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SCIENTIFIC OPINION

Scientific Opinion on the presence of dioxins (PCDD/Fs) and dioxin-like PCBs (DL-PCBs) in commercially available foods for infants and young children[1]

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

European Food Safety Authority (EFSA), Parma, Italy

This Scientific Opinion, published on 25 January 2013, replaces the earlier version published on 13 December 2012.[4]

ABSTRACT

EFSA was asked by the Federal Institute for Risk Assessment (BfR) to deliver a scientific opinion on the presence of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) in commercially available foods for infants and young children. It was requested to describe the relation of important parameters of the distribution of the occurrence data to the new EU maximum levels (MLs), and to assess whether these MLs are sufficient to aim to decrease the dietary exposure of infants and young children to dioxins and DL-PCBs. The CONTAM Panel did not perform an exposure or risk assessment, but evaluated whether the enforcement of the new EU MLs will result in a decrease in the concentration of dioxins and DL-PCBs in foods for infants and young children, and thus in a potential decrease in exposure of this population group. A total of 516 samples was included in the evaluation, reported by 13 European countries and covering the period 2003 to 2011. All accepted data (upper-bound) were below the current MLs for foods for infants and young children of 0.1 pg WHO_{2005}-TEQ/g w.w. for dioxins and 0.2 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs. Therefore, the CONTAM Panel concluded that, based on the available data, the current MLs are not an incentive to decrease the concentrations of dioxins and DL-PCBs in the relevant foods. From the reported data, it is not possible to conclude on any time trend concerning the dioxin and DL-PCB levels in foods for infants and young children. The Panel recommended that more occurrence data on representative samples are needed, particularly for those foods for infants and young children where only a few results are available so far. Moreover, the sensitivity of the analytical methods should be improved, if lower MLs were to be considered in the future.

[1] On request from the Federal Institute for Risk Assessment (BfR), Question No EFSA-Q-2011-01091, adopted on 21 November 2012.

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[4] Corrections were made to the 'suggested citation' section on the first page. The changes do not affect the overall conclusions of the opinion. To avoid confusion, the original version of the opinion has been removed from the website, but is available on request, as is a version showing all the changes made.

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KEY WORDS

dioxins (PCDD/Fs), dioxin-like PCBs, foods for infants and young children, legislation, occurrence, distribution

SUMMARY

Following a request from the Federal Institute for Risk Assessment (BfR), the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked to deliver a scientific opinion on the presence of dioxins (polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) and dioxin-like polychlorinated biphenyls (DL-PCBs) in commercially available foods for infants and young children. It was particularly requested to describe the relation of important parameters of the distribution of the occurrence data to the current existing European Union (EU) maximum levels (MLs), and to assess whether these levels are sufficient to aim to decrease the dietary exposure of infants and children to dioxins and DL-PCBs. The CONTAM Panel interpreted this request in such a way that it did not perform an exposure or risk assessment for infants and young children, but evaluated whether the enforcement of the new MLs, which are in force since 1 January 2012, will result in a decrease in the concentration of dioxins and DL-PCBs in foods for infants and young children, and thus in a potential decrease in exposure of this specific population group.

Analytical results from a total of 516 samples, reported by 13 European countries and covering the period 2003 to 2011, were evaluated. More than one third of the data were provided by the United Kingdom (UK) for samples collected in 2003. For samples derived from dry products, the limit of detection or limit of quantification (LOD or LOQ) and the reported levels of dioxins and DL-PCBs were recalculated as ready-to-eat equivalents. An average dilution factor of 7.1 was used for infant and follow-on formula in powder form, of 10.0 for cereals and other foods for infants and young children which have to be reconstituted with milk or other appropriate nutritious liquids, and of 5.0 for cereals and other foods which have to be reconstituted with water.

Certain products have to be prepared with milk and in principle this should be taken into account. Levels in milk may vary and as such cause variable levels in products as reconstituted for consumption. The CONTAM Panel noted that when milk is used for reconstitution, the variable levels of dioxins and DL-PCBs in milk could have a considerable impact on the concentration in the product ready for consumption.

Some groups of foods for infants and young children were poorly represented (N < 30), in particular 'Yoghurt, cheese and milk-based dessert for infants and young children', 'Cereal-based food for infants and young children' and 'Infant / Follow-on formula, liquid'.

The CONTAM Panel noted that the LODs and LOQs varied with the congener analysed, the food matrix and the reporting laboratory. Depending on the food group, the percentage of left-censored data ranged between 0 and 15.8 % for dioxins and between 0 and 10.5 % for the sum of dioxins and DL-PCBs.

Taking all food groups together (as stipulated in Commission Regulation (EC) No 1881/2006, amended by Commission Regulation (EU) No 1259/2011) and based on UB (upper-bound) [lower-bound (LB)] levels, the P50, P90 and P95 were <0.005 [<0.005], 0.02 [0.01] and 0.03 [0.01] pg WHO_{2005}-TEQ/g wet weight (w.w.) for dioxins. For the sum of dioxins and DL-PCBs, the P50, P90 and P95 for all food groups based on UB (LB) levels were 0.01 (<0.005), 0.04 (0.02) and 0.07 (0.04) pg WHO_{2005}-TEQ/g w.w. The maximum UB levels in this dataset were 0.08 and 0.19 pg WHO_{2005}-TEQ/g w.w. for dioxins and the sum of dioxins and DL-PCBs, respectively.

Liquid and powder infant and follow-on formula showed UB levels up to 0.05 and 0.06 pg WHO_{2005}-TEQ/g w.w for dioxins and for the sum of dioxins and DL-PCBs, respectively. The highest UB levels, up to 0.08 for dioxins and 0.19 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs, were found in ready-to-eat meals containing fish or meat.

The UB levels based on all accepted data were below the current MLs for foods for infants and young children of 0.1 pg WHO_{2005}-TEQ/g w.w. for dioxins and 0.2 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs which are in force since 1 January 2012. Therefore, the CONTAM Panel

concluded that, based on the available data, the current MLs are not an incentive to decrease the concentrations of dioxins and DL-PCBs in the relevant foods.

As the samples evaluated in this opinion represent different kinds of food, collected for different purposes, analysed in different laboratories in different countries and in different years, it is not possible to conclude on any time trend concerning the levels of dioxins and DL-PCBs in foods for infants and young children. In this respect it has also to be considered that maximum levels for these foods are only applicable from 2012, i.e. no legal or analytical requirements were set before and differences in the UB levels of samples analysed earlier may also have been the result of different LOQs. The large differences between LB and UB levels also imply that most levels are considerably overestimated even in the case of the higher levels.

The CONTAM Panel recommended that more occurrence data on representative samples are needed, particularly for those foods for infants and young children where only a few results are available so far. Moreover, the sensitivity of the analytical methods should be improved in order to decrease the difference between LB and UB concentrations, if lower MLs were to be considered in the future.

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BACKGROUND AS PROVIDED BY THE FEDERAL INSTITUTE FOR RISK ASSESSMENT (BFR)

Dioxins are widely distributed contaminants formed as unwanted by-products in a number of anthropogenic activities. The term 'dioxins' refers to a group of polychlorinated, planar aromatic compounds with similar structures, chemical and physical properties. This group of compounds consists of 75 dibenzo-*p*-dioxins (PCDDs) and 135 dibenzofurans (PCDFs), of which 2,3,7,8-TCDD is the most toxic and most studied congener. The group of polychlorinated biphenyls (PCBs) consists of 209 congeners of which 130 are likely to occur in commercial products.

In general environmental and biological samples contain complex mixtures of different dioxin congeners, thus the concept of Toxic Equivalency Factors (TEFs) has been developed to facilitate risk assessment. TEFs have been established to express concentrations of mixtures of 2,3,7,8-substituted PCDDs and PCDFs, and more recently, some planar non-*ortho* and mono-*ortho* chlorine substituted PCBs in toxic equivalents (TEQs) of 2,3,7,8-TCDD.

For the general population, the major pathway of exposure to dioxins and PCBs is food.

The Scientific Committee on Food (SCF)[5] established a group tolerable weekly intake (TWI) of 14 pg WHO-TEQ/kg body weight (b.w.) for 2,3,7,8-TCDD, all 2,3,7,8-substituted PCDDs and PCDFs and the dioxin-like PCBs in 2001. Due to the very long half-lives in humans the tolerable intake was expressed in a weekly basis rather than on a daily basis.

Commission Regulation (EC) No 1881/2006 of 19 December 2006 lays down maximum levels for certain contaminants in foodstuff. Amendment No 1259/2011 (2 December 2011) provides that the maximum level for the sum of dioxins and dioxin-like PCBs in foods for infants and young children is 0.2 pg (WHO-PCDD/F-PCB-TEQ)/g wet weight.

TERMS OF REFERENCE AS PROVIDED BY THE FEDERAL INSTITUTE FOR RISK ASSESSMENT (BFR)

In accordance with Art. 29 (1) of Regulation (EC) No 178/2002 the Federal Institute for Risk Assessment (BfR) asks the European Food Safety Authority to provide a scientific opinion on the presence of dioxins and DL-PCBs in commercially available food for infants and young children.

In particular the opinion should:

a) describe the relation of important parameters of distribution of the occurrence data (such as the 95th percentile) to the current existing maximum levels of 0.2 pg (WHO-PCDD/F-PCB TEQ)/g food ready to use dioxins and DL-PCBs;

b) to assess in the light of the outcome of point a), whether the current EU limit is sufficient in order to aim to decrease the dietary exposure of infants and children to dioxins and DL-PCBs,

   [1)] taking into consideration different food categories with special emphasis on formula, the main commercially available infant food;

   [2)] expressed as WHO-PCDD/F-PCB-TEQ$_{2005}$ per gram fat, per gram food as sold, and per gram food ready to use.

[5] Scientific Committee on Food, 2001. Opinion of the SCF on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food (update on the new scientific information available since the adoption of the SCF Opinions of 22 November 2000). Adopted by the SCF on 30 May 2001. Reports CS/CNTM/DIOXIN/20 final. Available at: http://ec.europa.eu/food/fs/sc/scf/out78_en.pdf

ASSESSMENT

1. Introduction

This opinion addresses the presence of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) in commercially available foods for infants and young children. The term 'dioxins' used in this opinion refers to the sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs). The term "sum of dioxins and DL-PCBs" refers to the sum of PCDDs/PCDFs and DL-PCBs.

