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SCIENTIFIC REPORT OF EFSA

Deoxynivalenol in food and feed: occurrence and exposure[1]

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ABSTRACT

Deoxynivalenol (DON) is a mycotoxin produced by various *Fusarium* species, which can co-occur in cereal-based food and feed together with its acetyl derivates and glucoside-conjugate. A total of 26,613 analytical results covering food, feed and unprocessed grains of undefined end-use, collected by 21 European countries between 2007 and 2012 were included in the present analysis. DON was found in almost half the samples, the highest levels being observed in wheat, maize and oat grains and derived products. Higher levels of DON were found in feed compared with food. DON levels exceeded the maximum limits for food or guidance values for feed in less than 2 % of the cases. DON acetyl derivates and conjugate were less frequently detected and at lower levels. Depending on the population group, defined as the combination of age class and the respective survey, chronic exposure to DON was estimated to be on average between 0.22 and 1.02 µg/kg b.w. per day and at the 95th percentile between 0.43 and 1.86 µg/kg b.w. per day. The main contributor was most often bread and rolls. The assessment of acute exposure resulted in a percentage of days with exposure levels above 8 µg/kg b.w. - Acute Reference Dose proposed by Joint FAO/WHO Expert Committee on Food Additives - estimated at 0.51 % for the most critical population group. Exposure days above the threshold were most frequently associated with the consumption of grain milling products in the groups of infants and of fine bakery wares in the other age groups. Chronic and acute exposure of animals were estimated to be between 3.9 and 43.3 µg/kg b.w. per day and between 11.6 and 137.9 µg/kg b.w., respectively. Poultry was the most exposed animal group, followed by pigs, companion animals and fish. It is recommended to further harmonise the monitoring strategy of DON throughout Europe and improve data reporting.

KEY WORDS

deoxynivalenol, 3-acetyldeoxynivalenol, 15-acetyldeoxynivalenol, deoxynivalenol-3-glucoside, food and feed, occurrence, exposure

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SUMMARY

Deoxynivalenol (DON) is a mycotoxin belonging to the group of trichothecenes, which contaminates grains and cereal-based food and feed. It is associated with acute gastrointestinal adverse effects such as vomiting (emesis) both in animals and humans. The main effects of long-term dietary exposure of animals to DON are weight gain suppression, anorexia and altered nutritional efficiency.

A provisional tolerable daily intake (TDI) for DON was set in 2002 by the Scientific Committee for Food (SCF) at 1 µg/kg body weight (b.w.) per day. In 2010, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) extended it to the group of DON and its acetyl derivatives (3-acetyl-DON (3-Ac-DON) and 15-acetyl-DON (15-Ac-DON) and also derived an Acute Reference Dose (ARfD) at 8 µg/kg b.w. The exposure assessments conducted to date at national or European level concluded that high consumers and young children were exposed to DON at levels close to or even higher than the TDI.

In order to actively decrease the presence of DON in food and feed, maximum limits and guidance values were set at European level, as well as monitoring programmes. Results from national monitoring programmes on the presence of DON in food and feed are to be reported on a regular basis at the European level. In 2010, EFSA received a mandate from the European Commission to collect and analyse, on a continuous basis, all available data on DON in food and feed. The mandate includes the publication of a report analysing these data.

A total of 26,613 analytical results available for DON and its derivatives (3-Ac-DON, 15-Ac-DON) and conjugate (DON-3-Glc), corresponding to 18,884 samples, were considered in this report. They were collected by 21 Member States and Norway between 2007 and 2012.

DON was found in 44.6 %, 43.5 % and 75.2 % of unprocessed grains of undefined end-use, food and feed samples, respectively. It was most frequently quantified and at the highest levels in maize, wheat and oat grains and derived food and feed products, compared to the other varieties of cereals.

Levels of DON were significantly higher in wheat bran than the other wheat milling products. DON levels in processed cereals (bread, fine bakery wares, breakfast cereals, pasta) were significantly lower than those in unprocessed grains and grain milling products.

Overall, feed contained higher levels of DON than unprocessed grains of undefined end-use and foods. DON levels were higher in compound feed for poultry than in compound feed for other animal species.

The level of DON exceeded maximum levels in 0.8 % of the food samples and guidance values in 1.7 % of the feed samples.

The DON derivatives (3-Ac-DON, 15-Ac-DON) were far less frequently found and at lower levels than DON. In almost all the cases, when 3-Ac-DON and/or 15-Ac-DON was quantified, DON was also present. The average percentage contribution of 3-Ac-DON to the sum of DON and its derivatives was less than 2 % at the lower bound estimate and around 13 – 20 % at the upper bound estimate. The percentage contribution of 15-Ac-DON to the sum of DON and its derivatives was up to 10 – 15 % at both lower and upper bound estimates for maize grains.

Very few data, from one Member State, were available for DON-3-Glc. DON-3-Glc was found in around 5 % of the samples, almost always together with DON, and represented on average 5.6 % of the lower bound sum of DON and DON-3-Glc.

Infants, toddlers and other children were the most exposed groups considering chronic exposure. Depending on the population group, chronic dietary exposure of children to DON (upper bound) was estimated to be on average between 0.54 and 1.02 µg/kg b.w. per day and at the 95th percentile between 0.95 and 1.86 µg/kg b.w. per day. Chronic dietary exposure of adolescents, adults, elderly

and very elderly to DON (upper bound) was estimated to be on average between 0.22 and 0.58 µg/kg b.w. per day and at the 95th percentile between 0.43 and 1.08 µg/kg b.w. per day depending on the population group.

In almost all population groups, the main contributor to the total chronic exposure was “bread and rolls” representing between 30.9 and 72.3 % of the total exposure. In few population groups, the main contributor was either “pasta, raw”, representing up to 63.8 % of the total exposure, “fine bakery wares”, representing up to 43.1 % of the total exposure, or “grain milling products” representing up to 76.9 % of the total exposure.

3-Ac-DON and 15-Ac-DON represented less than 2.2 % of the lower bound estimate of the chronic human exposure to the sum of DON, 3-Ac-DON and 15-Ac-DON. However, when considering the upper bound, they were found to represent up to 63.4 % of the total exposure, showing the uncertainty around their real contribution to the total exposure.

The assessment of the acute exposure of the European population resulted in an estimation of the percentage of days with exposure levels above the threshold of 8 µg/kg b.w. between 0.04 % (95% CI = 0 - 0.17) and 0.51 % (95 % CI = 0 – 2.53) for infants, toddlers and other children and between 0 % to 0.09 % (95 % CI = 0 – 0.62) for adolescents, adults, elderly and very elderly. Subjects with more than one day of exposure above the threshold represented less than 0.7 % of the population group.

The days of acute exposure above the threshold of 8 µg/kg b.w. were most frequently explained by the consumption of “fine bakery wares” in all age groups except infants. In infants, the days of acute exposure above the threshold were most frequently explained by the consumption of “grain milling products”, followed by “bread and rolls”, “fine bakery wares” and “pasta, raw”.

The chronic exposure of animals was estimated at the upper bound between 3.9 and 43.3 µg/kg b.w. per day, and the acute exposure levels between 11.6 and 137.9 µg/kg b.w. Poultry (chickens, hens, turkeys and ducks) were found to have the highest level of exposure, followed by pigs, companion animals and fish.

Due to a lack of occurrence data, DON-3-Glc was not taken into account in the exposure assessment, this is likely leading to an underestimation of total exposure. However, an overestimation of the DON exposure is expected considering the methodology used and the conservative assumptions made to assess the dietary exposure.

In order to improve the accuracy of the assessment of food contamination levels and exposure to DON throughout Europe, it would be important to further harmonise the sampling strategy (number of samples, food covered, targeting design) and the performance of the analytical methods used for the monitoring programmes. Further data should be collected on DON-3-Glc, 3-Ac-DON and 15-Ac-DON in order to better characterise their potential contribution to the total exposure to DON. It is also recommended to measure DON in those foods identified as main contributors to the total exposure, but for which the estimations of the contamination levels were not robust, such as oat flour, porridge and composite foods. Collecting more accurate data on the different feeding systems used in Europe would also improve the quality of the animal exposure assessment to contaminants. When reporting data to EFSA, particular attention should be drawn to the food description, especially in order to clearly distinguish the grains used for foods, those used for feed and unprocessed grains of undefined use. When a result is expressed on a dry weight basis, an indication of the moisture content should be provided. Finally, when several measurements are conducted on the same sample, even if different analytical techniques are used, only one result which is considered as the most accurate, should be reported.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION[4]

The European Food Safety Authority (EFSA) has adopted many scientific opinions related to undesirable substances in feed and on nitrates, non-dioxin like PCBs and certain mycotoxins in food. For some of these opinions, specific data collection exercises have been launched. In the frame of official control and monitoring more occurrence data are being generated. It is appropriate that these data are collected into one database, collated and analysed. Article 23 (and 33) of Regulation (EC) No 178/2002[5] laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, entrusts EFSA with this task.

The integration of newly generated data into existing databases on occurrence data (e.g. dioxins and PCBs) in the field of contaminants in feed and food on a permanent basis will ensure continuity of data collection. This would enable EFSA to access accurate data when quick action is required to handle urgent requests for scientific opinions/statements e.g. in the case of contamination incidents and/or requests for scientific opinions where scientific assessments are needed within a short period and separate calls for data would require too much time.

Furthermore, it is expected that the set up of these permanent data collection exercises will stimulate the generation of occurrence data and their electronic transmission in accordance with the Standard Sample Description for food and feed (EFSA, 2010a).

The permanent data collection exercises could in principle encompass the whole field of contaminants in feed and food. However, to focus the work it is appropriate also for the competent authorities and stakeholder organisations, which have to provide the data, to identify specific topics for which a permanent occurrence data collection exercise is to be set up. Several requests for data collections were already addressed by the Commission to EFSA e.g. on heavy metals, furan, acrylamide in food, etc. In the annex to this request, several topics that have not yet been the subject of a specific request are identified with an indication of priority/importance for the Commission services.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION[4]

The following tasks are related to data collection:

- publication of a report on a regular basis per topic. The report should contain, besides an analysis of the received data, also recommendations for improving data collection on this topic and ensure, in co-operation with the Commission services, the appropriate follow up to these recommendations;
- provide assistance/support/information to the Commission services based on *ad hoc* requests related to the occurrence data present in the database. Such requests might involve negotiations of timelines should they require the use of significant resources from EFSA.

[4] Request by the European Commission for continued data collection and data analysis for nitrates, mycotoxins and dioxins and PCBs in food and for undesirable substances in feed. Mandate M-2010-0374.

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24.

ANALYSIS

1. Introduction

Deoxynivalenol (DON) is a mycotoxin belonging to the group of trichothecenes. It is mainly produced by the fungi of the *Fusarium* genus, which are commonly found in the temperate areas of Europe. Crop infection by *Fusarium* is dependant of the weather and is favoured by high humidity at the time of flowering (WHO, 2001).

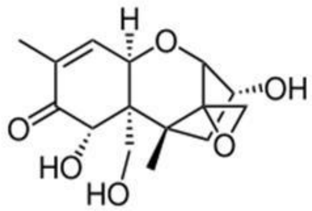

Figure 1: Chemical structure of DON

DON occurs predominantly in grains such as wheat, barley, oats, rye and maize, and less often in rice, sorghum and triticale. Cereal grain may become contaminated both in the field and during storage. DON is chemically stable and to some extent resistant to feed and food thermal processing (Kabak, 2009). Thus, DON can also be found in cereal-based foods (Sirot et al., 2013; Schothorst et al., 2005) and feedstuffs (Döll et al., 2011; Streit et al., 2012) ready for consumption.

The acetyl derivatives of DON (3-acetyl DON (3-Ac-DON), 15-acetyl DON (15-Ac-DON) and 3-15-acetyl-deoxynivalenol), generally considered as fungal derived metabolites, have been reported to occur together with DON, but at much lower levels (Pestka, 2010). DON-3-glucoside (DON-3-Glc), a plant metabolite of DON, has also been detected in cereal grains and cereal-based products (Berthiller et al., 2013). There is concern that DON-3-Glc may be metabolised in the gastro-intestinal tract by humans and animals to DON (Nagl et al., 2012) and thus may contribute to the overall exposure to DON.

Similar to other trichothecenes, the primary toxic effect of DON is the inhibition of protein synthesis (Shephard, 2011). Ingestion of highly contaminated feed by animals can lead to acute gastrointestinal symptoms such as vomiting (emesis), feed refusal and bloody diarrhoea. The most common effects of long-term dietary exposure of animals to DON are weight gain suppression, anorexia and altered nutritional efficiency. The acute effects of DON in humans are similar to those in animals. DON has been implicated in a number of incidents of human intoxication in Asia. There is no experimental or epidemiological evidence for mutagenic and/or carcinogenic properties of DON. DON was considered by the International Agency for Research on Cancer (IARC) as not classifiable as to its carcinogenicity to humans (Group 3) (IARC, 1993).

In 2003, the European Commission asked EFSA to evaluate DON as an undesirable substance in animal feed. Pigs were identified as the most sensitive animal species. However, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that the available data was inadequate to establish safe intake levels for pigs (EFSA, 2004).

Concerning human safety, the Scientific Committee on Food (SCF) established a temporary Tolerable Daily Intake (TDI) of 1 µg/kg body weight (b.w.) per day on the basis of a No Observed Adverse Effect Level (NOAEL) of 100 µg/kg b.w. per day for decreased body weight gain reported in a 2-year feeding study in mice (SCF, 2002). This TDI was in conformity with the Provisional Maximum Tolerable Daily Intake (PMTDI) derived by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2001 (JECFA, 2001). In 2010, JECFA extended this PMTDI to the group of DON and its acetylated derivatives 3-Ac-DON and 15-Ac-DON. Due to lack of information, DON-3-Glc was not included in the group PMTDI. The Committee also derived a group Acute Reference

Dose (ARfD) for DON and its acetylated derivatives of 8 µg/kg b.w. 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 (JECFA, 2010).

In 2001, the SCOOP-task "Collection of occurrence data on *Fusarium* toxins in food and assessment of dietary intake by the population of EU Member States" was established. In this framework, 11,022 samples collected by 12 countries were analysed for DON, with 57 % positive results. Chronic dietary exposure was assessed for 11 countries, which provided consumption estimates for the whole population and specific groups of consumers (consumers only, by age, gender and living place) derived from Food Balance Sheets (FBS) and dietary surveys (1-7 days diaries, 1 day recall, food frequency questionnaires). The mean dietary exposure of the total population to DON was below the TDI, but sometimes (very) close to it, especially for the young children groups. For high consumers, especially in the young children groups but also in the Austrian and French general populations, the exposure to DON exceeded the TDI. Wheat and wheat containing products (such as bread and pasta) were the major contributors to the total exposure (Schothorst and van Egmond, 2004).

In the last decade, several studies assessed the dietary exposure to DON at national or regional level in Europe. Although different methodologies were used, all studies concluded that high consumers and young children were chronically exposed to DON at levels close to or even higher than the TDI. The few studies focusing on acute exposure showed a probability to exceed the ARfD below 1 %.

- The assessment of chronic dietary exposure of the German population resulted in a mean exposure level of 0.3 µg/kg b.w. per day for adults, and up to 0.9 µg/kg b.w. per day for high consumers (90^{th} percentile). In the group of 4-6 year-old children, the mean dietary exposure was close to the TDI and for high consumers, it was 2.7-fold higher than the TDI (Curtui et al., 2006).
- In an assessment of chronic dietary exposure of the Catalonian (Spain) population to DON, the average exposure levels were, according to the population group, between 0.2 and 1 µg/kg b.w. per day, and the 95^{th} percentile between 0.6 and 3.8 µg/kg b.w. per day. Infants and individuals with ethnic dietary patterns were the most exposed groups (Cano-Sancho et al., 2011).
- A probabilistic exposure assessment was conducted on the Czech, Danish and Dutch populations based on DON monitoring data. The median chronic exposure levels of Czech, Danish and Dutch children aged 4 to 19 years old were between 0.1 - 0.4 µg/kg b.w. per day, and the 90^{th} percentile being comprised between 0.3 and 0.7 µg/kg b.w. per day. The median acute exposure levels of Czech, Danish and Dutch females aged 15 – 45 years old were between 0.03 and 0.2 µg/kg b.w. and the 90^{th} percentile between 0.2 and 0.5 µg/kg b.w. (Muri et al., 2009).
- A quantitative chronic dietary exposure assessment of the Belgian adult population to DON, its acetylated derivatives and DON-3-Glc, based on market basket data, resulted in an exposure level on average at 0.1 µg/kg b.w. per day and 95^{th} percentile exposure at 0.4 µg/kg b.w. per day. The estimated probability to exceed the TDI was 0.85 % (De Boevre et al., 2013).
- A probabilistic exposure assessment of the Hungarian adult population resulting from the consumption of white flour-based bread revealed that in 5-15 % of cases, chronic exposure exceeded the JECFA PMTDI of 1 µg/kg b.w. per day. The acute intake was at or below the JECFA ARfD in 99.94 – 99.97 % of cases (Ambrus et al., 2011).
- Based on the 2^{nd} French Total Diet Study (TDS2) data, the upper bound (UB) mean chronic exposure to DON and its acetylated derivatives was 0.4 µg/kg b.w. per day in adults and 0.6 µg /kg b.w. per day in children. The exposure was above the JECFA PMTDI for 0.7 % of French adults and for 10 % of French children. Bread and dried bread products were reported as the main contributors to the chronic exposure to DON (Sirot et al., 2013).
- Chronic exposure level of the Norwegian population was estimated on average between 0.3 (adults) and 2.0 (2 year-old children) µg/kg b.w. per day and at the 95^{th} percentile between 0.6 (adults) and 3.5 (2 year-old children) µg/kg b.w. per day. Acute exposure levels from the consumption of oatmeal porridge was estimated to be 1.5 µg/kg b.w. for 2 year-old children and 0.8 µg/kg b.w. for adults (Vitenskapskomiteen for mattrygghet (VKM), 2013).

At the European level, measures have been set to limit exposure to DON. Maximum levels (ML) for DON in cereal grains and cereal-based products for human consumption are laid down in Commission Regulation (EC) No 1881/2006[6] setting maximum levels (MLs) for certain contaminants in foodstuffs. Commission Recommendation 2006/576/EC[7] recommends Member States to increase monitoring for the presence of DON and other mycotoxins in cereals and cereal products intended for animal feeding and compound feedingstuffs and introduced guidance values (GV) for DON in these products.

In 2010, EFSA received from the European Commission a mandate to collect and analyse on a continuous basis all available data in European countries on DON in food and feed (M-2010-0374). The mandate includes the publication, on a regular basis, of a report analysing these data.

2. Objectives

In the framework of the continued data collection and analysis mandate, the present report presents a data analysis on DON in food and feed:

- Extraction from the Member States submissions of the original information for DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc,
- Collation and checking of the accuracy and details of the submitted information,
- Evaluation of contamination levels in food and feed,
- Assessment of the chronic and acute dietary exposure of humans and animals to DON.

3. Materials and methods

3.1. Sampling, analytical and reporting procedures

The procedures and requirements for sample collection, preparation and analyses to monitor the levels of DON in foodstuffs are detailed in Commission Regulation (EC) 401/2006[8]. In accordance with the provisions of Regulation (EC) No 882/2004[9] of the European Parliament and of the Council, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

According to Commission Regulation (EC) No 1881/2006 and Commission Recommendation 2006/576/EC, Member States and interested parties shall communicate each year the results of investigations taken including occurrence data of DON in food and feed.

Since January 2010, data submitted to EFSA should be compliant with the Standard Sample Description (SSD) agreed between EFSA and the EU Member States (EFSA, 2010). The SSD requires the nature of the food samples to be defined according to the FoodEx food classification catalogue (EFSA, 2011a). SSD allows a data provider to characterise precisely the sample and the context under which it was collected, as well as to report an individual result both qualitatively (quantified or not) and quantitatively, accompanied by information on its uncertainty and the analytical method used.

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

7 Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding. OJ L 229, 23.8.2006, p. 7-9.

8 Commission Regulation (EC) 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. OJ L 70, 9.3.2006, p.12-34.

9 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p.1-141.

3.2. Data management and validation

3.2.1. Automatic control process

Since 2011, data submitted directly to EFSA undergo an automatic control process, consisting of a list of business rules implemented automatically when data are uploaded into the main data repository for incoming data (Data Collection Framework). In brief, incoming data must fulfil specific requirements and reflect the SSD format. The system alerts when requirements are not fulfilled and a correction can be performed. Moreover, an advanced standardisation procedure is performed monthly on incoming data, addressing issues not covered by the SSD and the Specific Requirements for Chemical Contaminants Data Submission (EFSA, 2012a). The process is completed with a feedback request by EFSA to data providers, resulting in an approval of data as stored in the EFSA database or in a request of revision for specific issues by data providers.

3.2.2. Completeness of the dataset

All the data related to the presence of DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc in food and feed collected between 2007 and 2012 and submitted to EFSA at the closure of the 2012 data call were extracted from the EFSA chemical occurrence database. The data providers were asked to check the completeness of the dataset corresponding to their countries, and if needed, to submit any missing data.

3.2.3. Consistency of the information

Data were checked for potential duplicates. As several measurements were made with different analytical techniques on the same sample, in such cases, the results associated with the lowest limit of quantification (LOQ) were retained for further analysis. The consistency of the information related to the food description, the moisture content, the unit of expression of the result, the result and the limit of detection and/or quantification was checked at the sample level. Corrections to the dataset were applied if needed, after clarification from the data providers.

3.2.4. Food and feed classifications

The data were classified according to the most detailed items available in the FoodEx1 classification system for food and to the classification defined for feed in Commission Regulation (EU) No 575/2011[10] on the Catalogue of feed materials. The data were also expressed according to the food and feed groups defined in Commission Regulation (EC) No 1881/2006 and in Commission Recommendation 2006/576/EC. The legislation defines several categories of maize milling products according to the size of the milling fraction. Information about particle size is not collected in the EFSA data collection framework. In this report, maize flour and maize starch were considered as "milling fractions of maize with a particle size ≤ 500 micron" whereas maize semolina and maize meal were considered as "milling fractions of maize with a particle size > 500 micron". However, it is underlined that the particle size of maize semolina and cornmeal can vary greatly and could sometimes be lower than 500 micron.

