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STATEMENT OF EFSA

Statement of EFSA on the risks for public health due to the presence of dioxins in pork from Ireland

(Question No EFSA-Q-2008-777)

Issued on 10 December 2008[1]

Summary

The European Food Safety Authority (EFSA) received a request on 8 December 2008 from the European Commission, Directorate General Health and Consumers requesting urgent scientific advice on the risks to public health due to the contamination by dioxins in pork from Ireland. Considering the urgency of this request for advice, EFSA issued a statement following Art. 13 b of the **"**Decision concerning the establishment and operations of the scientific committee and panels**"** adopted by the Management Board of EFSA on 11 September 2007[2].

During routine monitoring of Irish pork, elevated levels of polychlorinated biphenyls (PCBs) were found. Further investigations revealed the presence of dioxins and dioxin-like PCBs at levels up to 200 pg WHO-TEQ / g fat.

The toxic responses to dioxins include dermal toxicity, immunotoxicity, carcinogenicity, reproductive and developmental toxicity. The toxicity of dioxins is related to the amount accumulated in the body during a lifetime, the so-called body burden. A tolerable weekly intake (TWI) of 14 pg WHO-TEQ/kg body weight (b.w.) has been established by the Scientific Committee on Food (SCF) in 2001.

EFSA has based this statement on a limited data set, assuming that the average person has an exposure at the TWI corresponding to a body burden of 4000 pg/kg body weight. EFSA also assumed that exposure at these high levels only began in September 2008 and that effective measures have now been taken to remove this excessive dietary exposure from Irish pork and pork products.

[1] This version incorporates minor editorial corrections to the text initially published on 10 December 2008.
[2] Available at URL: http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/mb_32ndmeet_annex_a_en_4.pdf?ssbinary=true

EFSA calculated several exposure scenarios for both average and high consumers assuming three different dioxin concentrations in the pork (50, 100, 200 pg WHO-TEQ/g fat), and three different proportions of contaminated meat (100, 10 and 1%).

In very extreme cases, assuming a daily consumption of 100% contaminated Irish pork, for a high consumer of pork fat during the respective period of the incidence (90 days), at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), EFSA concludes that the uncertainty factor embedded in the TWI is considerably eroded. Given that the TWI has a 10-fold built-in uncertainty factor, EFSA considers that this unlikely scenario would reduce protection, but not necessarily lead to adverse health effects.

In a more likely scenario with a daily consumption of 10% contaminated Irish pork for a mean consumer of pork fat for the respective period of the incidence (90 days), at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), the body burden would increase by approximately 10%. EFSA considers this increase in body burden of no concern for this single event.

Keywords: dioxins, pork and pork products, human health, body burden

Acknowledgement

This statement was prepared jointly by the risk assessment and scientific cooperation and assistance directorates. The European Food Safety Authority wishes to thank the following members for their scientific advice during the drafting of this statement: Rolaf van Leeuwen (vice chair of the CONTAM Panel) and John Christian Larsen (chair of the ANS Panel).

Background to this request as provided by the European Commission

During routine monitoring by the Irish authorities of the food chain for a range of contaminants, elevated levels of polychlorinated biphenyls (PCBs) were found in pork. As these PCB levels might be an indicator for unacceptable dioxin contamination, further investigations were immediately started to determine the dioxin content and to identify the possible source of contamination.

The use of contaminated animal feed was identified to be the source. Preliminary evidence indicates that the contamination problem is likely to have started in September 2008. All possibly contaminated feed has been blocked.

The contaminated feed was provided to 10 pig farms which are producing about 6-7 % of the total supply of pigs in Ireland. Pigs from these farms were after slaughter processed by meat processing plants which are responsible for about 80 % of the total supply of pork and pork products from Ireland.

High levels of dioxins (about 100 times the legal maximum limit) have been found in pork and pork products produced in Ireland.

