SCIENTIFIC OPINION

Statement on the risks for public health related to a possible increase of the maximum level of deoxynivalenol for certain semi-processed cereal products[1]

EFSA Panel on Contaminants in the Food Chain (CONTAM)[2, 3]

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This Scientific Opinion, published on 13 February 2014, replaces the earlier version published on 17 December 2013.

ABSTRACT

The European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the risks for public health related to a possible increase of the maximum level (ML) of deoxynivalenol (DON) for certain semi-processed cereal products from 750 µg/kg to 1000 µg/kg. For this statement, EFSA relied on existing occurrence data on DON in food collected between 2007 and 2012 and reported by 21 European countries. Due to the lack of appropriate occurrence data from pre-market monitoring, the impact of increasing the ML was estimated using a simulation approach, resulting in an expected increase in mean levels of the respective food products by a factor of 1.14-1.16. Based on median chronic exposure in several age classes, the percentage of consumers exceeding the group provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight (b.w.) for the sum of DON and its 3- and 15-acetyl-derivatives, established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2010, is approximately 2-fold higher with the suggested increased ML than with the current ML. Several acute exposure scenarios resulted in exceedance of the group acute reference dose (ARfD) of 8 µg/kg b.w. established by JECFA with up to 25.9 % of the consumption days above the group ARfD. The EFSA Scientific Panel on Contaminants in the Food Chain notes that the group health based guidance values (HBGVs) include 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not been covered in this statement, since the acetyl-derivatives are not included in the current or suggested increased ML and because only few occurrence data are available. An increase of the DON ML can be expected to be associated with an increase of the levels of DON and Ac-DONs, and can therefore increase the exposure and consequently the exceedances of the group HBGVs.

KEY WORDS

deoxynivalenol (DON), acetyl derivatives, semi-processed cereal products, occurrence, exposure, maximum level (ML), public health

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* Corrections of editorial nature were made on the first page. The changes do not affect the overall conclusions of the opinion. To avoid confusion, the original version of the opinion has been removed from the website, but is available on request, as is a version showing all the changes made.

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SUMMARY

Following a request from the European Commission, the EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) was asked to deliver a scientific opinion on the risks to human health related to a possible increase of the maximum level (ML) of deoxynivalenol (DON) for flour, semolina, meal and flakes derived from wheat, maize or barley used as an ingredient, from 750 µg/kg to 1000 µg/kg, with the understanding that the ML for bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals remains at the level of 500 µg/kg.

DON, also known as vomitoxin, is a mycotoxin mainly produced by *Fusarium graminearum* and *F. culmorum*. These fungi are plant pathogenic fungi that grow on the crop in the field and can grow in temperate climates. Besides DON, also the acetyl-derivatives, 3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON) can be formed by these fungi and have been reported to occur together with DON. Deoxynivalenol-3-glucoside (DON-3-glc) is the main plant metabolite of DON and is often termed a masked mycotoxin.

In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a group provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight (b.w.) for the sum of DON and its acetyl-derivatives (3-Ac-DON and 15-Ac-DON). In the same evaluation, the JECFA established a group acute reference dose (ARfD) of 8 µg/kg b.w. for the sum of DON and its acetyl-derivatives (3-Ac-DON and 15-Ac-DON). The European Food Safety Authority (EFSA) has also received in July 2013 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. The CONTAM Panel used the group health based guidance values (HBGV) established by JECFA in the current statement because the full assessment by EFSA has not been completed.

For this statement, the EFSA relied on existing occurrence data on DON in food collected between 2007 and 2012 and reported by 21 European countries. The short deadline of this request did not allow EFSA to issue a complementary call for data, in particular for data analysed as part of self-monitoring by the food business operators. Thus, an estimation of the percentage of samples that exceeded the current MLs and therefore were not placed on the market, was not feasible on the basis of submitted occurrence data.

The CONTAM Panel based its evaluation only on the occurrence data that were generated with analytical methods based on gas or liquid chromatography. In contrast to immunoassays, these methods are generally capable of differentiating between DON, its derivatives 3-Ac-DON, 15-Ac-DON and DON-3-glc. As the Commission Regulation (EC) No 1881/2006 only covers the parent compound DON but not the derivatives and conjugates, the possible increase of the ML relates only to the parent compound. Finally, 10 757 samples were included in the analysis, reported by 21 European countries.

The impact of increasing the ML from 750 to 1000 µg/kg was assessed considering barley flour, wheat flour (brown flour, white flour, wholemeal flour, flour from durum wheat, graham flour) and wheat semolina (couscous, semolina from durum wheat and from soft wheat). Due to the lack of appropriate occurrence data from pre-market monitoring, the influence of increasing the ML on the mean DON level in the semi-processed cereal products was estimated using a simulation approach. This was done by assuming that the proportion of non-compliant samples would remain the same after the suggested increase of the ML. From the simulation, it was estimated that changing the ML from 750 µg/kg to 1000 µg/kg in barley flour and wheat flour and semolina would increase the lower, middle and upper bound (LB, MB, UB) DON mean occurrence levels by factors of 1.16 (95 % confidence interval (CI) = 1.09 - 1.23), 1.15 (95 % CI = 1.09 – 1.21) and 1.14 (95 % CI = 1.08 – 1.20), respectively. These results were supported by a small data set of wheat samples from the Netherlands directly analysed after harvest. When evaluating the effect of raising the ML from 750 to 1000 µg/kg, the mean LB and

UB levels would increase by factors of 1.12 and 1.08, respectively, which is within the 95 % CI of the simulated factors.

Chronic exposure to DON was assessed at the individual level by multiplying the mean daily consumption for each food with the corresponding mean DON concentration, summing up the respective intakes throughout the diet, and finally dividing the results by the individual's body weight. The mean and the 95th percentile of dietary exposures were derived for each survey and age group combination. The chronic exposure was first assessed considering the mean DON concentration based on the reported data and secondly, considering an increase of the mean DON levels in all food products potentially containing barley flour, wheat flour and semolina as ingredients by a factor of 1.15 to assess the influence of increasing the ML

Under the current regulations, the mean exposure levels estimated for the parent compound DON from the reported data for 'infants', 'toddlers' and 'other children' are already in the range of the group PMTDI, with levels between 0.22 and 0.94 µg/kg b.w. per day at the LB and 0.49 and 1.10 µg/kg b.w. per day at the UB. The 95th percentile of dietary exposure is between 0.83 and 1.65 µg/kg b.w. per day at the LB and 0.92 and 2.13 µg/kg b.w. per day at the UB. The mean exposure levels are below the group PMTDI for 'adolescents', 'adults', 'elderly' and 'very elderly', ranging between 0.17 and 0.53 µg/kg b.w. per day at the LB and 0.21 and 0.55 µg/kg b.w. per day at the UB. The 95th percentile of dietary exposure is in the range of the group PMTDI for some surveys, ranging between 0.35 and 1.0 µg/kg b.w. per day at the LB and 0.43 and 1.04 µg/kg b.w. per day at the UB. The percentage of subjects with exposures above the group PMTDI is highest in 'toddlers' with 2.4-49.5 %, followed by 'other children' with 0.4-44.6 % (minimum LB-maximum UB across surveys), respectively.

Depending on the survey and age group, the mean and 95th percentile dietary exposure (LB and UB) estimated using the occurrence data simulating the suggested increased ML are 4.2 to 16.0 % higher than the levels estimated with the data set based on the reported data. The percentage of toddlers with exposures above the group PMTDI is increased to 6.4-64 % (minimum LB-maximum UB across surveys) when the occurrence data simulating the increased ML are used. Based on median chronic exposure in other children, adolescents and adults, the percentage of consumers exceeding the group PMTDI is approximately 2-fold higher with the suggested increased ML than with the current ML. The group PMTDI for DON and its acetyl-derivatives is based on a no-observed-effect level for decreased body weight gain in a long term feeding study in mice. This endpoint is of particular relevance for infants, toddlers, children and adolescents, since they are in growing life stages. Exposure above the group PMTDI for these age groups is therefore of concern.

Concerning acute exposure, two scenarios were considered. A first acute exposure scenario addressed people who consume mainly homemade cereal food using barley/wheat flour/semolina containing DON equal to the ML. The mean acute exposure levels resulting from the consumption of barley/wheat flour/semolina at an assumed concentration of 750 µg/kg DON are below the group ARfD in all combinations of surveys and age groups taken into account. The 95th percentile exposure levels are above the group ARfD in some surveys for the 'toddlers' and 'other children' age groups. Up to 15.7 % and up to 0.4 % of consumption days are found with exposure levels above the group ARfD across surveys for the children (infants, toddlers, other children) and adults (adolescents, adults, elderly, very elderly) age groups. When assuming the suggested increased ML for DON of 1000 µg/kg, the mean acute exposure levels are still below the group ARfD, whereas the 95th percentile exposure levels are above the group ARfD in some surveys for the 'toddlers' and 'other children' age groups. For this scenario, up to 25.9 % and up to 2 % of consumption days are found with exposure levels above the group ARfD across surveys in the children (infants, toddlers, other children) and adults (adolescents, adults, elderly, very elderly) age groups.

A further acute exposure scenario addressed people who consume commercially produced foods, since the concentration in these products may increase with the suggested increased ML, although being still below the ML for each final product, because a higher level in the ingredients can be expected. In general, this acute exposure scenario resulted in a low percentage of consumption days above the group ARfD of less than 1 % with the exception of wheat bread and rolls and pasta where the percentage of consumption days above the group ARfD could increase up to 2 and 13 %, respectively with the suggested increased ML. However, for pasta, this may be quite an overestimation, considering that the cooking effect on the DON level has not been taken into account.

Increased probabilities of exceeding the group ARfD with the suggested increased ML in cereal ingredients were seen with both the scenario addressing home-made cereal food and the one addressing commercially produced cereal-based food. The proportion of consumption days above the group ARfD was highest for the acute exposure estimate with home-made cereal-based food. Although indicating concern, this scenario may be seen as a worst case. For commercially produced food the percentage of consumption days with exposure above the group ARfD was generally low. However, the exposure scenario can be considered as realistic. Higher probabilities of having exposure above the group ARfD with the suggested increased ML is particularly associated with consumption of pasta, wheat bread and rolls, and indicate concern.

The CONTAM Panel noted that the group PMTDI and group ARfD for DON include the acetyl-derivatives 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not been covered in this statement, since the acetyl-derivatives are not included in the current or suggested increased ML and few data are available on their occurrence in food in the EU. The exposure estimations in this statement indicate that the group HBGVs are already exceeded by the parent compound DON in a number of cases. An increase of the DON ML can be expected to be associated with an increase of the levels of DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs.

The CONTAM Panel noted that there is a need for occurrence data on acetyl-derivatives with sufficiently sensitive methods in order to assess their impact on the health risk associated with an increase of the ML for DON.

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Background as provided by the European Commission

EU legislation

The Scientific Committee on Food (SCF) adopted in 1999 a scientific opinion on deoxynivalenol (DON)[4], establishing a tolerable daily intake (TDI) of 1µg/kg b.w.

Based on that scientific opinion and the assessment of the dietary intake, maximum levels (ML) for DON were set by Commission Regulation (EC) No 1881/2006[5].

At that time it was considered not necessary, due to co-occurrence, to consider specific measures for 3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON), as measures with regard to DON would also protect the human population from an unacceptable exposure from 3-Ac-DON and 15-Ac-DON.

The MLs established for DON are provided in the table hereafter:

	Deoxynivalenol	µg/kg
1	Unprocessed cereals other than durum wheat, oats and maize	1250
2	Unprocessed durum wheat and oats	1750
3	Unprocessed maize, with the exception of unprocessed maize intended to be processed by wet milling	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)	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	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

JECFA and Codex

Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated DON at its 72nd meeting in 2010.

The Committee decided to convert the provisional maximum tolerable daily intake (PMTDI) for DON to a group PMTDI of 1 µg/kg b.w. for DON and its acetylated derivatives (3-Ac-DON and 15-Ac-DON) as 3-Ac-DON is converted to DON in vivo and therefore contributes to the total DON-induced toxicity. In this regard, the Committee considered the toxicity of the acetylated derivatives to be equal to that of DON. The Committee concluded that there was insufficient information to include DON-3-glucoside in the group PMTDI.

The JECFA derived a group acute reference dose (ARfD) of 8 µg/kg b.w. for DON and its acetylated derivatives using the lowest lower limit on the benchmark dose for a 10 % response ($BMDL_{10}$) of 0.21 mg/kg b.w. per day for emesis in pigs. Limited data from human case reports indicated that dietary exposures to DON up to 50 µg/kg b.w. per day are not likely to induce emesis.

[4] Opinion of the Scientific Committee on Food on Fusarium-toxins Part 1: Deoxynivalenol (DON) (expressed on 2 December 1999). Available online: http://ec.europa.eu/food/fs/sc/scf/out44_en.pdf

[5] 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.

The JECFA concluded that all of the mean estimates of national exposure to DON were below the group PMTDI of 1 µg/kg b.w. National reports showed dietary exposures that were above 1 µg/kg b.w. per day in only a few cases, only for children at upper percentiles. For acute dietary exposure, the estimate of 9 µg/kg b.w. per day, based on high consumption of bread and a regulatory limit for DON of 1 mg/kg food, was close to the group ARfD.

At the 7th session of the Codex Committee on Contaminants in Foods (CCCF) in April 2013, the CCCF agreed to establish an ML of 1 mg/kg for flour, semolina, meal and flakes derived from wheat, maize and barley. The Delegations of the European Union and Norway asked for more time to consult with their risk assessment bodies before agreeing to the proposed ML of 1 mg/kg and the Delegation of the Russian Federation expressed its reservation about this decision. This conclusion was confirmed at the meeting of the Codex Alimentarius Commission (CAC) in July 2013.

Following this conclusion it was agreed at the Standing Committee on the Food Chain and Animal Health section on "Toxicological Safety of the Food Chain" in April 2013, that the European Food Safety Authority (EFSA) should be asked for a scientific opinion on the risks for public health related to the possible increase of the MLs for flour, semolina, meal and flakes derived from wheat, maize or barley.

Terms of reference as provided by the European Commission

In accordance with Art. 29 (1) (a) of Regulation (EC) No 178/2002 the Commission asks EFSA for a scientific opinion on the risks to human health related to a possible increase of the ML of DON for flour, semolina, meal and flakes derived from wheat, maize or barley from 750 µg/kg to 1000 µg/kg as an ingredient, with the understanding that the ML for bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereals remains at the level of 500 µg/kg.

ASSESSMENT

1. Introduction

Deoxynivalenol (DON), also known as vomitoxin, is a mycotoxin mainly produced by *Fusarium graminearum* and *F. culmorum*. These fungi are plant pathogenic fungi that grow on the cereals in the field and can grow in temperate climates (Marin et al., 2013). Besides DON, also the acetyl-derivatives, 3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON) can be formed by these fungi and have been reported to occur together with DON (Berthiller et al., 2013; Varga et al., 2013). Deoxynivalenol-3-glucoside (DON-3-glc) is the main plant metabolite of DON and is often termed a masked mycotoxin (Varga et al., 2013).

DON is a common contaminant in grains (wheat, maize, rye, barley, oats, and rice) and grain-based products. The acetyl-derivatives are infrequently detected, and levels are typically less than 10 % of those reported for DON (FAO/WHO, 2011).

DON belongs to the type B trichothecenes, which are 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. The analytical methods used for DON have been reviewed recently by Ran et al. (2013). Immunoassays, liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS) are the mostly used techniques for DON analysis. 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). Various commercial ELISA kits are available for DON and cross-reactivity has been observed against 3-Ac-DON, 15-Ac-DON, de-epoxy-DON and DON-3-glc, nivalenol, fusarenone X, diacetoxyscirpenol, T2-toxin, HT2-toxin, verrucarol, and zearalenone (Tangni et al., 2010).

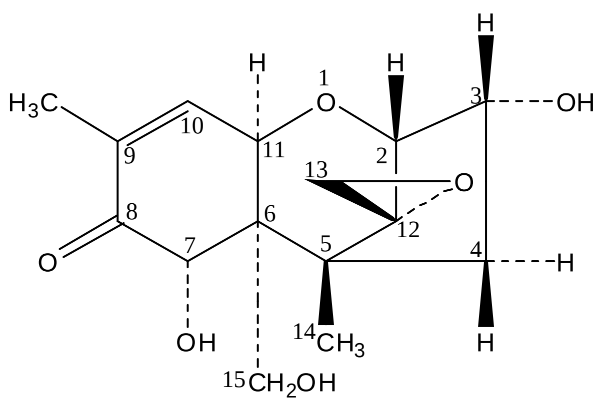

Figure 1: Chemical structure of deoxynivalenol

The Scientific Committee on Food (SCF) carried out a risk assessment in 1999 and established a temporary tolerable daily intake (tTDI) of 1 µg/kg body weight (b.w.) based on a no-observed-adverse-effect level (NOAEL) of 100 µg/kg b.w. per day for reduced growth in a 2-year feeding study in mice by Iverson et al. (1995) and an uncertainty factor of 100 (SCF, 1999). This tTDI was confirmed by the SCF in 2002 and a full tolerable daily intake (TDI) of 1 µg/kg b.w. was established (SCF, 2002).

In 2001, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the health risk of DON and established a provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg b.w.

(FAO/WHO, 2001). This was also based on the no-observed-effect level (NOEL) of 100 µg/kg b.w. per day for decreased body weight gain from the 2-year feeding study in mice by Iverson et al. (1995) and an uncertainty factor of 100. The JECFA concluded that intake at this level would not result in effects on the immune system, growth, or reproduction. Since 3-Ac-DON is converted to DON and contributes to the total DON-induced toxicity, the JECFA converted in 2010 the PMTDI for DON to a group PMTDI of 1 µg/kg b.w. for the sum of DON and its acylated derivatives (3-Ac-DON and 15-Ac-DON). The JECFA concluded that there was insufficient information to include DON-3-glc in the group PMTDI (FAO/WHO, 2011). Based on the lower 95 % confidence limit for a benchmark response of 10 % extra risk ($BMDL_{10}$) of 0.21 mg/kg b.w. per day for emesis in pigs and an uncertainty factor of 25, the JECFA established in 2010 a group acute reference dose (ARfD[6]) of 8 µg/kg b.w. for the sum of DON and its acylated derivatives (3-Ac-DON and 15-Ac-DON) (FAO/WHO, 2011).

The European Food Safety Authority (EFSA) also received in July 2013 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 that full risk assessment is substantially later than the deadline set by the Commission for the current request, the Panel used the group health based guidance values (HBGV) established by JECFA for the risk characterisation in this statement.

2. Legislation on deoxynivalenol in food[7]

In order to protect public health, Article 2 of the Council Regulation (EEC) No 315/93[8] stipulates that, where necessary, maximum tolerances for specific contaminants shall be established. Subsequently, a number of maximum levels (MLs) for mycotoxins in food were laid down in Commission Regulation (EC) No 1881/2006. The current MLs for DON in various foodstuffs are summarized in Table 1.

[6] The acute reference dose is the estimate of the amount of a substance in food or drinking water, expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation (FAO/WHO, 2009).

[7] Note: In this statement, where reference is made to European legislation (Regulations, Directives, Decisions), the reference should be understood as relating to the most current amendment, unless otherwise stated.

[8] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L 37, 13.2.1993, p. 1-3.

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

Category	Foodstuff	DON (µg/kg)
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

DON: deoxynivalenol; CN: combined nomenclature.

(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.