Dioxins have no technological use, but are generated in a number of thermal and industrial processes as unwanted, and often unavoidable, impurities or by-products. Important emission sources are, inter alia, metal production and processing, waste incineration and domestic furnaces. Dioxins are poorly soluble in water but highly soluble in lipids. Due to their lipophilic properties they accumulate in the food chain and are stored in fatty tissues of animals and humans. Human exposure to dioxins is mainly through food products of animal origin. Due to a number of regulatory measures since the 1980s the emission of dioxins into the environment has considerably decreased. Consequently, human exposure to dioxins has decreased significantly over the last decades.

PCBs are a group of organochlorine compounds that were synthesised by catalysed chlorination of biphenyl. Due to their physicochemical properties, such as non-flammability, chemical stability, high boiling point, low heat conductivity and high dielectric constants, technical PCB mixtures were widely used in a number of industrial and commercial closed and open applications. As a result of their widespread use, leakages and improper disposal practices, PCBs, like dioxins, have a global distribution in the environment. Many PCBs are persistent because they are poorly degraded and thus they bioaccumulate in the food chain. The main pathway of human exposure for the majority of the population is via food consumption. Based on structural characteristics and toxicological effects, PCBs can be divided into two groups. One group consists of 12 congeners that easily can adopt a coplanar structure and show toxicological properties similar to the dioxins of concern. This group is therefore called "dioxin-like PCBs" (DL-PCBs). The other PCBs do not show dioxin-like toxicity and have a different toxicological profile. This group, called "non dioxin-like PCBs" (NDL-PCBs) was beyond the terms of reference and not further considered in this opinion.

In order to compare the toxicity of a mixture of dioxins and DL-PCBs, the concept of toxic equivalents (TEQs)[6] based on different toxic equivalency factors (TEFs) for the different dioxin and DL-PCB congeners was introduced by several health authorities, such as the Environmental Protection Agency of the United States (US-EPA, 1989) and the World Health Organization (WHO) (Ahlborg et al., 1993; van den Berg et al., 1998, 2006). Thereby, it is assumed that the dioxins and DL-PCBs behave similarly by binding to the intracellular aryl hydrocarbon receptor (AhR), however with different affinity. They also show similar persistence to metabolic degradation. Moreover, it is assumed that the effects are additive. 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD) is assigned a TEF value of 1 and the TEFs for the other relevant 16 dioxins and 12 DL-PCBs are between 0.00003 and 1. It should be noted that a TEF indicates an order of magnitude estimate of the toxicity of a dioxin-like compound relative to 2,3,7,8-TCDD. To calculate the total TEQ value of a sample, the concentration of each congener is multiplied by its TEF and the respective values are added up. The resulting TEQ value expresses the toxicity of dioxins and DL-PCBs in a complex sample in terms of the congener 2,3,7,8-TCDD. Unless otherwise noted, in this opinion the TEFs proposed by WHO in 2005 (WHO_{2005}-TEF) (van den Berg et al., 2006) have been used to calculate the TEQ values for dioxins or the sum of dioxins and DL-PCBs (WHO_{2005}-TEQ).

[6] 'Toxic equivalents' and 'toxic equivalency factors' are often also denoted "toxicity equivalents" and 'toxicity equivalency factors'. The CONTAM Panel noted this inconsistency in the literature and decided to use the terms generally applied by the World Health Organization (WHO).

The European Food Safety Authority (EFSA) has been requested by the Federal Institute for Risk Assessment (BfR) to provide an overview of occurrence data on dioxins and DL-PCBs in foods for infants and young children and to assess whether the current maximum level (ML) for dioxins and DL-PCBs of 0.2 pg WHO_{2005}-TEQ/g for ready to use food, as laid down in Commission Regulation (EU) No 1259/2011[7] of 2 December 2011 which amended Commission Regulation (EC) No 1881/2006[8] of 19 December 2006, is sufficient in order to aim to decrease the dietary exposure of infants and children to dioxins and DL-PCBs (see the Terms of Reference (ToR)). It was particularly requested to describe the relation of important parameters of the distribution of the occurrence data to the current existing European Union (EU) MLs. The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) interpreted this ToR in such a way that it did not perform an exposure or risk assessment for infants and young children, but evaluated whether the enforcement of the new EU MLs will result in a decrease of the concentrations of dioxins and DL-PCBs in foods for infants and young children, and thus in a potential decrease in exposure of this specific population group. The results of this evaluation are presented in this opinion.

2. Legislation

2.1. Maximum and action levels

In order to protect public health, Article 2 of Council Regulation (EEC) No 315/93[9] of 8 February 1993 laying down Community procedures for contaminants in food stipulates that, where necessary, maximum tolerances for specific contaminants shall be established. Subsequently, a number of MLs for dioxins and PCBs in different foodstuffs were laid down in the Annex of Commission Regulation (EC) No. 1881/2006[8] of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, amended by Commission Regulation (EU) No 1259/2011.[7]

For this latter Regulation, the MLs for dioxins and for the sum of dioxins and DL-PCBs in food were reviewed taking into account new occurrence data, and amended accordingly. The revised MLs apply from 1st January 2012. In contrast to the former values, the revised MLs are expressed as TEQs using the WHO_{2005}-TEFs for human risk assessment based on the conclusions of the WHO-International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (van den Berg et al., 2006).

The new Regulation also introduced MLs for 'foods for infants and young children', being 0.1 pg WHO_{2005}-TEQ/g wet weight (w.w.) for dioxins, and 0.2 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs.

According to footnote 4 of Commission Regulation (EC) No 1881/2006,[8] the MLs for foods for infants and young children refer to the products ready to use (marketed as such or after reconstitution as instructed by the manufacturer).

All MLs are applied as upper-bound (UB)[10] concentrations.

As an early warning tool, the European Commission has set action levels for dioxins and DL-PCBs in food through Commission Recommendation 2011/516/EU.[11] Due to the fact that their sources are

[7] Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs. OJ L 320, 3.12.2011, p. 18-23.

[8] 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.

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

[10] 'Lower-bound' means the concept which requires using zero for the contribution of each non-quantified congener. 'Medium-bound' means the concept which requires using half of the limit of quantification calculating the contribution of each non-quantified congener. 'Upper-bound' means the concept which requires using the limit of quantification for the contribution of each non- quantified congener.

generally different, separate action levels for dioxins and DL-PCBs were established. In cases where levels of dioxins and/or DL-PCBs in excess of the action levels are found, it is recommended that Member States, in co-operation with food business operators, initiate investigations to identify the source of contamination, take measures to reduce or eliminate the source of contamination and check for the presence of NDL-PCBs. In contrast to various other food commodities, action levels were not set for 'foods for infants and young children'.

2.2. Interpretation of results

Requirements for reporting of results are laid down in Commission Regulation (EU) No 252/2012.[12] Annex III, 9 states: 'In so far as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCDD/F and dioxin-like PCB congeners and be reported as lower-bound, upper-bound and medium-bound [10] in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.'

In addition, Annex III, 7.1 requires: 'The difference between upper-bound (UB) level and lower-bound (LB) level shall not exceed 20 % for foodstuffs with a contamination of about 1 pg WHO-TEQ/g fat (based on the sum of PCDD/Fs and dioxin-like PCBs). For foodstuffs with a low fat content, the same requirements for contamination levels of about 1 pg WHO-TEQ/g product have to be applied. For lower contamination levels, for example 0.5 pg WHO-TEQ/g product, the difference between upper-bound and lower-bound level may be in the range of 25 % to 40 %.'

Another important criterion in Commission Regulation (EU) No 252/2012 is that the LOQ should be less than 1/5 of the level of interest, more specifically the ML.

3. Sampling and methods of analysis

Detailed requirements for methods of sampling and analysis for the official control of levels of dioxins and DL-PCBs in certain foodstuffs are laid down in Commission Regulation (EU) No 252/2012.[12] This Regulation contains inter alia a number of provisions concerning methods of sampling depending on the size of the lot, packaging, transport, storage, sealing and labelling.

Regarding analytical methods for the determination of dioxins and DL-PCBs in food and feed, the EU generally follows the 'criteria approach'. This means that no fixed methods are prescribed but detailed and strict performance criteria are established by the European Commission which have to be fulfilled. As long as it can be demonstrated in a traceable manner that these performance criteria are fulfilled and the method is fit for purpose, the analysts can apply any appropriate method. The respective performance criteria are also laid down in Commission Regulation (EU) No 252/2012.[12] As a basic requirement for acceptance of analytical procedures, the sensitivity for dioxins and DL-PCBs must be in the picogram TEQ range. According to this Regulation, monitoring for the presence of dioxins in foodstuffs may be performed by a strategy involving a screening method in order to select those samples with levels of dioxins and DL-PCBs that may exceed the maximum level. To avoid false-compliant results (< 5 %), a safe decision limit (cut-off) must be applied for deciding whether samples are negative or suspected to be non-compliant. A cut-off level of 2/3 ML was advised, which would also allow detection of most samples exceeding the action levels. Screening methods may comprise bioassays and GC/MS methods. The concentration of dioxins and the sum of dioxins and DL-PCBs in samples suspected of being non-compliant needs to be determined/confirmed by a confirmatory method. Confirmatory methods are based on gas chromatography/high resolution mass spectrometry (GC/HRMS, applying isotope-labelled standards for recovery correction and quantification. The

[11] Commission Recommendation of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food (2011/516/EU). OJ L 218, 24.08.2011, p. 23-25.