Given the high levels detected and that it is not possible to trace back the Irish pork and pork products to the farms affected by the dioxin contamination incident, the Irish authorities decided on Saturday 6 December 2008 to recall from the market, as a precautionary measure, all pig products produced from pigs slaughtered in Ireland, even if not more than 6-7 % of the Irish pork production is affected by the contamination incident. Distribution details of possibly contaminated pork and pork products to other Member States and third countries have been provided to the Member States and third countries involved through the Rapid Alert System for Feed and Food (RASFF).

The European Commission is closely following up this contamination incident and the actions taken to withdraw any potentially contaminated pork and pork products from the market ensuring consumer health protection.

In accordance with Article 31 of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide by 9 December 2008 scientific assistance on the risks for public health related to the possible presence of dioxins in pork and pork products from Ireland and the presence of possibly contaminated processed pork products from Ireland in composite foods.

Evaluation

Introduction

The term “dioxins” refers to a group of chemically and structurally related halogenated aromatic hydrocarbons, including 75 polychlorinated dibenzo-*p*-dioxin (PCDD) and 135 polychlorinated dibenzofuran (PCDF) congeners. Dioxins are widely distributed contaminants formed as unwanted by-products in a number of anthropogenic activities, involving incomplete combustion processes, both industrial and natural. They also occur as contaminants during various industrial processes, e.g. the chemical manufacture of some chlorinated compounds and chlorine bleaching of paper pulp (SCF, 2000; Srogi, 2008).

The toxicity of individual dioxin and dibenzofuran congeners differs considerably. From the 210 theoretically possible congeners, those substituted in each of the 2-, 3-, 7- and 8-positions of the two aromatic rings are of particular toxicological concern. These 17 congeners exhibit a similar toxicological profile, with 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD) being the most toxic congener. The toxic responses include dermal toxicity, immunotoxicity, carcinogenicity, reproductive and developmental toxicity and are mostly mediated *via* the aryl hydrocarbon (Ah) receptor present in most tissues of animals and humans (Poland *et al*., 1985; Safe, 1986; SCF 2000).

Polychlorinated biphenyls (PCBs) are chlorinated aromatic hydrocarbons which are synthesised by direct chlorination of biphenyl. Depending on the number of chlorine atom substituents (1-10) and their position on the two rings there are 209 theoretically possible congeners. Due to their physical and chemical properties, such as non-flammability, chemical stability, high boiling point, low heat conductivity and high dielectric constants, technical PCB mixtures were widely used in a number of applications such as coatings, inks and plasticizers in paints and rubber products, with the major use being in hydraulic and heat transfer systems as well as cooling and insulating fluids in transformers and capacitors (SCF, 2000; IPCS/WHO, 2003).

PCBs can be divided into different groups according to their biochemical and toxicological properties. Non-*ortho* and mono-*ortho* substituted PCBs show toxicological properties that are similar to dioxins, and are potent inducers of the cytochromes CYP1A1 and CYP1A2, which are markers of Ah receptor-mediated biochemical and toxicological effects (Safe *et al*., 1985). They are therefore often termed as the 12 “dioxin-like PCBs”. Most other PCBs do not show dioxin-like toxicity and many are inducers of CYP2B1 and CYP2B2 in the liver of rodents. Among the non-*ortho* and mono-*ortho*-substituted PCBs some are “mixed-type” inducers, increasing both CYP1A and CYP2B enzyme activities (SCF, 2000).

In order to be able to sum up the toxicity of the different congeners of concern (the seventeen 2,3,7,8-PCDD/Fs and 12 “dioxin-like” PCBs), Commission Regulation (EC) No 1881/2006[2] lays down the use of toxic equivalency factors (TEFs) to facilitate risk assessment and regulatory control. The analytical results relating to all the individual dioxin and “dioxin-like” PCB congeners should be expressed in terms of TCDD toxic equivalents (TEQs) using the TEF values proposed by the World Health Organization (WHO) Consultation in 1997 (WHO-TEFs) (Van den Berg *et al*., 1998).

