for increased incidence of megalocytic hepatocytes observed in a chronic mouse study mice was derived adding an UF of 100 for interspecies and intra-species differences.

1.3. Zearalenone

Zearalenone (ZON) is a 13eoxynival produced by different *Fusarium* species, particularly *F. graminearum* and also *F. culmorum*, *F.equiseti* and *F. verticillioides*, plant pathogens found in cereals on the field such as wheat, barley, sorghum and rye, and in particular in maize in moist and cool weather but it may also occur as a post-harvest contaminant. The chemical structure of zearalenone (3,4,5,6,9,10-hexahydro-14,16-dihydroxy-3-methyl-1H-2-benzoxacyclotetradecin-1,7(8H)-dione; $C_{18}H_{22}O5$; molecular weight: 318.36; CAS No: 17924-92-4) is depicted in Figure 3. ZON is detected with a wide variety of analytical methods coupling of HPLC and MS being the most commonly used technique (EFSA CONTAM Panel, 2011).

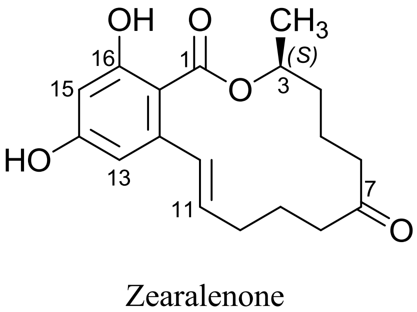

Figure 3: Chemical structure of zearalenone

Earlier assessments are available from JECFA (FAO/WHO, 2000b) who established a PMTDI of 0.5 µg/kg b.w. per day for ZON and its metabolite α-zearalanol based on oestrogenic effects seen in pigs. Likewise the SCF (SCF, 2000b) used the NOEL from this study but applied a higher safety factor to derive a temporary TDI (tTDI) of 0.2 µg/kg b.w. per day.

The most recent comprehensive risk assessment available for zearalenone which is serving as a basis for the present evaluation is a scientific opinion on the risks for public health related to the presence of zearalenone in food issued by EFSA (EFSA CONTAM Panel, 2011). Zearalenone is readily absorbed through the gastrointestinal tract and extensively metabolised and distributed to various tissues (Shin et al., 2009). It is of low acute toxicity (oral LD_{50} values are below 2000 mg/kg b.w.). Zearalenone is not mutagenic in bacteria but exerts *in vivo* clastogenicity in mice. Zearalenone is not tumorigenic in rats but caused a statistically significant increase in benign liver tumours in female mice at doses as high as 18 mg/kg b.w. per day (NTP, 1982). Zearalenone exerts haematological- and liver changes in subchronic and chronic animal tests. Zearalenone also adversely affects testosterone synthesis, sexual behaviour, sex organ weights, testicular histology and spermatogenesis in male animals. In female animals the reproductive tract, fertility an embryo survival are adversely affected. The female pig is particularly sensitive towards the oestrogenic effects of zearalenone (respective effects occur at doses around three orders of magnitude lower than those causing clastogenicity or adenomas described above).

Therefore the CONTAM Panel established a TDI of 0.25 µg/kg b.w. per day which was derived from a NOEL of 10 µg/kg b.w. per day for oestrogenic effects from a repeated dose study with gilts (Edwards et al., 1987). An uncertainty factor of 40 was applied to account for inter- and intra-species differences.

2. Legislation on fumonisins, deoxynivalenol and zearalenone in food[5]

Article 2 of Council Regulation (EEC) No 315/98[6] stipulates that food containing contaminants in amounts not acceptable from a public health viewpoint shall not be placed on the market. In addition contaminant levels shall be kept as low as possible. In order to protect public health maximum levels (ML) for specific contaminants in different foodstuffs have been laid down in Commission Regulation (EC) No 1881/2006[7]. The MLs established for deoxynivalenol, fumonisins and zearalenone and as listed in the Regulation are presented in Tables 1- 3.

Table 1: Maximum levels in µg/kg for deoxynivalenol in various foodstuffs as laid down in Commission Regulation (EC) No 1881/2006

Category	Foodstuff	ML
1	Unprocessed cereals[(a,b)] other than durum wheat, oats and maize	1250
2	Unprocessed durum wheat and oats[(a,b)]	1750
3	Unprocessed maize[(a)], with the exception of unprocessed maize intended to be processed by wet milling[(c)]	1750
4	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed in 7, 8 and 9	750
5	Pasta (dry)[(d)]	750
6	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals	500
7	Processed cereal-based foods and baby foods for infants and young children[(e,f)]	200
8	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 1010	750
9	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 1010	1250

CN: combined nomenclature; ML: maximum level.

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

(b): The maximum level applies to cereals harvested and taken over, as from the 2005/06 marketing year, in accordance with Commission Regulation (EC) No 824/2000 of 19 April 2000 establishing procedures for the taking-over of cereals by intervention agencies and laying down methods of analysis for determining the quality of cereals (OJ L 100, 20.4.2000, p. 31), as last amended by Regulation (EC) No 1068/2005 (OJ L 174, 7.7.2005, p. 65).

(c): The exemption applies only for maize for which it is evident e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production).

(d): Pasta (dry) means pasta with a water content of approximately 12 %.

(e): Foodstuffs listed in this category as defined in Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

(f): The maximum level refers to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.

[5] In this scientific statement, where reference is made to European legislation, the reference should be understood as relating to the most current amendment, unless otherwise stated.

[6] Council Regulation (EEC) No 315/93 of February 1993 laying down Community procedures for contaminants in food. OJ L 37, 13.2.1993, p. 1-5.

[7] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in food. OJ L 364, 20.12.2006, p. 5-24.

Table 2: Maximum levels in µg/kg for fumonisins in various foodstuffs as laid down in Commission Regulation (EC) No 1881/2006

Category	Foodstuff	ML
1	Unprocessed maize[(a)], with the exception of unprocessed maize intended to be processed by wet milling[(b)]	4000
2	Maize intended for direct human consumption, maize-based foods for direct human consumption, with the exception of foodstuffs listed in 3 and 4	1000
3	Maize-based breakfast cereals and maize-based snacks	800
4	Processed maize-based foods and baby foods for infants and young children [(c,d)]	200
5	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	1400
6	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	2000

CN: combined nomenclature; ML: maximum level.

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

(b): The exemption applies only for maize for which it is evident, e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production).'

(c): Foodstuffs listed in this category as defined in Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33).

(d): The maximum level refers to the dry matter. The dry matter is determined in accordance with Regulation (EC) No 401/2006.

Table 3: Maximum levels in µg/kg for zearalenone in various foodstuffs as laid down in Commission Regulation (EC) No 1881/2006

Category	Foodstuff	ML
1	Unprocessed cereals other than maize	100
2	Unprocessed maize with the exception of unprocessed maize intended to be processed by wet milling[(a)]	350
3	Cereals intended for direct human consumption, cereal flour, bran and germ as end product marketed for direct human consumption, with the exception of foodstuffs listed below in 6, 7, 8, 9 and 10	75
4	Refined maize oil	400
5	Bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals, excluding maize snacks and maize based breakfast cereals	50
6	Maize intended for direct human consumption, maize-based snacks and maize-based breakfast cereals	100
7	Processed cereal-based foods (excluding processed maize-based foods) and baby foods for infants and young children[(b,c)]	20
8	Processed maize-based foods for infants and young children[(b,c)]	20
9	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	200
10	Milling fractions of maize with particles 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	300

ML: maximum level; CN: combined nomenclature.

(a): The exemption applies only for maize for which it is evident e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production).

(b): The maximum levels refer to dry matter.

(c): Foodstuffs listed in this category as defined in Commission Directive 96/5/EC of 16 February 1996 on processed cereal based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17-28) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33-36.)

3. Occurrence data

3.1. Overview of the data available for the analysis

3.1.1. Data provided with the request

Individual occurrence data considered in this statement were received from three different sources: the FranceAgriMer collector survey, the IRTAC Cereal Sanitary Monitoring Plan and Euromaisiers.

- ✓ Data from FranceAgriMer collector survey

This survey provides a representative overview of DON, ZON and FUMO levels in the 2013 French maize grain harvest. Maize grains samples were taken at the collecting site. For each collecting site surveyed, three samples were taken after drying, one at the beginning of the collection, one at the middle and one at the end. The three samples were then pooled into one composite sample and crushed into particle size below 500 µm. A total of 221 composite samples were constituted. They were analysed for ZON, DON and FUMO using enzyme immunoassay kits (ELISA) with a limit of quantification (LOQ) of 25 µg/kg for ZON and 222 µg/kg for DON and FUMO, respectively. When levels were respectively above 225, 1400 and 2800 µg/kg, results were confirmed with an analytical method based on liquid chromatography with UV detection for DON and fluorescence detection for ZON and FUMO. The dataset contained 663 analytical results (221 for DON, 221 for FUMO, 221 for ZON).

✓ Data from IRTAC Cereal Sanitary Monitoring Plan

This monitoring plan integrates the results of self-checks realised by different operators of the French cereal sector (maize collectors and maize milling factories), which may not be representative of French maize production and collection. DON, ZON and FUMO were analysed by ELISA and high performance liquid chromatography (HPLC). The limit of detection (LOD) for the ELISA was at 25 µg/kg for ZON, at 100 µg/kg for FUMO and ranging from 100 to 250 µg/kg for DON. The LOQ for HPLC was at 20 µg/kg for FUMO, at 50 µg/kg for DON and ranging from 10 to 50 µg/kg for ZON. When, for a given sample, results were available for both ELISA and HPLC, only the result generated by HPLC was further considered. When several results were available for a same 17eoxynival in a given sample, the average was estimated and considered as the indicator of the corresponding 17eoxynival level in that sample. The final adjusted dataset contained 956 results (451 for DON, 175 for FUMO, 330 for ZON) covering the first part of the 2013/2014 campaign.

✓ Data from Euromaisiers

Euromaisiers provided a compilation of DON, ZON and FUMO levels found in maize received by milling factories, i.e. after a pre-selection of the grains by the suppliers, and in maize milling products. The data were provided by factories located in several European countries (Germany, Belgium, Spain, France, Hungary, Italy, Poland and the UK). The maize grains analysed were not only coming from France, but also from other European countries (detailed list not communicated) and from outside the Europe Union (EU) (Argentina, Serbia, Russia, Ukraine, Turkey). The maize milling products were prepared and analysed after the exclusion of non compliant grains. The analytical techniques and limits of detection/quantification were not systematically reported. From the reported data:

- DON was indicated to be analysed with ELISA, strip test and HPLC, with LOQ ranging from 10 to 500 µg/kg;
- ZON was indicated to be analysed with ELISA and HPLC, with LOQ ranging from less than 2 to 50 µg/kg;
- FUMO was indicated to be analysed with ELISA and HPLC, with LOQ ranging from 15 to 500 µg/kg.

The dataset contained 1,018 analytical results (387 for DON, 453 for FUMO, 178 for ZON) corresponding to samples taken between November 2013 to March 2014, out of which 16 % were indicated to correspond to maize grains coming from outside EU.

✓ Considerations on data quality and comparability

Due to the short deadline of the Commission request, EFSA used the results as received, without applying any quality criteria. It is underlined that the results originating from different analytical techniques (ELISA and HPLC) may not be strictly comparable. Indeed, whereas HPLC technique is generally capable of differentiating between the parent compound DON and its derivatives and conjugates, ELISA based methods cover also the derivatives and conjugates and even other mycotoxins due to the cross-reactivity of the antibodies (EFSA CONTAM Panel, 2013). Regarding FUMO, results from ELISA were indicated to correspond to the sum of fumonisins B_1, B_2 and B_3 whereas the results from HPLC corresponded to the sum of fumonisins B_1 and B_2 only. As done in the JECFA evaluation (FAO/WHO, 2012), the results corresponding to the sum of fumonisins B_1 and B_2 were used together with the ones corresponding to the sum of fumonisins B_1, B_2 and B_3, without any adjustment.

3.1.2. Data used in previous risk assessments

For this statement, EFSA also relied on occurrence data collated in the framework of the EFSA continuous data call[8] that were compiled in the framework of previous assessments.

The DON dataset was the one used in the statement of the CONTAM Panel on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products (EFSA CONTAM Panel, 2013). The dataset contained 10,757 analytical results on the DON parent compound, that were generated with analytical methods based on gas or liquid chromatography, obtained on food samples collected between 2007 and 2012 and reported by 21 European countries. Regarding 'Unprocessed grains', data corresponded to those that were compiled in the EFSA report on deoxynivalenol in food and feed: occurrence and exposure (EFSA, 2013). The dataset contained 975 analytical results, generated with analytical methods based on gas or liquid chromatography and ELISA, collected between 2007 and 2012 and reported by 12 European countries.

The ZON dataset was the one used in the scientific opinion of the CONTAM Panel on the risks for public health related to the presence of zearalenone in food (EFSA CONTAM Panel, 2011). The dataset contained 13,075 analytical results obtained on food samples and 9,877 results on 'Unprocessed grains' samples, generated with analytical methods based on gas or liquid chromatography and ELISA, collected between 2005 and 2010 and reported by 19 European countries.

The FUMO dataset corresponded to the European data that were considered by the JECFA in its risk assessment (FAO/WHO, 2012). The dataset contained 3,654 analytical results obtained on food samples and 864 results on 'Unprocessed grains' samples, generated with analytical methods based on gas or liquid chromatography and ELISA, collected between 2000 and 2010 and reported by 11 European countries. Around 44 % of the analytical results corresponded to the sum of fumonisins B_1, B_2 and B_3 whereas the other results corresponded to the sum of fumonisins B_1 and B_2 only. All these results were used together without any adjustment.

3.2. Description of occurrence levels

3.2.1. Levels of DON, ZON and FUMO in maize grains and maize milling products

Table 4 presents DON, FUMO and ZON levels estimated from different sources: the data used in previous assessments, the FranceAgriMer survey, the IRTAC monitoring plan and the Euromaisiers data. Three estimates were produced depending on the assessment made on the results below the LOD/LOQ: (i) the lower bound estimate (LB), replacing all results reported as below the LOD/LOQ by 0, (ii) the middle bound estimate (MB), replacing all results reported as below the LOD/LOQ by half their respective LOD/LOQ and (iii) the upper bound estimate (UB), replacing all results reported as below the LOD/LOQ to their respective LOD/LOQ. Mean and 95th percentile of the three estimates (LB, MB and UB) were then computed.

For comparison purposes with the other sources of data, results of the FranceAgriMer survey which were above the ML were not considered to derive the descriptive statistics. In order to get representative estimates of DON, FUMO and ZON levels found in the 2013 French harvest, descriptive statistics from the FranceAgriMer survey were weighted by means of information, available for each sample, related to the production of maize grains at national level.

Data from previous assessments were described according to FoodEx1 classification system for food, which does not include information on the particle size of maize milling fractions. By default, maize

[8] http://www.efsa.europa.eu/en/data/call/datex101217.htm

flour, maize meal and maize starch were considered as ‘Maize milling fractions with particle size ≤ 500 µm’ whereas maize semolina was considered as ‘Maize milling fractions with particle size > 500 µm’.

The mean levels of DON in unprocessed maize grains and maize milling fractions estimated from the FranceAgriMer survey, IRTAC monitoring plan and Euromaisiers data are found to be from 3 up to 6 times higher than the mean levels estimated over a five years period (2007 – 2012) in the previous assessment (EFSA CONTAM Panel, 2013). The mean level of DON estimated from Euromaisiers data appears to be 2 times higher than the mean level estimated from the FranceAgriMer survey, which may reflect differences between levels in the 2013 French maize grain harvest and levels in maize grains used for food processing at the European level.

The mean levels of ZON in unprocessed maize grains as estimated from the FranceAgriMer survey and IRTAC monitoring plan are 2 – 2.5 times higher than the mean levels estimated over a five years period (2005 – 2010) in the previous risk assessment (EFSA CONTAM Panel, 2011). However, results from Euromaisiers in unprocessed grains are in the same ranges as the ones previously reported. The mean levels of ZON in milling fractions estimated from the Euromaisiers data are from 1.3 up to 4 times higher than the mean levels.

The mean levels of FUMO in unprocessed maize grains as estimated from the Euromaisiers survey are twice higher than the mean levels estimated over a ten years period (2000 – 2010) in the previous risk assessment (FAO/WHO, 2012). However, results from the FranceAgriMer survey and IRTAC monitoring are below the mean levels. The mean levels of FUMO in maize milling fractions are from 2 to 5.6 times higher than the mean background levels.

In conclusion, it appears that levels of DON, ZON and FUMO in the maize grains and grain milling products as observed in the FranceAgriMer survey, the IRTAC monitoring plan and Euromaisiers data are 1.3 to 6 times higher compared to mean levels considered in previous assessments. Euromaisiers data indicate higher DON and FUMO levels and lower ZON levels than the FranceAgriMer survey and IRTAC monitoring plan. This may reflect differences between DON, ZON and FUMO levels in the 2013 French maize grain harvest and levels in maize grains used for food processing at the European level, which are not only coming from France but also from other European countries and from outside EU. All these observations have to be interpreted cautiously considering discrepancies regarding the compounds covered by the different analytical methods (ELISA vs. liquid and gas chromatography) present in each source of data.

