Opinion of the Panel on Contaminants of the Norwegian Scientific Committee for Food Safety

4 April 2008

Risk assessment of non dioxin-like PCBs in Norwegian food

ISBN: 978-82-8082-236-9

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Acknowledgements

VKM wishes to acknowledge Christiane Kruse Fæste, Helle Katrine Knutsen and Jan Alexander for their valuable contribution to this opinion.

SUMMARY

The European Commission is going to establish maximum levels for non-dioxin-like PCBs (NDL-PCBs) in food. To ensure a good risk management of NDL-PCBs in food as well as a scientific basis for their ongoing work on NDL-PCBs in EU, the Norwegian Food Safety Authority (Mattilsynet) has asked the Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) to comment on the EFSA report on NDL-PCBs in food and feed. The request has been answered by VKM Scientific Panel on Contaminants (Panel 5).

Dietary PCB-exposure involves both dioxin-like PCBs (DL-PCBs) and NDL-PCBs. Panel 5 has evaluated whether the TWI set for dioxins and DL-PCBs also will protect consumers against toxic effects that may arise after dietary exposure to NDL-PCBs. Panel 5 found that the TWI at 14 pg TEQ/kg body weight/week set for dioxins and DL-PCBs will generally also protect against adverse effects that may arise from dietary exposure to total PCB, including NDL-PCBs, given the present composition and levels of dioxins, DL-PCBs and NDL-PCBs in Norwegian food.

Information about the total content of NDL-PCBs (ΣNDL-PCBs) including all or many of the 195 possible congeners is limited. The sum of a few NDL-PCBs, referred to as indicator PCBs like ΣPCB_6 (28, 52, 101, 138, 153, 180) or ΣPCB_7 (ΣPCB_6 + congener 118), is more often published. In different food products ΣPCB_6 constitutes 38-59% of the different PCBs measured, on average 53%. PCB153 is the most abundant congener in ΣPCB_6, constituting on average 33%. PCB138 was the second most abundant congener contributing on average 29%. In most food samples, the ΣPCB_7 fraction was 65% or more. PCB118 constitutes on average 15% of ΣPCB_7.

The available data support the estimation made by EFSA that the contribution of ΣPCB_6 to total NDL-PCBs in foods is significant (about 50%).

Overall, there is high correlation between NDL-PCBs and DL-PCBs and between sum of DL-PCBs and dioxins in Norwegian foods. This is also reflected by the linear relationship between calculated dietary intake of dioxins and DL-PCBs on one hand and NDL-PCBs (ΣPCB_6) on the other hand.

There seems to be no general simple quantitative relationship between ΣPCB_7 or PCB153 and dioxins and DL-PCBs in Norwegian foods, since the slope in linear regressions vary between different foods. More data is needed in order to investigate quantitative relationship between DL-PCBs and NDL-PCBs in single foods in order to predict concentration of dioxin-like compounds from the concentration of NDL-PCBs.

$\Sigma PCB_{6\ \mathrm{or}\ 7}$ or possibly just PCB153 might be used as an indicator for the total concentration of NDL-PCBs. Panel 5 is, however, of the opinion that at least ΣPCB_6 should be measured in foods to ensure that possible changes in concentration of the individual congeners over time are registered. Panel 5 is not aware of that other PCB congeners occur in substantial amounts or have toxicological profiles that make it necessary to include them in monitoring programs.

SAMMENDRAG

Den europeiske kommisjonen skal fastsette grenseverdier for såkalte ikke-dioksinliknende PCB i mat. Dette er PCB-forbindelser som har ulik virkningsmekanisme enn de allerede regulerte dioksinliknende PCB. For å sikre god håndtering av disse forbindelsene i mat, samt gi Mattilsynet en vitenskapelig basis for det pågående regelverksarbeidet med ikke-dioksinliknende PCB i EU har Mattilsynet bedt Vitenskapskomiteen for mattrygghet (VKM) om å kommentere på en rapport fra EFSA om ikke-dioksinliknende PCB i mat og fôr. Oppdraget er besvart av VKMs faggruppe for forurensninger, naturlige gifter og legemiddelrester (Faggruppe 5).

Eksponering for PCB fra maten involverer en blanding av dioksinliknende PCB og ikke-dioksinliknende PCB. Faggruppe 5 har vurdert om tolerabelt ukentlig inntak (TWI) fastsatt for dioksiner og dioksinliknende PCB også vil beskytte mot toksiske effekter fra inntak av ikke-dioksinliknende PCB. Faggruppe 5 finner at TWI på 14 pg TE per kg kroppsvekt for dioksiner og ikke dioksinliknende PCB også vil beskytte mot effekter som kan oppstå etter eksponering for all PCB, inkludert de med ikke-dioksinliknende virkning, gitt dagens sammensetning og nivåer av dioksiner, dioksinliknende PCB og ikke-dioksinliknende PCB i norsk mat.

Informasjon om totalinnholdet av ikke-dioksinliknende PCB som inkluderer alle eller mange av de 195 mulige forbindelsene er begrenset. Data om summen av noen få ikke-dioksinliknende PCB, omtalt som indikator-PCB, slik som ΣPCB_6 (28, 52, 101, 138, 153, 180) eller ΣPCB_7 (ΣPCB_6 + PCB118) er mer vanlig å finne i litteraturen. I forskjellige matvaregrupper utgjør ΣPCB_6 mellom 38 og 59 % av PCB-forbindelsene som er målt, gjennomsnittlig 53 %. PCB153 er den viktigste forbindelsen blant de som inngår i ΣPCB_6, og står i gjennomsnitt for 33 %. I de fleste matvareprøvene utgjør ΣPCB_7 65 % eller mer av PCB-forbindelsene som er målt. PCB118 bidrar i gjennomsnitt med 15 % av ΣPCB_7.

De tilgjenglige dataene støtter beregningene foretatt av EFSA som viser at bidraget av forbindelsene som inngår i ΣPCB_6 i forholdt til total mengden av ikke-dioksinliknende PCB er betydelig (om lag 50 %). Samlet sett er det høy korrelasjon mellom de ikke-dioksinliknende PCB og de dioksinliknende PCB og summen av dioksinliknende PCB og dioksiner i norsk mat. Dette gjenspeiles i det lineære forholdet mellom beregnet daglig inntak av dioksiner og dioksinliknende PCB og ikke-dioksinliknende PCB (ΣPCB_6).

Det ser ikke ut til at det er noen generelle, enkle, kvantitative sammenhenger mellom ΣPCB_7 eller PCB153 og dioksiner og dioksinliknende PCB i norske matvarer, siden stigningen på linjen i de lineære regresjonene varierer for de forskjellige matvaregruppene. For å kunne forutsi konsentrasjoner av dioksinliknende forbindelser fra målte konsentrasjoner av ikke-dioksinliknende PCB i mat, er det nødvendig med mer data for å kunne undersøke om det finnes kvantitative sammenhenger mellom dioksinliknende PCB og ikke-dioksinliknende PCB.

$\Sigma PCB_{6\text{ eller }7}$, eller muligens bare PCB153 kan brukes som indikator for total mengde av ikke-dioksinliknende PCB. Faggruppe 5 er forøvrig av den oppfattning at i det minste ΣPCB_6 bør måles regelmessig i mat for å sikre at mulige forandringer i konsentrasjoner av de individuelle PCB-forbindelsene over tid registreres. Faggruppe 5 kjenner ikke til at det finnes andre PCB-forbindelser som forkommer i tilstrekkelige mengder og som har toksikologiske egenskaper som gjør at de bør inkluderes i overvåkningsprogrammene.