As requested by the EU Commission, this statement reappraises the risks to human health related to a possible increase of the ML for DON in flour, semolina, meal and flakes derived from wheat, maize or barley from 750 µg/kg to 1000 µg/kg as an ingredient. From a legislative point of view, wheat meal and wheat flour are understood as synonyms as also are barley meal and barley flour. Wheat flour and meal, as well as barley flour and meal fall under category 4 of Table 1. Wheat and barley semolina are not explicitly mentioned in the legislation, however they could eventually be covered by cereal flour in general (category 4). There are currently no MLs for wheat and barley flakes as an ingredient, unless they are mixed into breakfast cereals (category 6). Maize flour and meal are considered as milling fractions of maize with a particle size ≤ 500 micron and are covered by category 9 of Table 1. Depending on milling grade, maize semolina can either fall under category 8 or 9. Maize semolina used as an ingredient in polenta, snacks and baby food generally has a particle size ≤ 500 micron and therefore falls under category 9.

Thus, from a legislative point of view, wheat flour, meal and semolina, barley flour, meal and semolina, and maize semolina with particle size > 500 micron would be influenced by an increase of the ML for DON from 750 to 1000 µg/kg.

3. Occurrence data

3.1. Overview of the data available for the analysis

For this statement, EFSA relied on existing occurrence data on DON in food collected between 2007 and 2012 and reported by 21 European countries. The short deadline of the Commission request did not allow EFSA to issue a complementary call for data, in particular for data analysed as part of self-monitoring by the food business operators. Thus, an estimation of the percentage of samples that exceeded the current MLs and therefore were not placed on the market was not feasible on the basis of submitted occurrence data.

A detailed data quality control was performed in order to check for duplicate submissions, to identify potential errors in the food description and/or reporting the results and to ensure the overall comparability of the data. As a result, 27 samples were excluded from the analysis because they were found to be submitted twice, and 74 other samples were excluded because they were associated with uncertainties in the unit of expression of the results.

For this statement, the EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) decided to base its evaluation only on the occurrence data that were generated with analytical methods based on gas or liquid chromatography. These methods are generally capable of differentiating between DON, its derivatives 3-Ac-DON, 15-Ac-DON and DON-3-glc. As the Commission Regulation (EC) No 1881/2006 only covers the parent compound DON but not the derivatives and conjugates, the possible increase of the ML relates also only to the parent compound. However, for the risk assessment it is important to take also the derivatives into account. While the data on the parent compound DON are generated by the chromatographic methods, ELISA based methods may in total or in part cover besides the derivatives and conjugates also other mycotoxins due to the cross-reactivity of the antibodies (see Section 1). Thus, occurrence data generated with ELISA based methods presumably overestimate the occurrence of the parent compound DON. Therefore, the results generated with techniques other than gas or liquid chromatography, i.e. ELISA and High Performance Thin Layer Chromatography (2 787 samples), or for which the analytical technique was not indicated by the data provider (5 028 samples) were excluded from the analysis.

The cut-off values for the left-censored data (i.e. results below the limit of quantification (LOQ)) were set at 200 µg/kg for grains and grain-based products and 150 µg/kg for other foods. These corresponded to approximately the 75th percentile of the quantified results. All left-censored results associated with an LOQ above the cut-off value were excluded from the dataset (131 samples excluded, all reported as below the LOQ).

Finally, from an initial dataset of 18 804 samples, 10 757 samples were taken into account in this statement. Half of the data were reported by two countries, Germany (35 %) and Slovakia (16 %).

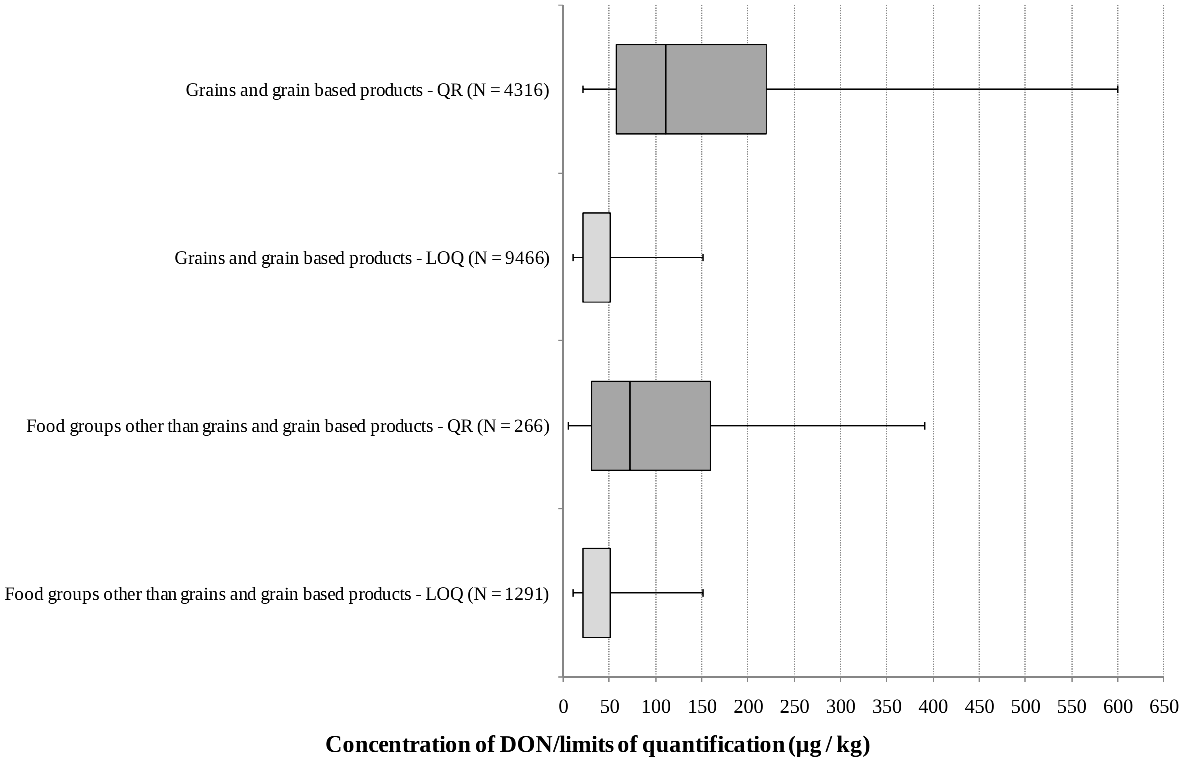

Figure 2: Distribution of the quantified results (QR; in dark grey) and of the reported limits of quantification (LOQ; light grey) for DON in µg/kg before the application of LOQ cut-off criteria (Box-plot: whiskers at 5th percentile and 95th percentile, box at 25th percentile and 75th percentile with line at 50th percentile; N: number of samples).

3.2. Distribution of deoxynivalenol levels in food

Appendix Tables A1 to A4 show the distribution of DON levels in the different foods covered by the dataset. Due to the smaller size of the dataset, DON levels cannot be described in as many food groups as in the EFSA report on occurrence of and exposure to DON in food and feed (EFSA, 2013). This concerns especially some foods other than grains and grain-based products (vegetable oils, oilseeds, tea and herbs infusion, confectionary, dried fruits, oat drinks, herbs spices and condiments, vegetable products) which are gathered in a group of 'other foods' (Appendix A, Table A4). Due to the lack of a sufficient number of results based on chromatographic methods, these 'other foods' cannot be properly considered in the exposure assessment. In the EFSA report they were found to represent, depending on surveys and age classes covered by the European Comprehensive Food Consumption Database (see Paragraph 4), from 0.2 up to 2 % of the chronic lower bound (LB) mean exposure estimate, and from 2 up to 16.2 % of the chronic upper bound (UB) mean exposure estimate. Concerning the grains and grain-based products, the data available do not distinguish between the different kinds of oat, spelt and rye milling products. However, no major difference between the DON levels measured in these products was previously identified. Since barley flour is included in the ingredients affected by the potential change of the ML, it is now treated as a specific food group, despite the very small number of data (n = 5).

Compared to the EFSA report on occurrence of and exposure to DON in food and feed (EFSA, 2013), the DON levels found in grains for human consumption and grain milling products are somewhat higher (mean estimated under the middle bound (MB) assumption at 141.5 µg/kg vs. 111.8 µg/kg in the report for grains for human consumption, 124.8 µg/kg vs. 103.5 µg/kg in the report for grain milling products) in the dataset used in the present statement. They are in the same ranges for processed cereal products (breads and rolls, breakfast cereals, fine bakery wares, raw pasta) and other foods, as in the EFSA report (EFSA, 2013). The differences are explained by the different data quality criteria applied in this statement compared to the report (selection of results generated with gas and liquid chromatography techniques, different cut-off values for limit of detection (LOD)/limit of quantification (LOQ)). As already observed in the EFSA report, DON is found at higher levels in maize and wheat grains and milling products than in products from other grains. The levels found in processed cereal products are lower than those observed in grains and grain milling products. Among the other foods, snacks (corn chips, curls and tortillas) contain the highest levels of DON.

Table 2 shows the summary statistics for those cereal products that would be affected by the potential increase of the ML for DON from 750 to 1000 µg/kg.

Table 2: Distribution of deoxynivalenol levels (expressed in µg/kg) across grain milling products affected by the potential increase of the maximum level for deoxynivalenol

Food group	N	LC (%)	Concentration (µg/kg)	
			Mean MB (LB – UB)[(a)]	P95 MB (LB – UB)[(a,b)]
Wheat products				
Wheat flour	1316	32.8	138.6 [130.3; 146.9]	550.0
Wheat semolina	116	59.5	193.9 [176.4; 211.3]	1398.0
Barley products				
Barley flour	5	80.0	28.2 [22.2; 34.2]	-
Total	1437	35.1	142.7 [133.6; 151.7]	600

N: number of samples; LC: left-censored results; LB: lower bound; MB: middle bound; UB: upper bound; P95: 95th percentile.
(a): When the MB, LB and UB estimates are equal, only one estimate is given.
(b): P95 is only reported for food groups for which at least 60 samples were available.

3.3. Contribution of acetyl-derivatives to total deoxynivalenol concentrations

The group HBGVs established by JECFA include 3-Ac-DON and 15-Ac-DON (See Section 1). Therefore, it is also important to estimate their contribution to total DON and to include these compounds in the current evaluation of human exposure.

Among the 10 757 samples that were taken into account in this statement, 2 684 were analysed for both DON and the two acetyl-deoxynivalenol (Ac-DON) compounds. However, only 53 samples contained a detectable level for one of the Ac-DONs, as compared to 1 153 samples in which DON was detected. Typically, none of these 53 samples contained both Ac-DONs. In six samples, both DON and 3-Ac-DON were quantified and the concentration of 3-Ac-DON was on average 20 % of the DON concentration (range: 8-71 %). In one sample of corn flakes, 118 µg 3-Ac-DON/kg was detected, but the concentration of DON was reported below the LOD. DON and 15-Ac-DON were both quantified in 46 samples and the concentration of 15-Ac-DON was on average 36 % of the DON concentration (range: 3-103 %).

Considering all 1 153 samples in which DON was quantified, the concentration of 3-Ac-DON was on average 0 to 26 % (LB-UB) of the DON concentration and ranged between 0 and 127 % (minimum LB-maximum UB). For 15-Ac-DON, this was on average 1 to 33 % (LB-UB) and ranged between 0 and 386 % (minimum LB-maximum UB). These high contributions of the acetyl-derivatives, compared to the quantified DON concentrations, are due to the higher LOD/LOQs that are often reported for the acetyl-derivatives compared to DON. In the samples with detectable Ac-DON levels, there was no clear relationship between the DON level and their relative contribution of the Ac-DONs, indicating that the relative contribution is not dependent on the DON level.

In their derivation of the group HBGVs, JECFA concluded that on average 3-Ac-DON and 15-Ac-DON add less than 10 % of the level of DON (FAO/WHO, 2011).

Data on levels of the two Ac-DONs and their contribution to total DON were reported by various authors as outlined below. Berthiller et al. (2005) examined five wheat and two corn samples and found DON levels between 90 and 1540 µg/kg. In the higher contaminated samples some 3- and/or 15-Ac-DON was detected (10-50 µg/kg) but was equivalent to less than 2 % of the DON concentration.

Asam and Rychlik (2009) analyzed 16 maize and maize products from Germany and observed 15-Ac-DON (range 10-150 µg/kg) in addition to DON (range 10-860 µg/kg), but no 3-Ac-DON. The relative level of 15-Ac-DON to that of DON was 23 ± 11 %.

During the period 2001-2005, Edwards (2009) analysed a total of 1624 grain samples from the United Kingdom (UK). DON was detected above the LOQ (10 µg/kg) in 86 %, 15-Ac-DON and 3-Ac-DON in respectively 2.7 and 1.2 % of the samples. In the samples with high DON levels, the Ac-DONs to DON ratio was 0.25-2.5 %. However, samples were observed with high DON and no Ac-DONs or low DON and high Ac-DON levels, the latter showing ratios of 25-150 %.

Malachova et al. (2011) analysed 116 cereal-based products from the Czech market and detected DON in 88 % of the 75 flour products with a mean of 125 µg/kg (LOD (expressed as lowest calibration level) of 12.5 µg/kg). Although included in the analytical method, Ac-DONs were not mentioned in the results and in fact were not detected (J. Hajslova, 2013, personal communication).

De Boevre et al. (2012) analysed 174 samples of wheat, wheat bran, cornflakes, popcorn and oatmeal for DON, the two Ac-DONs and the DON-3-glc. The sum of the glucoside and acetyl-derivatives contributed 44, 53, 45, 82 and 62 %, respectively, to the total sum in the five types of products, the two Ac-DONs alone contributing 22, 32, 32, 51 and 44 %. When ignoring the DON-3-glc, it can be estimated that the Ac-DONs contribute 40-78 % to the sum of DON and Ac-DONs. These values are clearly higher than the ones calculated from the EFSA and JECFA-database and those found by other investigators, indicating that the Ac-DONs can contribute substantially to the overall exposure.

Montes et al. (2012) analysed 148 breakfast cereal samples from the Spanish retail market, with LOQs around 20 µg/kg. Of 62 corn products, 19 were positive for DON with a mean of 86 µg/kg (range 33-191), as compared to 5 out of 27 wheat samples (mean 223, range 59-468 µg/kg) and 14 out of 46 multigrain samples (mean 66, range 32-127 µg/kg). In none of the samples were the Ac-DONs detected.

Dall'Asta et al. (2013) detected 3-Ac-DON in 86 out of 150 samples of Italian durum wheat (median 134, maximum 203 µg/kg) and 15-Ac-DON in all samples (median 92, max 244 µg/kg), as compared to DON in all samples (range 47-3715 µg/kg, no median provided). No Ac-DONs to DON ratios were described.

Ogiso et al. (2013) analysed corn-derived feed and feed ingredients, such as dried distillers grains with solubles (DDGS) and corn gluten meal. DON was detected in all DDGS samples (range 120-6200 µg/kg), 3- and 15-Ac-DON in 26 samples with ranges of 20-120 and 10-2100 µg/kg respectively. In corn gluten feed samples, all 39 samples were shown to contain DON, as well as 15-Ac-DON, and 27 of these samples also contained 3-Ac-DON. Ranges were 730-12000, 40-1600 and 10-40 µg/kg, respectively. For 36 corn gluten meal samples, DON, 15-Ac-DON and 3-Ac-DON were detected in 24, 20 and 0 samples, with ranges of 50-640 and 10-180 µg/kg. Of 30 mixed feed samples, DON was detected in all 30 samples (range 150-1200 µg/kg), 15-Ac-DON in 29 samples (30-290 µg/kg) and 3-Ac-DON in 1 sample (10 µg/kg). Overall, it was concluded that the levels of DON were higher than those of 15-Ac-DON and these in turn were higher than those for 3-Ac-DON. The relative ratio of Ac-DONs to DON varied from several per cent to more than 50 %, but no precise values were presented.

In summary, based on the published literature, it can be concluded that Ac-DONs may be present at higher percentages than those calculated from the EFSA and JECFA-database and thus may contribute substantially to the total DON exposure.

3.4. Food processing

The influence of food processing on mycotoxins in general, or on DON in particular, has been reviewed by several authors (FAO/WHO, 2001, 2011; Hazel and Patel, 2004; Castells et al., 2005; Bullerman and Bianchini, 2007; VKM, 2013).

Sorting and cleaning may lower DON levels, however the degree of decontamination varies among studies (FAO/WHO, 2001). During the milling process, DON is distributed between the milling fractions resulting in higher concentrations in the germ and bran fractions (Bullerman and Bianchini, 2007; Lancova et al., 2008).

Conflicting results have been reported for the effect of bread-making on DON concentrations, ranging from no significant effect to a reduction by 50 % (Lancova et al., 2008; Scudamore, 2008; Voss and Snook, 2010; Cano-Sancho et al., 2013). Bergamini et al. (2010) observed that an increase in time and/or temperature during baking could reduce the DON content in bread, but only when highly contaminated flour is used. Bretz et al. (2006) studied thermal degradation of DON in food models and observed DON degradation under all tested conditions (150 - 200 °C/5 - 20 minutes). Several degradation compounds were identified, and cell culture experiments with immortalized human kidney epithelial (IHKE) cells showed lower cytotoxicity of the degradation compounds compared to DON.

Conflicting results have also been reported for the influence of extrusion cooking[9] on DON concentrations in food. Scudamore et al. (2008a, b) reported that DON is relatively stable in wholemeal wheat grain, maize flour and grits during extrusion cooking, while Cazzaniga et al. (2001) reported a reduction in the DON content by more than 95 % in experimentally contaminated maize flour. Wu et al. (2011) showed that the reduction of DON concentrations during extrusion cooking of wheat grits depends on moisture content, pressure, residence time in the extruder, protein content of the food, temperature and pH.

Visconti et al. (2004) studied the DON concentrations during durum wheat processing and spaghetti cooking. Compared to uncleaned durum wheat, the mean concentrations of DON were 77 % in cleaned wheat, 37 % in semolina, 33 % in spaghetti and 20 % in cooked spaghetti. The observed reduction of DON in cooked spaghetti was due to leaching into the cooking water. A higher reduction was observed when a higher water to spaghetti ratio was used. Cano-Sancho et al. (2013) confirmed that DON is transferred into the cooking water during pasta boiling and observed a reduction of the DON content in pasta by up to 75 %. However, it should be noted that concentrations were expressed on a wet weight basis and pasta takes up water during cooking which dilutes the concentration in the boiled pasta.

Since the ingredients considered in this statement are not used for beer production, the influence of brewing on DON concentrations was not considered.

4. Consumption data

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

[9] Extrusion cooking is a high-temperature short-time process where the raw material is subjected to severe shear resulting in molecular transformations and chemical reactions. This techniques is used for the production of breakfast cereals and snack foods (Castells et al., 2005).

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 24h dietary recalls covering one or two days, 48h dietary recalls, or through dietary records covering 3 to 7 days.

For the 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 representing a total of 53 728 individuals from 28 surveys and 17 European countries (Appendix B). The mean consumption level was estimated at the individual level for the different food groups defined based on the occurrence data available (see Section 3.2). For the acute exposure assessment, all reporting days were considered, which represented a total of 195 200 days (Appendix B). For each reporting day, the total amount of each of the food groups of interest consumed that day was determined. Due to different methodologies, the data from the different surveys cannot be merged to produce one single estimate for the European population. The exposure (chronic/acute) is consequently assessed at the survey level for each age group covered by the survey.

5. Impact of increasing the maximum level

5.1. Impact on the mean deoxynivalenol level in semi-processed cereal products

The impact of increasing the ML from 750 to 1000 µg/kg was assessed considering barley flour, wheat flour (brown flour, white flour, wholemeal flour, flour from durum wheat, graham flour) and wheat semolina (couscous, semolina from durum wheat and from soft wheat). Flakes from wheat, maize and barley – as breakfast cereals – are not considered as ingredients and therefore not subject to a possible increase of the ML. Flour and meal from maize were not taken into account in this analysis, since the current ML is higher than 1000 µg/kg. Maize semolina used as ingredient of polenta, snacks and baby food has a particle size ≤ 500 micron and is therefore not affected by the potential increase of the ML.