[12] Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin- like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006. OJ L 84, 23.03.2012, p. 1-22.

criteria for confirmatory methods concerning trueness and precision (relative standard deviation calculated from results generated under reproducibility conditions, RSD_R), GC separation of congeners, maximum tolerances for retention time and isotope ratios based on the US-EPA method 1613 B, reporting of results and others are also described in the Commission Regulation (EU) No 252/2012.[12]

4. Occurrence and patterns of dioxins and DL-PCBs in foods for infants and young children

4.1. Occurrence of dioxins and DL-PCBs in foods for infants and young children

4.1.1. Overview of the data available for analysis

EFSA collated results on dioxins and DL-PCBs in foods for infants and young children mostly coming from national monitoring programmes, but also from market basket studies (UK-FSA, 2004a, b; Ceci et al., 2012). The data were either submitted directly to EFSA or sent to the European Commission and then forwarded to EFSA. A detailed data quality control was performed in order to standardise the data which were not compliant with the EFSA Standard Sample Description (SSD), to check for duplicate submissions and to ensure the overall comparability of the data. In particular, only samples with information available for all 29 dioxin and DL-PCB congeners were taken into account. In accordance with Commission Regulation (EU) No 252/2012,[12] an LOQ lower than 1/5 of the ML defined for the TEQ of dioxins and for the sum of dioxins and DL-PCBs was considered as a minimum requirement. This requirement was checked on those samples for which the information was available, i.e. all 29 congeners were not quantifiable. Three samples were rejected.

Three samples had UB levels above 0.2 pg WHO_{2005}-TEQ/g w.w. (0.25, 0.28 and 0.29 pg WHO_{2005}-TEQ/g). The percentage differences between the UB and LB levels of the sum of all congeners estimated for these 3 samples, taking the UB as a reference, were 94 %, >99 % and 67 %, respectively, being clearly outside the 25-40 % acceptable range mentioned in Commission Regulation (EU) No 252/2012,[12] and indicating that the UB is a considerable overestimation of the actual level. These samples were therefore excluded from the dataset.

The CONTAM Panel noted the relatively large differences between the LB and UB levels of samples with concentrations below 0.2 pg WHO_{2005}-TEQ/g. Taking into account that the MLs are based on UB levels and that the requirements laid down in Commission Regulation (EU) No 252/2012 regarding the difference between LB and UB for such low concentrations are not well defined, the Panel decided not to exclude any data below 0.2 pg WHO_{2005}-TEQ/g irrespective of the percentage difference between LB and UB. The Panel emphasises that many of these UB data reflect an overestimation of the actual levels of dioxins and DL-PCBs in foods for infants and young children.

Finally, 516 samples were included in the analysis (Table 1), reported by 13 European countries and covering the period 2003 to 2011. More than one third of the data were provided by the United Kingdom (UK) for samples collected in the year 2003.

Table 1: Number of accepted data for each sampling year for dioxins and DL-PCBs.

Sampling year	Number of samples [(a)]	Reporting country
2003	202	United Kingdom (202)
2004	Not reported	-
2005	4	Greece (3), Sweden (1)
2006	115	Finland (8), Germany (87), Sweden (15), Slovenia (5)
2007	25	Austria (1), Czech Republic (5), Denmark (7), Greece (2), Spain (2), Sweden (8)
2008	60	Austria (4), Cyprus (8), Czech Republic (4), Italy (24), Slovenia (9), Spain (1), Sweden (10)
2009	46	Austria (3), Italy (30), Slovenia (3), Sweden (10)
2010	54	Cyprus (3), Czech Republic (4), Germany (10), France (17), Greece (5), Slovenia (9), Sweden (6)
2011	10	Sweden (10)

(a): For data received through the EFSA call for continuous collection of data on occurrence of chemical contaminants in food and feed, only those submitted and validated before 26.06.2012 were taken into account.

Table 2 shows the number of samples available for the different types of food for infants and young children. Some food groups were poorly described (N<30), in particular 'Yoghurt, cheese and milk-based dessert for infants and young children', 'Cereal-based food for infants and young children' and 'Infant / Follow-on formula, liquid'.

For samples corresponding to dry products, the limit of detection (LOD)/limit of quantification (LOQ) and the reported levels of dioxins and DL-PCBs were recalculated as ready-to-eat equivalents. An average dilution factor of 7.1 was used for infant and follow-on formula in powder form, of 10.0 for cereals and other foods for infants and young children which have to be reconstituted with milk or other appropriate nutritious liquids, and of 5.0 for cereals and other foods which have to be reconstituted with water (Kersting et al., 1998).

Certain products have to be prepared with milk and in principle this should be taken into account when comparing the concentrations to the MLs. Levels in milk may vary and as such cause variable levels in products as reconstituted for consumption. Based on the median fat content of 3 % and the median level reported by EFSA for the sum of dioxins and DL-PCBs in retail milk (1 pg WHO_{2005}-TEQ/g fat) (EFSA, 2012), levels in whole milk may be around 0.03 pg WHO-TEQ/g. As a worst case, if milk containing dioxins and DL-PCBs at the ML of 5.5 pg WHO-TEQ/g fat were used for reconstitution, the level in the final product would already be close to the ML for foods for infants and young children. The CONTAM Panel noted that when milk is used for reconstitution, the variable levels of dioxins and DL-PCBs in milk could have a considerable impact on the concentration in the product ready for consumption.

Table 2: Number of accepted data by group of food for infants and young children.

Food group	Type of food for infants and young children	Number of occurrence data available	Total by group
Infant / Follow-on formula, powder	Infant formula, powder, unspecified	103	139
	Infant formula, milk-based, powder	17	
	Infant formula, soya-based, powder	1	
	Follow-on formula, milk-based, powder	14	
	Follow-on formula, hypoallergenic, powder	1	
	Follow-on formula, powder, unspecified	3	
Infant / Follow-on formula, liquid	Infant formula, liquid, unspecified	11	19
	Follow-on formula, milk-based, liquid	6	
	Follow-on formula, milk and soya-based, liquid	2	
Cereal-based food for infants and young children	Biscuits, rusks and cookies for children	7	27
	Cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid	7	
	Simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids	11	
	Cereal-based food for infants and young children, unspecified	2	
Ready-to-eat meal for infants and young children	Ready-to-eat meal for children, meat/fish-based	282	316
	• *Fish-based*	*65*	
	• *Meat-based*	*215*	
	Ready-to-eat meal for children, vegetable-based	10	
	Ready-to-eat meal for children, cereal-based	13	
	Fruit purée for children	5	
	Ready-to-eat meal for infants and young children, unspecified	8	
Yoghurt, cheese and milk-based dessert for infants and young children	Cheese preparations for infants and young children	3	15
	Dessert and puddings for infants and young children	11	
	Yoghurt, cheese and milk-based dessert for infants and young children, unspecified	1	

4.1.2. Analytical methods used and limits of detection/quantification (LODs/LOQs)

The information on the analytical methods used was provided for 55 % of the samples for dioxins and DL-PCBs. All these samples were analysed by GC in combination with HRMS.

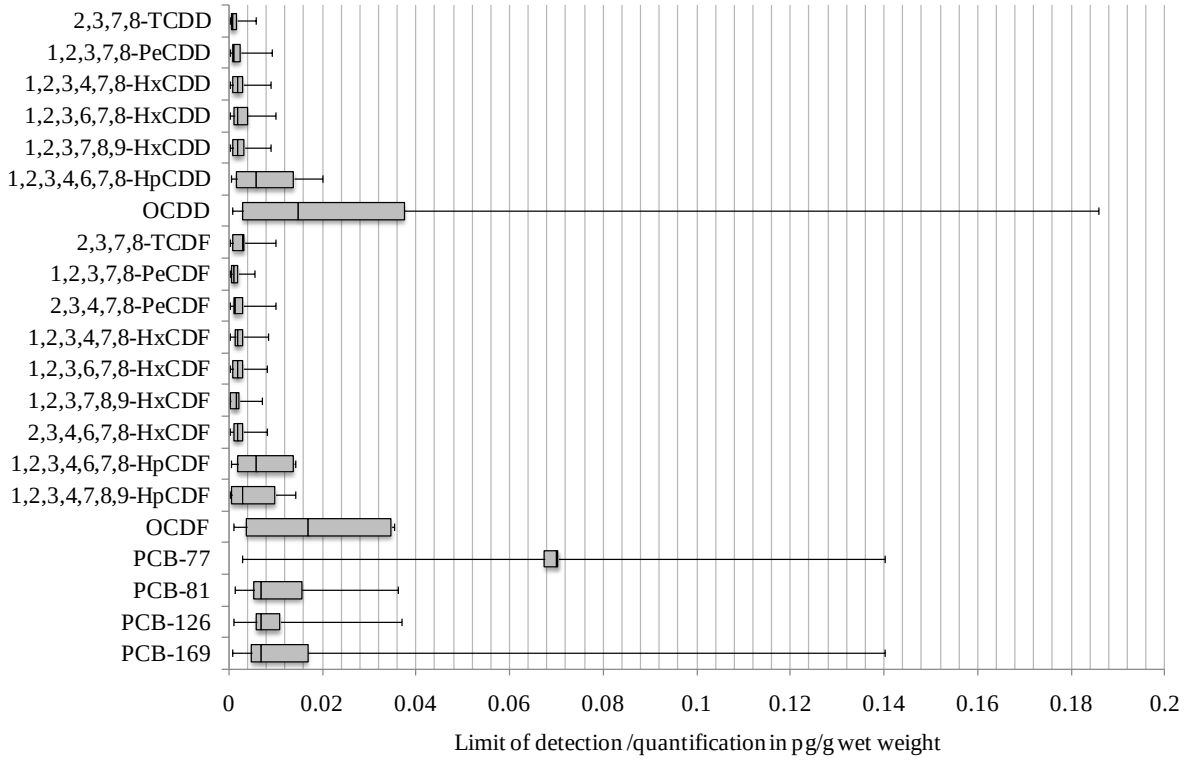
The LODs and LOQs varied with the congener analysed (Figures 1 and 2), the food matrix and the reporting laboratory.

For most of the dioxin congeners, the median LOD/LOQ was below 0.003 pg/g wet weight (w.w.) and the 95th percentile below 0.010 pg/g w.w. Exceptions were observed for 1,2,3,4,6,7,8-HpCDD, 1,2,3,4,6,7,8-HpCDF, 1,2,3,4,7,8,9-HpCDF, OCDD and OCDF for which the range taken by the

LOD/LOQ was larger, reaching at the 75th percentile 0.015 pg/g w.w. for the first three, and 0.038 pg/g w.w. for the last two congeners.

Except for PCB-77, the median LOD/LOQ observed for the non-*ortho* PCBs was around 0.007 pg/g w.w., and the 75th percentile not being above 0.017 pg/g w.w. The median LOD/LOQ for PCB-77 was almost ten times higher (0.070 pg/g w.w.).

