

The Director General

Maisons-Alfort, 10 November 2011

## **OPINION** **of the French Agency for Food, Environmental** **and Occupational Health & Safety**

### **on the interpretation of the results of the national ANSES/InVS study of PCB** **concentrations in consumers of freshwater fish**

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*ANSES undertakes independent and pluralistic scientific expert assessments.*

*ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.*

*It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.*

*It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).*

*Its opinions are made public.*

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#### **1. REVIEW OF THE REQUEST**

On 6 May 2011, the French Agency for Food, Environmental and Occupational Health & Safety issued an internal request regarding the following question: "Do the results of the national study of PCB concentrations in consumers of freshwater fish make it possible to refine the recommendations on fish consumption that were previously issued by the Agency?"

#### **2. BACKGROUND AND PURPOSE OF THE REQUEST**

European and international management measures have been taken to reduce risks related to PCBs, for example by setting maximum levels in fish (freshwater and marine) and other foods on the market. The primary aim of the regulatory limits that have been established in Europe (set in accordance with the ALARA<sup>1</sup> principle) for marketed fish species (Regulation (EC) no. 1881/2006) is to remove the most contaminated fish from the market.

In France, these levels have been exceeded in freshwater fish in several bodies of water. Since 2006, fishing restrictions and recommendations to not consume fish species with the highest levels of PCB accumulation (eel, oily fish, species with high levels of bioaccumulation) have thus been issued on the basis of the current regulations, particularly in the Rhône, Somme, Seine and Garonne sectors. A national inventory of at-risk bodies of water (PCB measurements in sediments and fish) was also undertaken in early 2008 in the framework of the national action plan on PCBs,

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<sup>1</sup> ALARA: As low as reasonably achievable. Principle applied when all possible reasonable efforts have been made to reduce exposure to contaminants.

on the basis of a methodology established by AFSSA in 2008 and improved in 2009<sup>2,3</sup>. Based on the data generated from this inventory, fish consumption advisories have been issued by sector (over 20 Opinions have been issued to date). In order to protect all types of consumers, including those who purchase fish from fish markets as well as amateur anglers who consume the fish that they catch, these recommendations apply irrespective of whether the fishing area is frequented by professional and/or amateur anglers.

Outside of the areas for which consumption advisories have been issued, the Agency, in an Opinion of 14 June 2010 regarding the benefits/risks of fish consumption<sup>4</sup>, recommended, for the entire population and as part of a balanced diet, consuming two servings of fish per week, including one with high EPA and DHA<sup>5</sup> levels, and varying the species and source (wild, farmed, fishing location, etc.). This consumption optimally meets nutritional requirements while limiting the risk of over-exposure to chemical contaminants. In addition, for women of childbearing age, pregnant and breastfeeding women, children under the age of three years, young girls and adolescent girls, this Opinion recommended avoiding, as a precautionary measure, the consumption of so-called PCB bioaccumulating fish, and particularly eel, barbel, bream, carp and sheatfish.

In addition, the Agency published an Opinion on 5 March 2010<sup>6</sup> on interpreting the health impact of PCB levels (plasma concentrations) in the French population, since plasma levels have the advantage of reflecting PCBs accumulated from prior exposure. In this Opinion, two critical thresholds were proposed:

- 700 ng total PCB/g of plasma lipids as the critical concentration threshold for pregnant women, women of childbearing age, breastfeeding women and children under three years of age, who are the most at-risk populations in terms of PCB exposure. The acknowledged toxic effects of PCBs mainly concern effects on the developing central nervous system in children exposed *in utero*. Due to the persistence of PCBs in the body and thus the gradual increase in concentration levels with age, this threshold value also applies to young and adolescent girls.
- 1800 ng total PCB/g of plasma lipids as the critical concentration level for the rest of the population (boys over three years of age, adult men, and women over 45 years). This value is given for information purposes only, in light of the incomplete results that are available for adults.

In 2008, in this context and in the framework of the French national action plan on PCBs, the French Ministry of Health requested that ANSES, in collaboration with the French Institute for Public Health Surveillance (InVS), undertakes a study on the consumption of freshwater fish in order to establish whether it was linked to blood PCB levels (blood plasma concentrations) in consumers of freshwater fish with high levels of bioaccumulation<sup>7</sup>. This study was intended to help define maximum frequencies for the consumption of these fish, i.e. with no long-term risks to human health.

### **3. ORGANISATION OF THE EXPERT APPRAISAL**

The expert appraisal was carried out in accordance with the French standard NF X 50-110 "Quality in Expertise – General Requirements of Competence for Expert Appraisals (May 2003)".