BACKGROUND

The European Food Safety Authority (EFSA) published in November 2005 a risk assessment on non-dioxin-like PCBs (NDL-PCBs) in food and feed (*Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to the presence of non dioxin-like polychlorinated biphenyls (PCB)*).

EFSA has not established a tolerable daily intake (TDI) for NDL-PCBs due to insufficient data for some of the NDL-PCB congeners, neither have other international bodies working with risk assessment of contaminants.

TERMS OF REFERENCE

The European Commission is going to establish maximum levels for NDL-PCBs in food. The Norwegian Food Safety Authority (Mattilsynet) has asked the Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) to comment on the EFSA report on NDL-PCBs in food and feed to ensure a good risk management of NDL-PCBs in food as well as a scientific basis for their ongoing work on NDL-PCBs in EU.

1) Health risk characterization on the intake of NDL-PCBs from food. Based on health risk assessment, is there a need to regulate NDL-PCBs in food when there are existing established maximum levels for dioxin-like PCBs (DL-PCBs)?

2) Which PCB indicators should be used for measuring the total content of NDL-PCBs in food? EFSA concludes that six NDL-PCBs (28, 52, 101, 138, 153, and 180), called PCB_6 contributes with 50% of the total NDL-PCBs level in food. Will the PCB_6 be representative for the PCB content in different Norwegian foods? Are there other congeners of NDL-PCBs that also should be measured in foods?

3) EFSA has studied the correlation between NDL-PCBs, TEQs from dioxin-like PCBs and total TEQs in some European food groups (vegetables, animals, fish) in general, but did not find any correlation. The Norwegian Food Safety Authority would like VKM to discuss the correlation between NDL-PCBs, dioxin-like PCBs, TEQs and total TEQs in a sample of different Norwegians food groups.

ASSESSMENT

1) ***Health risk characterization on the intake of non-dioxin-like PCB (NDL-PCBs) from food. Based on health risk assessment, is there a need to regulate NDL-PCBs in food when there are existing established maximum levels for dioxin-like PCBs (DL-PCBs)?***

Dietary PCB-exposure involves both DL-PCBs and NDL-PCBs. The optimal procedure for setting maximum levels for contaminants in food would be to base the maximum levels on health guidance levels, like tolerable daily/weekly intake (TDI, TWI). For the NDL-PCBs, there is no tolerable intake established by international bodies working with risk assessment of contaminants. For the dioxins and DL-PCBs the TWI at 14 pg TEQ/kg body weight/week was established by the Scientific Committee on Food (SCF) in 2001. The maximum level for dioxins and DL-PCBs for fish is generally 8 pg TEQ/g, while typical levels in Norwegian fish range from 0.05-3 pg TEQ/g (VKM, 2007a). A person (70 kg) eating one portion of 200 g fish a week with a concentration of dioxins and DL-PCBs of 8 pg TEQ/g would have an intake of nearly 23 pg TEQ/kg body weight, which is 1.6-fold the TWI. It can therefore be deduced that the current maximum level set for dioxins and DL-PCBs in food are not truly health based (VKM, 2004, TemaNord, 2008 "EU maximum levels for dioxins and dioxin-like PCBs - impact on exposure and food supply in the Nordic countries", *In Press*).

It is the opinion of VKM that, it is of interest to evaluate whether the TWI set for dioxins and DL-PCBs also protects against toxic effects that may arise after dietary exposure to NDL-PCBs.

The EFSA opinion on NDL-PCBs published in 2005 stated the following: "*The Panel noted that the comprehensive toxicological database on health effects of technical PCB mixtures was not suitable for the separate assessment of NDL-PCB, and that the human data on exposure to environmental mixtures containing PCB could not differentiate between the effects of NDL-PCB and DL-PCB and polychlorinated dibenzo-p-dioxins/polychlorinated dibenzofurans. Therefore, in its assessment the Panel concentrated on the toxicological information available for individual NDL-PCB congeners. Although the absence of mutagenicity indicates that a threshold approach is appropriate for the hazard characterisation, the toxicological database however, was considered to be too limited to allow the establishment of a health based guidance value for NDL-PCB. The Panel therefore decided to perform its health risk characterisation on the basis of a margin of exposure approach*". They concluded that the overall margin of the body burden (MoBB[1]) is about 10, based on median levels of NDL-PCBs in human milk samples in European countries (240 ng/g fat, corresponding to a body burden of 48 µg/kg body weight, assuming a body fat composition of 20%) and the NOAEL BB of the most sensitive effects in rats (500 µg/kg body weight, based on liver and thyroid toxicity). They noted that the observed effects in studies on NDL-PCBs might be explained by minor contamination (in the range of 0.1%) with potent dioxins and/or DL-PCBs. They also noted that subtle developmental effects, being caused by NDL-PCBs, DL-PCBs and/or dioxins, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake of these contaminants in European countries, which was estimated to range between 10-45 ng/kg body weight per day on average (EFSA, 2005).

Based on human studies involving perinatal exposure, benchmark dose calculations (5% incidence in neurological and immune effects in children) indicate a 95% lower confidence limit (BMDL) of approximately 1 µg PCB/g lipid in the body of the mother. Since effects of DL-PCBs could not be differentiated from those of NDL-PCBs, these studies were excluded as a basis for the evaluation of NDL-PCBs in EFSA's opinion on NDL-PCBs (EFSA, 2005). However, a recent study indicates that adverse effects on cognitive function are related to the total concentration of dioxins and PCBs rather than dioxins and DL-PCBs (Lee *et al.*, 2007). If the toxicokinetic model of the EFSA opinion is used (EFSA, 2005), a daily intake of 40 ng PCBs/kg body weight/day would result in a serum level of 1 µg PCB/g lipid. Assuming that the 6 indicator NDL-PCBs constitute about 50% of the BMDL value of 1 µg PCB/g lipid, this would correspond to 0.5 µg PCB_6/g lipid, and an intake of about 20 ng PCB_6/kg body weight per day.

Recently, the French Food Safety Agency (Afssa) published their opinion on the establishment of relevant maximum levels for NDL-PCBs in some foodstuffs (Afssa, 2007). In 2003, Afssa adopted a reference dose of 20 ng/kg body weight/day for all 209 PCB congeners. The reference dose was initially proposed by WHO at the "2nd PCB workshop" in Brno (Czech Republic, May 2002). Afssa has the following point of view in their opinion (Afssa, 2007):

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[1] BB: Total amount of substance in the body.

"The analysis of EFSA's 2005 opinion has not incited Afssa to question its opinion of 8 April 2003 on PCB. Afssa considers that, based on current knowledge, the most appropriate method for assessing PCB-related health risks is based on a tolerable daily intake (TDI) of 20 ng/kg b.w./d for all PCB, derived from neurological effects observed in monkeys.

The immunological effects observed at low doses only correspond to variations of biological parameters whose significance for human health is unclear (IPCS, 2003).

A TDI of 10 ng/kg b.w./d is adopted for the group of 6 or 7 PCB congeners most commonly found in food matrices (PCB-28, 52, 101, 118, 138, 153 and 180) as they account for almost 50% of all congeners present."

The tolerable daily intake of 10 ng PCB_6/kg body weight/day as established by Afssa, is half the intake value of 20 ng PCB_6/kg body weight/day that can be derived from the BMDL from human studies described in the EFSA opinion (see above). Based on these considerations, VKM's panel 5 decided to use 10 ng PCB_6/kg body weight per day as a reference value in its evaluation of the protective effect of the TWI for dioxins and DL-PCBs on NDL-PCBs in the diet of Norwegians.