The ranges of values of the LOD/LOQ are quite similar for the different mono-*ortho* PCBs, except for PCB-118, the 95th percentile not being above 1.83 pg/g w.w. The median LOD/LOQ was between 0.28 and 0.49 pg/g w.w. for PCB-114, PCB-123, PCB-157 and PCB-189, and between 1.60 and 1.74 pg/g w.w. for PCB-105, PCB-118, PCB-156 and PCB-167. The 95th percentile reached 2.60 pg/g w.w for PCB-118.



Legend: HpCDD: heptachlorodibenzo-*p*-dioxin; HpCDF: heptachlorodibenzofurans; HxCDD: hexachlorodibenzo-*p*-dioxin; HxCDF: hexachlorodibenzofuran; OCDD: octachlorodibenzo-*p*-dioxin; OCDF: octachlorodibenzofuran; PCB: polychlorinated biphenyl; PeCDD: pentachlorodibenzo-*p*-dioxin; PeCDF: pentachlorodibenzofuran; TCDD: tetrachlorodibenzo-p-dioxin; TCDF: tetrachlorodibenzofuran.

Figure 1: Distribution of limits of detection (LODs) or limits of quantification (LOQs) for the dioxin and non-*ortho* polychlorinated biphenyl congeners. The box indicates the 25th and 75th percentiles with a line at the median. The ends of the whiskers represent the 5th and 95th percentiles. The distributions are determined based on the numerical values provided for the censored results. According to the reporting laboratory, this value can be either an LOD or an LOQ, which may explain partly the variations observed.

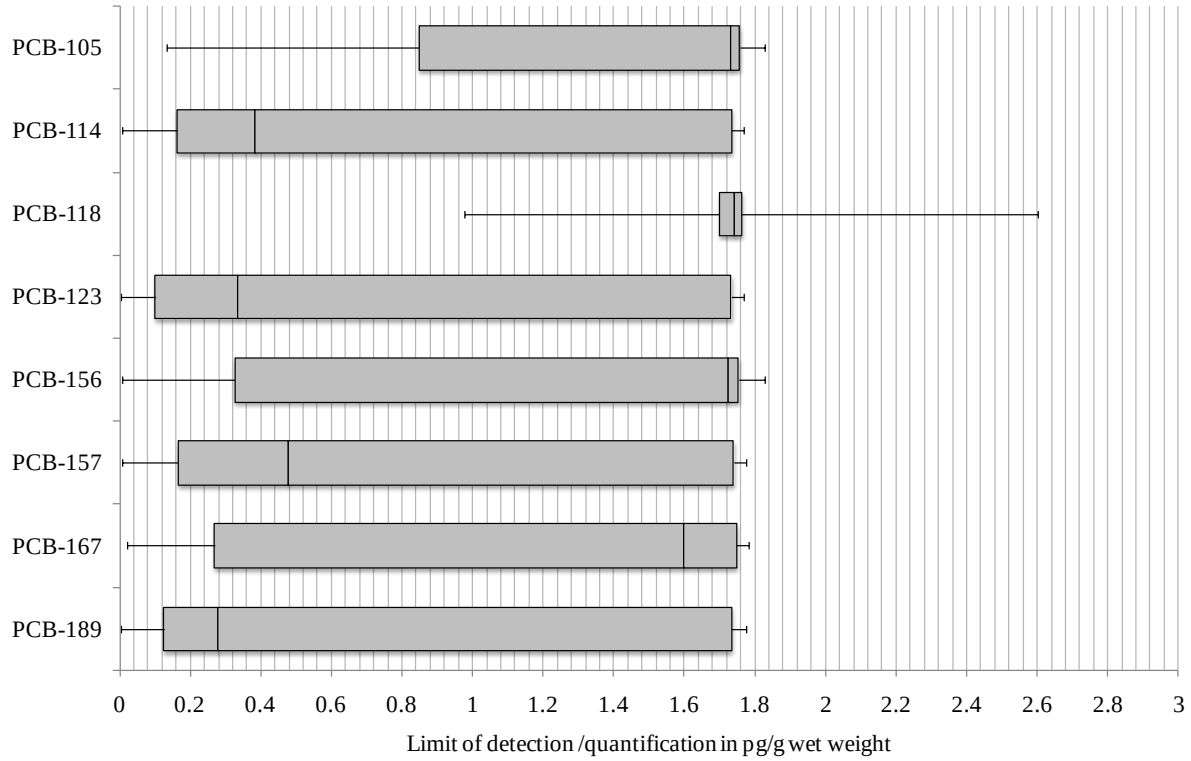


Figure 2: Distribution of limits of detection (LODs) or limits of detection (LOQs) for the mono-*ortho* polychlorinated biphenyl congeners. The box indicates the 25th and 75th percentiles with a line at the median. The ends of the whiskers represent the 5th and 95th percentiles. The distributions are determined based on the numerical values provided for the censored results. According to the reporting laboratory, this value can be either an LOD or an LOQ, which may explain partly the variations observed.

4.1.3. Distribution of analytical results reported for dioxins and for the sum of dioxins and DL-PCBs

4.1.3.1. Description of the levels of dioxins and the sum of dioxins and DL-PCBs

Tables 3 and 4 show the distribution of the total WHO_{2005}-TEQ for dioxins and for the sum of dioxins and DL-PCBs among the different food groups. Figure 3 and 4 (and Figures A1, A2, B1 and B2 in the Appendices) illustrate the distribution of the total WHO_{2005}-TEQ for dioxins and for the sum of dioxins and DL-PCBs across the different food groups.

Depending on type of food group, the percentage of left-censored data ranged between 0 and 15.8 % for dioxins and between 0 and 10.5 % for the sum of dioxins and DL-PCBs.

Taking all food groups together (as stipulated in Commission Regulation (EC) No 1881/2006,[8] amended by Commission Regulation (EU) No 1259/2011[7]) and based on UB (LB) levels, the P50, P90 and P95 were <0.005 (<0.005), 0.02 (0.01) and 0.03 (0.01) pg WHO_{2005}-TEQ/g w.w. for dioxins. For the sum of dioxins and DL-PCBs, the P50, P90 and P95 for all food groups based on UB (LB) levels were 0.01 (<0.005), 0.04 (0.02) and 0.07 (0.04) pg WHO_{2005}-TEQ/g w.w. The maximum UB levels measured in this dataset were 0.08 and 0.19 pg WHO_{2005}-TEQ/g w.w. for dioxins and for the sum of dioxins and DL-PCBs, respectively.

Liquid and powder infant and follow-on formula showed UB levels up to 0.05 and 0.06 pg WHO_{2005}-TEQ/g w.w. for dioxins and for the sum of dioxins and DL-PCBs, respectively. The highest UB levels, up to 0.08 for dioxins and 0.19 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs, were found in ready-to-eat meals based on fish and meat.

All accepted data were below the current MLs for foods for infants and young children of 0.1 pg WHO_{2005}-TEQ/g w.w. for dioxins and 0.2 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs which are in force since 1 January 2012.

The CONTAM Panel noted that for most food groups there were large differences between LB- and UB-levels at the P50 and even at the higher end of the distribution (Table 3 and 4). This has resulted in an overestimation of the levels in many samples.

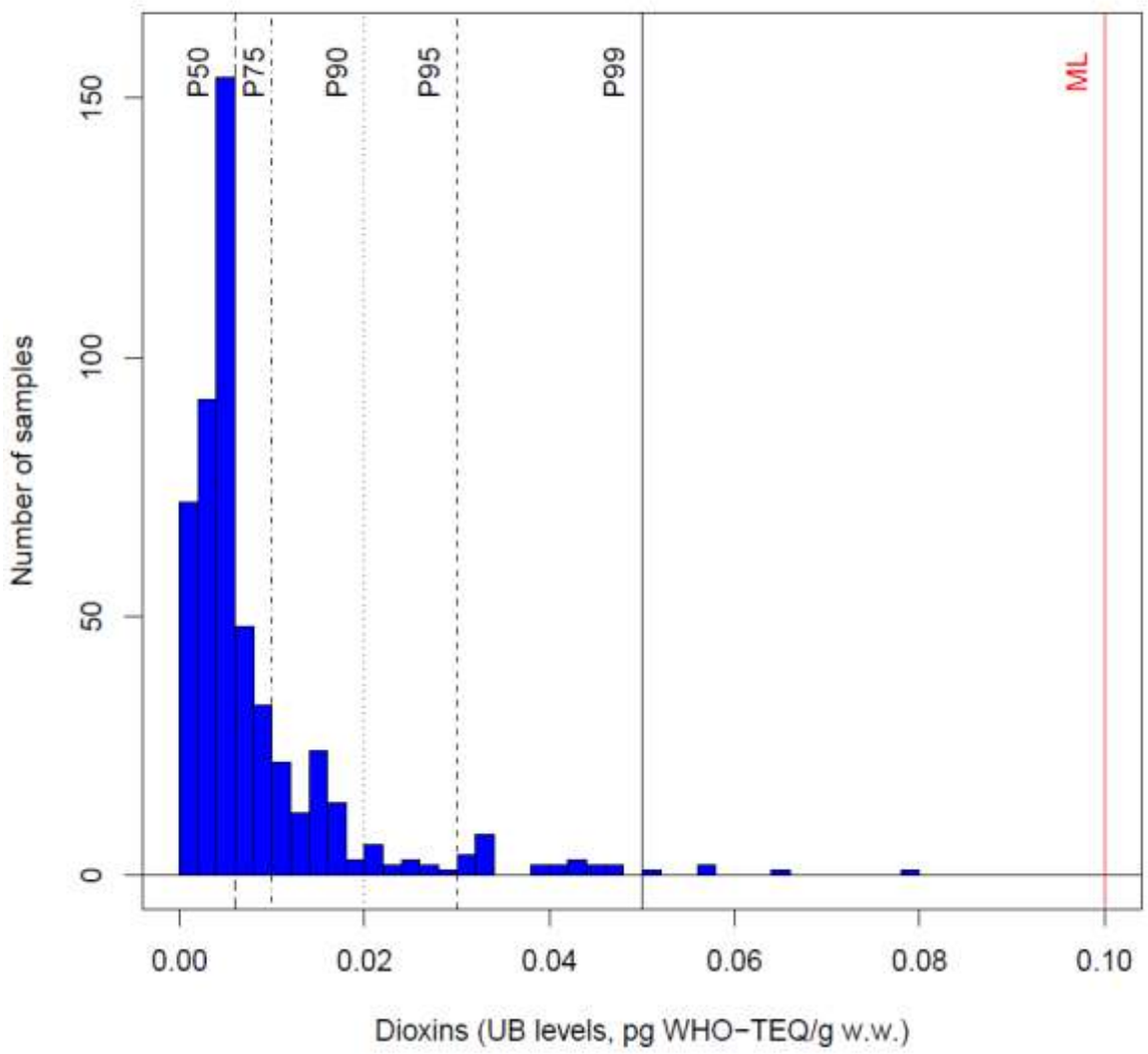
As shown in Table 3, none of the samples exceeded the ML of 0.1 pg WHO_{2005}-TEQ/g w.w. for dioxins. The two samples with levels above 0.06 pg WHO_{2005}-TEQ/g were meat-based meals for infants and young children. They were from the same country. When comparing the LB and UB levels, it appears that they are not associated with particularly high quantified values of some PCDD/F congeners, but with relatively high LODs/LOQs for the non quantified congeners.