Table 4: DON, FUMO and ZON levels in maize grains and maize milling products in µg/kg

Crop/food group	Source	N	Mean MB [LB – UB][(a)]	P95 MB [LB – UB] [(a,b)]
		DON		
Unprocessed maize grains	EFSA, 2013	246	318 [286; 350]	1367
Unprocessed maize grains	FranceAgriMer	166	996 [993; 1000]	1674
Unprocessed maize grains	IRTAC plan	451	1145 [1139; 1150]	2760
Unprocessed maize grains	Euromaisiers	147	1840 [1839; 1841]	15000
Maize milling fractions > 500 µm	EFSA CONTAM Panel, 2013	38	96 [79; 113]	-
Maize milling fractions > 500 µm	Euromaisiers	156	275	841
Maize milling fractions ≤ 500 µm	EFSA CONTAM Panel, 2013	133	106 [80; 131]	402
Maize milling fractions ≤ 500 µm	Euromaisiers	84	386	1117

Table 4: Continued

Crop/food group	Source	N	Mean MB [LB – UB][(a)]	P95 MB [LB – UB] [(a,b)]
FUMO				
Unprocessed maize grains	FAO/WHO, 2012	862	1035 [974; 1096]	4642
Unprocessed maize grains	FranceAgriMer	199	617 [564; 673]	2298
Unprocessed maize grains	IRTAC plan	175	325 [307; 344]	1900.7
Unprocessed maize grains	Euromaisiers	281	2771	15000
Maize milling fractions > 500 µm	FAO/WHO, 2012	535	230 [216; 243]	1064
Maize milling fractions > 500 µm	Euromaisiers	122	497	1674
Maize milling fractions ≤ 500 µm	FAO/WHO, 2012	549	471 [456; 486.2]	2288
Maize milling fractions ≤ 500 µm	Euromaisier	50	2672	-b
ZON				
Unprocessed maize grains	EFSA CONTAM Panel, 2011	2460	[76; 87]	319
Unprocessed maize grains	FranceAgriMer	157	167 [166; 167]	327
Unprocessed maize grains	IRTAC plan	330	192 [191; 193]	493
Unprocessed maize grains	Euromaisiers	65	51	297
Maize milling fractions > 500 µm	EFSA CONTAM Panel, 2011	351	[5; 7]	[22; 23]
Maize milling fractions > 500 µm	Euromaisiers	101	27	49
Maize milling fractions ≤ 500 µm	EFSA CONTAM Panel, 2011	382	[20; 22]	[73; 78]
Maize milling fractions ≤ 500 µm	Euromaisiers	12	30	-

N: number of samples; P95: 95th percentile; MB/LB/UB: middle bound/lower bound/upper bound estimates.
(a): When the MB, LB and UB estimates are equal, only one estimate is given.
(b): 95th percentile is only reported for food groups for which at least 60 samples were available.
Note: the occurrence values are rounded at the level of the microgram, however this does not reflect precision.

3.2.2. Levels of DON, ZON and FUMO in other foods

The LB and UB mean DON, ZON and FUMO levels in foods other than maize grains and maize-based products that were compiled in previous assessments are provided in Appendix A. DON, ZON and FUMO are mainly found in grains, grain-based products (grain milling products, bread, breakfast cereals, pasta, fine bakery wares) and other foods containing cereals (cereal-based dishes, cereal-based foods for infants and young children, snacks, products for special nutritional use). Depending on the grain and grain-based products, mean UB levels are comprised between 15.5 and 410 µg/kg for DON, 3.0 and 33 µg/kg for ZON, 37.4 and 315 µg/kg for FUMO. Overall, the highest average levels are observed in wheat or wheat milling products. DON, ZON and FUMO are also found in sweet corn with mean UB levels at respectively 53.2, 4.8 and 102 µg/kg. Finally, ZON is occurring in oils made from corn and wheat germ, with LB – UB mean levels comprised between 31 and 90 µg/kg, and in beer and beer-like beverages, with LB – UB mean levels comprised between 0.1 and 1.0 µg/kg.

4. Consumption data

4.1. EFSA's Comprehensive European Food Consumption Database

Food consumption data were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive database) which was built in 2010 from existing national information on food consumption at the individual level (EFSA, 2011; Huybrechts et al., 2011; Merten et al., 2011).

The Comprehensive database comprises consumption data of 66,642 individuals from 32 surveys carried out in 22 different European countries covering the following age-groups: infants (< 1 year old), toddlers (≥ 1 year to < 3 years old), children (≥ 3 years to < 10 years old), adolescents (≥ 10 years to < 18 years old), adults (≥ 18 years to < 65 years old), elderly (≥ 65 years to < 75 years old) and very elderly (≥ 75 years old). Consumption data were collected with 24 h dietary recalls covering one or two days, 48 h dietary recalls, or through dietary records covering 3 to 7 days. A total of 195,200 reporting days are available in the Comprehensive database (Table 5).

In view of performing a chronic exposure assessment, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011), only individuals with at least two days of reporting were considered (Table 5) which represented a total of 53,728 individuals from 28 surveys and 17 European countries. The average consumption level was estimated at the individual level for the different food groups taken into account in the exposure assessment (see Section 5).

In view of performing an acute exposure assessment, all consumption days, i.e. days with at least one consumption event of the food of interest, were considered. For each consumption day, the total amount of each food group taken into account in the exposure assessment (see Section 5) consumed that day was determined.

Table 5: Dietary surveys used for the chronic and acute dietary exposure assessments

Country	Dietary survey acronym	Method	Days	Number of subjects [(a)]/ days[(b)]						
				Infants	**Toddlers**	**Other**	**Adolescents**	**Adults**	**Elderly**	**Very Elderly**
Austria	ASNS	24 h recall	1					-/2123		
Belgium	Diet National 2004	24 h recall	2				584/1187	1304/2648	518/1045	712/1448
Belgium	Regional Flanders	record	3		36/108	625/1875				
Bulgaria	NUTRICHILD	24 h recall	2	860/1720	428/856	433/867				
Bulgaria	NSFIN	24 h recall	1				-/162	-/691	-/151	-/200
Cyprus	Childhealth	record	3				303/909			
The Czech	SISP04	24 h recall	2			389/778	298/596	1666/3332		
Germany	DONALD 2006	record	3		92/276	211/633				
Germany	DONALD 2007	record	3		85/255	226/678				
Germany	DONALD 2008	record	3		84/252	223/669				
Germany	National Nutrition Survey	24 h recall	2				1011/2022	10419/20838	2006/4012	490/980
Denmark	Danish Dietary Survey	record	7			490/3426	479/3398	2822/19722	309/2159	20/140
Greece	Regional Crete	record	3			839/2508				
Spain	AESAN	24 h recall	2					410/828		
Spain	AESAN-FIAB	record	3				86/226	981/2748		
Spain	NUT INK05	24 h recall	2			399/798	651/1302			
Spain	enKid	24 h recall	2		17/34	156/312	209/418			
Estonia	NDS_1997	24 h recall	1					-/1866		
Finland	DIPP	record	3		497/1486	933/2773				
Finland	FINDIET 2007	48 h recall	2					1575/3150	463/926	
Finland	STRIP	record	4			250/1000				
France	INCA2	record	7			482/3315	973/6728	2276/15727	264/1824	84/571
Hungary	National Repr Surv	record	3					1074/3222	206/618	80/240
Ireland	NSFC	record	7					958/6706		
Italy	INRAN-SCAI 2005–06	record	3	16/48	36/108	193/579	247/741	2313/6939	290/870	228/684
Latvia	EFSA_TEST	24 h recall	2			189/377	470/949	1306/2655		
The Netherlands	DNFCS 2003	24 h recall	2					750/1500		
The Netherlands	VCP kids	record	3		322/644	957/1914				
Poland	IZZ_FAO_2000	24-h recall	1		-/79	-/409	-/666	-/2527	-/329	-/124
Sweden	RIKSMATEN 1997-98	record	7					1210/8466		
Sweden	NFAn	24 h recall	4			1473/5875	1018/4047			
Slovakia	SK_MON_2008	24 h recall	1					-/2763		
Slovenia	CRP_2008	24 h recall	1					-/407		
The United Kingdom	NDNS	record	7					1724/12068		

(a): Number of subjects with at least two reporting days in each age class.
(b): Number of reporting days in each age class.

4.2. Consumption patterns of maize-based products in European countries

Consumption data for 'Maize grain for consumption', 'Maize milling fractions with particle size > 500 µm' and 'Maize milling fractions with particle size ≤ 500 µm' consumed as such or as ingredients of a processed or composite food were analysed in all dietary surveys used for the exposure assessment. Table 6 details the food items, according to the FoodEx system, considered in each of these three food groups, and the processed/composite foods containing maize as ingredient, classified as well according to the FoodEx system, for which consumption data are available in the Comprehensive database. The percentage contents of maize ingredient in the processed/composite foods are also indicated. These were extracted from the draft European food conversion model and from information provided by the requestor. Only processed/composite food containing on average more than 10 % maize ingredient were considered in this statement. Sweet maize, maize oil and maize syrup consumed as such or as ingredient of composite foods as well as the foods for infants and young children and alcoholic beverages made from maize grain were considered out of the scope of the derogation request. In this statement, they were handled in a similar manner as the foods not containing maize.

Table 6: Ingredients and processed/composite foods containing maize for which consumption data are available in the Comprehensive Database and taken into consideration in this statement

Food group	Food items	Processed/composite foods (% content of maize)
Maize grain for consumption	Maize grain	Maize popped (100 %)
Maize milling fractions ≤ 500 µm	Flour , Starch, Meal	Maize-based breakfast cereals: • Mixed breakfast cereals (80 %) • Maize meal porridge (10 %) Maize-based snacks: • Corn curls and cheese puffs (80 %) Other maize-based products: • Maize bread (37 %) Flan, sponge cakes, baklava (11 %) • Gravy (40 %) and baking ingredients (50 %)
Maize milling fractions > 500 µm	Semolina	Maize-based breakfast cereals: • Corn flakes (100 %) • Muesli (11 %) • Cereal bars (15 %) Maize-based snacks: • Corn chips and tortillas (80 %)

The ranges of mean and 95th percentile of average consumption levels determined for the total population (all subjects of the survey) and for the 'consumption-days only' (reporting days with at least one consumption event of the food of interest) estimated for the 3 food groups are detailed in Appendix B.

4.2.1. Maize grain for consumption

This category includes 'Maize grain for direct consumption' as well as 'Maize popped'. According to the Comprehensive database, 'Maize grain for consumption' is consumed in less than 5.8 % of the reporting days, whatever the age group and survey considered (Appendix B, Table B1). In all age groups except 'other children' and 'adolescents', there are surveys without any reported consumption event of 'Maize grain for consumption'. The highest daily portion sizes (consumption estimated over the consumption days) are observed in the groups of 'adolescents' and 'adults', with a median average and 95th percentile respectively comprised between 51 and 57 g and between 88 and 100 g. The smallest daily portion sizes are observed in the groups of 'infants' and 'toddlers', with average daily portion sizes estimated between 3.0 and 32 g. Due to the small number of consumption days, the average and 95th percentile consumption levels estimated at the population level (considering all subjects) are low, respectively comprised between 0 (no consumer) and 7.5 g/day and between 0 and 15 g/day.

4.2.2. Maize milling fractions ≤ 500 µm

This category includes maize flour, maize starch and maize meal consumed as such or as ingredients of breakfast cereals, extruded snacks, bread, pastries, gravy and other baking ingredients. According to the Comprehensive database, the percentage of 'Maize milling fractions ≤ 500 µm' consumption days varies from 0 (no consumption) to 28 % across the surveys and age groups (Appendix B, Table B2). The absence of consumption was observed in one infant survey and one adult survey only. The highest daily portion sizes are observed in the groups of 'adolescents', 'adults', 'elderly' and 'very elderly', with a median average and 95th percentile respectively comprised between 10 and 13 g and between 19 and 32 g. Slightly smaller daily portion sizes are observed in the groups of 'infants', 'toddlers' and 'other children', with a median average and 95th percentile respectively comprised between 4.5 and 8.1 g and between 12 and 28 g. The average and 95th percentile consumption levels estimated at the population level are comprised between 0 and 7.5 g/day and between 0 and 40 g/day, respectively. The highest consumption levels are observed in the 'adolescents' age group.

4.2.3. Maize milling fractions > 500 µm

This category includes maize semolina consumed as such or as ingredients of corn flakes and snacks. According to the Comprehensive database, the percentage of 'Maize milling fractions > 500 µm' consumption days varies from 0 to 36.4 % across the surveys and age groups (Appendix B, Table B3). The absence of consumption was observed in one infant, one toddler and one very elderly survey only. The highest daily portion sizes are observed in the groups of 'other children', 'adolescents' and 'adults', with a median average and 95th percentile respectively comprised between 24 and 32 g and between 60 and 90 g. Smaller daily portion sizes are observed in the groups of 'infants', 'toddlers', 'elderly' and 'very elderly', with a median average and 95th percentile respectively comprised between 12 and 18 g and between 16 and 44 g. The average and 95th percentile consumption levels estimated at the population level are respectively comprised between 0 and 17 g/day and between less than 0 and 50 g/day. The highest consumption levels are observed in the 'other children' and 'adolescents' age groups.

5. Impact of temporary maximum levels (tMLs)

5.1. Impact on the mean DON, ZON and FUMO levels in maize-based products

5.1.1. Methodology

The impact of tMLs on the mean DON, ZON and FUMO levels in maize grains and maize-based products was assessed considering the results from the FranceAgriMer survey. Despite the fact that this survey was only representative of the French maize grains harvest and lacked representativeness for the European level, it was the only source of information suitable for such impact assessment. Indeed, this survey provided an indication of the DON, ZON and FUMO levels in maize grains as harvested, i.e. before any selection and rejection of non-compliant grains by maize grains suppliers or by maize milling factories. The IRTAC monitoring plan lacked of representativeness and included data of heterogeneous origin (coming from different levels of the production chain). For these reasons, this survey was considered not suitable for the impact assessment. The data from Euromaisiers were considered as the most representative of the European level. However, the results provided for the maize grains corresponded to levels found at the entry of the factory, i.e., after a selection and rejection of non-compliant grains by the maize grains suppliers. In addition, results provided for grain milling products corresponded to products made after the rejection of maize grains found to be non-compliant to the ML by the maize milling factories. For these reasons, the dataset provided by Euromaisiers was considered not suitable to assess the impact of tMLs on DON, ZON and FUMO levels in maize grains and maize-based products.

The impact of tMLs was assessed independently for DON, ZON and FUMO. The assessment was performed for each of the three processing levels covered by ML (unprocessed maize grain, maize milling fractions and maize-based products for consumption) as follows:

- ✓ Unprocessed maize grains

In a first scenario [A], all concentration values above the current ML for unprocessed maize grains were excluded from the dataset and LB/MB/UB mean levels were estimated considering the volume of grains represented by each sample. In a second scenario [B], all concentration values above the tML for unprocessed maize grains were excluded from the dataset and LB/MB/UB mean levels estimated considering the volume of grains represented by each sample. The volume of unprocessed maize grains non compliant to the current ML and tML was also estimated and expressed as a percentage of the total production of maize grain.

- ✓ Maize milling fractions and maize grains for direct consumption

Concentration values remaining after the exclusion of values above the current ML and tML defined for the unprocessed maize grains were adjusted with transfer rates in order to reflect levels in maize milling fractions and in maize grains for direct consumption. The transfer rate was set at 1 for maize grains for direct consumption. For maize milling fractions, it was set at the ratio between the tML in maize milling fractions and the tML in the unprocessed maize grain (Table 7). For example, for DON, it was set at 0.67 for the 'Maize milling fractions ≤ 500 µm', which corresponds to the ratio between 1500 µg/kg – the tML for DON in 'Maize milling fractions ≤ 500 µm' – and 2250 µg/kg – the tML for DON in 'Unprocessed maize grains'. This approach was motivated by the fact that the requestor reported higher transfer rates in products made from 2013 harvest than usually observed. It was consequently considered the tMLs to better reflect the average transfer rate in products made from the 2013 harvest than the current MLs.

Table 7: Transfer rates from unprocessed maize grain to maize milling fractions considered in this statement

Mycotoxin	Maize milling fractions ≤ 500 µm	Maize milling fractions > 500 µm
DON	0.67	0.44
FUMO	0.78	0.42
ZON	0.80	0.60

Adjusted concentration values above the current MLs and tMLs defined for maize milling fractions and maize grains for direct consumption were excluded from the dataset and LB/MB/UB mean levels estimated considering the volume of products represented by each sample. The percentage of maize milling fractions and maize grains for direct consumption non compliant to the current MLs and tMLs was also estimated.

- ✓ Maize-based products for direct consumption

Concentration values remaining after the exclusion of values above the current ML and the tML defined for maize milling fractions were finally adjusted in order to reflect levels in processed/composite maize-based products, considering the percentage content of maize milling fractions in the final products. The different kinds of processed/composite products and maize percentage contents described in Table 6 were considered. In this assessment, it was assumed that other ingredients of the processed/composite maize-based products did not contain DON, FUMO and ZON. For example, 'Muesli' usually contains different types of grains (wheat, oat, rice, maize, etc…).

It was considered that only the maize fraction of 'Muesli' was containing DON, FUMO and ZON, and not the other grains. In addition, it was assumed that there were no processing effects (bread-baking, extrusion cooking, etc.) on the DON, FUMO and ZON levels. Adjusted concentration values above the current MLs and tMLs defined for the different maize-based snacks and breakfast cereals and other maize-based foods taken into consideration were excluded from the dataset and LB/MB/UB mean levels estimated considering the volume of products represented by each sample. The percentage of processed/composite products non compliant to the current MLs and tMLs was also estimated.

For each of the three processing levels covered by ML, the impact of tMLs was described as the percentage difference between the mean MB level estimated after the exclusion of concentration values above the tML and the mean level estimated after the exclusion of concentration values above the current ML.

5.1.2. Results of the impact on occurrence levels

- ✓ Unprocessed maize grains and maize milling fractions

Table 8 shows the mean DON, FUMO and ZON levels in unprocessed maize grains and in maize milling fractions below and above 500 µm estimated considering the current ML and the tML.