The calculated dietary intake of PCB_6 versus the calculated dietary intake of dioxins and DL-PCBs for participants in the Norwegian Fish- and Game Study is shown in **Figure 1** (*H.E. Kvalem et al, manuscript in preparation)*. The 184 participants are not representative for the entire country, since 2/3 of them have been specially selected due to high consumption of food known to contain relatively high levels of different contaminants, including PCBs, in order to ensure a wide range of exposures. A very good correlation and linear relationship between exposure to dioxins and DL-PCBs and PCB_6 from the Norwegian diet were found. Furthermore, the majority of the participants who had a calculated intake of dioxins and DL-PCBs below TWI (red horizontal line) also had a calculated daily intake of PCB_6 that is below the reference value for PCB_6 (red vertical line). Only a few of the participants had a dietary intake that exceeded the reference value for PCB_6, but they were still below EU's TWI for dioxins and DL-PCBs. However, the excursions for those participants were marginal. When dietary intake will be calculated with 2005 TEFs, total TEQ will probably be approximately 15% lower (VKM, 2007b). As a consequence, a slightly higher proportion of the participants will have dietary exposure which is below the TWI for dioxins and DL-PCBs, but above the reference value for PCB_6 (10 ng PCB_6/ kg body weight per day). However, the excursions will still be marginal and below the 20 ng PCB_6/kg body weight/day derived from the BMDL for perinatal PCB exposure in humans.

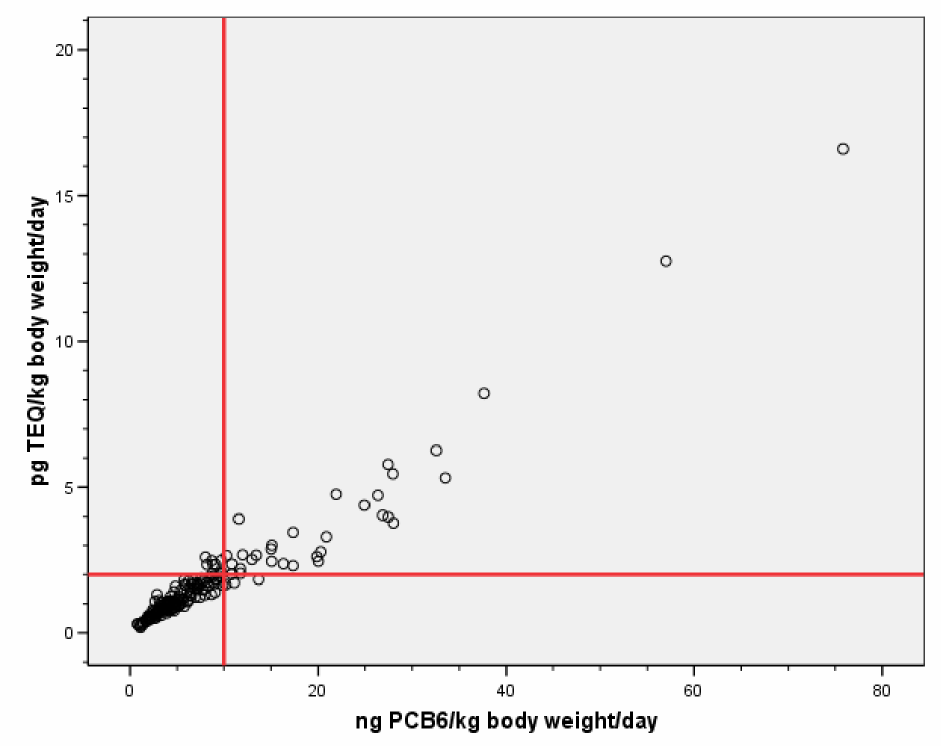


***Figure 1:** Dietary intake of PCB_6 versus dietary intake of dioxins and DL-PCBs (WHO 1998 TEFs) in the Norwegian Fish & Game study, part C.* Horizontal solid line: TDI for dioxins and DL-PCBs. Vertical line: reference value for PCB_6. *H.E. Kvalem et al., manuscript in preparation.*

In conclusion: In general, the TWI at 14 pg TEQ/kg body weight/week for dioxins and DL-PCBs will also protect against adverse effects that may arise from exposure to total PCB including NDL-PCBs given the present composition and levels of dioxins, DL-PCBs and NDL-PCBs in a general Norwegian diet.

2) ***Which PCB indicators should be used for measuring the total content of NDL-PCBs in food? EFSA concludes that six NDL-PCBs (28, 52, 101, 138, 153, and 180), called PCB$_6$ contributes with 50% of the total NDL-PCBs level in food. Will PCB$_6$ be representative for the PCB content in different Norwegian foods? Are there other congeners of NDL-PCBs that also should be measured in food?***

Information about the total content of NDL-PCBs (ΣNDL-PCBs) including all or many of the 195 possible congeners is rare. The sum of the regulatory relevant NDL-PCBs, referred to as ΣPCB$_6$ (28, 52, 101, 138, 153, 180) or ΣPCB$_7$ (ΣPCB$_6$ + congener 118), is more often published. Considering the available data, it is therefore difficult to evaluate the contribution of ΣPCB$_6$ to ΣNDL-PCBs in different foods and to estimate the importance of the respective congeners.

The different PCBs show a great variation in stability and occurrence. Environmental degradation half-lives vary considerably (Sinkkonen & Paasivirta, 2000) and great differences have been measured for the elimination (Ogura, 2004) (**Table 1**). Due to restrictions in use and discharge of PCBs and differences in environmental half-lives, the future relative abundance of the PCB congeners may be different from the present situation. PCB 153 has been shown to be the most prevalent PCB congener in biological tissues (Krogenaes *et al.*, 1998).

Table 1. *Estimated half-lives (years) of the PCB$_7$ congeners in sediment and in man.*

Congener	Structure[*]	$t_{1/2}$ [y] sediment[a]	$t_{1/2}$ [y] man[b]
PCB 28	244'-trichloro-	3	16
PCB 52	22'55'-tetra-	10	10
PCB 101	22'455'-penta-	10	11
PCB 118	23'44'5-penta-	7	28
PCB 138	22'344'5'-hexa-	19	27-36
PCB 153	22'44'55'-hexa-	19	29-41
PCB 180	22'344'55'-hepta-	38	65-67

[*] chloro-biphenyl
[a] Half-lives (years) in sediment from the Baltic environment based on Sinkkonen and Paasirvirta (2000)
[b] Half-lives (years) due to fecal excretion, in German male and female volunteers (Ogura, 2004)

Restrictions and bans on production and use of PCBs in the early eighties led to a relatively strong reduction of the PCB-inflow, so that the ratio of the individual NDL-PCBs in the environment might change over time according to their respective half-lives.

In monitoring programmes coordinated by the Norwegian Food Safety Authority in 2005 and 2006, 25 individual PCB-congeners were measured in a number of different foods. The analysis showed that the ΣPCB$_7$ accounted for about two-thirds of the ΣPCB$_{25}$ in almost all food products studied (**Figure 2**). ΣPCB$_6$ generally accounted for approximately 50% of ΣPCB$_{25}$ (**Table 2**).