<sup>2</sup> Scientific and technical support of 5 February 2008 from the French Food Safety Agency regarding the national PCB sampling plan for river fish: proposed methodology.

<sup>3</sup> Scientific and technical support of 13 May 2009 from the French Food Safety Agency on the interpretation of the data from the 2008 national plan on PCBs in river fish and the proposed 2009 sampling plan.

<sup>4</sup> Opinion of 14 June 2010 of the French Food Safety Agency regarding the benefits/risks of fish consumption.

<sup>5</sup> EPA: eicosapentaenoic acid; DHA: docosahexaenoic acid.

<sup>6</sup> Opinion of 5 March 2010 of the French Food Safety Agency on interpreting the health impact of PCB concentration levels in the French population.

<sup>7</sup> The term 'fish with high bioaccumulation' refers to fish that are likely to be highly contaminated with PCBs, contamination being dependent upon the species and the contamination level of the area where the fish live. These fish include eel, barbel, bream, carp and sheatfish.

It fell within the sphere of competence of the Expert Committee (CES) on Physical and chemical contaminants and residues. ANSES entrusted the expert appraisal to the working group on 'Blood PCB concentrations related to the consumption of freshwater fish'. The methodological and scientific aspects of the study were presented to the CES between 2 December 2008 and 13 September 2011, when the CES's conclusions were validated.

#### **4. PRESENTATION OF THE STUDY'S RESULTS**

##### **Presentation of the study**

A total of 21,180 amateur angler households were contacted by telephone in order to collect data on the consumption of fish with high levels of bioaccumulation in anglers and their family members (only those between the ages of 18 and 75 years were eligible). These households were spread across six study sites (in six groups of fishing areas). These fishing areas had been selected beforehand based on data on the environmental contamination of sediments: the Seine and Somme were considered to be areas with high PCB contamination, the Rhône and Rhine (and Moselle) as areas with moderate contamination, and the Loire and Garonne as the least contaminated areas.

The eligible individuals<sup>8</sup> who agreed to participate were then interviewed in their homes about their general eating habits. A blood sample was also taken to determine PCB levels. A total of 606 anglers or members of their households took part in the study.

Moreover, 16 professional anglers (practising on the study sites) or members of their households also took part in the study. However, considering the small sample size and the methods used to gather separate information, it was not possible to use the results for these individuals to define maximum consumption frequencies.

Further details on the study procedures are available in the study report and summary<sup>9</sup>.

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<sup>8</sup> Consumers and non-consumers of freshwater fish with high bioaccumulation (eel, barbel, bream, carp, roach and sheatfish). In the framework of this study, in order to increase the number of eligible individuals, consumers of roach (a very commonly consumed fish and one of the most contaminated species in the category of fish with low bioaccumulation) were included.

<sup>9</sup> ANSES/InVS (2011) National study of PCB concentrations in consumers of freshwater fish (ICAR-PCB). Scientific study report and summary. Maisons-Alfort, Saint-Maurice, France.

## **Primary study results**

### *Description of consumption profiles in amateur angler households*

Freshwater fish consumption in angler households is fairly low (approximately once a month on average, or 13 times per year, all fish species combined). There is higher consumption of fish with low bioaccumulation levels<sup>10</sup> (10.5 times per year on average versus 2.5 times per year for fish with high levels). Only 5% of the population consumes freshwater fish once a week or more.

The consumption of marine fish in the households of anglers who catch freshwater fish is similar to that in the general French population. It is of the same magnitude irrespective of the level of consumption of freshwater fish with high bioaccumulation levels.

The consumption of highly contaminated freshwater fish is similar in men and women. It is slightly higher in the least contaminated areas. Furthermore, the most commonly consumed fish species with high levels of bioaccumulation are eel and catfish. Bleak, perch, zander and pike are the most commonly consumed species with low levels.

Thirteen percent of the study's population consumes fish with high levels of bioaccumulation and is thus the most at-risk population group. On average, it consumes fish with high levels slightly more than once a month in addition to consuming fish with low levels. Overall, this population consumes freshwater fish three to four times per month on average.

### *Concentrations of total PCBs<sup>11</sup> in amateur angler households and description of the factors that determine PCB levels*

The average concentration<sup>12</sup> of total PCBs in the study's sample was 492 ng/g of plasma lipids. It was similar to that observed in the general French population during the 2006-2007 period (480 ng/g of plasma lipids<sup>13</sup>). For women of childbearing age (18-44 years), who are the most susceptible population considering the effects of PCBs in young children exposed during pregnancy, the average PCB concentration was 231 ng/g of plasma lipids.

