

## INFORMATION DOCUMENT ON DIOXINS AND PCBs

The aim of this document is to provide food business operators, enforcement officers and other stakeholders with a concise overview of the health hazards of, and sources of dietary exposure to, dioxins and PCBs. It gives information on methods of sampling and analysis for these contaminants and the legislative control measures in place to minimise their presence in food. Finally, it provides short guidance to Food Business Operators on the risk management measures that they should have in place and also a bibliography giving sources of further information. The Summary below gives a short synopsis of the information, while the following pages provide more technical detail.

### Summary

Dioxins are a group of persistent chemicals which are not produced intentionally but are formed during combustion (burning) processes and as by-products of industrial processes. PCBs, or polychlorinated biphenyls, are similar chemically to the dioxins. They have been used in transformers, building materials, lubricants, coatings, plasticizers and inks, although their use has now largely been phased out. Both the dioxins and the PCBs are highly resistant to breakdown processes, and consequently persist in the environment, followed by uptake into the food chain. Up to 90% of human exposure to dioxins results from the consumption of food containing dioxins, mainly foodstuffs of animal origin with a high fat content, since these contaminants accumulate in fatty tissues. Foodstuffs in which dioxins can occur include meat, fish, eggs and milk

Dioxins and PCBs are toxic chemicals that can provoke serious health effects such as cancer, hormone disruption, reduced ability to reproduce, skin toxicity and immune system disorders. Because of their serious health effects and their persistence in the environment, it is essential to minimize their release into the environment, including the establishment of emission limits for dioxins to air, prohibition of the use of PCBs, and safe collection, storage and environmentally compatible disposal or destruction of dioxin and PCB-contaminated devices and products.

Maximum levels (MLs) for dioxins and PCBs in meat, fish, eggs, milk and other foods have been set by Commission Regulation via Commission Regulation No [1881/2006](#), the framework EU legislation which sets maximum levels for chemical contaminants in foodstuffs. These MLs are set at a very low level (as low as reasonably achievable for the particular foodstuff in question), in order to ensure that consumers' health is not affected by consuming these products. Separate legislation applies to levels of dioxins and PCBs in animal feeds, since this is another important source of contamination of the human food chain.

In order to ensure that these MLs are not exceeded, routine surveillance of food and feed must be carried out, involving the taking of samples of potentially contaminated product followed by laboratory analysis to determine the levels of dioxins and PCBs in the sample. The Food Safety Authority of Ireland in collaboration with its agencies carries out regular checks on levels of dioxins and PCBs in the food chain (see Bibliography for further details). The results of these checks show that the levels in Irish food are generally low compared with other industrialized countries and are considered to present a low risk to the health of the Irish consumer.

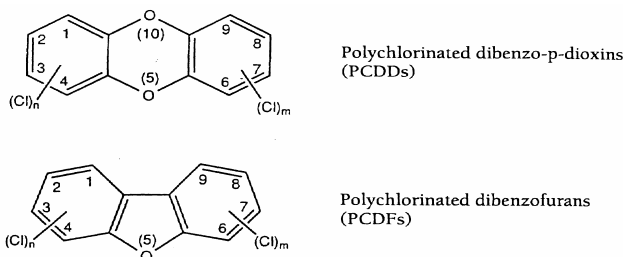
Food Business Operators (FBOs) must also ensure that their products comply with the legislative limits for dioxins and PCBs as laid down in Commission Regulation (EC) No 1881/2006. It is important that FBOs identify critical control points (CCPs) in their processes that may result in dioxin

and PCB contamination; the identification of appropriate CCPs along their process chain will enable them to develop and apply proper HACCP systems which will ensure that there are no unforeseen sources of dioxin contamination in their products.

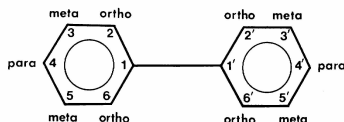
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### 1. Introduction

The term “dioxin” covers a group of 75 chemically similar polychlorinated dibenzo-p-dioxins (PCDDs) and 135 polychlorinated dibenzofurans (PCDFs). The individual chemicals within the group are termed congeners. The following figure shows the general structural formulae for PCDDs and PCDFs.



