

Comments on proposed maximum levels for dioxin-like PCBs in food

*Panel on Contaminants
Norwegian Scientific Committee for Food Safety*

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Summary

The Norwegian Food Safety Authority has asked the Norwegian Scientific Committee for Food Safety for their comments on the EU proposed maximum levels (MLs) for dioxins and dioxin-like PCBs in food, and if the proposed maximum levels would affect exposure to the Norwegian population.

Due to a strict time schedule for the discussion of the proposed MLs for dioxin-like PCBs before a possible adoption by EU and since intake estimates have clearly indicated that fish is one of the food groups that contributes most to the overall exposure to dioxins and dioxin-like PCBs among Norwegians, the further discussion will for the time being focus on the proposed MLs for fish and fish oil only. Since the ML for fish is set on fresh weight basis, a high maximal level for dioxin-like PCBs may influence the intake of dioxin-like PCBs from fish in a much broader extent than a high ML in meat, where levels are set on fat weight basis. The same will apply for fish oils which are sold as products ready to eat.

It is important to keep the dietary exposure as low as possible due to possible negative health effects from exposure to dioxins and dioxin-like PCBs. Exposure estimates indicate that a considerable proportion of the Norwegian population has a dietary intake in excess of the tolerable intake. The aim should be to reduce the exposure to these contaminants.

The Norwegian Scientific Committee on Food Safety finds the proposed maximum levels for dioxin-like PCBs in fish and fish oil to be too high compared with the actual levels found in food. It is reason to believe that if the proposed MLs are made applicable the mean exposure to dioxin-like PCBs may increase among the Norwegians. The definition of lower maximum levels for farmed fish and lean fish than for other fish, as well as excluding unrefined fish oil for use as food supplements, would be prudent from a public health point of view and would more adequately protect the population from unnecessary exposure to dioxin-like PCBs.

1. Terms of reference

The Norwegian Food Safety Authority has asked the Norwegian Scientific Committee on Food Safety for their comments on the EU proposed maximum levels (MLs) for dioxins and dioxin-like PCBs in food, and if the proposed maximum levels would affect exposure to the Norwegian population.

The proposed MLs should be included in the Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs by the end of 2004.

2. Introduction

On May 30, 2001 the Scientific Committee on Food (SCF) adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food based on new scientific information which had become available since the adoption of the SCF opinion on this matter on November 22, 2000. A tolerable weekly intake (TWI) for dioxins and dioxin-like PCBs of 14 pg World Health Organisation (WHO)-toxic equivalent (TEQ)/kg bodyweight was established. Exposure estimates indicate that a considerable proportion of the Community population has a dietary intake in excess of the tolerable intake. Certain population groups in some countries could be at higher risk due to particular dietary habits (Commission Recommendation, 2002/201/EC).

The maximum levels established for foodstuffs by Commission Regulation (EC) No 466/2001 of March 8, 2001 setting maximum levels for certain contaminants in foodstuffs, as amended by Council Regulation (EC) No 2375/2001, are fixed at a strict but feasible level, while taking background contamination into account. These maximum levels should prevent unacceptably high exposure levels among the human population and the distribution of foodstuffs with an unacceptably high contamination (Council Regulation (EC) No 2375/2001).

It is further stated in the Regulation that all operators in the food and feed chain should continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food. Furthermore, the maximum levels applicable should be reviewed within a defined period of time with the objective to set lower maximum levels. An overall reduction of at least 25 % of the human exposure to dioxins should be achieved by the year 2006.

The MLs shall be reviewed for the first time by December 31, 2004 at the latest in the light of new data on the contamination levels of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set. The MLs shall be further reviewed by December 31, 2006 at the latest with the aim of significantly reducing the maximum levels and possibly laying down maximum levels for other foodstuffs.

All previous and new estimates of intake have clearly indicated that fish is one of the food groups that contribute most to the overall exposure to dioxins and dioxin-like PCBs among Norwegians. For the Norwegian population it is therefore important that levels of dioxin and dioxin-like PCBs are kept as low as possible in fish species that are commonly eaten. For the same reason The Norwegian Food Safety Authority has excluded fish from local areas contaminated with environmental contaminants (harbours, fjords) from the marked.