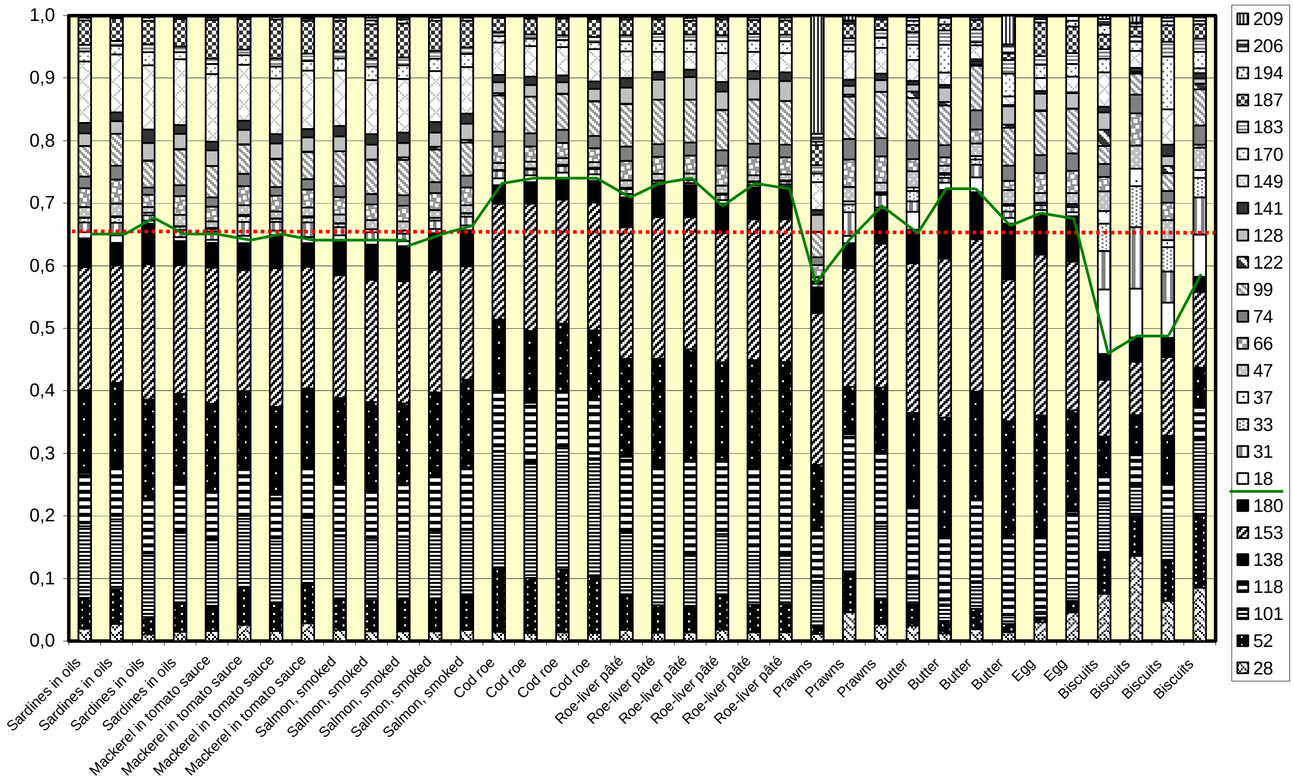


Figure 2. *Contribution of 25 individual PCB-congeners to*ΣPCB_{25} *measured in different food products from the Norwegian market. Dotted line: 66 % (two-thirds of* ΣPCB_{25}*); uninterrupted line: indicates* ΣPCB_7 *in each food product.*

The ratios $\Sigma PCB_6/\Sigma PCB_{25}$ and $\Sigma PCB_7/\Sigma PCB_{25}$ remained relatively constant even if the absolute amounts of ΣPCB_{25} differed widely as e.g. for roe-liver pâté and butter (**Table 2 and Figure 3**).

***Table 2.** Mean levels of ΣPCB_{25}, ΣPCB_7, and ΣPCB_6, and the calculated ratios $\Sigma PCB_7/\Sigma PCB_{25}$ and $\Sigma PCB_6/\Sigma PCB_{25}$ in different food products from the Norwegian marked (2005/06).*

food	ΣPCB_{25} [ng/g]	ΣPCB_7** [ng/g]	ΣPCB_6* [ng/g]	$\Sigma PCB_7/\Sigma PCB_{25}$ [%]	$\Sigma PCB_6/\Sigma PCB_{25}$ [%]
sardines in oil	19.8	12.9	11.2	65	57
salmon, smoked	12.5	8.00	6.91	64	56
cod roe	5.74	2.53	2.18	44	38
mackerel in tomato sauce	7.77	4.97	4.38	64	56
prawns	0.62	0.37	0.31	60	51
roe-liver pâté	57.8	41.8	33.9	72	59
roe-liver pâté	66.2	47.4	38.7	72	58
butter	2.54	1.78	1.48	70	58
biscuits	0.16	0.08	0.07	50	44
egg	0.76	0.52	0.43	68	56

* ΣPCB_6: PCB28 + PCB52 + PCB101 + PCB139 + PCB 153 + PCB180
** ΣPCB_7: ΣPCB_6 + PCB118

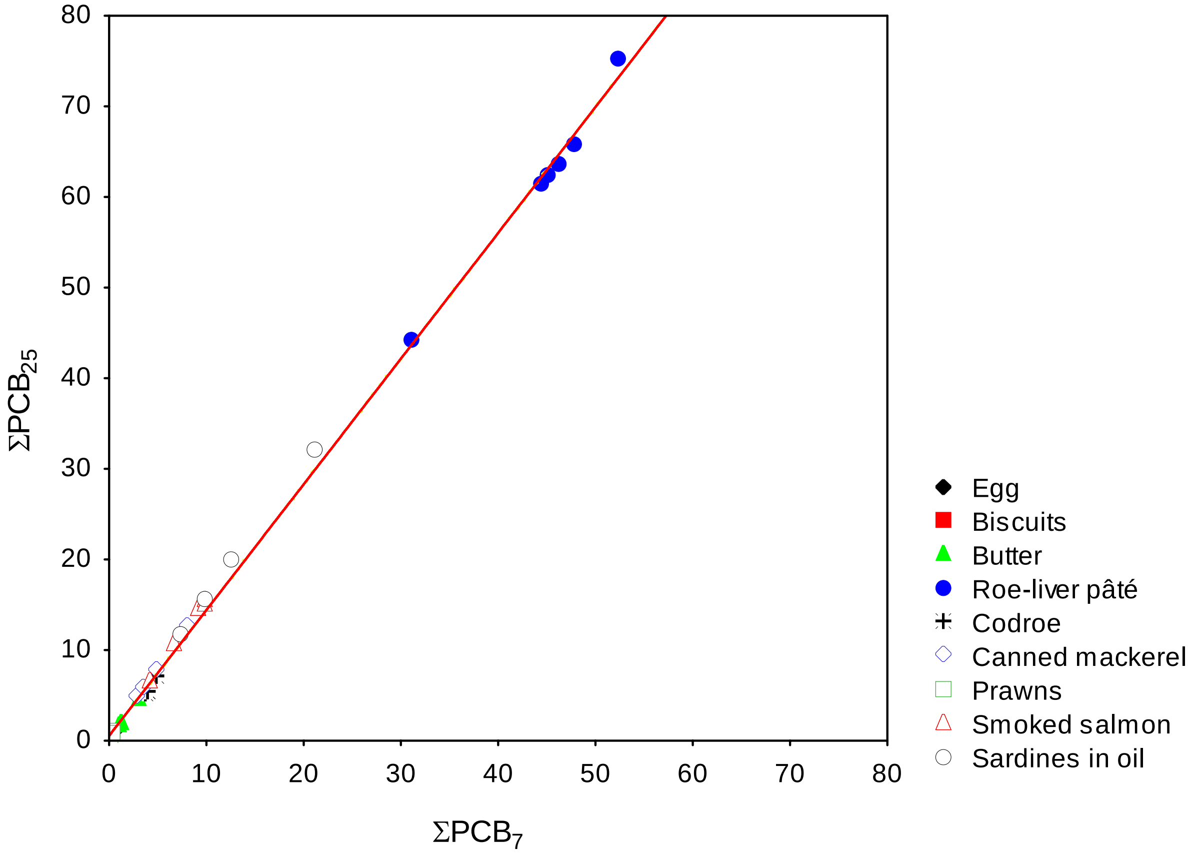


***Figure 3**. Correlation between levels of ΣPCB_{25} (same food samples as presented in Figure 2, levels given in ng/g) and ΣPCB_7 measured in different food products from the Norwegian market. ΣPCB_{25} = 0.53 + 1.39(PCB_7). R^2 = 0.999.*

The contribution of the individual congeners to ΣPCB_6, and the contribution of PCB118 to ΣPCB_7 in food samples from the Norwegian monitoring programme are shown in **Table 3**.