The mean levels estimated in unprocessed maize grains and maize milling fractions for DON after the exclusion of samples non compliant to the tML are increased by 16 – 18 % compared to the mean levels estimated after the exclusion of samples non compliant to the current ML. The mean levels estimated in unprocessed maize grains and maize milling fractions for ZON after the exclusion of samples non compliant to the tML are increased by 25 – 27 % compared to the mean levels estimated after the exclusion of samples non compliant to the current ML. Results are more heterogeneous for FUMO. Whereas the percentage increase of the mean level after the exclusion of samples non compliant to the tML is estimated at 7.8 % for unprocessed maize grains, it is estimated at 12 % for the milling fractions with particle size above 500 µm and 23 % for the milling fractions with particle size below 500 µm.

Some maize milling fractions appear to be non compliant to the current ML, even if made from maize grains compliant to the current ML. Indeed, 3.3 % of maize milling fractions with particle size below 500 µm were estimated as non-compliant to the current ML for FUMO, and less than 0.8, 1.8 and 2.2 % of milling fractions with particle size above 500 µm were estimated as non-compliant to the current ML for FUMO, ZON and DON, respectively. The maize milling fractions made from grains compliant to the tML were estimated to be compliant to their corresponding tML.

Table 8: Mean DON, FUMO and ZON levels estimated in unprocessed maize grains and maize milling fractions considering current MLs and tMLs expressed in µg/kg

Food group	Scenario A (current ML)		Scenario B (tML)		% INC[(c)]
	% NC[(a)]	Mean MB [LB – UB][(b)]	% NC[(a)]	Mean MB [LB – UB][(b)]	
DON					
Unprocessed maize grains	23	996 [993; 1000]	7.9	1156 [1154; 1159]	16
Maize milling fractions ≤ 500 µm	0	668 [665; 670]	0	775 [773; 777]	16
Maize milling fractions > 500 µm	2.2	431 [430; 433]	0	509 [508; 510]	18
FUMO					
Unprocessed maize grains	9.5	619 [564; 673]	8.3	666 [612; 720]	7.6
Maize milling fractions ≤ 500 µm	3.3	422 [378; 466]	0	520 [478; 561]	23
Maize milling fractions > 500 µm	0.8	251 [228; 274]	0	280 [257; 302]	12

Table 8: Continued

Food group	Scenario A (current ML)		Scenario B (tML)		% INC[(c)]
	% NC[(a)]	Mean MB [LB – UB][(b)]	% NC[(a)]	Mean MB [LB – UB][(b)]	
ZON					
Unprocessed maize grains	27	167 [166; 167]	13	208 [207; 208]	25
Maize milling fractions ≤ 500 µm	0	133 [133; 134]	0	166	25
Maize milling fractions > 500 µm	1.8	98.0 [97.8; 98.2]	0	125 [124; 125]	27

(a): % NC: percentage of products (in a volume basis) non compliant to the ML.
(b): Mean MB [LB – UB]: mean middle bound [lower bound – upper bound]. When the LB, MB and UB estimates are equal, only one estimate is indicated.
(c): % INC: percentage difference determined as the difference between the mean MB obtained with scenario B (tML) and mean MB obtained with scenario A (current ML) divided by the mean MB obtained with scenario A.
Note: the numbers for the occurrence values are all given with 3 figures, and the percentages with 2 figures but this does not reflect precision.

- ✓ Maize grains and maize-based products for direct consumption

Table 9 shows the mean DON, FUMO and ZON levels estimated in maize grain for direct consumption and in some maize-based foods considering current ML and tML.

Depending on the kind of ingredient (grain, milling fractions ≤ 500 µm, milling fractions > 500 µm) and its percentage content, the percentage increase of DON and FUMO mean levels in the final processed/composite products is comprised between 12 and 58 %. The percentage increase is higher for ZON, comprised between 25 and 99 %.

Table 9: Mean DON, FUMO and ZON levels estimated in maize intended for direct consumption and in maize-based processed/composite foods considering current MLs and tMLs expressed in µg/kg

Food group	Scenario A (current ML)		Scenario B (tML)		% INC[(c)]
	% NC[(a)]	Mean MB [LB – UB] [(b)]	% NC[(a)]	Mean MB [LB – UB][(b)]	
DON					
Maize grain for consumption	73	419 [406; 431]	62	596 [588; 603]	42
Maize-based breakfast cereals and snacks					
- made of maize milling fractions ≤ 500 µm:					
- 80 %	59	302 [298; 307]	29	477 [475; 480]	58
- 10 %	0	66.8 [66.5; 67.0]	0	77.5 [77.3; 77.7]	16
- made of maize milling fractions >500 µm:					
- 100 %	44	297 [294; 300]	18	431 [430; 433]	45
- 80 %	11	319 [318; 320]	2.6	398 [397; 399]	25
- 15 %	0	64.7 [64.4; 64.9]	0	76.3 [76.1; 76.5]	18
- 11 %	0	47.4 [47.3; 47.6]	0	56.0 [55.8; 56.1]	18
Other maize-based products					
- made of maize milling fractions ≤ 500 µm:					
- 50 %	9.7	311 [309; 312]	0	387 [387; 388]	25
- 40 %	0	267 [266; 268]	0	310 [309; 311]	16
- 37 %	0	245 [244; 246]	0	284 [284; 285]	16
- 11 %	0	71.4 [71.2; 71.7]	0	82.9 [82.7; 83.1]	16
FUMO					
Maize grain for consumption	20	279 [211; 347]	16	346 [282; 410]	24
Maize-based breakfast cereals and snacks					
- made of maize milling fractions ≤ 500 µm:					
- 80 %	15	189 [148; 230]	10	274 [237; 311]	45
- 10 %	0	42.2 [37.8; 46.6]	0	51.9 [47.8; 56.1]	23
- made of maize milling fractions >500 µm:					
- 100 %	11	160 [134; 186]	2.1	251 [228; 274]	57
- 80 %	3.1	178 [159; 197]	1.3	208 [190; 226]	17
- 15 %	0	37.6 [34.1; 41.0]	0	42 [38.6; 45.3]	12
- 11 %	0	27.6 [25.0; 30.1]	0	30.8 [28.3; 33.3]	12
Other maize-based products					
- made of maize milling fractions ≤ 500 µm:					
- 50 %	0	211 [189; 233]	1.3	241 [220; 263]	14
- 40 %	0	169 [151; 186]	0	208 [191; 225]	23
- 37 %	0	155 [139; 171]	0	191 [175; 206]	23
- 11 %	0	45.2 [40.5; 49.9]	0	55.6 [51.1; 60.1]	23
ZON					
Maize grain for consumption	71	53.1 [51.9; 54.3]	47	106 [105; 106]	99
Maize-based breakfast cereals and snacks					
- made of maize milling fractions ≤ 500 µm:					
- 80 %	53	50.6 [50.2; 51.1]	24	95.9 [95.7; 96.2]	90
- 10 %	0	13.3 [13.3; 13.4]	0	16.6 [16.6; 16.6]	25
- made of maize milling fractions >500 µm:					
- 100 %	48	51.7 [51.3; 52.1]	18	98.0 [97.8; 98.2]	89
- 80 %	33	52.3 [52.0; 52.5]	9.3	87.4 [87.3; 87.6]	67
- 15 %	0	14.7 [14.7; 14.7]	0	18.7 [18.6; 18.7]	27
- 11 %	0	10.8 [10.8; 10.8]	0	13.7 [13.7; 13.7]	27

Table 9: Continued.

Food group	Scenario A (current ML)		Scenario B (tML)		% INC[(c)]
	% NC[(a)]	Mean MB [LB – UB] [(b)]	% NC[(a)]	Mean MB [LB – UB][(b)]	
ZON					
Other maize-based products					
- made of maize milling fractions ≤ 500 µm:					
- 50 %	23	50.1 [49.9; 50.2]	0	83.0 [82.9; 83.1]	66
- 40 %	9.4	48.0 [47.8; 48.1]	0	66.4 [66.3; 66.5]	38
- 37 %	1.7	48.0 [47.9; 48.1]	0	60.9 [60.8; 61.0]	27
- 11 %	0	14.3 [14.2; 14.3]	0	17.8 [17.7; 17.8]	25

(a): % NC: percentage of products (in a volume basis) non compliant to the ML.
(b): Mean MB [LB – UB]: mean middle bound [lower bound – upper bound].
(c): % INC: percentage difference determined as the difference between the mean MB obtained with scenario B (tML) and mean MB obtained with scenario A (current ML) divided by the mean MB obtained with scenario A.
Note: the numbers for the occurrence values are all given with 3 figures, but this does not reflect precision.

Some final processed/composite products appear to be non compliant to the current ML, even if made from ingredients compliant to the current ML. This is especially the case of processed/composite products containing more than 80 % maize as ingredient, with non compliant rates comprised between 11 and 73 % for DON, between 3.1 and 20 % for FUMO and between 33 and 71 % for ZON. Lower non compliant rates are estimated for the same products made from ingredients compliant to the tML, comprised between 2.6 and 62 % for DON, between 1.3 and 16 % for FUMO and between 9.3 and 47 % for ZON. For ZON, levels above the current ML are also observed in products containing between 37 and 50 % of maize milling fractions ≤ 500 µm. Same products made from milling fractions compliant to the tML are estimated to be compliant to their corresponding tML.

5.2. Impact on chronic exposure levels to DON, FUMO and ZON

5.2.1. Methodology

Chronic exposure was assessed at the individual level by multiplying the mean consumption for each food with the corresponding mean concentration, summing up the respective intakes throughout the diet, and finally dividing the results by the individual's body weight. The mean as well as the 95th percentile of exposure were then derived for each population group (i.e. [survey and age class] combinations). The percentage of individuals with an exposure higher than the chronic health-based guidance value (HBGV) was also estimated. Finally, the contribution of maize-based products to total exposure was determined for each population group, as the ratio between the average exposure resulting from the consumption of maize-based products and the total average exposure.

In a first scenario [A], the chronic exposure was assessed considering the mean concentrations estimated after the exclusion of concentration values above the current MLs for maize grains for consumption, milling fractions of maize consumed as such or as ingredients and in maize-based processed products (see Tables 8 and 9, Scenario A). In a second scenario [B], the chronic exposure was assessed considering the mean concentration estimated after the exclusion of concentration values above the tMLs (see Tables 8 and 9, Scenario B). In both scenarios, the mean levels estimated in the previous assessments were considered for the other foods, as detailed in Appendix A. The percentage difference between the exposure levels obtained from the two calculations (scenarios A and B) was characterised for each [survey and age class] combination across the Comprehensive Database.

Calculations were done independently for DON, FUMO and ZON.

5.2.2. Results of the impact on chronic exposure levels

Tables 10, 11 and 12 present the ranges (minimum, median and maximum) of the mean and 95th percentile exposure levels and of the percentage of subjects with an exposure above the chronic HBGVs, estimated across the different surveys and age groups for the current MLs and tMLs for DON, ZON and FUMO, respectively. Whereas all surveys and age groups were used to derive the ranges of the mean exposure levels, only those with more than 60 subjects were used to derive the ranges of the 95th percentiles and percentages of subjects above the chronic HBGV. For each age group, the minimum and maximum relative contribution of maize-based products in percentage to the overall LB mean exposure determined across the surveys are provided in Appendix C. Table 13 summarizes the percentage increase of exposure from scenario A to B estimated across surveys for each age group.

- ✓ DON

The mean exposure levels estimated in scenario A, reflecting exposure resulting from the specific contamination of the 2013 maize grains harvest and implementation of current MLs, are in the region of the group PMTDI of 1 µg/kg b.w. for some surveys covering children age groups (‘infant’, ‘toddlers’, ‘other children’) (Table 10). The mean exposure levels range between 0.22 and 0.98 µg/kg b.w. per day at the LB and 0.52 and 1.11 µg/kg b.w. per day at the UB. The 95th percentile of exposure for these three groups is between 0.94 and 1.79 µg/kg b.w. per day at the LB and between 0.99 and 2.10 µg/kg b.w. per day at the UB. In the surveys covering adult age groups (‘adolescents’, ‘adults’, ‘elderly’ and ‘very elderly’), the mean exposure levels, being between 0.18 and 0.55 µg/kg b.w. per day at the LB and 0.21 and 0.56 µg/kg b.w. per day at the UB, remain below the group PMTDI. However, the 95th percentile of exposure is in the region of the group PMTDI for some surveys, being between 0.36 and 1.04 µg/kg b.w. per day at the LB and 0.38 and 1.05 µg/kg b.w. per day at the UB.

Despite the higher DON levels in maize-based products considered in this statement in comparison to the levels considered in the previous assessment (EFSA CONTAM Panel, 2013), the exposure estimates are in the same ranges (Table 10). This is explained by the fact that the total exposure is mainly driven by foods other than maize-based ones (Appendix C, Table C.1), representing between 75 and 100 % of the total exposure depending on the surveys and age groups.

Depending on the surveys and age groups (with the exclusion of the ‘infants’ age group), the mean and 95th percentile exposure levels (LB and UB) estimated in scenario B – considering average DON levels in maize-based products resulting from the implementation of the tML – resulted up to 20 % higher than the levels estimated for the chronic exposure with the current ML (Table 13). The highest percentage increase is observed in the ‘adolescents’ age group, who are the highest consumers of maize-based products (see Section 4.2). The percentage difference of 95th percentile exposure levels estimated between the two scenarios is 4.5 % in the ‘infants’ age group, due to the low consumption of the products concerned by the derogation request.

Table 10: Chronic exposure to DON estimated in scenarios A and B expressed in µg/kg b.w. per day across surveys for each age group

Background exposure (EFSA, 2013)			Scenario A (current MLs)			Scenario B (tMLs)		
	Mean LB-UB	**P95 LB-UB**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above HBGV LB-UB[(a)] (%)**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above HBGV LB-UB[(a)] (%)**
Infants (N[(b)] = 2/1)								
Minimum	0.22 - 0.78	1.05 - 1.86	0.22 - 0.78	1.06 - 1.89	5.8 - 33	0.22 - 0.78	1.11 - 1.92	6.4 - 33
Median	-	-	-	-	-	-	-	-
Maximum	0.30 - 0.79	1.05 - 1.86	0.31 - 0.80	1.06 - 1.89	5.8 - 33	0.32 - 0.81	1.11 - 1.92	6.4 - 33
Toddlers (N[(b)] = 9/6)								
Minimum	0.47 - 0.70	0.94 - 1.20	0.53 - 0.72	1.00 - 1.28	5.4 - 17	0.54 - 0.73	1.02 - 1.4	6.1 - 18
Median	0.56 - 0.92	1.02 - 1.72	0.68 - 0.85	1.18 - 1.67	11 - 26	0.69 - 0.86	1.26 - 1.84	11 - 28
Maximum	0.94 - 1.10	1.55 - 2.13	0.98 - 1.11	1.79 - 2.10	44 - 52	1.03 - 1.12	1.99 - 2.13	46 - 54
Other children (N[(b)] = 17/17)								
Minimum	0.45 - 0.49	0.83 - 0.92	0.48 - 0.52	0.94 - 0.99	2.7 - 4.2	0.50 - 0.54	0.98 - 1.03	4.2 - 6.5
Median	0.59 - 0.64	1.00 - 1.11	0.62 - 0.67	1.17 - 1.26	12 - 15	0.64 - 0.70	1.23 - 1.41	12 - 15
Maximum	0.94 - 0.96	1.65 - 1.73	0.98 – 1.00	1.76 - 1.78	45 - 46	1.02 - 1.04	1.91 - 1.93	47 - 49
Adolescents (N[(b)] = 12/12)								
Minimum	0.30 - 0.32	0.63 - 0.66	0.32 - 0.33	0.68 - 0.69	0 - 0.2	0.34 - 0.35	0.74 - 0.75	1.1 - 1.3
Median	0.38 - 0.41	0.73 - 0.77	0.41 - 0.43	0.80 - 0.81	1.1 - 1.5	0.42 - 0.46	0.87 - 0.89	2.2 - 2.7
Maximum	0.53 - 0.55	1.00 - 1.04	0.55 - 0.56	1.04 - 1.05	6.7 - 7.4	0.56 - 0.57	1.04 - 1.13	7.0 - 7.4
Adults (N[(b)] = 15/15)								
Minimum	0.18 - 0.24	0.35 - 0.47	0.19 - 0.22	0.39 - 0.42	0	0.19 - 0.22	0.39 - 0.43	0
Median	0.25 - 0.32	0.49 - 0.59	0.26 - 0.28	0.50 - 0.52	< 0.1	0.27 - 0.29	0.54 - 0.56	0.2
Maximum	0.35 - 0.43	0.63 - 0.97	0.36 - 0.37	0.64 - 0.66	0.6	0.36 - 0.37	0.66 - 0.68	0.6
Elderly (N[(b)] = 7/7)								
Minimum	0.17 - 0.21	0.36 - 0.43	0.18 - 0.21	0.36 - 0.38	0	0.18 - 0.21	0.36 - 0.40	0
Median	0.24 - 0.28	0.48 - 0.52	0.23 - 0.24	0.47 - 0.48	0	0.23 - 0.24	0.48	0
Maximum	0.31 - 0.32	0.51 - 0.59	0.32 - 0.33	0.52 - 0.54	< 0.1	0.32 - 0.33	0.54 - 0.55	< 0.1
Very elderly (N[(b)] = 6/5)								
Minimum	0.22 - 0.25	0.42 - 0.44	0.22 - 0.23	0.41 - 0.43	0	0.22 - 0.23	0.42 - 0.44	0
Median	0.24 - 0.28	0.52 - 0.55	0.23 - 0.24	0.50 - 0.51	0	0.24	0.51	0
Maximum	0.33 - 0.34	0.56 - 0.57	0.33 - 0.35	0.57 - 0.58	0.3	0.34 - 0.35	0.60 - 0.61	0.3

LB: lower bound; UB: upper bound; P95: 95th percentile. (a) Percentage above chronic HBGV: Percentage of subjects with an exposure above the health-based guidance value; (b): Number of surveys used to derive the minimum/median/maximum mean exposure levels/number of surveys used to derive the minimum/median/maximum 95th percentile exposure levels and percentages of individuals with an exposure above the chronic HBGV. Note: The numbers for the exposure values (mean, P95) are all given with 3 figures, and the percentage above chronic HBGV with 2 figures, but this does not reflect precision. When LB and UB estimates are identical, only one estimate is provided.