Due to a strict time schedule for the discussion of the proposed MLs for dioxin-like PCBs before a possible adoption by EU and since fish and fish products are very important food groups for the dioxin-like PCBs exposure among Norwegians, the further discussion will for the time being focus on the proposed MLs for fish and fish oil only. Since the ML for fish is set on fresh weight basis, a high maximum level for dioxin-like PCBs may influence the intake of dioxin-like PCBs from fish to a much broader extent than a high ML in meat, where levels are set on fat weight basis. The same will apply for fish oils which are sold as products ready to eat. The panel of contaminants in The Norwegian Scientific Committee on Food Safety plans to make a broader evaluation on the topics, including all food groups, before the end of 2006 when the EU Regulation should be reviewed with the aim of significantly reducing the maximum levels.

3. The proposed maximum levels and occurrence data in Norway

Table 1 shows the maximum levels (MLs) for dioxins laid down in Council Regulation (EC) No 2375/2001, the proposed MLs for dioxin-like PCBs and total WHO-TEQ by the European Commission in October 2004 and an overview of most of the Norwegian analytical data on dioxins and dioxin-like PCBs in fish and fish oil used for human consumption. The analytical results are from 1999-2004.

Table 1: Overview of Norwegian data on dioxins and dioxin-like PCBs. All data are reported as upper bound results and are expressed as pg TEQ/g wet weight for fish and as pg TEQ/g fat for fish oil.

FOOD	DIOXIN + FURANS pg (WHO-TEQ) /g		DIOXIN – LIKE PCB pg (WHO-TEQ) /g		TOTAL pg (WHO-TEQ) /g	
	ML proposed	Measured	ML proposed	Measured	ML proposed	Measured
5.2.1 Muscle meat of fish and fishery products and products thereof						
Farmed fish, salmon (n=37)	4	0.64	4	1.3	8	1.9
Wild fish/fish products (n=60)	4	0.52	4	0.57	8	1.02
<i>Atlantic halibut (3)</i>	4	3.1	4	5.1	8	8.2
<i>Cod (6)</i>	4	0.02	4	0.02	8	0.04
<i>Haddock (2)</i>	4	0.02	4	0.03	8	0.06
<i>Herring (4)</i>	4	0.76	4	0.72	8	1.5
<i>Mackerel (4)</i>	4	0.16	4	0.56	8	0.73
<i>Plaice (2)</i>	4	0.21	4	0.34	8	0.55
<i>Redfish (10)</i>	4	0.2	4	0.32	8	0.54
<i>Trout, freshwater (14)</i>	4	0.35	4	0.36	8	0.71
5.2.2. Liver and liver products originated from fish and fishery products						
Fish liver (n=16)	?	4.7	?	27	?	31
5.5. Oils and fats						
Marine oils (n=25)	2	0.48	8	2.0	10	2.5

In table 1, 5.2.1 a mean value for the content of dioxin and dioxin-like PCBs in wild fish and fish products (60 fish samples) is presented. However, such a mean value is highly influenced by the fish species that are included. A low mean value could camouflage some very high levels, if most of the samples are from lean fish. Further down in table 1, 5.2.1 some of the fish species included in the mean value are listed. Results for Atlantic halibut are high. Atlantic halibut is a fish species that can grow particularly old and large. Increasing age and weight often causes increased levels of dioxins and dioxin-like PCBs in fish. Other factors that affect the levels of dioxins and dioxin-like PCBs in wild fish include season, area of catch, and trophic position in the food chain. Although mean values of pooled samples are given in table 1 large variations in wild caught fish can be expected.

Fish

The proposed ML for fish does not take into account the huge variation seen in levels of dioxin and dioxin-like PCBs found in different fish species (Table 1 and Joint Report DG SANCO). Fish is not a homogeneous food group and the biological variation among fish species should therefore also be taken into account when setting MLs. Dioxins and dioxin-like PCBs accumulate in the fatty tissue in fish. This is reflected in the difference in levels found in fish species with different fat content when the analytical results is expressed on wet weight basis. Lean fish have much lower levels of dioxins and dioxin-like PCB than oily fish. Farmed salmon seems to have lower levels than some wild oily fish species (Joint Report DG SANCO). Herring and mackerel from Norway have lower levels of dioxins and dioxin-like PCBs than the farmed salmon. However, the large variations seen in wild caught fish are not expected for farmed fish since the fish feed used for farmed fish is regulated and since farmed fish has a shorter lifespan.