PCB153 was the most abundant congener, constituting 15-50% of these six indicator NDL-PCBs depending on the food type, with a mean of about 33%. PCB138 was the second most abundant congener contributing on average 29% (**Table 3**).

It can be seen that the respective foods were quite differently contaminated, with relatively low concentration of ΣPCB_6 in non-fish products and low-fat fish, whereas the highest levels were found in cod liver, fish oil, roe-liver pâté and pollack.

As mentioned before, it has been common to calculate ΣPCB_7 in Norwegian food samples, and often the individual congener composition is not available. ΣPCB_7 consists of ΣPCB_6 plus PCB118, which has a TEF-factor of 0.0001 (Van den Berg *et al.*, 1998)[2]. PCB118 constitutes 10-26% of ΣPCB_7, and on average 15% (**Table 3)**. PCB118 constitutes approximately 60% of the sum of DL-PCBs when they are expressed as ng/g (data not shown). The DL-PCBs constitute approximately 6% of PCB_{36} (PCB_{25} + 11 DL-PCBs).

[2] In the revised WHO-TEF from 2005, the TEF for PCB118 is reduced to 0.00003. WHO TEF values from 1998 should still be used until the next revision of the EU Regulation on maximum levels for dioxins and DL-PCBs in food. The revision will take place by the end of 2008.

Table 3. *Percentage of the six indicator PCBs relative to ΣPCB_6 and PCB118 relative to ΣPCB_7 in different food products from the Norwegian marked in 2005 and 2006.*

food	n	PCB28 /ΣPCB$_6$ [%]	PCB52 /ΣPCB$_6$ [%]	PCB101 /ΣPCB$_6$ [%]	PCB138 /ΣPCB$_6$ [%]	PCB153 /ΣPCB$_6$ [%]	PCB180 /ΣPCB$_6$ [%]	PCB118 /ΣPCB$_7$ [%]
trout, f*	15	2.7	11	22	28	31	5.7	14
trout	3	3.6	5.2	15	33	32	11	13
sardine, oil	4	2.8	7.2	19	26	36	8.9	13
herring	7	3.9	12	18	33	29	3.9	13
halibut	30	1.8	5.9	14	31	38	9.6	14
halibut, f*	5	2.0	6.0	17	32	32	11	13
salmon	4	3.6	10	16	30	31	8.9	13
salmon, f*	24	3.5	7.9	18	32	31	8.0	13
salmon, s*	5	2.9	9.3	18	25	35	10	14
cod	6	8.2	12	12	26	24	17	17
cod liver	14	1.5	4.4	11	32	39	12	16
cod roe	8	2.6	14	28	20	30	6.1	14
roe-liver pâté	6	2.6	8.0	15	29	38	8.6	19
pollack	2	7.5	15	21	26	26	4.2	17
mackerel	8	2.7	7.6	16	33	33	7.9	13
mackerel,ts	4	3.5	8.5	17	24	37	7.7	12
haddock	2	10	15	15	20	15	25	13
redfish	1	3.3	12	22	27	27	8.3	18
sprat	2	3.5	5.5	16	34	33	8.1	12
crab	8	2.6	2.6	8.1	36	42	8.1	17
lobster	3	2.6	2.6	1.7	34	50	9.7	13
prawns	5	6.5	9.5	17	19	33	15	15
fish oil	15	1.2	2.1	7.1	36	33	21	10
seal oil	5	5.7	13	4.5	37	18	21	26
butter	4	2.7	4.1	5.2	31	42	15	17
biscuits	4	21	17	18	14	23	8.2	10
egg	2	6.4	2.1	3.0	32	45	12	18
beef	4	4.8	6.1	5.3	22	49	14	13
Mean (median)		4 (3)	8 (8)	14 (16)	29 (31)	33 (33)	11 (9)	15 (14)
Min-Max		1.2-21	2.1-17	1.7-28	14-37	15-50	3.9-25	10-26

f* : farmed; s*: smoked; ts: tomato sauce

A good correlation between PCB153 and ΣPCB$_{25}$, as well as between PCB153 and ΣPCB$_6$ became evident when a linear regression was performed with the food data presented in **Figure 2** (**Figure 4a and 4b**).

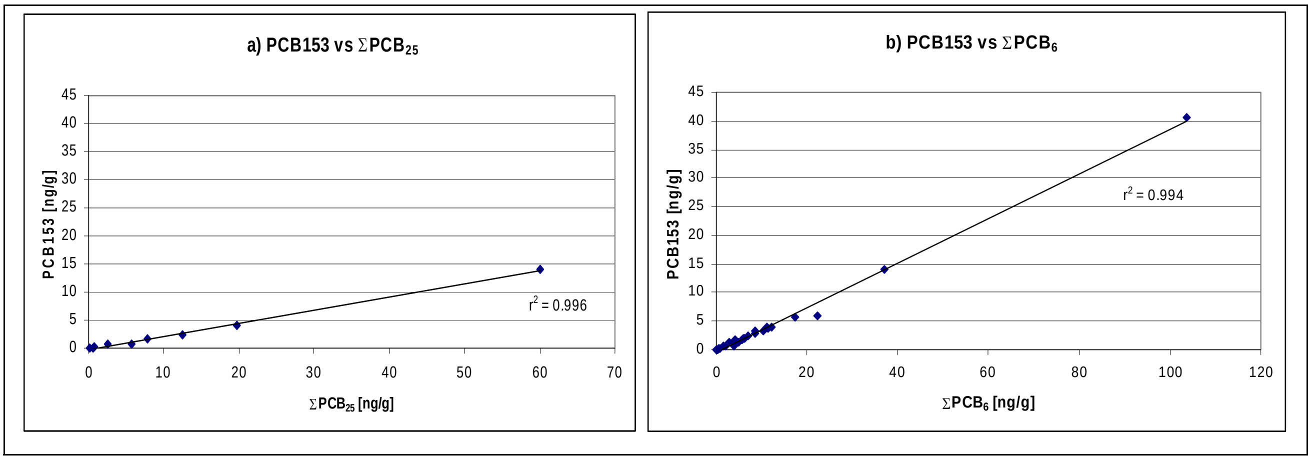


Figure 4a and 4b*. Linear correlations in Norwegian food products, same data as presented in* ***Figure 2*** *(9 different food commodities):* ***a)*** *PCB153 versus ΣPCB$_{25}$ and* ***b)*** *PCB153 versus ΣPCB$_6$.*

Food from contaminated area

A similar composition of ΣPCB$_6$ or sum ΣPCB$_7$ can be seen in seafood samples collected in areas with local contamination influences. In a summary report, the absolute concentrations of the respective congeners and of ΣPCB$_6$ were dependent on the locality where the samples of cod liver were collected (Økland, 2006). Nevertheless, the ratios of congener/ΣPCB$_{6 \text{ or } 7}$ were almost constant and independent of the fishing ground for all 7 PCBs analysed. There were no differences, if ΣPCB$_6$ or ΣPCB$_7$ was chosen as reference value. PCB153 showed consistently the highest concentration of the congeners, followed by PCB138 (**Table 4**).