3.2.5. Expression of results

The legislation prescribes how the results should be expressed for the respective food and feed groups, either on whole weight (ww), dry weight (dw) or 88% dry matter (for feed). When not reported, the expression of results was assumed to be compliant with the legislation. When the expression of results was not in agreement with legislation requirements, the concentration was converted to the correct unit using the reported moisture content. An exception was made for foods for infants and small children. Only few results were expressed on a dw basis, which is the expected unit of expression, and the

[10] Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials. OJ L 159, 17.6.2011, p. 25-65. Note that this regulation has been recently repealed by the Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials. OJ L 29, 30.1.2013, p. 1-64.

moisture content was not indicated for most of the results which were expressed on a ww basis. Consequently, all the results on foods for infant and small children were converted to a ww basis.

When the information required to convert the result into the correct unit was missing, the random hot-deck imputation technique, as described in the 2012 EFSA report on update of the monitoring of levels of dioxins and PCBs in food and feed (EFSA, 2012b), was applied in order to approximate the missing value. This technique failed for a few feed products, for which the moisture content was not indicated. By default, a moisture content of 22 % was assumed for "Tubers, roots, and products derived thereof" (Legrand, 2005), 4 % for "Processed animal protein", 6.2 % for "Perilla seed" (Sargi *et al*., 2013), 15 % for "Buckwheat seed", and 1 % for "Fermentation (by-) products from microorganisms the cells of which have been inactivated or killed".

3.2.6. Left censoring limits

Data were checked for the consistency between the quantified results and the associated limit of detection (LOD) or quantification (LOQ). When a "quantified" value was below the LOD, then the result was assumed to be not detected, and when a "quantified" value was between the LOD and LOQ, then it was assumed there were some traces.

A rough comparison was conducted between the limits of quantification and the quantified levels of DON in food and feed (Figure 1). Some LOQs were found to overlap with the distribution of the quantified levels. To prevent such LOQs adding a bias to the description of the contamination levels, the maximum left-censoring limit accepted for each compound (DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc) was set:

- at 250 µg/kg for unprocessed grains of undefined end-use,
- at 200 µg/kg for feed,
- at 100 µg/kg for cereals for human consumption,
- at 50 µg/kg for the other foods.

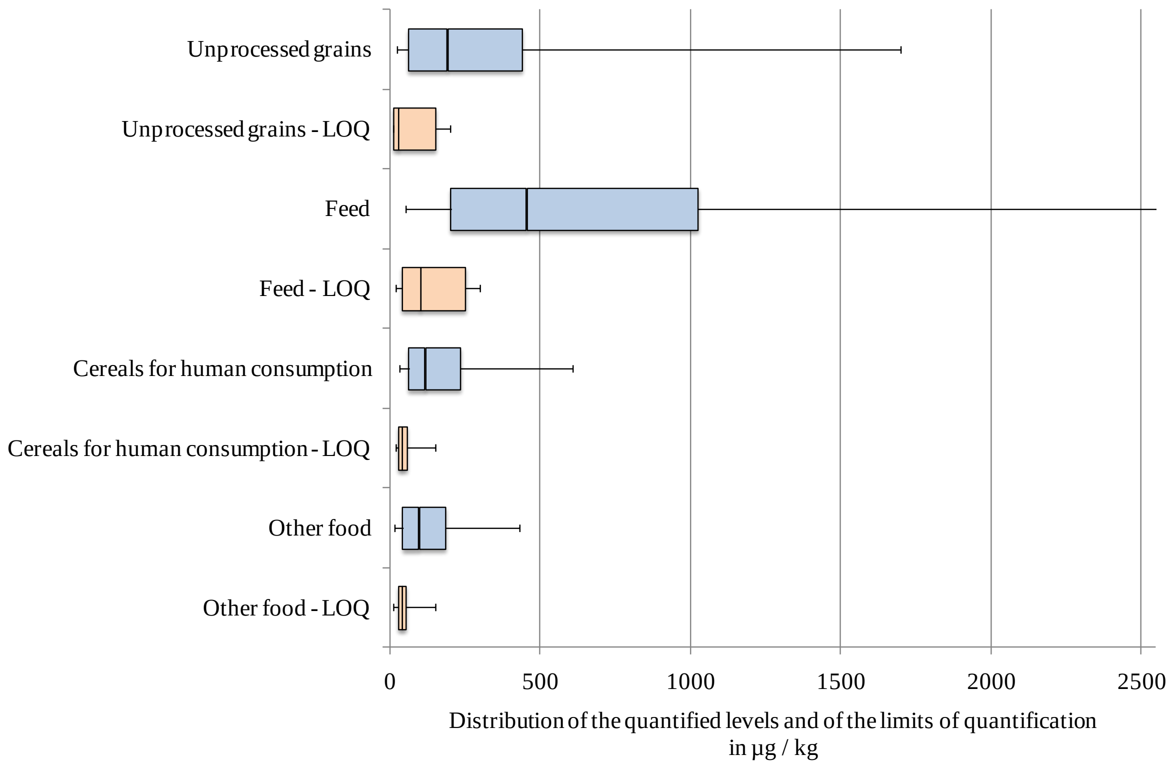

Figure 2: Distribution of the quantified levels (in blue) and of the reported limits of quantification (in orange) for DON (Box-plot: whiskers at P5 and P95, box at P25 and P75 with line at P50).

Where the reported LOQ did not comply with the qualifying criteria, the analytical results were not included in the assessment, regardless of whether they were quantified results or left-censored results.

3.2.7. Outliers analysis

As a final step, an outlier analysis was performed at the 2nd level of hierarchy of the FoodEx 1 classification and of the catalogue of feed materials according to the Tukey's method (Tukey, 1977), which identifies as a statistical outlier a value greater than the 75th percentile plus 1.5 times the inter-quartile distance, or less than the 25th percentile minus 1.5 times the inter-quartile distance. Among the statistical outliers identified, some were suspected to be related to an error in reporting the unit and/or unit of expression of the analytical result, the LOD and LOQ or the moisture content. In such cases the data provider was asked to check the data. According to the answers received, the dataset was either kept as such (no error identified) or corrected (error identified). In case the data provider couldn't exclude an error in reporting the results but without being able to correct it, the corresponding data or datasets were not further taken into account in the analysis.

3.2.8. Conclusion of the data quality control

A total 33,632 analytical results covering DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc, corresponding to 23,326 samples, were initially extracted from the EFSA chemical occurrence database. The cleaning process led to the exclusion of 20.9 % of analytical results:

- 0.2 % corresponded to duplicate submission,
- 8.5 % were associated with an LOQ above the qualifying criteria,
- 12.2 %, mostly coming from two datasets, were associated with uncertainties in the unit of expression of the results, which were not removed by the data provider.

The final dataset used in the present analysis contained 26,613 analytical results, corresponding to 18,884 samples: 18,482 analytical results for DON, 3,922 analytical results for 3-Ac-DON, 4,032 analytical results for 15-Ac-DON and 177 analytical results for DON-3-Glc.

3.3. Statistical analysis for the evaluation of the contamination levels

3.3.1. Level of aggregation of the data

Unprocessed grains of undefined end-use, food (including cereals for human consumption) and feed commodities were described according to the FoodEx classification and Feed Materials Catalogue, which contains respectively 1,909 crop and foods items and 825 feed items at different levels of hierarchy. While working at the finest level of the food/feed description has the advantage of increased precision, those estimates may lack robustness when too few samples are available to describe the contamination level of the food. A specific analysis was conducted to define the appropriate level of aggregation of the data.

The hierarchical level of the food/feed classification retained for the description of the occurrence levels was the one for which most of the detailed food/feed items belonging to a same food/feed group were covered by at least 30 samples. The detailed food/feed items covered by less than 30 samples were either merged into a group of "other" or kept separately especially when, due to their ingredient composition or kind of processing, they were suspected to contain different DON levels than the other feed/food items of the same group.

3.3.2. Descriptive statistics

Frequency tables were produced to describe the number of analytical results of DON and its derivatives and conjugate by year of collection, country of testing and main groups defined in the FoodEx classification and Feed Materials Catalogue.

In order to describe the contamination levels of DON, its derivatives and conjugates in the products available on the EU market, all data from different countries were merged into the categories of unprocessed grains, feed and food groups, irrespective of the sampling design. Three estimates were produced depending on the assumption made on the results below the LOD/LOQ: the lower bound estimate (LB), replacing all the results reported as below the LOD/LOQ by 0, the middle bound estimates (MB), replacing all the results reported as below the LOD/LOQ by half their respective LOD/LOQ and the upper bound estimate (UB), replacing all the results reported as below the LOD/LOQ to their respective LOD/LOQ. Mean and the 95th percentile concentration levels were computed for the three estimates (MB, LB, UB) for DON, DON-3-Glc, 3-Ac-DON and 15-Ac-DON.

A statistical comparison in the distribution of DON levels was conducted between different unprocessed grains/food/feed groups. For example, differences between cereal varieties, unprocessed cereals and the processed cereals, and between different processing types were tested. The parametric T-test, with the Bonferroni adjustment in case of more than two modalities, was used for this. Comparisons were made only for groups with a sample size above 30.

The average percentage contribution of DON-3-Glc to the total (sum of DON-3-Glc and DON), and of 3-Ac-DON and 15-Ac-DON to the total (sum of 3-Ac-DON, 15-Ac-DON and DON) was estimated in samples for which results were available for both DON-3-Glc and DON, and 3-Ac-DON, 15-Ac-DON and DON, and with at least one compound quantified. This was computed for the three estimates (MB, LB, UB).

Finally, levels of DON were compared to their corresponding maximum limits or guidance values – defined for DON only – in order to estimate the percentage of samples above the respective limits.

All analyses were run using the SAS Statistical Software (SAS enterprise guide 5.1).

3.4. Exposure assessment of humans

Chronic exposure of the European (sub)populations to DON was estimated and compared to a threshold of 1 µg/kg b.w./day, corresponding to the TDI set by the SCF (SCF, 2002). Acute exposure was also estimated and was compared to a threshold of 8 µg/kg b.w., corresponding to the JECFA ARfD (JECFA, 2010). Finally, a sensitivity analysis was conducted in order to estimate the contribution of 3-Ac-DON and 15-Ac-DON to the chronic exposure to the sum of 3-Ac-DON, 15-Ac-DON and DON. The contribution of DON-3-Glc to the total exposure was not estimated due to lack of a data available for this conjugate.

3.4.1. Food contamination

The occurrence data and the level of aggregation used for the exposure assessment were the same as those used for the evaluation of the contamination levels. In the absence of data on the contamination of infant and follow-up formulae liquids, these were assumed to be contaminated at the levels measured in infant and follow-up formulae powder adjusted by a dilution factor of 7.1 (Kersting *et al*., 1998). The other foods for which no data were available were not considered in the exposure assessment (see section 4.5 on uncertainties).

According to the WHO guidelines on the censorship treatment (GEMS/Food-EURO, 1995), when more than 40 % of the results were quantified at the food and food group levels, the average contamination level was estimated considering the non detected/quantified results at half of their respective LOD/LOQ (middle bound approach). For the food and food groups with less than 40 % of quantified results, the average contamination level was estimated at the lower and upper bound levels.

3.4.2. Food consumption

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, 2011b, Huybrechts *et al*., 2011, Merten *et al*., 2011).

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

In view of performing a chronic exposure assessment, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011b), only individuals with at least two days of reporting were considered (Table 1) which represented a total of 53,728 individuals from 28 surveys and 17 European countries. The average consumption level was estimated at the individual level for the different food groups defined based on the occurrence data available.

In view of performing an acute exposure assessment, all reporting days were considered, which represented a total of 195,200 days (Table 1). For each reporting day, the total amount of each of the food groups consumed that day was determined.

3.4.3. Exposure modelling

3.4.3.1. Chronic exposure to DON

Chronic exposure to DON was assessed at the individual level by multiplying the average daily consumption for each food with the corresponding average contamination, summing up the respective intakes throughout the diet, and finally dividing the results by the individual's body weight. The whole diet was taken into account, except for foods not covered by occurrence data and for which an assumption on their contamination level was not possible.

The average as well as the 95th percentile of exposure were derived for each population group (i.e. [survey x age class] combinations). The percentage of individuals with an exposure higher than 1 µg/kg b.w. per day was estimated. The confidence limits around this percentage for a confidence level of 95 % were also estimated. The formula presented in Figure 3 was used when n (number of subjects in the population) was higher than 100 (Brown *et al*., 2001). When n was below 100, statistical tables were used (Tassi, 2003).

$$CI\ 95\% = p \pm 1.96\sqrt{\frac{p\,(1-p)}{n}}$$

with:

- *CI95%: confidence limits with a confidence level of 95%*
- *p: sample proportion*
- *n: sample size*

Figure 3: Formula used to determine the confidence limits around the percentage

The contribution of each food group to total exposure to DON was determined for each population group, as the ratio between the average DON intake resulting from the consumption of the food group and the total average exposure to DON. The food groups associated with an average DON intake above 10 % of 1 µg/kg b.w. per day were also identified for each population group considering:

- the total population (all the subjects of the population group),
- the 5 % subjects of the population group who were the most exposed. This calculation was done only for population groups with more than 60 subjects.

The exposure was modelled using SAS software.

Table 1: Dietary surveys used for the chronic and acute dietary exposure assessments

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

(a): Number of available subjects for chronic exposure assessment in each age class. (b): Number of available days for acute exposure assessment in each age class.

3.4.3.2. Acute exposure to DON

An acute exposure assessment, estimating DON levels resulting from one day of exposure, was also performed.

Acute exposure was assessed for each reporting day by multiplying the total consumption amount for each food by an occurrence level randomly drawn among the individual results available for that food. Respective intakes of the foods consumed that day were then summed and finally divided by the individual's body weight. This process was iterated 100 times for each reporting day.

For each population group, the mean, the 95th percentile of exposure, the percentage of days with an exposure level higher than the threshold of 8 µg/kg b.w., as well as the percentage of individuals with at least one day of exposure higher than 8 µg/kg b.w. were characterised. For each of these endpoints, the 95 % confidence interval was defined as the 2.5th and 97.5th percentiles obtained from the 100 iterations.

For each day resulting in an exposure level above the threshold of 8 µg/kg b.w., the food group contributing the most to the total exposure was identified. Its contribution expressed as a percentage of the threshold of 8 µg/kg b.w. was determined.

The exposure was modelled using SAS software and R software.

3.4.3.3. Sensitivity analysis concerning the contribution of DON derivatives to the total exposure

The chronic exposure to the sum of DON, 3-Ac-DON and 15-Ac-DON was assessed as described in paragraph 3.4.3.1 considering the average contamination levels estimated for the sum of DON, 3-Ac-DON and 15-Ac-DON. The average contribution of each compound to the average exposure to the sum of DON, 3-Ac-DON and 15-Ac-DON was estimated for each population group.

3.5. Exposure assessment of animals

Chronic and acute exposure of DON to animals was assessed using a selection of animal species considered to be the most sensitive to the adverse effects of DON, namely pigs, poultry, companion animals (dogs and cats) and fish (salmon) (EFSA, 2004, Hooft et al., 2011).

3.5.1. Feed contamination

DON occurrence levels in complete feed were sufficiently described to assess the exposure levels of pigs and poultry from the direct consumption of complete feeds. However, there were insufficient data on complete feeds for dogs, cats and fish to allow exposure to be calculated; therefore, in these cases exposure was estimated considering the DON levels in raw materials.

The average and 95th percentile contamination levels of DON in feed were estimated for the lower, middle and upper bounds, as previously described.

3.5.2. Feed intake

There is considerable variation in both the feed and feeding systems used throughout Europe for farm livestock, companion animals and fish. The feed intake data used in this report corresponded to those already compiled in previous EFSA opinions related to the risk posed by mycotoxins to animals, and are based on published guidelines on nutrition and feeding, data on EU manufacture of compound feeds and expert knowledge of production systems in Europe (EFSA CONTAM Panel, 2011 and 2013). The total daily feed intake and body weight are summarised in Table 2. The composition, expressed as raw materials of the example diet used for dogs and cats, and fish are detailed in Table 3. As already stressed in the previous opinions (EFSA CONTAM Panel, 2011 and 2013), these data don't represent "average" diets, nor are the feeding systems "typical" for all Europe. Instead, they are used to estimate exposure levels that might not be atypical.

Table 2: Body weight and feed intake for pigs, poultry, fish and companion animals (dogs and cats)

	Body weight (kg)	Feed intake (kg dw/day)
Pigs: piglets	20	1.0
Pigs: pigs for fattening	100	3.0
Pigs: sows for lactating	200	6.0
Poultry: chickens for fattening	2	0.12
Poultry: laying hens	2	0.12
Turkeys: turkeys for fattening	12	0.4
Ducks: ducks for fattening	3	0.14
Salmon	2	0.04
Dogs	25	0.36
Cats	4	0.06

Table 3: Composition of the example diet used for dogs and cats, and fish

Salmon		Dogs and cats	
Feed material	**% of total diet**	**Feed material**	**% of total diet**
Fishmeal	30.5	Wheat grain	15
Wheat grain	13.2	Barley	15
Toasted soya (beans)	12.3	Maize	15
Maize gluten feed	11.5	Maize gluten feed	15
Fish and vegetable oils	31.9	Others[(a)]	40
Minerals, vitamins etc.	0.6		

(a): "Others" correspond to other feed materials, especially animal proteins.

3.5.3. Exposure modelling

Chronic exposure of animals to DON was assessed by combining the average contamination level estimated for the complete feed/feed materials to the total feed intake/relative intake of the feed materials, and dividing the results by the body weight. Acute exposure was assessed in a similar manner, considering the 95th percentile of contamination instead of the average contamination level.

The calculations were done in Excel spreadsheets.

4. Results and discussion

4.1. Overview of the cleaned dataset

The final dataset obtained after the data quality control process included 26,613 analytical results corresponding to 18,884 samples from 21 EU Members States and Norway (Table 4). Four Member States provided together more than three quarters of the samples: Germany (51.0 %), Austria (10.3 %), Slovakia (10.1 %) and Hungary (5.3 %). Six EU Member States didn't submit any data related to the presence of DON and its derivatives in food and feed in the last five years: Bulgaria, Italy, the Netherlands, Malta, Poland and Portugal. This uneven sample coverage of Europe introduces a possible bias in the representativeness of the results.

Table 4: Total number of analytical results (DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc) available for each sampling year by the respective country.

Country	2007	2008	2009	2010	2011	2012	Total
Austria	657	268	57	792	959	-	2733
Belgium	-	-	-	-	52	-	52
Cyprus	18	14	25	20	47	40	164
Czech Republic	42	-	28	78	91	354	593
Germany	2262	1955	2458	3582	3317	-	13574
Denmark	101	81	74	89	90	-	435
Estonia	-	1	3	4	4	-	12
Spain	119	118	45	-	-	-	282
Finland	-	127	101	159	36	-	423
France	-	-	-	121	719	-	840
United Kingdom	45	-	660	231	-	-	936
Greece	-	-	-	-	15	-	15
Hungary	-	207	209	151	845	-	1412
Ireland	-	77	95	40	41	-	253
Lithuania	50	31	7	17	23	-	128
Luxembourg	-	-	67	32	-	-	99
Latvia	-	12	18	-	-	-	30
Norway	75	237	197	150	-	-	659
Romania	-	-	-	-	692	199	891
Sweden	-	37	-	-	64	-	101
Slovenia	-	-	-	135	159	-	294
Slovakia	619	650	462	487	460	9	2687
Total	3988	3815	4506	6088	7614	602	26613

Five countries submitted results for both DON and its derivatives 3-Ac-DON and 15-Ac-DON: Austria, Germany, Finland, France and the United Kingdom. Only one Member State, Czech Republic, submitted results for DON-3-Glc.

The dataset covered results on samples collected from 2007 to 2012, with the majority of samples taken between 2007 and 2011. Only a limited number of data was reported for 2012, as the closing date for submitting these data to EFSA is the end of 2013.

The food and feed groups sampled are illustrated in Table 5. There were 1,257 analytical results for unprocessed grains of undefined end-use, 22,899 for food and 2,457 for feed corresponding to 975, 15,452 and 2,457 samples respectively. The best represented food groups were “Grains and grain-based products” and “Food for infants and small children”, which represented respectively 87 % and 5 % of the data available. The best represented feed groups were “Compound feed” and “Cereal grains, their products and by-products”, which represented respectively 60 % and 34 % of the data available.

Table 5: Number of analytical results for each sampling year by unprocessed grains/food/feed.

Unprocessed grains/Food/Feed	2007	2008	2009	2010	2011	2012	Total
Unprocessed grains of undefined end-use	**128**	**166**	**145**	**279**	**185**	**354**	**1257**
Food, total	**3631**	**3339**	**4057**	**5641**	**5983**	**248**	**22899**
Alcoholic beverages	267	39	8	-	28	-	342
Animal and vegetable fats and oils	126	17	15	-	-	-	158
Composite food	-	22	13	1	1	5	42
Food for infants and small children	244	212	233	402	144	14	1249
Fruit and fruit products	-	-	-	71	-	-	71
Grains and grain-based products	2980	2837	3337	5038	5500	227	19919
Herbs, spices and condiments	3	-	13	2	26	-	44
Legumes, nuts and oilseeds	-	60	195	82	88	-	425
Milk and dairy products	-	-	7	-	-	-	7
Products for special nutritional use	4	65	30	7	1	-	107
Snacks, desserts, and other foods	3	28	124	20	185	-	360
Sugar and confectionary	1	6	3	6	1	-	17
Vegetables and vegetable products	3	53	79	12	9	2	158
Feed, total	**229**	**310**	**304**	**168**	**1446**	**-**	**2457**
Cereal grains, their products and by-products	99	134	115	40	443	-	831
Compound feed	114	149	150	113	962	-	1488
Forages and roughage, and products derived	6	20	4	7	21	-	58
Oil seeds, oil fruits, and products derived	8	2	4	6	5	-	25
Miscellaneous	1	2	2	2	12	-	19
Legume seeds and products derived	-	-	1	-	-	-	1
Tubers, roots, and products derived	1	2	-	-	-	-	3
Land animal products and products derived	-	-	-	-	3	-	3
Fermentation (by-)products	-	1	-	-	-	-	1
Feed, not specified	-	-	28	-	-	-	28
Total	3988	3815	4506	6088	7614	602	26613

More than half of the countries submitted data only on food and unprocessed grains of undefined end-use (Austria, Belgium, Cyprus, Czech Republic, Germany, Denmark, the United Kingdom, Greece, Sweden, Luxembourg, Latvia and Ireland). Estonia submitted data only for feed. The other countries (Spain, Finland, France, Hungary, Norway, Romania, Lithuania, Slovenia and Slovakia) submitted data for both food and feed.