Fish oils for human consumption

The proposed ML for fish oil does not separate between pure fish oil and refined fish oil. Refining fish oil is an excellent way of removing dioxins and dioxin-like PCB from the product before it is put on the market. Fish oil is one of the few food products that could directly be decontaminated before used for human consumption.

4. Intake estimates

Intake estimation among the Norwegian population

When calculating the estimated weekly intake among the Norwegian population data on consumption were combined with data on the levels of dioxins and dioxin-like PCBs. The data on food consumption among adults were obtained from the national dietary survey NORKOST 1997 (Johansson & Solvoll, 1999) and among children from the national dietary survey UNGKOST 2000 (Overby & Andersen, 2002). In NORKOST 1997 a sample of 2 672 persons in the age of 16 to 79 years participated (average body weight=73 kg). The method used in NORKOST was a quantitative food frequency questionnaire, which was distributed and collected in four different periods spread through the year. The survey tries to capture information about the usual diet during the prior year among the participants. UNGKOST 2000 was carried out in Norway in the period of 2000-2001. The sample consisted of children in the age of 4 years (n=391), 9 years (n=810) and 13 years (n=1005). The methodology used was a precoded 4-d record and data refer to food as consumed with weight of food using photographs of foods items.

One of the weaknesses regarding the survey NORKOST 1997 is that the questionnaire, on which the data are based, only includes four questions regarding fish consumption (“How often do you eat oily fish, lean/semi-oily fish, freshwater fish and shellfish?”). Thus, the data do not give detailed information about the consumption of specific fish species. Therefore, a second calculation (“Adults ²” in Table 2) was made based on data from the Norwegian Fish and Game Study, part A. The Norwegian Fish and Game Study, part A, was carried out in November 1999 on a nation-wide randomly chosen sample of 10 000 individuals. Of these, 6015 adults answered a food frequency questionnaire, which included 25 questions about the consumption of fish and shellfish. The findings from part A provided information about fish and game consumption in the general population (Meltzer et al., 2002). In the second calculation (“Adults ²” in Table 2) the estimated average and high (95th percentile) intake of dioxins and dioxin-like PCBs from fish and shellfish based on Fish and Game Study was added to the *average* intake based on NORKOST 1997 from all of the other food (milk, egg, cereal products, etc).

Preliminary estimates on the intake of dioxins and dioxin-like PCBs among Norwegians are based on analytical data on dioxins and dioxin-like PCB in different food commodities from 1999-2004 (medium bound results) combined with data from food consumption.

Table 2: Estimated intake of dioxins and dioxin-like PCBs among different population groups based on analytical data (medium bound) from Norway (all food groups, not only fish) expressed as pg TEQ/kg body weight/week.

Population group	Adults¹	Adults²	Children. 13 years³	Children. 9 years³	Children. 4 years³
Estimated intake mean (95-perc)	7.7 (15.2)	13.7 (25.8)	6.4 (12.9)	10.2 (20.7)	14.9 (28.0)

¹ Norkost 1997

² Norkost 1997 & Fish and game study, part A, 1999

³ Ungkost 2000

The estimated average intake of dioxins and dioxin-like PCBs among adults in Norway based on data for fish consumption from the Norwegian Fish and Game Study, part A, became twice as high as the corresponding intake based on NORKOST 1997 solely, and was equal to TWI of 14 pg TEQ/kg body weight. This intake estimate is considered to provide a result that is closer to the “true” intake of dioxin and dioxin-like PCBs than the intake based on data from NORKOST 1997 solely. The estimated average weekly intake for adults of 14 pg TEQ/kg body weight is just a bit lower than the corresponding estimated intake from 1997 of 16.3 pg TEQ/kg body weight (SNT-rapport 9, 1997). However, the current intake calculation is not quite comparable with the corresponding calculation done in 1997, due to differences in methodology and analytical data included in the calculations.

Furthermore, the results from the intake calculation showed that the estimated average intake among 4-year old children is equal to TWI, whereas the estimated average intake among 13-year old children is approximately half of the TWI.