The main factors which determined PCB concentrations in this study (i.e. the parameters that were associated with increased or decreased blood PCB levels) were socio-demographic factors and primarily age. In fact, PCB concentrations increase with age, due to the persistence of PCBs and their gradual accumulation in the body during a lifetime. Age therefore reflects past exposure, particularly through food. Moreover, a generational effect is presumed to reflect the level of environmental contamination at an individual's birth. This tended to decrease after PCBs were prohibited in the late 1980s. Values greater than the critical contamination levels proposed by the Agency<sup>14,15</sup> for total PCBs were observed in 2.5% of the study's population (0.3% were women of childbearing age<sup>16</sup>). The average age of these individuals was higher than that of the study population. They were mainly consumers of fish with high levels of bioaccumulation and were evenly distributed across the study areas.

In addition, to a lesser extent, the fishing area was a factor of blood PCB levels since consumers of fish from the most contaminated areas had higher levels than consumers of fish from areas with low or moderate contamination.

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<sup>10</sup> Bleak, gudgeon, pike, black bass, crucian carp, chub, nase, perch, catfish, zander, tench, trout, dace, minnow

<sup>11</sup> Estimated by applying a multiplier of 1.7 to the sum of PCBs 138, 153 and 180 (AFSSA, Opinion of 5 March 2010).

<sup>12</sup> Geometric mean

<sup>13</sup> French Institute for Public Health Surveillance (InVS), 2010. Exposure to environmental pollutants in the French population – Environmental component of the National Nutrition and Health Study.

<sup>14</sup> Opinion of 5 March 2010 of the French Food Safety Agency on interpreting the health impact of PCB concentration levels in the French population.

<sup>15</sup> Opinion of 28 March 2008 of the French Food Safety Agency related to blood concentrations of dioxins in high consumers of animal products of local origin within the framework of the InVS-AFSSA study of November 2006

<sup>16</sup> These were two individuals in the total sample who were respectively 41 and 43 years of age.

The consumption of fish with high levels of bioaccumulation was the dietary factor most closely linked to total PCB concentrations: it increases the level of total PCBs in the blood<sup>17</sup>. It should be noted that current dietary habits are minor factors in the determination of blood PCB levels in populations.

#### *Determination of maximum consumption frequencies*

On the basis of these results, PCB levels were modelled to estimate a maximum frequency for the consumption of fish with high levels of bioaccumulation without the threshold values being exceeded and thereby avoiding unacceptable risks to consumer health.

The most conservative scenario corresponds to an individual with the characteristics of populations who have the highest concentration levels (greater than or equal to the 95<sup>th</sup> percentile) and live in areas with the highest PCB contamination. Women of childbearing age are the most susceptible population in terms of PCB risk. In order to protect this population and considering that PCB levels increase with age, the age of 44 years was identified as the most conservative scenario. For the rest of the population, the scenario is that of a 60-year-old man, to take into account PCB accumulation while limiting the impact of the generational effect.

The modelling results show that for a 44-year-old woman, consuming fish with high levels from the most contaminated area more than once every two months leads to the critical contamination threshold being exceeded (700 ng/g fat).

This same model shows that for a 60-year-old man, consuming fish with high levels from the most contaminated area more than two to three times per month leads to the critical contamination threshold being exceeded (1800 ng total PCBs/g fat (threshold set for boys over three years of age, adult men and women over 45 years)).

## **5. ANALYSIS AND CONCLUSION OF THE CES**

The conclusions of this study, based on the PCB levels of consumers of freshwater fish, can be used to refine the recommendations on the consumption of freshwater fish with high levels of bioaccumulation that were previously issued by the Agency and were based on food contamination levels.

Considering that:

- The study's results show that for a 44-year-old woman, consuming fish with high bioaccumulation levels from the most contaminated area more than once every two months leads to the critical contamination threshold being exceeded (700 ng/g fat);
- The study's results show that for a 60-year-old man, consuming fish with high levels of bioaccumulation from the most contaminated area more than twice a month leads to the critical contamination threshold being exceeded (1800 ng/g fat);
- These recommendations were issued based on data (collected from 2008 and onwards) from the most contaminated areas in France (Annex 1);
- The blood PCB levels observed in the sample of amateur anglers were similar to those observed in the general population<sup>11</sup>;

The Expert Committee considers that the recommendations from this study, issued on the basis of the population of amateur anglers, can be extended to the general population. They apply to the entire French territory (apart from accidental situations) with the exception of sectors where the

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<sup>17</sup> Detailed results for the other contaminants analysed in this study (DL-PCBs, dioxins and furans) are available in the study report and summary.