4.1.1. Source of data

The source of the data was indicated in 95 % of the samples: 90 % were collected in the framework of official monitoring programmes, 6 % in the framework of industry/private programmes and 4 % in the framework of other surveys (detailed results not shown). The samples collected in the framework of industry/private programmes appeared to be overall more contaminated than those coming from official programmes and other surveys, and data coming from other surveys were in the same range than those coming from the official programmes. All sources of data were retained for further analysis.

4.1.2. Sampling strategy

Information on the sampling strategy was provided for around 87 % of the samples (detailed results not shown). When it was reported, it appeared that overall 47 % of the samples were coming from random sampling, 51 % from selective sampling – which may be based on a risk analysis – and 2 % from suspect sampling in order to investigate a suspicion of non-conformity. This varied according to the countries. Some countries only submitted data from random sampling: Cyprus, Denmark, the United Kingdom, Greece and Latvia, and some others only from targeted sampling: Belgium, Spain and Sweden. Some countries submitted data from different kinds of sampling and the proportion of random *vs*. targeted sampling varied according to the countries: from more than 75 % random for Austria, Czech Republic, Estonia, France, Lithuania, Romania, Slovenia andSlovakia to more than 90 % targeted for Germany and Hungary, the balance being almost reached for Finland. Due to the targeting strategy, data available from some countries may overestimate the levels of DON, its derivatives and conjugate in products available on the market.

4.1.3. Analytical methods

4.1.3.1. Analytical techniques

Accurate information on the analytical methods used was provided for respectively 73 %, 70 %, 65 % and 100 % of the analytical results available for DON, 3-Ac-DON, 15-Ac-DON and DON-3-Glc (detailed results not shown).

Concerning DON, most of the samples (55 %) were reported to be analysed with liquid chromatography coupled with various detection systems (ultraviolet, fluorescent detection, mass spectrometry), 23 % with gas chromatography coupled either with an electron capture detector or with mass spectrometry and 22 % with enzyme-linked immunosorbent assay (ELISA).

Concerning 3-Ac-DON and 15-Ac-DON, around 90 % of the samples were reported to be analysed with gas chromatography coupled either with an electron capture detector or with mass spectrometry, the rest being analysed with liquid chromatography coupled with mass spectrometry. The DON-3-Glc was analysed with liquid chromatography coupled with mass spectrometry.

4.1.3.2. Limits of quantification

The distributions of the limits of quantification (LOQ) for DON across the food groups and for feed and unprocessed grains of undefined end-use are illustrated in Figure 4. The median LOQ was in the range of 30-50 µg/kg for all food, feed and unprocessed grains, except for milk and dairy products and alcoholic beverages for which it was respectively at 10 and 20 µg/kg. The 95th percentile was in the range of the cut-off applied as a qualifying criteria, i.e., around 200 µg/kg for unprocessed grains of undefined end-use, 150 µg/kg for feed, 100 µg/kg for grains and grain-based products for human consumption and below 50 µg/kg for the other foods.

The LOQ of DON-3-Glc was 10 µg/kg. The median LOQ of 3-Ac-DON and 15-Ac-DON was 40 µg/kg, and the 5th and 95th percentile LOQ were 10 and 50 µg/kg, respectively.

4.1.3.3. Recovery

The level of recovery was reported in only 14.5 % of the analytical results and was always in the range of the performance criteria set in the Commission Regulation (EC) No 401/2006 (detailed results not shown).

The information about the correction for recovery was provided for 80.6 % of the samples, out of which 89.8 % were indicated to be corrected for recovery or as the most accurate result value estimate (detailed results not shown).

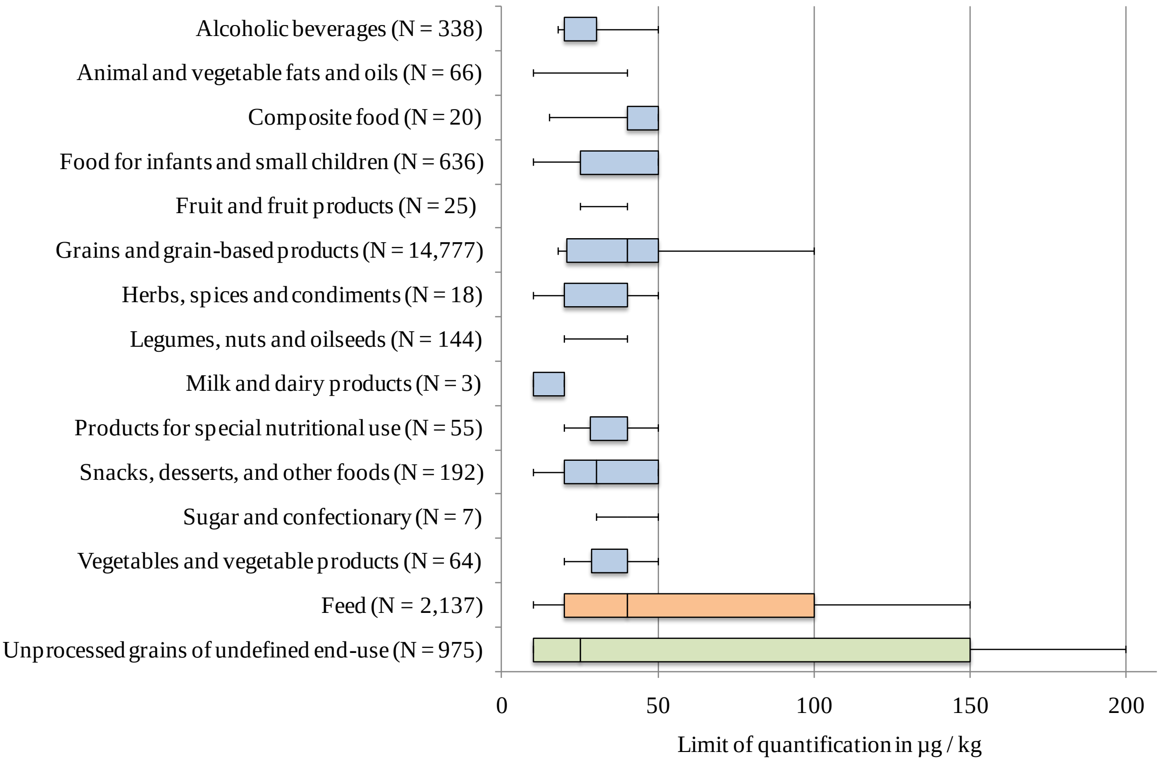

Figure 4: Distribution of the limits of quantification for DON after applying the qualifying criteria (Box-plot: whiskers at P5 and P95, box at P25 and P75 with line at P50).

4.2. Contamination levels

4.2.1. DON levels across the unprocessed grains of undefined end-use, food and feed groups

4.2.1.1. Unprocessed grains of undefined end-use

Table 6 shows the distribution of DON across the unprocessed grains of undefined end-use.

Table 6: Distribution of DON levels across unprocessed grains of undefined end-use

Unprocessed grains of undefined end-use group	N[(a)]	LC (%)[(b)]	Concentration (µg/kg) Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Unprocessed grains, all	**975**	**55.4**	**223.3 [204.1; 242.5]**	**920.8**
Barley grain	198	53.0	133.2 [114.4; 152.1]	489
Maize grain	235	50.2	326.1 [292.5; 359.7]	1555.8
Oat grain	82	42.7	155.1 [136.8; 173.3]	640
Rye grain	130	60.8	57.5 [43.2; 71.7]	212 [212; 250]
Wheat grain	295	59.3	312.3 [301.6; 323.1]	1610
Other grains[(d)]	35	80.0	66.6 [50.3; 82.9]	-

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (d) Other grains: buckwheat grain (17), millet grain (7), rice grain (4), spelt grain (2) and other (2).

DON was found in around half of the samples of barley, maize, oats, rye and wheat analysed. It was less frequently quantified in other cereals (buckwheat, millet, rice, spelt). The highest levels were found in maize and wheat, with average MB levels higher than 300 µg/kg and 95th percentile above 1500 µg/kg, followed by oat and barley, with average MB levels around 150 µg/kg and 95th percentile around 500 µg/kg. The rye and the other grains were less contaminated (average MB level around 60 µg/kg).

4.2.1.2. Foods

Table 7 shows the distribution of DON across grains for human consumption. Overall, grains for human consumption appeared to be less contaminated than unprocessed grains of undefined end-use. As observed for the unprocessed grains of undefined end-use, maize, oats and wheat had the highest levels (on average around 150 – 250 µg/kg, and at the 95th percentile around 600 – 1450 µg/kg). Rye and other grains were less contaminated. Finally, wheat grain, durum was statistically significantly more contaminated than wheat grain, soft ($p < 0.05$).

Table 7: Distribution of DON levels expressed in µg/kg across grains for human consumption

Food group	N[(a)]	LC (%)[(b)]	Concentration (µg/kg) Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Grains for human consumption	**2936**	**64.3**	**111.8 [99.4; 124.1]**	**520**
Barley grain	209	70.3	49.6 [31.2; 68.1]	170
Maize grain	136	48.5	237.9 [231.5; 244.2]	1453
Oats, grain	203	35.0	209 [203.4; 214.6]	738
Rye grain	615	84.1	38.1 [20.8; 55.3]	137.1
Wheat grain	1357	52.1	154.3 [143.8; 164.8]	660
Wheat germ	*12*	*25.0*	*414.2 [411.3; 417.1]*	-
Wheat grain	*1064*	*50.8*	*162.8 [152.3; 173.3]*	*682*
Wheat grain, durum	*46*	*60.9*	*341.3 [326.2; 356.5]*	-
Wheat grain, soft	*141*	*29.8*	*98.4 [93.6; 103.3]*	*447*
Bulgur wheat	*94*	*100.0*	*17.4 [0; 34.9]*	*25 [0; 50]*
Other grains[(d)]	399	92.5	21.3 [8.4; 34.2]	53.2 [53.2; 79]
Grains, unspecified	17	64.7	96.7 [82.9; 110.5]	-

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (d) Other grains: buckwheat grain (36), Einkorn (6), millet grain (24), rice grain (214), spelt grain (94), mixtures (22) and other (3).

Tables 8 and 9 show the distribution of DON in processed cereals. DON was found in around half of the samples analysed. The contamination levels in grain milling products were in the same range as grains for human consumption, whereas they were significantly lower ($p < 0.05$) in the other processed cereals (bread, breakfast cereals, fine bakery wares and pasta).

Maize and wheat milling products contained higher levels of DON than the other milling products (oat, rye, spelt, other), which is consistent with previous observations in unprocessed grains of undefined end-use and grains for human consumption. No major differences in DON levels were observed between the different kinds of oat, rye and spelt milling products. From the data available, DON levels were significantly lower ($p < 0.05$) in maize meal than in maize flour and maize semolina. However, such observation should be interpreted cautiously considering the heterogeneity of products and their variability in composition (parts and proportion of maize seed incorporated), which may be classified as “maize meal” (Scudamore et al., 2009). Indeed, more than half of the maize meal samples were found to correspond to dry polenta. Wheat bran contained DON in significantly ($p < 0.05$) higher levels than the other wheat milling products. No significant difference was detected between the different kinds of wheat flours (durum, brown, white, wholemeal) and semolina (durum, soft wheat).

Table 8: Distribution of DON levels expressed in µg/kg across grain milling products

Food group	N(a)	LC (%)(b)	Concentration (µg/kg) Mean MB (LB – UB)(c)	P95 MB (LB – UB)(c)
Grain milling products	**3650**	**47.4**	**103.5 [93.4; 113.5]**	**382**
Buckwheat milling products	41	90.2	32.9 [12.2; 53.6]	-
Maize milling products	382	44.2	141.4 [133.4; 149.3]	533.5
Maize flour	*136*	*34.6*	*176.5 [168.8; 184.3]*	*645*
Maize semolina	*106*	*43.4*	*119 [109.7; 128.2]*	*403*
Maize meal	*42*	*64.3*	*30.4 [22; 38.9]*	-
Maize starch	*27*	*100.0*	*11.4 [0; 22.8]*	-
Maize milling products, unspecified	*71*	*31.0*	*222.6 [217.8; 227.3]*	*978*
Oat milling products	159	56.0	64.8 [56.3; 73.4]	240
Oat bran	*62*	*77.4*	*48.3 [34.3; 62.3]*	*183*
Oat flour	*5*	*80.0*	*140.6 [129.6; 151.6]*	-
Oat groats	*87*	*40.2*	*73.4 [68.7; 78.1]*	*260*
Oat milling products, unspecified	*5*	*40.0*	*45.4 [39.4; 51.4]*	-
Rye milling products	557	65.5	56.9 [42.6; 71.2]	223
Rye flour, light	*168*	*78.6*	*51.9 [32; 71.8]*	*194*
Rye flour, medium	*173*	*71.7*	*66.6 [51.6; 81.7]*	*244*
Rye flour, wholemeal	*81*	*65.4*	*56.3 [42.8; 69.7]*	*265*
Rye milling products, unspecified	*135*	*41.5*	*50.9 [44.2; 57.7]*	*201*
Spelt milling products	179	59.2	50 [39.1; 60.9]	190
Spelt flour, light	*33*	*51.5*	*70.1 [60.4; 79.8]*	-
Spelt flour, medium	*18*	*61.1*	*44.4 [32.5; 56.4]*	-
Spelt flour, wholemeal	*59*	*62.7*	*47.5 [34.8; 60.2]*	-
Spelt milling products, unspecified	*69*	*59.4*	*44 [34.4; 53.7]*	*240*
Wheat milling products	2176	39.7	119.1 [110.2; 128]	401.7
Wheat bran	*234*	*21.8*	*195.6 [190.8; 200.4]*	*567*
Wheat flour, Durum	*12*	*50.0*	*98.8 [73.8; 123.8]*	-
Wheat flour, brown	*34*	*52.9*	*80.4 [71; 89.7]*	-
Wheat flour, white	*1376*	*43.0*	*113.3 [103.8; 122.9]*	*398*
Wheat flour, wholemeal	*259*	*20.5*	*131.9 [128.2; 135.5]*	*446*
Wheat semolina, Durum	*107*	*55.1*	*71.7 [59; 84.4]*	*218*
Wheat semolina, soft wheat	*76*	*63.2*	*58.1 [42.7; 73.5]*	*211*
Wheat milling products, other(d)	*24*	*62.5*	*73.3 [54.8; 91.9]*	-
Wheat milling products, unspecified	*54*	*40.7*	*101.6 [91.7; 111.6]*	-
Other milling products(e)	48	72.9	50 [37.5; 62.4]	-
Grain milling products, unspecified	108	60.2	91.9 [77; 106.8]	352.1

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (d) Wheat milling products, other: couscous (13), Graham flour (11). (e) Other milling products: amaranth flour (2), barley flour (6), millet flour and groats (6), rice milling products (2), mix (16) and other (16).

Table 9: Distribution of DON levels expressed in µg/kg across other cereal products

Food group	N(a)	LC (%)(b)	Concentration (µg/kg) Mean MB (LB – UB)(c)	P95 MB (LB – UB)(c)
Bread and rolls	**3238**	**45.6**	**70.4 [61.1; 79.8]**	**239.5**
Bread products	125	25.6	83.6 [79.8; 87.4]	256
Mixed wheat and rye bread and rolls	503	44.3	73.5 [64.8; 82.2]	240.6
Multigrain bread and rolls	108	37.0	68.8 [58.7; 79]	230
Other bread(d)	143	58.0	66.8 [58.7; 74.9]	238
Rye bread and rolls	351	66.4	43.7 [31.1; 56.4]	154.6
Unleavened bread, crisp bread and rusk	1108	42.8	72.3 [62.8; 81.9]	251.5
Wheat bread and rolls	107	53.3	63.1 [53.1; 73.1]	208
Bread and rolls, unspecified	793	42.1	77.5 [68.7; 86.3]	244
Breakfast cereals	**1511**	**66.4**	**69.1 [56.4; 81.8]**	**253**
Cereal bars	22	72.7	43.8 [27.3; 60.4]	-
Cereal flakes	756	64.8	81.9 [69.5; 94.3]	284.2
Maize flakes	*192*	*67.2*	*63.7 [47.9; 79.5]*	*253*
Oat flakes	*317*	*62.8*	*109.5 [98.7; 120.3]*	*332*
Spelt flakes	*80*	*78.8*	*28.8 [15.6; 42]*	*95.8*
Wheat flakes	*67*	*35.8*	*85 [76.9; 93.2]*	*171.7*
Mixed cereal flakes and other	*40*	*65.0*	*100.7 [91.4; 110.1]*	-
Cereal flakes, unspecified	*60*	*81.7*	*48.8 [32.6; 65]*	*228.5*
Grits	29	55.2	187.2 [179.4; 195.1]	-
Mixed breakfast cereals	28	50.0	54.4 [45.1; 63.7]	-
Muesli	451	69.8	45.5 [32.7; 58.3]	179
Popped cereals	75	80.0	59 [39.2; 78.8]	150
Porridge	19	68.4	55.1 [40.6; 69.6]	-
Breakfast cereals, unspecified	131	61.1	65.6 [54.7; 76.5]	262.3
Fine bakery wares	**1102**	**54.0**	**75.9 [66.2; 85.7]**	**267.3**
Biscuits	642	58.3	72.5 [62.1; 82.9]	295.7
Biscuits, salty	*275*	*52.0*	*98.7 [89.7; 107.7]*	*429.2*
Biscuits, other than salty	*260*	*63.5*	*49.5 [38.2; 60.7]*	*185.6*
Biscuits, unspecified	*107*	*61.7*	*61.1 [49.1; 73.1]*	*243*
Pastries and cakes	214	43.5	89.4 [81.7; 97.2]	250.8
Fine bakery wares, unspecified	246	52.0	73.3 [63.3; 83.2]	217
Pasta (Raw)	**1365**	**50.8**	**88.5 [77.7; 99.3]**	**349**
Pasta, wheat flour	970	47.7	91.1 [81.3; 100.9]	355
Pasta, wheat wholemeal	181	63.0	87.4 [71.9; 102.9]	365
Pasta, other(e)	18	55.6	42.9 [34.9; 50.9]	-
Pasta, unspecified	196	54.6	80.6 [68.8; 92.4]	300

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (d) Other bread: buckwheat (1), maize bread (8), oat (4), potato (46), rice (3), soya (1) and other (44). (e) Pasta, other: rice (1), spelt (10) and mixed (7).

The levels found in the other processed cereals were overall in the same range, with average MB around 70 – 90 µg/kg. The only detectable difference was observed for salty biscuits which were significantly ($p < 0.05$) more contaminated than the other biscuits. This may be attributed to a difference in the type of cereals used.

Table 10 shows the distribution of DON in the other foods groups. Overall, they appeared to be less frequently contaminated by DON and at lower levels than the cereals products. The exception was the group of "Snacks, desserts and other foods". Indeed, the levels found in corn chips, curls and tortillas were in the range of those observed in the grain milling products and salty biscuits. The groups with the highest levels observed, on average around 30 – 50 µg/kg, corresponded to sweet maize and to foods or ingredients mainly containing cereals: "composite food", "food for infants and small children" (cereal-based food for infant and young children), "herbs, spices and condiments" (malt extract), products for special nutritional use (bakery products for diabetic and formulas for metabolic disorders). DON was found in less than 10 % of the samples of the other food groups: "beer and beer-like beverages", "vegetable oil", "dried fruits", "oats drink", "sugar and confectionary", "legumes and oilseeds", and "vegetables and vegetable products", sweet maize excepted.

4.2.1.3. Feed

Table 11 shows the distribution of DON across feed groups. DON was found in around 60 % samples. The levels were higher than those measured in unprocessed grains of undefined end-use and foods.

The overall quantification rate of DON in "cereal grains, their products and by-products" was 72.2 %. DON was quantified in almost all samples of oats (95.2 %). DON levels found in maize and oats (average 1041.9 – 1355.8 µg/kg, respectively, and 95th percentile 4840 – 4489 µg/kg for the MB estimate) were significantly ($p < 0.05$) higher than levels found in other cereals. DON levels in wheat were on average at 434.4 µg/kg and at the 95th percentile at 2484.1 µg/kg, whereas DON levels were on average around 176.1 – 195.3 µg/kg and around 529.6 – 877 µg/kg at the 95th percentile for the other cereals.

The overall quantification rate of DON in "compound feed" was 78 %. Among the "complete feed", DON was most frequently found and at significantly ($p < 0.05$) higher levels in complete feed for poultry (poultry (starter diets), fattening chickens, laying hens, geese and duck) than in complete feed for other animal species. Indeed, the average MB DON levels ranged from 413.9 µg/kg (poultry starter diets) to 893.7 µg/kg (fattening turkeys) and the 95th percentile from 1734.4 (fattening geese) to 2417.5 µg/kg (fattening turkeys) in complete feed for poultry, whereas the average for other compound feed ranged from 136.5 µg/kg (pet food, dogs and cats) to 453.3 µg/kg (lactating sows) and the 95th percentile from 576.1 µg/kg (piglets) to 2207.7 µg/kg (pet food, dogs and cats). This may be attributed to the fact that wheat is included at higher levels in compound feed for poultry than for other species.

The other feed materials were less represented than the cereal grains and compound feed. The highest DON level was observed in "forages and roughage, and products derived thereof" (mean MB 1007.1 µg/kg), which was in the same range as the levels observed in cereal grains. The lowest DON level was observed in "Oil seeds, oil fruits, and products", with LB and UB averages of 36.8 and 95.9 µg/kg, respectively. In this feed group, DON was found in less than 26 % of the samples.