Legislation

Commission Regulation (EC) No 1881/2006 of 19 December 2006[3] lays down maximum levels for certain contaminants in foodstuffs. For meat and meat products (excluding edible offal) of pigs maximum levels of 1.0 pg WHO-TEQ per g fat for the sum of dioxins and 1.5 pg WHO-TEQ per g fat for the sum of dioxins and dioxin-like PCBs have been set. For liver of pigs and derived products thereof a level of 6.0 pg WHO-TEQ per g fat and 12.0 pg WHO-TEQ per g

[3] OJ L 364, 20.12.2006, p. 5-17

fat for the sum of dioxins and dioxin-like PCBs apply. The maximum level is not applicable for food containing less than 1% fat.

Health based guidance value

The Scientific Committee on Food (SCF) established a group tolerable weekly intake (TWI) of 14 pg WHO-TEQ/kg body weight (b.w.) for 2,3,7,8-TCDD, all 2,3,7,8-substituted PCDDs and PCDFs and the dioxin-like PCBs in 2001 (SCF, 2001). This is equivalent to a tolerable daily intake (TDI) of 2 pg WHO TEQ/kg b.w., but due to the very long half-lives in humans the tolerable intake should be expressed on a weekly rather than daily basis.

This assessment was based on the most sensitive adverse effects of 2,3,7,8-TCDD that were observed in rodent studies, namely developmental effects in rat male offspring (SCF, 2001). Thus experimental studies together with epidemiological studies support that the developing foetus is the most sensitive segment of the population to the adverse effects of dioxins. In four critical animal studies lowest observed adverse effect levels (LOAELs) were estimated to occur at maternal body burden levels between 40 and 100 ng/kg b.w. These were assumed to be associated with human daily intakes in the range of 20-50 pg 2,3,7,8-TCDD/kg b.w.

The LOAEL for decreased sperm production and altered sexual behaviour from the pivotal study in rats by Faqi (1998) (for details see SCF, 2001) was associated with a maternal steady state body burden of 40 ng/kg b.w. and an estimated human daily intake of 20 pg 2,3,7,8-TCDD/kg b.w. per day. In its derivation of the TWI of 14 pg WHO-TEQ/kg b.w., an uncertainty factor of 9.6 was applied to the human daily intake.

The toxicity of dioxins is related to the amount accumulated in the body during lifetime, the so-called body burden.

The WHO proposed to calculate the relationship between the total body burden and intake as follows:

Body burden (ng/kg b.w.) = f * intake (ng/kg b.w./day)*half-life in days/ln(2),

where f is the fraction of dose absorbed (assumed to be 50% for absorption from food for humans), and an estimated half-life for 2,3,7,8-TCDD of 2740 days (equal to 7.5 years).

Occurrence

Dioxin (PCDD/F) and PCB concentrations and congener profiles of 16 Irish pork fat samples were provided to EFSA by two Member States on 9 December 2008. Samples were analysed for the levels of dioxins and non- and mono-*ortho* PCBs (DL-PCBs).

Upper bound dioxin concentrations ranged from 1.1 to 191.8 pg WHO-TEQ per g fat. When DL-PCBs are included, the upper bound concentrations ranged from 1.2 to 199.4 pg WHO-TEQ per g fat. For most of these samples the reported concentrations are above the maximum levels laid down in the Commission Regulation (EC) No 1881/2006[2]. The main group of congeners contributing to the total WHO-TEQ value were PCDD/Fs (92-97%) with furans dominating, followed by mono-*ortho* PCBs (3-6%). Non-*ortho* PCBs contributed with the lowest percentage (0.2-2%). Concerning the mono-*ortho* PCBs profile, PCB 156 and PCB 118 and to a lesser extent PCB 189 were the predominant dioxin-like congeners, while for PCDD/Fs, 2,3,4,7,8-PeCDF followed by 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF were the dominant isomers in most of the samples.

Occurrence data compiled under the SCOOP task in 2000 reported levels for PCDD/Fs of 0.13-3.8 pg WHO-TEQ per g fat in pork and pork products (samples originating from Denmark, Italy, The Netherlands and Sweden), while for dioxin-like PCBs the levels in such products ranged between 0.9-0.81 pg WHO-TEQ per g fat (samples originating from The Netherlands and Sweden) (SCOOP, 2000).

