

New EU maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in livers of terrestrial animals and in sheep liver

BfR opinion No 014/2014, 11 March 2014

In vertebrates, the liver is the central metabolic organ for detoxification. Certain environmental contaminants such as dioxins and polychlorinated biphenyls (PCBs) are increasingly deposited in the fat of this organ, meaning that the liver of terrestrial animals often shows higher concentrations of dioxins and PCBs than other tissue. In the EU, the maximum levels for dioxins, dioxin-like (dl) PCBs and non-dioxin-like (ndl) PCBs in the livers of terrestrial animals are laid down in Regulation (EC) No. 1881/2006 (according to the EU regulation, terrestrial animals are livestock such as cattle, pigs, sheep and poultry; game meat is not covered by the regulation). In the past, the maximum levels were expressed on fat basis of the liver. When the regulation (EU) No. 1067/2013 came into force, the reference value was changed from fat to the wet weight of the liver. In line with this change, the previous maximum levels were increased, depending on the maximum level for a specific animal species, by factor 2 to factor 5. In addition, separate maximum levels were defined for the first time for livers of cattle, pigs and poultry on the one hand and sheep liver on the other hand. Due to a lower enzyme activity in the liver compared to other livestock sheep generally show a higher level of dioxins and PCBs in the liver.

The Federal Institute for Risk Assessment (BfR) has assessed the health implications of the new maximum levels for dioxins and PCBs in livers of terrestrial animals laid down in Regulation (EU) No. 1067/2013 with regard to the wet weight. The BfR concludes that adverse health effects through the higher maximum levels for livers of terrestrial animals (with the exception of sheep) are unlikely, provided that the consumers eat liver in the low quantities that are typical for Germany.

In the case of sheep liver, the increase of the maximum level as part of the change of the reference value from fat to wet weight means that even one-off consumption of a 250 g portion of sheep liver containing dioxins and dl-PCBs in the range of the maximum level of 2 pg WHO-PCDD/F-PCB-TEQ per gram of wet weight would exhaust 51% of the tolerable weekly intake (TWI). If in addition the daily intake of dioxins and dl-PCBs from the consumption of other foods (apart from sheep liver) is taken into account, even the consumption of sheep liver on a single occasion may lead to the TWI being exceeded.

In general, the German population very rarely consumes sheep liver. Accordingly, the BfR concludes that due to infrequent consumption, the increase in the maximum level for sheep liver is unlikely to lead to adverse health effects for the general population. However, there are population groups from other geographical areas living in Germany who more frequently eat sheep offal and hence also regularly consume sheep liver or sheep liver products. This was shown by a survey conducted with Greek, Italian and Turkish immigrants (only females) living in Germany. For these special consumer groups, adverse health effects resulting from the regular consumption of sheep liver and sheep liver products which contain, in accordance with Regulation (EU) No. 1067/2013, the applicable maximum level of 2 pg WHO-PCDD/F-PCB-TEQ per gram of wet weight, are possible. Due to the significantly increased permissible maximum levels for dioxins and PCBs in sheep liver and the higher intake of dioxins and PCBs potentially resulting from these new maximum levels, the BfR recommends that consumers generally avoid the consumption of sheep liver. In contrast, sheep, lamb and mutton meat can be safely consumed.

		BfR risk profile: New EU maximum levels for dioxins and PCB in sheep liver (Opinion No. 014/2014)			
A Who is affected	Persons who frequently eat sheep liver				
B Probability of health impairment if sheep liver with dioxin and PCB contents corresponding to the maximum levels is eaten frequently	Practically non-existent	Unlikely	Possible	Likely	Certain
C Severity of health impairments if sheep liver with dioxin and PCB contents corresponding to the maximum levels is eaten frequently	Chronic effects of dioxins and PCB described in animal experiments included impairment of the reproductive function, the immune system and the nervous system as well as disturbance of the hormonal balance.				
D Informative value of the available data	High: Essential data are available and free of contradictions	Medium: Some essential data missing or contradictory		Low: Large amounts of data missing or contradictory	
E Controllability by consumers	Control not necessary	Controllable by taking precautionary measures	Controllable by refraining from consumption	Not controllable	

Dark blue shaded fields designate the characteristics of the risk assessed in this opinion (more detailed information on this can be found in the text of BfR Opinion No. 014/2014, 11/March/2014).