Table 10: DON concentrations expressed in µg/kg across food groups other than cereals

Food group	N[(a)]	LC (%)[(b)]	Concentration (µg/kg) Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Alcoholic beverages	**338**	**92.3**	**13.5 [3.1; 24]**	**25 [3; 50]**
Beer and beer-like beverages	338	92.3	13.5 [3.1; 24]	25 [3; 50]
Animal and vegetable fats and oils	**66**	**100.0**	**9.7 [0; 19.4]**	**10 [0; 20]**
Vegetable oil	66	100.0	9.7 [0; 19.4]	10 [0; 20]
Composite food[(d)]	**20**	**75.0**	**49.4 [39.6; 59.1]**	**-**
Food for infants and small children	**636**	**85.1**	**24 [11; 36.9]**	**73**
Cereal-based food	532	82.7	26 [12.7; 39.2]	79
Infant/follow-on formulae, powder	16	100.0	12.7 [0; 25.3]	-
Ready-to-eat meals	34	97.1	16.6 [0.2; 33]	-
Yoghurt, cheese and milk-based dessert	9	100.0	12.8 [0; 25.6]	-
Infant food, unspecified	45	95.6	12.1 [4.4; 19.8]	-
Fruit and fruit products	**25**	**96.0**	**13.9 [3.8; 24]**	**-**
Dried fruits	25	96.0	13.9 [3.8; 24]	-
Herbs, spices and condiments	**18**	**66.7**	**34.5 [25.7; 43.2]**	**-**
Milk and dairy products	**3**	**100.0**	**6.7 [0; 13.3]**	**-**
Oats drink	3	100.0	6.7 [0; 13.3]	-
Vegetables and vegetable products	**64**	**92.2**	**18.7 [9.1; 28.4]**	**31.9 [31.9; 50]**
Sweet corn	20	80.0	36.2 [26.8; 45.5]	-
Tea and herbs for infusions (Solid)	23	100.0	10 [0; 20]	-
Vegetable products	20	95.0	11.7 [2.2; 21.2]	-
Vegetables, unspecified	1	100.0	12.5 [0; 25]	-
Sugar and confectionary	**7**	**100.0**	**11.4 [0; 22.9]**	**-**
Products for special nutritional use	**55**	**69.1**	**39.1 [31.4; 46.8]**	**188.8**
Medical food	47	72.3	33.4 [26.2; 40.6]	-
Dietetic food for diabetics	4	0.0	123.9 [123.9; 123.9]	-
Other and unspecified	4	100.0	21.9 [0; 43.8]	-
Legumes, nuts and oilseeds	**144**	**99.3**	**10.3 [0.3; 20.3]**	**12.5 [0; 25]**
Oilseeds	91	98.9	10.5 [0.5; 20.6]	10 [0; 20]
Legumes, beans, dried	53	100.0	10 [0; 19.9]	-
Snacks, desserts, and other foods	**192**	**39.6**	**104.3 [97.9; 110.7]**	**390**
Corn chips, curls and tortillas	37	21.6	202.9 [198.4; 207.3]	-
Other snacks	153	43.1	81.5 [74.8; 88.2]	320
Other foods	2	100.0	18.8 [0; 37.5]	-

(a) N: number of samples. (b) LC: percentage of censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given.(d) Composite food: cereal-based dishes (N=5), rice-based meals (N=7), vegetable-based meals (N=1), potato based dishes (N=2), unspecified composite foods (N=5).

Table 11: DON concentrations (µg/ kg 88 % dry matter) across feed groups

Feed group	N[(a)]	LC (%)[(b)]	Concentration (µg/kg 88% dry matter) Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Cereal grains, their products and by-products	**627**	**27.8**	**741.5 [727.5; 755.5]**	**3108.4**
Barley	154	28.6	176.1 [169; 183.1]	877
Maize	205	29.3	1041.9 [1019.2; 1064.6]	4840
Maize grains	*137*	*27.0*	*1110.2 [1091.6; 1128.8]*	*5980*
Maize gluten feed	*25*	*8.0*	*1134.4 [1128.3; 1140.5]*	-
Maize other	*43*	*48.8*	*770.4 [725.1; 815.6]*	-
Oats	124	4.8	1355.8 [1355.2; 1356.4]	4489
Wheat	117	39.3	434.4 [418.6; 450.2]	2484.1
Wheat, grain	*74*	*45.9*	*289.2 [272.5; 305.9]*	*1089.3*
Wheat, feed	*12*	*25.0*	*941.2 [939.9; 942.4]*	-
Wheat, other	*31*	*29.0*	*584.8 [565.6; 604.1]*	-
Cereal grains, other and unspecified[(d)]	27	66.7	195.3 [154.1; 236.5]	-
Compound feed	**1372**	**22.0**	**548.4 [536.3; 560.5]**	**1940**
Complete feed	1252	21.7	573.7 [561.3; 586.2]	2028.7
Piglets (weaning diets)	*60*	*66.7*	*179.2 [136.9; 221.6]*	*576.1*
Growing/Fattening pigs	*116*	*25.0*	*365.2 [349.5; 380.9]*	*1307.8*
Lactating sows	*58*	*25.9*	*453.3 [434.2; 472.4]*	-
Poultry (starter diets)	*54*	*16.7*	*413.9 [406.8; 421]*	-
Fattening chickens (broilers)	*509*	*15.5*	*638.5 [630.4; 646.7]*	*1940*
Laying hens	*82*	*28.0*	*575.9 [560; 591.8]*	*2022.4*
Fattening turkeys	*113*	*17.7*	*893.7 [882.5; 904.9]*	*2417.5*
Fattening geese	*63*	*6.3*	*677.1 [675.7; 678.5]*	*1734.4*
Fattening ducks	*80*	*5.0*	*817.2 [815.9; 818.5]*	*2207.7*
Pet food, dog and cat	*21*	*71.4*	*136.5 [84.7; 188.2]*	-
Complete feed, other and unspecified[(e)]	*96*	*35.4*	*337.9 [319.8; 356.1]*	*1385.7*
Complementary feed	77	35.1	390.2 [378.1; 402.3]	1304.8
Compound feed, unspecified	43	7.0	94.3 [92.4; 96.3]	-
Forages and roughage, and products derived	**58**	**37.9**	**1007.1 [992.8; 1021.5]**	**-**
Oil seeds, oil fruits, and products	**25**	**72.0**	**66.4 [36.8; 95.9]**	**-**
Toasted soya (beans)	15	73.3	35.9 [12.9; 59]	-
Other oilseeds[(f)]	10	70.0	112 [72.8; 151.3]	-
Miscellaneous[(g)]	**19**	**36.8**	**416.8 [401.5; 432.2]**	**-**
Feed, other and unspecified[(h)]	**36**	**16.7**	**130.7 [125.1; 136.3]**	**-**

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (d) Cereal grains, other and unspecified: rice (2), rye (2), spelt (1), triticale (2), mixed grain (6), malt (8), unspecified (6). (e) Complete feed, other and unspecified: breeding pigs (21), calves (5), dairy cows (10), fattening calves (4), fattening cattle (2), fattening rabbits (6), fattening sheep (6), fur animals (1), horses (1), lambs (1), pet food, birds (5), unspecified (34). (f) Other oilseeds: sunflower seed (3), rape seed (7). (g) Miscellaneous: caramelized sugar (5), plants by-products from spirits production (5), products from the bakery and pasta industry (6), unspecified (3). (h) Feed, other and unspecified: sugar beet (3), pea (1), minerals and products derived (1), processed animal proteins (3), unspecified (28).

4.2.2. DON-3-Glc, 3-Ac-DON and 15-Ac-DON levels across the unprocessed grains of undefined end-use, food and feed groups

4.2.2.1. DON-3-Glc levels and co-occurrence with DON

The few data available on DON-3-Glc were provided by the Czech Republic in 2012. They corresponded to 177 samples of unprocessed wheat and rye grains of undefined end-use (Table 12). DON-3-Glc was found in 9 samples (5 %, all wheat grains), almost all of them (8 samples) being also positive for DON. Among the samples with no detectable levels of DON-3-Glc (N = 66), two third (N = 44) contained detectable levels of DON. The percentage contribution DON-3-Glc to the sum of DON and DON-3-Glc (LB estimate) was 5.6 % on average and 32.2 % at the 95th percentile in samples of wheat grains positive for DON and/or DON-3-Glc (N = 53).

Table 12: Distribution of DON-3-Glc levels expressed in µg/kg

Unprocessed grains group	N[(a)]	LC (%)[(b)]	Concentration (µg/kg) Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Unprocessed grains, all	177	94.9	9.1 [4.4; 13.9]	44.6
Rye grain	33	100	5 [0; 10][(e)]	-
Wheat grain	144	93.8	10.1 [5.4; 14.8]	62.1

(a) N: number of samples. (b) LC: percentage of left censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given. (e): all the results being censored, 10 corresponds to the level of the LOQ, and 5 to half the level of the LOQ.

4.2.2.2. 3-Ac-DON and 15-Ac-DON levels

In total, 3,922 and 4,032 analytical results were available for 3-Ac-DON and 15-Ac-DON, respectively. Table 13 shows the distribution of 3-Ac-DON and 15-Ac-DON across the unprocessed grains of undefined end-use, food and feed groups. Overall, 3-Ac-DON and 15-Ac-DON were less frequently detected and at lower levels than DON.

In unprocessed grains of undefined end-use, 3-Ac-DON was determined in 86 samples of barley, corn, oats, rye and wheat. The MB level was on average 12.8 µg/kg and 32 µg/kg at the 95th percentile. 15-Ac-DON was determined in only 19 samples of maize and wheat. As a whole, the MB level was on average 48.5 µg/kg.

In foods, 3-Ac-DON and 15-Ac-DON were quantified in less than 5 % of the samples, maize grain excepted. According to the food group, the MB levels were on average around 10 – 20 µg/kg and the 95th percentile around 25 – 50 µg/kg. Concerning maize grain, 3-Ac-DON and 15-Ac-DON were quantified in 4 (12.5 %) and 17 (53.1 %) out of 32 samples, respectively. The MB level of 3-Ac-DON and 15-Ac-DON was on average between 19.5 and 65.4 µg/kg. However, the number of samples available is too low to conclude that the DON derivatives are more likely to be present in maize grain than in other grains and food products.

In feed, 3-Ac-DON was quantified in 12.5 % and 2.1 % of cereals and compound feed, respectively. The MB levels were on average around 15 µg/kg and the 95th percentile around 50 µg/kg. 15-Ac-DON was more commonly quantified than 3-Ac-DON, in 25.9 % and 29.4 % of cereals and compound feed, respectively. The MB levels were on average 46.9 µg/kg and 245 µg/kg at the 95th percentile in cereals. Maize and wheat contained higher levels than barley and other grains. The MB levels in compound feed were in the same range as those observed for 3-Ac-DON.

Table 13: Distribution of 3-Ac-DON and 15-Ac-DON levels across the unprocessed grains (µg/kg), food (µg/kg) and feed groups (µg/kg 88% dry matter)

Unprocessed grains/food/feed groups	3-Ac-DON: N[(a)]	LC (%)[(b)]	Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]	15-Ac-DON: N[(a)]	LC (%)[(b)]	Mean MB (LB – UB)[(c)]	P95 MB (LB – UB)[(c)]
Unprocessed grains, all	**86**	**82.6**	**12.8 [9.4; 16.2]**	**32 [32; 44]**	**19**	**21.1**	**48.5 [46.4; 50.6]**	**-**
Barley grain	28	57.1	28.5 [26.8; 30.2]	-	-	-	-	-
Maize grain	15	100	5 [0; 10]	-	15	6.7	53.8 [53.5; 54.1]	-
Oats grain	3	33.3	16.7 [15; 18.3]	-	-	-	-	-
Rye grain	36	97.2	3.3 [0.3; 6.3]	-	-	-	-	-
Wheat grain	4	100	15 [0; 30]	-	4	75	28.8 [20; 37.5]	-
Grains for human consumption	**534**	**99.1**	**14.2 [0.7; 27.7]**	**25 [0; 50]**	**618**	**97.2**	**15.5 [3.1; 27.9]**	**25 [0; 50]**
Barley grain	43	100	10.6 [0; 21.2]	-	49	100	10.2 [0; 20.4]	-
Maize grain	32	87.5	19.5 [7.8; 31.1]	-	32	46.9	65.4 [60.3; 70.5]	-
Oats, grain	39	97.4	12.9 [3.2; 22.7]	-	42	100	9.8 [0; 19.6]	-
Rye grain	145	100	14 [0; 28.1]	25 [0; 50]	166	100	13.2 [0; 26.4]	25 [0; 50]
Wheat grain	120	100	14.2 [0; 28.4]	50 [0; 100]	166	100	12.6 [0; 25.1]	50 [0; 100]
Grains, other and unspecified	155	100	14.5 [0; 29.1]	25 [0; 50]	163	100	14.2 [0; 28.4]	25 [0; 50]
Grain milling products	**813**	**99.8**	**13.1 [0.1; 26.2]**	**25 [0; 50]**	**862**	**95.7**	**17.7 [5; 30.4]**	**25 [0; 50]**
Bread and rolls	**526**	**100**	**13 [0; 26.1]**	**25 [0; 50]**	**516**	**100**	**13.5 [0; 27.1]**	**25 [0; 50]**
Breakfast cereals	**556**	**97.1**	**15.8 [2.8; 28.8]**	**25 [0; 50]**	**543**	**98.7**	**17.3 [3.7; 30.8]**	**25 [0; 50]**
Fine bakery wares	**353**	**99.7**	**11.9 [0.1; 23.7]**	**25 [0; 50]**	**355**	**99.4**	**12.5 [0.3; 24.7]**	**25 [0; 50]**
Pasta (Raw)	**215**	**100**	**20.9 [0; 41.8]**	**25 [0; 50]**	**226**	**100**	**20.3 [0; 40.5]**	**25 [0; 50]**
Other foods	**703**	**100**	**10.6 [0; 21.2]**	**25 [0; 50]**	**709**	**98.4**	**11.1 [0.5; 21.7]**	**25 [0; 50]**
Cereal grains, products and by-products	**88**	**87.5**	**13.4 [5.5; 21.4]**	**50 [25; 98.4]**	**116**	**74.1**	**46.9 [40.5; 53.3]**	**245**
Barley	29	96.6	7 [0.7; 13.2]	-	33	87.9	8.1 [2.4; 13.9]	-
Maize	29	69.0	24 [15.7; 32.3]	-	52	51.9	91.3 [86.1; 96.6]	-
Wheat	29	96.6	9.6 [0.1; 19.1]	-	2	50.0	75 [72.5; 77.5]	-
Cereal grains, other and unspecified	1	100	5 [0; 10]	-	29	100	9.5 [0; 19.1]	-
Compound feed	**48**	**97.9**	**15.8 [0.9; 30.6]**	**-**	**68**	**70.6**	**18 [7.2; 28.8]**	**49.8 [35; 99.7]**

(a) N: number of samples. (b) LC: percentage of censored results. (c) MB (LB-UB): mean and 95th percentile presented as the middle bound estimate (lower bound estimate; upper bound estimate). When the middle, lower and upper bound estimates are equal, only one estimate is given.

4.2.2.3. Co-occurrence of 3-Ac-DON, 15-Ac-DON and DON

Results were available for 3-Ac-DON, 15-Ac-DON and DON in 3,593 samples. DON, 15-Ac-DON and 3-Ac-DON were simultaneously found in only two samples of maize grains for human consumption. 3-Ac-DON was found in 12 samples with no detectable levels of 15-Ac-DON, 11 of which also contained DON. 15-Ac-DON was found in 83 samples with no detectable levels of 3-Ac-DON, all of them containing DON. Finally, DON was found in 1,280 samples without any detectable levels of 3-Ac-DON and 15-Ac-DON. Table 14 shows the average percentage contribution of 3-Ac-DON, 15-Ac-DON to the sum of 3-Ac-DON, 15-Ac-DON and DON in samples with at least one compound quantified (N = 1,377). In unprocessed grains of undefined end-use, the average percentage contribution of 3-Ac-DON and 15-Ac-DON was null (i.e. no quantified results) and 13.6 % respectively at the lower bound level. Concerning food, with the exception of maize grain, the average percentage contribution of 3-Ac-DON and 15-Ac-DON was less than 2 % at the lower bound estimate and around 13 – 20 % at the upper bound estimate, respectively. For maize grain, the average percentage contribution of 15-Ac-DON was 11.7 and 13.7 % for the lower and upper bound estimates respectively, whereas the average percentage contribution of 3-Ac-DON was 0.9 and 7.2 % for the lower and upper bound estimates respectively.

Table 14: Average percentage contribution of DON, 3-Ac-DON and 15-Ac-DON to the sum of DON, 3-Ac-DON and 15-Ac-DON across the unprocessed grains and food groups

Unprocessed grains/food groups	N(a)	% DON MB (LB – UB) (b)	% 3-Ac-DON MB (LB – UB) (b)	% 15-Ac-DON MB (LB – UB) (b)
Unprocessed grains, all	**16**	**84.1 [86.4; 82]**	**2.2 [0; 4.2]**	**13.7 [13.6; 13.8]**
Maize grain	15	83.6 [85.9; 81.5]	2.2 [0; 4.2]	14.2 [14.1; 14.3]
Wheat grain	1	91.3 [93.2; 89.4]	2.1 [0; 4.1]	6.6 [6.8; 6.5]
Grains for human consumption	**147**	**81.3 [97.9; 71.4]**	**8.7 [0.2; 13.8]**	**10 [1.9; 14.8]**
Barley grain	18	78.4 [100; 65.3]	10.8 [0; 17.3]	10.8 [0; 17.3]
Maize grain	24	82.4 [87.5; 79.1]	4.5 [0.9; 7.2]	13.1 [11.7; 13.7]
Oats, grain	10	80.1 [99.5; 68.1]	10.2 [0.5; 16.1]	9.7 [0; 15.7]
Rye grain	18	77.3 [100; 65.5]	11.3 [0; 17.3]	11.3 [0; 17.3]
Wheat grain	67	83.6 [100; 73.3]	8.2 [0; 13.3]	8.2 [0; 13.3]
Grains, other and unspecified	10	77.1 [100; 64.2]	11.5 [0; 17.9]	11.5 [0; 17.9]
Grain milling products	**414**	**82.3 [98.2; 72.3]**	**8 [0; 13]**	**9.7 [1.7; 14.7]**
Bread and rolls	**279**	**80.3 [100; 68.5]**	**9.5 [0; 15.3]**	**10.2 [0; 16.2]**
Breakfast cereals	**167**	**78.3 [97.7; 67.2]**	**10.4 [0.9; 15.9]**	**11.3 [1.4; 16.9]**
Fine bakery wares	**176**	**78.8 [99.7; 66.7]**	**10.1 [0.2; 15.9]**	**11 [0.1; 17.4]**
Pasta (Raw)	**96**	**72.2 [100; 58.3]**	**13.9 [0; 20.9]**	**13.9 [0; 20.9]**
Other foods	**82**	**76.2 [97.4; 64.7]**	**10.8 [0; 16.8]**	**13 [2.6; 18.5]**

(a): number of samples. (b) MB (LB-UB): average percentage distribution presented as the middle bound estimate (lower bound estimate; upper bound estimate).

4.2.3. Comparison with maximum levels and guidance values

Table 15 shows an estimation of the percentage of results exceeding the legal maximum levels or guidance values defined for DON across the food and feed groups.

Taking into account all food groups, 0.8 % of sample results exceeded the MLs. The highest exceedence of MLs was found for "unprocessed maize" (2.2 %). However, none of the samples of milling fractions of maize exceeded MLs. Two other food groups were found with more than 1 % of the results above the MLs: "unprocessed durum wheat and oats" (1.6 %) and "processed cereal-based foods for infants and young children" (1.3 %). However, it should be noted that in the latter food group, levels expressed on a ww basis were compared to the ML which is expressed on a dw basis.

Table 15: Percentage of samples with DON upper bound levels higher than the ML/GV

Food/Feed group	ML/GV[(a)]	N[(b)]	Perc [IC95][(c)]
Food groups:			
Unprocessed durum wheat and oats	1750	249	1.6 [0; 3.2]
Unprocessed maize	1750	136	2.2 [0; 4.7]
Other unprocessed cereals	1250	2534	0.8 [0.5; 1.2]
Cereals intended for direct consumption, cereal flour, bran and germ	750	3268	0.8 [0.5; 1.1]
Milling fractions of maize with particle size > 500 micron	750	148	0
Milling fractions of maize with particle size ≤ 500 micron	1250	163	0
Milling products derived from wheat, maize and barley	*1000*	*2564*	*0.6 [0.3; 0.9]*
Bread, pastries, biscuits, cereal snacks and breakfast cereals	500	5999	0.7 [0.5; 0.9]
Pasta (dry)	750	1365	0.6 [0.2; 1]
Processed cereal-based foods for infants and young children	200	532	1.3 [0.3; 2.3]
Feed groups:			
Cereals and cereals products except maize by-products	8000	564	1.6 [0.6; 2.6]
Maize by-products	12000	57	0 [0; 6.3]
Complementary and complete feedingstuffs:			
- for calves, lambs and kids	2000	20	10 [1.2; 31.7]
- for pigs	900	259	6.9 [3.9; 10]
- other	5000	1011	0.3 [0; 0.6]

(a): maximum limit/guidance value expressed in µg/kg and in µg/kg 88% dry matter basis respectively. (b): number of samples. (c): Perc: percentage of samples with levels higher than the limit, [IC95]: corresponding 95 % confidence interval defined according to the methodology described in paragraph 3.4.3.1.

The percentage of results exceeding GVs was about 1.7 %. The highest rate was observed for "complementary and complete feedingstuffs for calves, lambs and kids" (10 %) but this may be biased due to the few number of data available, followed by "complementary and complete feedingstuffs for pigs" (6.9 %). The exceeding rates observed in the other feed groups ("maize by-products", "cereals and cereal products except maize by-products", and "other complementary and complete feedingstuffs") were in the same range as the ones observed in foods.

4.3. Exposure levels of the European population to DON

Dietary exposure to DON was based on 93 food groups for which DON occurrence data were available; these included: all grains and grain based products, beer and beer-like beverages, oats drinks, dried fruits, vegetable oils and fats, herbs, spices and condiments, legumes dried, oilseeds, snack foods, sugar and confectionary, sweet corn, tea and herbs for infusion, vegetable products, composite foods based on cereals, rice and vegetables, products for special nutritional use (except food for weight reduction, dietary supplements other than fibre supplements and food for sport people), foods for infants and young children (except fruit juice and herbal tea for infants and young children).