5.1.1. Methodology

Due to the lack of appropriate occurrence data from pre-market monitoring, the impact of increasing the ML on the mean DON level in semi-processed cereal products was assessed using a simulation approach. A new dataset, of equal size to the observed dataset, was generated by resampling the observed dataset under the constraint that the proportion of non-compliant samples would remain the same after the increase of the ML. This approach was implemented in the SAS software (version 9.3) as follows:

- n concentration values were randomly drawn with replacement, where n is the total number of concentration values available in the reported dataset, as follows:
  - $n\ p$ values were drawn from a uniform distribution between 1000 µg/kg and the maximum DON level reported, where p is the proportion of non-compliance in the reported dataset.
  - $n\ p\ p'/(1 - p')$ values were drawn from a uniform distribution between 750 µg/kg and 1000 µg/kg, where p' is the proportion of samples between 750 and 1000 µg/kg among the total number samples above 750 µg/kg estimated from the reported dataset,
  - $n - n\ p - n\ p\ p'/(1 - p')$ values were drawn from the reported values below 750 µg/kg.
- The LB/MB/UB mean DON level was estimated from the simulated dataset and divided by the LB/MB/UB mean DON level estimated from the reported dataset.
- This procedure was repeated 1 000 times and the mean of the values obtained from the 1 000 iterations was calculated with its 95 % CI (confidence interval). In a sensitivity analysis, the number of iterations was increased by a factor of 10 to 10 000, in order to check whether 1 000 iterations were sufficient to fully reflect the variability of the reported dataset.

In this simulation study, barley flour, wheat flour and wheat semolina were considered as a single food group.

This process is further explained based on the actual numbers in Section 5.1.2 and Figure 3.

5.1.2. Results of the simulation of the occurrence data

The reported dataset contained 1 437 samples (*n*) of barley flour, wheat flour and wheat semolina, with LB, MB and UB mean levels respectively at 133.6 µg/kg, 142.7 µg/kg and 151.7 µg/kg. The highest DON level was observed in a sample of white wheat flour at 3410 µg/kg. The proportion of non-compliance (*p*) was estimated at 1.67 % (i.e. 24 reported values above 750 µg/kg). The proportion of samples (*p'*) between 750 and 1000 µg/kg among the total number of samples above 750 µg/kg was 38 % (i.e. 9 reported values).

The simulated dataset (Figure 3) was built with:

- 24 values (*n p)* drawn from a uniform distribution between the suggested increased ML of 1000 and 3410 µg/kg,
- 15 values (*n p p'/(1 –* p*'*)) drawn from a uniform distribution between 750 and 1000 µg/kg,
- 1 398 (*n – n p – n p p'/(1 – p') = 1437 – 24* - *15*) values were drawn from the 1 413 results below 750 µg/kg available in the reported dataset.

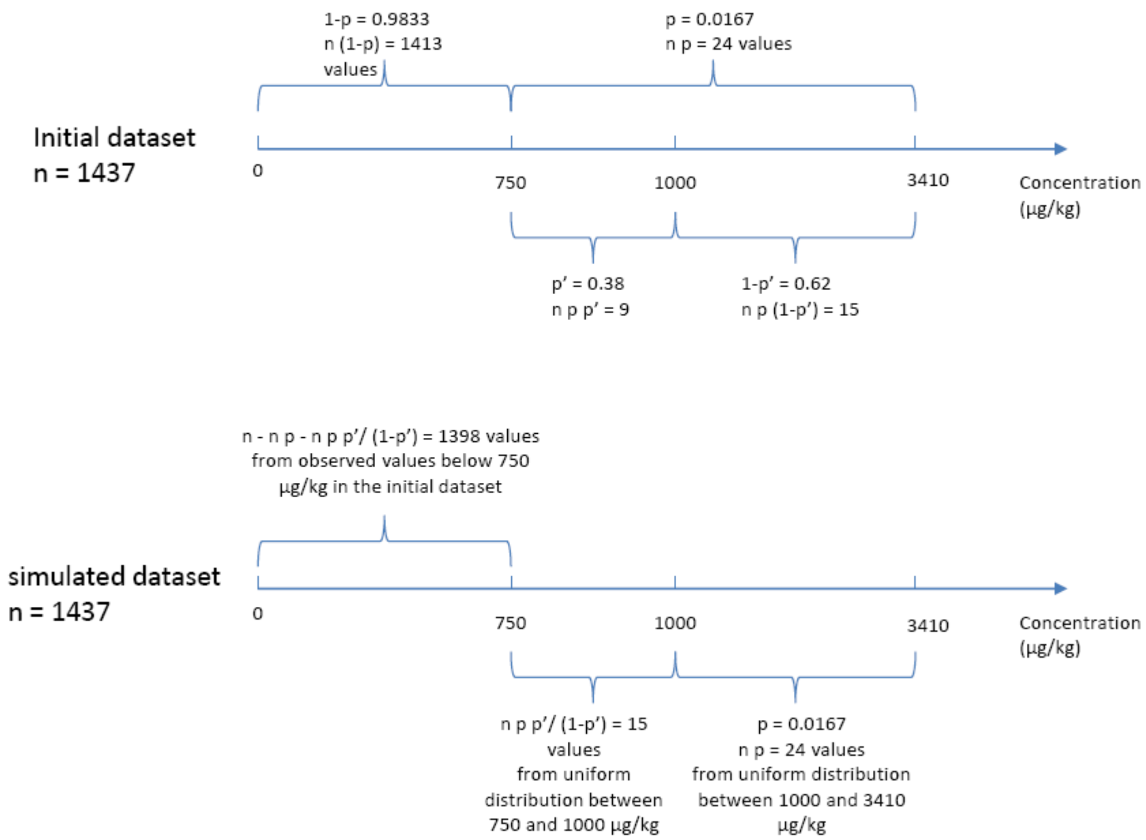

Figure 3: Illustration of the methodology to simulate the dataset on the occurrence of DON after the increase of the maximum level (n = number of samples; p = probability of non-compliance with the maximum level; p' = probability of a concentration between 750 and 1 000 when non-compliant with the current maximum level).

The distributions of the reported and simulated data set of DON concentrations in barley/wheat flour/semolina are given in the Appendix C.

From the 1 000 iterations, it was estimated that changing the ML from 750 µg/kg to 1000 µg/kg in barley flour and wheat flour and semolina would increase the LB, MB and UB DON mean levels by factors of 1.16 (95 % CI = 1.09 – 1.23), 1.15 (95 % CI = 1.09 – 1.21) and 1.14 (95 % CI = 1.08 – 1.20), respectively. Same CIs were obtained while increasing the number of iterations by a factor of 10 to 10 000.

5.1.3. Occurrence data in field samples of wheat from the Netherlands

A potential problem when evaluating the EFSA database is that samples exceeding the ML may be underrepresented since the batches they represent were not put on the market. In the Netherlands, during the years 2009-2011, samples of wheat were collected directly after harvesting and analysed for DON with LC-MS (Van der Fels-Klerx et al., 2012; R. Hoogenboom, 2013, personal communication). A set of 143 samples was obtained and these were evaluated for the effect of applying different MLs (excluding samples above the applied ML) on the mean LB and UB concentration (Table 3).

DON could be quantified in 70 out of 143 samples (LOQ of 100 µg/kg). The mean LB concentration of the 143 samples was 631 µg/kg, due to some samples with very high levels. Applying a ML of 750 µg/kg, the mean level would be significantly reduced by a factor of 4.64 to 136 µg/kg. When applying a ML of 1000 µg/kg, there would be a reduction by a factor of 4.15 to a mean level of 152 µg/kg. When raising the ML from 750 to 1000 µg/kg, the increase in the mean level would be by a factor of 1.12.

The mean UB concentration level would decrease from 682 to 194 µg/kg by applying an ML of 750 µg/kg, and to 210 with an ML of 1000 µg/kg. In that case, the increase in the ML from 750 to 1000 µg/kg would result in an increase in the mean level by a factor of 1.08.

These data show that the mean LB and UB DON levels would increase by a factor of 1.12 and 1.08, respectively when raising the ML from 750 to 1000 µg/kg. These factors are within the 95 % CI of the simulated factors and support the outcome of the simulation approach (see Section 5.1.2).

Table 3: Summary statistics of DON concentrations in Dutch wheat samples when applying different maximum levels (based on Van der Fels-Klerx et al., 2012; R. Hoogenboom, 2013, personal communication).

Maximum level (µg/kg)	N	LC (N)	Mean (LB) (µg/kg)	Mean (UB) (µg/kg)	P95 (µg/kg)
None	143	73	631	682	2505
1000	127	73	152	210	630
750	124	73	136	194	583

N: number of samples; LC(N): number of left-censored data; LB: lower bound; UB: upper bound; P95: 95th percentile

5.2. Influence of increasing the maximum level on chronic exposure levels

5.2.1. Methodology

Chronic exposure to DON was assessed at the individual level by multiplying the mean daily consumption for each food with the corresponding mean DON 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 1 µg/kg b.w. per day was estimated.

The chronic exposure was first assessed considering the mean DON concentration as estimated from the existing dataset (see appendix A), hereafter referred to as 'chronic exposure estimation with current ML'. In order to assess the influence of increasing the ML on chronic exposure levels, the chronic exposure was also assessed considering an increase by a factor of 1.15 of the mean DON levels in all food products potentially containing barley flour, wheat flour and semolina as ingredients. This mainly concerned bread and rolls (except those exclusively made with flours other than wheat, such as rye bread and crisp), mixed breakfast cereals and porridge, fine bakery wares, pasta, some composite foods and snacks (sandwiches, pizza, pretzels), some foods for infants and young children (cereal-based foods, and ready-to-eat meals based on cereals) and some products for special nutritional use (fine bakery wares for diabetics and complete formulas). For the other foods, the mean DON levels were the ones estimated from the reported dataset. This scenario is hereafter referred to as 'simulated chronic exposure with suggested increased ML'.

The percentage difference between the exposure levels obtained from the two calculations was characterised for each [survey and age class] combination across the Comprehensive Database.

5.2.2. Results

Table 4 presents 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 group PMTDI of 1 µg/kg b.w., estimated across the different surveys and age groups for the current exposure estimation and the simulated exposure scenario (detailed results by survey and age class are available in Appendix D). Whereas all surveys and age groups were used to derive the ranges of the mean exposure levels, only the ones with more than 60 subjects were used to derive the ranges of the 95th percentiles and percentages of subjects above the group PMTDI.

Table 4: Current and simulated chronic exposure to deoxynivalenol expressed in µg/kg b.w. per day across surveys for each age group

	Chronic exposure estimation with current ML			Simulated chronic exposure with suggested increased ML		
	Mean LB-UB	**P95 LB-UB**	**Percentage above group PMTDI LB-UB(a) (%)**	**Mean LB-UB**	**P95 LB-UB**	**Percentage above group PMTDI LB-UB(a) (%)**
			Infants (N(b) = 2/1)			
Minimum	0.22 - 0.78	1.05 - 1.86	5.6 - 32.6	0.25 - 0.83	1.20 - 1.91	7.1 - 36.9
Median	-	-	-	-	-	-
Maximum	0.30 - 0.79	1.05 - 1.86	5.6 - 32.6	0.34 - 0.86	1.20 - 1.91	7.1 - 36.9
			Toddlers (N(b) = 9/6)			
Minimum	0.47 - 0.70	0.94 - 1.20	2.4 - 13.4	0.50 - 0.75	1.04 - 1.39	6.4 - 18.5
Median	0.56 - 0.92	1.02 - 1.72	5.7 - 33.1	0.63 - 1.02	1.17 - 1.92	9.6 - 39.1
Maximum	0.94 - 1.10	1.55 - 2.13	42.1 - 49.5	1.07 - 1.25	1.77 - 2.27	54.2 – 64.0
			Other children (N(b) = 17/17)			
Minimum	0.45 - 0.49	0.83 - 0.92	0.4 - 2.2	0.50 - 0.54	0.92 - 1.02	3.8 - 5.9
Median	0.59 - 0.64	1.00 - 1.11	5.1 - 8.5	0.68 - 0.73	1.15 - 1.25	11.0 - 15.3
Maximum	0.94 - 0.96	1.65 - 1.73	43.0 - 44.6	1.07 - 1.10	1.90 - 1.97	52.9 - 55.4
			Adolescents (N(b) = 12/12)			
Minimum	0.30 - 0.32	0.63 - 0.66	0	0.34 - 0.36	0.72 - 0.74	0 - 0.4
Median	0.38 - 0.41	0.73 - 0.77	0.6 - 1.2	0.43 - 0.46	0.83 - 0.87	1.5 - 2.7
Maximum	0.53 - 0.55	1.00 - 1.04	4.7 – 6.0	0.61 - 0.63	1.16 - 1.17	11.1- 12.8
			Adults (N(b) = 15/15)			
Minimum	0.18 - 0.24	0.35 - 0.47	0	0.20 - 0.26	0.40 - 0.51	0 - 0.1
Median	0.25 - 0.32	0.49 - 0.59	0 - 0.2	0.28 - 0.35	0.56 - 0.67	0.1 - 0.4
Maximum	0.35 - 0.43	0.63 - 0.97	0.5 - 4.8	0.40 - 0.48	0.73 - 1.05	0.8 - 6.3
			Elderly (N(b) = 7/7)			
Minimum	0.17 - 0.21	0.36 - 0.43	0	0.19 - 0.23	0.41 - 0.46	0
Median	0.24 - 0.28	0.48 - 0.52	0	0.27 - 0.30	0.56 - 0.60	0 - 0.4
Maximum	0.31 - 0.32	0.51 - 0.59	0.1 - 0.5	0.36 - 0.37	0.59 - 0.65	0.2 - 0.6
			Very elderly (N(b) = 6/5)			
Minimum	0.22 - 0.25	0.42 - 0.44	0	0.26 - 0.28	0.48 - 0.50	0
Median	0.24 - 0.28	0.52 - 0.55	0	0.27 - 0.31	0.60 - 0.63	0 - 0.3
Maximum	0.33 - 0.34	0.56 - 0.57	0.3 - 1.2	0.38 - 0.39	0.65	0.4 - 1.2

ML: maximum level; PMTDI: provisional maximul tolerable daily intake; N: number of samples; LB: lower bound; UB: upper bound; P95: 95th percentile

(a): Percentage of subjects with an exposure above the group PMTDI LB – UB.

(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 group PMTDI.

Note: The numbers for the exposure values are all given with 3 figures but this does not reflect precision.

As already shown in the EFSA report (2013), the mean exposure levels estimated from the reported data (chronic exposure estimation with current ML) are in the range of the group PMTDI of 1 µg/kg b.w. for some surveys covering children age groups (infant, toddlers, other children). Indeed, the mean exposure levels range between 0.22 and 0.94 µg/kg b.w. per day at the LB and 0.49 and 1.10 µg/kg b.w. per day at the UB. The 95th percentile of exposure was between 0.83 and 1.65 µg/kg b.w. per day at the LB and between 0.92 and 2.13 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 remain below the group PMTDI, being between 0.17 and 0.53 µg/kg b.w. per day at the LB and 0.21 and 0.55 µg/kg b.w. per day at the UB. However, the 95th percentile of exposure is in the range of the group PMTDI for some surveys, being between 0.35 and 1.0 µg/kg b.w. per day at the LB and 0.43 and 1.04 µg/kg b.w. per day at the UB.

Depending on the surveys and age groups, the mean and 95th percentile exposure levels (LB and UB estimates) calculated for the simulated chronic exposure with the suggested increased ML are 4.2 to 16.0 % higher than the levels estimated for the chronic exposure with the current ML (Table 5). In some [survey x age group] combinations, the percentage increase of exposure is equal to the simulated percentage increase of the mean DON concentration in barley flour, wheat flour and semolina. This is explained by the fact that almost all exposure to DON is from the consumption of cereal-based products, most of them containing wheat flour or semolina.

Based on the reported data, the exceedance of the group PMTDI is the highest for the toddlers age group and ranges between 2.4 and 49.5 % (minimum LB and maximum UB). For the simulated chronic exposure with the suggested increased ML, this is increased to between 6.4 and 64 %. Based on median chronic exposure in other children and adults, the percentage of consumers exceeding the group PMTDI is approximately 2-fold higher with the suggested increased ML (0.1 – 15.3 %) than with the current ML (0 – 8.5 %). This is also the case for the majority of the surveys in adolescents.

Table 5: Percentage increase of exposure from current to simulated exposure 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
Infants	-[(b)][11.9; 14.9]	-[(b)][5.3; 10.0]	14.6	2.8
Toddlers	13.8 [7.3; 15.4]	12.9 [6.0; 15.0]	14.6 [6.4; 15.1]	8.9 [4.2; 15.1]
Other children	13.6 [10.9; 15.4]	12.8 [10.0; 14.8]	13.6 [11.6; 16.0]	12.8 [7.7; 16.0]
Adolescents	13.9 [11.5; 15.4]	13.0 [10.9; 15.1]	14.6 [9.6; 16.0]	13.1 [10.1; 15.9]
Adults	13.4 [9.9; 15.3]	11.1 [8.3; 14.5]	13.0 [9.3; 15.8]	9.5 [6.0; 14.6]
Elderly	14.7 [10.1; 15.5]	12.8 [8.4; 14.8]	15.1 [7.8; 16.0]	10.9 [7.6; 15.6]
Very elderly	14.9 [11.5; 15.6]	13.6 [9.1; 15.1]	15.7 [13.5; 16.0]	13.6 [10.9; 14.8]

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 simulated chronic exposure scenario and the mean/95th percentile obtained with current chronic exposure estimation divided by the mean/95th percentile obtained with current chronic exposure scenario, 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.

5.3. Influence of increasing the maximum level on acute exposure levels

5.3.1. Methodology

The influence of increasing the ML on acute exposure levels was assessed through two different scenarios:

- A first scenario (A) was considered, reflecting the situation where a consumer would prepare all the cereal-based foods (bread, pastries, pasta, etc.) by himself, using the same batch of flour or semolina. In this scenario, all the barley flour, wheat flour and wheat semolina eaten as such or present in composite products (Appendix E) during a day were considered to contain DON at the level of the ML. In a first sub-scenario (A.1) all the barley flour, wheat flour and semolina were considered at the current ML of 750 µg/kg. In a second sub-scenario (A.2), they were considered at the suggested increased ML of 1000 µg/kg. The other foods consumed the same day were considered at the background DON levels (mean LB - UB level), as estimated from the reported data.

For each age group and survey combination, the mean and the 95th percentile of exposure derived from all the consumption days as well as the percentage of consumption days with an exposure level higher than the group ARfD were estimated. A minimum of 60 consumption days were required for the estimation of the 95th percentile of exposure and the percentage of days above the group ARfD (Appendix F).

- A second scenario (B) was designed to reflect the situation of a consumer who eats commercially produced (not home-made) cereal-based products (bread, pastries, pasta). This scenario aims to reflect the impact on acute dietary exposure of increasing the ML on the ingredients taking into consideration that the ML applying on the final products will not be changed. In this scenario, the acute exposure resulting from the consumption of cereal-based food was assessed independently for each processed cereal-based product containing barley and/or wheat flour and semolina. Indeed, the probability that different commercially produced foods consumed the same day simultaneously contain high concentrations of DON is small. For this scenario, the concentration of DON in the final product was calculated by using the ML of the ingredient and the percentage of the ingredient in the final product. In a first sub-scenario (B.1), the current ML of 750 µg/kg in ingredients was used and in a second sub-scenario (B.2), the suggested increased ML of 1000 µg/kg in ingredients was used. In both sub-scenarios, if the calculated concentration of DON in the final product is above the ML defined for the final product, then the ML of the final product was used in the exposure calculation. The other foods consumed the same day were considered at the background mean UB DON concentrations as estimated from the reported data.