The polychlorinated biphenyls or PCBs are structurally somewhat similar to the dioxins. There are 209 PCB congeners, divided into 2 main groups: (1) the “dioxin-like PCBs”, a group of 12 PCBs showing similar toxicological properties to the dioxins, and (2) the non-dioxin-like PCBs, which are of lower toxicity, and which are normally the predominant congeners in environmental samples. The following shows the general structure of PCBs.



### 2. Toxicity of dioxins and PCBs

The PCDDs/PCDFs and PCBs are fat-soluble compounds which accumulate in the tissues of animals and humans, in addition to binding to soil and other organic matter in the environment. Their ability to accumulate in the body, together with their chlorinated structure, in part explains their toxicity. The various dioxin congeners contain between 1 and 8 atoms of chlorine, and those that are of concern in terms of their effects on health contain chlorine in each of the 2-, 3-, 7- and 8-positions of the molecule. Thus, from the 210 theoretically possible congeners, only 17 are of toxicological concern, the most toxic being 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). The toxic congeners bind to the aryl hydrocarbon (Ah) receptor present in most tissues of animals and humans, triggering a toxic response.

Exposure to dioxins can result in a wide range of health effects including cancer, disturbance of the reproductive and immune systems and chloracne (an effect on the skin). TCDD is considered to be a human carcinogen, and by analogy the other dioxins are also considered to be carcinogenic. Expert bodies such as the EU Scientific Committee for Food (SCF) and the World Health Organisation (WHO) have concluded however that the carcinogenic effect of dioxins does not occur at levels below a certain threshold. Children exposed before birth to dioxins are reported to show endocrine and developmental changes and possible neurobehavioral effects (learning difficulties). The dioxin-like PCBs are considered to be similar in toxicity to the dioxins since they also bind to the Ah receptor.

Other PCBs (non-dioxin-like PCBs) do not exert their toxicological effects via binding to the Ah receptor but nonetheless are associated with a wide spectrum of toxic responses in toxicological studies, including developmental effects, immuno- and neurotoxicity, endocrine disrupting effects and tumour promotion. A risk assessment for the non-dioxin-like PCBs (ndl-PCBs) in food has been carried out recently by the Scientific Panel on Contaminants of the European Food Safety Authority (EFSA). The Panel concluded that the toxicological database on health effects of these compounds is insufficient for a separate risk assessment.

The toxicity of PCDD, PCDF and dioxin-like PCB congeners are expressed using Toxic Equivalence Factors (TEFs), representing the toxicity of a particular congener relative to the most toxic congener, TCDD. Several different TEF schemes have been proposed. The most common scheme currently used is that of WHO-TEFs, developed by the WHO-ECEH (European Centre for Environment and Health of the World Health Organization). These have recently been updated by WHO-ECEH, but the new scheme is not yet widely in use. The currently used WHO-TEFs for the dioxin and dioxin-like PCB congeners of main concern are shown in the Appendix.

### **3. Exposure to dioxins and PCBs**

Dioxins are not produced commercially and have no applications, other than for preparation of analytical standards and research materials. They are formed during combustion processes, for example in the incineration of municipal waste. They can also occur as by-products of industrial processes, for example bleaching of paper pulp using chlorine. They are highly resistant to degradation processes, due to their lipophilic characteristics, and consequently persist in the environment, followed by uptake into the food chain, into animals and fish.

In the case of cows or other lactating species, high levels of dioxins can potentially occur in milk fat, in cream and in products such as cheese, in addition to levels in carcass meat. In fish, high levels may be found in fatty tissues such as liver and consequently in fish liver oils. It is estimated that up to 90% of human exposure to dioxins results from the consumption of food containing dioxins, mainly foodstuffs of animal origin. Fruit and vegetables provide only a minor contribution to human intake. Exposure by routes such as inhalation and ingestion of particles from air normally contributes less than 10% of daily intake. The presence of dioxins in food has been a matter of concern for a number of years, particularly since the Belgian dioxin crisis in 1999, when industrial transformer oil containing dioxins was included in fat that was being recycled for animal feed, resulting in entry of the contaminants into the human food chain.