4.3.1. Chronic exposure levels

4.3.1.1. DON exposure levels across the different population groups

Table 16 presents lower and upper bound estimates of chronic dietary exposure to DON across the different population groups.

Table 16: Chronic exposure to DON expressed in µg/kg b.w. per day across population groups

Country	Survey acronym	N[(a)]	Mean LB-UB[(b)]	P95 LB-UB[(c)]	Percentage above 1 LB-UB[(d)]
		Infants			
Bulgaria	NUTRICHILD	860	0.25 - 0.73	0.92 - 1.61	4.2 - 28.4
Italy	INRAN_SCAI_2005_06	16	0.16 - 0.68	-*	-*
		Min	**0.16 – 0.68**	**0.92 – 1.61**	**4.2 – 28.4**
		Median	**-**	**-**	**-**
		Max	**0.25 – 0.73**	**0.92 – 1.61**	**4.2 - 28.4**
		Toddlers			
Belgium	Regional_Flanders	36	0.76 - 0.89	-*	-*
Bulgaria	NUTRICHILD	428	0.86 - 1.02	1.48 - 1.61	30.1 - 50.2
Finland	DIPP	497	0.49 - 0.8	1.02 - 1.50	5.2 - 21.1
Germany	DONALD_2006	92	0.50 - 0.96	0.95 - 1.81	2.2 - 39.1
Germany	DONALD_2007	85	0.51 - 0.87	0.88 - 1.58	1.2- 25.9
Germany	DONALD_2008	84	0.48 - 0.91	0.92 - 1.79	2. - 27.4
Italy	INRAN_SCAI_2005_06	36	0.73 - 0.98	-*	-*
Netherlands	VCP_kids	322	0.63 - 0.78	1.10 - 1.33	9.9 - 19.9
Spain	enKid	17	0.51 - 0.67	-*	-*
		Min	**0.48 - 0.67**	**0.88 - 1.33**	**1.2 - 5.9**
		Median	**0.51 - 0.89**	**1.10 - 1.61**	**5.2 - 21.1**
		Max	**0.86 - 1.02**	**1.48 - 1.81**	**30.1 - 50.2**
		Other children			
Belgium	Regional_Flanders	625	0.66 - 0.77	1.18 - 1.36	10.1 - 17.8
Bulgaria	NUTRICHILD	433	0.88 - 0.97	1.58 - 1.65	34.4 - 46
Czech Republic	SISP04	389	0.62 - 0.73	1.12 - 1.33	9.3 - 16.7
Denmark	Danish_Dietary_Survey	490	0.61 - 0.7	0.95 - 1.10	4.1 – 9.0
Finland	DIPP	933	0.43 - 0.59	0.76 - 0.98	0.0 - 0.04
Finland	STRIP	250	0.66 - 0.84	1.06 - 1.35	8.8 - 25.6
France	INCA2	482	0.57 - 0.70	1.01 - 1.22	5.4 - 10.8
Germany	DONALD_2006	211	0.53 - 0.63	0.89 - 1.01	1.9 - 5.2
Germany	DONALD_2007	226	0.53 - 0.63	0.82 - 0.98	0.4 - 3.1
Germany	DONALD_2008	223	0.54 - 0.64	0.81 - 0.95	0.4 - 3.1
Greece	Regional_Crete	839	0.63 - 0.77	1.14 - 1.36	8.9 - 22.6
Italy	INRAN_SCAI_2005_06	193	0.73 - 0.84	1.39 - 1.60	20.7 - 26.9
Latvia	EFSA_TEST	189	0.45 - 0.54	0.99 - 1.10	0.04 - 0.04
Netherlands	VCP_kids	957	0.57 - 0.69	1.01 - 1.15	5.2 - 11.1
Spain	enKid	156	0.54 - 0.64	1.04 - 1.21	7.1 - 11.5
Spain	NUT_INK05	399	0.55 - 0.65	0.93 - 1.09	4.3 - 7.3
Sweden	NFA	1473	0.59 - 0.75	0.98 - 1.24	4.5 - 16.2
		Min	**0.43 - 0.54**	**0.76 - 0.95**	**0.4 - 3.1**
		Median	**0.57 - 0.70**	**1.01 - 1.21**	**5.2 - 11.1**
		Max	**0.88 - 0.97**	**1.58 - 1.65**	**34.4 – 46**
		Adolescents			
Belgium	Diet_National_2004	584	0.36 - 0.43	0.68 - 0.84	0.7 - 1.9
Cyprus	Childhealth	303	0.32 - 0.4	0.59 - 0.71	0.0 - 0.3
Czech Republic	SISP04	298	0.50 - 0.58	0.96 - 1.08	3.4 - 8.7
Denmark	Danish_Dietary_Survey	479	0.34 - 0.41	0.62 - 0.72	0.0 – 0.0

Country	Survey acronym	N[(a)]	Mean LB-UB[(b)]	P95 LB-UB[(c)]	Percentage above 1 LB-UB[(d)]
France	INCA2	973	0.36 - 0.42	0.69 - 0.78	0.3 - 0.9
Germany	National_Nutrition_Survey_II	1011	0.30 - 0.37	0.63 - 0.76	0.5 - 1.4
Italy	INRAN_SCAI_2005_06	247	0.45 - 0.51	0.85 - 0.93	1.2 - 2.4
Latvia	EFSA_TEST	470	0.35 - 0.41	0.78 - 0.87	1.1 - 2.3
Spain	AESAN_FIAB	86	0.28 - 0.33	0.65 - 0.70	0.0 - 1.2
Spain	enKid	209	0.40 - 0.46	0.83 - 0.92	3.3 - 3.3
Spain	NUT_INK05	651	0.38 - 0.45	0.71 - 0.79	0.5 - 0.8
Sweden	NFA	1018	0.39 - 0.49	0.65 - 0.80	0.5 - 1.3
		Min	**0.28 - 0.33**	**0.59 - 0.70**	**0.0 – 0.0**
		Median	**0.36 - 0.43**	**0.68 - 0.79**	**0.5 - 1.3**
		Max	**0.50 - 0.58**	**0.96 - 1.08**	**3.4 - 8.7**
		Adults			
Belgium	Diet_National_2004	1304	0.28 - 0.36	0.56 - 0.72	0.3 - 1.2
Czech Republic	SISP04	1666	0.32 - 0.46	0.61 - 1.02	0.2 - 5.5
Denmark	Danish_Dietary_Survey	2822	0.24 - 0.32	0.40 - 0.56	0.0 - 0.3
Finland	FINDIET_2007	1575	0.17 - 0.25	0.31 - 0.49	0.0 - 0.3
France	INCA2	2276	0.25 - 0.30	0.45 - 0.53	0.04 – 0.04
Germany	National_Nutrition_Survey_II	10419	0.25 - 0.33	0.51 - 0.68	0.1 - 0.7
Hungary	National_Repr_Surv	1074	0.27 - 0.33	0.47 - 0.58	0.0 – 0.0
Ireland	NSIFCS	958	0.24 - 0.36	0.42 - 0.76	0.0 - 1.4
Italy	INRAN_SCAI_2005_06	2313	0.30 - 0.34	0.53 - 0.59	0.0 – 0.04
Latvia	EFSA_TEST	1306	0.23 - 0.28	0.52 - 0.60	0.1 - 0.3
Netherlands	DNFCS_2003	750	0.26 - 0.36	0.47 - 0.76	0.0 - 2.9
Spain	AESAN	410	0.21 - 0.27	0.46 - 0.56	0.0 – 0.0
Spain	AESAN_FIAB	981	0.21 - 0.25	0.42 - 0.49	0.0 – 0.0
Sweden	Riksmaten_1997_98	1210	0.26 - 0.37	0.45 - 0.63	0.0 - 0.2
United Kingdom	NDNS	1724	0.23 - 0.34	0.40 - 0.66	0.0 - 0.7
		Min	**0.17 - 0.25**	**0.31 - 0.49**	**0.0 – 0.0**
		Median	**0.25 - 0.33**	**0.46 - 0.60**	**0.0 - 0.3**
		Max	**0.32 - 0.46**	**0.61 - 1.02**	**0.3 - 5.5**
		Elderly			
Belgium	Diet_National_2004	518	0.22 - 0.28	0.46 - 0.60	0.0 - 0.2
Denmark	Danish_Dietary_Survey	309	0.21 - 0.29	0.36 - 0.49	0.0 - 0.3
Finland	FINDIET_2007	463	0.16 - 0.22	0.31 - 0.43	0.0 – 0.0
France	INCA2	264	0.23 - 0.27	0.44 - 0.48	0.0 – 0.0
Germany	National_Nutrition_Survey_II	2006	0.24 - 0.31	0.46 - 0.62	0.0 - 0.2
Hungary	National_Repr_Surv	206	0.26 - 0.31	0.42 - 0.49	0.0 - 0.5
Italy	INRAN_SCAI_2005_06	290	0.26 - 0.30	0.44 - 0.49	0.0 – 0.0
		Min	**0.16 - 0.22**	**0.31 - 0.43**	**0.0 – 0.0**
		Median	**0.23 - 0.29**	**0.44 - 0.49**	**0.0 - 0.2**
		Max	**0.26 - 0.31**	**0.46 - 0.62**	**0.0 - 0.5**
		Very elderly			
Belgium	Diet_National_2004	712	0.21 - 0.27	0.40 - 0.51	0.1 - 0.1
Denmark	Danish_Dietary_Survey	20	0.22 - 0.31	-*	-*
France	INCA2	84	0.21 - 0.25	0.42 - 0.49	0.0 - 1.2
Germany	National_Nutrition_Survey_II	490	0.25 - 0.30	0.51 - 0.59	0.0 – 0.0
Hungary	National_Repr_Surv	80	0.29 - 0.33	0.47 - 0.52	0.0 – 0.0
Italy	INRAN_SCAI_2005_06	228	0.28 - 0.31	0.48 - 0.53	0.0 – 0.0
		Min	**0.21 - 0.25**	**0.40 - 0.49**	**0.0 – 0.0**
		Median	**0.23 - 0.30**	**0.45 - 0.53**	**0.0 – 0.0**
		Max	**0.29 - 0.33**	**0.51 - 0.59**	**0.1 - 1.2**

(a): N: number of subjects. (b) mean LB-UB: mean lower bound – upper bound. (c) P95 LB – UB: 95th percentile lower bound – upper bound. (d): Percentage above 1: percentage of individuals with an exposure above 1 µg/kg b.w. per day lower bound – upper bound. *** 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.**

Infants, toddlers and other children were the most exposed groups. The mean exposure levels – between 0.16 and 0.88 µg/kg b.w. per day at the lower bound and 0.54 and 1.02 µg/kg b.w per day at the upper bound – were for some population groups in the range of 1 µg/kg b.w. per day. The 95th percentile of exposure was between 0.76 and 1.58 µg/kg b.w. per day at the lower bound and 0.95 and 1.86 µg/kg b.w. per day at the upper bound. These estimates were in the range of chronic exposure estimates reported in the literature for the French, German and Catalonian (Spain) children (Cano-Sancho et al., 2011, Curtui et al., 2006, Sirot et al., 2013). They were above chronic exposure estimates derived from a probabilistic exposure assessment for the Czech, Danish and Dutch populations (Muri et al., 2009) and below those indicated in a recent Norwegian assessment (VKM, 2013).

The percentage of infants, toddlers and other children with dietary exposure above 1 µg/kg b.w. per day varied according to the population group: it was estimated between 0.4 and 30.1 % at the lower bound and between 3.1 and 46 % at the upper bound. The highest estimates were observed for the Bulgarian toddlers and other children, at 30.1 and 34.4 % respectively for the lower bound and at 46 and 50.2 % respectively for the upper bound. These were attributed to high consumption levels of breads and fine bakery wares. Indeed, the average consumption level of breads and fine bakery wares was estimated to be around 9 g/kg b.w per day for Bulgarian toddlers and other children, whereas in half the other groups of toddlers and other children, average consumption levels were less than 5 g/kg b.w. per day (EFSA, 2011b).

Adolescents, adults, elderly and very elderly had lower dietary exposure compared to infants, toddlers and other children, with an average exposure between 0.16 and 0.5 µg/kg b.w. per day at the lower bound and between 0.22 and 0.58 µg/kg b.w. per day at the upper bound and a 95th percentile of exposure between 0.31 and 0.96 µg/kg b.w. per day at the lower bound and between 0.43 and 1.08 µg/kg b.w. per day at the upper bound. The percentage of individuals with dietary exposure above 1 µg/kg b.w. per day was estimated to be between 0 % and 0.3 % depending on the population group at the lower bound and up to 5.5 % at the upper bound. These estimates were in the range of those reported in the literature for the French, German, Catalonian (Spain), Belgian and Norwegian populations (Cano-Sancho et al., 2011, Curtui et al., 2006, De Boevre et al., 2013, Sirot et al., 2013, VKM, 2013). They were below the estimates indicated for the Hungarian adult population (Ambrus et al., 2011).

4.3.1.2. Foods contributing to the total DON exposure

- ✓ *Relative contribution to total exposure*

For each age group, the minimum and maximum relative contribution in percentage to the overall lower bound mean DON exposure determined across the surveys are indicated in Table 17. Grains and grain-based products were the main contributors to the total exposure; the type of products depending on the level of disaggregation of the food consumption reported in the consumption surveys and on the food habits across the age groups and countries.

In some surveys, food consumption data have been highly disaggregated. For example, the consumption of bread was expressed as flour, water, salt and yeast. This was especially the case in two Finnish surveys, for which the grain milling products represented between 69.0 and 76.9 % of the total exposure depending on the age group (data not shown).

In groups of adults, elderly and very elderly from other surveys than the surveys mentioned above, the main contributor to total lower bound mean DON exposure was "bread and rolls" representing between 32.1 and 72.3 % of the total exposure. This was followed by "fine bakery wares" (15.7 – 34.0 %) in all countries, except in Italy, where "pasta, raw" was the main contributor (23.9 – 27.6 %), and Denmark and Hungary, where the food group "grain milling products" was the main contributor (13.9 – 23.2 %). Other food groups did not contribute more than 10 % of the total exposure, except in the case of "breakfast cereals" and "composite foods" for Swedish adults (data not shown).

Table 17: Minimum and maximum relative contribution of food groups (in percentage) to the overall lower bound mean DON exposure across the surveys and age groups

Food group	Infants	Toddlers	Other children	Adolescents	Adults	Elderly	Very elderly
Grains	1.2 - 2.1	0 - 1.8	0.1 - 2.9	0.3 - 2.9	0.3 - 6	0.2 - 2.1	0.2 - 1.5
Grain milling products	18 - 19.2	0.2 - 76.9	0 - 69	0.2 - 21.1	0.1 - 72.8	0.2 - 75.1	0.2 - 23.2
Bread and rolls	3.2 - 47.5	1.2 - 58.5	2.7 - 64.6	31.6 - 59.9	1.4 - 66.1	1.3 - 72.3	50.7 - 65.9
Breakfast cereals	0 - 0.1	0.1 - 7.2	0.3 - 13.3	0.8 - 5.5	0.5 - 10.3	0.1 - 14.1	0.2 - 3.7
Fine bakery wares	0 - 17.6	1.1 - 27.6	2.9 - 43.1	4.4 - 37.4	0 - 30	0 - 30.7	7.3 - 34
Pasta (Raw)	4.3 - 63.8	3.8 - 41.9	2.5 - 30.5	1.4 - 23.9	0.1 - 23.9	1.1 - 27.3	1.1 - 26.7
Other grain products	0	0 - 1.2	0 - 1.9	0	0 - 0.1	0	0
Composite food[(a)]	0 - 0.6	0.7 - 4.3	0 - 28.5	0 - 26.3	0 - 17.4	0 - 2.5	0 - 2.7
Snacks	0 - 5.7	0.1 - 9.4	0.7 - 6.6	0.9 - 9.9	0.3 - 5.2	0 - 0.5	0 - 0.3
Beer beverages	0	0	0 - 0.1	0 - 0.9	0.5 - 5.3	0.2 - 3.9	0 - 4.2
Herbs, spices, condiments	0.9 - 0.9	0.8 - 3.2	0.2 - 5	0.2 - 5.5	1.4 - 5.3	1.2 - 3.8	1.2 - 3.2
Vegetable products[(b)]	0 - 0.1	0 - 2.1	0 - 0.6	0 - 0.5	0 - 0.7	0.1 - 0.5	0.1 - 0.4
Dried fruits	0	0 - 0.1	0 - 0.1	0	0 - 0.1	0	0 - 0.1
Sugar and confectionary	0	0	0	0	0	0	0
Vegetable fats and oils	0	0	0	0	0	0	0
Dried beans and oilseeds	0	0	0	0	0	0	0
Oats drink	0	0	0	0	0	0	0
Infant foods[(c)]	2.8 - 12	0.3 - 7.1	0 - 1	0	0	0	0
Products for special use[(d)]	0 - 0	0 - 0.2	0 - 0.1	0 - 0.2	0 - 1	0 - 1.3	0 - 2.3

(a): cereal, rice and vegetable based composite foods. (b): sweet corn, tea and herbal infusions and vegetable products (c): all foods for infants and young children, except juice and herbal tea for infants and young children. (d): fibre supplements, dietetic foods for diabetics, medical foods.

In groups of infants, toddlers, other children and adolescents from other surveys than those mentioned above, the pattern of exposure was more variable. In most but not all the population groups, “bread and rolls” (30.9 – 64.2 %) were the main contributor to the total LB mean DON exposure, followed by “fine bakery wares” (10.6 – 34.3 %), “grain milling products” (18.4 – 21.1 %), “pasta, raw” (11.9 – 30.5 %) and “composite dishes” (26.3 – 28.5 %) according to the population groups. In the French children and adolescents groups, and in the Swedish and Greek children groups, “fine bakery wares” (29.2 – 43.1%) was the main contributor to total LB mean exposure to DON, followed by “bread and rolls” (23.1 – 31.6 %) and “composite dishes” (28.5 %). In the Italian infants and toddlers group, “pasta, raw” (41.9 – 63.8 %) was the main contributor, followed by “grain milling products” (18.0 %) and “bread and rolls” (22%). The other food groups did not contribute more than 10 % of the total exposure, except in the case of “breakfast cereals” for some Finnish children.

✓ *Main contributors to the TDI of 1 µg/kg b.w. per day*

The food groups contributing more than 10 % to the TDI of 1 µg/kg b.w. per day at the lower bound estimate were identified for each population group considering the total population, and the 5 % most exposed subjects for the population group containing more than 60 subjects. Table 18 presents the list of foods contributing to more than 10 % of the threshold in at least one population group. For each food, the table details the number of population groups for which the food was identified as contributing to more than 10 % of the threshold, together with the minimum and maximum contribution identified across these population groups.

When considering the total population, 8 foods/food groups were identified as main contributors in at least one population group. The two food groups most frequently identified as main contributors were “Wheat bread and rolls” and “Pastries and cakes”. When considering the 5 % most exposed subjects, 10 additional foods/food groups contributed, in at least one population group, to more than 10 % of the threshold of 1 µg/kg b.w. per day. “Wheat flour, white” and “Pasta, wheat flour” were two additional foods most frequently identified as main contributors.

Table 18: Food contributing to more than 10% of 1 µg/kg b.w. per day

Food description	Total population[(a)]		5 % most exposed subjects[(b)]	
	N population group[(c)]	Contribution range expressed in µg/kg b.w/day[(d)]	N population group[(c)]	Contribution range expressed in µg/kg b.w./day[(d)]
Grain and grain-based products				
Wheat flour, white	2	0.11 - 0.18	14	0.1 - 0.41
Other wheat milling products	-	-	1	0.25
Oat flour	1	0.19	2	0.15 - 0.42
Wheat bread and rolls	37	0.1 - 0.37	44	0.1 - 0.68
Rye bread and rolls	-	-	4	0.13 - 0.19
Mixed wheat and rye bread	-	-	5	0.13 - 0.24
Multigrain bread and rolls	2	0.1 - 0.11	1	0.1
Other bread (incl. maize bread)	-	-	1	0.25
Bread and rolls unspecified	3	0.14 - 0.17	4	0.13 - 0.3
Porridge	-	-	1	0.27
Pasta, wheat flour	3	0.11 - 0.31	10	0.11 - 0.49
Pasta, unspecified	-	-	3	0.11 - 0.4
Biscuits (cookies)	-	-	1	0.16
Pastries and cakes	16	0.1 - 0.28	40	0.1 - 0.77
Food for infants and young children				
Cereal-based food	-	-	1	0.11
Composite food				
Cereal, rice and vegetable based	1	0.18	7	0.1 - 0.39
Snack food				
Maize chips	-	-	3	0.12 - 0.3
Other and unspecified snack food	-	-	1	0.13

(a): all individuals: determination of the food contributing to more than 10 % of 1 µg/kg b.w. per day considering all the individuals in each population group (N = 68 population groups). (b) 5 % most exposed subjects: determination of the food contributing to more than 10% of 1 µg/kg b.w. per day considering only the 5 % most exposed subjects in each population group (N = 62 population groups). (c): N population groups: number of population groups for which the food contributed to more than 10 % of the threshold of 1 µg/kg b.w. per day. (d): contribution range, expressed in µg/kg b.w. per day, defined as minimum and maximum average contribution across these population groups for which the food contributed to more than 10 % of the threshold of 1 µg/ kg b.w. per day.

However, it should be pointed out that the data available for oat flour, porridge and composite foods were very limited. When considering the upper bound estimates (results not shown), two additional foods, with quantified levels of DON, were found to contribute to more than 10 % of 1 µg/kg b.w. per day in at least one population group: “beer and beer-like beverage”, “ready-to-eat meal for infants and young children”.

4.3.1.3. Contribution of DON derivatives to the total exposure

An exposure assessment to the sum of DON, 3-Ac-DON and 15-Ac-DON was performed based on the 3,577 food samples, covering 83 foods/food groups. Table 19 shows the percentage contribution of 3-Ac-DON, 15-Ac-DON and DON to the exposure to the sum of 3-Ac-DON, 15-Ac-DON and DON for the lower and upper bound estimates. At the lower bound estimate, 3-Ac-DON was found to contribute from 0 to 0.7 % of the total exposure and 15-Ac-DON from 0.1 to 1.7 % of the total exposure. At the upper bound estimate, 3-Ac-DON and 15-Ac-DON were contributing each to around 20 – 30 % of the total exposure. This big difference between the lower and upper bound shows the influence of the limit of quantifications in the exposure estimates.