  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

✓ Scenario A

Exposure levels estimated from scenario A are detailed for each survey and age class in Appendix F. For each age class, the minimum, median and maximum mean, 95th percentile acute dietary exposure and percentage of days above the group ARfD across the European surveys are shown in Table 6. The influence of changing the ML is expressed as a percentage difference between the exposure levels estimated with the suggested increased ML and the one estimated with the current ML, which is characterised for each age class and survey combination. The mean acute exposure levels resulting from the consumption of barley/wheat flour/semolina at 750 µg/kg DON are below the group ARfD in all [survey x age group] combinations. In the surveys covering children age groups, the mean exposures are between 1.62 and 4.54 µg/kg b.w. at the LB, and between 1.65 and 4.66 µg/kg b.w. at the UB. In surveys covering adult age groups, the mean exposures are between 0.72 and 2.61 µg/kg b.w. at the LB, and between 0.76 and 2.62 µg/kg b.w. at the UB. However, the 95th percentile acute exposures of toddlers and other children are, in some surveys, in the range of the group ARfD, being between 3.88 and 10.40 µg/kg b.w. at the LB, and between 3.96 and 10.90 µg/kg b.w. at the UB. In the surveys covering adult age groups the 95th percentile acute exposures are between 1.64 and 5.38 µg/kg b.w. at the LB, and between 1.66 and 5.38 µg/kg b.w. at the UB. Up to 15.7 % and up to 0.4 % of consumption days are found with exposure levels above the group ARfD across the surveys covering children and adults age groups, respectively.

Table 6: Acute exposure to deoxynivalenol expressed in µg/kg b.w. across surveys for each age group

	Scenario A.1 (Current ML)			Scenario A.2 (Suggested increased ML)		
	Mean LB-UB[(a)]	**P95 LB-UB[(b)]**	**Percentage days above group ARfD LB-UB[(c)]**	**Mean LB-UB[(a)]**	**P95 LB-UB[(b)]**	**Percentage days above group ARfD LB-UB [(c)]**
			Infants (N[(d)] = 2/1)			
Minimum	2.37 - 2.75	6.31 - 6.59	2.1 - 2.2	3.15 - 3.53	8.29 - 8.54	6.3 – 8.0
Median	-	-	-	-	-	-
Maximum	3.10 - 3.56	6.31 - 6.59	2.1 - 2.2	4.09 - 4.56	8.29 - 8.54	6.3 – 8.0
			Toddlers (N[(d)] = 10/9)			
Minimum	2.36 - 2.54	5.01 - 5.05	0.3	3.07 - 3.25	6.66 - 6.66	2.3
Median	3.35 - 3.59	7.31 - 7.45	3.6 - 3.7	4.43 - 4.67	9.71 - 9.87	8.8 - 11.2
Maximum	4.54 - 4.66	10.4 - 10.9	14.8 - 15.7	6.04 - 6.17	13.8 - 14.3	25.9
			Other children (N[(d)] = 18/18)			
Minimum	1.62 - 1.65	3.88 - 3.96	0	2.12 - 2.15	5.07 - 5.21	0.5
Median	2.40 - 2.45	5.10 - 5.13	0.8 - 0.8	3.16 - 3.21	6.78 - 6.80	2.7 - 2.8
Maximum	4.12 - 4.15	8.74	6.4 - 6.6	5.48 - 5.51	11.7	16.7 - 16.9
			Adolescents (N[(d)] = 14/14)			
Minimum	1.18 - 1.22	2.66 - 2.70	0	1.56 - 1.60	3.54 - 3.58	0
Median	1.63 - 1.66	3.92 - 3.95	0.1	2.16 - 2.19	5.20 - 5.22	0.8
Maximum	2.61 - 2.62	5.38	0.4	3.47 - 3.48	7.18	2
			Adults (N[(d)] = 21/21)			
Minimum	0.78 - 0.82	1.80 - 1.85	0	1.01 - 1.06	2.37 - 2.44	0
Median	1.19 - 1.24	2.40 - 2.53	0	1.57 - 1.62	3.17 - 3.28	0
Maximum	1.76 - 1.78	3.57 - 3.60	0.2	2.34 - 2.36	4.75 - 4.79	0.5
			Elderly (N[(d)] = 9/9)			
Minimum	0.72 - 0.76	1.64 - 1.66	0	0.94 - 0.98	2.17 - 2.18	0
Median	1.12 - 1.13	2.41 - 2.43	0	1.49 - 1.50	3.22 - 3.23	0
Maximum	1.56 - 1.57	2.94 - 2.97	0.2	2.08 - 2.09	3.92 - 3.96	0.2
			Very elderly (N[(d)] = 8/8)			
Minimum	0.77 - 0.80	1.73 - 1.78	0	1.01 - 1.04	2.28 - 2.33	0
Median	1.10 - 1.11	2.22 - 2.28	0	1.46 - 1.47	2.96 – 3.00	0
Maximum	1.67 - 1.68	3.41 - 3.44	0.1	2.23 - 2.24	4.55 - 4.57	0.1

N: number of samples; LB: lower bound; UB: upper bound; P95: 95th percentile; ARfD: acute reference dose; ML: maximum level

(a): mean LB-UB: mean lower bound – upper bound derived from the consumption days.
(b): P95 LB – UB: 95th percentile lower bound – upper bound derived from the consumption days.
(c): Percentage of consumption days with an exposure above the group ARfD.
(d): Number of surveys used to derive the mean exposure levels/number of surveys used to derive the 95th percentile exposure levels and percentages of days with exposure above the group ARfD.

Note: The numbers for the exposure values are all given with 3 figures but this does not reflect precision.

Depending on age class and survey combinations, the mean and 95th percentile exposure levels (LB and UB estimates) estimated with scenario A.2 (barley/wheat flour/semolina at 1000 µg/kg) are 26.9 to 33.3 % higher than the levels estimated with scenario A.1 (Table 7). As observed in scenario A.1, the mean acute exposure levels are below the group ARfD, whereas the 95th percentile exposure levels of toddlers and other children are above the group ARfD for some surveys. Up to 25.9 % and up to 2 % of consumption days are found with exposure levels above the group ARfD across the surveys in the children and adults age groups, respectively (Table 6). The percentage of days with an acute exposure above the group ARfD is increased by a factor of 2 or more in some surveys for several age groups, especially the younger age groups, when comparing scenario A.2 (suggested increased ML) with scenario A.1 (current ML).

Table 7: Percentage increase of exposure from scenario A.1 to scenario A.2 estimated across surveys for each age group

Age class	Median percentage increase of exposure [minimum; maximum][(a)] Mean[(c)]		P95[(d)]	
	LB	**UB**	**LB[(f)]**	**UB[(g)]**
Infants	-[(b)] [32.0; 33.0]	-[(b)] [27.8; 28.5]	31.5	29.5
Toddlers	32.4 [27.7; 33.1]	31.2 [26.9; 32.9]	32.8 [28.9; 33.3]	31.9 [28.3; 33.3]
Other children	32.1 [30.6; 33.1]	31.6 [30.0; 32.8]	32.9 [30.5; 33.3]	32.5 [30.7; 33.3]
Adolescents	32.4 [31.1; 33.1]	31.8 [30.7; 32.9]	32.7 [30.1; 33.3]	32.6 [31.2; 33.3]
Adults	32.2 [30.3; 33.1]	30.8 [28.7; 32.7]	32.5 [31.3; 33.3]	32.0 [27.6; 32.9]
Elderly	32.8 [30.4; 33.1]	32.4 [28.9; 32.8]	33.3 [31.8; 33.3]	32.7 [29.2; 33.3]
Very elderly	32.8 [30.9; 33.2]	32.3 [28.9; 33.0]	33.2 [31.8; 33.3]	32.2 [30.4; 33.3]

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

(a) Percentage difference, determined for each [age group x survey] combination, as the difference between the mean/95th percentile obtained with scenario A.2 and the mean/95th percentile obtained with scenario A.1 divided by the mean/95th percentile obtained with scenario A.1, and presented for each age group 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.

✓ Scenario B

The acute exposure was assessed for 18 processed cereal-based food groups containing barley/wheat flour/semolina and with more than 60 consumption days available in at least one [survey x age group] combination (Table 8). Not enough consumption data were available for assessing the acute exposure resulting from the consumption of two infant foods: pasta for children, and cereals with added high protein food that are or have to be reconstituted with water or other protein-free liquid.

More than half of these processed cereal-based food groups (n = 10) were not associated with any consumption day above the group ARfD for either scenario B.1 or B.2 (Table 8): other bread, bread products, mixed breakfast cereals, porridge, biscuits salty, biscuits other, sandwich, pretzel, simple cereals and biscuits, rusks and cookies for children. For simple cereals and biscuits, rusks and cookies for children, the current ML of 200 µg/kg was used for both scenarios whereas for the other products, the current or suggested increased ML corrected by the flour content were used to estimate the acute dietary exposure.

Table 8 shows, for all processed cereal-based food groups, 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 (B.1 and B.2). The wheat bread and rolls and pasta were found with at least one consumption day above the group ARfD in 10 surveys (out of 64 and 60 surveys, respectively, taken into account in the acute assessment) with scenario B.1. In these surveys, the percentage of consumption days above the group ARfD were estimated to be up to 0.9 % and up to 6.5 % for wheat bread and rolls and pasta, respectively. In scenario B.2, which was corresponding to the ML applying for these products (500 µg/kg for bread and rolls and 750 µg/kg for pasta), the number of surveys with at least one consumption day above the group ARfD was increased to 16 and 20 for wheat bread and rolls and pasta, respectively, with a percentage of consumption days above the group ARfD of up to 2.2 % and up to 13.2 %. However, it should be noted that a decrease of DON concentration during pasta cooking of up to 75 % has been observed (Cano-Sancho et al., 2013; see Section 3.4). This decrease is caused by the transfer of DON into the cooking water and the uptake of water into the pasta during cooking. This reduction has not been taken into account in this exposure assessment, which was done considering both pasta consumption levels and DON occurrence levels expressed on a dry equivalent basis.

Pastries and cakes were found in scenario B.1 with at least one consumption day above the group ARfD in 4 surveys, out of 58 surveys taken into account in the acute exposure assessment. In these surveys, the percentage of consumption days above the group ARfD was up to 0.4 %. In scenario B.2, the number of surveys with at least one consumption day above the group ARfD increased to 5 for the pastries and cakes. The percentage of consumption days above the group ARfD was up to 0.8 %.

In the only infant survey taken into account in the acute exposure assessment, a ready-to-eat cereal-based meal for children was associated with 1.1 % of consumption days above the group ARfD in both scenarios.

In the other food groups (mixed wheat and rye bread and rolls, unleavened bread, crisp bread, and rolls, multigrain bread and rolls and pizza), 1 or 2 surveys were found with at least one consumption day above the group ARfD with scenario B.1 and up to 4 surveys with scenario B.2. The percentage of consumption days above the group ARfD was up to 1.04 % in both scenarios.

Table 8: Acute exposure to deoxynivalenol expressed in µg/kg b.w. across surveys and age groups

Food	Age class	N[(a)]	Range of consumption days[(b)]	Scenario B.1 (Current ML)		Scenario B.2 (Suggested increased ML)	
				N > group ARfD[(c)]	Range of percentage days above group ARfD[(d)]	N > group ARfD(c)	Range of percentage days above group ARfD[(d)]
Bread and rolls							
Wheat bread and rolls	Infants	1	379	0	-	1	0.53
	Toddlers	4	90 - 691	1	0.58	3	0.3 - 2.22
	Other children	13	161 - 2907	5	0.17 - 0.93	7	0.17 - 1.6
	Adolescents	12	132 - 4571	1	0.07	2	0.09 - 0.37
	Adults	19	66 - 16855	3	0.01 - 0.18	3	0.02 - 0.18
	Elderly	8	104 – 1879	0	-	0	-
	Very elderly	7	112 - 1346	0	-	0	-
Mixed wheat and rye bread and rolls	Other children	6	69 - 3034	1	0.03	1	0.1
	Adolescents	5	371 - 2424	1	0.04	2	0.04 - 0.17
	Adults	8	114 - 16369	0	-	1	0.05
	Elderly	4	156 – 2019	0	-	0	-
	Very elderly	3	93 - 350	0	-	0	-
Unleavened bread, crisp bread and rusk	Infants	1	156	0	-	0	-
	Toddlers	3	120 – 223	0	-	0	-
	Other children	10	70 – 891	0	-	0	-
	Adolescents	8	72 – 445	1	0.46	1	0.46
	Adults	10	120 – 1694	0	-	0	-
	Elderly	5	70 – 313	0	-	0	-
	Very elderly	4	79 - 206	0	-	0	-
Multigrain bread and rolls	Toddlers	1	136	0	-	0	-
	Other children	3	95 - 385	0	-	0	-
	Adolescents	3	71 - 434	1	1.04	1	1.04
	Adults	6	126 - 5932	1	0.23	1	0.23
	Elderly	1	1309	0	-	0	-
	Very elderly	1	313	0	-	0	-

Table 8: Continued

Food	Age class	N[(a)]	Range of consumption days simulated[(b)]	Scenario B.1 (Current ML): N > group ARfD[(c)]	Scenario B.1 (Current ML): Range of percentage days above group ARfD[(d)]	Scenario B.2 (Suggested increased ML): N > group ARfD(c)	Scenario B.2 (Suggested increased ML): Range of percentage days above group ARfD[(d)]
Bread and rolls							
ther bread	Toddlers	1	183	0	-	0	-
	Other children	3	96 – 467	0	-	0	-
	Adults	7	67 - 1172	0	-	0	-
	Elderly	2	76 - 105	0	-	0	-
Bread products	Toddlers	1	159	0	-	0	-
	Other children	8	84 - 653	0	-	0	-
	Adolescents	5	162 - 744	0	-	0	-
	Adults	13	75 – 2947	0	-	0	-
	Elderly	7	80 - 425	0	-	0	-
	Very elderly	2	73 – 80	0	-	0	-
Breakfast cereals							
Mixed breakfast cereals	Other children	2	63 - 110	0	-	0	-
	Adults	2	279 – 454	0	-	0	-
Porridge	Other children	2	87 - 761	0	-	0	-
	Adolescents	1	145	0	-	0	-
	Adults	1	1170	0	-	0	-
Fine bakery wares							
Pastries and cakes	Infants	1	90	0	-	0	-
	Toddlers	3	95 - 383	0	-	0	-
	Other children	14	102 - 2207	3	0.2 - 0.4	4	0.28 - 0.78
	Adolescents	12	97 - 3434	1	0.08	1	0.08
	Adults	18	93 - 7450	0	-	0	-
	Elderly	6	113 - 1698	0	-	0	-
	Very elderly	4	94 - 440	0	-	0	-
Biscuits, salty	Other children	2	125 - 135	0	-	0	-
	Adolescents	1	156	0	-	0	-
	Adults	6	76 – 527	0	-	0	-
	Elderly	1	71	0	-	0	-
Biscuits, other	Infants	1	338	0	-	0	-
	Toddlers	4	124 - 257	0	-	0	-
	Other children	12	86 - 1136	0	-	0	-
	Adolescents	9	62 - 1496	0	-	0	-
	Adults	13	60 - 2570	0	-	0	-
	Elderly	4	132 - 237	0	-	0	-
	Very elderly	2	221 - 278	0	-	0	-
Pasta							
Pasta	Toddlers	5	77 - 381	2	0.26 - 2.37	4	0.26 – 4.14
	Other children	13	102 - 2258	5	0.22 – 6.51	7	0.1 – 13.19
	Adolescents	10	146 - 2096	2	0.16 - 0.39	4	0.05 - 1.54
	Adults	19	92 - 5174	1	0.38	3	0.16 - 0.76
	Elderly	8	89 - 572	0	-	1	1.12
	Very elderly	5	94 - 454	0	-	1	1.06

Table 8: Continued

Food	Age class	N(a)	Range of consumption days simulated(b)	Scenario B.1 (Current ML)		Scenario B.2 (Suggested increased ML)	
				N > group ARfD(c)	Range of percentage days above group ARfD(d)	N > group ARfD(c)	Range of percentage days above group ARfD(d)
Cereal-based dishes							
Sandwich	Other children	3	80 - 273	0	-	0	-
	Adolescents	2	78 - 83	0	-	0	-
	Adults	2	76 - 82	0	-	0	-
Pizza and pizza-like pies	Other children	4	90 - 553	0	-	2	0.18 - 0.39
	Adolescents	6	61 - 529	1	0.19	1	0.19
	Adults	5	84 - 705	0	-	0	-
Snack							
Pretzel	Toddlers	1	60	0	-	0	-
	Other children	1	91	0	-	0	-
Food for infants							
Simple cereals	Infants	1	180	0	-	0	-
	Toddlers	1	197	0	-	0	-
Biscuits, rusks and cookies	Infants	1	88	0	-	0	-
	Toddlers	2	249 - 644	0	-	0	-
	Adults	1	189	0	-	0	-
Ready-to-eat meal for children, cereal-based	Infants	1	182	1	1.1	1	1.1

N: number of surveys; ML: maximum level; ARfD: acute reference dose.

(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): number of surveys with a least one consumption day above the group ARfD.

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

6. Risk characterisation

When characterising the risk associated with the suggested increased DON ML, the CONTAM Panel has used the group PMTDI of 1 µg/kg b.w. and the group ARfD of 8 µg/kg b.w., which were established by JECFA in 2010. The CONTAM Panel notes that these group HBGVs include the acetyl-derivatives 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not been covered in this statement, since the acetyl-derivatives are not included in the current or suggested increased ML and few data are available on their occurrence in food in the EU.

The suggested increase of the ML for barley flour, wheat flour and semolina from 750 to 1000 µg/kg is expected to give a LB to UB increase in mean DON concentration in these cereal products of 1.14 to 1.16 (95 % CI = 1.08-1.23).

Chronic exposure

Across age groups and dietary surveys, the increased level of DON in ingredients resulting from a higher ML will lead to an increase in mean chronic DON exposure of 7.3 % to 15.1 % (minimum LB to maximum UB), and an increase of 95th percentile DON exposure of 6.4 % to 16 % (minimum LB to maximum UB). In some [survey x age group] combinations, the percentage increase of exposure is equal to the simulated percentage increase of the mean DON concentration in barley flour, wheat flour and semolina. Barley flour, wheat flour and semolina are main ingredients of the bread and rolls, pasta and fine bakery wares, which, together with grain milling products, have been previously reported as main contributors to the total chronic exposure to DON (EFSA, 2013).

At the current ML, the exposure to the parent compound DON of some consumers in all age groups exceeds the group PMTDI for DON and its acetyl-derivatives. The proportion exceeding is highest in the younger age groups (infants, toddlers, other children and adolescents). The proportion of people exceeding the group PMTDI is expected to increase with the suggested increased ML. Among infants (represented by only two surveys), a range from 5.6 % to 32.6 % (minimum LB to maximum UB) exceeds the group PMTDI with the current ML, and 7.1 % to 36.9 % is expected to exceed the group PMTDI with the suggested increased ML. Among toddlers (6 to 9 surveys), 2.4 % to 49.5 % exceeds the group PMTDI with the current ML, increasing to 6.4 % to 64 % with the suggested increased ML. A similar pattern is seen in the group of other children, who are represented by 17 surveys. At the current ML, 0.4 % to 44.6 % exceeds the group PMTDI. This is expected to increase to a range of 3.8 % to 55.4 % with the suggested increased ML. The proportion exceeding the group PMTDI both with the current and suggested increased ML is lower among adolescents, adults, elderly and very elderly. Based on median chronic exposure in other children, adolescents and adults, the percentage of consumers exceeding the group PMTDI is approximately 2-fold higher with the suggested increased ML than with the current ML.

The group PMTDI for DON and its acetyl-derivatives was established by JECFA based on a NOEL for decreased body weight gain in a long term feeding study in mice, and an uncertainty factor of 100. This endpoint is of particular relevance for infants, toddlers, children and adolescents, since they are in growing life stages. Exposure above the group PMTDI for these age groups is therefore of concern.