Table 4. *Percentage of individual congeners to ΣPCB$_7$ and ΣPCB$_6$ in cod liver (wet weight) from different marine environments in Norway (1994- 2005).*

l[a]	n[b]	ΣPCB$_7$ ΣPCB$_6$ [µg/kg]	PCB28 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB52 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB101 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB118 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB138 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB153 /ΣPCB$_7$ /ΣPCB$_6$ [%]	PCB180 /ΣPCB$_7$ /ΣPCB$_6$ [%]
A	59	1754 ±1222	1.0	2.4	9.2	17	25	34	11
		1361 ± 996	1.2	3.0	12		33	44	14
B	54	1387 ±1353	1.3	3.3	9.4	17	25	36	11
		1154 ±1084	1.6	4.3	12		32	46	14
C	5	370 ±182	1.2	3.5	9.7	16	27	34	8.7
		310 ±144	1.4	4.2	12		32	41	10

l[a]: location: A: near cities/villages or heavy industry, B: inner fjords, near small settlements/small industry, C: on the coastline
n[b]: number of samples with complete data set (ΣPCBs and individual congeners)

In conclusion: Summarizing the data presented, it can be concluded that ΣPCB_6 constitutes 38-59% of the different PCBs measured, on average 53%. However, the individual six PCB-congeners (ΣPCB_6) contribute differently. PCB153 is the most abundant congener in ΣPCB_6, constituting on average 33%. PCB138 was the second most abundant congener contributing on average 29%. In most food samples, the ΣPCB_7 fraction was 65% or more. PCB118 constitutes on average 15% of ΣPCB_7.

To our knowledge, no other PCB congeners occur in substantial amounts or have toxicological profiles that make it necessary to include them in monitoring programs.

The available data support the estimation made by EFSA that the contribution of ΣPCB_6 to the total NDL-PCBs in foods is significant (about 50%).

$\Sigma PCB_{6\ or\ 7}$ or possibly just PCB153 might be used as an indicator for the total content of NDL-PCBs. However, panel 5 is of the opinion that, at least ΣPCB_6 should be measured in foods to ensure that possible changes in relative concentration of the individual congeners over time are registered.

3) ***EFSA has studied the correlation between NDL-PCBs, TEQs from dioxin-like PCBs and total TEQs in some European food groups (vegetables, animals, fish) in general, but did not find any correlation. The Norwegian Food Safety Authority would like VKM to discuss the correlation between NDL-PCBs, dioxin-like PCBs, TEQs and total TEQs in a sample of different Norwegians food groups.***

The present calculations are based on a database at the Norwegian Institute of Public Health containing data on dioxins, DL-PCBs and NDL-PCBs analyzed in the same sample of Norwegian food items. Data are based on analyses performed for the Norwegian Food Safety Authority in different laboratories, supplemented with some data from National Institute of Nutrition and Seafood Research on concentrations in fish.

Correlations are calculated for some food items for which there were several samples where dioxins, mono-*ortho* PCBs, non-*ortho* PCBs and ΣPCB_7 (PCB 28, 52, 101, 118, 138, 153, 180) had been determined. All calculations are based on lower bound levels. It has been common to register ΣPCB_7, which includes the DL-PCB 118, in Norway. PCB118 constituted approximately 13-18% of ΣPCB_7 in food samples included here.

The occurrence data for dioxins and PCBs in herring and farmed salmon and the data on PCBs in cod liver oil were suitable for performing parametric correlation analysis. Consequently, both parametric and non-parametric correlations are presented for herring, farmed salmon, and cod liver oil (only for PCBs) and non-parametric correlations are presented for the other food commodities (**Table 5**).

***Table 5**: Parametric (Pearson) and non-parametric (Spearman's) correlation coefficients (R) between PCB 7 (ng/g) versus DL-PCBs (pg TEQ/g), dioxins (pg TEQ/g) and PCB 153 (ng/g) in different foods.*

	n		R non-*ortho* PCBs	R mono-*ortho* PCBs	R sum DL-PCBs	R dioxins	R Dioxins + DL-PCBs	R PCB 153
Eggs	11	Non-parametric	0,373	0,891**	0,755	0,600	0,764**	0,882**
Dairy products	12	Non-parametric	0,410	0,734**	0,853**	-0,189	0,811**	0,986**
Beef	4	Non-parametric	0,400	0,800	0,800	0,000	0,400	0,800
Halibut	19	Non-parametric	0,960**	0,972**	0,961**	0,925**	0,968**	0,993
Herring[1]	16	Parametric	0.583*	0.176	0.499*	0.549*	0.560*	0.949**
		Non-parametric	0,576**	0,099	0,338	0,550*	0,497	0,965**
Farmed salmon[1]	42	Parametric	0.768**	0.895**	0.831**	0.770**	0.834**	0.984**
		Non-parametric	0,763**	0,900**	0,815**	0,774**	0,818**	0,987**
Cod liver oil	5	Parametric	0.935*	0.983**	0.982**		0.971**	0.997**
		Non-parametric	0,900*	1,000**	1,000**	-0,224	1,000**	1,000**

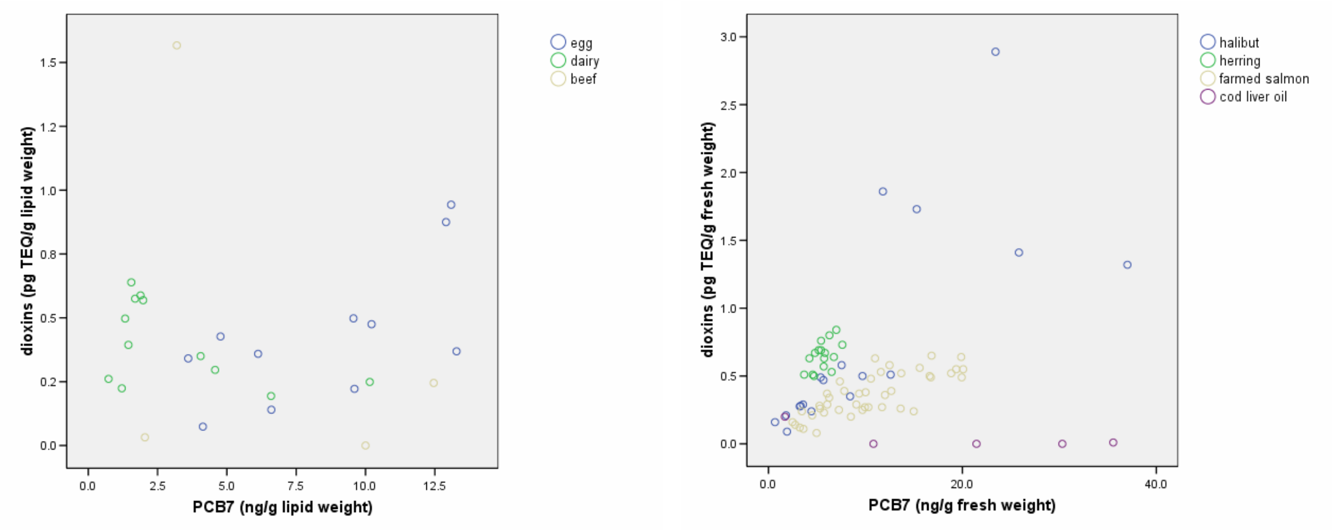
*significant ay the 0.05 level
**significant at the 0.01 level
[1]Only data from herring, farmed salmon and cod liver oil could be regarded as normally distributed and suitable for parametric correlation analysis.