Table 11: Chronic exposure to ZON estimated in scenarios A and B expressed in ng/kg b.w. per day across surveys for each age group

	Background exposure (EFSA, 2011)		Scenario A (current MLs)			Scenario B (tMLs)		
	Mean LB-UB	**P95 LB-UB**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above HBGV LB-UB[(a)] (%)**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above HBGV LB-UB[(a)] (%)**
Infants (N[(b)] = 2/1)								
Minimum	3.3 - 87	33	9.7 - 115	57 - 292	0.3 - 9.2	9.7 - 115	68 - 301	0.7 - 9.8
Median	-	-	-	-	-	-	-	-
Maximum	9.4 - 88	217	16 - 126	57 - 292	0.3 - 9.2	19 - 128	68 - 301	0.7 - 9.8
Toddlers (N[(b)] = 9/6)								
Minimum	9.3 - 51	24 - 104	14 - 62	52 - 128	0	16 - 63	64 - 151	< 0.1 - 0.9
Median	13 - 83	31 - 182	20 - 107	82 - 217	0.5 - 3.3	25 - 111	106 - 260	0.9 - 6.3
Maximum	23 - 100	50 - 277	53 - 118	145 - 303	1.0 - 9.2	70 - 133	233 - 304	4.2 - 9.8
Other children (N[(b)] = 17/17)								
Minimum	5.7 - 29	9.9 - 59	17 - 45	47 - 99	0	21 - 53	61 - 108	0
Median	11 - 44	22 - 80	27 - 63	78 - 125	0 - 0.1	38 - 73	114 - 153	0.4 - 0.8
Maximum	22 - 75	42 - 124	48 - 103	148 - 200	0.5 - 1.6	64 - 118	233 - 275	3.7 - 7.2
Adolescents (N[(b)] = 12/12)								
Minimum	3.6 - 17	7.5 - 38	11 - 30	35 - 68	0	13 - 32	44 - 76	0
Median	6.1 - 26	15 - 53	17 - 40	51 - 82	0	23 - 47	74 - 110	< 0.1 - 0.2
Maximum	12 - 42	26 - 76	35 - 64	70 - 117	0.5	40 - 66	111 - 133	0.5 – 1.0
Adults (N[(b)] = 15/15)								
Minimum	2.4 - 14	4.7 - 28	6.3 - 19	16 - 42	0	7.7 - 20	18 - 46	0
Median	4.3 - 18	9.5 - 35	8.6 - 29	30 - 58	0	11 - 30	42 - 64	0
Maximum	7.2 - 29	14 - 54	21 - 42	46 - 83	0	22 - 43	72 - 95	0.2
Elderly (N[(b)] = 7/7)								
Minimum	2.0 - 13	3.5 - 25	4.4 - 17	11 - 33	0	5.1 - 17	12 - 33	0
Median	3.4 - 16	7.5 - 31	6.2 - 20	17 - 42	0	6.6 - 21	26 - 47	0
Maximum	6.4 - 26	12 - 42	13 - 35	38 - 62	0	14 - 36	45 - 67	0
Very elderly (N[(b)] = 6/5)								
Minimum	2.3 - 12	7.0 - 26	4.5 - 18	13 - 37	0	5.7 - 19	13 - 41	0
Median	2.9 - 16	7.7 - 35	6.5 - 22	20 - 46	0	7.0 - 23	26 - 46	0
Maximum	7.1 - 29	13 - 47	12 - 34	29 - 56	0	13 - 35	46 - 65	0

LB: lower bound; UB: upper bound; P95: 95th percentile. (a) Percentage above chronic HBGV: Percentage of subjects with an exposure above the health-based guidance value; (b): Number of surveys used to derive the minimum/median/maximum mean exposure levels/number of surveys used to derive the minimum/median/maximum 95th percentile exposure levels and percentages of individuals with an exposure above the chronic HBGV. Note: The numbers for the exposure values (mean, P95) are all given with 2 figures and the percentage above chronic HBGV with 2 figures, but this does not reflect precision. When LB and UB estimates are identical, only one estimate is provided.

Table 12: Chronic exposure to FUMO estimated in scenarios A and B expressed in µg/kg b.w. per day across surveys for each age group

	Scenario A (current MLs)			**Scenario B (tMLs)**		
	Mean LB-UB	**P95 LB-UB**	**Percentage above HBGV LB-UB(a) (%)**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above HBGV LB-UB(a) (%)**
Infants (N(b) = 2/1)						
Minimum Median	0.17 - 0.47	0.77 - 1.94	0.1 - 4.5	0.17 - 0.47	0.79 - 1.96	0.1 - 4.7
Maximum	0.18 - 0.59	0.77 - 1.94	0.1 - 4.5	0.19 - 0.60	0.79 - 1.96	0.1 - 4.7
Toddlers (N(b) = 9/6)						
Minimum	0.34 - 0.81	0.77 - 1.91	0 - 4.2	0.35 - 0.82	0.79 - 1.93	< 0.1 - 4.6
Median	0.58 - 1.49	1.33 - 2.54	1.2 - 16	0.58 - 1.50	1.39 - 2.59	1.2 - 16
Maximum	0.80 - 1.74	1.58 - 2.75	2.7 - 22	0.8 - 1.74	1.59 - 2.75	2.7 - 24
Other children (N(b) = 17/17)						
Minimum	0.25 - 0.61	0.54 - 1.09	0 - 0.1	0.26 - 0.62	0.58 - 1.14	< 0.1 - 0.1
Median	0.52 - 1.29	1.30 - 2.23	0.5 - 8.6	0.53 - 1.29	1.30 - 2.23	0.6 - 8.6
Maximum	1.52 - 2.11	3.44 - 4.39	25 - 47	1.54 - 2.13	3.46 - 4.47	26 - 48
Adolescents (N(b) = 12/12)						
Minimum	0.20 - 0.55	0.45 - 1.03	0	0.22 - 0.57	0.49 - 1.05	0
Median	0.33 - 0.75	0.87 - 1.48	0 - 1.2	0.34 - 0.76	0.89 - 1.48	< 0.1 - 1.2
Maximum	0.81 - 1.19	1.76 - 2.30	1.7 - 9.9	0.84 - 1.22	1.76 - 2.37	2.6 - 10
Adults (N(b) = 15/15)						
Minimum	0.04 - 0.17	0.11 - 0.32	0	0.04 - 0.17	0.12 - 0.33	0
Median	0.16 - 0.47	0.43 - 0.92	0	0.17 - 0.47	0.44 - 0.92	0
Maximum	0.47 - 0.73	0.97 - 1.36	0.3 - 0.6	0.47 - 0.73	0.98 - 1.36	0.3 - 0.6
Elderly (N(b) = 7/7)						
Minimum	0.03 - 0.15	0.08 - 0.31	0	0.03 - 0.15	0.09 - 0.31	0
Median	0.12 - 0.40	0.29 - 0.78	0	0.12 - 0.40	0.31 - 0.78	0
Maximum	0.29 - 0.53	0.61 - 0.95	< 0.1	0.29 - 0.53	0.61 - 0.95	< 0.1
Very elderly (N(b) = 6/5)						
Minimum	0.09 - 0.35	0.22 - 0.71	0	0.09 - 0.35	0.23 - 0.72	0
Median	0.14 - 0.42	0.32 - 0.81	0	0.15 - 0.42	0.32 - 0.81	0
Maximum	0.30 - 0.57	0.67 - 1.05	0.2	0.30 - 0.57	0.68 - 1.05	0.2

LB: lower bound; UB: upper bound; P95: 95^{th} percentile.

(a): Percentage above chronic HBGV: Percentage of subjects with an exposure above the health-based guidance value;

(b): Number of surveys used to derive the minimum/median/maximum mean exposure levels/number of surveys used to derive the minimum/median/maximum 95^{th} percentile exposure levels and percentages of individuals with an exposure above the chronic HBGV.

Note: The numbers for the exposure values (mean, P95) are all given with 3 figures, and the percentage above chronic HBGV with 2 figures, but this does not reflect precision. When LB and UB estimates are identical, only one estimate is provided.

✓ ZON

The mean exposure levels estimated in scenario A, reflecting exposure resulting from the specific contamination of the 2013 maize grains harvest and implementation of current MLs, are lower than the chronic HBGV (TDI) of 250 ng/kg b.w. in all age groups and surveys (Table 11). The mean exposure levels range between 9.7 and 53 ng/kg b.w. per day at the LB and 45 and 126 ng/kg b.w. per day at the UB in the children age groups. In the adults age groups, the mean exposure levels range between 4.4 and 35 ng/kg b.w. per day at the LB and 17 and 64 ng/kg b.w. per day at the UB. In the children age groups, whereas the LB estimate of the 95^{th} percentile of exposure is below the TDI, the UB estimate is above the TDI in some surveys. Indeed, the LB 95^{th} percentile estimate is between 47 and 148 ng/kg b.w. per day and the UB 95^{th} percentile estimate between 99 and 303 ng/kg b.w. per day. In the adult age groups, the 95th percentile of exposure is always below the TDI, being between 11 and 70 ng/kg b.w. per day at the LB and between 33 and 117 ng/kg b.w. per day at the UB.

Such estimates are higher than those estimated in previous assessment (EFSA CONTAM Panel, 2011) (Table 11) especially at the LB. In the previous assessment, the maximum mean exposure level was estimated at 23 ng/kg b.w. per day (*vs*. 53 ng/kg b.w. per day in this assessment) at the LB and at 100 ng/kg b.w. per day (*vs*. 126 ng/kg b.w. per day in this assessment) at the UB. The maximum 95th percentile exposure level was estimated at 50 ng/kg b.w. per day (*vs*. 148 ng/kg b.w. per day in this assessment) at the LB and at 277 ng/kg b.w. per day (*vs*. 303 ng/kg b.w. per day in this assessment). This is explained by the fact that the total exposure is mainly driven by maize-based products, which represent up to 77.8 % of the total exposure depending on the surveys and age groups (Appendix C, Table C.3).

Depending on the surveys and age groups (with the exclusion of the 'infants' age group), the mean and 95th percentile exposure levels (LB and UB estimates) estimated in scenario B – considering average ZON levels in maize-based products resulting from the implementation of the tML – are up to 83 % higher than the levels estimated for the chronic exposure with the current ML (Table 13). The highest percentage increase is observed in the 'other children' and 'adolescents' age groups. The percentage difference of 95th percentile exposure levels estimated between the two scenarios is 19 % in the 'infants' age group due to the low consumption of the products concerned by the derogation request.

- ✓ FUMO

The mean exposure levels estimated in scenario A, reflecting exposure resulting from the specific contamination of the 2013 maize grains harvest and implementation of current MLs, are in the region of the HBGV (group PMTDI) of 2 µg/kg b.w. for some surveys covering children age groups (Table 11). Indeed, the mean exposure levels range between 0.17 and 1.52 µg/kg b.w. per day at the LB and 0.47 and 2.11 µg/kg b.w. per day at the UB. The 95th percentile of exposure was between 0.54 and 3.44 µg/kg b.w. per day at the LB and between 1.09 and 4.39 µg/kg b.w. per day at the UB. In the surveys covering adult age groups, the mean exposure levels remain below the group PMTDI , being between 0.03 and 0.81 µg/kg b.w. per day at the LB and 0.15 and 1.19 µg/kg b.w. per day at the UB. However, the 95th percentile of exposure is in the region of the group PMTDI for some surveys, being between 0.08 and 1.76 µg/kg b.w. per day at the LB and 0.31 and 2.30 µg/kg b.w. per day at the UB. Maize-based foods were found to represent from 0.4 to 22 % of the total exposure in all age groups except 'infants'. The percentage contribution of maize-based foods to the total exposure of 'infants' was ranging from 0 to 8.2 % (Appendix C, Table C.2).

Depending on the surveys and age groups (with the exclusion of the 'infants' age group), the mean and 95th percentile exposure levels (LB and UB estimates) estimated in scenario B – considering average DON levels in maize-based products resulting from the implementation of the tML – are up to 17 % higher than the levels estimated for the chronic exposure with the current ML (Table 13). The percentage difference of 95th percentile exposure levels estimated between the two scenarios is less than 1.8 % in the 'infants' age group due to the low consumption of the products concerned by the derogation request.

Table 13: Percentage increase of exposure from scenario A to scenario B estimated across surveys for each age group

Age group	Median percentage increase of exposure [minimum; maximum][(a)]			
	Mean exposure		P95 exposure	
	LB	UB	LB	UB
		DON		
Infants	-[(b)] [0; 2.2]	-[(b)] [0; 0.9]	4.5	1.6
Toddlers	1.9 [0.6; 4.5]	1.4 [0.6; 4.1]	7.4 [1.8; 11]	7.7 [0; 15]
Other children	4.1 [1.5; 8.6]	3.8 [1.3; 8.2]	6.1 [0; 18]	5.7 [0; 14]
Adolescents	3.9 [1.4; 12]	3.5 [1.4; 11]	6.9 [0.2; 20]	6.1 [0.4; 19]
Adults	2.1 [0.8; 8.3]	2.0 [0.8; 7.6]	4.0 [0.4; 16]	3.0 [0.4; 12]
Elderly	1.0 [0.1; 2.2]	1.0 [0.1; 2.1]	1.4 [0; 4.5]	1.5 [0; 3.4]
Very elderly	1.2 [0.1; 1.6]	1.2 [0.1; 1.5]	2.8 [0; 5.2]	1.5 [0; 3.9]
		FUMO		
Infants	-[(b)] [0; 1.8]	-[(b)] [0; 0.5]	1.8	0.8
Toddlers	1.2 [0.5; 4.1]	0.3 [0.2; 1.3]	3.0 [0.3; 6.3]	1.5 [0; 2.2]
Other children	2.1 [1; 9.4]	1.0 [0.4; 3.7]	2.3 [0; 12]	1.5 [0; 7.5]
Adolescents	2.6 [0.9; 10]	1.0 [0.4; 3.4]	2.7 [0; 9.3]	1.0 [0; 4.3]
Adults	2.1 [0.5; 11]	0.7 [0.3; 2.4]	2.8 [0.5; 17]	1.0 [0; 4.4]
Elderly	2.0 [0.2; 3.5]	0.5 [0.1; 0.9]	0.5 [0; 5.4]	0 [0; 0.8]
Very elderly	1.4 [0.3; 3.1]	0.5 [0.1; 0.7]	0.9 [0; 2.3]	0 [0; 1.5]
		ZON		
Infants	-[(b)] [0; 18]	-[(b)] [0; 2.3]	19	3.1
Toddlers	14 [6.4; 32]	4.1 [1.9; 15]	39 [14; 60]	12 [0; 34]
Other children	27 [11; 70]	11 [4.3; 32]	49 [15; 83]	22 [8.4; 56]
Adolescents	30 [6.6; 70]	13 [3.6; 42]	54 [0; 79]	31 [0.9; 57]
Adults	22 [4.6; 47]	7.2 [2.3; 18]	43 [5.7; 73]	12 [3.1; 40]
Elderly	10 [1.9; 36]	3.0 [0.5; 8.6]	16 [2.1; 58]	8.9 [0; 34]
Very elderly	11 [2.3; 27]	3.8 [0.6; 6.2]	19 [0; 58]	7.4 [0; 16]

LB: lower bound; UB: upper bound; P95: 95th percentile.

(a): Percentage difference, determined for each [age class x survey] combination, as the difference between the mean/95th percentile obtained with scenario B and the mean/95th percentile obtained with scenario A divided by the mean/95th percentile obtained with scenario A, and presented for each age class as the median [minimum; maximum] across the surveys. When the median, minimum and maximum are equal, only one value is given.

(b): the median is not indicated as there are only two surveys for this age group.

Note: The numbers for the percentage increase values are all given with 2 figures, but this does not reflect precision.

5.3. Impact on acute exposure levels to DON

5.3.1. Methodology

The impact of the tMLs on acute exposure levels to DON was also assessed, as a group ARfD has been established as acute HBGV by JECFA for DON and its derivatives. Two scenarios of acute exposure were designed: a first scenario (scenario C) at the ingredient level (maize grain, maize milling fractions with particle size > 500 µm, maize milling fractions with particle size ≤ 500 µm), and a second scenario (scenario D) at the processed/composite product level (maize-based breakfast cereals, maize-based snacks, maize-based pastries). The acute exposure was assessed independently for each ingredient and processed/composite product considered.

In scenario C, the ingredient eaten as such or present in composite products during a day was considered to contain DON at the level of the ML defined for the ingredient. In scenario D, the processed/composite product eaten during a day was considered to contain DON at the ML defined for the final processed/composite product. In a first sub-scenario (C.1 and D.1), the current ML was used whereas in a second sub-scenario (C.2 and D.2), the tML was considered. The other foods consumed during the same day were at the background DON levels (mean LB - UB level), as considered in the chronic exposure assessment.

For each [survey x age group] combination and food considered, when more than 60 consumption days were available, the percentage of consumption days with exposure level above the group ARfD was estimated and compared between the two sub-scenarios.