Explanations

The purpose of the risk profile is to visualise the risk described in the BfR opinion. It is not intended for risk comparisons. The risk profile should only be read in the context of the opinion.

Row D – Informative value of the available data

No representative quantitative data on the consumption of sheep liver for frequent consumers are available.

BUNDESINSTITUT FÜR RISIKOBEWERTUNG (BfR)

1 Subject of the Assessment

In connection with the new regulation of maximum levels for dioxins and PCBs in livers of terrestrial animals, the Federal Institute for Risk Assessment (BfR) has been asked by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) for its opinion on the following points:

1. Assessment of the health implications of the maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in livers of terrestrial animals laid down in Regulation (EU) No. 1067/2013 of the Commission from 30 October 2013 amending Regulation (EC) No. 1881/2006.
2. Investigation of the necessity to keep or change the current consumption recommendation for sheep liver.

2 Results

The BfR came to the following conclusions:

1. With Commission Regulation (EU) No. 1067/2013 of 30 October 2013 amending Regulation (EC) No. 1881/2006 on maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in livers of terrestrial animals, the reference value for the maximum levels in livers of terrestrial animals is changed from “fat” to “wet weight”.

The change of the reference value is accompanied by an increase of the values for selected maximum levels ranging from factor 2 to factor 5.

Livers of terrestrial animals and notably sheep livers are among a group of foods which can contain especially high levels of dioxins and PCBs. Although livers of terrestrial animals belong to a type of food which is rarely eaten, the relatively high dioxin and PCB contents of livers of terrestrial animals can nevertheless lead to high intake of dioxins and PCBs.

Acting on the assumption that all consumed livers of terrestrial animals show levels of dioxins, dl-PCBs and ndl-PCBs corresponding to the current maximum levels specified in Regulation (EU) No. 1067/2013, the BfR has conducted model calculations.

The BfR concludes that due to low consumption, adverse health effects are unlikely to result from the increase of the maximum levels for **livers of terrestrial animals with the exception of sheep**.

In contrast, high consumption even on a single occasion of **sheep liver** (250 g) with dioxin and dl-PCB contents corresponding to the currently applicable maximum level of 2 pg WHO-PCDD/F-PCB-TEQ/g wet weight would exhaust 51 % of the TWI.

For consumer groups with special eating habits such as persons who have migrated to Germany from other countries, regular consumption of sheep liver and sheep liver-derived products can be assumed. In the opinion of the BfR, adverse health effects resulting from regular and high consumption of sheep liver and sheep liver-derived products containing levels of dioxins and PCBs of 2 pg WHO-PCDD/F-PCB-TEQ/g of wet weight are possible.

2. The BfR furthermore recommends that consumers avoid the consumption of sheep liver.

3 Rationale

- 3.1 Health based risk assessment of the current maximum levels for dioxins, dl-PCBs and ndl-PCBs in livers of terrestrial animals in accordance with Regulation (EU) No. 1067/2013

With Regulation (EU) No. 1067/2013 amending Regulation (EC) No. 1881/2006 with regard to the maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in livers of terrestrial animals, the reference value for the maximum levels in livers of terrestrial animals is changed from fat to wet weight. However, the previous maximum levels do not remain unchanged as a result of direct conversion. As already shown in a previous BfR opinion, the current maximum levels are significantly increased in the range of factor 2 to factor 5.

Even though contamination has been decreasing for many years, dioxins and PCBs still constitute a general problem for humans, since these substances are found everywhere in the environment due to their stability and also because they accumulate in fatty tissue and in the liver. Animals ingest both substance groups with their feed, meaning that in particular foods such as meat, milk and eggs can be contaminated with dioxins and PCBs. Some of the compounds are thought to be cancer-causing or cancer-promoting.

