POLYCHLORINATED BIPHENYLS (PCBS)

See also fiche about dioxins and dioxin-like PCBs

Chemical structure

PCBs are a group of organochlorine compounds that are synthesised by catalysed chlorination of biphenyl. Depending on the number of chlorine atoms (1-10) and their position on the two rings, 209 different compounds, also named “congeners” are possible. 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 dioxins. 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 is called “non dioxin-like PCBs” (NDL-PCBs). Six PCBs are considered as “indicator-PCB” or “marker-PCB” : PCB 28, 52, 101, 138, 153, 180. The sum of the six PCB congeners -28, -52, -101, -138, -153 and -180 are used for the risk assessment of NDL-PCBs.

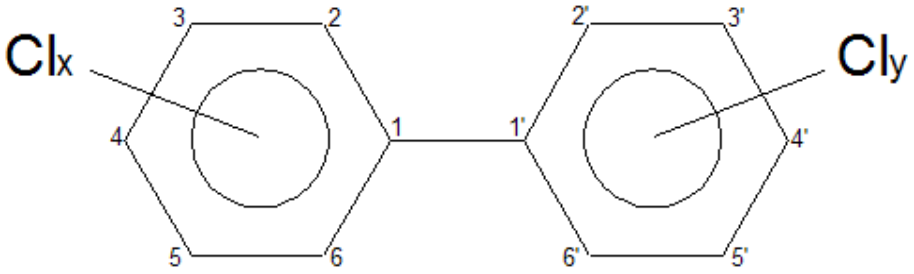

Figure 1: Structure of PCBs. Cly + Clx = 1-10. (EFSA, 2011)

PCBs are characterized by two benzene rings attached by a carbon-carbon link. The general formula is $C_{12}H_{(10-n)}Cl_n$.

Contamination source

Due to their physico-chemical properties, such as chemical stability, low heat conductivity and high dielectric constants, PCBs were widely used in a number of industrial and commercial applications such as hydraulic and heat transfer systems, cooling and insulating fluids in transformers and capacitors, pigments, dyes, repellents and carbonless copy paper or as plasticizers in paints, sealants, plastics and rubber products. For technical purposes, PCBs have been used as complex, technical mixtures and not as single compounds. The different technical mixtures contain in total about 130 individual congeners (Safe, 1990; Dobson and van Esch, 1993; UNEP, 1993; EPA, 2003). Breivik et al. (2002) estimated an historical global production of 1.3 million tonnes of PCBs of which almost 97% was used in the Northern Hemisphere (EFSA, 2010).

In contrast to dioxins, PCBs had widespread use in numerous industrial applications, generally in the form of technical mixtures with various chlorine content. They were massively produced for over four decades, from 1929 until they were banned. According to Directive 96/59/EC Member States should have taken the necessary measures to ensure that used PCBs were disposed off and equipment containing PCBs were decontaminated or disposed off at the latest by the end of 2010. In fires and other thermal events, PCBs can be converted to PCDFs and other products (EFSA, 2011).

As a result of their widespread use, leakages and improper disposal practices, PCBs (like dioxins) also have a global distribution in the environment where they are persistent because they are poorly degraded and thus they are bioaccumulated in the food chain. Like dioxins, PCBs belong to the initial list of 12 persistent organic pollutants (POPs) that are regulated under the Stockholm Convention on POPs. The main pathway of human exposure for the majority of the population is via food consumption with the exception of specific cases of accidental or occupational exposure (EFSA, 2011).

Analytical method

Since 2012, six NDL-PCBs (28, 52, 101, 138, 153, 180) are to be screened for the monitoring of food according to the European legislation. They are found at higher levels compared to dioxins (i.e., low nanogram to microgram per gram of matrix depending on the investigated biological sample). For

this reason, the analytical methodologies are less complex (Scippo et al., 2008).

Currently, gas chromatography with low resolution mass spectrometry (GC/MS) is the analytical method of choice for the analysis of PCBs.

Toxicity

PCBs have been demonstrated to cause a variety of adverse health effects. PCBs have been shown to cause cancer in animals. PCBs have also been shown to cause a number of serious non-cancer health effects in animals, including effects on the immune system, reproductive system, nervous system, endocrine system and other health effects. Studies in humans provide supportive evidence for potential carcinogenic and non-carcinogenic effects of PCBs. The different health effects of PCBs may be interrelated, as alterations in one system may have significant implications for the other systems of the body (EPA, 1996).

Some NDL-PCBs elicit different types of responses than the DL-PCBs, including neurological, neuroendocrine, endocrine, immunological and carcinogenic effects. These effects occur via multiple toxicity pathways, not involving the Ah receptors (EPA, 2003).