Irish data combined from the years 2003 and 2006 reported background levels for total PCDD/F and dioxin-like PCB for pork and pork products to the EU for Ireland are within this range with an average of 0.37 pg WHO-TEQ /g fat (EFSA, unpublished results).

Exposure scenarios

EU SCOOP estimated earlier that the average dietary exposure to PCDDs and PCDFs is between 0.4 and 1.5 pg WHO-TEQ/kg b.w. per day for an adult person. An additional average dietary exposure to dioxin-like PCBs was estimated to be between 0.8 and 1.5 pg WHO-TEQ/kg b.w per day (SCOOP, 2000).

Based on the very limited new data related to the current contamination incident of pork, which were made available to EFSA, dietary exposure scenarios were calculated. For these calculations the following assumptions have been used:

- the percentage of potentially contaminated pork in different EU countries was based on the export figures from Ireland and production figures from the respective Member State (see Table 1) resulting in three scenarios (1, 10 and 100% contaminated pork),
- consumption data on pork and processed meat from 10 European countries collected within the European Prospective Investigation into Cancer and Nutrition (EPIC) (Linseisen *et al.*, 2006),
- pork and pork products were assumed to represent 50% of the total "meat and meat products, offal" in each of the above mentioned 19 Member States,
- Fat intake per kg b.w. was then estimated by assuming a fat content equal to 20 g per 100g. This assumption has been considered adequate based on the fact that fat in pork is less than 10% whereas most of the other pork products (e.g. sausages, bacon, etc.) do not exceed 30% fat.

Table 1. Export volumes of pork from Ireland into other EU Member States.

EU Member State	Volume (1,000t)		Import vs. production
	Production	Export	
Belgium/Luxembourg	1073	0.7012	0.07%
Bulgaria	41	0.0402	0.10%
Czech republic	360	0.0218	0.01%
Denmark	1802	3.7694	0.21%
Germany	4985	8.3532	0.17%
Estonia	38	2.0500	5.39%
Spain	3439	0.0289	0.00%
France	2281	4.7164	0.21%
Italy	1603	3.7115	0.23%
Cyprus	55	0.1245	0.23%
Hungary	499	0.0200	0.00%
Netherlands	1290	4.4625	0.35%
Austria	531	0.0019	0.00%
Poland	2091	1.5050	0.07%
Portugal	364	1.2557	0.34%
Romania	491	0.0176	0.00%
Finland	213	0.0609	0.03%
Sweden	265	1.7356	0.65%
United Kingdom	739	42.6245	5.77%

A deterministic approach was used based on mean and 95th percentile intake of fat from all pork and pork products using consumption figures of **"**meat and meat products, offal**"**. These consumption figures were reported in the Concise European Food Consumption Database (EFSA, 2008) (Table 2). Three different dioxin concentrations in the meat (50, 100, 200 pg WHO-TEQ /g fat) and three different proportions of contaminated meat (100, 10 and 1%) were assumed.

The EFSA´s Concise European Food Consumption Database includes data from 19 Member States. Table 3 indicates the estimated dietary exposure based on WHO-TEQ pg/ kg b.w. per day for average fat intake and Table 4 for the 95th percentile.

Table 2. Estimated consumption figures of meat and meat products and offal and calculated average and 95th percentile pork fat intake (g per kg body weight).