3.1.1 Agent

3.1.1.1 Dioxins

The term “dioxins” refers to two classes of differently chlorinated compounds. They consist of 75 polychlorinated dibenzo-p-dioxins (PCDD) and 135 polychlorinated dibenzofurans (PCDF). Dioxins (PCDD/F) have similar chemical, physical and toxic properties and are lipophilic compounds which accumulate in the fatty tissue of animals and humans. 17 congeners are seen as especially toxic and at the same time persistent. They are chlorinated in 2,3,7,8-position. The congener with the highest toxicity is 2,3,7,8-TCDD, the so-called Seveso dioxin. In relation to this congener, the other 2,3,7,8-substituted dioxins are assigned toxicity equivalent factors (TEF). The concentrations of the individual congeners are multiplied by the TEFs laid down by the World Health Organisation (WHO) and then added up. The result is the sum of dioxin toxicity equivalent concentration (WHO-PCDD/F-TEQ).

Dioxins are unwanted by-products which are predominantly produced and released during certain industrial and combustion processes (e.g. burning of domestic and hazardous waste). This means that they have not, either in the past or present, been produced for a specific purpose (except for scientific purposes).

3.1.1.2 Polychlorinated biphenyls

Polychlorinated biphenyls (PCBs) are a group of 209 congeners of chlorinated substances which differ from each other on account of their different number and position of chlorine atoms on the biphenyl. 130 of these congeners are found in produced compounds. In contrast to dioxins, PCBs have been produced specifically for various applications, largely as non-inflammable and non-electricity conducting viscous fluids in transformers and in hydraulics (mining). Like dioxins, PCBs are lipophilic, in some cases persistent, and they accumulate in the fatty tissue of humans and animals.

Some PCBs have a molecular structure similar to dioxins and comparable biological effects. For this reason, they are called dioxin-like PCBs (dl-PCBs). As is the case with dioxins, dl-PCBs are assigned TEF which rate these PCB congeners according to their toxicity compared to 2,3,7,8-TCDD. Analogous to PCDD/F, dl-PCBs can thus be summarised as toxicity equivalent concentrations (WHO-PCB-TEQ). However, dl-PCBs only account for a small proportion of PCBs. The so-called non-dioxin-like PCBs (ndl-PCBs) are much more common.

The sum of WHO-PCDD/F-TEQ and WHO-PCB-TEQ is referred to as the total dioxin equivalent (WHO-PCDD/F-PCB-TEQ). The appendix to Regulation (EC) No. 1881/2006 passed by the European Commission on 19 December 2006, last amended by Regulation (EU) No. 1259/2011 lists both maximum levels for WHO-PCDD/F-TEQ and for WHO-PCDD/F-PCB-TEQ.

3.1.2 Hazard Characterisation

The acute effects of high dioxin and dl-PCB doses are described for humans only in connection with absorption at the workplace or following an accident. The most common symptom are prolonged inflammatory skin lesions which are referred to as “chloracne”. Changes in the clinical and chemical parameters (especially an increase in the concentration

of triglycerides, cholesterol and transaminases in the blood) are a sign of liver damage and / or changes in lipid metabolism.

In terms of chronic effects of dioxins and PCBs, animal experiments describe impairment of the reproductive functions, the immune system and the nervous system and disturbance of the hormonal balance. The liver and thyroid gland have been identified as the most sensitive target organs for dioxin and PCB exposure. Various dioxins and PCBs are considered to be tumour promoters. Most recently, the findings of epidemiological studies in particular have caused controversy. The studies focused on the impairment – deemed to be reversible – of the neuropsychological development of children through prenatal (via the placenta) and postnatal (via breast milk) PCB exposure.