Eight samples had levels of the sum of dioxins and DL-PCBs equal to or above 0.10 pg WHO_{2005}-TEQ/g, but below the ML of 0.2 pg WHO_{2005}-TEQ/g w.w. The highest value was for an organic meat-based meal for infants and young children taken through a targeted sampling design, followed by three samples of meals based on horse meat. The other samples were fish-based meals for infants and young children, three of them based on salmon, the fish species not being specified for the fourth sample.

Table 3: Distribution of dioxin levels expressed in pg WHO_{2005}-TEQ/g wet weight across the food groups.

Food group	N[(a)]	LC(%)[(b)]	Mean [LB; UB][(c)]	P50 [LB; UB][(d)]	P75 [LB; UB][(d)]	P90 [LB; UB][(d)]	P95 [LB; UB][(d)]	P99 [LB; UB][(d)]	Max [LB; UB][(e)]
Foods for infants and young children (all accepted samples)	516	4.7	[<0.005; 0.01]	[<0.005; <0.005]	[<0.005; 0.01]	[0.01; 0.02]	[0.01; 0.03]	[0.03; 0.05]	[0.06; 0.08]
Cereal-based food	27	7.4	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	-[(f)]	-[(f)]	-[(f)]	[0.02; 0.03]
Infant/follow-on formula	158	10.1	[<0.005; 0.01]	[<0.005; <0.005]	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	-[(f)]	[0.01; 0.05]
- Infant/follow-on formula, liquid	19	15.8	[<0.005; 0.01]	[<0.005; <0.005]	[<0.005; 0.01]	-[(f)]	-[(f)]	-[(f)]	[0.01; 0.05]
- Infant/follow-on formula, powder	139	9.4	[<0.005; <0.005]	[<0.005; <0.005]	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	-[(f)]	[0.01; 0.02]
Ready-to-eat meals	316	1.9	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.03]	[0.04; 0.06]	[0.06; 0.08]
- Ready-to-eat meals, meat/fish based	280	1.8	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.03]	-[(f)]	[0.06; 0.08]
• *Fish based*	65	3.1	[0.01; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.03]	[0.02; 0.03]	-[(f)]	[0.04; 0.04]
• *Meat based*	215	1.4	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	[0.01; 0.03]	-[(f)]	[0.06; 0.08]
- Other ready-to-eat meals (cereals-based, legume-based, fruit purée, unspecified)	36	2.8	[<0.005; 0.01]	[<0.005; <0.005]	[<0.005; 0.01]	[0.01; 0.02]	-[(f)]	-[(f)]	[0.02; 0.04]
Yoghurt, cheese and milk-based dessert	15	0.0	[<0.005; <0.005]	[<0.005; <0.005]	[<0.005; <0.005]	-[(f)]	-[(f)]	-[(f)]	[0.02; 0.02]

LB: lower-bound; LC: left-censored; Max: maximum; N: number of samples; UB: upper-bound.
(a): Number of samples.
(b): Percentage of censored results. A result is considered as censored if none of the 17 dioxins congeners is detected/quantified.
(c): Mean contamination presented as [lower-bound (LB); upper-bound (UB)].
(d): P50, P75, P90, P95, P99: 50^{th}, 75^{th}, 90^{th}, 95^{th} and 99^{th} percentiles of contamination presented as [lower-bound (LB); upper-bound (UB)].
(e): Maximum observed value presented as [lower-bound (LB); upper-bound (UB)].
(f): The estimation of high percentiles is not reliable when too few observations are available (less than 11 for the P75, 29 for the P90, 60 for the P95 and 298 for the P99).



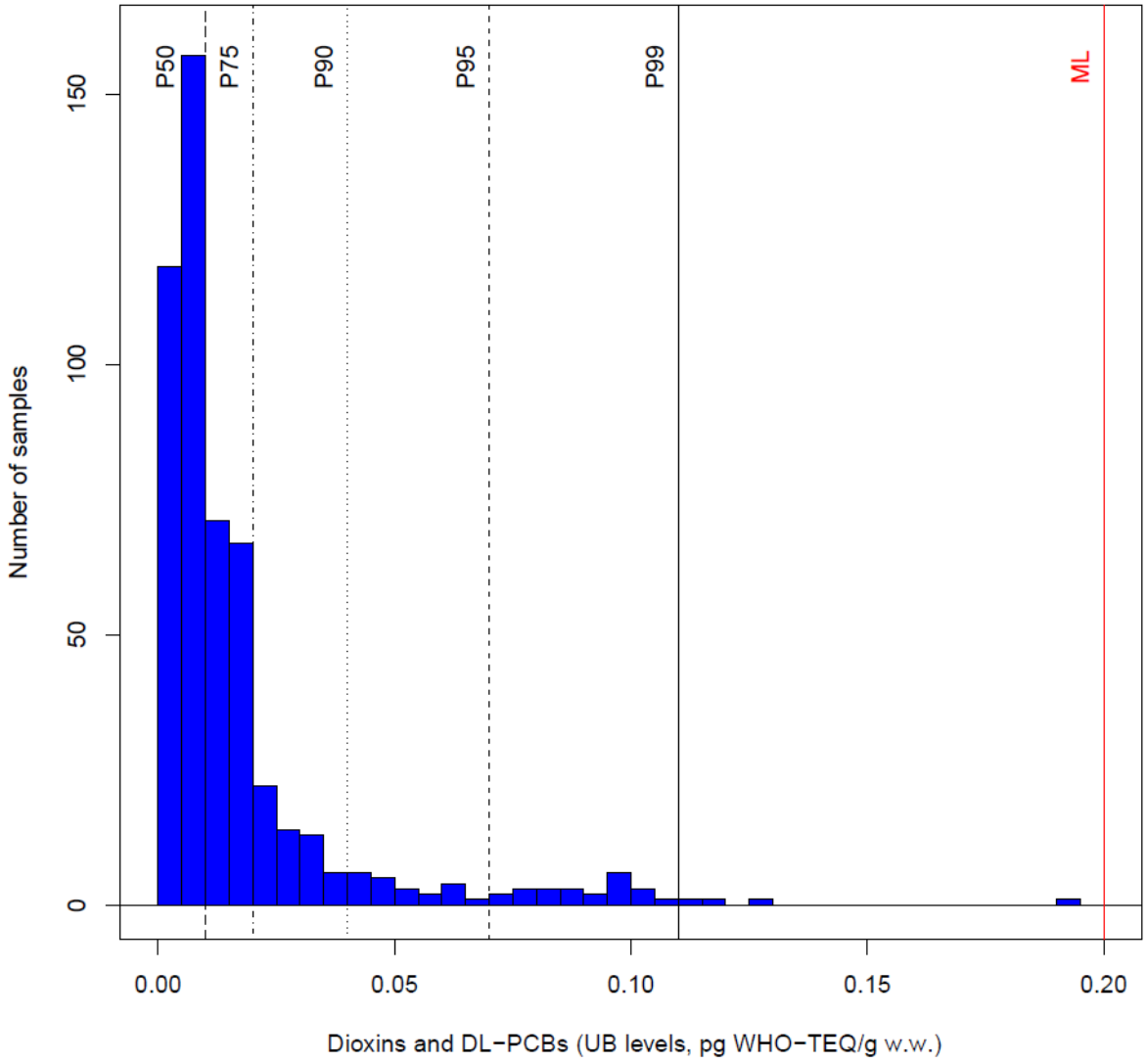
Legend: ML: maximum level; P50, P75, P90, P95, P99: 50th, 75th, 90th, 95th and 99th percentiles of contamination presented as UB; UB: upper-bound.

Figure 3: Distribution of the dioxin levels (upper-bound (UB) levels) expressed in pg WHO_{2005}-TEQ/g wet weight in foods for infants and young children (all accepted data).

Table 4: Distribution of the sum of dioxin and DL-PCB levels expressed in pg WHO_{2005}-TEQ/g wet weight across the food groups.