Country	Consumption of "Meat and meat products, offal" Concise European Food Consumption Database Total population (EFSA, 2008)					Average pork fat intake (g /day per kg b.w.) *	95th perc. pork fat intake (g / day per kg b.w.) *
	Number of subjects	Mean (g/day)	STD (g/day)	Median (g/day)	95th perc. (g/day)		
Austria	2123	186	186	150	525	0.31	0.88
Belgium	1723	123	89	109	296	0.20	0.49
Bulgaria	853	114	111	96	333	0.19	0.56
Czech Republic	1751	187	125	165	421	0.31	0.70
Denmark	3150	135	65	123	258	0.23	0.43
Estonia	2010	157	147	120	450	0.26	0.75
Finland	2007	120	88	104	286	0.20	0.48
France	1195	202	97	190	376	0.34	0.63
Germany	3550	167	94	150	341	0.28	0.57
Hungary	927	186	86	173	343	0.31	0.57
Iceland	1075	110	111	86	343	0.18	0.57
Ireland	1373	148	77	136	288	0.25	0.48
Italy	1544	137	68	127	264	0.23	0.44
Netherlands	4285	152	90	139	305	0.25	0.51
Norway	2321	109	59	99	209	0.18	0.35
Poland	2692	259	217	221	680	0.43	1.13
Slovakia	2208	156	368	100	500	0.26	0.83
Sweden	1088	150	70	141	269	0.25	0.45
United Kingdom	1724	161	94	152	324	0.27	0.54

*Assumptions:
1) 50% of "Meat and meat products, offal" is considered as pork and pork products. Hypothesis based on: Linseisen *et al*., 2006.
2) 20% fat content in pork and pork products
3) 60 kg body weight

Table 3: Dioxin exposure (pg WHO-TEQ/ kg b.w. per day) based on average fat intake (g per kg b.w.) and different scenarios related to the occurrence of dioxins in fat and the percentage from contaminated pork.

Country	Average fat intake (g / day per kg b.w.)	dioxins exposure (pg WHO-TEQ/kg b.w. per day)								
		50 pg TEQ/g fat			100 pg TEQ/g fat			200 pg TEQ/g fat		
		% of fat from contaminated pork			% of fat from contaminated pork			% of fat from contaminated pork		
		100%	10%	1%	100%	10%	1%	100%	10%	1%
Austria	0.31	15.5	1.5	0.2	31.0	3.1	0.3	61.9	6.2	0.6
Belgium	0.20	10.2	1.0	0.1	20.5	2.0	0.2	40.9	4.1	0.4
Bulgaria	0.19	9.5	1.0	0.1	19.1	1.9	0.2	38.1	3.8	0.4
Czech Republic	0.31	15.6	1.6	0.2	31.2	3.1	0.3	62.4	6.2	0.6
Denmark	0.23	11.3	1.1	0.1	22.5	2.3	0.2	45.1	4.5	0.5
Estonia	0.26	13.1	1.3	0.1	26.1	2.6	0.3	52.2	5.2	0.5
Finland	0.20	10.0	1.0	0.1	20.0	2.0	0.2	40.0	4.0	0.4
France	0.34	16.9	1.7	0.2	33.7	3.4	0.3	67.4	6.7	0.7
Germany	0.28	13.9	1.4	0.1	27.8	2.8	0.3	55.5	5.6	0.6
Hungary	0.31	15.5	1.5	0.2	31.0	3.1	0.3	61.9	6.2	0.6
Iceland	0.18	9.2	0.9	0.1	18.4	1.8	0.2	36.7	3.7	0.4
Ireland	0.25	12.3	1.2	0.1	24.6	2.5	0.2	49.3	4.9	0.5
Italy	0.23	11.4	1.1	0.1	22.8	2.3	0.2	45.7	4.6	0.5
Netherlands	0.25	12.7	1.3	0.1	25.3	2.5	0.3	50.6	5.1	0.5
Norway	0.18	9.1	0.9	0.1	18.1	1.8	0.2	36.3	3.6	0.4
Poland	0.43	21.6	2.2	0.2	43.2	4.3	0.4	86.5	8.6	0.9
Slovakia	0.26	13.0	1.3	0.1	26.1	2.6	0.3	52.2	5.2	0.5
Sweden	0.25	12.5	1.3	0.1	25.0	2.5	0.3	50.0	5.0	0.5
United Kingdom	0.27	13.4	1.3	0.1	26.8	2.7	0.3	53.6	5.4	0.5
Minimum	0.18	9.1	0.9	0.1	18.1	1.8	0.2	36.3	3.6	0.4
Median	0.25	12.7	1.3	0.1	25.3	2.5	0.3	50.6	5.1	0.5
Maximum	0.43	21.6	2.2	0.2	43.2	4.3	0.4	86.5	8.6	0.9

Table 4: Dioxin exposure (pg WHO-TEQ/ kg b.w. per day) for high consumers (based on 95th percentile) fat intake (g per kg b.w.) and different scenarios related to the occurrence of dioxins in fat and the percentage from contaminated pork.