Table 19: Percentage contribution of 3-Ac-DON, 15-Ac-DON and DON to the total exposure

Age group[(a)]		Lower bound estimate expressed in %			Upper bound estimate expressed in %		
		3-Ac-DON	15-Ac-DON	DON	3-Ac-DON	15-Ac-DON	DON
Infants (N = 2)	Min	0.0	0.1	98.9	31.0	31.1	36.5
	Median	0.1	0.5	99.4	31.4	31.4	37.2
	Max	0.2	0.9	99.9	31.7	31.7	37.9
Toddlers (N = 9)	Min	0.1	0.1	98.5	24.1	24.4	41.5
	Median	0.1	0.6	99.2	25.8	26.1	48.1
	Max	0.3	1.4	99.8	29.1	29.4	51.3
Other children (N = 17)	Min	0.1	0.4	98.3	21.3	21.6	50.2
	Median	0.2	0.9	98.9	22.9	23.3	53.8
	Max	0.6	1.3	99.5	24.7	25.1	57.1
Adolescents (N = 12)	Min	0.1	0.4	97.9	20.8	21.0	50.0
	Median	0.2	0.9	98.9	22.9	23.2	53.9
	Max	0.4	1.7	99.5	24.8	25.1	58.2
Adults (N = 15)	Min	0.0	0.3	97.8	20.9	21.0	49.4
	Median	0.1	0.4	99.4	23.3	23.5	53.1
	Max	0.4	2.0	99.7	25.1	25.4	58.0
Elderly (N = 7)	Min	0.0	0.2	99.1	20.8	20.6	50.4
	Median	0.1	0.2	99.7	22.9	23.0	54.1
	Max	0.7	0.3	99.8	24.7	24.9	58.6
Very elderly (N = 6)	Min	0.0	0.2	99.6	20.8	21.0	50.2
	Median	0.1	0.2	99.7	23.7	23.8	52.5
	Max	0.1	0.3	99.8	24.8	25.0	58.2

(a): for each age group, the minimum, median and maximum percentage contribution across the different population groups is indicated.

4.3.2. Acute exposure assessment

4.3.2.1. DON exposure levels across the different population groups

The distribution of the mean and 95th percentile of acute exposure (upper bound estimate) obtained for infants and toddlers, which were the most exposed population groups, is shown in Figures 5 and 6. The distributions obtained for the other population groups are displayed in the Appendix.

Overall, the average acute exposure level of infants, toddlers and other children ranged from 0.55 (95% CI = 0.47 – 0.68) to 1.04 (95% CI = 0.79 – 1.30) µg/kg b.w., the 95th percentile from 1.72 (95% CI = 1.59 – 1.85) to 3.35 (95% CI = 1.95 – 6.25) µg/kg b.w., depending on the population group. The acute exposure levels of adolescents, adults, elderly and very elderly were lower than those estimated for children. Depending on the population group, average acute exposure levels ranged from 0.22 (95% CI = 0.21 – 0.24) to 0.65 (95% CI = 0.62 – 0.70) µg/kg b.w.; the 95th percentile ranged from 0.58 (95% CI = 0.53 – 0.65) to 1.75 (95% CI = 1.56 – 1.95) µg/kg b.w., depending on the age group.

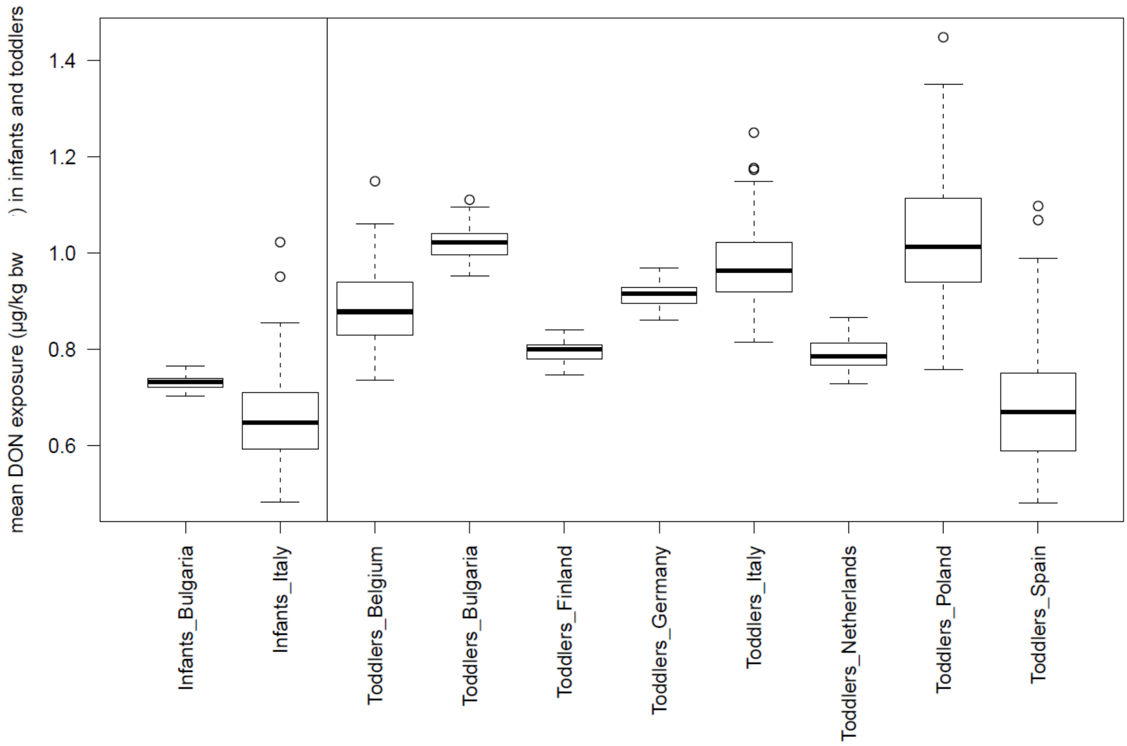

Figure 5: Distribution of average acute exposure to DON in µg/kg b.w. across the infants and toddlers population groups (Box-plot: whiskers at P5 and P95, box at P25 and P75 with line at P50. The dots represent values above the 75th percentile plus 1.5 times the inter-quartile distance, or less than the 25th percentile minus 1.5 times the inter-quartile distance).

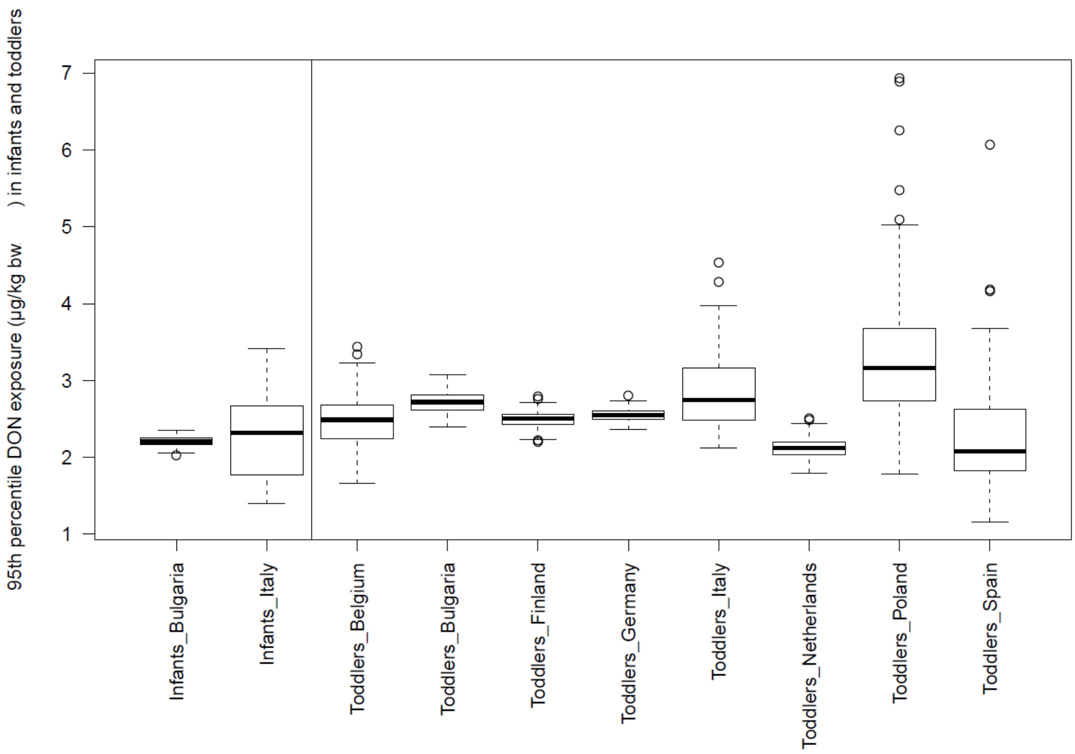

Figure 6: Distribution of 95th percentile of acute exposure to DON in µg/kg b.w. across the infants and toddlers population groups (Box-plot: whiskers at P5 and P95, box at P25 and P75 with line at P50. The dots represent values above the 75th percentile plus 1.5 times the inter-quartile distance, or less than the 25th percentile minus 1.5 times the inter-quartile distance).

Table 20 shows the percentage of days with upper bound exposure levels above 8 µg/kg b.w. (corresponding to the JECFA ARfD) as well as the corresponding percentage of individuals with at least one day of exposure above the threshold of 8 µg/kg b.w. For infants, toddlers and other children, the percentage of exposure days above 8 µg/kg b.w. ranged from 0.04 % (95% CI = 0 - 0.17) to 0.51 % (95 % CI = 0 – 2.53) depending on the population groups. For adolescents, adults, elderly and very elderly, the percentage of exposure days above the threshold ranged from 0 % to 0.09 % (95 % CI = 0 – 0.62) depending on the population group. In almost all cases, the days of exposure above 8 µg/kg b.w. corresponded to different individuals. Indeed, individuals with more than one exposure day above 8 µg/kg b.w. were identified in only 10 out of the 73 population groups taken in consideration. Except for Italian toddlers (only one individual (out of 36) exposed more than once at a level above the threshold), individuals with more than one exposure day above the threshold represented between 0.07 and 0.7 % of the population group (results not shown).

Table 20: Percentage of exposure days above 8 µg/kg b.w. and percentage of individuals with at least one exposure day above 8 µg/kg b.w. (upper bound estimates)

Country	N days[(a)]	Percentage of days above 8 µg/kg b.w.[(b)]	N individuals[(c)]	Percentage of individuals with at least one exposure day above 8 µg/kg b.w.[(b)]
Infants				
Bulgaria	1720	0.04 [0; 0.17]	861	0.08 [0; 0.35]
Italy	48	0.13 [0; 2.08]	16	0.38 [0; 6.25]
Toddlers				
Belgium	108	0.13 [0; 0.93]	36	0.39 [0; 2.78]
Bulgaria	856	0.24 [0; 0.58]	428	0.48 [0; 1.17]
Finland	1486	0.07 [0; 0.2]	500	0.21 [0; 0.6]
Germany	783	0.06 [0; 0.26]	261	0.19 [0; 0.77]
Italy	108	0.25 [0; 0.93]	36	0.72 [0; 2.78]
Netherlands	644	0.13 [0; 0.47]	322	0.26 [0; 0.93]
Poland	79	0.51 [0; 2.53]	79	0.51 [0; 2.53]
Spain	34	0.15 [0; 1.47]	17	0.29 [0; 2.94]
Other children				
Belgium	1875	0.14 [0; 0.32]	625	0.42 [0; 0.96]
Bulgaria	867	0.3 [0.06; 0.58]	434	0.59 [0.12; 1.15]
Czech Republic	778	0.11 [0; 0.32]	389	0.22 [0; 0.64]
Denmark	3426	0.07 [0; 0.15]	490	0.48 [0; 1.02]
Finland	3773	0.08 [0.03; 0.16]	1198	0.27 [0.08; 0.5]
France	3315	0.2 [0.09; 0.35]	482	1.37 [0.62; 2.28]
Germany	1980	0.07 [0; 0.18]	660	0.2 [0; 0.45]
Greece	2508	0.25 [0.08; 0.42]	847	0.74 [0.24; 1.24]
Italy	579	0.16 [0; 0.52]	193	0.46 [0; 1.55]
Latvia	377	0.17 [0; 0.53]	190	0.33 [0; 1.05]
Netherlands	1914	0.1 [0; 0.26]	957	0.2 [0; 0.52]
Poland	409	0.2 [0; 0.49]	409	0.2 [0; 0.49]
Spain	1110	0.06 [0; 0.23]	555	0.13 [0; 0.45]
Sweden	5875	0.15 [0.07; 0.25]	1473	0.59 [0.27; 0.98]
Adolescents				
Belgium	1187	0.03 [0; 0.17]	611	0.06 [0; 0.33]
Bulgaria	162	0.09 [0; 0.62]	162	0.09 [0; 0.62]
Cyprus	909	0.01 [0; 0.11]	303	0.03 [0; 0.33]
Czech Republic	596	0.06 [0; 0.17]	298	0.12 [0; 0.34]
Denmark	3348	0.03 [0; 0.09]	479	0.19 [0; 0.63]
France	6728	0.07 [0.01; 0.13]	973	0.46 [0.1; 0.87]
Germany	2022	0.04 [0; 0.1]	1011	0.07 [0; 0.2]
Italy	741	0.04 [0; 0.2]	247	0.13 [0; 0.61]
Latvia	949	0.07 [0; 0.26]	496	0.13 [0; 0.5]
Poland	666	0.1 [0; 0.3]	666	0.1 [0; 0.3]
Spain	1946	0.02 [0; 0.05]	946	0.04 [0; 0.11]

Country	N days[(a)]	Percentage of days above 8 µg/kg b.w.[(b)]	N individuals[(c)]	Percentage of individuals with at least one exposure day above 8 µg/kg b.w.[(b)]
Sweden	4047	0.07 [0; 0.14]	1018	0.25 [0; 0.49]
Adults				
Austria	2123	0.01 [0; 0.05]	2123	0.01 [0; 0.05]
Belgium	2648	0.02 [0; 0.08]	1356	0.04 [0; 0.15]
Bulgaria	691	0.02 [0; 0.14]	691	0.02 [0; 0.14]
Czech Republic	3332	0.03 [0; 0.09]	1666	0.07 [0; 0.18]
Denmark	19722	0.01 [0; 0.03]	2822	0.07 [0; 0.18]
Estonia	1866	0.01 [0; 0.05]	1866	0.01 [0; 0.05]
Finland	3150	0.01 [0; 0.06]	1575	0.02 [0; 0.13]
France	15727	0.02 [0; 0.04]	2276	0.12 [0.02; 0.26]
Germany	20838	0.02 [0; 0.04]	10419	0.04 [0.01; 0.08]
Hungary	3222	0.01 [0; 0.03]	1074	0.02 [0; 0.09]
Ireland	6706	0.03 [0; 0.07]	958	0.23 [0; 0.52]
Italy	6939	0.01 [0; 0.03]	2313	0.03 [0; 0.09]
Latvia	2655	0.01 [0; 0.04]	1384	0.02 [0; 0.07]
Netherlands	1500	0.03 [0; 0.13]	750	0.05 [0; 0.27]
Poland	2527	0.01 [0; 0.06]	2527	0.01 [0; 0.06]
Slovakia	2763	0.04 [0; 0.11]	2761	0.04 [0; 0.11]
Slovenia	407	0.01 [0; 0]	407	0.01 [0; 0]
Spain	3576	0.01 [0; 0.03]	1400	0.02 [0; 0.07]
Sweden	8466	0.01 [0; 0.04]	1210	0.08 [0; 0.25]
United Kingdom	12068	0.02 [0; 0.05]	1724	0.14 [0; 0.35]
Elderly				
Belgium	1045	0.01 [0; 0.1]	534	0.02 [0; 0.19]
Bulgaria	151	0.01 [0; 0]	151	0.01 [0; 0]
Denmark	2159	0.01 [0; 0.05]	309	0.04 [0; 0.32]
Finland	926	0.01 [0; 0.11]	463	0.02 [0; 0.22]
France	1824	0.01 [0; 0.05]	264	0.09 [0; 0.38]
Germany	4012	0.02 [0; 0.06]	2006	0.03 [0; 0.12]
Hungary	618	0.01 [0; 0.08]	206	0.02 [0; 0.24]
Italy	870	0	290	0.01 [0; 0]
Poland	329	0	329	0
Very elderly				
Belgium	1448	0.01 [0; 0.07]	744	0.01 [0; 0.13]
Bulgaria	200	0.01 [0; 0]	200	0.01 [0; 0]
Denmark	140	0	20	0
France	571	0.02 [0; 0.18]	84	0.11 [0; 1.19]
Germany	980	0.03 [0; 0.1]	490	0.05 [0; 0.2]
Hungary	240	0	80	0.01 [0; 0]
Italy	684	0	228	0.01 [0; 0]
Poland	124	0	124	0

(a): number of reporting days available in the Comprehensive Database. Each reporting day was simulated 100 times. (b) average and 95% confidence interval determined on the upper bound estimate. **In case of low number of days / individuals available, the estimation of percentage of days above 8 µg/kg b.w. / individuals with at least one day of exposure above 8 µg/kg b.w. may be biased.**

4.3.2.2. Food group contributing to the total exposure to DON

The contribution of food groups to the total exposure to DON was estimated for the very few days of exposure to DON above 8 µg/kg b.w (7,953 days out of 19,520,000 days simulated). For each of these days, the food group contributing the most to the total exposure was identified (hereafter referred as "main contributor") and its contribution, expressed as a percentage of the threshold of 8 µg/kg b.w., was estimated. Table 21 shows, for each food group, the number of exposure days – out of the 7,953 days considered – with the corresponding food group identified as main contributor, and its contribution range of 8 µg/kg b.w. (40-85 %, 85-<100% or above 8 µg/kg b.w.). Note that the main contributors were never found to contribute less than 40 % of 8 µg/kg b.w.

For example, considering the adolescents age group, "Fine bakery wares" were identified as the main contributor to the total exposure for 764 days of exposure above 8 µg/kg b.w. The DON intake resulting from the consumption of "fine bakery wares" during these days was higher than 8 µg/kg b.w. in 674 days, comprised between 85 and 100 % of 8 µg/kg b.w. in 74 days, and between 40 and 85 % of 8 µg/kg b.w. in 16 days.

Table 21: Main contributors and contribution range expressed in percentage of 8 µg/kg b.w. during days of exposure above 8 µg/kg b.w.

Food group	Number of days with exposure above 8 µg/kg b.w.							
	with the corresponding food group identified as main contributor	with the main contributor contributing to the following percentage ranges of 8 µg/kg b.w.			with the corresponding food group identified as main contributor	with the main contributor contributing to the following percentage ranges of 8 µg/kg b.w.		
		40 – 85%	85 – 100%	≥ 100 %		40 – 85%	85 – 100%	≥ 100 %
	Infants				**Adolescents**			
Grains	0	0	0	0	74	3	4	67
Grain milling products	24	1	5	18	98	0	10	88
Bread and rolls	19	2	4	13	70	7	9	54
Breakfast cereals	0	0	0	0	76	1	6	69
Fine bakery wares	19	0	2	17	764	16	74	674
Pasta (Raw)	13	0	5	8	16	3	2	11
Other grains products	0	0	0	0	0	0	0	0
Composite food	0	0	0	0	40	4	0	36
Snacks	1	0	0	1	0	0	0	0
Beer beverages	0	0	0	0	39	0	5	34
Infant foods	0	0	0	0	0	0	0	0
Products for special use	-	-	-	-	0	0	0	0
	Toddlers				**Adults**			
Grains	15	0	3	12	75	1	6	68
Grain milling products	78	4	12	62	177	1	24	152
Bread and rolls	75	10	11	54	53	3	5	45
Breakfast cereals	63	9	14	40	104	1	10	93
Fine bakery wares	249	17	38	194	827	6	81	740
Pasta (Raw)	33	2	8	23	20	0	2	18
Other grains products	2	0	0	2	2	0	0	2
Composite food	9	1	0	8	0	0	0	0
Snacks	1	0	1	0	0	0	0	0
Beer beverages	0	0	0	0	772	7	60	705
Infant foods	6	1	2	3	0	0	0	0
Products for special use	0	0	0	0	0	0	0	0
	Other children				**Elderly and very elderly**			
Grains	104	4	19	104	5	0	0	5
Grain milling products	308	11	49	308	11	0	1	10
Bread and rolls	234	29	56	234	10	0	2	8
Breakfast cereals	192	8	21	192	14	0	1	13
Fine bakery wares	2019	60	283	2019	115	0	7	108
Pasta (Raw)	91	11	32	91	3	0	1	2
Other grains products	5	0	0	5	-	-	-	-
Composite food	263	45	72	263	4	0	4	0
Snacks	13	7	4	13	-	-	-	-
Beer beverages	1	1	0	1	18	0	2	16
Infant foods	6	1	2	6	-	-	-	-
Products for special use	7	1	0	7	-	-	-	-

Overall, in 84.4 % of the cases (N = 6,716 exposure days out of 7,953 exposure days considered), the consumption of one single food was sufficient to explain an exposure above 8 µg/kg b.w. In the other cases (15.6 %, N = 1,267 exposure days) the threshold was exceeded due to the combination of several foods more or less heavily contaminated with DON.

Concerning infants, four main food groups were most frequently identified as the main contributors to the total exposure: “grain milling products”, “bread and rolls”, “fine bakery wares” and “pasta raw” with respectively 32 %, 25 %, 25 % and 17 % of exposure days above the threshold. Except the “snacks”, which were responsible in only one exposure day above 8 µg/kg b.w., the other food groups were never identified as first contributor during a day of exposure above the threshold (they appear with a 0 in Table 21) .