5.3.2. Results of the impact on acute DON exposure levels

- ✓ Maize grain for consumption and maize milling fractions

Table 14 shows, for the three ingredients considered, the number of surveys in each age group found with at least one consumption day with exposure above the group ARfD and the range of percentage of days with exposure above the group ARfD estimated for both scenarios (C.1 and C.2).

'Maize milling fractions ≤ 500 µm' were found with at least one consumption day above the group ARfD in 3 surveys (out of 46 surveys taken into account in the acute assessment) with scenario C.1 (current ML). In these surveys, the percentage of consumption days above the group ARfD was estimated to be up to 0.2 %, and the highest acute exposure level at 16.6 µg/kg b.w. In scenario C.2, which was corresponding to the tML, the percentage of consumption days above the group ARfD was estimated to be up to 0.6 %, and the highest acute exposure level at 19.6 µg/kb b.w.

Table 14: Acute exposure to DON estimated in scenario C expressed in µg/kg b.w. across surveys and age groups

Food group	Age class	N[(a)]	Range of consumption days simulated[(b)]	Scenario C.1 (Current ML)			Scenario C.2 (Suggested increased ML)		
				Range of acute exposure levels[(c)]	N > acute HBGV[(d)]	Range of percentage days above acute HBGV[(e)]	Range of acute exposure levels[(c)]	N > acute HBGV[(d)]	Range of percentage days above acute HBGV[(e)]
Maize grain for consumption	Other children	3	72 – 298	0.14 - 6.47	0	0	0.15 - 8.45	1	0.7
	Adolescents	2	146 - 181	0.12 - 5.67	0	0	0.15 - 6.99	0	0
	Adults	7	62 – 393	0.03 - 4.45	0	0	0.04 - 5.80	0	0
Maize milling fractions ≤ 500 µm	Toddlers	3	63 – 250	0.06 - 6.12	0	0	0.06 - 7.08	0	0
	Other children	12	61 – 700	< 0.005 - 16.6	3	0.1 - 0.2	< 0.005 - 19.6	3	0.1 - 0.6
	Adolescents	8	63 - 1199	< 0.005 - 4.49	0	0	< 0.005 - 5.31	0	0
	Adults	16	70 - 2719	< 0.005 - 3.75	0	0	< 0.005 - 4.48	0	0
	Elderly	4	131 - 364	< 0.005 - 1.85	0	0	< 0.005 - 1.94	0	0
	Very elderly	3	62 – 165	0.03 - 1.41	0	0	0.03 - 1.64	0	0
Maize milling fractions > 500 µm	Toddlers	3	86 – 277	0.21 - 6.37	0	0	0.21 - 8.37	1	0.8
	Other children	11	81 - 1247	0.02 - 12.4	1	0.1	0.03 - 16.4	3	0.1 - 0.5
	Adolescents	7	87 – 986	0.04 - 7.96	0	0	0.04 - 10.5	1	0.2
	Adults	16	62 - 3283	0.01 - 5.08	0	0	0.01 - 6.61	0	0
	Elderly	2	291 - 353	0.01 - 1.13	0	0	0.02 - 1.40	0	0
	Very elderly	1	81	0.06 - 1.65	0	0	0.06 - 1.79	0	0

(a): number of surveys with at least 60 consumption days available for the corresponding food product and taken into account in the acute exposure assessment.

(b): minimum and maximum number of consumption days available across surveys taken into account for the acute exposure assessment. When the minimum and the maximum are equal, only one value is given.

(c): minimum and maximum upper bound acute exposure levels estimated across the surveys taken into account for the acute exposure assessment.

(d): number of surveys with at least one consumption day above the acute HBGV.

(e): minimum and maximum percentage of consumption days above the acute HBGV for the surveys with at least one consumption day above the acute HBGV. When the minimum and the maximum are equal, only one value is given.

Note: The numbers for the exposure values are all given with 3 figures, and percentage of days above the acute HBGV with two figures, but this does not reflect precision.

'Maize milling fractions > 500 µm' were found with at least one consumption day above the acute HBGV (group ARfD) in only 1 survey (out of 40 surveys taken into account in the acute assessment) with scenario C.1 (current ML). In this survey, the percentage of consumption days above the group ARfD was estimated at 0.1 % and the highest acute exposure level at 12.4 µg/kg b.w. In scenario C.2, which was corresponding to the tML, five surveys were found with at least one consumption day above the group ARfD, with a percentage of consumption days above the group ARfD estimated up to 0.8 % and the highest acute exposure level at 16.4 µg/kg b.w.

Whereas 'Maize grain for consumption' was not associated with any consumption day above the group ARfD in scenario C.1 (current ML), it was associated with 0.7 % consumption days above the group ARfD in one survey out of the 12 considered in scenario C.2 (tML). The highest acute exposure level was estimated at 8.45 µg/kg b.w.

- ✓ Maize-based processed/composite products

Table 15 shows the results obtained from the acute exposure scenario on processed/composite products.

'Maize-based breakfast cereals' were found with at least one consumption day above the group ARfD in 2 surveys (out of 39 surveys taken into account in the acute assessment) with scenario D.1 (current ML). In these surveys, the percentage of consumption days above the group ARfD was estimated to be up to 0.9 % and the highest acute exposure level estimated at 10.2 µg/kg b.w. Same percentage of consumption days above the group ARfD was estimated in scenario D.2 (tML), with the highest acute exposure level at 14.4 µg/kg b.w.

'Maize-based pastries' were found with at least one consumption day above the group ARfD in 2 surveys (out of 28 surveys taken into account in the acute assessment) with scenario D.1 (current ML). In these surveys, the percentage of consumption days above the group ARfD was estimated up to 1.2 % and the highest acute exposure level at 14.0 µg/kg b.w. In scenario D.2, which was corresponding to the tML, 9 surveys were found with at least one consumption days above the group ARfD, with a percentage of consumption days above the group ARfD estimated up to 8.1 % and the highest acute exposure level estimated at 20.8 µg/kg b.w.

Whereas 'Maize-based snacks' were not associated with any consumption day above the group ARfD in scenario D.1 (current ML), it was associated with 0.2 % consumption days above the group ARfD in one survey out of the 12 surveys considered in scenario D.2 (tML). The highest acute exposure level was estimated at 9.40 µg/kg b.w.

Table 15: Acute exposure to DON estimated in scenario D expressed in µg/kg b.w. across surveys and age groups

Food group	Age class	N(a)	Range of consumption days simulated(b)	Scenario D.1 (Current ML)			Scenario D.2 (Suggested increased ML)		
				Range of acute exposure levels(c)	N > acute HBGV(d)	Range of percentage days above acute HBGV(e)	Range of acute exposure levels(c)	N > acute HBGV(d)	Range of percentage days above acute HBGV(e)
Maize-based breakfast cereals	Toddlers	1	90	0.26 - 5.18	0	0	0.29 - 7.76	0	0
	Other children	10	95 - 1247	0.14 - 10.2	2	0.2 - 0.9	0.16 - 14.4	2	0.2 - 0.9
	Adolescents	8	64 - 986	0.07 - 5.41	0	0	0.08 - 7.96	0	0
	Adults	17	62 - 3282	0.02 - 4.11	0	0	0.03 - 6.04	0	0
	Elderly	2	291 - 350	0.07 - 4.73	0	0	0.10 - 6.93	0	0
	Very elderly	1	81	0.10 - 1.73	0	0	0.12 - 1.98	0	0
Maize-based pastries	Toddlers	1	130	1.35 - 7.79	0	0	1.88 - 10.7	1	4.6
	Other children	6	104 - 433	0.41 - 10.1	1	1.2	0.59 - 13.8	3	1.8 - 8.1
	Adolescents	6	65 - 741	0.14 - 14.0	1	0.7	0.22 - 20.8	2	1.2 - 2.4
	Adults	11	70 - 1603	0.10 - 6.37	0	0	0.13 - 9.37	3	0.1 - 0.6
	Elderly	3	100 - 202	0.17 - 4.47	0	0	0.21 - 6.62	0	0
	Very elderly	1	130	0.24 - 2.77	0	0	0.32 - 4.08	0	0
Maize-based snacks	Toddlers	1	127	0.61 - 5.37	0	0	0.65 - 7.87	0	0
	Other children	3	99 - 414	0.14 - 7.05	0	0	0.15 - 9.40	1	0.2
	Adolescents	2	146 - 234	0.12 - 3.32	0	0	0.15 - 4.08	0	0
	Adults	6	89 - 393	0.03 - 5.08	0	0	0.04 - 6.62	0	0

(a): number of surveys with at least 60 consumption days available for the corresponding food product and taken into account in the acute exposure assessment.
(b): minimum and maximum number of consumption days available across surveys taken into account for the acute exposure assessment. When the minimum and the maximum are equal, only one value is given.
(c): minimum and maximum upper bound acute exposure levels estimated across the surveys taken into account for the acute exposure assessment.
(d): number of surveys with at least one consumption day above the acute HBGV.
(e): minimum and maximum percentage of consumption days above the acute HBGV for the surveys with at least one consumption day above the acute HBGV. When the minimum and the maximum are equal, only one value is given.
Note: The numbers for the exposure values are all given with 3 figures and percentage of days above the acute HBGV with two figures, but this does not reflect precision.

6. Risk characterization

6.1. Deoxynivalenol

The group PMTDI of 1 µg/kg b.w. per day and the group ARfD of 8 µg/kg b.w., established by JECFA (FAO/WHO, 2011), includes the acetyl-derivatives 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not partially taken into account in this statement. Indeed, whereas ELISA results available for maize and maize-based products include the DON derivatives, the results considered for the other foods, generated by gas and liquid chromatography, were exclusively referring to the parent DON compounds.

Acute and chronic exposure calculations for the different age groups have been carried out to estimate the impact of temporary increase of the ML for DON in:

i) unprocessed maize with the exception of unprocessed maize intended to be processed by wet milling, from 750 to 2250 µg/kg,

ii) milling fractions of maize with a particle size of less than or equal to 500 microns from 200 to 300 µg/kg,

iii) milling fractions of maize with a particle size of more than 500 microns from 1250 to 1500 µg/kg,

iv) maize and maize milling products intended for direct human consumption from 750 to 1000 µg/kg,

v) maize-based breakfast cereals and maize-based snacks and maize-based foods for direct human consumption from 500 to 750 µg/kg.

6.1.1. Chronic risk characterisation

Chronic exposure calculations for DON are presented and discussed in Section 5.2. Impact on chronic exposure levels to DON, FUMO and ZON and summarised in Table 10 of that section. The exceedance of the group PMTDI is higher in ‘toddlers’ than in the other age groups, ranging between 5.4 and 52 % (minimum LB and maximum UB) when considering the specific contamination of the 2013 maize grains harvest and implementation of current MLs. This is increased to between 6.1 and 54 % when considering the chronic exposure reflecting the implementation of tML.

Such results suggest a low impact of a temporary increase in MLs for chronic exposure levels in all age groups, which is explained by the fact that overall dietary DON exposure is mainly driven by foods other than maize-based products. However, application of both of current and increased MLs led to exposures in the region of the group PMTDI of 1 µg/kg b.w. per day in several age groups being highest in the ’toddlers’. It has to be noted that this group PMTDI is based on a NOEL for decreased body weight gain in mice upon chronic exposure, an endpoint particularly relevant for infants, toddlers children and adolescents age groups in growing life stages. Any exposures exceeding the PMTDI in these age groups are therefore of particular concern, as already pointed out in the earlier assessment on DON (EFSA CONTAM Panel, 2013).

6.1.2. Acute risk characterisation

Acute exposure scenarios addressed people who would consume maize grains, maize milling products, maize-based breakfast cereals, maize-based snacks and maize-based pastries containing DON equal to the ML. Results are presented and discussed in Section 5.3. Impact on acute exposure levels to DON are summarised in Tables 15 and 16 of that section.

Such assessment resulted in a very low percentage of consumption days above the group ARfD (< 1%) for all products except the maize-based pastries, whatever the ML (current, tML) considered.

For maize-based pastries when applying the increased tMLs, the probability of exceedance of the ARfD increased from 1.2 up to 8.1 % and from 0.7 up to 2.4 % of consumption days for the 'other children' and 'adolescents' age groups, respectively. The highest acute exposure level resulting from the consumption of maize-based pastries at the ML was observed in the 'adolescents' age group, estimated at 14.0 and 20.8 µg/kg b.w. with the current ML and tML, respectively. For toddlers, no exposure days above the ARfD was observed when considering current ML, whereas 4.6 % of consumption days were estimated to exceed the ARfD when considering the tML. These increased probabilities indicate a potential concern resulting from the consumption of maize-based pastries containing high DON level for these age groups.

6.2. Fumonisins

Since no recent risk assessment for fumonisins is available from EFSA, the HBGV derived from most recent comprehensive risk assessment for fumonisins carried out by the JECFA in 2011 (FAO/WHO, 2012) have been considering in the present statement. JECFA has identified kidney and liver effects as crucial effects of fumonisin mediated toxicity and established a group PMTDI of 2 µg/kg b.w. per day as HBGV. It has to be noted that the mandate from the Commission for the present assessment concerns FB_1 and FB_2. However, part of the occurrence data available the present assessment was covering the sum of FB_1, FB_2 and FB_3. Taking into account that most toxicological assessments and also the PMTDI are derived mainly from data with FB_1 and the structural similarities of the different fumonisin derivatives of relevance, this is considered acceptable.

Chronic exposure calculations for the different age groups have been carried out to estimate the impact of temporary increase of the ML for FUMO in:

i) unprocessed maize,with the exception of unprocessed maize intended to be processed by wet milling, from 4000 to 4500 µg/kg,

ii) milling fractions of maize with a particle size of less than or equal to 500 microns from 2000 to 3500 µg/kg,

iii) milling fractions of maize with a particle size of more than 500 microns from 1400 to 1900 µg/kg,

iv) maize intended for direct human consumption, maize-based foods for direct human consumption with the exception of maize-based breakfast cereals and maize-based snacks from 1000 to 1500 µg/kg,

v) maize-based breakfast cereals and maize-based snacks from 800 to 1300 µg/kg.

Chronic exposure calculations for FUMO are presented and discussed in Section 5.2. Impact on chronic exposure levels to DON, FUMO and ZON and summarised in Table 13 of that section. The exceedance of the group PMTDI is higher in 'other children' than in other age groups, ranging between 0 and 25.3 % at the LB and between 0.1 and 47.2 % at the UB when considering the specific contamination of the 2013 maize grains harvest and implementation of current MLs. This is increased to between less than 0.1 % and 26 % at the LB and between 0.1 % and 47.6 % at the UB when considering the chronic exposure reflecting the implementation of tML.

Overall, the results show that a temporary increase in MLs has a low impact on exposure levels and consequently on any risk estimates. However, when considering the current MLs, exposure levels of FUMO are already in the region of the group PMTDI of 2 µg/kg b.w. per day in several age groups, being highest for the 'other children', and are therefore of health concern.

6.3. Zearalenone

In its recent assessment (EFSA CONTAM Panel, 2011), the CONTAM Panel concluded that the most critical effect of zearalenone mediated toxicity are oestrogenic effects occurring already at low dose levels and therefore the Panel established a TDI of only 0.25 µg/kg b.w. per day (or 250 ng/kg b.w. per day). The CONTAM Panel pointed out in their opinion that it is possible that elevated circulating levels of oestrogens could lead to adverse effects either from long term exposure or from short-term exposure during a sensitive stage of development.

Chronic exposure calculations for the different age groups have been carried out to estimate the impact of temporary increase of the ML for ZON for:

i) unprocessed maize ,with the exception of unprocessed maize intended to be processed by wet milling, from 350 to 500 µg/kg;

ii) milling fractions of maize with a particle size of less than or equal to 500 microns from 200 to 300 µg/kg;

iii) milling fractions of maize with a particle size of more than 500 microns from 300 to 400 µg/kg;

iv) maize intended for direct human consumption, maize-based foods including snacks, breakfast cereals and milling products for direct consumption from 100 to 200 µg/kg.

Chronic exposure calculations for ZON are presented and discussed in Section 5.2. Impact on chronic exposure levels to DON, FUMO and ZON and summarised in Table 12 of that section. The exceedance of the TDI is the higher in 'toddlers' than in other age groups, ranging between 0 and 9.2 % (minimum LB and maximum UB) when considering the specific contamination of the 2013 maize grains harvest and implementation of current MLs. This is increased to between less than 0.1 % and 9.8 % when considering the chronic exposure reflecting the implementation of tML.

Increasing the tMLs for ZON in maize and maize-based products will also lead to a more pronounced increase in overall dietary ZON exposure (as compared to DON and FUMO) since maize and maize-based products are the main contributors to total ZON exposure. High exposure levels for ZON both with current and increased ML levels are around or above the TDI for the age groups 'infants', 'toddlers' and 'other children' at the upper bound estimate and thus might be considered as being a health concern. The CONTAM Panel pointed out that it is possible that elevated circulating levels of oestrogens could lead to adverse effects either from long term exposure, but also from short-term exposure to ZON during a sensitive stage of development. Thus, the impact of the proposed temporary increases in MLs for ZON need to be considered also in the light of these conclusions.