Country	95th perc. fat intake (g / day per kg b.w.)	dioxins exposure (pg WHO-TEQ/kg b.w. per day)								
		50 pg TEQ/g fat			100 pg TEQ/g fat			200 pg TEQ/g fat		
		% of fat from contaminated pork			% of fat from contaminated pork			% of fat from contaminated pork		
		100%	10%	1%	100%	10%	1%	100%	10%	1%
Austria	0.88	43.8	4.4	0.4	87.5	8.8	0.9	175.0	17.5	1.8
Belgium	0.49	24.6	2.5	0.2	49.3	4.9	0.5	98.6	9.9	1.0
Bulgaria	0.56	27.8	2.8	0.3	55.5	5.6	0.6	111.0	11.1	1.1
Czech Republic	0.70	35.1	3.5	0.4	70.2	7.0	0.7	140.4	14.0	1.4
Denmark	0.43	21.5	2.2	0.2	43.0	4.3	0.4	86.1	8.6	0.9
Estonia	0.75	37.5	3.8	0.4	75.0	7.5	0.8	150.0	15.0	1.5
Finland	0.48	23.8	2.4	0.2	47.6	4.8	0.5	95.3	9.5	1.0
France	0.63	31.3	3.1	0.3	62.6	6.3	0.6	125.3	12.5	1.3
Germany	0.57	28.4	2.8	0.3	56.9	5.7	0.6	113.7	11.4	1.1
Hungary	0.57	28.6	2.9	0.3	57.2	5.7	0.6	114.4	11.4	1.1
Iceland	0.57	28.6	2.9	0.3	57.2	5.7	0.6	114.3	11.4	1.1
Ireland	0.48	24.0	2.4	0.2	48.0	4.8	0.5	96.1	9.6	1.0
Italy	0.44	22.0	2.2	0.2	44.0	4.4	0.4	88.0	8.8	0.9
Netherlands	0.51	25.4	2.5	0.3	50.8	5.1	0.5	101.5	10.2	1.0
Norway	0.35	17.4	1.7	0.2	34.9	3.5	0.3	69.7	7.0	0.7
Poland	1.13	56.7	5.7	0.6	113.3	11.3	1.1	226.7	22.7	2.3
Slovakia	0.83	41.7	4.2	0.4	83.3	8.3	0.8	166.7	16.7	1.7
Sweden	0.45	22.4	2.2	0.2	44.9	4.5	0.4	89.8	9.0	0.9
United Kingdom	0.54	27.0	2.7	0.3	54.0	5.4	0.5	108.1	10.8	1.1
Minimum	0.35	17.4	1.7	0.2	34.9	3.5	0.3	69.7	7.0	0.7
Median	0.56	27.8	2.8	0.3	55.5	5.6	0.6	111.0	11.1	1.1
Maximum	1.13	56.7	5.7	0.6	113.3	11.3	1.1	226.7	22.7	2.3

For each of the foods recalled a backward calculation has been produced in order to estimate the quantities of food products (g per day) that need to be consumed in order to reach the TWI (14 pg WHO-TEQ/kg b.w.). These estimates have been produced under different scenarios related to the occurrence of WHO-TEQ in fat and the percentage from contaminated pork (Table 5). As an example, the average consumption of a reference food category has also been reported for each of the food products listed, consumption figures are referred to consumers only in the United Kingdom (Henderson *et al*., 2002)

Table 5: Quantities of food products (g per day) that need to be consumed to reach the TWI (14 pg WHO-TEQ/kg b.w.) according to different scenarios related to the occurrence of dioxins in fat and the percentage from contaminated pork.