In the other population groups, the food group most frequently associated with an acute exposure above the threshold of 8 µg/kg b.w. was “fine bakery wares”. Indeed, depending on the age group, this food group was identified as the first contributor to the total exposure in between 47 % to 65 % of exposure days above the threshold. This was mainly explained by high DON levels observed in some samples of “fine bakery wares”, especially salty biscuits (95th percentile at 429.2 µg/kg). This food group was followed by the “beer beverages” for adults and elderly and very elderly, associated with respectively 38 % and 10 % of exposure days above the threshold of 8 µg/kg b.w. (Table 21). “Bread and rolls”, “breakfast cereals” and “grain milling products” were identified as the main contributors to the total exposure with 12 to 15 % of exposure days above the threshold in the case of toddlers and with 6 to 9 % of the exposure days above the threshold for the other age groups. Other foods groups were identified as main contributor to the total exposure with less than 5 % of exposure days above the threshold or not at all.

4.4. Exposure assessment of animals to DON

Table 22 presents chronic and acute estimates of exposure to DON obtained across the different animal species.

Table 22: Dietary exposure to DON expressed in µg/kg b.w. per day for the different animal species

	Chronic exposure in µg/kg b.w. per day MB [LB-UB][(a)]	**Acute exposure in µg/kg MB [LB-UB][(a)]**
Pigs: piglets	10.2 [7.8; 12.6]	32.7
Pigs: pigs for fattening	12.5 [11.9; 13]	44.6
Pigs: lactating sows	15.5 [14.8; 16.1]	-
Poultry: chickens for fattening	43.5 [43; 44.1]	132.3
Poultry: laying hens	39.3 [38.2; 40.4]	137.9
Turkeys: turkeys for fattening	33.9 [33.4; 34.3]	91.6
Ducks: ducks for fattening	43.3 [43.3; 43.4]	92.0
Salmon	3.9 [3.8; 4.1]	11.6 [11.6; 11.8]
Dogs	6.7 [6.5; 6.8]	27.1
Cats	6.9 [6.8; 7.1]	28.3

(a) middle bound [lower bound – upper bound]. When the middle bound, lower bound and upper bound are equal, only one estimate is indicated.

Chronic exposure levels of pigs, which are considered as the most sensitive animal species to DON exposure (EFSA, 2004), were estimated between 10.2 and 15.5 µg/kg b.w. per day for the middle bound estimate and acute exposure between 32.8 and 66.3 µg/kg b.w. Poultry, turkeys and ducks were more exposed than pigs, with chronic and acute middle bound exposure levels respectively ranging from 33.9 to 43.3 µg/kg b.w./day and from 91.6 to 137.9 µg/kg b.w. Companion animals and salmon were estimated to have lower exposure; chronic exposure levels ranged between 3.9 and 6.9 µg/kg b.w./day and acute exposure levels between 11.6 and 28.3 µg/kg b.w.

As previously described (EFSA CONTAM Panel, 2011, EFSA CONTAM, 2013), these estimates are intended to provide an indication of likely exposure to DON across a range of feeding systems in Europe. In some situations, exposure may be higher or lower than described above depending on the diets for animal feeding which may apply in different areas.

4.5. Uncertainties

Evaluation of the inherent uncertainties in the assessment of exposure to DON was performed following the guidance of the Opinion of the Scientific Committee related to Uncertainties in the Dietary Exposure Assessment (EFSA, 2007). Uncertainties and limitations related to the use of the EFSA Comprehensive Food Consumption Database in view of exposure assessment have already been described in EFSA (2011b) and won't be further detailed. Specific uncertainties related to DON are summarised in Table 23.

The occurrence data used in the exposure assessment were mainly the results of monitoring programmes. Due to the sampling strategy (selective/targeted sampling design) and to the performance of the analytical methods (which aimed to verify compliance with maximum limits/guidance values), the data are considered to overestimate the background level of DON, especially the upper bound estimate, in unprocessed grains of undefined end-use, food and feed available on the EU market. Moreover, the cooking effect, such as cooking in water (pasta), which is known to decrease the level of DON in foods (JECFA, 2010, VKM, 2013), was not taken into account in the exposure assessment, especially in those surveys for which the consumption habits were expressed at the raw ingredient level.

Not the total diet has been taken into account in the exposure assessments. Products of animal origin, starchy roots and tubers, fruits, nuts and vegetables (sweet corn and dried fruits excepted) and beverages (beer excepted) have not been taken into account in the human exposure assessment. Fishmeal, fish and vegetable oils, minerals and vitamins and other feedstuffs (including animal proteins) have not been taken into account in the exposure assessment of salmon, cats and dogs. However, since DON is predominantly found in cereals, the absence of data for these foods and feeds are unlikely to contribute to any underestimation of exposure. The variability of feeding systems throughout Europe was not taken into account, leading to potential under- or overestimation of the exposure levels.

3-Ac-DON and 15-Ac-DON were not systematically considered in the exposure assessment. However, a sensitivity analysis was conducted, considering the samples for which results were available for DON, 3-Ac-DON and 15-Ac-DON. 3-Ac-DON and 15-Ac-DON represented less than 2.2 % of the LB estimate of the total chronic human exposure and as much as 63.4 % of the UB estimate. In the French TDS survey, 3-Ac-DON and 15-Ac-DON represented 0.1 % of the mean LB exposure to DON and about 10 % in UB estimate (Sirot et al., 2013). Too few data were available to describe the presence of DON-3-Glc in food and feed and to consider them in the exposure assessment. This may have led to an underestimation of the total exposure of humans and animals.

It should also be noted that all available occurrence data have been used altogether in order to produce a single "European" estimate without taking into account the variability of contamination throughout Europe. However, the presence of DON in food and feed is affected by agronomic and climatic conditions (Van Der Fels-Klerx *et al*., 2012) and may consequently vary over Europe. As a consequence, the exposure estimates at population group level may either be over- or underestimated.

There is no European guideline to assess acute exposure to food contaminants. A probabilistic acute exposure assessment of the European population was performed. However, the methodology used needs further consolidation. Especially, the within day food contamination variability was not included. The contamination levels simulated were taken from the observed values and not from a modelled distribution. Finally, the exposure assessment was by default iterated one hundred times for each reporting days. This may have not been sufficient to take into account the overall variability of food contamination to DON at the European level. The number of iterations required in order to fully describe the acute exposure levels of the European population would need to be better characterized, by rerunning the exposure assessment a couple of times and comparing the results.

Overall, the exposure estimates presented in this report are considered to overestimate the true exposure levels of the European population.

Table 23: Summary of qualitative evaluation of the uncertainties on the dietary exposure estimates.

Sources of uncertainty	Dietary exposure estimates	Direction and magnitude*
Occurrence data		
Sampling strategy (selective, targeted sampling design)	Mean, 95th percentile	++
Lack of sensitivity of some analytical methods leading to some assumptions for censored results (lower, middle, upper bound estimate)	Mean, 95th percentile	- / +
Low number of samples available in some food/feed group and for the DON derivatives/conjugate	95th percentile	-- / ++
Assumption made on the contamination level of some foodstuffs (infant liquid milk)	Mean, 95th percentile	- / +
Effect of cooking on DON concentration not taken into account	Mean, 95th percentile	++
Assumption that available occurrence data represented whole Europe	Mean, 95th percentile	-- / ++
Feed intake data		
Variability of feeding systems in Europe not taken into account	Mean, 95th percentile	-- / ++
Exposure modelling		
Food/feed not taken into account when no samples available	Mean, 95th percentile	-
Long-term (chronic) exposure assessed from few days of consumption without removing the within-individual variability	95th percentile	+
Acute exposure assessed considering the one single DON level for all food of the same kind consumed the same day	Mean, 95th percentile	- / +
Occurrence levels drawn among the observed values	95th percentile	-
Probabilistic acute exposure was iterated 100 times, which may not be enough to fully describe the DON food contamination variability	95th percentile	- / +
3-Ac-DON, 15-Ac-DON, DON-3-Glc not taken into account. 3-Ac-DON and 15-Ac-DON considered only in a sensitivity analysis	Mean, 95th percentile	-

* Key to direction and magnitude:
+, ++ = uncertainty likely to cause small, medium or large overestimation of exposure;
-, - -= uncertainty likely to cause small, medium or large underestimation of exposure.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- A total of 26,613 analytical results available for DON and its derivatives (3-Ac-DON, 15-Ac-DON) and conjugate (DON-3-Glc), corresponding to 18,884 samples, were considered in this report. They were collected by 21 Member States and Norway between 2007 and 2012.

- DON was found in 44.6 %, 43.5 % and 75.2 % of unprocessed grains of undefined end-use, food and feed samples, respectively. It was most frequently quantified and at the highest levels in maize, wheat and oat grains and derived food and feed products, compared to the other varieties of cereals.

- Levels of DON were significantly higher in wheat bran than the other wheat milling products. DON levels in processed cereals (bread, fine bakery wares, breakfast cereals, pasta) were significantly lower than those in unprocessed grains and grain milling products.

- Overal, feed contained higher levels of DON than unprocessed grains of undefined end-use and foods. DON levels were higher in compound feed for poultry than in compound feed for other animal species.

- The level of DON exceeded maximum levels in 0.8 % of the food samples and guidance values in 1.7 % of the feed samples.

- The DON derivatives (3-Ac-DON, 15-Ac-DON) were far less frequently found and at lower levels than DON. In almost all the cases, when 3-Ac-DON and/or 15-Ac-DON was quantified, DON was also present. The average percentage contribution of 3-Ac-DON to the sum of DON and its derivatives was less than 2 % at the lower bound estimate and around 13 – 20 % at the upper bound estimate. The percentage contribution of 15-Ac-DON to the sum of DON and its derivatives was up to 10 – 15 % at both lower and upper bound estimates for maize grains.

- Very few data, from one Member State, were available for DON-3-Glc. DON-3-Glc was found in around 5 % of the samples, almost always together with DON, and represented on average 5.6 % of the lower bound sum of DON and DON-3-Glc.

- Infants, toddlers and other children were the most exposed groups considering chronic exposure. Depending on the population group, chronic dietary exposure of children to DON (upper bound) was estimated to be on average between 0.54 and 1.02 µg/kg b.w. per day and at the 95th percentile between 0.95 and 1.86 µg/kg b.w. per day. Chronic dietary exposure of adolescents, adults, elderly and very elderly to DON (upper bound) was estimated to be on average between 0.22 and 0.58 µg/kg b.w. per day and at the 95th percentile between 0.43 and 1.08 µg/kg b.w. per day depending on the population group.

- In almost all population groups, the main contributor to the total chronic exposure was “bread and rolls” representing between 30.9 and 72.3 % of the total exposure. In few population groups, the main contributor was either “pasta, raw”, representing up to 63.8 % of the total exposure, “fine bakery wares”, representing up to 43.1 % of the total exposure, or “grain milling products” representing up to 76.9 % of the total exposure.

- 3-Ac-DON and 15-Ac-DON represented less than 2.2 % of the lower bound estimate of the chronic human exposure to the sum of DON, 3-Ac-DON and 15-Ac-DON. However, when considering the upper bound, they were found to represent up to 63.4 % of the total exposure, showing the uncertainty around their real contribution to the total exposure.

- The assessment of the acute exposure of the European population resulted in an estimation of the percentage of days with exposure levels above the threshold of 8 µg/kg b.w. between 0.04 % (95% CI = 0 - 0.17) and 0.51 % (95 % CI = 0 – 2.53) for infants, toddlers and other children and between 0 % to 0.09 % (95 % CI = 0 – 0.62) for adolescents, adults, elderly and very elderly. Subjects with more than one day of exposure above the threshold represented less than 0.7 % of the population group.

- The days of acute exposure above the threshold of 8 µg/kg b.w. were most frequently explained by the consumption of “fine bakery wares” in all age groups except infants. In infants, the days of acute exposure above the threshold were most frequently explained by the consumption of “grain milling products”, followed by “bread and rolls”, “fine bakery wares” and “pasta, raw”.

- The chronic exposure of animals was estimated at the upper bound between 3.9 and 43.3 µg/kg b.w. per day, and the acute exposure levels between 11.6 and 137.9 µg/kg b.w. Poultry (chickens, hens, turkeys and ducks) were found to have the highest level of exposure, followed by pigs, companion animals and fish.

- Due to a lack of occurrence data, DON-3-Glc was not taken into account in the exposure assessment, this is likely leading to an underestimation of total exposure. However, an overestimation of the DON exposure is expected considering the methodology used and the conservative assumptions made to assess the dietary exposure.

RECOMMENDATIONS

- In order to improve the accuracy of the assessment of food contamination levels and exposure to DON throughout Europe, it would be important to further harmonise the sampling strategy (number of samples, food covered, targeting design) and the performance of the analytical methods used for the monitoring programmes.

- Further data should be collected on DON-3-Glc, 3-Ac-DON and 15-Ac-DON in order to better characterise their potential contribution to the total exposure to DON. It is also recommended to measure DON in those foods identified as main contributors to the total exposure, but for which the estimations of the contamination levels were not robust, such as oat flour, porridge and composite foods. Collecting more accurate data on the different feeding systems used in Europe would also improve the quality of the animal exposure assessment to contaminants.

- When reporting data to EFSA, particular attention should be drawn to the food description, especially in order to clearly distinguish the grains used for foods, those used for feed and unprocessed grains of undefined use. When a result is expressed on a dry weight basis, an indication of the moisture content should be provided. Finally, when several measurements are conducted on the same sample, even if different analytical techniques are used, only one result which is considered as the most accurate, should be reported.

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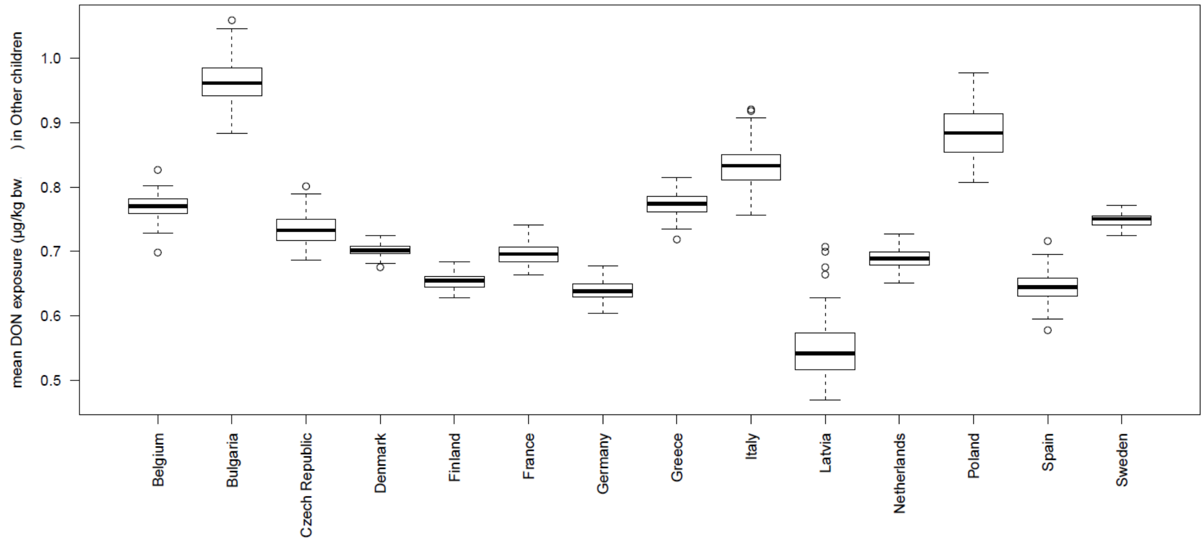
APPENDIX: ACUTE EXPOSURE LEVELS OF THE EUROPEAN POPULATION TO DON

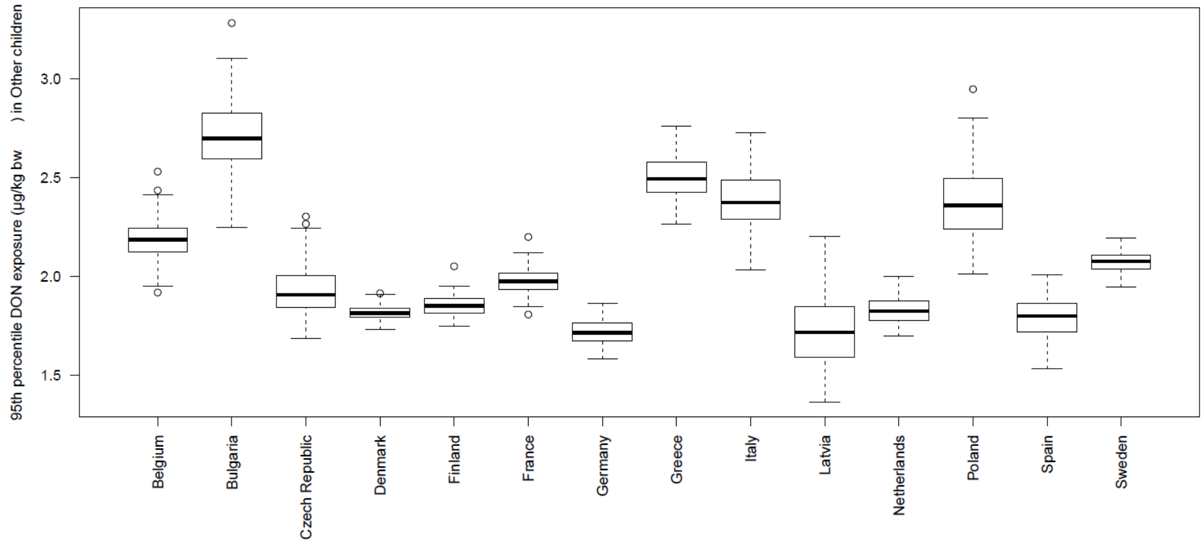
In all graphs, the box plots shows whiskers at P5 and P95, box at P25 and P75 with line at P50. The dots represent values above the 75th percentile plus 1.5 times the inter-quartile distance, or less than the 25th percentile minus 1.5 times the inter-quartile distance

✓ Other children

Mean acute exposure level to DON in µg/kg b.w.

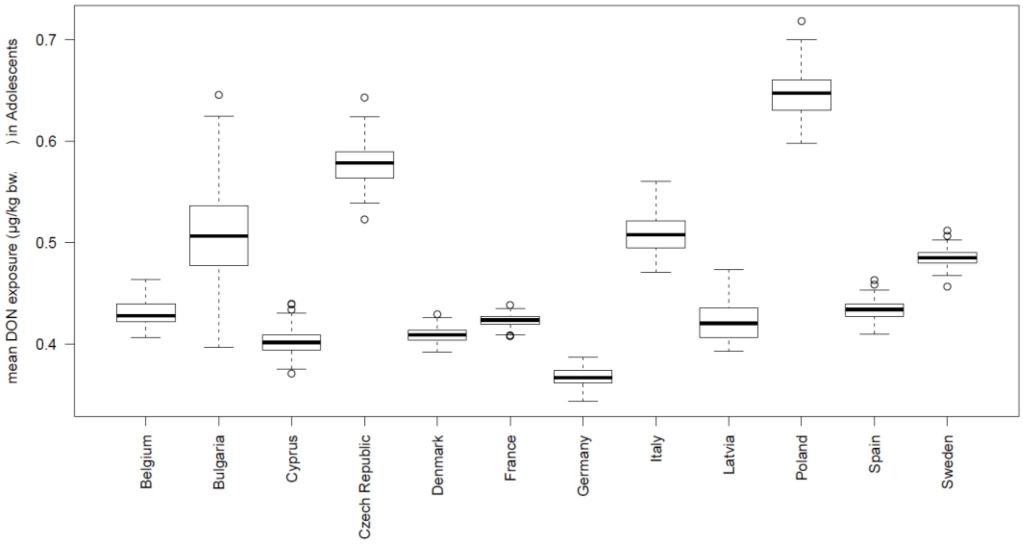


P95 acute exposure level to DON in µg/kg b.w.

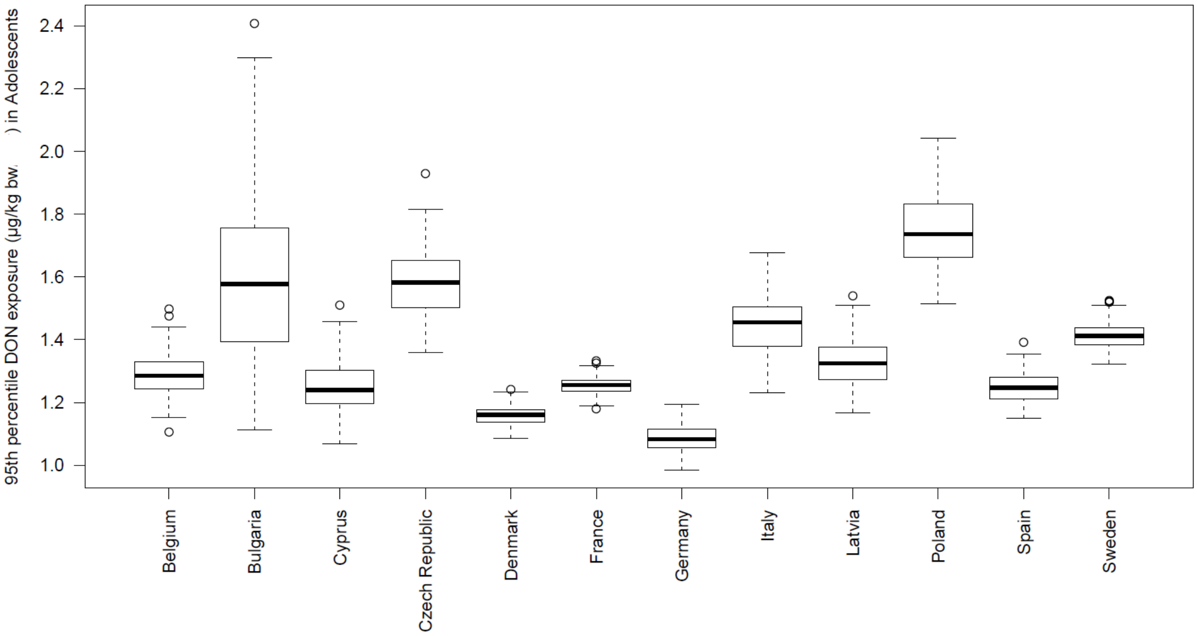


✓ Adolescents

Mean acute exposure level to DON in µg/kg b.w.