The WHO has defined a tolerable daily intake (TDI) in the range of 1 to 4 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and day (WHO 2000). This definition sees the maximum value, (i.e. the TDI of 4 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight) as a provisional basis of the maximum tolerable daily intake. The lower value documents the goal of the WHO of reducing the daily intake of WHO-PCDD/F-PCB-TEQ in humans to less than 1 pg/kg of bodyweight. As a basis of the TDI range, the WHO has used the *Lowest Observed Adverse Effect Level* (LOAEL) which is described by various authors for different species and various endpoints.

In 2001, the Scientific Committee on Food (SCF) of the European Union (EU) defined a tolerable weekly intake, TWI, of 14 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight. As a basis for deriving the TWI, the SCF used the LOAEL for reduced sperm production and the changed sexual behaviour of male Wistar rats, as described by Faqi et al. (1998).

3.1.3 Exposure Assessment

3.1.3.1 Special Consumer Groups

As a possible risk group for the increased intake of dioxins and PCBs via the consumption of livers, persons who have migrated to Germany from certain other countries were identified. The BfR refers to a study on the consumption behaviour of various female migrants living in Germany (Schmid, 2003). In the study, the frequency of consumption of sheep meat and offal (the latter with no specification of animal species) was, among other things, recorded for each of three groups of 100 persons (Italian, Greek and Turkish female immigrants living in Germany). One of the survey instruments used was a qualitative Food Frequency Questionnaire (FFQ) with a set of possible answers (frequently, occasionally, rarely, never). Whereas no estimates of the intake quantities can be made on the basis of this type of survey, it nevertheless provides clues about different food consumption behaviours.

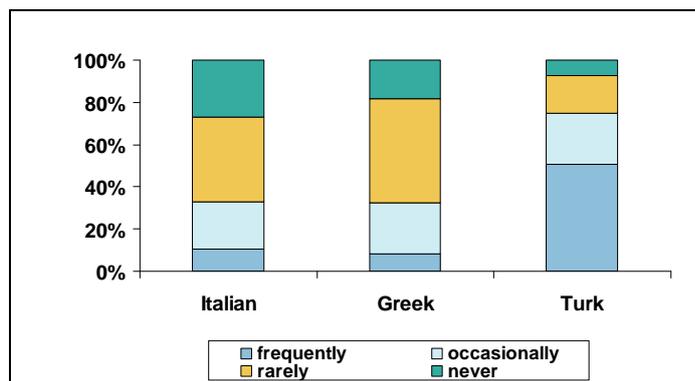


Figure 1: Frequency of consumption of sheep and lamb meat among female immigrants from different origins living in Germany

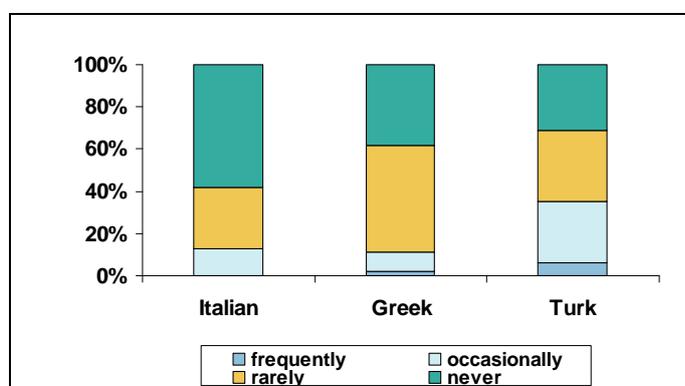


Figure 2: Frequency of consumption of offal (from any animal species) among female immigrants from different origins living in Germany

As Figures 1 and 2 illustrate, a majority of female Italians, Greeks and Turks eat sheep and lamb meat and offal. In particular female immigrants from Turkey show, compared to female immigrants from other countries and probably also compared to the average population in Germany, higher sheep meat and offal consumption. However, it is not possible to quantify consumption levels on the basis of the available data.

3.1.3.2 Consumption Data

For the purpose of calculating consumption quantities, scenarios are used on the intake of dioxins and PCBs via sheep liver by analogy to previous BfR opinions. The reason for this approach is that sheep liver is a rarely eaten food.