Acute exposure

Since the ML for cereal flour is higher than for flour-containing end-products such as bread and pasta, the first acute exposure scenario (scenario A) addressed people who consume mainly home-made cereal food. This exposure scenario indicates that acute DON exposure would increase by approximately 30 % across surveys and age groups with the suggested increased ML. The acute exposure scenario using DON concentrations equal to the current ML in barley flour, wheat flour and wheat semolina indicated that DON exposure could exceed the group ARfD in up to 16 % of the consumption days in toddlers and up to 0.2 % in adults. With the suggested increased ML, this proportion would increase to 26 % in toddlers and 0.5 % in adults.

However, the probability that all barley flour, wheat flour and wheat semolina present in different cereal-based products consumed during one day have a DON level equal to the ML is unlikely, and the scenario can be considered as a worst-case scenario.

The second acute exposure scenario (scenario B) addressed people who consume commercially produced foods (not home-made), since the concentration in these products may increase with the suggested increased ML for the ingredients, although still below the ML for the final product, because a higher level in the ingredients can be expected.

The scenario with wheat bread and rolls and pasta resulted in at least one consumption day above the group ARfD in several surveys, both with the current ML and with the suggested increased ML. The percentage of consumption days exceeding the ML was up to 0.9 % for wheat bread and rolls and up to 6.5 % for pasta, with the current ML. With the suggested increased ML, the number of consumption days above the group ARfD was approximately doubled, to 2.2 % for wheat bread and rolls and up to 13.2 % for pasta. However for pasta, this may be quite an overestimation, considering that the cooking effect on the DON level has not been taken into account.

In addition, acute DON exposure from pastries and cakes made with ingredients with a DON concentration at the ML (in addition to the background exposure from other food) were found to exceed the group ARfD in some surveys for at least one consumption day. The percentage of consumption days exceeding the group ARfD increased from 0.4 % with the current ML to 0.8 % with the suggested increased ML.

A ready-to-eat cereal-based meal for children was associated with 1.1 % of consumption days above the group ARfD, but with no difference between the scenarios. Also for some other food groups (mixed wheat and rye bread and rolls, unleavened bread, crisp bread, and rolls, multigrain bread and rolls and pizza), there were no differences between the two acute exposure scenarios in percentage of days above the group ARfD.

Increased probabilities of exceeding the group ARfD with the suggested increased ML in cereal ingredients were seen with both the scenario addressing home-made cereal food and the one addressing commercially produced cereal food. The proportion of consumption days above the group ARfD was highest for the acute exposure estimate with home-made cereal food. Although indicating concern, this scenario may be seen as a worst case. For commercially produced food, the percentages of consumption days with exposure above the group ARfD was generally low. However, the exposure scenario can be considered as realistic. Higher probabilities of having exposure above the group ARfD with the suggested increased ML is particularly associated with consumption of pasta, wheat bread and rolls, and indicate concern.

The CONTAM Panel noted that the group PMTDI and group ARfD for DON include the acetyl-derivatives 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not been covered in this statement, since the acetyl-derivatives are not included in the current or suggested increased ML. The estimations in this statement indicate that the group HBGVs are already exceeded by the parent compound DON in a number of cases. An increase of the DON ML can be expected to be associated with an increase of both the levels of DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs.

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, exposure scenario, exposure model, and model input (parameters).

7.1. Assessment objectives

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

7.2. Exposure model/exposure scenario

As data from food business operators on results of self-monitoring could not be retrieved and thus an estimation of the percentage of samples that exceeded the current ML and therefore were not placed on the market was not feasible, the respective data were generated by a simulation approach. The approach relied on the assumption that the proportion of non-compliant samples (based on the reported data) would remain the same over time. The approach can consequently lead to an over- or underestimation. Although analytical results on unprocessed grains substantiate the outcome of the simulation approach, this introduces some uncertainty into the assessment.

In order to assess the impact of increasing the ML on the chronic exposure assessment, the mean DON levels were considered to increase by the same factor in all cereal-based products containing barley/wheat flour/semolina as in the ingredients that were considered in this statement. This assumption is equivalent to assuming that all DON present in the processed cereal-based products is from the barley/wheat flour/semolina. This is considered as a conservative approach, as DON could also stem from other ingredients, such as other kinds of flours.

In the acute exposure scenario addressing people who consume home-made cereal food, it was assumed that all the wheat/barley flours and semolina present in cereal food consumed during the same day contain DON at the current and suggested increased ML. This scenario is considered as a worst-case scenario, as processed cereal-based products such as bread and rolls and pasta are most often bought as such rather than prepared at home, and the probability that batches of wheat flour, barley flour and wheat semolina used in one household contain DON at a level equal to the ML at the same time is low.

In the acute exposure scenario addressing people who consume commercially produced foods, each cereal-based food containing barley and/or wheat flour and semolina at the ML 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.

Not all chronic and acute exposure scenarios took the effect of processing into account, such as cooking in water (pasta) which is known to decrease the level of DON in foods. This may have led to an overestimation of the acute exposure levels, especially the ones resulting from the consumption of cereal-based dishes.

Due to limited data, products of animal origin, starchy roots and tubers, fruits, nuts and oilseeds, vegetables (sweet corn excepted), beverages (beer excepted), vegetable oils, herbs spices and condiments and confectionary have not been taken into account in the exposure assessments. In the EFSA report, dried fruits, oilseeds, vegetable oils, tea and herbs infusion, confectionary, oat drinks, herbs spices and condiments and vegetable products were found to represent, depending on surveys and age classes, from 0.2 up to 2 % of the chronic LB average exposure estimate, and from 2 up to 16.2 % of the chronic UB average exposure estimate (EFSA, 2013). In addition, due to the lack of consumption data, the acute exposure resulting from the consumption of two infant foods namely, pasta for children and cereals with added high protein food which are or have to be reconstituted with water or other protein-free liquid, was not assessed.

Due to the limited number of samples with a DON concentration above the current ML of 750 µg/kg (N = 24), the distribution of DON levels above the ML was uncertain. Therefore, it was assumed that any value between the ML and the maximum reported concentration could be taken with the same probability. This assumption is considered to be conservative, as it is known from the usual distributions of contaminants in foods that the highest levels have generally a lower probability. However, a validation with observed concentrations in grains has supported the outcome of the simulation approach.

Overall, the exposure estimates performed in this statement are considered to overestimate the true exposure levels of the European population and introduce some uncertainty in the evaluation of the impact of increasing the ML in barley/wheat flour/semolina.

7.3. Model input (parameters)

The occurrence data, which were reported by the European countries and used in this assessment, are mainly from official food control programmes. The objective of these programmes is to check for compliance with MLs, rather than analysing background concentrations. Thus, the performance of the analytical methods is adapted to the MLs that have to be controlled. Consequently, the LODs/LOQs of the methods show a broad range and are often substantially higher than those that would be mandatory for assessments that realistically reflect human exposure. This may lead to a certain overestimation in the calculation of UB concentrations. In addition, a number of samples were generated with methods that were reported not to be validated. A further uncertainty is added to the assessment because for 22 % of the samples there was no indication of whether the results were corrected for recovery.

7.4. Other uncertainties

As the ML for DON only relates to the parent compound but does not include the acetyl-derivatives or bound conjugates, the impact of a possible increase of the ML was only estimated for DON itself, based on those occurrence data that were generated with analytical methods, which differentiate between the different forms. Although data on the acetyl-derivatives and the bound conjugates are scarce, they indicate that their contribution to total DON can be substantial. An increase of the DON ML can be expected to be associated with an increase of the levels of both DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs. In addition, the group PMTDI and group ARfD established by JECFA in 2010 were used in this statement. However, the full risk assessment that will be carried out by the CONTAM Panel could lead to the establishment of different group HBGVs.

7.5. Summary of uncertainties

In Table 9, 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 9: Summary of qualitative evaluation of the impact of uncertainties on the risk assessment of the dietary exposure of deoxynivalenol

Sources of uncertainty	Direction
Uncertainty in analytical results	+/-[(a)]
Influence of food processing on DON stability not considered	+
Broad range of LOQs	+
Use of UB data in the acute exposure assessment	+
Limited data on contribution of DON derivatives and conjugates to exposure	-
No information on self-monitoring data of food business operators	+/-
Generation of a new data set by simulation approach	+/-

DON: deoxynivalenol; LOQ: limit of quantification; UB: upper bound

(a): + = uncertainty with potential to cause over-estimation of exposure/risk; - = uncertainty with potential to cause under-estimation of exposure/risk

The CONTAM Panel considered that the impact of the uncertainties on the assessment of the risk for public health related specifically to a possible increase of the ML for DON for certain semi-processed cereal products is moderate.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

General

- Deoxynivalenol (DON) belongs to the group of trichothecene mycotoxins and is mainly produced by *Fusarium graminearum* and *F. culmorum*. Besides DON, also the acetyl-derivatives, 3-acetyl-deoxynivalenol (3-Ac-DON) and 15-acetyl-deoxynivalenol (15-Ac-DON) can be formed by these fungi and have been reported to occur together with DON.

- DON is a common contaminant in grains (wheat, maize, rye, barley, oats, and rice) and grain-based products.

- In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a group provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight (b.w.) for the sum of DON and its acylated derivatives (3-Ac-DON and 15-Ac-DON). In the same evaluation, the JECFA established a group acute reference dose (ARfD) of 8 µg/kg b.w. for the sum of DON and its acylated derivatives (3-Ac-DON and 15-Ac-DON). These group health based guidance values (HBGVs) were used in the current statement because the full assessment by the European Food Safety Authority (EFSA), requested by the European Commission in July 2013, has not been completed.

Impact of the ML on the occurrence levels and dietary exposure

- Existing occurrence data on DON in food generated with analytical methods based on gas or liquid chromatography, collected between 2007 and 2012 and reported by 21 European countries were used for the exposure assessment.

- The impact of increasing the maximum level (ML) for DON from 750 to 1000 µg/kg was assessed for barley flour, wheat flour and wheat semolina.

- Due to the lack of appropriate occurrence data from pre-market monitoring, the influence of increasing the ML on the mean DON level in the semi-processed cereal products was estimated using a simulation approach. It was estimated that changing the ML from 750 to 1000 µg/kg would increase the lower, middle and upper bound (LB, MB, UB) mean DON levels by factors of 1.16, 1.15 and 1.14, respectively.

- The outcome of the simulation approach was supported by a small data set of wheat samples from the Netherlands which indicated that the mean LB and UB levels of DON would increase by factors of 1.12 and 1.08, respectively, when increasing the ML from 750 to 1000 µg/kg.

- The mean chronic dietary exposure estimated from the reported data for ‘infants’, ’toddlers’ and ‘other children’ were between 0.22 and 1.10 µg/kg b.w. per day (minimum LB-maximum UB). The 95th percentile dietary exposure was between 0.83 and 2.13 µg/kg b.w. per day (minimum LB-maximum UB).

- The mean chronic dietary exposure estimated from the reported data for the adult age groups (adolescents, adults, elderly and very elderly), ranged between 0.17 and 0.55 µg/kg b.w. per day (minimum LB-maximum UB). The 95th percentile dietary exposure ranged between 0.35 and 1.04 µg/kg b.w. per day (minimum LB-maximum UB).

- Depending on the survey and age group, the mean and 95th percentile chronic dietary exposure estimated with the occurrence data simulating the suggested increased ML were 4.2 to 16.0 % higher than the levels estimated with the data set based on the reported data.

- Based on the reported data, the exceedance of the group PMTDI is the highest in the children age groups and ranges between 0.4 and 49.5 % (minimum LB to maximum UB). For the simulated chronic exposure with the suggested increased ML, this is increased and estimated to range between 3.8 and 64 %.

- An acute exposure scenario addressed people who consume mainly home-made cereal food prepared with barley/wheat flour/semolina containing DON equal to the ML.

- In the children age groups (infants, toddlers, other children), the mean acute dietary exposure resulting from the consumption of barley/wheat flour/semolina at an assumed DON concentration of 750 µg/kg ranged between 1.62 and 4.66 µg/kg b.w. (minimum LB-maximum UB) across the surveys. The 95th percentile acute dietary exposure levels ranged between 3.88 and 10.9 µg/kg b.w. (minimum LB-maximum UB). Up to 15.7 % of the consumption days were found with exposure levels above the group ARfD.

- In the adult age groups (adolescents, adults, elderly and very elderly), the mean acute exposure resulting from the consumption of barley/wheat flour/semolina at an assumed DON concentration of 750 µg/kg was between 0.72 and 2.62 µg/kg b.w. (minimum LB-maximum UB) across the surveys. The 95th percentile acute dietary exposure levels was between 1.64 and 5.38 µg/kg b.w. (minimum LB-maximum UB). Up to 0.4 % of the consumption days were found with exposure levels above the group ARfD.

- Depending on the survey and age group, the mean and 95th percentile acute dietary exposure estimated from the consumption of barley/wheat flour/semolina at the suggested increased ML of 1000 µg/kg were 26.9 to 33.3 % higher than when an ML of 750 µg/kg was assumed. Up to 25.9 and 2 %, respectively, of the consumption days were found with exposure levels above the group ARfD in the children and adults age groups, when assuming a DON concentration of 1000 µg/kg.

- A second acute exposure scenario addressed people who consume commercially produced foods. In general, this scenario resulted in a low percentage of consumption days above the group ARfD (< 1 %) except for wheat bread and rolls and pasta for which the percentage of consumption days above the group ARfD could increase up to 2 and 13 %, respectively, relative to the suggested increased ML. However for pasta, this may be an overestimation, considering that the effect of cooking on the DON level has not been taken into account.

- The EFSA Scientific Panel on Contaminants in the Food Chain noted that the group PMTDI and group ARfD for DON include the acetyl-derivatives 3-Ac-DON and 15-Ac-DON. The exposure from the acetyl-derivatives has not been covered in this statement, since the acetyl-derivatives are not included in the current or suggested increased ML and few data are available on their occurrence in food in the EU.

- Based on the published literature, it can be concluded that Ac-DONs may be present at higher percentages than those calculated from the EFSA and JECFA databases and thus may contribute substantially to the total DON exposure.

- Food processing (e.g. milling, bread making, boiling) can result in a decrease of the DON concentration. The extent may depend on the type of food, level of DON present and the processing conditions but no processing factors can be established.

Risk characterisation

- At the current ML, the exposure to the parent compound DON of some consumers in all age groups exceeds the group PMTDI for DON and its acetyl-derivatives. The proportion exceeding is highest in the younger age groups (infants, toddlers, other children and adolescents).

- The group PMTDI for DON and its acetyl-derivatives is based on a no-observed-effect level for decreased body weight gain in a long term feeding study in mice. This endpoint is of particular relevance for infants, toddlers, children and adolescents, since they are in growing life stages. Exposure above the group PMTDI for these age groups is therefore of concern.

- The proportion of people exceeding the group PMTDI is expected to increase with the suggested increased ML. Based on median chronic exposure in other children, adolescents and adults, the percentage of consumers exceeding the group PMTDI is approximately 2-fold higher with the suggested increased ML than with the current ML.

- Increased probabilities of exceeding the group ARfD with the suggested increased ML in cereal ingredients were seen with two different acute exposure scenarios addressing home-made and commercially produced foods. Higher probabilities of having exposure above the group ARfD with the suggested increased ML is particularly associated with consumption of pasta, wheat bread and rolls, and indicate concern.

- The exposure estimations in this statement indicate that the group HBGVs are already exceeded by the parent compound DON in a number of cases. An increase of the DON ML can be expected to be associated with an increase of the levels of DON and Ac-DONs in barley flour, wheat flour and semolina, and can therefore increase the exposure and consequently the exceedances of the group HBGVs.

RECOMMENDATIONS

- There is a need for occurrence data on acetyl-derivatives with sufficiently sensitive methods in order to assess their impact on the health risk associated with an increase of the ML for DON.

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APPENDICES

APPENDIX A: DISTRIBUTION OF DEOXYNIVALENOL LEVELS IN GRAINS AND GRAIN-BASED PRODUCTS

Table A1: Distribution of DON levels expressed in µg/kg across grains for human consumption

Foodex level	Food group	N	LC (%)	Concentration (µg/kg) Mean MB (LB – UB)[(a)]	P95 MB (LB – UB)[(a, c)]
2	**Grains for human consumption**	**1 642**	**62.1**	**141.5 [126.8; 156.2]**	**618.1**
3	Barley grain	137	78.8	50.5 [27.8; 73.2]	171.0
3	Maize grain	32	25.0	428.3 [422.5; 434.2]	-
3	Oats, grain	146	19.2	255.8 [251.6; 259.9]	756.0
3	Rye grain	337	85.2	38.1 [17.9; 58.4]	113.0
3	Wheat grain	802	51.9	192.4 [180.7; 204]	783.2
4	*Wheat germ*	*12*	*33.3*	*409.9 [400.3; 419.5]*	-
4	*Wheat grain*	*619*	*52.3*	*196.5 [184.1; 208.9]*	*806.5*
4	*Wheat grain, durum*	*47*	*61.7*	*335.1 [319.3; 351]*	-
4	*Wheat grain, soft*	*85*	*23.5*	*137.1 [131.6; 142.7]*	*480.0*
4	*Bulgur wheat*	*39*	*100*	*7.8 [0; 15.5]*	-
3	Other grains[(b)]	164	91.5	33.0 [14.4; 51.6]	60.0 [56.5; 100]
3	Grains, unspecified	24	91.7	77.6 [31.4; 123.9]	-

DON: deoxynivalenol; N: number of samples; LC: left-censored results; LB: lower bound; MB: middle bound; UB: upper bound; P95: 95th percentile.

(a): When the middle, lower and upper bound estimates are equal, only one estimate is given.

(b): Other grains: buckwheat grain (18), Einkorn (4), millet grain (5), rice grain (91), spelt grain (36), mixtures (7) and other (3).

(c): P95 is only reported for food groups for which at least 60 samples were available.

Table A2: Distribution of DON levels expressed in µg/kg across grain milling products

Foodex level	Food group	N	LC (%)	Concentration (µg/kg) Mean MB (LB – UB)[(a)]	P95 MB (LB – UB)[(a,d)]
2	**Grain milling products**	**2 771**	**44.3**	**124.8 [112.8; 136.8]**	**477.0**
3	Buckwheat milling products	29	96.6	31 [6.7; 55.3]	-
3	Maize milling products	240	51.3	134.4 [116.3; 152.4]	433.9
4	*Maize flour*	*85*	*51.8*	*128.6 [108.7; 148.6]*	*452.5*
4	*Maize semolina*	*38*	*60.5*	*95.8 [78.9; 112.7]*	-
4	*Maize meal*	*27*	*55.6*	*57.8 [31.1; 84.4]*	-
4	*Maize starch*	*21*	*90.5*	*73.7 [29; 118.3]*	-
4	*Maize milling products, unspecified*	*69*	*31.9*	*211.1 [206.2; 216]*	*640.0*
3	Oat milling products	131	50.4	74.8 [65.1; 84.6]	260.0
3	Rye milling products	378	67.7	48.6 [33.1; 64.1]	200.0
3	Spelt milling products	114	60.5	74.7 [61.6; 87.8]	352.0
3	Wheat milling products	1 703	33.4	152 [143.1; 161]	600.0
4	*Wheat bran*	*207*	*18.4*	*226.1 [221.2; 230.9]*	*600.0*
4	*Wheat flour, Durum*	*14*	*42.9*	*150.2 [128.7; 171.6]*	-
4	*Wheat flour, brown*	*15*	*46.7*	*73.2 [62.4; 84]*	-
4	*Wheat flour, white*	*1 077*	*34.6*	*140.8 [132; 149.7]*	*600.0*
4	*Wheat flour, wholemeal*	*203*	*20.2*	*133.9 [129.6; 138.1]*	*446.0*
4	*Wheat semolina, Durum*	*53*	*56.6*	*329.9 [313.6; 346.2]*	-
4	*Wheat semolina, soft wheat*	*50*	*64.0*	*79.1 [59.2; 98.9]*	-
4	*Wheat milling products, other*[(b)]	*20*	*60.0*	*71.7 [58.2; 85.2]*	-
4	*Wheat milling products, unspecified*	*64*	*45.3*	*112.5 [92.2; 132.9]*	*359.0*
3	Other milling products	49	67.3	87 [73.5; 100.4]	-
4	*Barley flour*	*5*	*80.0*	*28.2 [22.2; 34.2]*	-
4	*Other milling products*[(c)]	*44*	*65.9*	*93.6 [79.3; 107.9]*	-
3	Grain milling products, unspecified	127	66.1	101 [72.7; 129.3]	346.0

DON: deoxynivalenol; N: number of samples; LC: left-censored results; LB: lower bound; MB: middle bound; UB: upper bound; P95: 95th percentile.
(a): When the middle, lower and upper bound estimates are equal, only one estimate is given.
(b): Wheat milling products, other: couscous (13), Graham flour (7).
(c): Other milling products: amaranth flour (2), millet flour and groats (4), rice milling products (5), mix (19) and other (14).
(d): P95 is only reported for food groups for which at least 60 samples were available.