Estimated high intake (95th percentile) of dioxins and dioxin-like PCBs are close to or higher than TWI for all population-groups. For small children and adults (based on the Fish and Game Study) high intake is approximately twice of the value of TWI.

Since the average intakes among Norwegian adults and small children are equal to TWI and high intakes among most of the population-groups exceed TWI, it is expected that a larger proportion of the Norwegian population exceeds TWI. However, these estimates have not been validated using biomarkers of dioxin exposure.

Table 3 shows the distribution from food to the dietary intake of dioxins and dioxin-like PCBs. Fish is an important contributor to the overall intake among all population groups. The food group “Fish on sandwiches” consists mostly of mackerel in tomato sauce and herring, which both fall into the group of oily fish. Thus, oily fish is definitely the food that contributes most to the total weekly intake of dioxins and dioxin-like PCBs.

Table 3: Contribution from various food categories to the dietary intake of TEQ (%)

Food groups	Adults	Children. 13 years	Children. 9 years	Children. 4 years
Cereal products	4.4	12.4	10.5	8.5
Meat	19.7	31.4	31.6	25.7
Fish	43.6	17.6	18.7	23.3
- Oily fish	15.3	9.4	7.6	8.5
- Fish on sandwich	20.3	5.3	8.5	11.2
- Lean, semi-oily	1.2	0.6	0.6	0.6
- Fish products	0.6	0.7	1.0	1.0
- Shellfish	5.4	1.2	0.8	1.3
- Unspecified	-	0.4	0.4	0.7
Egg	5.1	4.6	5.0	5.5
Milk, cheese	13.2	20.2	21.1	22.7
Butter	13.4	11.2	11.9	13.4
Other (snacks)	0.6	2.5	1.2	0.4

Theoretical intake calculation

In order to see if the proposed MLs are set at acceptable levels theoretical intake calculations have been carried out in which all foods consumed have a content of dioxins and dioxin-like PCBs equal to the proposed MLs. If the estimated theoretical intake is far below the TWI, the proposed MLs should not cause any risk to human health. If the theoretical intake is higher than the TWI, further investigation should be initiated. A theoretical intake calculation with MLs is of course a gross overestimation of the actual intake and the conservativeness will depend on the difference between the actual levels found in food and the proposed MLs.

Table 4: Theoretical intake of dioxins and dioxin-like PCBs based on proposed MLs among adults and children (4-years) compared with estimated intake in Norway based on analytical data from Norway. Results are expressed as mean (95th percentile) pg TEQ/kg body weight/week.

	Adults Norkost 1997 <i>TEQ/kg body weight/week</i>	Children, 4 years Ungkost 2000 <i>TEQ/kg body weight/week</i>
Theoretical intake based on proposed ML	71 (146)	148 (320)
Estimated intake based on analytical data	7.7 (15.2)	14.9 (28.0)

The theoretical weekly intake among adults was based only on consumption data from NORKOST 1997. The result from the calculation based on the proposed MLs shows that the theoretical intake of dioxins and dioxin-like PCBs is a factor of 10 higher than estimated intake based on occurrence data. If the theoretical weekly intake among adults were to be based on data from the Norwegian Fish and Game Study in combination with NORKOST 1997, this intake would have been considerably higher.

When the proposed MLs are compared with the Norwegian occurrence data, the difference seems particularly high for some fish species and fish oil. Those food categories will be discussed further.

Fish

The consumption of fish in Norway is quite high (55-60g/day, table 5) compared to Finland (27.4 g/day, H. Kiviranta et al, 2004) and Sweden (38.3 g/day, SLV-rapport nr 26, 2002) and the contribution to the dietary intake for dioxins and dioxin-like PCBs from fish is substantial, especially for adults (Table 3).

Table 5: Average consumption of fish and shellfish in Norway (g/day)

Foods	NORKOST 1997 (g/day)	Fish & Game part A, 1999 (g/day)
Fish total	55	60
- Oily fish	9	18
- Fish for sandwiches	9	3
- Fish. Lean and semi-fat	23	26
Fish liver	0.1	0.3
Fish products	13	11
Shellfish	5	10

To see how lower MLs for different fish groups would affect the theoretical intake, different theoretical calculations have been carried out as presented in table 6.