As indication for the rationale of the scenarios, data of the National Nutrition Survey II (NVS II) of the Max Rubner-Institute (MRI) were used. NVS II is the most recent representative study on nutrition among the German population. Conducted between 2005 and 2006 all over Germany and making use of three different survey methods (Dietary History, 24h-recall and a weighing record), the study interviewed about 20,000 persons aged between 14 and 80 years on their food consumption behaviour (MRI 2008).

The consumption analysis is based on the data of the “Dietary History” interviews of NVS II which were collected through the programme “DISHES 05”. Using “Dietary History” method,

15,371 persons were interviewed to retrospectively establish their typical consumption over the last four weeks. As part of the LExUKon project, all foods consumed were calculated based on the foods of the maximum level categories for environmental contaminants (Blume et al. 2010). These calculations take into account all contributions from liver used in recipes.

The “Dietary History” method provides good estimates of the long-term intake of substances when foods are summarised in categories or where foods are considered which are subject to regular consumption. For foods which are only sporadically eaten but are not part of the daily nutrition, it is possible that intake is underestimated due to the survey period of four weeks as well as the limited accuracy of the individual foods covered by the survey.

For this reason, data on the consumption frequency of rarely eaten foods are still used which were collected on behalf of the BfR as part of a representative survey of the population. 1,005 persons aged 14 or older participated in the telephone interviews. The interviewees constituted a representative selection based on ADM telephone sampling. The interviews were conducted between 21 September and 27 September 2011.

Liver and especially sheep liver belong to food that is rather infrequently eaten by the population (Figure 3). This is illustrated clearly by the findings of the representative population survey according to which 41 % of respondents had eaten liver from pigs, cattle or calves in the course of the previous year, either as a whole or as an ingredient in ragout. In contrast, only 7% had eaten sheep liver in the same time period.

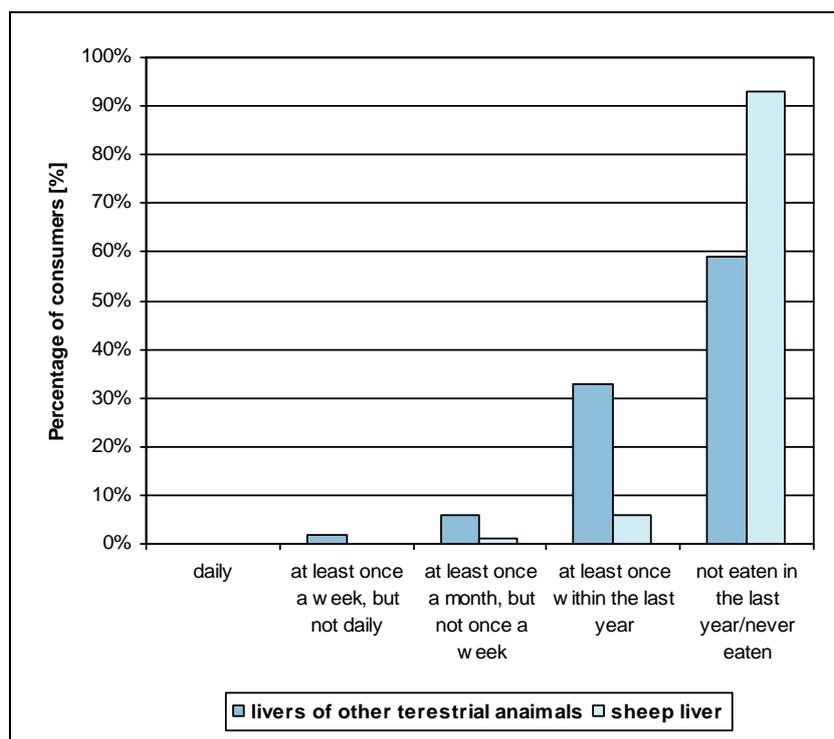


Figure 3: Frequency of consumption of sheep liver and livers of other terrestrial animals according to a representative telephone survey of the adult German population conducted on behalf of the BfR in 2011

Based on the consumption frequencies shown in Figure 3, those scenarios that assume a frequency of consumption of 1 x per week for a high consumer and 2 x per months for an average consumer must be regarded as conservative. According to data from NVS II, portions of 160 g must be assumed for the average consumer and 250 g for high consumers.