Table A3: Distribution of DON levels expressed in µg/kg across other cereal products

Foodex level	Food group	N	LC (%)	Concentration (µg/kg) Mean MB (LB – UB)[(a)]	P95 MB (LB – UB)[(a, d)]
2	**Bread and rolls**	**2 249**	**45.7**	**71.6 [58.1; 85.1]**	**240.0**
3	Bread products	29	27.6	124.4 [118.9; 129.9]	-
3	Mixed wheat and rye bread and rolls	375	41.6	64 [55.4; 72.6]	240.6
3	Multigrain bread and rolls	95	44.2	81.3 [59.4; 103.2]	270.0
3	Rye bread and rolls	81	48.1	60.3 [50.5; 70]	282.0
3	Unleavened bread, crisp bread and rusk	279	59.9	48.7 [35.1; 62.3]	162.5
3	Wheat bread and rolls	730	34.1	83.1 [72.2; 94.1]	281.6
3	Other bread[(b)]	87	54.0	69.9 [57; 82.7]	243.0
3	Bread and rolls, unspecified	573	55.7	70.6 [51.2; 90]	210.0
2	**Breakfast cereals**	**1 104**	**66.6**	**75.9 [60.5; 91.3]**	**269.9**
3	Cereal bars	23	78.3	45.2 [23.4; 66.9]	-
3	Cereal flakes	511	60.9	99.7 [84.9; 114.6]	379.8
4	*Maize flakes*	*155*	*69.7*	*73.1 [50.3; 95.8]*	*359.0*
4	*Oat flakes*	*208*	*56.7*	*132 [120.5; 143.5]*	*367.0*
4	*Spelt flakes*	*38*	*81.6*	*36.2 [25.2; 47.3]*	-
4	*Wheat flakes*	*61*	*37.7*	*95.3 [85.1; 105.6]*	*254.7*
4	*Mixed cereal flakes and other*	*24*	*62.5*	*120.5 [109.4; 131.7]*	-
4	*Cereal flakes, unspecified*	*25*	*64.0*	*83.7 [69.4; 98]*	-
3	Grits	10	70.0	340.2 [325.7; 354.7]	-
3	Mixed breakfast cereals	26	57.7	71.2 [46.6; 95.7]	-
3	Muesli	338	72.8	41.8 [27.1; 56.6]	142.5 [142.5; 150]
3	Popped cereals	76	84.2	66.6 [40.8; 92.4]	301.0
3	Porridge	18	66.7	56.8 [42.9; 70.7]	-
3	Breakfast cereals, unspecified	102	60.8	62 [52.6; 71.4]	229.0
2	**Fine bakery wares**	**849**	**51.0**	**72.7 [63.3; 82.2]**	**290.9**
3	Biscuits	512	51.6	68.9 [60.2; 77.7]	274.9
4	*Biscuits, salty*	*148*	*40.5*	*119.5 [114; 124.9]*	*491.5*
4	*Biscuits, other than salty*	*245*	*53.1*	*47 [36.1; 58]*	*165.0*
4	*Biscuits, unspecified*	*119*	*62.2*	*51.2 [42.7; 59.8]*	*209.0*
3	Pastries and cakes	198	41.9	81.6 [73.9; 89.3]	494.0
3	Fine bakery wares, unspecified	139	61.9	74.1 [59.7; 88.6]	193.0
2	**Pasta (Raw)**	**216**	**62.5**	**95 [69.2; 120.9]**	**300.0**
3	Pasta, wheat flour	555	54.1	120 [105.6; 134.4]	561.0
3	Pasta, wheat wholemeal	92	79.3	71.9 [49.3; 94.6]	350.5
3	Pasta, other[(c)]	7	85.7	99.4 [85.7; 113]	-
3	Pasta, unspecified	216	62.5	95 [69.2; 120.9]	300.0

DON: deoxynivalenol; N: number of samples; LC: percentage of left-censored results; LB: lower bound; MB: middle bound; UB: upper bound; P95: 95th percentile.
When the middle, lower and upper bound estimates are equal, only one estimate is given.
(a): Other bread: buckwheat (1), maize bread (10), oat (4), potato (43), rice (2), soya (1) and other (26).
(b): Pasta, other: rice (1) and spelt (6).
(c): P95 is only reported for food groups for which at least 60 samples were available.

Table A4: DON concentrations expressed in µg/kg across food groups other than cereals

Foodex level	Food group	N	LC (%)	Concentration (µg/kg) Mean MB (LB – UB)[(a)]	Concentration (µg/kg) P95 MB (LB – UB)[(a, e)]
1	**Alcoholic beverages**	**255**	**86.3**	**14.2 [4.5; 23.9]**	**27 [6.7; 50]**
2	Beer and beer-like beverages	255	86.3	14.2 [4.5; 23.9]	27 [6.7; 50]
1	**Composite food[(b)]**	**30**	**46.7**	**33.3 [27.2; 39.3]**	**-**
1	**Food for infants and small children**	**673**	**86.9**	**26.7 [9.1; 44.3]**	**68.5 [64; 100]**
2	Cereal-based food	559	85.2	27.8 [10; 45.6]	70 [68.5; 100]
2	Infant/follow-on formulae, powder	15	100.0	13.2 [0; 26.3]	-
2	Ready-to-eat meals	40	95.0	21.7 [2.8; 40.6]	-
2	Yoghurt, cheese and milk-based dessert	9	100.0	12.8 [0; 25.6]	-
2	Infant food, unspecified	50	94.0	25.6 [9; 42.1]	-
1	**Vegetables and vegetable products**	**16**	**81.3**	**42.6 [32; 53.2]**	**-**
3	Sweet corn	16	81.3	42.6 [32; 53.2]	-
1	**Legumes**	**46**	**100.0**	**5 [0; 9.9]**	**-**
2	Legumes, beans, dried	46	100.0	5 [0; 9.9]	-
2	**Snacks**	**196**	**41.3**	**109.7 [101.2; 118.1]**	**444.0**
3	Corn chips, curls and tortillas	39	17.9	204.4 [200.4; 208.4]	-
3	Other snacks	157	47.1	86.1 [76.6; 95.7]	360.0
1	**Products for special nutritional use[(c)]**	**26**	**69.2**	**47.6 [34.4; 60.9]**	**-**
-	**Other foods[(d)]**	**30**	**76.7**	**32 [18.6; 45.3]**	**-**

DON: deoxynivalenol; N: number of samples; LC: percentage of left-censored results; LB: lower bound; MB: middle bound; UB: upper bound; P95: 95th percentile.

(a): When the middle, lower and upper bound estimates are equal, only one estimate is given.

(b): Composite food: cereal-based dishes (N=15), rice-based meals (N=7), vegetable-based meals (N=1), potato based dishes (N=2), unspecified composite foods (N=5).

(c): Products for special nutritional use: dietetic foods for diabetics (N=2), dietary supplements (N=2), medical foods (N=17), unspecified products for special nutritional use (N=2).

(d): Other foods: herbs, spices and condiments (N=10), vegetable oil (N=4), oat milk (N=3), dried fruit (N=2), oilseeds (N=4), unspecified vegetables and vegetables products (N=2), confectionary (N=3), unspecified other foods (N=2).

(e): P95 is only reported for food groups for which at least 60 samples were available.

APPENDIX B: BARLEY/WHEAT FLOUR/SEMOLINA CONSUMPTION

Table B1: Consumption levels of barley flour, wheat flour and wheat semolina available in the Comprehensive database

Country	Survey acronym	Chronic food consumption statistics (mean consumption level of barley/wheat flour/semolina over the reporting days at the individual level expressed in g/day)			Acute food consumption statistics (total consumption of barley/wheat flour/semolina per day over the consuming days expressed in g)			
		Number of subjects	Mean	P95	N reporting days	N consumption days (%)	Mean	P95
Infants								
Bulgaria	NUTRICHILD	860	19.0	60.4	1 720	957 (56 %)	34.1	70.9
Italy	INRAN_SCAI_2005_06	16	19.3	-	48	33 (69 %)	28.1	95.0
Toddlers								
Belgium	Regional_Flanders	36	70.0	-	108	108 (100 %)	70.0	139.2
Bulgaria	NUTRICHILD	428	64.4	105.0	856	853 (100 %)	64.6	114.4
Finland	DIPP	497	25.4	76.9	1 486	1331 (90 %)	28.3	83.8
Germany	DONALD_2006	92	46.7	80.9	276	272 (99 %)	47.4	107.4
Germany	DONALD_2007	85	48.5	98.6	255	244 (96 %)	50.7	130.9
Germany	DONALD_2008	84	43.6	85.5	252	250 (99 %)	44.0	101.3
Italy	INRAN_SCAI_2005_06	36	75.4	-	108	108 (100 %)	75.4	169.5
The Netherlands	VCP_kids	322	49.0	82.8	644	640 (99 %)	49.3	89.6
Poland	IZZ_FAO_2000	-	-	-	79	76 (96 %)	41.4	94.5
Spain	enKid	17	71.1	-	34	33 (97 %)	73.3	309.2
Other children								
Belgium	Regional_Flanders	625	73.5	125.2	1 875	1875 (100 %)	73.5	152.6
Bulgaria	NUTRICHILD	433	85.5	138.8	867	864 (100 %)	85.8	150.9
Czech Republic	SISP04	389	94.0	162.5	778	778 (100 %)	94.0	188.9
Denmark	Danish_Dietary_Survey	490	84.2	139.6	3 426	3419 (100 %)	84.5	183.8
Finland	DIPP	933	48.7	95.8	2 773	2725 (98 %)	49.6	116.1
Finland	STRIP	250	80.7	144.0	1 000	959 (96 %)	84.1	220.1
France	INCA2	482	66.8	128.5	3 315	3206 (97 %)	69.3	159.5
Germany	DONALD_2006	211	59.2	123.3	633	617 (97 %)	60.7	138.7
Germany	DONALD_2007	226	61.2	115.0	678	656 (97 %)	63.3	141.1
Germany	DONALD_2008	223	60.4	105.2	669	653 (98 %)	61.9	134.8
Greece	Regional_Crete	839	71.9	136.8	2 508	2431 (97 %)	74.3	193.0
Italy	INRAN_SCAI_2005_06	193	131.5	229.9	579	575 (99 %)	132.4	259.8

Table B1: Continued

Country	Survey acronym	Chronic food consumption statistics (mean consumption level of barley/wheat flour/semolina over the reporting days at the individual level expressed in g/day)			Acute food consumption statistics (total consumption of barley/wheat flour/semolina per day over the consuming days expressed in g)			
		Number of subjects	Mean	P95	N reporting days	N consumption days (%)	Mean	P95
Other children								
Latvia	EFSA_TEST	189	51.9	129.2	377	327 (87 %)	60.3	146.3
The Netherlands	VCP_kids	957	58.7	99.0	1 914	1909 (100 %)	58.8	107.7
Poland	IZZ_FAO_2000	-	-	-	409	408 (100 %)	87.2	179.8
Spain	enKid	156	77.7	140.1	312	306 (98 %)	79.3	157.3
Spain	NUT_INK05	399	78.0	132.9	798	795 (100 %)	78.3	156.1
Sweden	NFA	1 473	66.2	125.2	5875	5771 (98 %)	67.4	163.1
Adolescents								
Belgium	Diet_National_2004	584	124.2	271.4	1 187	1159 (98 %)	129.1	318.8
Bulgaria	NSFIN	-	-	-	162	158 (98 %)	158.6	359.5
Cyprus	Childhealth	303	107.5	196.4	909	859 (94 %)	113.8	257.5
Czech Republic	SISP04	298	138.1	282.0	596	593 (99 %)	138.8	299.1
Denmark	Danish_Dietary_Survey	479	101.5	174.7	3 348	3313 (99 %)	102.5	233.8
France	INCA2	973	95.8	180.9	6 728	6430 (96 %)	100.4	228.5
Germany	National_Nutrition_Survey_II	1 011	90.2	182.6	2 022	1923 (95 %)	94.9	207.6
Italy	INRAN_SCAI_2005_06	247	172.8	293.4	741	735 (99 %)	174.2	331.2
Latvia	EFSA_TEST	470	74.5	166.1	949	848 (89 %)	84.5	198.3
Poland	IZZ_FAO_2000	-	-	-	666	665 (100 %)	135.3	282.7
Spain	AESAN_FIAB	86	100.2	188.5	226	223 (99 %)	99.9	244.6
Spain	enKid	209	122.6	267.4	418	418 (100 %)	122.6	278.3
Spain	NUT_INK05	651	107.7	198.2	1 302	1297 (100 %)	108.1	219.4
Sweden	NFA	1 018	69.6	126.9	4 047	3914 (97 %)	72.0	169.1
Adults								
Austria	ASNS	-	-	-	2 123	2104 (99 %)	115.0	301.9
Belgium	Diet_National_2004	1 304	116.3	254.4	2 648	2573 (97 %)	120.1	304.7
Bulgaria	NSFIN	-	-	-	691	672 (97 %)	134.0	303.0
Czech Republic	SISP04	1 666	135.5	272.1	3 332	3295 (99 %)	137.1	292.4
Denmark	Danish_Dietary_Survey	2 822	93.2	163.4	19 722	19600 (99 %)	93.9	206.7
Estonia	NDS_1997	-	-	-	1 866	1577 (85 %)	64.7	170.7

Table B1: Continued

Country	Survey acronym	Chronic food consumption statistics (mean consumption level of barley/wheat flour/semolina over the reporting days at the individual level expressed in g/day)			Acute food consumption statistics (total consumption of barley/wheat flour/semolina per day over the consuming days expressed in g)			
		Number of subjects	Mean	P95	N reporting days	N consumption days (%)	Mean	P95
				Adults				
Finland	FINDIET_2007	1 575	70.7	153.0	3 150	3068 (97 %)	72.6	168.0
France	INCA2	2 276	102.3	199.5	15 727	15090 (96 %)	106.8	241.0
Germany	National_Nutrition_Survey_II	10 419	82.5	173.5	20 838	19720 (95 %)	87.2	199.3
Hungary	National_Repr_Surv	1 074	142.6	251.0	3 222	3199 (99 %)	143.6	282.8
Ireland	NSIFCS	958	107.6	198.4	6 706	6563 (98 %)	109.9	234.3
Italy	INRAN_SCAI_2005_06	2 313	157.3	277.3	6 939	6868 (99 %)	158.9	313.1
Latvia	EFSA_TEST	1 306	62.1	164.3	2 655	2113 (80 %)	79.4	206.9
The Netherlands	DNFCS_2003	750	111.3	203.5	1 500	1483 (99 %)	112.6	225.5
Poland	IZZ_FAO_2000	-	-	-	2 527	2517 (100 %)	131.8	284.7
Slovakia	SK_MON_2008	-	-	-	2 763	2569 (93 %)	120.0	279.6
Slovenia	CRP_2008	-	-	-	407	400 (98 %)	118.3	245.5
Spain	AESAN	410	85.9	184.2	828	807 (97 %)	87.7	195.6
Spain	AESAN_FIAB	981	82.3	164.0	2 748	2691 (98 %)	83.8	183.1
Sweden	Riksmaten_1997_98	1 210	75.5	145.2	8 466	8065 (95 %)	79.3	194.8
United Kingdom	NDNS	1 724	86.4	159.3	12 068	11331 (94 %)	92.1	203.5
				Elderly				
Belgium	Diet_National_2004	518	94.8	194.3	1 045	1036 (99 %)	96.3	215.9
Bulgaria	NSFIN	-	-	-	151	149 (99 %)	141.4	266.9
Denmark	Danish_Dietary_Survey	309	75.9	137.2	2 159	2157 (100 %)	76.0	160.3
Finland	FINDIET_2007	463	66.1	147.3	926	912 (98 %)	67.1	154.3
France	INCA2	264	103.4	206.4	1 824	1791 (98 %)	105.6	224.8
Germany	National_Nutrition_Survey_II	2 006	71.6	144.1	4 012	3817 (95 %)	75.3	169.2
Hungary	National_Repr_Surv	206	136.1	232.0	618	618 (100 %)	136.1	253.7
Italy	INRAN_SCAI_2005_06	290	144.8	247.5	870	860 (99 %)	146.5	275.8
Poland	IZZ_FAO_2000	-	-	-	329	328 (100 %)	107.6	223.0

Table B1: Continued

Country	Survey acronym	Chronic food consumption statistics (mean consumption level of barley/wheat flour/semolina over the reporting days at the individual level expressed in g/day)			Acute food consumption statistics (total consumption of barley/wheat flour/semolina per day over the consuming days expressed in g)			
		Number of subjects	Mean	P95	N reporting days	N consumption days (%)	Mean	P95
				Very elderly				
Belgium	Diet_National_2004	712	88.4	170.5	1 448	1438 (99 %)	89.3	186.5
Bulgaria	NSFIN	-	-	-	200	199 (100 %)	141.9	275.0
Denmark	Danish_Dietary_Survey	20	79.4	-	140	140 (100 %)	79.4	153.9
France	INCA2	84	99.1	193.1	571	563 (99 %)	101.1	221.0
Germany	National_Nutrition_Survey_II	490	68.7	145.9	980	929 (95 %)	72.5	162.3
Hungary	National_Repr_Surv	80	145.1	246.7	240	240 (100 %)	145.1	277.6
Italy	INRAN_SCAI_2005_06	228	146.6	254.4	684	679 (99 %)	147.7	280.6
Poland	IZZ_FAO_2000	-	-	-	124	124 (100 %)	95.5	175.8