Food group	N[(a)]	LC(%)[(b)]	Mean [LB; UB][(c)]	P50 [LB; UB][(d)]	P75 [LB; UB][(d)]	P90 [LB; UB][(d)]	P95 [LB; UB][(d)]	P99 [LB; UB][(d)]	Max [LB; UB][(e)]
Foods for infants and young children (all accepted samples)	516	1.9	[0.01; 0.02]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.04]	[0.04; 0.07]	[0.1; 0.11]	[0.19; 0.19]
Cereal-based food	27	0.0	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.02]	-[(f)]	-[(f)]	-[(f)]	[0.03; 0.04]
Infant/follow-on formula	158	5.7	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	-[(f)]	[0.01; 0.06]
- Infant/follow-on formula, liquid	19	10.5	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	-[(f)]	-[(f)]	-[(f)]	[0.01; 0.06]
- Infant/follow-on formula, powder	139	5.0	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[<0.005; 0.01]	[0.01; 0.01]	-[(f)]	[0.01; 0.02]
Ready-to-eat meals	316	0.3	[0.01; 0.02]	[0.01; 0.01]	[0.01; 0.02]	[0.03; 0.06]	[0.07; 0.09]	[0.11; 0.11]	[0.19; 0.19]
- Ready-to-eat meals, meat/fish based	280	0.4	[0.02; 0.02]	[0.01; 0.02]	[0.01; 0.03]	[0.04; 0.06]	[0.08; 0.1]	-[(f)]	[0.19; 0.19]
• *Fish based*	65	0.0	[0.03; 0.04]	[0.02; 0.03]	[0.05; 0.07]	[0.08; 0.09]	-[(f)]	-[(f)]	[0.11; 0.11]
• *Meat based*	215	0.5	[0.01; 0.02]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.03]	[0.03; 0.07]	-[(f)]	[0.19; 0.19]
- Other ready-to-eat meals (cereals-based, legume-based, fruit purée, unspecified)	36	0.0	[0.01; 0.01]	[<0.005; 0.01]	[0.01; 0.02]	[0.02; 0.03]	-[(f)]	-[(f)]	[0.03; 0.06]
Yoghurt, cheese and milk-based dessert	15	0.0	[0.01; 0.01]	[<0.005; <0.005]	[0.01; 0.01]	-[(f)]	-[(f)]	-[(f)]	[0.03; 0.04]

LB: lower-bound; LC: left-censored; Max: maximum; N: number of samples; UB: upper-bound.
(a): Number of samples.
(b): Percentage of censored results. A result is considered as censored if none of the 17 dioxins congeners is detected/quantified.
(c): Mean contamination presented as [lower-bound (LB); upper-bound (UB)].
(d): P50, P75, P90, P95, P99: 50th, 75th, 90th, 95th and 99th percentiles of contamination presented as [lower-bound (LB); upper-bound (UB)].
(e): Maximum observed value presented as [lower-bound (LB); upper-bound (UB)].
(f): The estimation of high percentiles is not reliable when very few observations are available (less than 11 for the P75, 29 for the P90, 60 for the P95 and 298 for the P99).



Legend: ML: maximum level; P50, P75, P90, P95, P99: 50th, 75th, 90th, 95th and 99th percentiles of contamination presented as UB; UB: upper-bound.

Figure 4: Distribution of the sum of dioxin and DL-PCB levels (UB levels) expressed in pg WHO_{2005}-TEQ/g wet weight in foods for infants and young children (all accepted data).

4.1.3.2. Time trends

It is not possible to conclude on any time trend concerning the dioxin and DL-PCB levels in foods for infants and young children, as these samples represent different kinds of food, collected for different purposes, analysed in different laboratories in different countries in different years. Also the differences between LB and UB levels indicate that for most samples the actual level could not be determined. In this respect it has to be considered that MLs for these foods are only applicable from 2012, i.e. no legal or analytical requirements were set before and differences in the UB levels of samples analysed earlier may have been the result of differences in LOQs.

4.2. Previously reported literature data on dioxins and DL-PCBs in foods for infants and young children in European countries

In Slovakia, Chovancová et al. (2005) reported a mean (min-max) UB concentration of dioxins in four samples of infant formula of 0.64 (0.36-0.78) pg WHO_{1998}-TEQ/g w.w. For non-*ortho* and mono-*ortho* PCBs, the authors reported concentrations of 0.30 (0.010-0.50) and 0.040 (0.0007-0.068) pg WHO_{1998}-TEQ/g w.w., respectively. The authors did not specify whether these results corresponded to the infant formula diluted as for consumption.

Lorán et al. (2009) reported the concentration of dioxins in initial formula (n = 25), follow-on formula (n = 25) and special lactose-free formula (n = 20) acquired from local markets, supermarkets and pharmacies in Zaragoza (Spain). A total of 14 pooled samples (5 of infant formula, 5 of follow-on formula and 4 of special lactose-free formula) were analysed, each comprising 5 different batches from the same commercial brand. The concentrations (medium-bound) were 0.30, 0.46 and 0.43 pg WHO_{1998}-TEQ/g fat for infant, follow-on and special lactose-free formula, respectively (or 0.08, 0.11 and 0.11 pg WHO_{1998}-TEQ/g product, respectively). These results were not expressed as infant formula reconstituted ready to eat. In another study, the same authors analysed commercial baby foods (n = 80) also acquired from local markets, supermarkets and pharmacies in Zaragoza (Spain) (Lorán et al., 2010). A total of 16 pooled samples (6 of processed cereals (gluten-free and containing gluten), 6 of meat-based baby food and 4 of fish-based baby food) each comprising 5 individual samples were analysed for dioxins only. The LB concentrations were 0.055-0.089 pg WHO_{1998}-TEQ/g dry weight for cereal-based baby food, and 0.018 and 0.014 pg WHO_{1998}-TEQ/g product for meat- and fish-based baby food, respectively. Considering both studies, PCDFs were the predominant congeners in all types of samples except in initial formula where PCDDs were the main contributors. Comparison with the ML is difficult since these were pooled samples, DL-PCBs were not analysed in the samples and the results were expressed in WHO_{1998}-TEQ and using the LB approach.

In the context of the Cascade Network of Excellence, a market basket study was conducted focusing on European Union commercial baby foods (Pandelova et al., 2010). EU market baskets were designed in order to represent the diet for each of the first 9 months of life of children not breastfed and fed with commercial baby foods only. Market share data covering 22 EU countries from year 2007 were used. A total of 42 infant formula products were sampled from 6 countries (France, Germany, Italy, Portugal, Sweden and the UK, half of them from Germany), and then were gathered into 6 pooled samples: infant formula -milk-based, -soy-based, -hypoallergenic-based, follow-on formula -milk-based, -soy-based, -hypoallergenic-based. The concentration of the sum of dioxins and DL-PCBs ranged from 0.011 to 0.050 pg WHO_{1998}-TEQ/g powder, with one sample showing higher levels (0.1105 pg WHO_{1998}-TEQ/g powder, corresponding to starting hypoallergenic infant formula). These results were not expressed as infant formula reconstituted ready to eat. In a further study by the same authors and within the same project, the concentration of dioxins and DL-PCBs in solid baby foods and beverages was reported (Pandelova et al., 2011). Five pooled samples of solid foods and beverages designed for 5-9 month-old infants were analysed, including baby food cereal-based, vegetable-based, meat and fish-based among others. The UB dioxin concentrations ranged from 0.03 to 0.0693 pg WHO_{1998}-TEQ/g w.w., while the DL-PCBs concentrations ranged from 0.01 to 0.17 pg WHO_{1998}-TEQ/g w.w. For both studies, the comparison with the ML is difficult considering that these are pooled samples, the results were expressed in WHO_{1998}-TEQ and not in WHO_{2005}-TEQ, and in the case of the infant formula results were not expressed as reconstituted ready to eat.

5. Impact of the ML on the existing levels

The EU strategy on the reduction of the exposure to dioxins and DL-PCBs is *inter alia* based on setting MLs according to the principle 'strict but feasible'. Following an inventory on the existing levels, MLs were generally set taking into account the range of P90 to P99 of the distribution. Follow-up studies should result in the identification of a limited number of samples with levels above the MLs and the subsequent elucidation and elimination of sources. Eventually, this should cause a shift in the distribution to lower levels.

As demonstrated in Tables 3 and 4, the UB levels for dioxins and for the sum of dioxins and DL-PCBs in foods for infants and young children are below the current MLs of 0.1 and 0.2 pg WHO_{2005}-TEQ/g product, respectively. Therefore, the CONTAM Panel concluded that based on the available data, the current MLs are not an incentive to decrease the concentrations of dioxins and DL-PCBs in the relevant foods.

The CONTAM Panel noted that the sensitivity of the analytical methods should be improved in order to decrease the difference between LB and UB concentrations, if lower MLs were to be considered in the future.

6. Uncertainty

A total of 516 samples reported by 13 European countries and covering the period 2003-2011 were included in the evaluation of this opinion. More than one third of the data were provided by the UK for samples collected in 2003.

All samples were collected before 2012 when for the first time MLs for dioxins and for the sum of dioxins and DL-PCBs in foods for infants and young children, and requirements for their analytical determination, were stipulated by the EC. This means that no requirements for the analytical determination in terms of LOD or LOQ existed when the samples considered in this opinion were analysed. No percentage difference threshold between UB and LB levels was applied for the samples with quantified levels below 0.2 pg WHO_{2005}-TEQ/g product which corresponded to almost all samples available in the dataset. The CONTAM Panel noted the relatively large differences between the LB and the UB levels. As all results have to be expressed as UB concentrations for assessing compliance with the MLs, they reflect an overestimation of the actual levels of dioxins and DL-PCBs in foods for infants and young children.

The analytical capability for the analysis of dioxins and PCBs has improved during the past decade. This introduces some uncertainty in the interpretation of the results as it can be assumed that a number of UB results of earlier analysed samples are likely to considerably overestimate the actual dioxin and DL-PCB concentration.

As the MLs are set for products ready for consumption, some results were recalculated as ready-to-eat equivalent using default dilution factors. Especially, in the absence of clear reporting, it was considered that all results corresponding to infant/follow-on formula powder and cereals which have to be reconstituted were expressed on the product as sold and not as ready for consumption. The dilution factors may not exactly reflect the mode of preparation of each individual product analysed.

The CONTAM Panel noted that when milk is used for reconstitution, the variable levels of dioxins and DL-PCBs in milk could have a considerable impact on the concentration in the product ready for consumption.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) interpreted the terms of reference (ToR) in such a way that it did not perform an exposure or risk assessment for infants and young children, but evaluated whether the enforcement of the new EU maximum levels (MLs) will result in a decrease in the concentration of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) in foods for infants and young children, and thus in a potential decrease in exposure of this specific population group.

- A total of 516 samples on different types of food for infants and young children, submitted by 13 European countries, were considered in this opinion. Some of the food groups were poorly represented.

- Depending on the food group, the percentage of left-censored data ranged between 0 and 15.8 % for dioxins, and between 0 and 10.5 % for the sum of dioxins and DL-PCBs.

- For comparison with MLs, according to the EU legislation upper-bound (UB) levels must be used, meaning that levels of non-detected congeners are assumed to be equal to the limit of quantification (LOQ). This will result in an overestimation of the actual levels. For most groups of food for infants and young children there were large differences between lower-bound (LB)- and UB-levels even at the higher end of the distribution.