The ATHON project funded through the DG Research 6th Framework program aims to clarify biological mechanisms underlying the various types of toxicity of NDL-PCBs and to evaluate these data from a regulatory toxicology point-of-view (http://ec.europa.eu/research/biosociety/food_quality/projects/114_en.html).

Metabolism

PCBs are extensively absorbed from the gastrointestinal tract by passive diffusion (EFSA, 2005). Studies in rats have shown that all PCB congeners are well absorbed, with >90% absorption of the lower chlorinated congeners, and possibly lower absorption (about 75%) of the higher chlorinated congeners, such as octachlorobiphenyls.

Carcinogenicity

PCBs without distinction in dioxin-like or non dioxin-like congeners, were classified by IARC (1987) in Group 2A (probably carcinogenic to humans), based on limited evidence in humans and sufficient in animals. PCBs are also classified as probable human carcinogens by the US Environment Protection Agency (EPA, 1996) and the Agency for Toxic Substances and Disease Registry (ATSDR, 2000). It should be noted that in assessing the carcinogenic potential of PCBs no clear distinction was made between DL-PCBs and NDL-PCBs (EFSA, 2010).

No published peer reviewed data are available on the carcinogenic potency of single congeners. In the draft abstract of the NTP (2005) long-term and carcinogenicity study with PCB 153 in female rats, it was concluded that the evidence of carcinogenicity of PCB 153 was equivocal.
The interpretation of carcinogenicity studies with technical mixtures is however hampered by the fact that these mixtures contain both dioxin-like and non dioxin-like congeners. Since liver carcinogenicity has been shown in female rats for the prototype dioxin 2,3,7,8-TCDD, but also for 2,3,4,7,8-PCDD and for the most potent DL-PCB congener PCB 126, the possibility has to be considered that the liver carcinogenicity of technical PCB mixtures is due to the dioxin-like compounds present in these mixtures.

Genotoxicity

The negative results of *in vitro* and *in vivo* genotoxicity studies indicate that technical PCB mixtures are not mutagenic at gene or chromosome level (EFSA, 2005).
Some NDL-PCBs, in particular the lower chlorinated congeners, caused DNA damage, probably resulting from the formation of reactive oxygen species. In two-stage initiation-promotion studies, technical PCB mixtures containing NDL-PCBs as well as DL-PCBs promote liver carcinogenesis in rats, following initiation with genotoxic carcinogens. Data from animal experiments with several technical mixtures (Aroclor 1016, 1242, 1254 and 1260) indicate that PCBs can cause liver and thyroid neoplasms in rats.

Endocrine effect

“Both estrogenic activity and anti-estrogenic activity have been observed for NDL-PCBs and hydroxylated metabolites of lower chlorinated NDL-PCBs. Structure activity relationships were

complex and differed from one *in vitro* assay to another (Connor, 1997). *In vivo* animal studies, using single congeners, showed estrogenic effects such as increases in uterine weight, and changes in oestrogen and progesterone receptors. NDL-PCBs may also interfere with the binding of testosterone to the androgen receptor (Schrader and Cooke, 2003). NDL- and DL-PCBs interfere with thyroid hormone status through both distinct and similar mechanisms. NDL-PCBs and hydroxy-PCBs may bind to the hormone receptor and affect thyroid hormone status by inhibiting the binding of T4 to transthyretin, which is an important transport protein for both T4 and T3 in rats (Chauhan, 2000). Some hydroxy-PCBs are potent inhibitors of thyroid hormone sulfation (Schuur, 1998). Furthermore, NDL-PCBs can induce a UDP-glucuronosyltransferase which can enhance the elimination of T4 from the circulation via glucuronidation (Hood and Klaassen, 2000)" (cited in EFSA, 2005).

PCBs and several isomers, hydroxylated metabolites and commercial PCB mixtures have been reported to be oestrogenic. The potency of the active PCB isomers is around 1 mg/kg (rat LOEL) and the metabolites are slightly more potent (cited in Miyamoto and Klein, 1998). Certain PCB metabolites found in plasma are actually oestrogen antagonists (cited in Preziocsi, 1998).
Certain PCB are known to alter thyroid function (Preziosi, 1998) and have anti-thyroid activity (Ashby, 1998)