6.4. Risk consideration of individuals suffering from celiac disease

Celiac disease is provoked by an immune reaction to food containing gluten. The prevalence of celiac disease in Europe is estimated to be 1.0 % (95% CI 0.9 – 1.1) (Mustalahti et al., 2010). The management of the disease consists in a gluten-free diet. Maize is among the cereals – together with rice, buckwheat and millet – which do not contain gluten. Consequently, subjects suffering from celiac disease may consume higher levels of maize grain and maize-based products than the general population. There is no survey on the specific consumption habits of subjects suffering from celiac disease available for risk assessment in EFSA. However, people suffering from celiac disease are considered to be represented in the Comprehensive database according to the prevalence of disease. In addition, the Comprehensive database covers a wide range of individual consumption patterns, which are taken into account when assessing the exposure levels of the European population. Thus, it is considered that those subjects suffering from celiac disease who choose to preferably consume maize grains and maize-based products are represented by the high consumers of maize and maize-based products. The exposure levels of these subjects can be approached by the high exposure levels (95^{th} percentile) estimated for the general population. At the current MLs, 95^{th} percentile of exposure levels above the respective chronic HBGVs were estimated for DON and FUMO for some surveys in the younger age groups (infants, toddlers, other children and adolescents) for both the LB and UB. Regarding ZON, the LB estimates of the 95th percentile of exposure were below the chronic HBGV in all surveys and age groups whereas the UB exposure estimates were above the HBGV in some surveys in the infants and toddlers age groups. At the tML, the 95th percentile of exposures were increased by up to 20, 17 and 83 % for DON, FUMO and ZON respectively. The age groups with at least one survey with a 95th percentile above the chronic HBGV remain the same. For ZON, an additional age group appears with a least one survey with a UB 95th percentile above the HBGV: the other children.

7. Uncertainty analysis

The evaluation of the inherent uncertainties in the assessment of exposure to DON has been performed following the guidance of the Opinion of the Scientific Committee related to Uncertainties in Dietary Exposure Assessment (EFSA, 2006). In addition, the report on ‘Characterizing and Communicating Uncertainty in Exposure Assessment’ has been considered (WHO/IPCS, 2008). According to the guidance provided by the EFSA opinion (2006) the following sources of uncertainties have been considered: assessment objectives, model input (parameters) and exposure scenarios/model.

7.1. Assessment objectives

The objectives of the assessment were clearly specified in the terms of reference.

7.2. Model input (parameters)

The impact of the tMLs was assessed considering the results from FranceAgriMer collector survey, the only source of information considered suitable for such assessment. This survey provides a representative overview of DON, FUMO and ZON in the 2013 French maize grains harvest, which represents around 25 % of the maize grains produced in the European Union. In this assessment, it was assumed that such data are also representative of maize grains at the European level. However, results from the Euromaisiers data, which provide a better overview at European level, showed higher DON and FUMO levels and lower ZON levels in maize grains than those observed in the FranceAgriMer survey. Such differences may be explained by differences in the analytical techniques used. They can also reveal a variability of contamination of maize grains used for food processing at the European level, which come not only from France but also from other European and non European countries, which are not covered by the FranceAgriMer survey. As a consequence, the impact of tML on DON, FUMO and ZON occurrence and exposure levels at the European level may have been under or over estimated.

In order to assess the impact of tML in maize milling products, transfer rates from grains to milling products were used, set at the ratio between the tML defined for maize milling products and one defined for unprocessed maize grain. Such transfer rates are considered to reflect average transfer observed in maize milling products made from the 2013 maize grains harvest. However, according to information provided by the requestor, high variability was observed regarding the transfer of DON and FUMO from grains to grain milling products with particle size below 500 µm, from 0.25 to 1.1 for DON and from 0.7 to 1.4 for FUMO. Considering on a worst case basis a transfer rate of 1.1 for DON and 1.4 for FUMO in grain milling products with particle size below 500 µm, the average level in DON and FUMO in grain milling products would be around 10 % higher and exposure levels up to 4 % higher when considering current ML than occurrence and exposure levels estimated with the average transfer rates considered in this assessment.

In order to assess the impact of tML in maize-based products, it was assumed that other ingredients composing the products were not containing DON, FUMO and ZON. This may have lead to an underestimation of the occurrence and exposure levels. Any processing effect on DON, FUMO and ZON levels was also not considered. According to previous statements (EFSA CONTAM Panel, 2011, 2013), DON and ZON were found to be quite stable during cooking. However, extrusion cooking would decrease ZON levels. As a consequence, the impact of tML on DON, FUMO and ZON occurrence in maize-based products may have been over estimated.

DON and FUMO levels considered in the present statement were originating from different analytical techniques (ELISA and HPLC). On one hand, results from ELISA cover compounds (DON derivatives, FB_3) which are not included in the current definition of the ML, leading to a potential overestimation of the non-compliance rates in maize and maize-based products and bias in the impact of tML on occurrence and exposure levels. On the other hand, results from HPLC cover the parent DON compound and the sum of FB1 and FB2 only, which differs from the definition of the HBGVs considered in the present statement, leading to a potential underestimation of the risk of exposure.

7.3. Exposure model/exposure scenarios

While assessing the impact of the current MLs and tMLs on occurrence and exposure levels, it was assumed that non compliant products would not be on the European market. This is considered to be an optimistic scenario, which may have lead to potential underestimation of occurrence and exposure levels.

The impact of the tMLs on occurrence and exposure levels has been assessed independently for the three mycotoxins, without considering potential correlations (positive or negative) between them. The effect of potential correlations was roughly assessed considering the data from FranceAgriMer survey, which provided results for all three mycotoxins in each sample. The average occurrence level in grains and grains milling products were estimated after the exclusion of samples non compliant for at least one out of the three mycotoxins. This analysis revealed that average levels in maize grains and milling products estimated independently for each 44eoxynival after the exclusion of samples non compliant to the current level were around 5 - 6 %, 26 - 41 % and 7 - 8 % higher than the average levels estimated considering the correlations between the mycotoxins, for DON, FUMO and ZON respectively. The impact of tMLs on DON and ZON levels were in the same ranges considering or not the correlations between the three mycotoxins. It was higher for FUMO, estimated at 41 – 65 % increase when considering the correlations between the three mycotoxins compared to 7 – 23 % increase when assessed independently.

In both chronic and acute exposure assessments, two extreme scenarios (LB – UB) were made regarding the results below the LOD/LOQ. True exposure levels are considered to be comprised between the LB and UB estimates provided. Big differences between the LB and UB estimates were observed for ZON, due to high LOQs associated with censored data.

In the acute exposure scenario done at the ingredients level, it was assumed that all the maize grains or maize milling products present in all maize-based foods consumed during the same day contain DON at the current ML and tML. This scenario is considered as a worst-case scenario, as processed maize-based products such as maize-based breakfast cereals or snacks are most often bought as such and the probability that their ingredients are simultaneously at a level equal to the ML is low.

In the acute exposure scenario done at the processed maize-based products level, each kind of maize-based products was considered independently. This scenario may underestimate some situations of high exposure resulting from the consumption of several products simultaneously containing high DON concentrations. However, in the recent EFSA report on DON in food and feed, it was shown that in most cases the events of DON acute exposure above the group ARfD were explained by the consumption of one single food.

In all exposure scenarios, it was considered that sweet corn, maize oil, maize syrup, as well as foods for infants and young children and some alcoholic beverages made from maize grains would not be impacted by the higher levels of DON, FUMO and ZON observed in the 2013 maize grain harvest. This may have lead to an underestimation of the total exposure levels.

A number of food groups (products of animal origin, starchy roots and tubers, fruits, nuts and oilseeds, vegetables (sweet corn excepted), beverages (beer excepted), animal and vegetable oils and fats (vegetable oil excepted), herbs spices and condiments, sugar and confectionary, juice and herbal tea for infants and young children, composite dishes other than cereal, rice and vegetable based, desserts) have not been taken into account in the exposure assessments. However, the contribution of such food groups to the total DON, ZON and FUMO exposure is expected to be low.

Subjects suffering from celiac disease can be considered as specific population group due to potentially high consumption habits of maize and maize-based products. Risk of exposure could not be specifically characterized for this population group, but was approached considering high exposure levels (95th percentile) estimated in the general population. Considering the low prevalence of celiac disease in the general population – at 1 % – the 95th percentile of exposure of the general population may provide an underestimation of the high exposure levels that may be observed in this population group.

7.4. Other uncertainties

Overall, all the uncertainties identified in previous assessments of DON, FUMO and ZEA (EFSA, CONTAM Panel, 2011; FAO/WHO, 2011, 2012,) as regards toxicity assessment are also applicable for the present statement and are therefore not repeated here. An additional uncertainty for the present assessment results from the fact that calculations have been carried out for chronic i.e. lifelong daily exposure while possibly increased exposures (due to a temporary increase are only to be expected for a short period (i.e. until end of 2014).

7.5. Summary of uncertainties

In Table 16, a summary of the uncertainty evaluation is presented, highlighting the main sources of uncertainty and indicating an estimate of whether the respective source of uncertainty might have led to an over- or underestimation of the exposure or the resulting risk.

Table 16: Summary of qualitative evaluation of the impact of uncertainties on the risk assessment of the dietary exposure to DON, FUMO and ZON

Source of uncertainty	Direction of uncertainty[(a)]		
	DON	FUMO	ZON
Calculations have been carried out for chronic i.e. lifelong daily exposure while increased exposures are only to be expected for a short period (i.e. until end of 2014)	+	+	+
Lack of representativeness of occurrence data for the European level	+/-	+/-	+/-
Variability of transfer coefficient from maize grains to maize milling products not considered	+/-	+/-	+/-
Correlation between DON, ZON and FUMO levels in foods not considered	+/-	+/-	+/-
Influence of food processing on DON, ZON, FUMO stability not considered	+	+	+
Broad range of LOQs, especially for ZON	-	-	+
Use of LB data in the chronic exposure assessment	-	-	-
Use of UB data in the chronic exposure assessment	+	+	+
Use of UB background levels in the acute exposure assessment	+	N.A	N.A
Heterogeneity of the data regarding DON derivatives and conjugates and FUMO compounds to exposure	+/-	+/-	N.A
Subjects suffering from celiac disease not considered as a specific population group	-	-	-

(a): + = uncertainty with potential to cause over-estimation of exposure/risk; - = uncertainty with potential to cause underestimation of exposure/risk; N.A. = not applicable

The impact of the uncertainties on the assessment of the risk for public health related specifically to a potential temporary derogation from the maximum levels of DON, ZON and FUMO for maize and maize products is substantial.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Impact of the tMLs on the occurrence levels and dietary exposure

- Occurrence data on deoxynivalenol (DON), zearalenone (ZON) and fumonisins (FUMO) in maize grains and maize milling products from the 2013 harvest originating from three different sources (FranceAgriMer collector survey, IRTAC Cereal Sanitary Monitoring Plan, and Euromaisiers) were provided with the request. Depending on the source, maize samples were taken at the maize collector and/or at maize milling factory. Data were mainly coming from France. DON, ZON and FUMO were analysed with enzyme-linked immunosorbent assays (ELISA) and high-performance liquid chromatography (HPLC). This represented a total of 2,637 analytical results.

- Existing occurrence data on DON, ZON and FUMO compiled in previous risk assessments conducted by the European Food Safety Authority (EFSA) and by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) were also considered. These were mainly corresponding to results from official monitoring programmes, collected over a 5 - 10 years period between 2000 and 2012, and reported by up to 21 European countries. This represented a total of 39,202 analytical results.

- Mean DON, ZON and FUMO levels in maize grains and maize milling products estimated from the datasets provided with the request appeared to be 1.3 to 6 times higher compared to mean levels considered in previous assessments.

- The impact of a temporary derogation from the maximum levels (tMLs) of DON, ZON and FUMO for maize and maize products was assessed considering the data from FranceAgriMer survey which was the most suitable source of information for such assessment. This represented a total of 663 analytical results, 221 results for each deoxynivalenol. Transfer rates from grain to grain milling products were assumed to correspond to the ratio between the tML defined in the grain milling products and the tML defined for the unprocessed grains.

- Compared to the current MLs, it was estimated that the tMLs would increase mean MB levels of DON, ZON and FUMO in unprocessed maize grains and milling fractions by 16 – 18 %, 25 – 27 % and 7.6 – 23 % respectively. Depending on the kind of ingredient and its percentage content in final processed/composite products, the mean middle bound (MB) levels of DON and FUMO in final processed/composite products were increased by 12 – 58 %, whereas mean MB levels of ZON were increased by 25 – 99 %.

- The chronic dietary exposure to DON of children age groups (‘infants’, ‘toddlers’ and ‘other children’) estimated with occurrence data reflecting current MLs ranged on average between 0.22 and 1.11 µg/kg body weight (b.w.) per day (minimum lower bound (LB)-maximum upper bound (UB)) and at the 95th percentile between 0.94 and 2.10 µg/kg b.w. per day. The chronic dietary exposure to DON of the adult age groups (adolescents, adults, elderly and very elderly) ranged on average between 0.18 and 0.56 µg/kg b.w. per day and at the 95th percentile between 0.38 and 1.01 µg/kg b.w. per day.

- Depending on the survey and age group, the mean and 95th percentile chronic dietary exposure to DON estimated with the occurrence data reflecting tML were up to 20 % higher than the levels estimated with the occurrence data reflecting current ML.

- The chronic dietary exposure to ZON of children age groups estimated with occurrence data reflecting current MLs ranged on average between 9.7 and 118 ng/kg b.w. per day (minimum LB-maximum UB) and at the 95th percentile between 47 and 303 ng/kg b.w. per day. The chronic dietary exposure to ZON of the adult age groups ranged on average between 4.4 and 64 ng/kg b.w. per day and at the 95th percentile between 11 and 117 ng/kg b.w. per day.

- Depending on the survey and age group, the mean and 95th percentile chronic dietary exposure to ZON estimated with the occurrence data reflecting tML were up to 83 % higher than the levels estimated with the occurrence data reflecting current ML.

- The chronic dietary exposure to FUMO of children age groups estimated with occurrence data reflecting current MLs ranged on average between 0.17 and 2.11 µg/kg b.w. per day (minimum LB-maximum UB) and at the 95th percentile between 0.54 and 4.39 µg/kg b.w. per day. The chronic dietary exposure to FUMO of the adult age groups ranged on average between 0.03 and 1.19 µg/kg b.w. per day and at the 95th percentile between 0.08 and 2.30 µg/kg b.w. per day.

- Depending on the survey and age group, the mean and 95th percentile chronic dietary exposure to FUMO estimated with the occurrence data reflecting tML were up to 17 % higher than the levels estimated with the occurrence data reflecting current ML.

- Acute exposure scenarios addressed people who would consume maize grains, maize milling products, maize-based breakfast cereals, maize-based snacks and maize-based pastries containing DON equal to the ML. Such assessment resulted in a very low percentage of consumption days above the group acute reference dose (ARfD) (< 1%) for all products except the maize-based pastries, whatever the ML (current, tML) considered. For maize-based pastries, percentage of consumption days above the group ARfD estimated up to 1.2 % with the current ML was increased up to 8.1 % considering the tML, with a maximum acute exposure level estimated at 20.8 µg/kg b.w.

Risk characterisation

- The exceedance of the group PMTDI (provisional maximum tolerable daily intake) for DON is higher in the children than in the adults age groups, ranging between 2.7 and 52 % (minimum LB to maximum UB) when considering the current MLs. When considering the tMLs, this is slightly increased and estimated to range between 4.2 and 54 %.

- The results obtained suggest a low impact of a temporary increase in MLs for chronic exposure levels of DON in all age groups which is explained by the fact that overall dietary DON exposure is mainly driven by foods other than maize-based ones. However, both application of current and increased MLs lead to average exposures in the region of the group PMTDI of 1 µg/kg b.w. per day especially in the 'toddlers' age group.

- The percentage of consumption days above the group ARfD estimated up to 1.2 and 8.1 % with the current MLs and tMLs, respectively, indicates a potential concern resulting from the consumption of maize-based pastries containing high DON level for the children age groups.

- Although the mandate from the Commission for the present assessment concerns FB_1 and FB_2, based on the occurrence data available the present assessment was based on total fumonisin occurrence data. Taking into account that most toxicological assessments and also the PMTDI are derived mainly from data with FB_1 and the structural similarities of the different fumonisin derivatives of relevance, this is considered acceptable.

- The exceedance of the PMTDI defined for FUMO is the higher in the children than in the adults age groups, ranging between 0 and 47 % (minimum LB to maximum UB) when considering current ML. When considering tML, this is slightly increased and estimated to range between less than 0.1 % and 48 %.

- Results show that a temporary increase in MLs has only a very minor impact on exposure levels of FUMO and consequently on any risk estimates. However, when applying the current MLs, the exposure levels of FUMO are already in the region of the PMTDI of 2 µg/kg b.w. per day in several age groups, being highest in ’other children’ age group.

- The exceedance of the TDI for ZON is the higher in the children than in the adults age groups, ranging between 0 and 9.2 % (minimum LB to maximum UB) when considering the current MLs. When considering the tMLs, this is slightly increased and estimated to range between 0 and 9.8 %.

- Exposure levels for ZON both with current and increased ML levels are around or above the TDI for the age groups of infants, toddlers and other children and thus might be considered as being a health concern. It is important to add in also in the context of this statement that although no acute reference value has been derived for ZON in a previous assessment (EFSA CONTAM Panel, 2011) it is possible that elevated circulating levels of oestrogens could lead to adverse effects either from long term exposure but also from short-term exposure during a sensitive stage of development. The impact of the increased ML for ZON needs to be considered in the light of these conclusions.

- It was assumed that increased exposure of individuals suffering from celiac disease due to a temporary increase of MLs for DON, FUMO and ZON for maize and maize products were reflected in the high exposure levels (95th percentile) estimated for the general population.

RECOMMENDATIONS

- There is a need to better assess the DON, ZON and FUMO levels in maize grains and maize milling products from the 2013 harvest coming from other countries than France and used for food processing at the European level.