Food products	Fat content (g/100g)[a]	Maximum amounts of food that can be consumed without exceeding the TWI (14 pg WHO-TEQ/kg b.w. per week)									Average consumption (g/day) in UK adults (consumers only)[b]	
		50 pg TEQ/g fat			100 pg TEQ/g fat			200 pg TEQ/g fat				
		% of fat from contaminated pork									g/day	Reference category
		100	10	1	100	10	1	100	10	1		
Pork suet (lard)	90	3	27	267	1	13	133	1	7	67	2	Other oils and cooking fats, not polyunsaturated
Salami	40	6	60	600	3	30	300	2	15	150	22	Sausages
White pudding	40	6	60	600	3	30	300	2	15	150	30	Other cereal-based puddings
Rashers	30	8	80	800	4	40	400	2	20	200	21	Bacon and ham
Lardons	30	8	80	800	4	40	400	2	20	200	21	Bacon and ham
Bacon	30	8	80	800	4	40	400	2	20	200	21	Bacon and ham
Pork paté	30	8	80	800	4	40	400	2	20	200	17	Liver, liver products & dishes
Sausage meat	30	8	80	800	4	40	400	2	20	200	22	Sausages
Pork sausages	30	8	80	800	4	40	400	2	20	200	22	Sausages
Sausage rolls	30	8	80	800	4	40	400	2	20	200	37	Meat pies and pastries
Black pudding	20	12	120	1200	6	60	600	3	30	300	22	Sausages
Pork pies	15	16	160	1600	8	80	800	4	40	400	37	Meat pies and pastries
Crubeens	15	16	160	1600	8	80	800	4	40	400	30	Pork & dishes
Ready made bacon sandwiches	15	16	160	1600	8	80	800	4	40	400	45	Pizza
Ready made pizza with ham, pepperoni, bacon	15	16	160	1600	8	80	800	4	40	400	45	Pizza
Ready meals with pork/bacon ngredient	10	24	240	2400	12	120	1200	6	60	600	30	Pork & dishes
Ham	10	24	240	2400	12	120	1200	6	60	600	21	Bacon and ham
Pork	10	24	240	2400	12	120	1200	6	60	600	30	Pork & dishes
Ham sandwiches	10	24	240	2400	12	120	1200	6	60	600	45	Pizza
Gammon steaks	5	48	480	4800	24	240	2400	12	120	1200	30	Pork & dishes
Offal from pigs	5	48	480	4800	24	240	2400	12	120	1200	17	Liver, liver products & dishes

[a] Values estimated using data from the EFSA national food composition database containing data from 9 EU countries and assuming all fat originates from pork sources

[b] Henderson L., *et al.* 2002

Fat content values reported in Table 5 are just a rough estimate since fat content will vary considerably for each of these products. Moreover, it is important to mention that calculations provided in Table 5 assume that all fat in the different products comes from pork, whereas other important sources of fat are possible, especially for ready to eat products and sausages.

Although we did not consider other foods, the fat content of the listed food products can be used as a guide to judge also other composite products not included in Table 5.

Exposure estimates compared to the health based guidance value

Comparison with the TWI

Estimated daily dietary exposure data (see Table 3 and 4) converted into weekly exposure are compared with the TWI of 14 pg WHO-TEQ per kg b.w. Depending on the different scenarios presented in these tables the TWI is exceeded 6 to 25-fold when 100 % of the pork is considered contaminated with 50 and 200 pg WHO-TEQ/g fat, respectively, for average pork consumption. In a high consumption scenario the TWI can be exceeded 13 to 55-fold at the same contamination concentrations. Thus the TWI can be considerably exceeded. However, this has to be put in perspective that it is only for a relatively short period of time whereas the TWI is based on long term exposure. Considering the long biological half life of dioxins, the impact of an additional exposure on the body burden is a more relevant indicator of the potential health risk rather than the daily dose.

Comparison with the body burden

The pivotal exposure measure for risk assessment of compounds such as PCDD/PCDFs and dioxin-like PCBs that accumulate in the human body, is the cumulative body burden attained from daily or weekly dietary exposure. Thus, the TWI of 14 pg WHO-TEQ/kg b.w. per week established by the SCF, corresponding with a daily dose of 2 pg WHO-TEQ/kg b.w., can be seen as being based on extrapolation of an established tolerable body burden at steady state of 4000 pg WHO-TEQ/kg b.w.

