

Maisons-Alfort, 9 December 08

Opinion

of the French Food Safety Agency (Afssa) on the assessment of the risk of consuming pork contaminated with PCDD/Fs and DL-PCBs (dioxin-like PCBs)

THE DIRECTOR GENERAL

I - CONTEXT OF THE REQUEST

On 8 December 2008, the Ministry for Agriculture and Fisheries (Directorate General for Food) requested the French Food Safety Agency (Afssa) to issue an opinion on the assessment of the risk of consuming Irish pork contaminated with Dioxins and Furans (PCDD/Fs) and Dioxin-Like PCBs (DL-PCBs).

2 – GENERAL CONTEXT AND QUESTIONS RAISED

The Irish authorities informed the EU Member States through the Rapid Alert System for Food and Feed (RASFF) that pork contamination by chlorobiphenyls had been detected on a dozen Irish farms, accounting for around 10% of total pork production in this country.

According to the Irish authorities, the contamination source may come from animal feed.

According to the few data available, the concentrations currently identified are 100 pg/g of fat for PCDD/Fs and 150 pg/g of fat for the sum of PCDD/Fs + DL-PCBs (the maximum levels set by the European Commission for the sum of PCDD/Fs + DL-PCBs in pork is 1.5 pg TEQ/g of fat¹).

Contaminated meat has been exported to Europe, France included, and to third countries. France imports around 4,400 tons of Irish pork a year, for a total national consumption level of 2 million tons.

Contaminated Irish products have probably been exported to Member States since 1 September 2008. For this period, current Irish data report 1,600 tons exported to six companies in France. The Ministry for Agriculture has investigated the traceability of products with a view to withdrawing them.

Afssa received an urgent request in this context on 8 December 2008 to assess the impact in terms of exposure of consuming pork-based products, assuming a maximum contamination level of 200 pg/g fat PCDD/F + DL-PCB.

Following an internal expert assessment by the Risk Assessment Scientific Support Unit and Physicochemical Risk Assessment Unit and discussions with the chairpeople of the "Physical and Chemical Contaminant Residues" Scientific Panel and "Assessment of Risks associated with PCBs in Food and Feed" Emergency Collective Expert Assessment Group, Afssa issues the following opinion.

3- COMMENTS ON THE TYPE OF CONTAMINATION

In the event of accidental contamination of meat by PCBs, the analysis of animal tissue generally detects the concomitant presence of i-PCBs (up to 90% of all congeners), DL-PCBs (less than 10% of all congeners), furans or PCDFs (impurities present in commercial mixtures of PCB) and possibly traces of dioxin or PCDD.

At present, it would be useful for specifying the type of contamination (by dioxins or PCBs):

- i) to obtain analysis results distinguishing furans (PCDFs) from dioxins (PCDDs)
- ii) to complete the DL-PCB analyses with i-PCB analyses

For this opinion, the risk assessment was carried out on the basis of available data on PCDD/Fs and DL-PCBs. This assessment may nevertheless be extended if additional information on the contamination source becomes available.

4- REMINDER ABOUT DIOXIN AND DL-PCB HAZARD CHARACTERISATION

Afssa has published numerous opinions and reports on PCDD/Fs and DL-PCBs.

Knowledge of dioxin effects comes from the results of animal studies and epidemiological surveys on populations that used to be exposed to levels 100 to 1000 times higher (Agent Orange during the Vietnam War, Seveso industrial accident, workers, etc.) than those currently observed for the general population.

Dioxins tend to accumulate in the liver and fatty tissue of the human body. They are eliminated in faeces and can also be found in breast milk. The average half-life of accumulated dioxins is 7 years and, in the case of DL-PCBs, can vary from 5.5 to 11 years depending on congener. The toxicological and biochemical effects of PCDD/Fs and DL-PCBs are therefore correlated to tissue concentration levels, and not directly to the daily intake.

Effects reported in laboratory animals after acute, sub-acute or chronic exposure, at high doses of dioxin and DL-PCB concern reproduction (reduced fertility, role of endocrine disruptors), development (foetotoxicity and teratogenicity), immunity, the nervous system, metabolism and the induction of certain cancers.

However, transposing the effects observed in animals under test conditions to humans is a delicate matter. This is because the only proven effects in humans at present are dermatological (chloracne: skin disorder observed after acute exposure at a high dose) and temporary increases in hepatic enzymes. Some observations also suggest increased cardiovascular risk and point to a teratogenic risk in the event of high exposure. No malformation seems to have been induced specifically by dioxins or DL-PCBs. The other risks mentioned by certain authors are debatable (immune system disorders, endocrine system disorders, alteration of hepatic function, reproduction problems, neurological disorders).

Referring firstly to current scientific knowledge on the dangers of dioxin and secondly to assumptions of dietary exposure, Afssa, in its opinion of 4 June 1999 on the contamination of products and foodstuffs by dioxins, had recommended assessing the risk by using the following hazard appearance scale:

1. Appearance of serious pathological effects that may cause death in the event of one-off exposure to higher doses than $\mu\text{g}/\text{kg}/\text{d}$ (microgram per kilogram of body weight and per day),
2. Appearance in monkeys of effects on the immune, nervous, hormone and reproductive systems after chronic exposure (several months) to $0.1 \text{ ng}/\text{kg}/\text{d}$ (nanogram per kilogram of body weight and per day). However, only reversible modifications of some thyroid and neurological parameters have been observed in humans exposed to these doses.
3. Induction of carcinogenic effects in rodents in the event of chronic exposure to doses exceeding $10 \text{ ng}/\text{kg}/\text{d}$ (nanograms per kilogram of body weight and per day). In humans, slight excess risks of all types of cancer have been observed in workers exposed to dioxins. Excess risks of specific cancers (lymphoma, multiple myeloma, soft tissue sarcoma, lung cancer or liver cancer) have been reported in some studies, but the results are inconsistent. Only the Seveso dioxin was classified, in 1996, as a known human carcinogen by the International Agency for Research on Cancer (IARC). The 16 other dioxin molecules qualified as toxic are not classified as carcinogens because of lack of proof.