- The P50, P90 and P95 (expressed as UB values) were <0.005, 0.02 and 0.03 pg WHO_{2005}-TEQ/g wet weight (w.w.) for dioxins, and 0.01, 0.04 and 0.07 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs. The maximum UB levels reported were 0.08 and 0.19 pg WHO_{2005}-TEQ/g w.w. for dioxins and for the sum of dioxins and DL-PCBs, respectively.

- Liquid and powder infant and follow-on formula showed UB levels up to 0.05 and 0.06 pg WHO_{2005}-TEQ/g w.w. for dioxins and for the sum of dioxins and DL-PCBs, respectively. The highest UB levels, up to 0.08 for dioxins and 0.19 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs, were found in ready-to-eat meals based on fish and meat.

- All accepted data were below the current MLs of 0.1 pg WHO_{2005}-TEQ/g w.w. for dioxins and 0.2 pg WHO_{2005}-TEQ/g w.w. for the sum of dioxins and DL-PCBs which are in force since 1 January, 2012.

- The CONTAM Panel noted that when milk is used for reconstitution, the variable levels of dioxins and DL-PCBs in milk could have a considerable impact on the concentration in the product ready for consumption.

- The CONTAM Panel concluded that, based on the available data, the current MLs are not an incentive to decrease the concentrations of dioxins and DL-PCBs in the relevant foods.

- As the samples represent different kinds of food, collected for different purposes, analysed in different laboratories from different countries in different years, and often with insufficient sensitivity to determine the actual levels, it is not possible to conclude on any time trend concerning the levels of dioxins and DL-PCBs in foods for infants and young children.

RECOMMENDATIONS

- More occurrence data on representative samples are needed, particularly for those foods for infants and young children where only a few results are available so far.

- The sensitivity of the analytical methods should be improved in order to decrease the differences between LB and UB concentrations, if lower MLs were to be considered in the future.

- Reporting of results should include details on reconstitution when this is required for particular foods.

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APPENDICES

A. DISTRIBUTION OF DIOXIN LEVELS ACROSS DIFFERENT FOOD GROUPS FOR INFANTS AND YOUNG CHILDREN

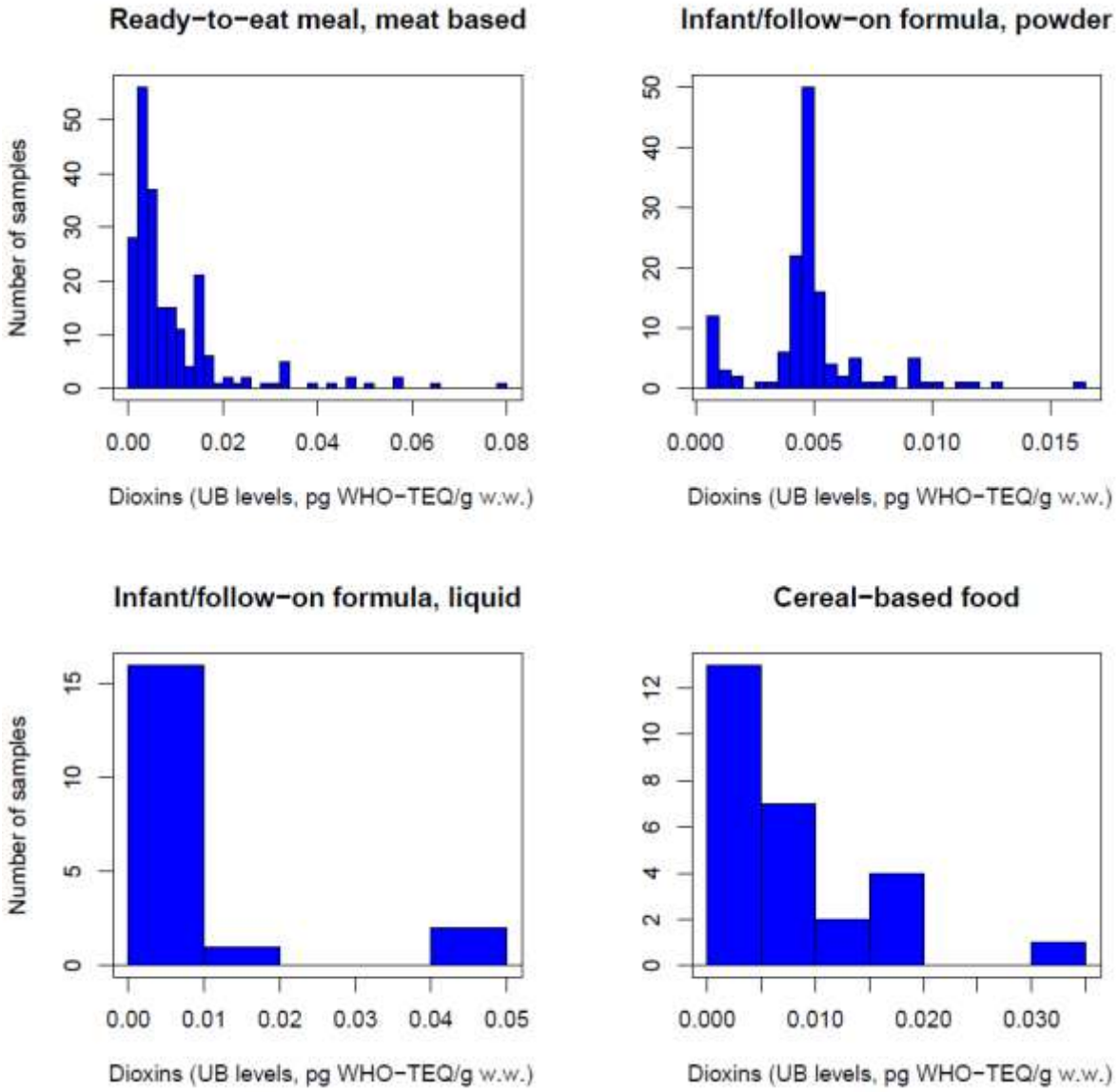

Figure A1: Distribution of upper-bound (UB) dioxin levels expressed in pg WHO_{2005}-TEQ/g wet weight (w.w.) across different food groups.

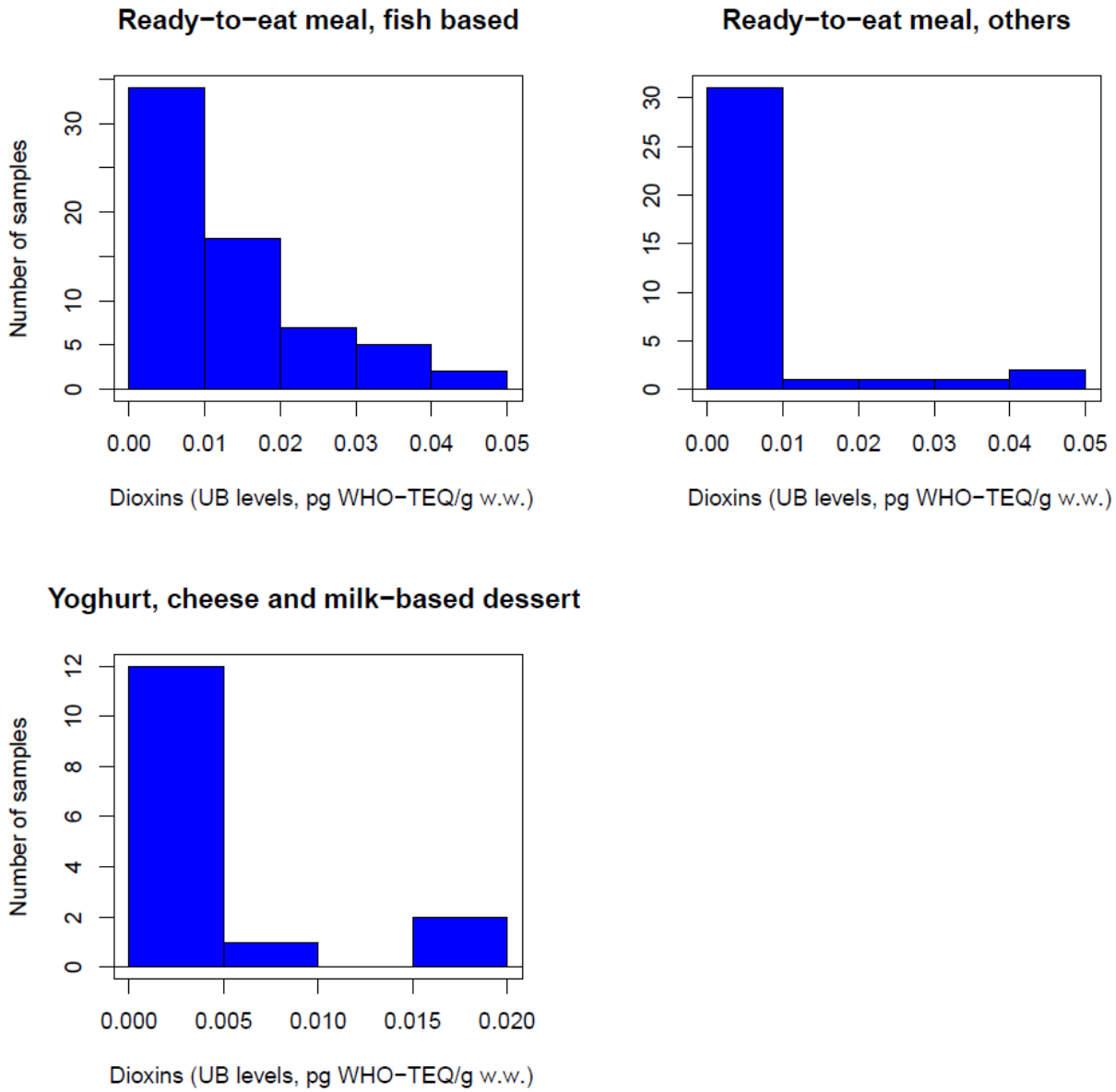

Figure A2: Distribution of upper-bound (UB) dioxin levels expressed in pg WHO_{2005}-TEQ/g wet weight (w.w.) across different food groups.