Concentrations of dioxins and PCBs in human milk can be used as biomarkers for the body burden of dioxins. EFSA noted that more recent reported mean levels of dioxins in pooled samples of human milk were about 10 pg/g fat for Ireland and about 20 pg/g fat for the Netherlands. Assuming a body weight of 60 kg and 20% fat in the human body these levels in human milk corresponding with a body burden of 2000-4000 pg WHO-TEQ/kg b.w., are consistent with mean daily exposures to dioxins of 1-2 pg WHO-TEQ/kg b.w. (7-14 pg WHO-TEQ/kg b.w. per week).

For the situation in Ireland and other European countries, EFSA made the following two scenarios based on the mean and 95th percentile daily intakes of WHO-TEQs estimated in Table 3 and 4 for the mean European intake and assuming that pork meat and products were consumed over the questioned period of 90 days (see Table 6 and 7).

Table 6: Estimation of body burden based on mean European daily intake of dioxins.

Contamination	**50 pg TEQ/g fat**		**100 pg TEQ/g fat**		**200 pg TEQ/g fat**	
	Intake (pg/kg b.w.per 3 month	**% increase in body burden**	**Intake (pg/kg b.w. per 3 month**	**% increase in body burden**	**Intake (pg/kg b.w. per 3 month**	**% increase in body burden**
100% fat from contaminated meat	1107	27.7	2214	55.3	4428	110
10% fat from contaminated meat	111	2.8	221	5.5	443	11
1% fat from contaminated meat	11	0.3	22	0.6	44	1.2

Table 7: Estimation of body burden based on 95th percentile European daily intake of dioxins.

Contamination	**50 pg TEQ/g fat**		**100 pg TEQ/g fat**		**200 pg TEQ/g fat**	
	Intake (pg/kg b.w. per 3 month	**% increase in body burden**	**Intake (pg/kg b.w. per 3 month**	**% increase in body burden**	**Intake (pg/kg b.w. per 3 month**	**% increase in body burden**
100% fat from contaminated meat	2520	63	5040	126	10080	252
10% fat from contaminated meat	252	6	504	13	1008	25
1% fat from contaminated meat	25	0.6	50.4	1	100.8	3

In very extreme cases, assuming a daily consumption of 100% contaminated Irish pork, for a high a consumer of pork fat during the respective period of the incidence (90 days), at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), EFSA concludes that the uncertainty factor embedded in the TWI is considerably eroded. Given that the TWI has a 10-fold built-in uncertainty factor, EFSA considers that this unlikely scenario would reduce protection, but not necessarily lead to adverse health effects.

In a more likely scenario with a daily consumption of 10% contaminated Irish pork for an average consumer of pork fat (assumed to have a “normal” weekly exposure at the TWI) for the respective period of the incidence (90 days) at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), the body burden would increase by approximately 10%. EFSA considers this increase in body burden of no concern for this single event.

Conclusions

EFSA based this statement on a limited data set assuming that the average person has an exposure at the tolerable weekly intake corresponding to a body burden of 4000 pg/kg body weight. EFSA also assumed that exposure at these high levels only began in September 2008 and that effective measures have now been taken to remove this excessive exposure from Irish pork and pork products.

In very extreme cases, assuming a daily consumption of 100% contaminated Irish pork, for a high consumer of pork fat during the respective period of the incidence (90 days), at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), EFSA concludes that the uncertainty factor embedded in the TWI is considerably eroded. Given that the TWI has a 10-fold built-in uncertainty factor, EFSA considers that this unlikely scenario would reduce protection, but not necessarily lead to adverse health effects.

In a more likely scenario with a daily consumption of 10% contaminated Irish pork for an average consumer of pork fat for the respective period of the incidence (90 days) at the highest recorded concentration of dioxins (200 pg WHO-TEQ/g fat), the body burden would increase by approximately 10%. EFSA considers this increase in body burden of no concern for this single event.

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