N: number of days; P95: 95th percentile

APPENDIX C: DISTRIBUTION OF DON CONCENTRATIONS

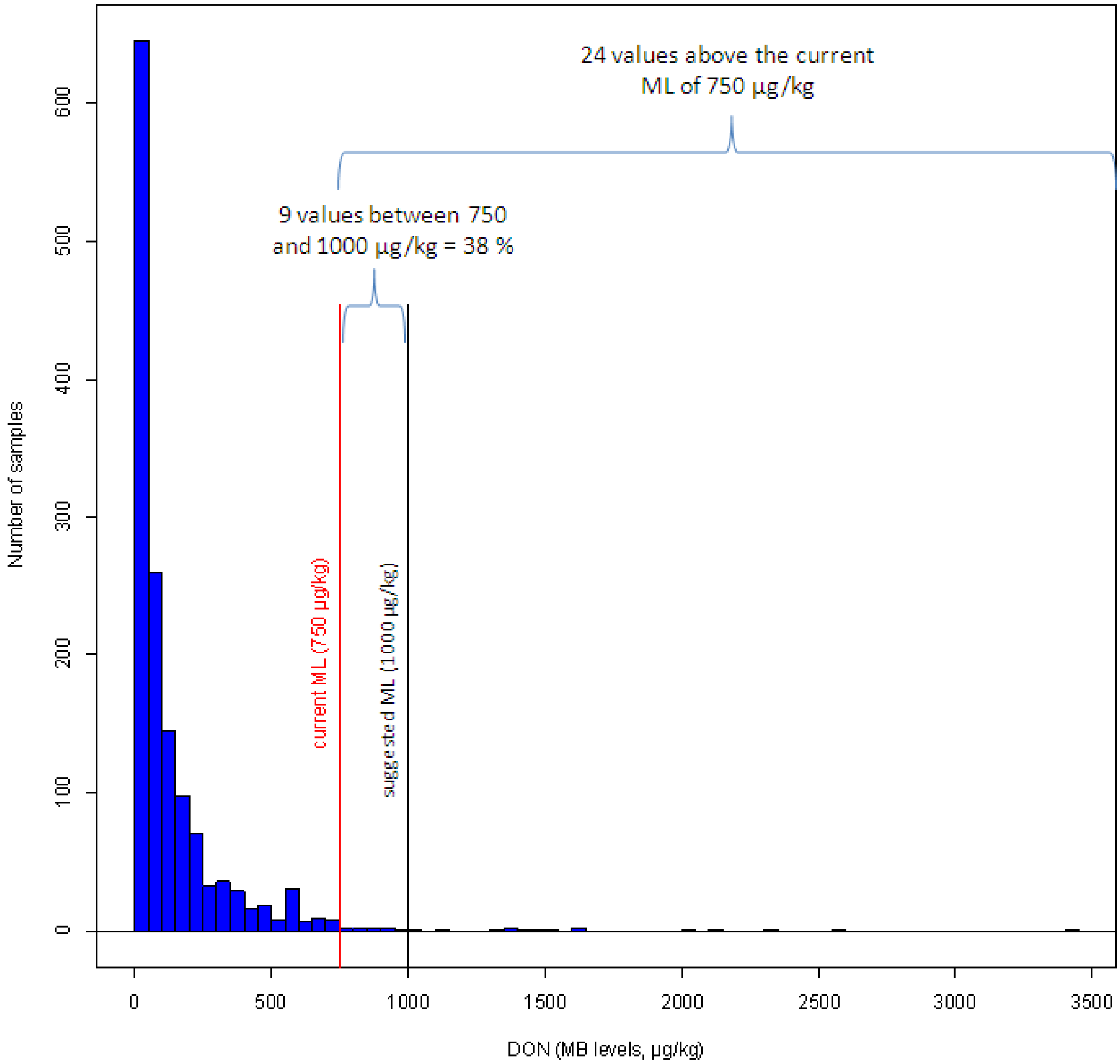

Figure C1: Distribution of the reported middle bound (MB) deoxynivalenol (DON) levels in barley/wheat flour/semolina (ML: maximum level)

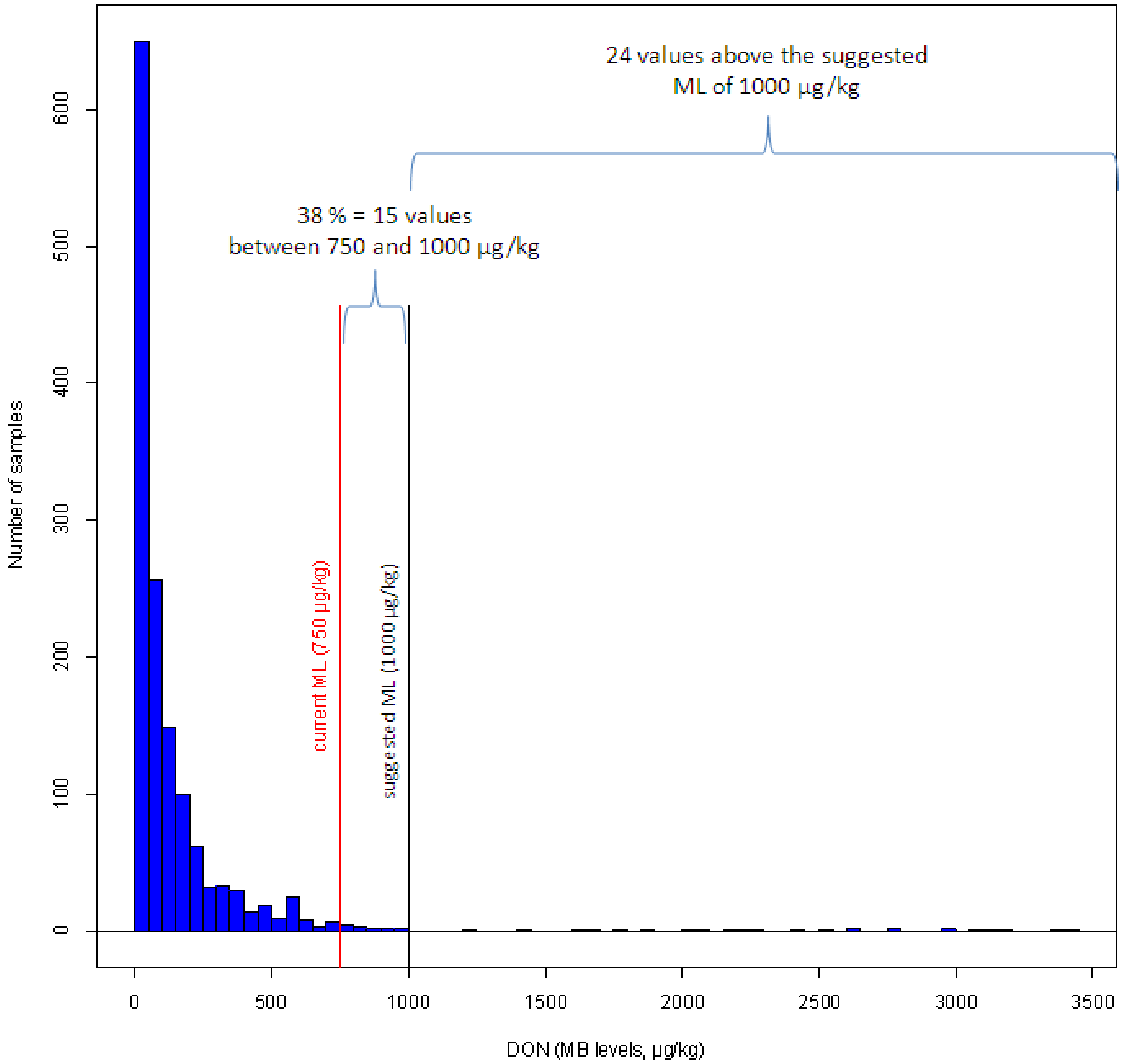

Figure C2: Distribution of the simulated middle bound (MB) deoxynivalenol (DON) levels in barley/wheat flour/semolina (ML: maximum level)

APPENDIX D: CHRONIC EXPOSURE

Table D1: Chronic exposure levels of the European population to deoxynivalenol

Country	Survey acronym	N	Chronic exposure estimation with current ML			Simulated chronic exposure with suggested increased ML		
			Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB[(c)]	Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB [(c)]
Infants								
Bulgaria	NUTRICHILD	860	0.30 - 0.79	1.05 - 1.86	5.6 - 32.6	0.34 - 0.83	1.20 - 1.91	7.1 - 36.9
Italy	INRAN_SCAI_2005_06	16	0.22 - 0.78	-[(d)]	-[(d)]	0.25 - 0.86	-[(d)]	-[(d)]
Toddlers								
Belgium	Regional_Flanders	36	0.81 - 0.85	-	-	0.93 - 0.97	-	-
Bulgaria	NUTRICHILD	428	0.94 - 1.02	1.55 - 1.65	42.1 - 49.5	1.07 - 1.15	1.77 - 1.85	54.2 - 64.0
Finland	DIPP	497	0.47 - 0.70	0.98 - 1.35	4.4 - 14.1	0.50 - 0.75	1.04 - 1.44	6.4 - 18.5
Germany	DONALD_2006	92	0.56 - 1.04	1.00 - 2.12	5.4 - 41.3	0.63 - 1.15	1.15 - 2.27	9.8 - 51.1
Germany	DONALD_2007	85	0.55 - 0.92	0.94 - 1.79	2.4 - 31.8	0.63 - 1.02	1.08 - 1.98	9.4 - 38.8
Germany	DONALD_2008	84	0.54 - 0.98	1.04 - 2.13	6.0 - 34.5	0.61 - 1.08	1.20 - 2.22	8.3 - 39.3
Italy	INRAN_SCAI_2005_06	36	0.88 - 1.10	-[(d)]	-[(d)]	1.02 - 1.25	-[(d)]	-[(d)]
The Netherlands	VCP_kids	322	0.65 - 0.70	1.12 - 1.20	10.6 - 13.4	0.75 - 0.80	1.29 - 1.39	18.3 - 23.3
Spain	enKid	17	0.55 - 0.71	-[(d)]	-[(d)]	0.63 - 0.81	-[(d)]	-[(d)]
Other children								
Belgium	Regional_Flanders	625	0.70 - 0.74	1.28 - 1.31	13.4 - 16.2	0.81 - 0.85	1.45 - 1.51	21.3 - 25.9
Bulgaria	NUTRICHILD	433	0.94 - 0.96	1.65 - 1.69	43.0 - 44.6	1.07 - 1.10	1.90 - 1.94	52.9 - 55.4
Czech Republic	SISP04	389	0.65 - 0.69	1.19 - 1.23	11.6 - 13.1	0.75 - 0.79	1.38 - 1.42	20.1 - 22.6
Denmark	Danish_Dietary_Survey	490	0.62 - 0.67	1.00 - 1.08	5.1 - 7.1	0.70 - 0.75	1.13 - 1.20	11.0 - 13.1
Finland	DIPP	933	0.47 - 0.54	0.83 - 0.92	2.4 - 3.1	0.53 - 0.60	0.92 - 1.02	3.8 - 5.9
Finland	STRIP	250	0.64 - 0.72	1.07 - 1.25	7.6 - 17.2	0.72 - 0.81	1.21 - 1.38	16.0 - 22.8
France	INCA2	482	0.60 - 0.66	1.05 - 1.15	6.4 - 8.5	0.69 - 0.74	1.19 - 1.31	11.4 - 16.2
Germany	DONALD_2006	211	0.56 - 0.61	0.99 - 1.04	4.7 - 6.2	0.63 - 0.69	1.14 - 1.19	6.6 - 10.0
Germany	DONALD_2007	226	0.56 - 0.62	0.87 - 0.95	0.4 - 3.1	0.63 - 0.69	1.00 - 1.06	4.9 - 9.3
Germany	DONALD_2008	223	0.57 - 0.62	0.88 - 0.94	0.9 - 2.2	0.64 - 0.70	0.99 - 1.05	4.5 - 8.1
Greece	Regional_Crete	839	0.61 - 0.64	1.12 - 1.16	8.0 - 10.3	0.70 - 0.72	1.26 - 1.31	14.7 - 16.7
Italy	INRAN_SCAI_2005_06	193	0.86 - 0.91	1.64 - 1.73	29.5 - 33.7	1.00 - 1.04	1.89 - 1.97	42.0 - 43.0
Latvia	EFSA_TEST	189	0.45 - 0.49	0.99 - 1.08	4.8 - 7.9	0.50 - 0.54	1.11 - 1.16	7.4 - 10.1
The Netherlands	VCP_kids	957	0.58 - 0.61	1.00 - 1.05	4.9 - 6.3	0.67 - 0.70	1.15 - 1.21	10.9 - 13.3

Table D1: Continued

Country	Survey acronym	N	Chronic exposure estimation with current ML: Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB[(c)]	Simulated chronic exposure with suggested increased ML: Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB[(c)]
Other children								
Spain	enKid	156	0.58 - 0.62	1.13 - 1.15	9.6 - 12.8	0.67 - 0.72	1.27 - 1.34	17.9 - 19.9
Spain	NUT_INK05	399	0.59 - 0.64	0.99 - 1.11	4.8 - 9.0	0.68 - 0.73	1.15 - 1.25	11.0 - 15.3
Sweden	NFA	1 473	0.57 - 0.64	0.97 - 1.09	3.9 - 8.2	0.65 - 0.73	1.09 - 1.23	9.2 - 15.1
Adolescents								
Belgium	Diet_National_2004	584	0.38 - 0.41	0.72 - 0.83	1.0 - 2.1	0.43 - 0.46	0.83 - 0.94	2.6 - 3.9
Cyprus	Childhealth	303	0.33 - 0.36	0.63 - 0.66	0	0.37 - 0.40	0.73 - 0.74	0.7 – 1.0
Czech Republic	SISP04	298	0.52 - 0.54	1.00 - 1.04	4.7 – 6.0	0.60 - 0.62	1.16 - 1.17	11.1 - 12.8
Denmark	Danish_Dietary_Survey	479	0.36 - 0.40	0.64 - 0.72	0	0.41 - 0.45	0.73 - 0.79	0 - 0.4
France	INCA2	973	0.38 - 0.41	0.73 - 0.76	0.5 - 0.8	0.44 - 0.47	0.83 - 0.86	1.5 - 3.1
Germany	National_Nutrition_Survey_II	1 011	0.30 - 0.34	0.63 - 0.70	0.4 - 1.3	0.35 - 0.38	0.72 - 0.80	0.9 - 1.8
Italy	INRAN_SCAI_2005_06	247	0.53 - 0.55	0.95 - 0.96	4.5	0.61 - 0.63	1.11	8.5 - 8.9
Latvia	EFSA_TEST	470	0.35 - 0.37	0.76 - 0.79	0.6 - 1.3	0.39 - 0.41	0.84 - 0.87	1.5 - 2.3
Spain	AESAN_FIAB	86	0.30 - 0.32	0.69 - 0.70	0 - 1.2	0.34 - 0.36	0.80 - 0.81	1.2 - 2.3
Spain	enKid	209	0.43 - 0.45	0.86 - 0.90	3.3	0.50 - 0.52	0.99 - 1.04	4.8 - 5.7
Spain	NUT_INK05	651	0.40 - 0.44	0.74 - 0.81	0.6 - 0.9	0.46 - 0.50	0.85 - 0.91	2.3 - 3.4
Sweden	NFA	1 018	0.38 - 0.41	0.63 - 0.68	0.5 - 0.7	0.43 - 0.47	0.72 - 0.77	1.0 - 1.5
Adults								
Belgium	Diet_National_2004	1 304	0.30 - 0.34	0.63 - 0.73	0.5 - 1.2	0.34 - 0.39	0.73 - 0.82	0.8 - 1.4
Czech Republic	SISP04	1 666	0.33 - 0.43	0.63 - 0.97	0.2 - 4.8	0.38 - 0.48	0.72 - 1.05	0.8 - 6.3
Denmark	Danish_Dietary_Survey	2 822	0.25 - 0.31	0.41 - 0.55	0 - 0.3	0.28 - 0.34	0.46 - 0.60	0 - 0.4
Finland	FINDIET_2007	1 575	0.18 - 0.24	0.35 - 0.47	0 - 0.2	0.20 - 0.26	0.40 - 0.51	0 - 0.2
France	INCA2	2 276	0.27 - 0.29	0.49 - 0.52	0	0.30 - 0.33	0.56 - 0.60	0.2
Germany	National_Nutrition_Survey_II	10 419	0.25 - 0.30	0.50 - 0.64	0.1 - 0.5	0.28 - 0.34	0.57 - 0.71	0.3 - 0.9
Hungary	National_Repr_Surv	1 074	0.31 - 0.33	0.54 - 0.59	0	0.36 - 0.38	0.62 - 0.67	0.3 - 0.4
Ireland	NSIFCS	958	0.27 - 0.36	0.47 - 0.73	0 - 1.4	0.30 - 0.39	0.53 - 0.78	0.1 - 1.6
Italy	INRAN_SCAI_2005_06	2 313	0.35 - 0.37	0.61 - 0.64	0 - 0.1	0.40 - 0.42	0.70 - 0.73	0.2 - 0.4
Latvia	EFSA_TEST	1 306	0.22 - 0.25	0.50 - 0.54	0.1 - 0.2	0.25 - 0.27	0.55 - 0.60	0.1 - 0.2
The Netherlands	DNFCS_2003	750	0.28 - 0.34	0.49 - 0.74	0 - 2.5	0.32 - 0.38	0.57 - 0.79	0 - 2.9
Spain	AESAN	410	0.24 - 0.27	0.53 - 0.59	0.2	0.27 - 0.31	0.59 - 0.64	0.2

Table D1: Continued

Country	Survey acronym	N	Chronic exposure estimation with current ML			Simulated chronic exposure with suggested increased ML		
			Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB[(c)]	Mean LB-UB[(a)]	P95 LB-UB[(b)]	Percentage above group PMTDI LB-UB [(c)]
Adults								
Spain	AESAN_FIAB	981	0.23 - 0.25	0.46 - 0.50	0	0.26 - 0.28	0.52 - 0.55	0.1
Sweden	Riksmaten_1997_98	1 210	0.25 - 0.32	0.44 - 0.56	0 - 0.1	0.28 - 0.35	0.49 - 0.61	0 - 0.2
United Kingdom	NDNS	1 724	0.24 - 0.32	0.43 - 0.65	0 - 0.8	0.27 - 0.36	0.48 - 0.69	0 - 1.0
Elderly								
Belgium	Diet_National_2004	518	0.23 - 0.26	0.49 - 0.58	0	0.26 - 0.30	0.56 - 0.65	0.2 - 0.6
Denmark	Danish_Dietary_Survey	309	0.22 - 0.28	0.38 - 0.47	0 - 0.3	0.25 - 0.30	0.41 - 0.51	0 - 0.3
Finland	FINDIET_2007	463	0.17 - 0.21	0.36 - 0.43	0	0.19 - 0.23	0.41 - 0.46	0
France	INCA2	264	0.25 - 0.26	0.48 - 0.48	0	0.28 - 0.30	0.56	0 - 0.4
Germany	National_Nutrition_Survey_II	2 006	0.24 - 0.29	0.46 - 0.59	0.1 - 0.1	0.27 - 0.32	0.53 - 0.64	0.2 - 0.4
Hungary	National_Repr_Surv	206	0.29 - 0.30	0.48 - 0.52	0 - 0.5	0.33 - 0.35	0.56 - 0.60	0 - 0.5
Italy	INRAN_SCAI_2005_06	290	0.31 - 0.32	0.51 - 0.54	0	0.36 - 0.37	0.59 - 0.62	0
Very elderly								
Belgium	Diet_National_2004	712	0.22 - 0.25	0.44 - 0.50	0.3	0.26 - 0.29	0.51 - 0.56	0.3
Denmark	Danish_Dietary_Survey	20	0.23 - 0.29	-[(d)]	-[(d)]	0.26 - 0.32	-[(d)]	-[(d)]
France	INCA2	84	0.23 - 0.25	0.42 - 0.44	0 - 1.2	0.27 - 0.28	0.48 - 0.50	0 - 1.2
Germany	National_Nutrition_Survey_II	490	0.24 - 0.27	0.52 - 0.55	0	0.27 - 0.31	0.60 - 0.63	0
Hungary	National_Repr_Surv	80	0.32 - 0.34	0.55 - 0.57	0	0.38 - 0.39	0.63 - 0.65	0
Italy	INRAN_SCAI_2005_06	228	0.33 - 0.34	0.56 - 0.57	0	0.38 - 0.39	0.65	0.4

N: number of subjects; LB: lower bound; UB: upper bound; PMTDI: provisional maximum tolerable daily intake; P95: 95th percentile
(a): mean LB-UB: mean lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(b): P95 LB – UB: 95th percentile lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(c): Percentage of individuals with an exposure above the group PMTDI lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(d): P95 and percentage of individuals with an exposure above the group PMTDI for dietary surveys/age classes with less than 60 subjects were not reliable and therefore not presented.
Note: The numbers for the exposure values are all given with 3 figures but this does not reflect precision.