B. DISTRIBUTION OF THE SUM OF DIOXIN AND DL-PCB LEVELS ACROSS DIFFERENT FOOD GROUPS FOR INFANTS AND YOUNG CHILDREN

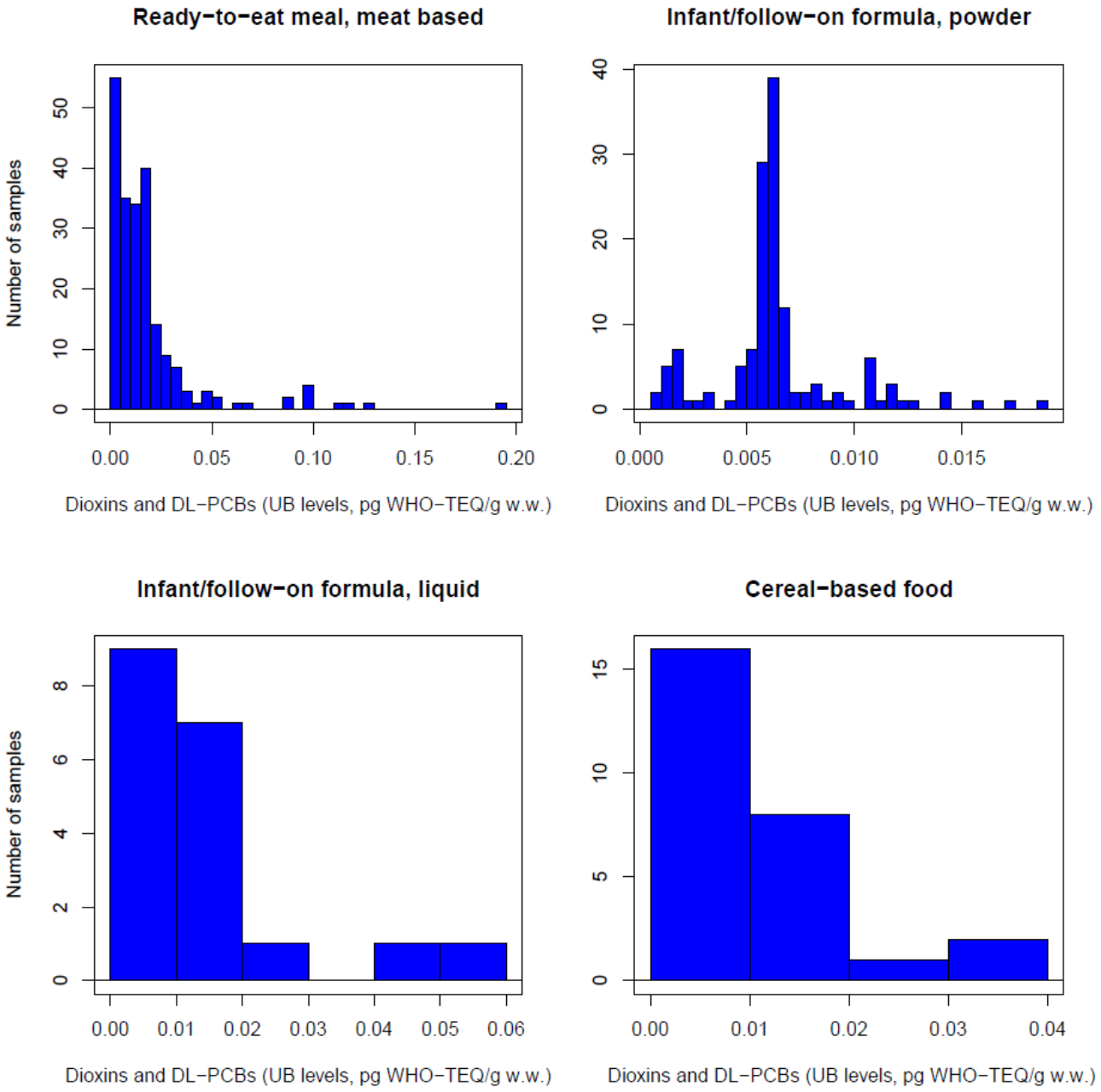

Figure B1: Distribution of the upper-bound (UB) levels of the sum of dioxins and DL-PCBs, expressed in pg WHO_{2005}-TEQ/g wet weight (w.w.) across the different food groups.

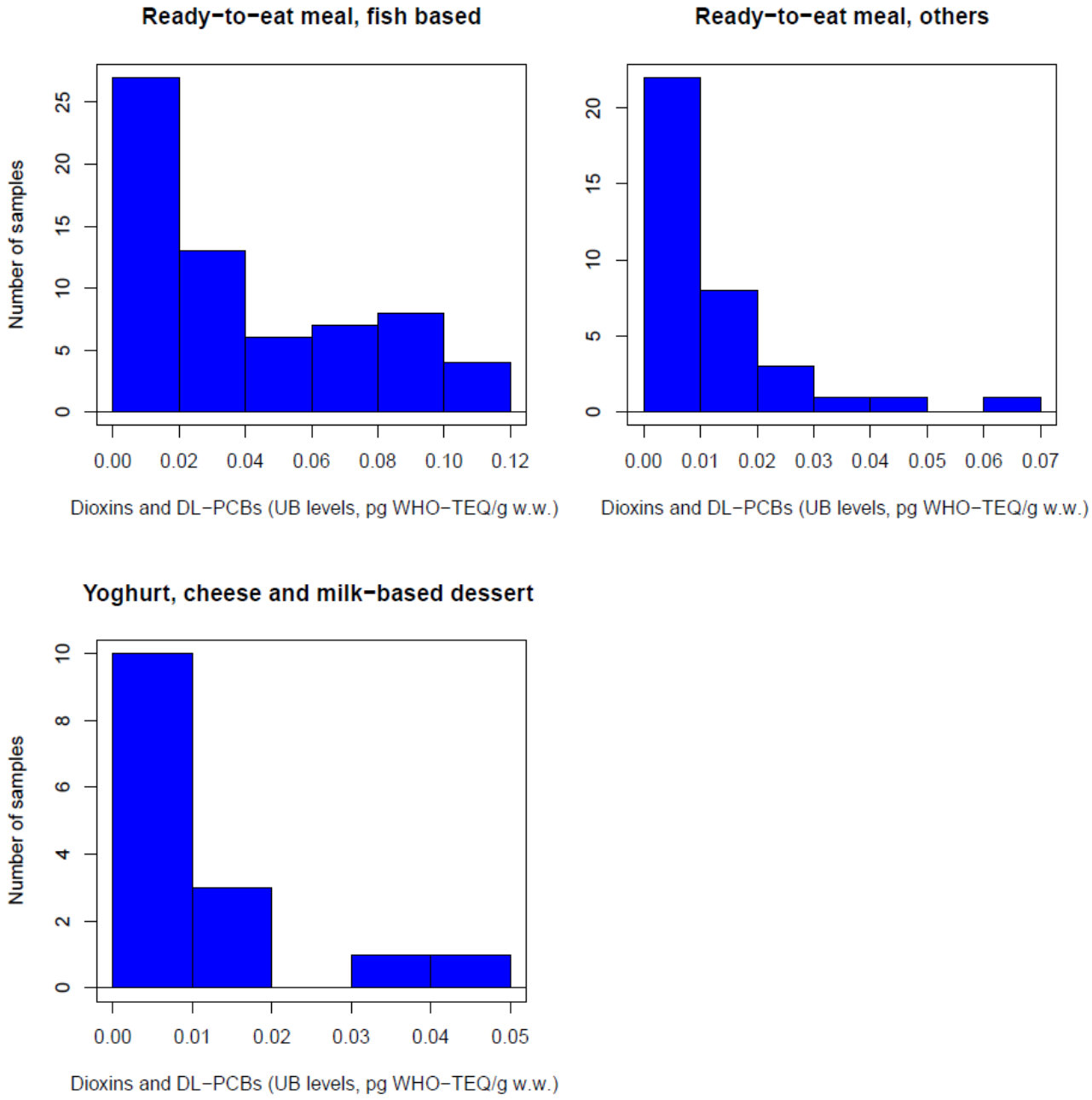

Figure B2: Distribution of the upper-bound (UB) levels of the sum of dioxins and DL-PCBs, expressed in pg WHO_{2005}-TEQ/g wet weight (w.w.) across the different food groups.

ABBREVIATIONS

2,3,7,8-TCDD	2,3,7,8-Tetrachlorodibenzo-p-dioxin
AhR	Aryl hydrocarbon receptor
BfR	Federal Institute for Risk Assessment
b.w.	Body weight
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
DL-PCBs	Dioxin-like polychlorinated biphenyls
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
GC	Gas Chromatography
GC/MS	Gas Chromatography / Mass spectrometry
HpCDD	Heptachlorodibenzo-*p*-dioxin
HpCDF	Heptachlorodibenzofurans
HxCDD	Hexachlorodibenzo-*p*-dioxin
HxCDF	Hexachlorodibenzofuran
HRMS	High resolution mass spectrometry
IPCS	International Programme on Chemical Safety
LB	Lower-bound
LC	Left-censored
LOD	Limit of detection
LOQ	Limit of quantification
Max.	Maximum
ML	Maximum level
N	Number of samples
NDL-PCBs	Non dioxin-like polychlorinated biphenyls
OCDD	Octachlorodibenzo-*p*-dioxin
OCDF	Octachlorodibenzofuran
P50	50^{th} percentile
P75	75^{th} percentile
P90	90^{th} percentile
P95	95^{th} percentile
P99	99^{th} percentile
PeCDD	Pentachlorodibenzo-*p*-dioxin
PeCDF	Pentachlorodibenzofuran
PCB	Polychlorinated biphenyl
PCDDs	Polychlorinated dibenzo-*p*-dioxins
PCDFs	Polychlorinated dibenzofurans
RSDR	Relative standard deviation calculated from results generated under reproducibility conditions
SCF	Scientific Committee on Food
SSD	Standard Sample Description
TCDF	Tetrachlorodibenzofuran
TEF	Toxic equivalency factor
TEQ	Toxic equivalent
ToR	Term of reference
TWI	Tolerable weekly intake
UB	Upper-bound
UK-FSA	Food Standards Agency of the United Kingdom
US-EPA	Environmental Protection Agency of the United States
WHO	World Health Organization
w.w.	Wet weight