PCBs were widely used in the past in industry, in applications such as hydraulic and heat transfer systems and as insulating fluids in transformers and capacitors. The production and use of PCBs has been discontinued in most countries, but large amounts remain in e.g. electrical equipment, disposal of which results in continued release to the environment, where, like the dioxins, they are resistant to degradation. Because the PCBs, in particular the dioxin-like PCBs, have similar characteristics to the PCDDs/PCDFs, the pattern of human exposure is similar to that of the dioxins, i.e. predominantly via contaminated food.

The Food Safety Authority of Ireland in collaboration with its agencies carries out regular checks on levels of dioxins and PCBs in the food chain (see Bibliography for further details). The results of these checks show that the levels in Irish food are generally low, and are considered to present little risk to the health of the Irish consumer.

### **4. Sampling and analysis**

The PCDDs/PCDF and PCBs, are determined in food (or animal feed) using sophisticated analytical techniques such as high-resolution gas chromatography/high resolution mass spectrometry (HRGC/HRMS) methods. [Regulation 1883/2006](#) laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs specifies that the

analytical methods used must meet criteria of high sensitivity, low limits of detection, high selectivity (specificity) and high accuracy, in order to enable specific identification and quantification of the individual congeners in a particular sample of food. The Directive also lays down requirements for laboratories carrying out dioxin analyses, core requirements being accreditation, competence in the specific analyses and ongoing participation in inter-laboratory studies for the determination of dioxins and dioxin-like PCBs in food/feed matrices.

Laboratories with the analytical capability to carry out these methods are however limited in number and the analyses are costly to carry out. [Regulation 1883/2006](#) therefore provides for use of screening methods in order to select samples with levels that are close to (within 30-40%) or exceed the limits set for dioxins in foodstuffs (see below). The actual dioxin level in the sample must then be determined by a confirmatory method. Currently available screening methods include both bioassay and GC/MS methods. The chemical-activated luciferase gene expression (CALUX) assay is currently undergoing international validation as a suitable bioassay for dioxins in food. It uses genetically modified cell lines containing the Ah-receptor involved in dioxin activity, coupled to an enzymatic signal generating system, providing a reliable indication of the presence of dioxins or dioxin-like PCBs in a food or feed sample. It cannot, however, provide information on the congener pattern.

[Regulation 1883/2006](#) also lays down sampling procedures which must be followed when determining dioxin and dioxin-like PCB levels in food and feedstuffs. Official sampling must be carried out by an authorised person (e.g. an Environmental Health Officer), and incremental samples taken to give an aggregate sample which is representative of the lots or sublots from which it has been taken. Laboratory samples for analysis are then taken from this aggregate sample. Similar procedures should be followed by industry when determining dioxin levels in the products it places on the market.

### **Reporting of results**

Given that food and feed samples contain complex mixtures of different dioxin and PCB congeners, results of analyses are normally reported in Toxic Equivalents (TEQs). The total TEQ value of a particular sample is determined by multiplying the analytically determined concentration of each congener by its corresponding Toxic Equivalency Factor (TEF) and summing the contribution from each to give a total for all dioxin-like compounds, expressed in toxic equivalents (TEQs) of 2,3,7,8-TCDD (TEF = 1). This provides a more useful estimate for risk assessment purposes than absolute concentrations.

### **5. Legislative limits for dioxins and dioxin-like PCBs**

Maximum levels have been set at European level for PCDDs/PCDFs and dioxin-like PCBs in key foodstuffs, e.g. meat and meat products, fish and fishery products, milk and milk products, oils and fats, via Commission Regulation (EC) No [1881/2006](#), the framework EU legislation which sets maximum levels for chemical contaminants in foodstuffs. The maximum levels for PCDDs/PCDFs in food are shown in column 2 of Table 1, while column 3 shows the maximum levels for the sum of dioxins, furans and dioxin-like PCBs. There are currently no separate legislative limits established for the non-dioxin-like PCBs in food, although these are under discussion at EU level. .