Establishment of Health Based Reference Values
The most sensitive effects seen in studies with individual NDL-PCB congeners in experimental animals were liver and thyroid toxicity. The NOAELs for these effects in 90-day rat studies with the individual NDL-PCB congeners PCB 28, 128, and 153 were in the range of 30-40 µg/kg bw/day. For compounds that accumulate in the body, such as NDL-PCBs, evaluations based on body burden (BB) calculations are considered more appropriate than evaluations based on the external dose. The Panel therefore applied a body burden approach to the results of the 90-day rat studies, and estimated body burdens at the "no observed adverse effect level" (NOAEL) of 400, 800, and 1,200 µg/kg bw for PCB 28, 128, and 153, respectively. The Panel compared estimated body burdens at the NOAEL for different effects in animals with the estimated median human body burden derived from the analyses of human milk. The "margin of body burdens" at the NOAEL (NOAEL MoBB) were calculated by dividing the estimated animal body burden with the estimated median human body burden (EFSA, 2005). By comparing an overall body burden of 500 µg/kg bw at the NOAEL for the most sensitive effects in liver and thyroid in rats with an estimated median human body burden for total NDL-PCB of about 48 µg/kg bw, a margin of body burdens (MoBB) was about 10 (EFSA, 2005). The MoBB was calculated on the basis of the median concentrations of NDL-PCBs in human milk, and some populations in Europe may have considerably higher body burdens (EFSA, 2005).

The RIVM has set a TDI at 10 ng/kg bw/day for the six indicator PCBs considering that the 6 indicator PCBs account for almost 50% of all congeners present (209 PCBs). This value was also adopted by AFSSA (2007) and VKM (VitensKapskomiteen for Mattrygghet, Norwegian Scientific Committee for Food Safety (2008). It is important to note that their opinion is focused on toxicological data coming from the exposure to mixture of PCBs thus, not on individual dl-PCBs. Therefore, some of the observed adverse effects are probably also related to the presence of DL-PCBs.

Occurrence in food

Goscinny et al. (2012) have analyzed the six indicator NDL-PCB (# 28, 52, 101, 138, 153, and 180) in composite samples of food from the Belgian market collected in 2008. In term of PCB profiles, the most prevalent congener is PCB 138, detected in 39 of 40 samples analyzed. The second most commonly detected congener is PCB 153, detected in 34 of 40 samples analyzed. The fishery products are the dominating food group in terms of level of contamination. The ranking of concentrations levels based on fresh weight are fish and fishery products > dairy products > miscellaneous products > meat > eggs.

EFSA (2010) has collected a total of 12,563 food and feed samples in the period 1995 - 2008 from 18 EU Member States for the analysis of the occurrence of the six indicator NDL-PCBs (# 28, 52, 101, 138, 153, and 180) and other NDL-PCBs. PCB-153 and PCB-138 were the most commonly detected congeners. In food, the highest mean contamination level was observed in fish and fish derived products followed by eggs, milk and their products, and meat and meat products from terrestrial animals. The lowest contamination was observed in foods of plant origin.

The Scientific Panel on Contaminants in the Food Chain of EFSA (CONTAM Panel) noted in its Scientific Opinion related to the presence of NDL-PCBs in feed and food that the sum of the six indicator PCBs represented about 50% of the total NDL-PCBs in food.
More than 90% of the NDL-PCBs exposure in the general population is via food.

NDL-PCB were detected in all samples of Belgian human milk collected in 2006 during the fourth World Health Organization Human biomonitoring campaigns (Colles et al., 2008). Median concentration of the sum of six markers PCB was 112.9 ng/g lipid base. The sum of six marker PCBs in the pooled sample was 80.1 ng/g lipid base, which is comparable to recent findings in Sweden (78.1 ng/g lipid base) and Greece (94.4 ng/g lipid base). Over the five years, level of markers PCB in human milk decreased.

Dietary exposure assessment

The dietary intake estimated by Goscinny et al. (2012) for the six indicator PCB of the mean Belgian population are 5.3, 5.72, and 6.05 ng/kg bw/day for lower, medium and upper bound scenario, respectively and, for the P95 of the population, are 10.8, 11.6 and 12.2 for lower, medium and upper bound scenario, respectively. The largest contribution to the mean intake comes from fishery products with 54.3 %, followed by dairy products with 28.5 %.

Voorspoels et al. (2008) have estimated PCB intake of the Belgian population between 404 and 535 ng/day for the sum of 23 PCB congeners (lower and upper bound) on basis on average daily food consumption. Fish is the major contributor to the total daily PCB intake (around 50%) due to the high PCB levels. Meat products account for around 20% of the total dietary intake of PCB, while dairy products and eggs contribute to a less degree (less than 20%).