Overall, there is high correlation between NDL-PCBs and DL-PCBs and between sum of DL-PCBs and dioxins in Norwegian foods. Correlations are significant for eggs, dairy products, halibut, herring, farmed salmon and cod liver oil, but not for beef. This may be due to a low number of beef samples with complete analysis of dioxins, non-*ortho* PCBs, and mono-*ortho* PCBs. Correlations are higher for mono-*ortho* PCBs than for non-*ortho* PCBs and not significant for dioxins alone in eggs, dairy products, beef and cod liver oil. PCB153 shows consistently high correlation with ΣPCB_7, reflecting that PCB153 is a major constituent of ΣPCB_7.

Figures 5-6 show scatter plots between ΣPCB_7 and dioxins and DL-PCBs in the food samples. In eggs, dairy, beef (**Figure 5A**) and cod liver oil (**Figure 5B**) there is no increasing trend in dioxin-concentration with increasing ΣPCB_7 concentration. In halibut, farmed salmon and herring (**Figure 5B**) there is an increasing trend in dioxin concentration with increasing ΣPCB_7 concentration. For all the investigated food items, there is an increasing trend in concentration of DL-PCBs with increasing ΣPCB_7 concentration (**Figure 6**). The slope of the increasing trends seems to be different in different food items, indicating that the level of ΣPCB_7 in one food item can probably not be used to predict the level of DL-PCBs or dioxins in another food item.

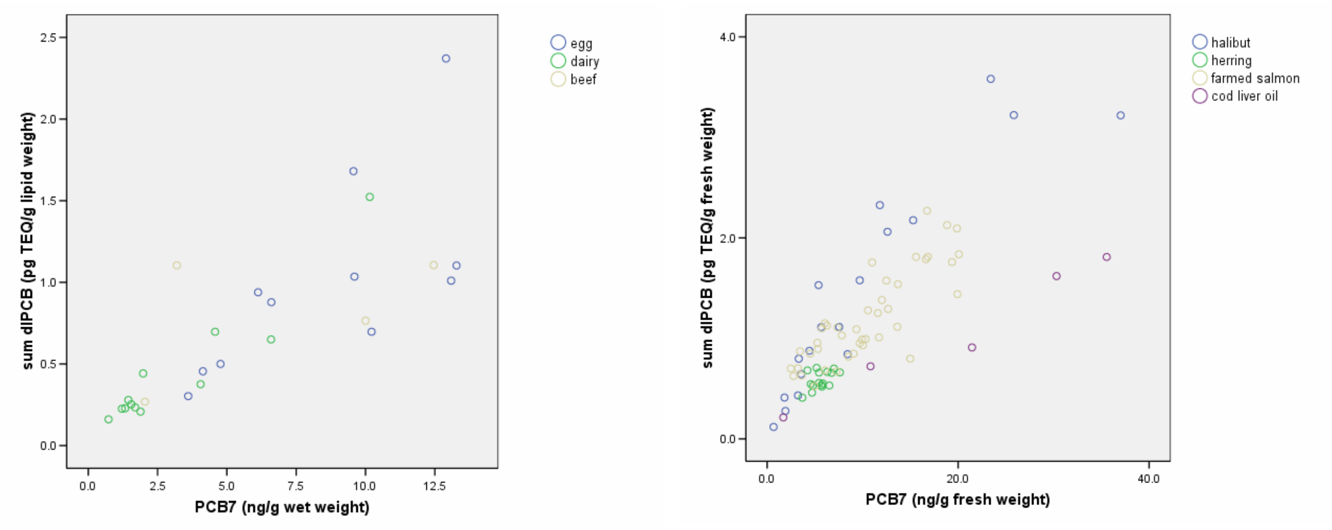
It would have been time- and resource saving to be able to predict the concentration of dioxins and DL-PCBs from the ΣPCB_7 concentration in food. However, the criteria for performing linear regression between ΣPCB_7 and sum of dioxins and DL-PCBs are fulfilled only in herring, farmed salmon and cod liver oil. This may partly be explained by too few samples. However, for halibut the number of samples is high, but, there seems to be additional reasons for variations, e.g. age/size of the fish. Even after exclusion of the highest observation (124 ng ΣPCB_7/g fresh weight), the criteria for performing linear regression were violated.

In **Figure 6** the linear regression and 95% CI for ΣPCB_7 versus sum of dioxins and DL-PCBs are shown. The 95% CI for the three regressions are quite similar. However, the R^2 is low for herring and this should be interpreted with care.



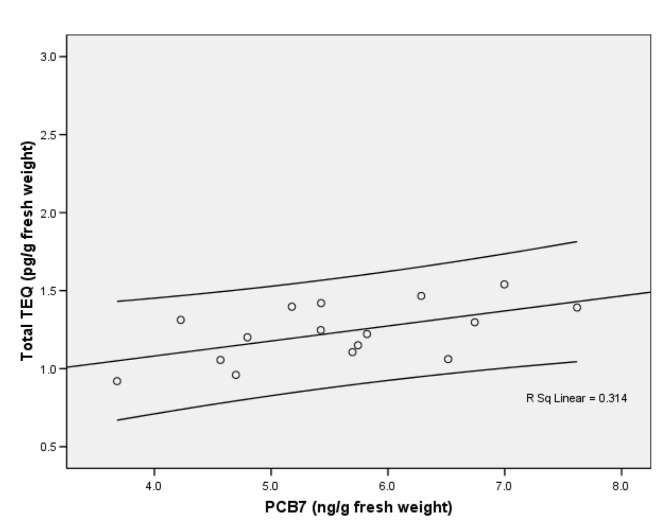
A **B**

***Figure 5**. **A**: ΣPCB$_7$ (ng/g lipid weight) versus sum dioxins (dioxins and furans, pg TEQ/g lipid weight) in eggs, dairy products and beef. TEQ calculations are based on the 1998 WHO TEF values. **B**: ΣPCB$_7$ (ng/g fresh weight) vs. sum dioxins (pg TEQ/g fresh weight) in halibut, herring, farmed salmon and cod liver oil. Data on one halibut with very high concentration of ΣPCB$_7$, dioxins and DL-PCBs has been omitted. TEQ calculations are based on the 1998 WHO TEF values.*