DOCUMENTATION PROVIDED TO EFSA

1. DOSSIER DEROGATION MAIS - 22-04-14.pdf (22 April 2014)
2. DOSSIER DEROGATION MAIS - Annexes - 22-04-14.pdf (22 April 2014)
3. Données maïs récolte 2013_FranceAgriMer_Arvalis_avec tonnages.xls (29 April 2014)
4. DOSSIER DEROGATION MAIS - 28-04-14 - EN.pdf (29 April 2014)
5. DOSSIER DEROGATION MAIS - 28-04-14.pdf (29 April 2014)
6. DOSSIER DEROGATION MAIS - Annexes - 28-04-14.pdf (29 April 2014)
7. DOSSIER DEROGATION MAIS - Annexes - 28-04-14_EN.pdf(29 April 2014)
8. Réponses Questions de F Verstraete sur le dossier dérogation maïs.doc (30 April 2014)
9. Données mycotoxines maïs 2013 IRTAC (070514).xls (7 May 2014)

REFERENCES

Berthiller F, Crews C, Dall'Asta C, De Saeger S, Haesaert G, Karlovsky P, Oswald IP, Seefelder W, Speijers G and Stroka J, 2013. Masked mycotoxins : A review. Molecular Nutrition and Food Research, 57, 165-186.

Collins TF, Sprando RL, Black TN, Olejnik N, Eppley RM, Hines FA, Rorie J and Ruggles DI, 2006. Effects of deoxynivalenol (DON, vomitoxin) on *in utero* development in rats. Food and Chemical Toxicology, 44, 747–757.

Döll S and Dänicke S, 2011. The Fusarium toxins deoxynivalenol (DON) and zearalenone (ZON) in animal feeding. Preventive Veterinary Medicine, 102, 132-145.

Edwards S, Cantley TC, Rottinghaus GE, Osweiler GD and Day BN, 1987. The effects of zearalenone on reproduction in swine. I. The relationship between ingested zearalenone dose and anestrus in nonpregnant, sexually mature gilts. Theriogenology, 28, 43-49.

EFSA (European Food Safety Authority), 2006. Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. The EFSA Journal 2006, 438, 1-54. Doi:10.2903/j.efsa.2006.438

EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. doi:10.2903/j.efsa.2011.2097

EFSA (European Food Safety Authority), 2013. Deoxynivalenol in food and feed: occurrence and exposure. EFSA Journal 2013;11(10):3379, 56 pp. doi:10.2903/j.efsa.2013.3379

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2011. Scientific Opinion on the risks for public health related to the presence of zearalenone in food. EFSA Journal 2011;9(6):2197, 124 pp. doi:10.2903/j.efsa.2011.2197

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

FAO/WHO (Food and Agriculture Organization - World Health Organization), 2000. Zearalenone. Prepared by the Fifty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In: Safety Evaluation of Certain Food Additives and Contaminants, WHO Food Additives Series 44. International Programme on Chemical Safety, World Health Organization, Geneva.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization), 2001. Safety evaluation of certain food additives and contaminants. Deoxynivalenol. WHO Food Additives Series, 47. Available at: http://www.inchem.org/documents/jecfa/jecmono/v47je05.htm.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization), 2002.Evaluation of certain mycotoxins in food. Fumonisins. WHO Technical Report Series, 906, 16 -27.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization), 2011. Safety evaluation of certain food additives and contaminants. Deoxynivalenol. WHO Food Additives Series, 63, 317-485.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization), 2012. Safety evaluation of certain food additives and contaminants. Fumonisins. WHO Food Additives Series, 65, 325- 794.

Huybrechts I, Sioen I, Boon PE, Ruprich J, Lafay L, Turrini A, Amiano P, Hirvonen T, De Neve M, Arcella D, Moschandreas J, Westerlund A, Ribas-Barba L, Hilbig A, Papoutsou S, Christensen T, Oltarzewski M, Virtanen S, Rehurkova I, Azpiri M, Sette S, Kersting M, Walkiewicz A, Serra-

Majem L, Volatier JL, Trolle E, Tornaritis M, Busk L, Kafatos A, Fabiansson S, De Henauw S and Van Klaveren J, 2011. Dietary Exposure Assessments for Children in Europe (the EXPOCHI project): rationale, methods and design. Archives of Public Health, 69, 12 pp.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2011. Evaluation of certain food additives and contaminants. Seventy fourth report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series n°966, 70-94.

Merten C, Ferrari P, Bakker M, Boss A, Hearty A, Leclercq C, Lindtner O, Tlustos C, Verger P, Volatier JL and Arcella D, 2011. Methodological characteristics of the national dietary surveys carried out in the European Union as included in the European Food Safety Authority (EFSA) Comprehensive European Food Consumption Database, Food Additives and Contaminants. Part A, 28, 975-995.

Marin S, Ramos AJ, Cano-Sancho G and Sanchis V, 2013. Mycotoxins: Occurrence, toxicology, and exposure assessment. Food and Chemical Toxicology, 60, 218-237.

Mustalahti K, Catassi C, Reunanen A, Fabiani E, Heier M, McMillan S, Murray L, Metzger MH, Gasparin M, Bravi E, Maki M and Coeliac EU Cluster, Project Epidemiology, 2010. The prevalence of celiac disease in Europe: results of a centralized, international mass screening project. Annals of Medicine, 42, 587-595.

NTP (National Toxicology Program), 1982. NTP Carcinogenesis Bioassay of Zearalenone in F 344/N Rats and F6C3F1 Mice (Technical Report Series No. 235), Research Triangle Park, North Carolina, Department of Health and Human Services.

Ran R, Wang C, Han Z, Wu A, Zhang D and Shi J, 2013. Determination of deoxynivalenol (DON) and its derivatives: Current status of analytical methods. Food Control, 34, 138-148.

SCF (Scientific Committee on Food), 1999. Opinion on *Fusarium* toxins. Part 1: Deoxynivalenol (DON). SCF/CS/CNTM/MYC/19, 1-9.

SCF (Scientific Committee for Food), 2000a. Opinion on *Fusarium* Toxins. Part 3: Fumonisin B_1 (FB1). SCF/CS/CNTM/MYC/ 24 FINAL, 1- 33.

SCF (Scientific Committee on Food), 2000b. Opinion on *Fusarium* toxins. Part 2: Zearalenone (ZEA). SCF/CS/CNTM/MYC/22 Rev 3 Final, 1-12.

SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on food on *Fusarium* toxins. Part 6: Group evaluation of T-2 toxin, HT-2 toxin, nivalenol and deoxynivalenol. SCF/CS/CNTM/MYC/27, 1-12.

SCF (European Commission), 2003. Updated opinion of the Scientific Committee on Food on Fumonisin B_1, B_2 and B_3. SCF/CS/CNTM/MYC/28 Final, 1 – 4.

Shin BS, Hong SH, Bulitta JB, Hwang SW, Kim HJ, Lee JB, Yang SD, Kim JE, Yoon HS, Kim do J and Yoo SD, 2009. Disposition, oral bioavailability, and tissue distribution of zearalenone in rats at various dose levels. Journal of Toxicology and Environmental Health. Part A, 72, 1406-1411.

Sprando RL, Collins TF, Black TN, Olejnik N, Rorie JI, Eppley RM and Ruggles DI, 2005. Characterization of the effect of deoxynivalenol on selected male reproductive endpoints. Food and Chemical Toxicology, 43, 623-635.

Varga E, Malachova A, Schwartz H, Krska R and Berthiller F, 2013. Survey of deoxynivalenol and its conjugates deoxynivalenol-3-glucoside and 3-acetyl-deoxynivalenol in 374 beer samples. Food Additives and Contaminants. Part A, 30, 137-146.

WHO/IPCS (World Health Organization/International Programme on Chemical Safety Evaluation), 2008. Uncertainty and Data Quality in Exposure Assessment. Part 1: Guidance document on Characterizing and communicating uncertainty in exposure assessment. Part 2: Hallmarks of data quality in chemical exposure assessment. Available at: http://www.who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf.

Appendix A: Mean levels of DON, ZON and FUMO reported in previous assessments in other foods than maize-based ones

Table A1: Grains and grain-based products

Foodex level	Food groups	Concentration LB – UB (µg/kg) DON	ZON	FUMO
	Grains for human consumption			
4	Wheat germ	410	2.4 - 5.4	11.0 - 39.5
4	Wheat grain, Durum	319 - 351	2.4 - 5.4	11.0 - 39.5
4	Wheat grain, soft	137	2.4 - 5.4	11.0 - 39.5
4	Bulgur wheat	0 - 15.5	2.4 - 5.4	18.5 - 146
4	Wheat grain, unspecified	197	2.4 - 5.4	11.0 - 39.5
3	Barley grain	27.8 - 73.2	2.6 - 5.6	18.5 - 146
3	Rye grain	17.9 - 58.4	0.7 - 3.4	28.1 - 66.4
3	Spelt grain	14.4 - 51.6	0.3 - 3.5	18.5 - 146
3	Oats, grain	256	2.0 - 3.7	18.5 - 146
3	Rice	14.4 - 51.6	3.8 - 9.7	0 - 115
3	Other grains	14.4 - 51.6	0.9 - 3.4	18.5 - 146
3	Grains for human consumption, unspecified	127 - 156	2.7 - 5.7	102 - 161
	Grain milling products			
4	Wheat flour, brown	73.2	4.9 - 13	0 - 108
4	Wheat flour, Durum	150	4.9 - 13	0 - 108
4	Wheat flour, white	141	1.8 - 9.3	0 - 67.0
4	Wheat flour, wholemeal	134	1.5 - 4.7	0 - 108
4	Graham flour	71.7	4.9 - 13	0 - 108
4	Wheat flour, gluten free	152	4.9 - 13	0 - 108
4	Couscous	71.7	4.9 - 13	188 - 273
4	Wheat bran	226	18 - 33	188 - 273
4	Wheat groats	152	4.9 - 13	188 - 273
4	Wheat semolina, Durum	330	0.1 - 3.0	188 - 273
4	Wheat semolina, soft wheat	59.2 - 98.9	0.2 - 6.6	188 - 273
4	Wheat starch	152	4.9 - 13	0 - 67.0
4	Wheat milling products, unspecified	152	4.9 - 13	73.5 - 152
3	Rye milling products	33.1 - 64.1	0.9 - 4.4	0 - 37.4
3	Buckwheat milling products	6.7 - 55.3	0.4 - 3.5	71.9 - 120
3	Oat milling products	74.8	2.9 - 9.0	71.9 - 120
3	Rice milling products	79.3 - 108	2.8 - 10	71.9 - 120
3	Spelt milling products	61.6 - 87.8	0.3 - 3.6	0 - 72.3
3	Barley flour	22.2 - 34.2	2.8 - 10	71.9 - 120
ahg 3	Other milling products	79.3 - 108	2.8 - 10	71.9 - 120
3	Grain milling products, unspecified	125	5.4 - 12	279 - 315
	Bread and rolls			
3	Wheat bread and rolls	83.1	0.2 - 4.7	0 - 132
3	Rye bread and rolls	60.3	0.2 - 3.5	145 - 159
3	Mixed wheat and rye bread and rolls	64.0	0.9 - 4.5	67.4 - 83.6
3	Multigrain bread and rolls	81.3	0.6 - 4.1	112 - 199
3	Unleavened bread, crisp bread and rusk	48.7	0.5 - 3.8	79.1 - 181
3	Other bread	69.9	1.1 - 7.7	96.3 - 141
3	Bread products	124	0.9 - 5.2	112 - 199
3	Bread and rolls, unspecified	71.6	0.9 - 5.2	112 - 199
	Pasta			
3	Glass noodle	109	0.6 - 5.8	137 - 201
3	Noodle, rice	85.7 - 113	0.6 - 5.8	137 - 201
ahg 3	Pasta and noodle, wheat flour	120	0.6 - 5.8	137 - 201
3	Pasta, mixed cereal flour	85.7 - 113	0.6 - 5.8	137 - 201

Table A1: Continued

Foodex level	Food groups	Concentration LB – UB (µg/kg)		
		DON	ZON	FUMO
3	Pasta, rye flour	109	0.6 - 5.8	137 - 201
3	Pasta, spelt wholemeal	85.7 - 113	0.6 - 5.8	137 - 201
ahg 3	Pasta, wheat wholemeal	49.3 - 94.6	0.6 - 5.8	137 - 201
3	Pasta, gluten free	109	0.6 - 5.8	137 - 201
3	Pasta (Raw), unspecified	109	0.6 - 5.8	137 - 201
	Breakfast cereals			
4	Barley flakes	109 - 132	0.3 - 6.3	0 - 99.5
4	Millet flakes	109 - 132	0.3 - 6.3	0 - 99.5
4	Mixed cereal flakes	109 - 132	0.3 - 6.3	0 - 99.5
ahg 4	Oat and oat bran flakes	132	0.5 - 3.1	9.30 - 95.1
ahg 4	Rice flakes	109 - 132	0.3 - 6.3	22.5 - 133
4	Spelt flakes	25.2 - 47.3	0 - 4.8	0 - 57.8
ahg 4	Wheat and wheat germs flakes	95.3	8.4 - 23	18.1 - 143
4	Cereal flakes, unspecified	84.9 - 115	2.2 - 10	36.4 - 80.9
ahg 4	Rice, popped	40.8 - 92.4	0.3 - 6.3	22.5 - 133
ahg 4	Wheat, popped	40.8 - 92.4	0.3 - 6.3	18.1 - 143
4	Popped cereals, unspecified	40.8 - 92.4	0.3 - 6.3	41.0 - 84.8
4	Barley grits	326 - 355	2.6 - 3.9	0 - 99.5
4	Oat grits	326 - 355	2.6 - 3.9	9.30 - 95.1
4	Rye grits	326 - 355	2.6 - 3.9	15.3 - 46.3
4	Spelt grits	326 - 355	2.6 - 3.9	0 - 57.8
4	Wheat grits	326 - 355	2.6 - 3.9	18.1 - 143
4	Grits, unspecified	326 - 355	2.6 - 3.9	41.0 - 84.8
4	Oat porridge	42.9 - 70.7	0.3 - 6.3	9.30 - 95.1
4	Rice porridge	42.9 - 70.7	0.3 - 6.3	22.5 - 133
4	Wheat semolina porridge	42.9 - 70.7	0.3 - 6.3	18.1 - 143
4	Barley porridge	42.9 - 70.7	0.3 - 6.3	0 - 99.5
4	Porridge, unspecified	42.9 - 70.7	0.3 - 6.3	41.0 - 84.8
4	Breakfast cereals, unspecified	60.5 - 91.3	1.2 - 5.7	41.0 - 84.8
	Fine bakery wares			
2	**Pastries and cakes**	**81.6**	**1.4 - 4.8**	**109 - 164**
ahg 3	Biscuits, salty	120	5.8 - 9.0	114 - 162
ahg 3	Biscuits, sweet	47.0	5.8 - 9.0	110 - 165
3	Biscuits, unspecified	68.9	5.8 - 9.0	110 - 165
2	**Fine bakery wares, unspecified**	**72.7**	**4.2 - 7.7**	**109 - 164**
	Other			
2	**Grains and grain-based products, unspecified**	**115**	**2.7 - 5.7**	**170- 215**

DON: deoxynivalenol; FUMO: fumonisins; LB: lower bound; UB: upper bound; ZON: zearalenone.

Table A2: Other food groups

Foodex level	Food groups	Concentration LB – UB (µg/kg) DON	ZON	FUMO
	Vegetables and vegetable products			
3	Sweet corn (Zea mays var. saccharata)	32.0 - 53.2	1.4 - 4.8	80.9 - 102
Not taken into account in the exposure assessment: Vegetables and vegetable products other than sweet corn				
	Legumes, nuts and oilseeds			
2	**Legumes, beans, dried**	**0 - 9.90**	**0**	**0**
Not taken into account in the exposure assessment: Legumes, nuts and oilseeds other than legumes, beans dried				
	Animal and vegetable fats and oils			
3	Corn oil	0	90	0
3	Wheat germ oil	0	31 - 35	0
ahg 3	Other vegetable oil	0	10 - 20	0
3	Vegetable oil, unspecified	0	70 - 72	0
Not taken into account in the exposure assessment: Animal and vegetable fats other than vegetable oils				
	Alcoholic beverages			
2	**Beer and beer-like beverages**	**0**	**0.1 - 1.0**	**0**
Not taken into account in the exposure assessment: Alcoholic beverages other than beer and beer-like beverages				
	Foods for infants and young children			
2	**Infant formulae, powder**	**0 - 26.3**	**0.3 - 8.2**	**0**
2	**Infant formulae, liquid**	**0 - 3.30**	**0 - 0.9**	**0**
2	**Follow-on formulae, powder**	**0 - 26.3**	**0.2 - 11**	**0**
2	**Follow-on formulae, liquid**	**0 - 3.30**	**0 - 1.4**	**0**
3	Simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids	10.0 - 45.6	0.2 - 6.0	1.00 - 205
3	Cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid	10.0 - 45.6	0.2 - 6.0	9.10 - 90.1
3	Biscuits, rusks and cookies for children	10.0 - 45.6	0.2 - 6.0	3.40 - 92.5
3	Pasta for children	10.0 - 45.6	0.2 - 6.0	2.90 - 98.1
3	Cereal-based food for infants and young children, unspecified	10.0 - 45.6	0.2 - 6.0	2.90 - 98.1
2	**Ready-to-eat meal for infants and young children**	**2.80 - 40.6**	**0 - 5.5**	**0**
2	**Yoghurt, cheese and milk-based dessert for infants and young children**	**0 - 25.6**	**0**	**0**
ahg 2	**Food for infants and small children, unspecified**	**11.1 - 38.3**	**0.3 – 7.0**	**3.20 - 99.9**
Not taken into account in the exposure assessment: Fruit juice and herbal tea for infants and young children				
	Products for special nutritional use			
2	**Food for weight reduction**	**0**	**1.5 - 4.2**	**0**
3	Fiber supplements	38.9 - 56.3	1.5 - 4.2	0
ahg 3	Dietary supplements, other and unspecified	0	1.5 - 4.2	0
2	**Food for sports people (labelled as such)**	**0**	**1.5 - 4.2**	**0**
3	Fine bakery products for diabetics	38.9 - 56.3	1.5 - 4.2	0
ahg 3	Dietetic food for diabetics, other and unspecified	0	1.5 - 4.2	0
3	Nutritionally complete formulas	38.9 - 56.3	1.5 - 4.2	0
3	Nutritionally incomplete formulas	38.9 - 56.3	1.5 - 4.2	0
ahg 3	Medical food, other and unspecified	0	1.5 - 4.2	0
ahg2	**Products for special nutritional use, unspecified**	**38.9 - 56.3**	**1.5 - 4.2**	**0**

Table A2: Continued

Foodex level	Food groups	Concentration LB – UB (µg/kg) DON	ZON	FUMO
	Composite dishes			
2	**Cereal-based dishes**	**33.3**	**0**	**290 - 337**
2	**Rice-based meals**	**33.3**	**0**	**0**
2	**Vegetable-based meals**	**33.3**	**0**	**0**
2	**Composite food, unspecified**	**33.3**	**0**	**290 - 337**
Not taken into account in the exposure assessment: Composite dishes other than cereal, rice and vegetable based				
	Snacks, desserts and other foods			
3	Potato crisps	86.1	2.6 - 12	0
3	Pretzels	86.1	2.6 - 12	0
3	Fish-based snacks	86.1	2.6 - 12	0
3	Seafood chips	86.1	2.6 - 12	0
ahg 3	Snack food, unspecified	110	2.6 - 12	52.6 - 163
Not taken into account in the exposure assessment: Desserts, other foods				
	Other food groups			
Not taken into account in the exposure assessment: juice, water and non alcoholic beverages, eggs and egg products, fish and other seafood, fruit and fruit products, herbs, spices and condiments, meat and meat products, milk and dairy products, starchy roots and tubers, sugars and confectionary.				