3.1.3.3 Exposure Assessment

The exposure assessment is based on worst-case calculations which assume that all consumed livers from terrestrial animals contain levels of dioxins, dl-PCBs and ndl-PCBs which correspond to the current maximum levels as specified in Regulation (EU) No. 1067/2013 (Table.1).

Table 1: Maximum levels for dioxins, dl-PCBs and ndl-PCBs in accordance with Regulation (EU) No. 1067/2013.

Food category	PCDD/F *	PCDD/F +dl-PCBs *	ndl-PCBs
	[pg/g of wet weight] *		[ng/g of wet weight]
Liver of terrestrial animals (with the exception of sheep) and derived products thereof	0.30	0.50	3.00
Liver of sheep and derived products thereof	1.25	2.00	3.00

* PCDD/F and PCDD/F + dl-PCBs expressed as toxicity equivalents (TEQ) of the WHO using the WHO TEF (toxicity equivalence factors). TEF of the WHO for assessing the risk in humans on the basis of the conclusions of the conference of experts of the WHO and the IPCS in Geneva in July 2005 (Van den Berg, M. et al., 2006).

For the consumption data, the above derived scenarios for average consumers (2 x 160 g per month) and for high consumers (1 x 250 g per week) of the adult German population (70 kg bodyweight) are used as a basis. Both scenarios are to be regarded as conservative for the respective group they represent.

Table 2: Model calculation of the average weekly intake of dioxins (PCDD/F), the sum of dioxins and dl-PCBs (PCDD/F+dl-PCBs) as well as non-dioxin-like PCBs (ndl-PCBs) by the adult German population (70 kg bodyweight) in dependence of whether sheep liver or sheep liver-derived products are eaten and differentiated between average consumers and high consumers (worst-case scenario).

Food category	Consumption scenario	Intake of		
		PCDD/F *	PCDD/F + dl-PCBs *	ndl-PCBs
		[pg/kg of bodyweight and week]*		[ng/kg of bodyweight and week]
Liver of terrestrial animals (with the exception of sheep) and derived products thereof	Average consumer scenario	0.3	0.6	3.4
	High consumer scenario	1.1	1.8	10.7
Liver of sheep and derived products thereof	Average consumer scenario	1.4	2.3	3.4
	High consumer scenario	4.5	7.1	10.7

* PCDD/F and PCDD/F + dl-PCBs expressed as toxicity equivalents (TEQ) of the WHO using the WHO TEF (toxicity equivalence factors). TEF of the WHO for assessing the risk in humans on the basis of the conclusions of the conference of experts of the WHO and the IPCS in Geneva in July 2005 (Van den Berg, M. et al., 2006).

For average consumers eating **livers of terrestrial animals except sheep**, the worst-case scenario shown in Table 2 results in intake levels of 0.3 pg WHO-PCDD/F-TEQ/kg of

bodyweight and week, 0.6 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week and 3.4 ng ndl-PCBs/kg of bodyweight and week. An analogous calculation yielded weekly intakes for high consumers of 1.1 pg WHO-PCDD/F-TEQ/kg of bodyweight and week, 1.8 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week and 10.7 ng ndl-PCBs/kg of bodyweight and week.

In contrast, the calculated weekly intake from the consumption of **sheep liver** and products derived thereof of average consumers amounts to 1.4 pg WHO-PCDD/F-TEQ/kg of bodyweight and week, 2.3 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week and 3.4 ng ndl-PCBs/kg of bodyweight and week. For the high consumers, the analogous weekly intake levels are 4.5 pg WHO-PCDD/F-TEQ/kg of bodyweight and week, 7.1 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week and 10.7 ng ndl-PCBs/kg of bodyweight and week.