Table 6: Theoretical average (95th percentile) intake of dioxins and dioxin-like PCBs based on proposed MLs and with lower MLs for different fish categories among adults and children (4-years) in Norway (expressed as pg TEQ/kg body weight/week).

Theoretical intake	Adults Norkost 1997 TEQ/kg body weight/week	Children, 4 years Ungkost 2000 TEQ/kg body weight/week
Alternative 1 Mean (95-perc)	71 (146)	148 (320)
Alternative 2 Mean (95-perc)	51 (96)	101 (195)
Alternative 3 Mean (95-perc)	48 (90)	105(204)
Alternative 4 Mean (95-perc)	38 (70)	88 (154)

1. Proposed MLs
2. Proposed MLs, but lean fish=2 pg TEQ/g, farmed salmon=4pg TEQ /g
3. Proposed MLs, but Fish = 4 pg TEQ /g
4. Proposed MLs, but Fish = 2 pg TEQ /g

The results indicate that, when lean fish was given a ML of 2 pg TEQ/g and farmed salmon a ML of 4 pg TEQ/g whereas the rest of the fish was given the proposed ML of 8 pg TEQ/g (Alternative 2), the theoretical intake among Norwegians was reduced by nearly 30%. In small children the reduction was more than 30 %, although the intake is still far above TWI.

In alternative 3, all fish was given a level of 4 pg TEQ/g, but this did not make much of a difference from alternative 2 regarding the intake levels. It would however also be difficult to keep a ML of 4 pg TEQ/g for most of the oily fish. In alternative 4, all fish was given a ML of 2 pg TEQ/g, and this would reduce the theoretical intake further. However, a ML of 2 pg TEQ/g for all fish species would lead to withdrawal of a substantial amount of fish from the market.

Fish oil

Fish oil supplements are widely used in Norway. The Norwegian Directorate for Health and Social Affairs recommends a daily use of fish oil supplements to the whole population, including infants and small children in order to secure a sufficient intake of vitamin D and omega-3 fatty acids. It is recommended to take two capsules of fish oil supplement containing 1 g of fish oil daily. However, some producers of such capsules recommend a daily intake of eight capsules, equal to a content of about 4 g fish oil. The recommended intake of one teaspoon (5 ml) of cod liver oil is equal to about 5 g fish oil. When calculating the estimated intake of dioxins and dioxin-like PCBs from fish oil supplement, a level of 2.3 pg TEQ/g fat found by analyses in one of the most popular brands sold in Norway (“Møllers tran”) was used. However, it is important to be aware that there is a great variation in the contents of dioxins and dioxin-like PCBs in such products (average=2.5 pg TEQ/g fat, range=0.6-6.9 pg TEQ/g fat) (table 1).

Table 7: Additional dietary intake of dioxin and dioxin-like PCBs expressed as pg TEQ/kg body weight/week among adults (b.w. 74 kg) and young children (b.w. 18 kg) from fish oil supplement with a content of 2.3 pg TEQ/g.

	Adults Norkost 1997 <i>TEQ/kg body weight/week</i>	Children, 4 years Ungkost 2000 <i>TEQ/kg body weight/week</i>
1 g fish oil	0.2	0.9
5 g fish oil	1.1	4.5

Estimated intake pg TEQ/kg b.w./week, mean (95th percentile):

Adults: 13.7 (25.8)

Children 4 years old: 14.9 (28.0)

Fish oil consumption is not included in the food consumption surveys used. As table 7 shows, additional intake among small children from a recommended dose of fish supplements will contribute with at least 1/3 of the TWI for dioxins and dioxin-like PCBs.

The proposed ML for fish oil is 10 pg TEQ/g, whereas national ML in Norway is 5 pg TEQ/g. Table 8 shows the additional intake of dioxins and dioxin-like PCBs from fish oils with a content of 5 and 10 pg TEQ/g respectively.

Table 8: The additional theoretical intake of dioxins and dioxin-like PCBs from fish oils based on a content of 10 pg TEQ (proposed ML in EU) and 5 pg TEQ (Norwegian ML), respectively. The estimated intake is based on a body weight of 74 kg (adults) and 18 kg (4-year-old children) and the results are expressed as pg TEQ/kg body weight/week.