APPENDIX E: CONTENT OF BARLEY/WHEAT FLOUR AND SEMOLINA IN CEREAL-BASED PRODUCTS

The percentage contents of barley/wheat flour and semolina in cereal-based products were extracted from the draft European Food Conversion Model from food as consumed to raw agricultural commodities, which is currently under construction within EFSA.

Table E1: Percentage content of barley/wheat flour and wheat semolina in cereal-based products

Food groups	Range of percentage contents
Bread, rolls and bread products	24.6 – 86.1 %
Porridge and mixed breakfast cereals	1.6 – 30.5 %
Fine bakery wares (including fine bakery wares for diabetics)	2.6 – 64.8 %
Pasta	48.7 – 80 %
Cereal-based dishes	21.3 – 61.9 %
Other composite dishes (including for medical purposes)	1.1 – 8.8 %
Cereal-based food for infants and young children	30.7 – 100 %
Ready-to-eat meals for infants and young children	3 – 47.1 %
Snack food	5.1 – 45.1 %

APPENDIX F: ACUTE EXPOSURE

Table F1: Acute exposure levels of the European population to deoxynivalenol – scenario A

Country	Survey acronym	N reporting days	N consumption days (%)	Scenario A.1 (Current ML)			Scenario A.2 (Suggested increased ML)		
				Mean LB-UB[(a)]	P95 LB-UB[(b)]	% above group ARfD LB-UB[(c)]	Mean LB-UB[(a)]	P95 LB-UB[(b)]	% above group ARfD LB-UB [(c)]
				Infants					
Bulgaria	NUTRICHILD	1 721	957 (55.6 %)	3.10 - 3.56	6.31 - 6.59	2.1 - 2.2	4.09 - 4.56	8.29 - 8.54	6.3 - 8.0
Italy	INRAN_SCAI_2005_06	48	33 (68.8 %)	2.37 - 2.75	-[(d)]	-[(d)]	3.15 - 3.53	-[(d)]	-[(d)]
				Toddlers					
Belgium	Regional_Flanders	108	108 (100 %)	3.89 - 3.90	7.64	3.7	5.17 - 5.19	10.2	17.6
Bulgaria	NUTRICHILD	856	853 (99.6 %)	4.20 - 4.27	7.49 - 7.51	3.3 - 3.4	5.56 - 5.63	9.99 - 10.0	15.6 - 15.9
Finland	DIPP	1 486	1 331 (89.6 %)	2.36 - 2.54	6.62 - 6.86	3.1 - 3.3	3.07 - 3.25	8.79 - 8.98	5.9 - 6.2
Germany	DONALD_2006	276	272 (98.6 %)	3.27 - 3.55	6.96 - 7.20	4.4	4.32 - 4.60	9.16 - 9.35	8.8 - 10.3
Germany	DONALD_2007	255	244 (95.7 %)	3.42 - 3.62	8.7	5.3 - 5.7	4.53 - 4.73	11.6	11.5 - 13.5
Germany	DONALD_2008	252	250 (99.2 %)	3.17 - 3.45	7.31 - 7.45	3.6 - 4.8	4.19 - 4.47	9.71 - 9.87	8.4 - 11.2
Italy	INRAN_SCAI_2005_06	108	108 (100 %)	4.54 - 4.66	10.4 - 10.9	14.8 - 15.7	6.04 - 6.17	13.8 - 14.3	25.9
The Netherlands	VCP_kids	644	640 (99.4 %)	2.72 - 2.74	5.01 - 5.05	0.3	3.61 - 3.63	6.66 - 6.66	2.3
Poland	IZZ_FAO_2000	79	76 (96.2 %)	2.95 - 3.04	6.24 - 6.26	2.6	3.76 - 3.85	8.03	6.6
Spain	enKid	34	33 (97.1 %)	3.72 - 3.76	-[(d)]	-[(d)]	4.94 - 4.98	-[(d)]	-[(d)]
				Other children					
Belgium	Regional_Flanders	1 875	1 875 (100 %)	3.24 - 3.26	6.75 - 6.78	2.6	4.30 - 4.32	9.01 - 9.01	7.4
Bulgaria	NUTRICHILD	867	864 (99.7 %)	4.10 - 4.12	7.57 - 7.62	3.6 - 3.7	5.44 - 5.46	10.0	16.7 - 16.9
Czech Republic	SISP04	778	778 (100 %)	2.89 - 2.91	5.68	1.3	3.84 - 3.86	7.58	3.5
Denmark	Danish_Dietary_Survey	3 427	3 419 (99.8 %)	2.63 - 2.66	5.60 - 5.61	1.3	3.45 - 3.48	7.37 - 7.43	3.8 - 3.9
Finland	DIPP	2 773	2 725 (98.3 %)	2.16 - 2.21	4.76 - 4.80	0.6	2.83 - 2.89	6.31 - 6.34	2.1
Finland	STRIP	1 000	959 (95.9 %)	2.42 - 2.48	6.23 - 6.26	1.3	3.18 - 3.24	8.30	5.6 - 5.8
France	INCA2	3 324	3 206 (96.5 %)	2.37 - 2.42	5.16 - 5.20	0.8 - 0.9	3.14 - 3.19	6.84 - 6.87	2.7 - 2.8
Germany	DONALD_2006	633	617 (97.5 %)	2.13 - 2.17	4.70 - 4.75	0.8	2.80 - 2.84	6.26 - 6.30	1.9
Germany	DONALD_2007	678	656 (96.8 %)	2.14 - 2.19	4.44 - 4.48	0.5	2.82 - 2.87	5.86 - 5.87	0.9
Germany	DONALD_2008	669	653 (97.6 %)	2.08 - 2.12	4.01 - 4.06	0	2.73 - 2.78	5.31 - 5.31	0.6
Greece	Regional_Crete	2 509	2 431 (96.9 %)	2.66 - 2.69	6.82 - 6.89	2.8 - 2.9	3.52 - 3.54	9.09 - 9.13	7.4
Italy	INRAN_SCAI_2005_06	579	575 (99.3 %)	4.12 - 4.15	8.74	6.4 - 6.6	5.48 - 5.51	11.7	16.5 - 16.7
Latvia	EFSA_TEST	379	327 (86.3 %)	1.62 - 1.65	3.88 - 3.96	0.3	2.12 - 2.15	5.07 - 5.21	1.2

Table F1: Continued

Country	Survey acronym	N reporting days	N consumption days (%)	Scenario A.1 (Current ML) Mean LB-UB[(a)]	Scenario A.1 (Current ML) P95 LB-UB[(b)]	Scenario A.1 (Current ML) % above group ARfD LB-UB[(c)]	Scenario A.2 (Suggested increased ML) Mean LB-UB[(a)]	Scenario A.2 (Suggested increased ML) P95 LB-UB[(b)]	Scenario A.2 (Suggested increased ML) % above group ARfD LB-UB [(c)]
Other children									
The Netherlands	VCP_kids	1 914	1 909 (99.7 %)	2.31 - 2.33	4.17 - 4.21	0	3.07 - 3.09	5.56	0.5
Poland	IZZ_FAO_2000	409	408 (99.8 %)	2.88 - 2.92	5.84 - 5.86	0.5	3.81 - 3.84	7.79 - 7.80	4.2
Spain	enKid	312	306 (98.1 %)	2.50 - 2.53	5.05	0.3	3.32 - 3.35	6.73	2.6
Spain	NUT_INK05	798	795 (99.6 %)	2.25 - 2.29	4.45 - 4.48	0.1	2.98 - 3.03	5.90 - 5.94	0.6
Sweden	NFA	5 875	5 771 (98.2 %)	2.13 - 2.18	4.95 - 4.99	1.3	2.81 - 2.86	6.57 - 6.60	2.7
Adolescents									
Belgium	Diet_National_2004	1 195	1 159 (97 %)	1.64 - 1.68	4.08 - 4.1	0.3	2.18 - 2.21	5.42 - 5.43	0.9
Bulgaria	NSFIN	162	158 (97.5 %)	2.03 - 2.06	4.52	0	2.70 - 2.73	6.03	1.3
Cyprus	Childhealth	909	859 (94.5 %)	1.76 - 1.79	4.2	0	2.33 - 2.36	5.54	1.2
Czech Republic	SISP04	596	593 (99.5 %)	2.34 - 2.36	5 - 5.01	0.2	3.11 - 3.13	6.63 - 6.67	1.5
Denmark	Danish_Dietary_Survey	3 349	3 313 (98.9 %)	1.62 - 1.65	3.76 - 3.8	0.1	2.14 - 2.17	4.99 - 5.02	0.6
France	INCA2	6 730	6 430 (95.5 %)	1.58 - 1.61	3.61 - 3.65	0.1	2.09 - 2.12	4.76 - 4.81	0.5
Germany	National_Nutrition_Survey_II	2 022	1 923 (95.1 %)	1.18 - 1.22	2.66 - 2.7	0.1	1.56 - 1.60	3.54 - 3.58	0.2
Italy	INRAN_SCAI_2005_06	741	735 (99.2 %)	2.61 - 2.62	5.38	0.4	3.47 - 3.48	7.18	2
Latvia	EFSA_TEST	966	848 (87.8 %)	1.38 - 1.40	3.26 - 3.27	0.1	1.81 - 1.83	4.24 - 4.29	0.5
Poland	IZZ_FAO_2000	666	665 (99.8 %)	2.21 - 2.22	4.73	0.2	2.93 - 2.94	6.30	1.2
Spain	AESAN_FIAB	226	223 (98.7 %)	1.24 - 1.26	2.7 - 2.71	0	1.65 - 1.66	3.60 - 3.62	0
Spain	enKid	418	418 (100 %)	1.89 - 1.91	4.24	0.2	2.52 - 2.53	5.63	1.4
Spain	NUT_INK05	1 302	1 297 (99.6 %)	1.57 - 1.60	3.24 - 3.26	0	2.08 - 2.11	4.27 - 4.32	0
Sweden	NFA	4 047	3 914 (96.7 %)	1.39 - 1.42	3.21 - 3.23	0.1	1.83 - 1.87	4.25 - 4.29	0.3
Adults									
Austria	ASNS	2 123	2 104 (99.1 %)	1.30 - 1.34	3.57 - 3.60	0	1.73 - 1.77	4.75 - 4.79	0.5
Belgium	Diet_National_2004	2 660	2 573 (96.7 %)	1.33 - 1.37	3.45 - 3.50	0.2	1.76 - 1.81	4.58 - 4.64	0.2
Bulgaria	NSFIN	691	672 (97.3 %)	1.44 - 1.47	3.06 - 3.15	0 - 0.1	1.91 - 1.94	4.07 - 4.17	0.1
Czech Republic	SISP04	3 332	3 295 (98.9 %)	1.40 - 1.51	2.92 - 3.20	0	1.86 - 1.96	3.87 - 4.13	0.2
Denmark	Danish_Dietary_Survey	19 742	19 600 (99.3 %)	1.03 - 1.09	2.25 - 2.33	0	1.35 - 1.41	2.98 - 3.05	0 - 0
Estonia	NDS_1997	1 866	1 577 (84.5 %)	0.78 - 0.82	1.91 - 2.05	0	1.01 - 1.06	2.55 - 2.61	0.1

Table F1: Continued

Country	Survey acronym	N reporting days	N consumption days (%)	Scenario A.1 (Current ML) Mean LB-UB[(a)]	Scenario A.1 (Current ML) P95 LB-UB[(b)]	Scenario A.1 (Current ML) % above group ARfD LB-UB[(c)]	Scenario A.2 (Suggested increased ML) Mean LB-UB[(a)]	Scenario A.2 (Suggested increased ML) P95 LB-UB[(b)]	Scenario A.2 (Suggested increased ML) % above group ARfD LB-UB [(c)]
				Adults					
Finland	FINDIET_2007	3 150	3 068 (97.4 %)	0.79 - 0.84	1.80 - 1.85	0	1.03 - 1.08	2.37 - 2.44	0
France	INCA2	15 737	15 090 (95.9 %)	1.20 - 1.22	2.64 - 2.67	0	1.59 - 1.61	3.51 - 3.54	0.1
Germany	National_Nutrition_Survey_II	20 838	19 720 (94.6 %)	0.91 - 0.96	2.05 - 2.13	0	1.20 - 1.26	2.71 - 2.80	0
Hungary	National_Repr_Surv	3 222	3 199 (99.3 %)	1.53 - 1.55	3.11 - 3.14	0	2.03 - 2.06	4.15 - 4.17	0.1
Ireland	NSIFCS	6 706	6 563 (97.9 %)	1.16 - 1.25	2.40 - 2.53	0	1.53 - 1.62	3.17 - 3.28	0
Italy	INRAN_SCAI_2005_06	6 939	6 868 (99 %)	1.76 - 1.78	3.48 - 3.52	0	2.34 - 2.36	4.64 - 4.67	0.2
Latvia	EFSA_TEST	2 690	2 113 (78.6 %)	0.87 - 0.90	2.12 - 2.15	0	1.14 - 1.16	2.80 - 2.81	0
The Netherlands	DNFCS_2003	1 500	1 483 (98.9 %)	1.19 - 1.24	2.32 - 2.52	0	1.57 - 1.63	3.07 - 3.28	0
Poland	IZZ_FAO_2000	2 527	2 517 (99.6 %)	1.41 - 1.43	3.01 - 3.03	0	1.87 - 1.89	4.01 - 4.02	0.1
Slovakia	SK_MON_2008	2 761	2 569 (93 %)	1.28 - 1.31	2.98 - 3.01	0	1.69 - 1.72	3.95 - 3.99	0.2
Slovenia	CRP_2008	407	400 (98.3 %)	1.25 - 1.27	2.71 - 2.72	0	1.66 - 1.68	3.60	0
Spain	AESAN	828	807 (97.5 %)	0.98 - 1.02	2.15 - 2.17	0	1.30 - 1.33	2.83 - 2.87	0
Spain	AESAN_FIAB	2 748	2 691 (97.9 %)	0.97 - 0.99	2.13 - 2.15	0	1.29 - 1.31	2.83 - 2.85	0
Sweden	Riksmaten_1997_98	8 470	8 065 (95.2 %)	0.89 - 0.94	2.08 - 2.14	0	1.16 - 1.21	2.75 - 2.80	0
United Kingdom	NDNS	12 068	11 331 (93.9 %)	0.98 - 1.06	2.10 - 2.25	0	1.29 - 1.37	2.79 - 2.92	0
				Elderly					
Belgium	Diet_National_2004	1 052	1 036 (98.5 %)	1.02 - 1.05	2.33 - 2.35	0.1	1.35 - 1.38	3.10 - 3.10	0.1
Bulgaria	NSFIN	151	149 (98.7 %)	1.48 - 1.50	2.74 - 2.77	0	1.97 - 1.99	3.66 - 3.68	0
Denmark	Danish_Dietary_Survey	2 160	2 157 (99.9 %)	0.85 - 0.91	1.75 - 1.83	0	1.12 - 1.18	2.30 - 2.36	0
Finland	FINDIET_2007	926	912 (98.5 %)	0.72 - 0.76	1.64 - 1.66	0	0.94 - 0.98	2.17 - 2.18	0
France	INCA2	1 824	1 791 (98.2 %)	1.13 - 1.15	2.41 - 2.43	0	1.51 - 1.53	3.22 - 3.24	0.1
Germany	National_Nutrition_Survey_II	4 012	3 817 (95.1 %)	0.78 - 0.82	1.72 - 1.78	0	1.02 - 1.07	2.26 - 2.33	0
Hungary	National_Repr_Surv	618	618 (100 %)	1.40 - 1.41	2.81 - 2.81	0.2	1.86 - 1.88	3.74 - 3.75	0.2
Italy	INRAN_SCAI_2005_06	870	860 (98.9 %)	1.56 - 1.57	2.94 - 2.97	0	2.08 - 2.09	3.92 - 3.96	0
Poland	IZZ_FAO_2000	329	328 (99.7 %)	1.12 - 1.13	2.43 - 2.44	0	1.49 - 1.50	3.23	0

Table F1: Continued

Country	Survey acronym	N reporting days	N consumption days (%)	Scenario A.1 (Current ML) Mean LB-UB[(a)]	P95 LB-UB[(b)]	% above group ARfD LB-UB[(c)]	Scenario A.2 (Suggested increased ML) Mean LB-UB[(a)]	P95 LB-UB[(b)]	% above group ARfD LB-UB [(c)]
				Very elderly					
Belgium	Diet_National_2004	1 456	1 438 (98.8 %)	0.99 - 1.02	2.00 - 2.08	0.1	1.31 - 1.34	2.67 - 2.73	0.1
Bulgaria	NSFIN	200	199 (99.5 %)	1.60 - 1.62	3.41 - 3.44	0	2.14 - 2.15	4.55 - 4.57	0
Denmark	Danish_Dietary_Survey	140	140 (100 %)	0.88 - 0.94	1.77 - 2.03	0	1.15 - 1.21	2.33 - 2.64	0
France	INCA2	571	563 (98.6 %)	1.10 - 1.11	2.43 - 2.48	0	1.46 - 1.48	3.24 - 3.27	0
Germany	National_Nutrition_Survey_II	980	929 (94.8 %)	0.77 - 0.80	1.73 - 1.78	0	1.01 - 1.04	2.28 - 2.33	0.1
Hungary	National_Repr_Surv	240	240 (100 %)	1.61 - 1.62	3.15 - 3.15	0	2.14 - 2.15	4.20 - 4.20	0
Italy	INRAN_SCAI_2005_06	684	679 (99.3 %)	1.67 - 1.68	3.21 - 3.24	0	2.23 - 2.24	4.28 - 4.30	0
Poland	IZZ_FAO_2000	124	124 (100 %)	1.10 - 1.11	2.01	0	1.46 - 1.47	2.67	0

N: number of days; LB: lower bound; UB: upper bound; ARfD: acute reference dose; P95: 95th percentile
(a): mean LB-UB: mean lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(b): P95 LB – UB: 95th percentile lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(c): Percentage of consumption days with an exposure above the group ARfD lower bound – upper bound. When the LB and UB are the same, only one estimate is presented.
(d): P95 and percentage of individuals with an exposure above 1 µg/kg b.w. per day for dietary surveys/age classes with less than 60 subjects were not reliable and therefore not presented.
Note: The numbers for the exposure values are all given with 3 figures but this does not reflect precision.

ABBREVIATIONS

15-Ac-DON	15-acetyl-deoxynivalenol
3-Ac-DON	3-acetyl-deoxynivalenol
Ac-DON	acetyl-deoxynivalenol
ARfD	Acute reference dose
b.w.	body weight
$BMDL_{10}$	Lower 95 % confidence limit for a benchmark response of 10 % extra risk
CAC	Codex Alimentarius Commission
CCCF	Codex Committee on Contaminants in Foods
CI	Confidence interval
CN	Combined nomenclature
CONTAM Panel	EFSA Scientific Panel on Contaminants in the Food Chain
DDGS	Dried Distillers Grains with Solubles
DON	Deoxynivalenol
DON-3-glc	Deoxynivalenol-3-glucoside
EC	European Commission
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
FAO	Food and Agriculture Organization of the United Nations
HBGV	Health based guidance value
IHKE	Immortalized human kidney epithelial
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LB	Lower bound
LC	Left-censored
LC-MS	Liquid chromatography-mass spectrometry
LC-MS/MS	Liquid chromatography-tandem mass spectrometry
LOD	Limit of detection
LOQ	Limit of quantification
MB	Middle bound
ML	Maximum level
N/n	Number of samples/days/values/surveys
NOAEL	No-observed-adverse-effect level
NOEL	No-observed- effect level
P95	95^{th} percentile
PMTDI	Provisional maximum tolerable daily intake
QR	Quantified results
SCF	Scientific Committee on Food
TDI	Tolerable daily intake
tTDI	Temporary tolerable daily intake
UB	Upper bound
UK	United Kingdom
WHO	World Health Organization