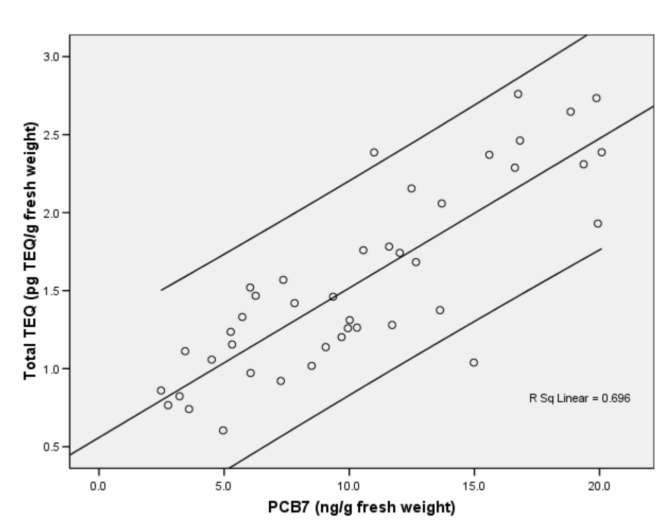


A **B**

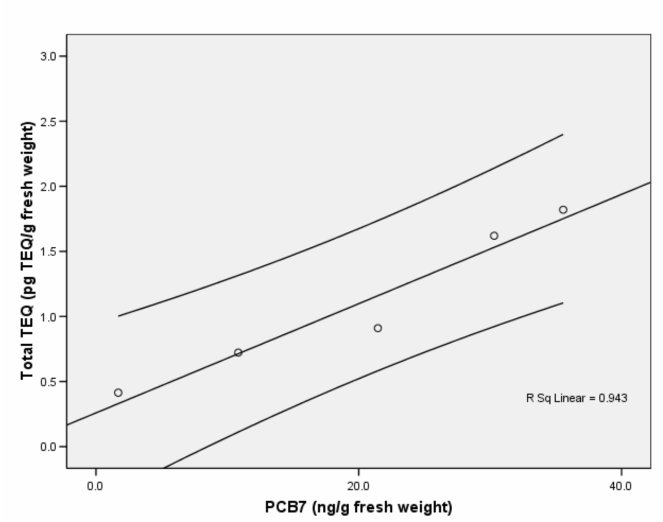
***Figure 6**: **A:** ΣPCB$_7$ (ng/g lipid weight) versus sum DL-PCBs (mono-*ortho* PCBs and non-*ortho* PCBs, pg TEQ/g lipid weight) in eggs, dairy products and beef. TEQ calculations are based on the 1998 WHO TEF values. **B:** ΣPCB$_7$ (ng/g fresh weight) vs. sum DL-PCBs (pg TEQ/g fresh weight) in halibut, herring, farmed salmon and cod liver oil. Data from one halibut sample with very high concentration of ΣPCB$_7$, dioxins and DL-PCBs has been omitted. TEQ calculations are based on the 1998 WHO TEF values.*



A Herring



B Farmed salmon



C Cod liver oil

Figure 7: *Linear regression and 95% CI of* ΣPCB_7 *versus sum dioxins in herring (**A**), farmed salmon (B) and cod liver oil (**C**).* R^2 *are indicated in each figure.*

It would be economically beneficial to only analyze ΣPCB_7 in farmed salmon, herring and cod liver oil instead of dioxins and DL-PCBs. However, the level in farmed fish is dependent on the congener profile and contamination level in feed, and a linear relationship between ΣPCB_7 and sum DL-PCBs may no more be valid if the source of marine oil in feed is changed. The linear relationship between ΣPCB_7 and total TEQs in cod liver oil is dependent on the refining of the oil. If other refining methods that are less efficient for removal of DL-PCBs are used, the relationship would probably no longer be valid. It seems possible to use ΣPCB_7 as an indicator of total TEQ only in herring. However, such analysis may not be able to differentiate between herring from uncontaminated and specific dioxin-contaminated areas.

Furthermore, congener composition in food changes with time, since background contamination with dioxins and PCBs is declining; the more persistent congeners will constitute a higher percentage of the total. This will complicate the future interpretation of results from PCB_7 analyses in food.

All together, there seems to be no general simple linear relationship between ΣPCB_7 and dioxins and DL-PCBs in Norwegian foods.

In conclusion: Overall, there is high correlation between NDL-PCBs and DL-PCBs and between sum of DL-PCBs and dioxins in Norwegian foods. This is also reflected by the linear relationship between calculated dietary intake of dioxins and DL-PCBs and NDL-PCBs (ΣPCB_6).

Correlations are higher between ΣPCB_7 and mono-*ortho* PCBs than between PCB_7 and non-*ortho* PCBs and not significant between ΣPCB_7 and dioxins alone in eggs, dairy products, beef and cod liver oil.

There seems to be no general simple quantitative relationship between ΣPCB_7 or PCB153 and dioxins and DL-PCBs in Norwegian foods, since the slopes in linear regressions vary between different foods. More data is necessary, in order to investigate quantitative relationship between DL-PCBs and NDL-PCBs in single foods in order to predict the concentration of dioxin-like compounds from the concentration of NDL-PCBs.

Congener composition in food changes with time. Background contamination with dioxins and PCBs is declining and the more persistent congeners will constitute a higher percentage of the total. This will complicate the future interpretation of calculations of DL-PCB concentrations from analysis of PCB_6 or PCB_7.

CONCLUSION

1*) Health risk characterization on the intake of NDL-PCBs from food. Based on health risk assessment, is there a need to regulate NDL-PCBs in food when there are existing established maximum levels (MLs) for dioxin-like PCBs (DL-PCBs)?*

The TWI at 14 pg TEQ/kg body weight/week for dioxins and DL-PCBs will generally also protect against adverse effects that may arise from dietary exposure to total PCB including NDL-PCBs given the present composition and levels of dioxins, DL-PCBs and NDL-PCBs in Norwegian food. Like the MLs for dioxins and DL-PCBs, the MLs for NDL-PCBs will probably be set at considerably higher levels than the current corresponding levels in Norwegian food, and thus will not be useful in risk assessment.

2) Which PCB indicator should be used for measuring the total content of NDL-PCBs in food? EFSA concludes that six NDL-PCBs (28, 52, 101, 138, 153, and 180), called PCB_6 contributes with 50% of the total NDL-PCBs level in food. Will the PCB_6 be representative for the PCB content in different Norwegian foods? Are there other congeners of NDL-PCBs that also should be measured in foods?

In different food products ΣPCB_6 constitutes 38-59% of the different PCBs measured, on average 53%. PCB153 is the most abundant congener in ΣPCB_6, constituting on average 33%. PCB138 was the second most abundant congener contributing on average 29%. In most food samples, the ΣPCB_7 fraction was 65% or more. PCB118 constitutes on average 15% of ΣPCB_7.

To our knowledge, no other PCB congeners occur in substantial amounts or have toxicological profiles that make it necessary to include them in monitoring programs.

The available data support the estimation made by EFSA that the contribution of ΣPCB_6 to total NDL-PCBs in foods is significant (about 50%).

$\Sigma PCB_{6 \text{ or } 7}$ or possibly just PCB153 might be used as an indicator for the total concentration of NDL-PCBs. Panel 5 is, however, of the opinion that at least ΣPCB_6 should be measured in foods to ensure that possible changes in concentration of the individual congeners over time are registered.

3) EFSA has studied the correlation between NDL-PCBs, dioxin-like PCBs TEQs and total TEQs in some European food groups (vegetables, animals, fish) in general, but did not find any correlation. The Norwegian Food Safety Authority would like VKM to discuss the correlation between NDL-PCBs, dioxin-like PCBs, TEQs and total TEQs in a sample of different Norwegians food groups.

Overall, there is high correlation between NDL-PCBs and DL-PCBs and between sum of DL-PCBs and dioxins in Norwegian foods. This is also reflected by the linear relationship between calculated dietary intake of dioxins and DL-PCBs and NDL-PCBs (ΣPCB_6).

There seems to be no general simple quantitative relationship between ΣPCB_7 or PCB-153 and dioxins and dioxin-like PCBs in Norwegian foods, since the slope in linear regressions vary between different foods. More data is needed in order to investigate quantitative relationship between DL-PCBs and NDL-PCBs in single foods in order to predict concentration of dioxin-like compounds from the concentration of NDL-PCBs.

Congener composition in food changes with time. Background contamination with dioxins and PCBs is declining and the more persistent congeners will constitute a higher percentage of the total. This will complicate the future interpretation of calculations of the concentration of DL-PCBs from concentrations of ΣPCB_6 or ΣPCB_7.

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