3.1.4 Risk Characterisation

For risk characterisation, the results of the worst-case calculations (Table 2) and the health-related reference value (TWI) of 14 pg WHO-PCDD/F-PCB-TEQ/ kg of bodyweight and week derived by the Scientific Committee on Food (SCF) in the year 2001 are used.

No separate assessment for the intake of dioxins (without dl-PCBs) is conducted.

In addition, an assessment of the health implications of the intake of ndl-PCBs resulting from the consumption of sheep liver cannot be conducted. The reason for this is that, due to missing data, it has not been possible to derive either a basis for comparison through the establishment of TEF values or toxicological reference values for the intake of ndl-PCBs (EFSA 2005).

Table 3: Risk characterisation for the intake of livers of terrestrial animals by the adult German population on the basis of worst-case calculations and in relation to the degree of exhaustion of the TWI (SCF, 2001) for the sum of dioxins and dioxin-like PCBs.

Food category	Consumption scenario	Intake of WHO-PCDD/F-PCB-TEQ [pg/kg of bodyweight and week]	Degree of exhaustion of the TWI [%]
Liver of terrestrial animals (with the exception of sheep) and derived products thereof	Average consumer scenario	0.6	4
	High consumer scenario	1.8	13
Liver of sheep and products derived thereof	Average consumer scenario	2.3	16
	High consumer scenario	7.1	51

For average consumers eating **livers of terrestrial animals except sheep**, the intake of dioxins and dl-PCBs amounts to 0.6 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week corresponding to 4 % of the TWI. For high consumers, the calculated weekly intake is 1.8 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week corresponding to 13 % of the TWI.

In contrast, average consumers eating **sheep liver** and derived products thereof show a weekly intake of 2.3 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week which is the

equivalent of 16 % of the TWI. For high consumers, a weekly intake of 7.1 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week can be calculated. This is the equivalent of 51 % of the TWI.

Since dioxins and PCBs are persistent substances, the average daily intake from the consumption of other foods amounting to approximately 1 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and day is taken into account in the assessment of their health effects. This results in a weekly intake from the consumption of other foods of 7 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week. This value already corresponds to 50 % of the TWI.

If **livers from terrestrial animals with the exception of sheep** are additionally eaten, the degree to which the TWI is exhausted increases to 54 % for the average consumer scenario and to 63 % for the high consumer scenario. The BfR therefore concludes that due to the low consumption rate, health problems as a consequence of the increased maximum values for livers of terrestrial animals except sheep are unlikely.

By analogy to the calculation of the degree to which the TWI is exhausted if livers of terrestrial animals except sheep are additionally eaten, it is possible to calculate the contribution to the exposure of consumers if they additionally eat **sheep liver** and derived products thereof. Assuming that the consumer already ingests 7 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week from other foods, these calculations show that the degree to which the TWI is exhausted increases to 66 % for average consumers and to 101 % for high consumers, if they additionally eat sheep liver and products derived thereof. This means that even high consumption of sheep liver (250 g) on a single occasion can lead to a situation where the TWI is exceeded.

The BfR concludes that if the TWI is exceeded on a single occasion to the extent calculated, adverse health effects are unlikely.

However, for special consumer groups, e.g. women who have immigrated to Germany from other countries, it must be assumed that sheep liver and derived products thereof are eaten on a regular basis, as shown in BfR Opinion No. 013/2009 from 7 April 2009 and in the doctoral thesis by Schmid (2003). The BfR comes to the conclusion that in case of high and regular consumption of sheep liver and derived products thereof with levels of dioxins and PCBs amounting to 2 pg WHO-PCDD/F-PCB-TEQ/g of wet weight adverse health effects are possible.

3.2 Discussion of the Need for Maintaining / Changing the Current Consumption Recommendation for Sheep Liver

Sheep liver is among the foods which can contain especially high levels of dioxins and PCBs. However, highly contaminated foods should generally not contribute significantly to the level to which the TWI is exhausted by consumers. Of course, this also applies to products that are eaten only by a small section of the population.