Agency has issued or will issue fish consumption advisories. It recommends, considering the risk related to PCB contamination in freshwater fish:

- For women of childbearing age and pregnant or breastfeeding women, as well as children under the age of three years and young and adolescent girls, limiting the consumption of freshwater fish with high bioaccumulation levels<sup>18</sup> to once every two months<sup>19</sup>.
- For the rest of the population, limiting their consumption of freshwater fish with high bioaccumulation levels<sup>18</sup> to twice a month<sup>19</sup>.

The members of the Expert Committee emphasise that these recommendations are issued solely with regard to the risk related to PCB contamination. Risks related to other contaminants were not taken into consideration in this study.

## **6. THE AGENCY'S CONCLUSION AND RECOMMENDATIONS**

**The French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions and recommendations of the Expert Committee on Physical and chemical contaminants and residues.**

Since 2008, the Agency (AFSSA and then ANSES) has received several requests and issued Opinions aiming to assess the health risks specific to various sectors, and has issued local consumption advisories. The Agency, in light of this new study's characteristics, and particularly the fact that it was a broad and national study, maintains its consumption advisories in sectors for which specific local assessments have been undertaken.

However, this ANSES-InVS study highlighted a statistical association between the consumption of fish with high levels of bioaccumulation and blood concentration levels. It can therefore be used to refine, for the rest of the country, the public health message recommended in the Opinion of 14 June 2010 on the consumption of fish with high levels. At that time the Agency recommended limiting the consumption of this type of fish and even advised to avoid it completely for certain population groups (children, women of childbearing age).

In light of this new study (specific to the PCB risk), ANSES now recommends limiting the consumption of freshwater fish with high levels of bioaccumulation (eel, barbel, bream, carp, catfish):

- to once every two months for women of childbearing age and pregnant or breastfeeding women, as well as children under the age of three years and young and adolescent girls,
- to twice a month for the rest of the population.

ANSES emphasises that the current PCB contamination map was based upon multiple information enabling it to target the most contaminated areas, and recommends remaining vigilant and monitoring these areas and continuing efforts to identify other highly contaminated areas. Indeed, the recommendations from this study do not apply to situations of accidental contamination.

In addition, ANSES stresses that this study has brought to light important results, i.e. that:

- freshwater fish consumption in angler households is low (once a month on average, all fish species combined),
- of the 21,180 surveyed households, only 13% consume fish with high bioaccumulation levels,

<sup>18</sup> Eel, barbel, bream, carp and sheatfish

<sup>19</sup> According to the study's data, the average serving is approximately 150 g.

- the PCB levels observed in the sample of amateur anglers were similar to those observed in the general population.

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**KEYWORDS**

**Keywords:** PCB, RECOMMENDATIONS, FISH

**ANNEX 1**

Levels of contamination (with PCB<sub>i</sub> and PCDD/F + DL-PCB) in eel and fish with high bioaccumulation levels in the study areas with low, moderate and high contamination

	PCB <sub>i</sub> <sup>a</sup>		PCDD/F + DL-PCB	
	Mean (ng/g FW)	Confidence interval (ng/g FW)	Mean (pg TEQ <sub>98</sub> /g FW)	Confidence interval (pg TEQ <sub>98</sub> /g FW)
<b>Eel</b>	1103.8	[934.4; 1273.2]	46.8	[40.1; 53.5]
High-contamination area	1708.4	[1455.0; 1961.7]	72.1	[61.0; 83.1]
Moderate-contamination area	604.0	[494.5; 713.5]	28.3	[23.3; 33.3]
Low-contamination area	242.8	[204.5; 281.1]	15.6	[13.2; 18.1]
<b>Fish with high bioaccumulation<sup>b</sup></b>	221.1	[184.8; 257.4]	11.4	[9.6; 13.1]
High-contamination area	364.1	[304.2; 424.0]	18.7	[15.8; 21.5]
Moderate-contamination area	76.5	[35.5; 117.6]	4.1	[2.4; 5.9]
Low-contamination area	53.0	[38.5; 67.5]	3.1	[2.6; 3.7]
<b>Fish with low bioaccumulation<sup>c</sup></b>	92.4	[65.7; 119.1]	4.8	[3.8; 5.8]
High-contamination area	171.4	[101.9; 241.0]	7.7	[5.5; 10.0]
Moderate-contamination area	80.5	[60.5; 100.5]	4.2	[3.4; 5.1]
Low-contamination area	27.2	[22.8; 31.5]	1.6	[1.4; 1.8]

a: indicator PCBs (PCBs 28, 52, 101, 118, 138, 153, 180)

b: Eel, barbel, bream, carp, roach and catfish

c: Bleak, gudgeon, pike, black bass, crucian carp, chub, nase, perch, catfish, zander, tench, trout, dace, minnow