Limits have also been set for animal feedstuffs via Commission Directive 2006/13/EC, (<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:032:0044:0053:EN:PDF>), amending Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed, recognizing the importance of establishing limits for both food and feed.

**Table 1\***  
**Maximum dioxin levels in certain foodstuffs (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and sum of dioxins and dioxin like PCBs expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997)**

Foodstuffs	Maximum levels	
	Sum of dioxins (WHO-PCDD/F-TEQ) <sup>(32)</sup>	Sum of dioxins and dioxin-like PCBs (WHO-PCDD/F-PCB-TEQ) <sup>(32)</sup>
5.1 Meat and meat products (excluding edible offal) of the following animals <sup>(6)</sup>		
– bovine animals and sheep	3 pg/g fat <sup>(33)</sup>	4.5 pg/g fat <sup>(33)</sup>
– poultry	2 pg/g fat <sup>(33)</sup>	4 pg/g fat <sup>(33)</sup>
– pigs	1 pg/g fat <sup>(33)</sup>	1.5 pg/g fat <sup>(33)</sup>
5.2 Liver of terrestrial animals referred to in 5.1 <sup>(6)</sup> and derived products thereof	6 pg/g fat <sup>(33)</sup>	12 pg/g fat <sup>(33)</sup>
5.3 Muscle meat of fish and fishery products and products thereof with the exception of eel <sup>(25) (34)</sup> . The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )	4 pg /g fresh weight	8 pg /g fresh weight
5.4 Muscle meat of eel ( <i>Anguilla anguilla</i> ) and products thereof	4 pg /g fresh weight	12 pg /g fresh weight
5.5 Raw milk <sup>(6)</sup> and dairy products <sup>(6)</sup> , including butter fat	3 pg/g fat <sup>(33)</sup>	6 pg/g fat <sup>(33)</sup>
5.6. Hen eggs and egg products <sup>(6)</sup>	3 pg/g fat <sup>(33)</sup>	6 pg/g fat <sup>(33)</sup>
5.7 Fat of the following animals		
– bovine animals and sheep	3 pg/g fat	4.5 pg/g fat
– poultry and farmed game	2 pg/g fat	4 pg/g fat
– pigs	1 pg/g fat	1.5 pg/g fat
5.8 Mixed fats	2.0 pg/g fat	3 pg/g fat
5.9. Vegetable Oils and fats	0.75 pg /g fat	1.5 pg /g fat
5.10 Marine oil (fish body oil, fish liver oil and oils from other marine organisms intended for human consumption )	2 pg /g fat	10 pg /g fat

\* Table 1 is reproduced from Commission Regulation (EC) No. 1881/2006. The references ( ) in the table refer to footnotes in this Regulation and persons intending to use the MLs should refer to the Regulation for details.

## 6. Other control measures for dioxins

In addition to the establishment of maximum levels for dioxins as shown in section 5, other initiatives have been taken with the aim of reducing levels of dioxins in the environment and in foodstuffs. In relation to tolerable levels of human exposure to dioxins, the European Union's Scientific Committee for Food (SCF) in 2000 recommended a group tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs of 14 pg/kg/week, but noted that the European average dietary intake estimated from a trans-European SCOOP (Scientific Programme for Co-operation) task was 1.2 to 3.0pg WHO-

TEQ/kg b.w./day, exceeding the TWI. The World Health Organisation's Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2001 recommended a provisional tolerable monthly intake (PTMI) of 70 pg/kg bw.