DON: deoxynivalenol; FUMO: fumonisins; LB: lower bound; UB: upper bound; ZON: zearalenone.
Note: The numbers for the occurrence values are all given with 2 figures for ZON and 3 figures for DON and FUMO, but this does not reflect precision.

Appendix B: Maize consumption habits in the European population

Table B1: Overview on ‘Maize grain’ consumption (g/day) by age class. Minimum, median and maximum of the mean and 95^{th} percentile values across European countries and dietary surveys are shown.

	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
			All population (chronic exposure assessment)				
Average (g/day)							
Minimum	0	< 0.05	0.1	0.2	0.1	0	0
Median	-[a]	< 0.05	0.5	0.9	0.5	< 0.05	< 0.05
Maximum	< 0.05	0.9	2.6	1.9	2.9	0.2	0.5
95^{th} percentile (g/day) [b]							
Minimum	0	0	0	0	0	0	0
Median	-[a]	0	0	0	0	0	0
Maximum	0	0	7.3	12	15	< 0.05	< 0.05
			Consumption days (acute exposure assessment)				
Percentage of consumption days							
Minimum	0	0	0.1	0.3	0	0	0
Median	-[a]	0.7	1.3	1.8	0.5	< 0.05	0
Maximum	0.1	2.9	5.8	4.5	7.5	0.3	1.3
Average (g/day)							
Minimum	18	3.0	11	22	10	4.8	3.0
Median	-[a]	20	41	51	57	33	41
Maximum	18	32	200	150	132	112	63
95^{th} percentile (g/day) [b]							
Minimum	-[b]	-[b]	30	75	75	-[b]	-[b]
Median	-[a,b]	-[b]	50	88	100	-[b]	-[b]
Maximum	-[b]	-[b]	100	100	200	-[b]	-[b]

(a): no median value is derived as there are only two surveys available for the infants’ age class.
(b): The 95^{th} percentile estimates obtained on dietary surveys/age classes with less than 60 observations may not be statistically robust (EFSA, 2011) and therefore they were not included in this table.
Note: The numbers for the consumption values are all given with 2 figures but this does not reflect precision. A “0” indicates the absence of consumption.

Table B2: Overview on 'Maize milling fractions ≤ 500 µm' consumption (g/day) by age class. Minimum, median and maximum of the mean and 95th percentile values across European countries and dietary surveys are shown.

	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
All population (chronic exposure assessment)							
Average (g/day)							
Minimum	0	0.1	< 0.05	< 0.05	0.1	< 0.05	< 0.05
Median	-[(a)]	0.2	1.0	1.2	1.2	0.6	0.8
Maximum	0.1	1.0	2.6	7.5	4.1	2.3	1.9
95th percentile (g/day)[(a)]							
Minimum	0	0.4	0	0	0	0	0
Median	-[(a)]	3.7	4.8	6.0	6.1	3.2	7.9
Maximum	0	5.2	12	40	24	17	9.9
Consumption days (acute exposure assessment)							
Percentage of consumption days							
Minimum	0	0.9	0.6	0.7	0	0.3	0.4
Median	-[(a)]	7.8	12	10	8.8	6.0	6.2
Maximum	1.9	22	25	20	28	21	18
Average (g/day)							
Minimum	4.5	2.7	2.5	3.5	2.7	3.0	0.1
Median	-[(a)]	5.1	8.5	11	13	11	10
Maximum	4.5	16	20	39	44	26	31
95th percentile (g/day)[(a)]							
Minimum	-[(b)]	11	14	21	9.0	10	17
Median	-[(a,b)]	12	28	32	31	24	19
Maximum	-[(b)]	27	56	64	80	32	32

(a): no median value is derived as there are only two surveys available for the infants' age class.

(b): The 95th percentile estimates obtained on dietary surveys/age classes with less than 60 observations may not be statistically robust (EFSA, 2011) and therefore they were not included in this table.

Note: The numbers for the consumption values are all given with 2 figures but this does not reflect precision. A "0" indicates the absence of consumption.

Table B3: Overview on 'Maize milling fractions > 500 µm' consumption (g/day) by age class. Minimum, median and maximum of the mean and 95th percentile values across European countries and dietary surveys are shown.

	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
All population (chronic exposure assessment)							
Average (g/day)							
Minimum	0	0	< 0.05	< 0.05	0.2	< 0.05	0.1
Median	-[(a)]	0.5	2.0	1.6	1.1	0.3	0.4
Maximum	0.5	3.4	10	17	6.6	2.5	1.8
95th percentile (g/day)[(a)]							
Minimum	0	1.4	0	0	0	0	0
Median	-[(a)]	3.7	10	7.9	5.5	0	0
Maximum	0	20	32	50	35	16	4.4
Consumption days (acute exposure assessment)							
Percentage of consumption days							
Minimum	0.0	0.0	0.3	0.5	0.6	0.2	0
Median	-[(a)]	7.5	11	7.3	4.7	2.6	2.2
Maximum	3.0	19	36	34	19	14	17
Average (g/day)							
Minimum	17	3.8	2.8	5.5	3.8	3.8	7.2
Median	-[(a)]	12	25	32	24	13	18
Maximum	17	32	82	84	97	47	34
95th percentile (g/day) [(a)]							
Minimum	-[(b)]	12	35	57	7.7	40	40
Median	-[(a,b)]	16	60	90	76	44	40
Maximum	-[(b)]	48	80	160	150	47	40

(a): no median value is derived as there are only two surveys available for the infants' age class.
(b): The 95th percentile estimates obtained on dietary surveys/age classes with less than 60 observations may not be statistically robust (EFSA, 2011) and therefore they were not included in this table.
Note: The numbers for the consumption values are all given with 2 figures but this does not reflect precision. A "0" indicates the absence of consumption.

Appendix C: Contribution of maize-based products to the total exposure to DON, FUMO and ZON

Table C1: Minimum and maximum relative contribution (%) of maize-based products to the DON total LB exposure

Food category	Scenario	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
All maize-based products	**Current ML**	**0 - 9.3**	**2 - 18**	**4.6 - 19**	**3.4 - 26**	**2.0 - 20**	**0.5 - 9.5**	**0.3 - 8.6**
	tML	**0 - 11**	**2.6 - 21**	**6 - 26**	**4.8 - 34**	**2.8 - 26**	**0.6 - 11**	**0.5 - 9.8**
Maize grain for consumption	Current ML	0	0 - 0.3	0 - 1.1	0 - 1.3	0 - 6.2	0 - 0.2	0 - 0.9
	tML	0	0 - 0.4	0 - 1.5	0 - 1.7	0 - 8.3	0 - 0.4	0 - 1.3
Grain milling fractions ≤ 500 µm	Current ML	0 - 0.4	0 - 7.3	0 - 6.1	0 - 1.9	0 - 5.9	0 - 3.4	0 - 2.0
	tML	0 - 0.5	0 - 8.2	0 - 6.8	0 - 2.2	0 - 6.7	0.1 - 3.9	0 - 2.2
Grain milling fractions > 500 µm	Current ML	0	0 - 4.6	0 - 1.4	0 - 0.5	0 - 0.7	0 - 0.2	0
	tML	0	0 - 5.3	0 - 1.6	0 - 0.5	0 - 0.8	0 - 0.3	0
Maize-based breakfast cereal	Current ML	0 - 0.2	0 - 3.4	0 - 17	0 - 24	0.1 - 12	0 - 5.0	0.1 - 3.5
	tML	0 - 0.3	0 - 5.0	0 - 22	0.1 - 31	0.1 - 17	0 - 7.0	0.2 - 4.9
Maize-based pastries	Current ML	0 - 1.6	0 - 4.6	0 - 6.2	0 - 5.8	0 - 6.5	0 - 8.2	0 - 7.8
	tML	0 - 1.9	0 - 5.1	0 - 7.0	0 - 6.6	0 - 7.4	0 - 9.4	0 - 8.9
Maize-based snacks	Current ML	0 - 7.1	0 - 13	0.1 - 9.2	0.1 - 8.4	0.1 - 3.6	0 - 0.3	0 - 0.1
	tML	0 - 8.7	0 - 15	0.1 - 11	0.2 - 12	0.2 - 5.3	0 - 0.5	0 - 0.1
Maize bread	Current ML	0	0	0 - 0.1	0 - 0.1	0 - 1.6	0 - 0.3	0
	tML	0	0	0 - 0.1	0 - 0.1	0 - 1.8	0 - 0.3	0
Other maize-based foods	Current ML	0	0 - 1.6	0 - 1.6	0 - 0.2	0 - 0.3	0 - 0.7	0 - 0.7
	tML	0	0 - 1.8	0 - 1.9	0 - 0.3	0 - 0.3	0 - 0.8	0 - 0.8

Note: The numbers for the percentage contributions are all given with 2 figures but this does not reflect precision. A “0” indicates the absence of contribution to the total exposure.

Table C2: Minimum and maximum relative contribution (%) of maize-based products to the FUMO total LB exposure

Food category	Scenario	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
All maize-based products	**Current ML**	**0 - 8.2**	**1.3 - 17**	**2.6 - 18**	**2.2 - 16**	**1.2 - 23**	**0.6 - 13**	**0.4 - 12**
	tML	**0 - 9.8**	**1.9 - 21**	**4.0 - 22**	**3.1 - 24**	**1.7 - 30**	**0.8 - 16**	**0.7 - 15**
Maize grain for consumption	Current ML	0	0 - 0.2	0 - 1.2	0 - 0.7	0 - 5	0 - 0.2	0 - 0.8
	tML	0	0 - 0.3	0 - 1.6	0 - 0.9	0 - 6.3	0 - 0.3	0 - 1.1
Grain milling fractions ≤ 500 µm	Current ML	0 - 0.4	0 - 6.3	0 - 7.4	0 - 1.6	0 - 17	0 - 10	0 – 2.0
	tML	0 - 0.5	0 - 7.8	0 - 8.9	0 - 1.9	0 - 21	0 - 13	0 - 2.4
Grain milling fractions > 500 µm	Current ML	0	0 - 3.7	0 - 1.6	0 - 0.3	0 - 0.6	0 - 0.3	0
	tML	0	0 - 4.1	0 - 1.7	0 - 0.4	0 - 0.7	0 - 0.3	0
Maize-based breakfast cereal	Current ML	0 - 0.2	0 - 1.6	0 - 13	0 - 13	0.3 - 14	0.1 - 3.2	0.2 - 2.2
	tML	0 - 0.3	0 - 2.5	0 - 19	0 - 21	0.3 - 20	0.1 - 4.9	0.2 - 3.5
Maize-based pastries	Current ML	0 - 1.6	0 - 4.9	0 - 6.5	0 - 4.6	0 - 6.3	0 - 11	0 - 11
	tML	0 - 2.0	0 - 6.0	0 - 7.8	0 - 5.6	0 - 7.8	0 - 14	0 - 14
Maize-based snacks	Current ML	0 - 6.0	0 - 12	0.1 - 9.4	0.1 - 6.8	0.1 - 2.8	0 - 1.1	0 - 0.1
	tML	0 - 7.1	0 - 14	0.1 - 11	0.1 - 9.3	0.1 - 3.7	0 - 1.8	0 - 0.1
Maize bread	Current ML	0	0	0 - 0.1	0 - 0.1	0 - 1.5	0 - 0.3	0
	tML	0	0	0 - 0.1	0 - 0.1	0 - 1.8	0 - 0.3	0
Other maize-based foods	Current ML	0	0 - 0.9	0 - 0.9	0 - 0.2	0 - 0.2	0 - 0.8	0 - 0.8
	tML	0	0 - 1.1	0 - 1.2	0 - 0.2	0 - 0.3	0 - 0.9	0 – 1.0

Note: The numbers for the percentage contributions are all given with 2 figures but this does not reflect precision. A “0” indicates the absence of contribution to the total exposure.

Table C3: Minimum and maximum relative contribution (%) of maize-based products to the ZON total LB exposure

Food category	Scenario	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
All maize-based products	**Current ML**	**0 - 32**	**11 - 57**	**13 - 79**	**8.8 - 77**	**6.3 - 55**	**4.1 - 49**	**2.5 - 47**
	tML	**0 – 42**	**17 - 67**	**22 - 87**	**14 - 87**	**11 - 70**	**5.9 - 62**	**4.7 - 54**
Maize grain for consumption	Current ML	0	0 - 0.5	0 - 2.8	0 - 3.1	0 - 13	0 - 1.0	0 - 3.3
	tML	0	0 - 1.0	0 - 3.9	0 - 4.6	0 - 18	0 - 1.8	0 - 6.1
Grain milling fractions ≤ 500 µm	Current ML	0 - 1.6	0 - 19	0 - 20	0 - 12	0 - 32	0.4 - 20	0 - 11
	tML	0 - 1.7	0 - 22	0 - 21	0 - 12	0 - 35	0.5 – 23	0 - 13
Grain milling fractions > 500 µm	Current ML	0	0 - 14	0 - 5.3	0 - 2.1	0 - 3.3	0 - 1.5	0
	tML	0	0 - 16	0 - 5.5	0 - 2.3	0 - 3.7	0 - 1.8	0
Maize-based breakfast cereal	Current ML	0 - 0.8	0 - 23	0.2 - 70	0.4 - 71	0.7 - 47	0.3 - 45	0.7 - 32
	tML	0 - 1.2	0 - 30	0.2 - 78	0.4 - 79	0.8 - 60	0.3 - 59	0.8 - 45
Maize-based pastries	Current ML	0 - 6.4	0 - 17	0 - 23	0 - 23	0 - 26	0 - 37	0 - 33
	tML	0 - 6.8	0 - 16	0 - 23	0 - 24	0 - 29	0 - 42	0 - 37
Maize-based snacks	Current ML	0 - 23	0 - 37	0.3 - 30	0.4 - 23	0.5 - 19	0 - 2.1	0 - 0.3
	tML	0 - 32	0 - 48	0.5 - 39	0.6 - 30	0.8 - 30	0 - 3.8	0 - 0.4
Maize bread	Current ML	0	0	0 - 0.8	0 - 0.4	0 - 10	0 - 1.3	0
	tML	0	0	0 - 0.8	0 - 0.4	0 - 11	0 - 1.5	0
Other maize-based foods	Current ML	0	0 - 9.6	0 - 10	0 - 1.1	0 - 1.7	0 - 4.6	0 - 4.8
	tML	0	0 - 11	0 - 12	0 - 1.1	0 - 1.9	0 - 5.5	0 - 5.7

Note: The numbers for the percentage contributions are all given with 2 figures but this does not reflect precision. A “0” indicates the absence of contribution to the total exposure.

ABBREVIATIONS

3-Ac-DON	3-acetyl-deoxynivalenol
15-Ac-DON	15-acetyl-deoxynivalenol
ARfD	Acute Reference Dose
$BMDL_{10}$	Lower 95 % confidence limit for a benchmark response of 10 % extra risk
b.w.	Body weight
CN	Combined Nomenclature
CONTAM Panel	EFSA Scientific Panel on Contaminants in the Food Chain
DON	Deoxynivalenol
EC	European Commission
EFSA	European Food Safety Authority
ELISA	Enzyme-Linked Immunosorbent Assay
FAO	Food and Agriculture Organization of the United Nations
FUMO	Fumonisins
HBGV	Health-Based Guidance Value
HPLC	High Performance Liquid Chromatography
IRTAC	Institut de Recherches Technologiques Agroalimentaires des Céréales
JECFA	Joint FAO/WHO Expert Committee on Food Additives and Contaminants
LB	Lower Bound
LOD	Limit of Detection
LOQ	Limit of Quantification
MB	Middle Bound
ML	Maximum Level
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
PMTDI	Provisional Maximum Tolerable Daily Intake
TDI	Tolerable Daily Intake
tTDI	temporary Tolerable Daily Intake
tML	temporary Maximum Level
UB	Upper Bound
UK	The United Kingdom
UF	Uncertainty Factor
WHO	World Health Organization
ZON	Zearalenone