Average exposure to the sum of the six NDL-PCB indicators was estimated in Europe by EFSA (2012) to be between 4.3 and 25.7 ng/kg bw/day and at the 95th percentile between 7.8 and 53.7 ng/kg bw/day, depending on the population group.
Upper bound mean NDL PCB indicators dietary exposure estimated recently by EFSA (2012) for the Belgian population are 11.8 ng/kg bw/day for toddlers in Flanders, 10.2 ng/kg bw/day for other children in Flanders, 4.5 ng/kg bw/day for adolescent, 5.4 ng/kg bw/day for adults, 6.6 ng/kg bw/day for elderly and 6.5 ng/kg bw/day for very elderly.
When comparing 2002-2004 data with data from 2008-2010, a decrease in the dietary exposure was observed in almost all (61/68) population groups in Europe, estimated to be between 2.0 and 75.6% (EFSA, 2012).

The major contributor to total exposure in Europe reported by EFSA (2012) was either the food category fish and seafood products or meat and meat products in the groups of adolescent, adult, elderly and very elderly. It was followed by milk and dairy products and animal and vegetable oils and fats. For some groups of infants, toddlers and other children, milk and dairy products and/or foods for infants and young children were the major contributors to total exposure. In the other children groups, the pattern was similar to exposure observed for groups of adolescents or adults of the same country.

Risk characterization

No health based guidance value for humans can be established for NDL-PCBs because simultaneous exposure to NDL-PCBs and dioxin-like compounds hampers the interpretation of the results of the toxicological and epidemiological studies, and the database on effects of individual NDL-PCB congeners is rather limited. There are however indications that subtle developmental effects, being caused by NDL-PCBs, DL-PCBs, or polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans alone, or in combination, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake in European countries. Because some individuals and some European (sub)-populations may be exposed to considerably higher average intakes, a continued effort to lower the levels of NDL-PCBs in food is warranted (EFSA, 2005).

Although no agreement has been reached on a ”safe acceptable daily intake” for indicator PCBs, Goscinny et al. (2012) used the guidance value of 10 ng/kg bw/day for risk characterization. The intake of the mean population is half this guidance value, contrary to the 99th percentile that has an intake around 1.5 times higher than 10 ng/kg bw/day.

Legislation

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. *Official Journal of the European Union*, L364, 5-24. Amended by 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. *Official Journal of the European Union*, L 320, 3.12.2011, p. 18–23.

Recommendations

The CONTAM panel of EFSA made the following recommendations (EFSA, 2010):

- The shortcomings in the occurrence data demonstrate the need for improvement of the analytical methodologies for determination of NDL-PCBs in feed, food and human samples. This particularly concerns harmonization of analytical requirements and performance criteria.
- Availability of certified reference materials for relevant matrices, such as fish oil, dairy products or human serum is a valuable means for laboratories to optimize their analytical methodologies. Because such certified reference materials are sparse, it is recommended that such materials are prepared and made available to analytical laboratories.
- Human samples from epidemiological studies should be collected and analyzed by comparable techniques to facilitate comparison between similar outcomes assessed in populations with different congener profiles. Emphasis should be placed on outcomes associated with NDL-PCBs exposure during early life stages.
- There is a need to study the contribution of exposure to NDL-PCBs especially during early life stage to adverse health effects. Further studies on individual NDL-PCBs should take into account contamination by dioxin-like compounds.
- A continuing effort to lower the levels of NDL-PCBs in food is warranted.

The EFSA made the following recommendations (EFSA, 2010):

- To improve the validity of any assessment of the presence of dioxins and PCBs in food and feed in Europe random testing and separate reporting of a sufficient number of samples in each food and feed group is important. Targeted sampling during contamination incidences should be clearly indicated as such in the reporting.

Recommendations of EFSA (2012)

- In order to improve the accuracy of the assessment of food contamination levels and exposure to dioxins and PCBs throughout Europe, it is important to clearly define the sampling strategy used both at the sample level and for the overall direction of monitoring programs. Further, results should be reported with a clear indication of the unit of expression of the result (on fat, whole weight or moisture basis), as it greatly impacts the estimation of the contamination levels of food and feed to dioxins and PCBs.
- Big discrepancies were observed concerning the limit of detection/quantification of NDL-PCBs as well as the unit of reporting of the results within the same food/feed group. These differences were interpreted to be a consequence of the different regulatory frameworks in existence for analyzing NDL-PCBs in food and feed at the time. The new regulations (EU) No 252/2012 and 278/2012 on the determination of the levels of dioxins and polychlorinated biphenyl in food and feed are a step forward. It is suggested to, as far as possible, measure dioxins and PCBs in food and feed samples according to the minimum analytical performance criteria applied as a cut-off in this report.

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