In 2001, the European Commission published a Community strategy for reduction of dioxins, furans and polychlorinated biphenyls in food and the environment, which established the principle of a proactive approach to reducing levels in combination with measures to limit emissions. Since then it has underpinned this with two Commission Recommendations, Recommendation [2006/88/EC](#) on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs, including the setting of action levels and target levels for dioxins, and Recommendation [2006/794/EC](#), which requires random monitoring of the presence of dioxins and dioxin-like PCBs in feed materials, feedingstuffs and foodstuffs. The Food Safety Authority of Ireland carries out regular checks on levels of dioxins and PCBs in the food chain under this programme (see Bibliography for further details).

Measures to control dioxin emissions have been taken by many countries including Ireland since the problem was first recognised, with a consequent decline in environmental levels, but it is recognised that further steps need to be taken. Measures taken in the European Union as part of the Community strategy referred to above include establishment of emission limits for dioxins to air, substitution of chlorine in processes and products where possible, prohibition of the use of PCBs, and safe collection, storage and environmentally compatible disposal or destruction of dioxin and PCB contaminated devices and products. Further information on reduction strategies for dioxins in the environment may be obtained from the Environmental Protection Agency, url: <http://www.epa.ie>.

## **7. Responsibilities of Food Business Operators**

Food Business Operators (FBOs) involved in the marketing of foods of animal origin should ensure that their products comply with the legislative limits for PCDD/Fs, dioxin like PCBs and (impending) non-dioxin-like PCBs. This is particularly important for FBOs marketing products such as milk and milk powders and other dairy products, fish oils and farmed fish products. While the high cost of analysis of food products for dioxins and dioxin-like PCBs makes dioxin analysis difficult on a routine basis, FBOs should be aware of the results of monitoring carried out by the Food Safety Authority on a range of Irish foodstuffs and should carry out independent monitoring of products that have been shown to have high levels of PCDD/Fs and dioxin-like PCBs. FBOs should also be aware of the measures that can be taken to reduce dioxin and PCB releases to the environment that can further contribute to the accumulation of these pollutants in the food chain.

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## APPENDIX I

## WHO-TEFs for dioxins and dioxin-like PCBs

PCDDs and PCDFs	Toxic Equivalency Factor (WHO-TEF)
2,3,7,8-TCDD	1
1,2,3,7,8-PnCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PnCDF	0.05
2,3,4,7,8-PnCDF	0.5
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0001

PCBs (IUPAC No. in parenthesis)	Toxic Equivalency Factor (WHO-TEF)
<b>Non-ortho PCBs</b>	
3,3',4,4'-TCB (77)	0.0001
3,4,4',5'-TCB (81)	0.0001
3,3',4,4',5'-PnCB (126)	0.1
3,3',4,4',5,5'-HxCB (169)	0.01
<b>Mono-ortho PCBs</b>	
2,3,3',4,4'-PnCB (105)	0.0001
2,3,4,4',5'-PnCB (114)	0.0005
2,3',4,4',5'-PnCB (118)	0.0001
2,3,4,4',5'-PnCB (123)	0.0001
2,3,3',4,4',5'-HxCB (156)	0.0005
2,3,3',4,4',5'-HxCB (157)	0.0005
2,3',4,4',5,5'-HxCB (167)	0.00001
2,3,3',4,4',5,5'-HpCB (189)	0.0001
<b>Di-ortho PCBs</b>	
2,2',3,3',4,4',5'-HpCB (170)	-
2,2',3,4,4',5,5'-HpCB (180)	-

**Abbreviations:** PnCDD, pentachlorodibenzo-*p*-dioxin; HxCDD, hexachlorodibenzo-*p*-dioxin; HpCDD, heptachlorodibenzo-*p*-dioxin; OCDD, octachlorodibenzo-*p*-dioxin; PnCDF, pentachlorodibenzofuran; HxCDF, hexachlorodibenzofuran; HpCDF, heptachlorodibenzofuran; OCDF, octachlorodibenzofuran; TCB, tetrachlorobiphenyl; PnCB, pentachlorobiphenyl; HxCB, hexachlorobiphenyl; HpCB, heptachlorobiphenyl.