	Adults Norkost 1997 <i>TEQ/kg body weight/week</i>		Children, 4 years Ungkost 2000 <i>TEQ/kg body weight/week</i>	
	Content of 10 pg TEQ/g	Content of 5 pg TEQ/g	Content of 10 pg TEQ/g	Content of 5 pg TEQ/g
1 g fish oil	0.9	0.5	3.8	1.9
2 g fish oil	1.8	1.0	7.6	3.8
5 g fish oil (recommended)	4.7	2.4	19.4	9.7

A content of both 10 and 5 pg TEQ/g fish oil will increase the intake of dioxins and dioxin-like PCBs substantially, especially among small children.

5. Discussion and conclusions

Due to possible negative health effects from exposure to dioxins and dioxin-like PCBs it is important to keep the dietary exposure as low as possible. Exposure estimates indicate that a considerable proportion of the Norwegian population has a dietary intake in excess of the tolerable intake and the aim should be to reduce the exposure to these contaminants.

When setting MLs for different food categories it should be taken into account what is found in food on the market. The 95th percentile for the analytical results from member states (Joint Report DG SANCO) has been used as a basis for the proposed MLs. The proposed ML for fish does not take into account the huge variation seen in levels of dioxin and dioxin-like PCBs found in different fish species. This leads to an unnecessary and hence an unacceptable high proposed ML for lean fish and farmed fish. In the theoretical intake calculations where the farmed fish was given a level of 4 pg TEQ/g and lean fish was given a level of 2 pg TEQ/g (table 6) the exposure among all population groups was reduced. The actual intake among Norwegians would not decrease since levels of dioxins and dioxin-like PCBs found in fish on the market today are lower. However, this could change, since we by the new proposal have no tool or argument to exclude clearly contaminated foods from the market. Although the maximal levels of dioxins and dioxin-like PCBs are not expected to increase in European farmed salmon due to fish feed restrictions, import of contaminated fish from other regions could not be excluded. Likewise, wild lean fish with very high levels of dioxins and dioxin-like PCBs compared with background contamination level could not be excluded from the market.

For the analytical results leading to the proposed ML for fish oil there is no separation between refined and unrefined oils. The consequence is that the proposed ML for fish oil is equal to the level found in unrefined oils and not equal to refined fish oils recommended as

food supplements. This is not in accordance with the ALARA-principle. In 2001, The Norwegian Food Control Authority carried out a survey on fish oils and dietary supplements (Miljøgifter i marine oljer, 2002). Several products were taken off the market due to high levels of dioxins and dioxin-like PCBs. In particular, the investigation revealed that several marine oil products were not purified properly (unrefined oil). With the new proposal, these may be put back on the market, and this is expected to increase the average exposure to dioxins and dioxin-like PCBs in Norway. The consequence would be that the use of fish oil supplements can no longer be recommended by the Health Authorities. Today it is recommended a daily intake of 5 ml cod liver oil to the whole population, including infants (from 4 weeks old, intake of 2.5 ml) and small children (intake of 5 ml) in order to secure a sufficient intake of vitamin D and omega-3 fatty acids. It is stated in the Council Regulation (EC) No 2375/2001 that all operators in the food and feed chain should continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food. This statement will not be followed if the proposed MLs for farmed fish (8 pg TEQ/g) and fish oil (10 pg TEQ/g) are adopted. Farmed fish with a content of dioxins and dioxin-like PCBs above 3-4 pg TEQ/g fresh weight has not been treated with all possible effort to reduce the levels of those contaminants. Likewise, fish oil with content above 5 TEQ/g fat has not been refined in a proper way.

In conclusion, the Norwegian Scientific Committee on Food Safety find the proposed maximum levels for dioxin-like PCBs in fish and fish oil too high compared with the actual levels found in food. It is reason to believe that if the proposed MLs are made applicable the mean exposure to dioxin-like PCBs may increase among the Norwegians. The definition of lower maximum levels for farmed fish and lean fish than for other fish, as well as excluding unrefined fish oil for use as food supplements, would be prudent from a public health point of view and would more adequately protect the population from unnecessary exposure to dioxin-like PCBs.

List of references:

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