4. In 2001, the JECFA² set a provisional tolerable monthly intake (PTMI) of 70 mg TEQ_{WHO}/kg bw/month, or an intake of 2.33 pg TEQ_{WHO}/kg bw/day. The dioxin body burdens revealed in studies used to set this PTMI are 10 times less than the body burden required to induce a carcinogenic effect in rats. The SCF³ and JECFA considered that the PTMI calculated from this intake was also protective for carcinogenic effects.

5. EXPOSURE STUDY

In 2005, Afssa updated the estimated exposure of the French population to PCDD/Fs and DL-PCBs through common food⁴. Average exposure of the French population was estimated to be 1.8 pg TEQ_{WHO}/kg/bw/d in adults and 2.8 pg TEQ_{WHO}/kg/bw/d in children aged 3 to 14 years. The main contributing foods, excluding incidents of acute contamination, are seafood and dairy products (meat and eggs contribute less). It is estimated that dioxin exposure of the mainland French population has fallen by around 60% since 2000.

In the current context of Irish pork contamination, Afssa applied a conservative scenario intended to estimate the potential increase in exposure of the French population through the consumption of contaminated pork. Note that this scenario is mainly retroactive insofar as the contaminated pork and pork-based products from Ireland have already been withdrawn.

Consumption data: Adults consume an average of 57 g/d of pork and pork-based products in France, with the highest consumers eating 128 g/d (P95) (source: INCA1 survey, see Table 1).

Children aged 3 to 14 years consume an average of 41 g/d of pork and pork-based products in France, with the highest consumers eating 87 g/d (P95) (source: INCA1 survey, see Table 2).

Exposure scenario: The scenario applied takes account of the fact that annual imports of Irish pork and pork products (4,431 T) only account for a very small proportion (0.22%) of national pork consumption (2,000,000 T). Preliminary data report 1,600 T of imported pork since September and contamination affecting 10% of Irish pork production. At this early stage of investigation, and pending confirmation of these data, a protective scenario has been adopted, assuming that all French imports of Irish pork estimated for the year (4,400 T) were contaminated at a maximum level of 200 pg/g of fat for the sum of PCDD/Fs + DL-PCBs. An average fat level of 15% has been adopted (fat levels in pork range from 5 to 35% depending on the pieces).

Results:

In adults, exposure would be 0.06 pg TEQ_{WHO}/kg bw/d for an average consumer and 0.13 pg TEQ_{WHO}/kg bw/d for high consumers (P95).

In children aged 3 to 14 years, exposure would be 0.1 pg TEQ_{WHO}/kg bw/d for an average consumer and 0.23 pg TEQ_{WHO}/kg bw/d for high consumers (P95).

The detailed data on pork consumption per product group (meat, pork products and pork-based ingredients) and on consumer exposure, according to the scenario applied, are described in the tables below.

Table 1: Consumption of and exposure to pork and pork products in adults according to the scenario applied

Product group	Consumer rate (in %)	Consumption (in g/d)		Exposure (in pg TEQ _{WHO} /kg bw/d)	
		mean	p95	mean	p95
pork	54.3	16.8	60.7	0.017	0.061
pork products	91.6	31.2	81.5	0.031	0.081
other (ingredients)	80.7	9.1	32.2	0.009	0.033
total	98.2	57.1	128.3	0.057	0.126

² JECFA, Summary of the fifty-seventh meeting of the Joint FAO/WHO Expert committee on Food additives. Rome, 5-14 June 2001.

³ Scientific Committee on Food

⁴ For more information, see Afssa's opinion of 9 January 2006 on the assessment of French population exposure to dioxins, furans and DL-PCBs, as well as the appended report of November 2005, available on www.afssa.fr

Table 2: Consumption of and exposure to pork and pork products in children according to the scenario applied

Product group	Consumer rate (in %)	Consumption (in g/d)		Exposure (in pg TEQ _{WHO} /kg bw/d)	
		mean	p95	mean	p95
pork	48.6	10.3	37.1	0.024	0.094
pork products	89.9	23.6	61.4	0.057	0.155
other (ingredients)	88.4	7.0	23.3	0.016	0.052
total	98.2	40.9	86.6	0.097	0.229

According to the INCA2 consumption data (2005-2007), the proportion of ham and pork products in pieces (ham, bacon bits, coppa, bacon slices, etc.) in the pork products category accounts for around 35% in children and 45% in adults.

6. CONCLUSIONS

Having regard to:

- the toxicologically reference value determined for chronic exposure over a lifetime⁵
- the mean exposure level of the French population to DL-PCBs and PCDD/Fs,
- the conservative scenario applied to estimate potential population exposure through the consumption of contaminated pork,

Afssa considers that this time-limited increase exposure to DL-PCBs and PCDD/Fs is very low and unlikely to significantly modify the risk for consumers.

This initial assessment may nevertheless be extended if additional information on the contamination source becomes available.

8. KEY WORDS

PCBs, Dioxins, Pork, Ireland, Imports

⁵ Provisional Tolerable Maximum Intake of 2.33 pg TEQ/kg bw/d