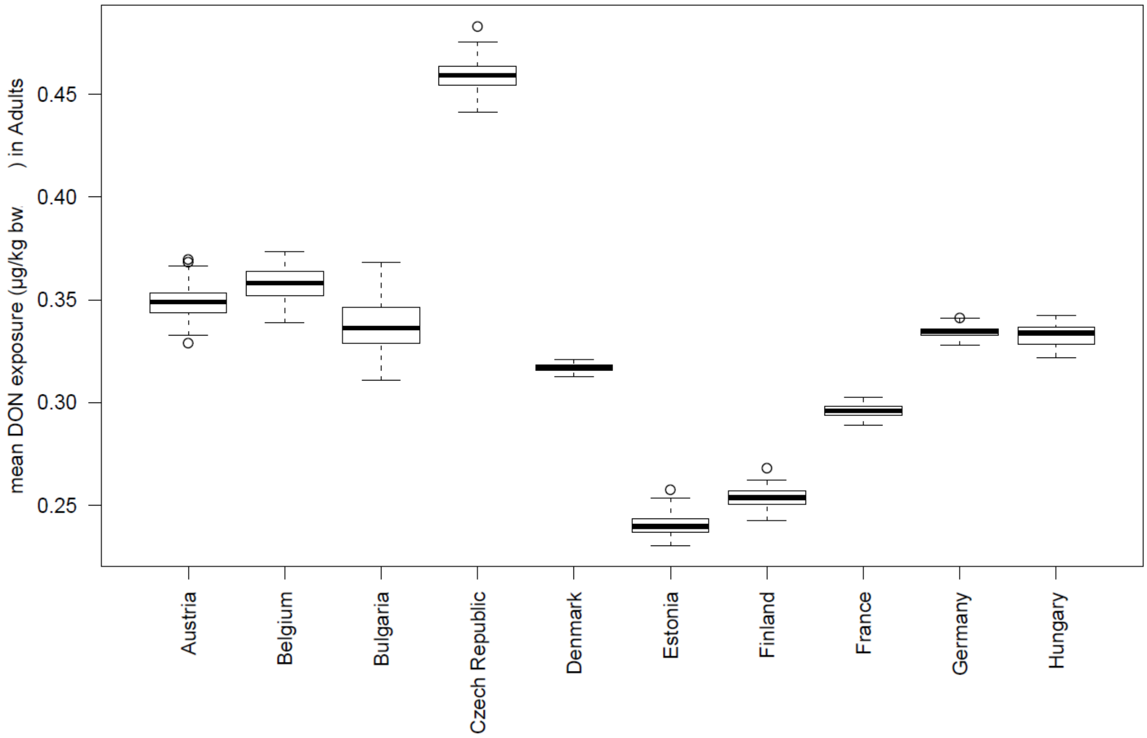


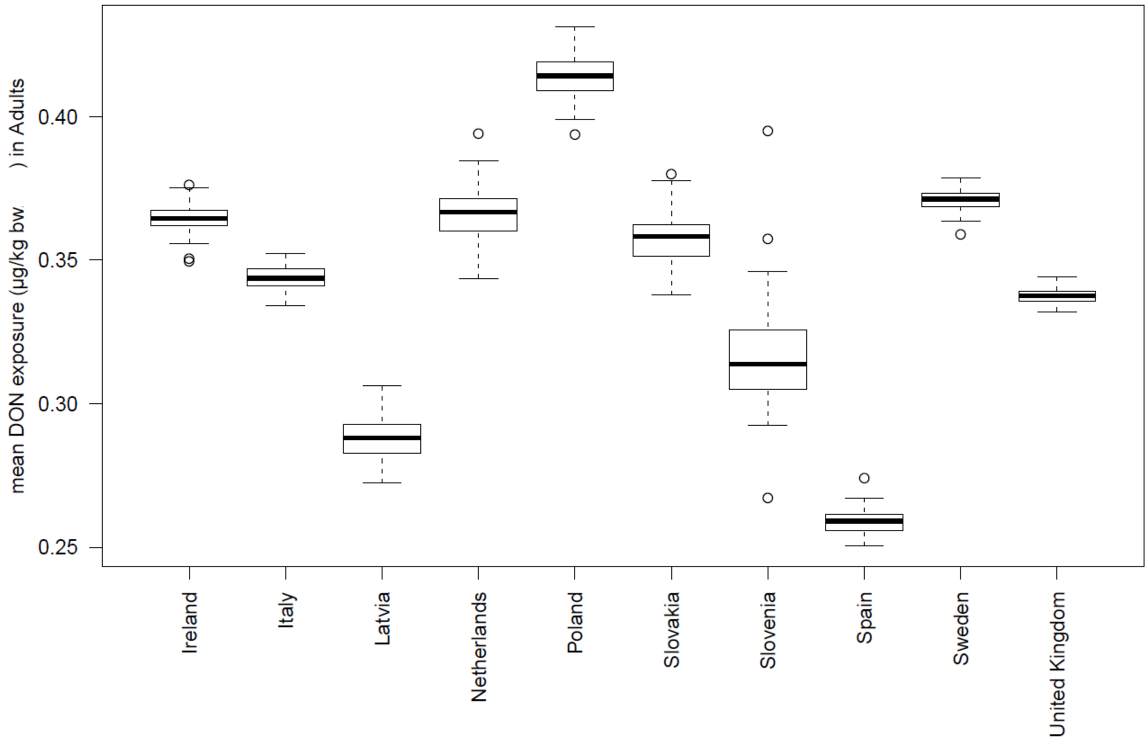
P95 acute exposure level to DON in µg/kg b.w.



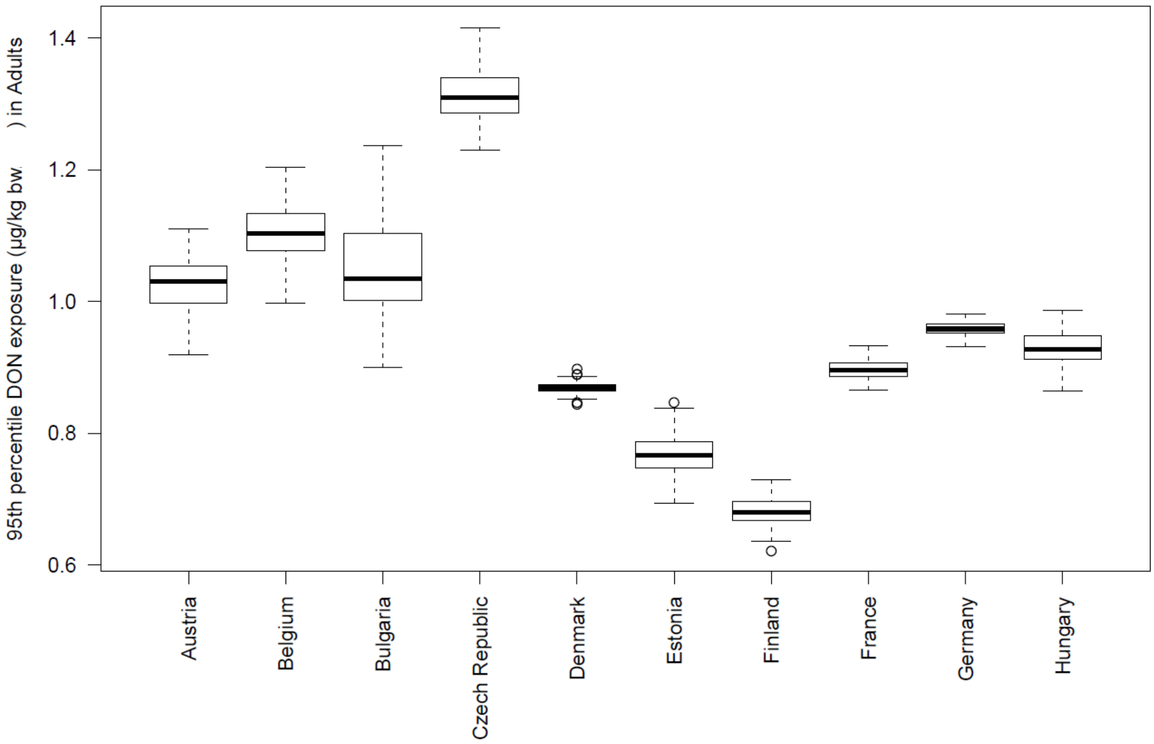
✓ Adults

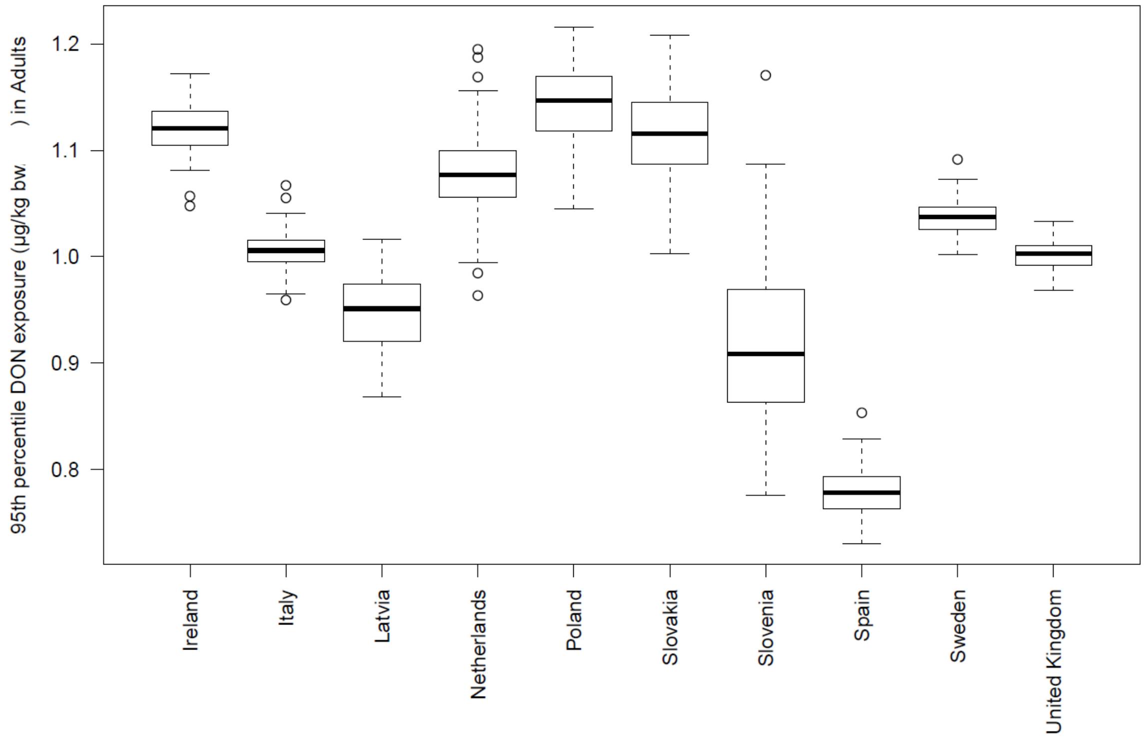
Mean acute exposure level to DON in µg/kg b.w.





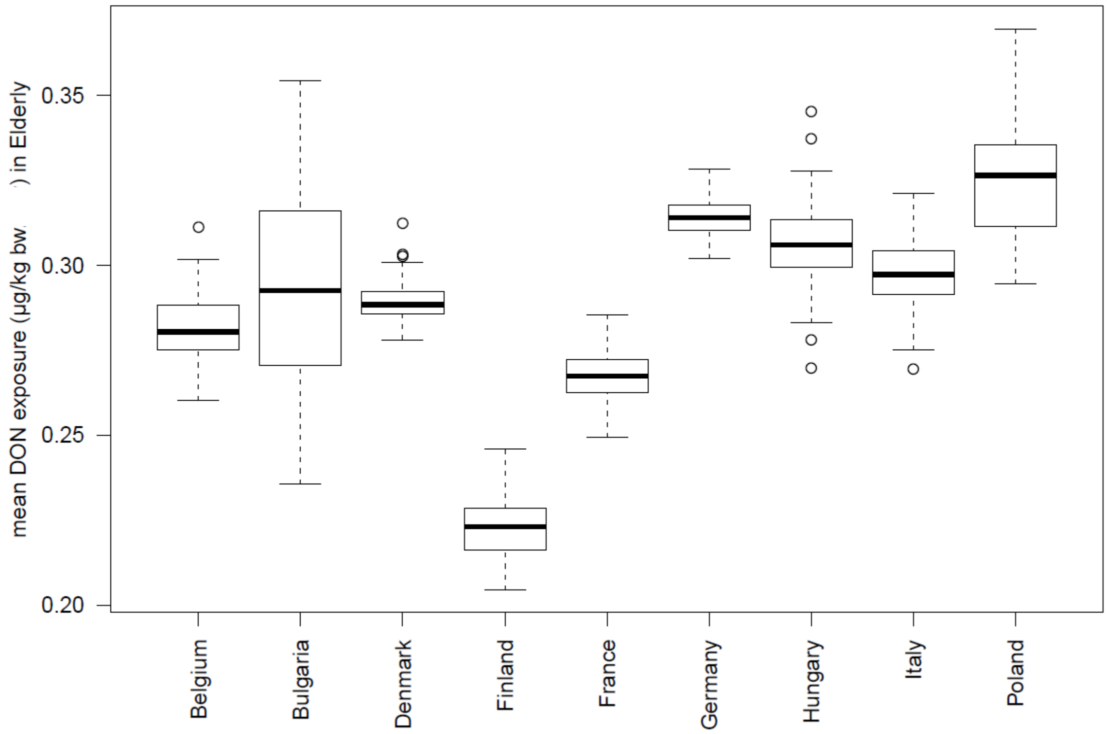
P95 acute exposure level to DON in µg/kg b.w.



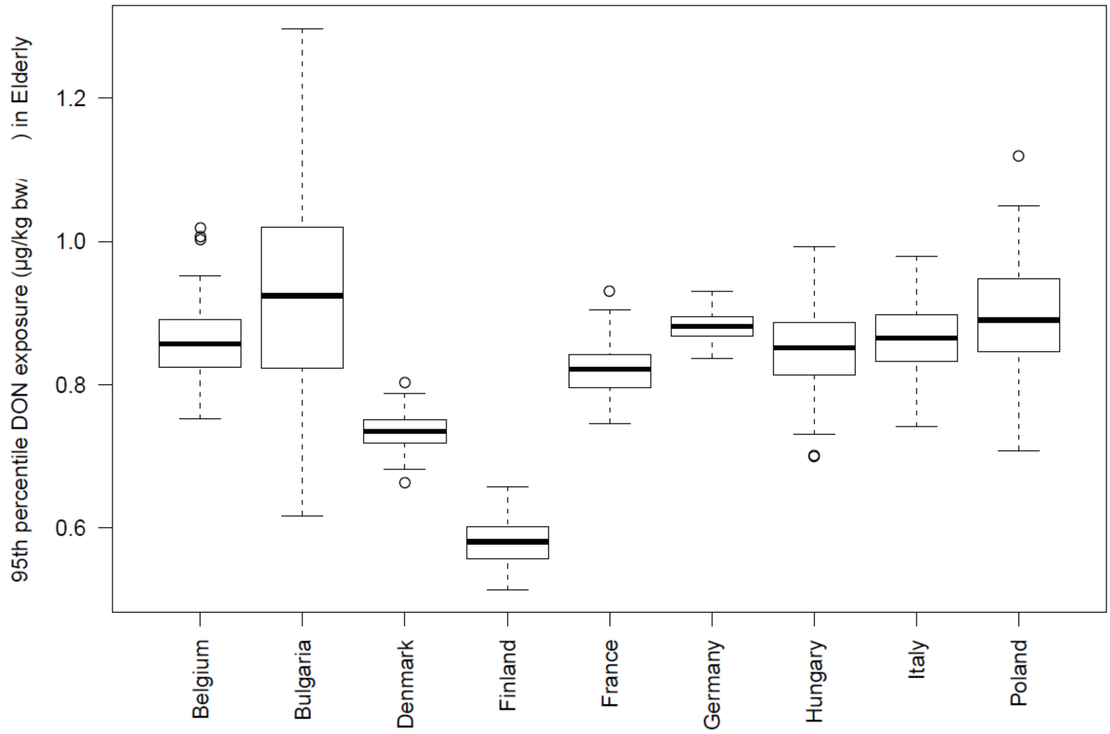


✓ Elderly

Mean acute exposure level to DON in µg/kg b.w.

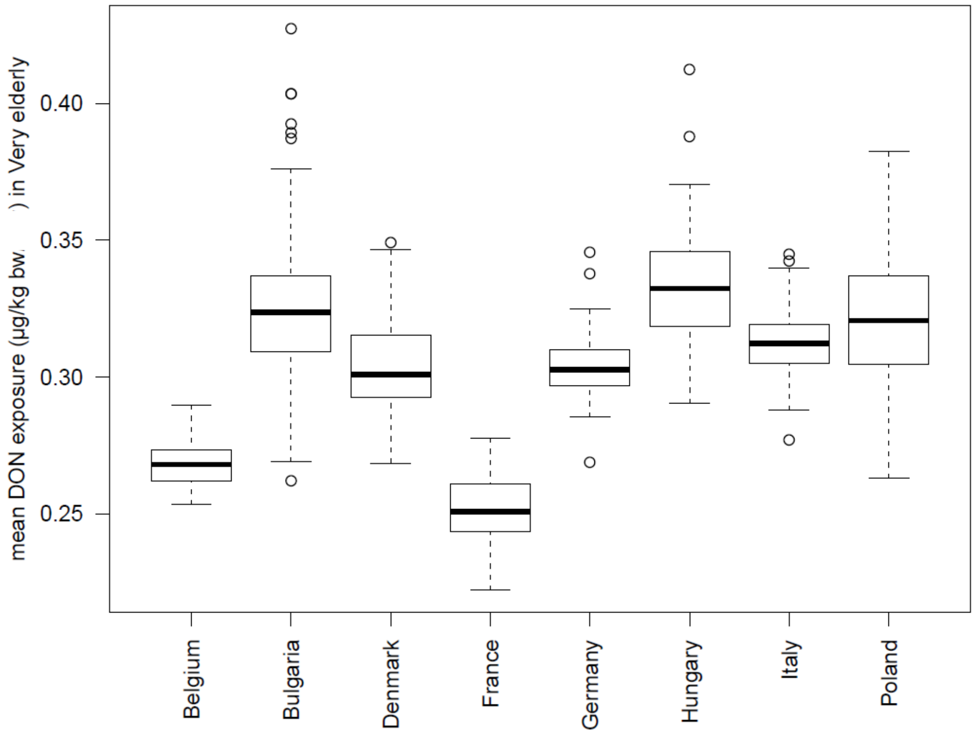


P95 acute exposure level to DON in µg/kg b.w.

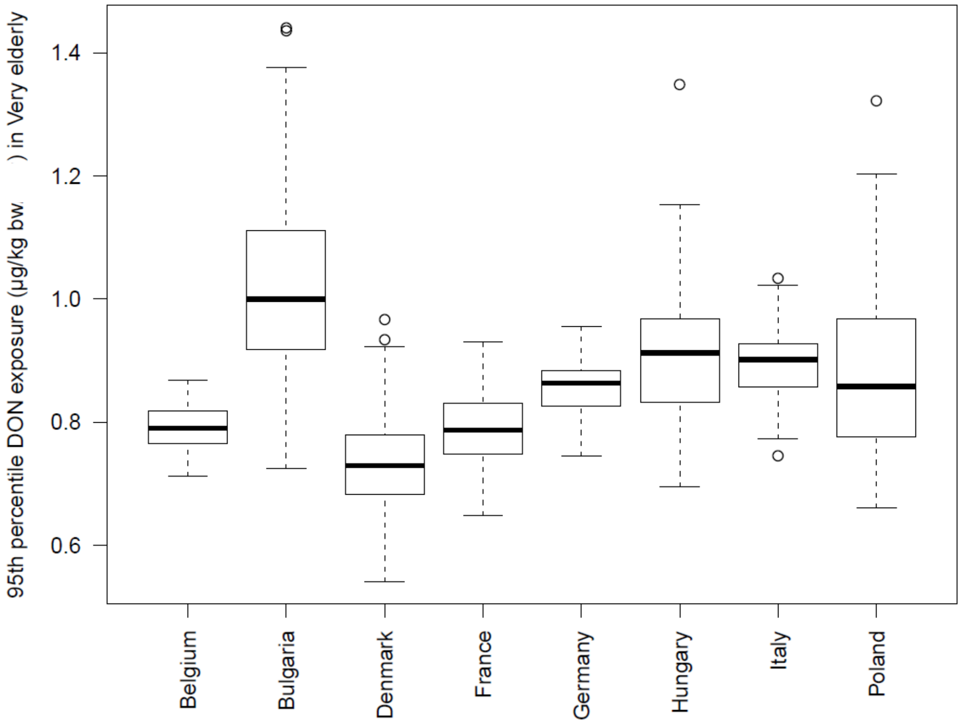


✓ Very elderly

Mean acute exposure level to DON in µg/kg b.w.



P95 acute exposure level to DON in µg/kg b.w.



GLOSSARY AND ABBREVIATIONS

µg/kg: microgram per kilogram

15-Ac-DON: 15-acetyl Deoxynivalenol

3-Ac-DON: 3-acetyl Deoxynivalenol

ARfD: Acute Reference Dose

$BMDL_{10}$: Lowest lower limit on the benchmark dose for a 10% response

b.w.: body weight

CONTAM Panel: Scientific Panel on Contaminants in the Food Chain

DON: Deoxynivalenol

DON-3-Glc: DON-3-Glucoside.

dw: dry weight

EFSA: European Food Safety Authority

ELISA: Enzyme-linked immunoorbent assay

FBS: Food Balance Sheets

GV: Guidance Value

LB: Lower Bound

LOD: Limit Of Detection

LOQ: Limit Of Quantification

MB: Middle Bound

ML: Maximum Level

NOEL: No Observed Effect Level

PMTDI: Provisional Maximum Tolerable Daily Intake

SCF: Scientific Committee on Food

SSD: Standard Sample Description

TDI: Tolerable Daily Intake

UB: Upper Bound

ww: whole weight