On the basis of model calculations, the BfR has shown that high consumption once a week of sheep liver (250 g) with levels of dioxins and dl-PCBs amounting to the maximum level of 2 pg WHO-PCDD/F-PCB-TEQ/g of wet weight would exhaust 51 % of the TWI of 14 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week.

For the purpose of deriving consumption recommendations, the BfR refers to BfR Opinion No. 005/2010 from 12 October 2009. Therein, the following passage can be found:

"It must be ensured that the intake of consumers in terms of their WHO TEQ levels does not, in the longer term, exceed the tolerable weekly intake (TWI) of 14

pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week as defined by the Scientific Committee on Food (SCF, 2001). In this calculation, the intake of WHO TEQ from other foods must also be taken into account. These calculations are based on an assumed daily intake of WHO-TEQ of 1 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and day (7 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week)."

If the intake levels of dioxin and PCBs from other foods amounting to 7 pg WHO-PCDD/F-PCB-TEQ/kg of bodyweight and week are factored into the model calculation, high consumption of sheep liver even on a single occasion can lead to the TWI being exceeded. For this reason, the BfR's recommendation remains unchanged: consumers should avoid the consumption of sheep liver.

The data from the BVL database covering the time span from 01/2000 to 03/2013 document that the analysed livers of sheep exceed the maximum levels previously laid down in Regulation (EC) No. 1881/2006, amended by Regulation (EU) No. 1259/2011 as follows: 78 % of the analysed livers exceed the maximum level for dioxins of 4.5 pg WHO-PCDD/F-TEQ/g of fat; 72 % exceed the maximum level for dioxins and dl-PCBs of 10 pg WHO-PCDD/F-PCB-TEQ/g of fat; and 30 % exceed the maximum level for ndl-PCBs of 40 ng/g of fat (Tab. 4), as can be extracted from a report of the Federal Office of Consumer Protection and Food Safety (BVL).

Tab. 4: Summary of the results from the BVL database on sheep livers (time period 01/2000 – 03/2013). Source: BVL report from 04 April 2013

	n	Reference value "fat"		Reference value "wet weight" (and simultaneous increase of the maximum levels)	
		previous maximum level until 2013 *	Not marketable livers	New maximum level since 2013 **	Not marketable livers
Dioxins	322	4.5 pg WHO-TEQ/g of fat	78 %	1.25 pg WHO-TEQ/g of FW	8 %
Dioxins and dl-PCBs	242	10 pg WHO-TEQ/g of fat	72 %	2 pg WHO-TEQ/g of FW	12 %
ndl-PCBs	201	40 ng/g of fat	30 %	3 ng/g of wet weight	11 %

* PCDD/F and PCDD/F + dl-PCBs expressed as toxicity equivalents (TEQ) of the WHO using the WHO TEF (toxicity equivalence factors). TEF of the WHO for assessing the risk in humans on the basis of the conclusions of the conference of experts of the WHO and the IPCS in Geneva in July 2005 (Van den Berg, M. et al., 2006).

* Regulation (EC) No. 1881/2006, amended by Regulation (EU) No. 1259/2011

** Regulation (EC) No. 1881/2006, last amended by Regulation (EU) No. 1067/2013

However, if the results are applied to the current maximum levels in pg WHO-TEQ/g of wet weight in accordance with Regulation (EU) No. 1067/2013, the number of marketable livers increases significantly as a result of the simultaneous increase of the maximum levels (Table 4).

In earlier opinions (e.g. in BfR Opinion Nr. 013/2009), the BfR came to the conclusion that sheep liver showing concentrations of dioxins and PCBs that do not exceed the maximum

levels laid down in the previous version of Regulation (EC) No. 1881/2006, amended by Regulation (EU) No. 1259/2011, can be safely eaten. However, if the current maximum levels in accordance with Regulation (EU) No. 1067/2013 are applied, this changes the BfR's consumption recommendation. Thus the BfR no longer recommends that consumers should precautionary avoid eating sheep liver which exceed the current maximum levels. Instead, the BfR recommends now that consumers should generally avoid the consumption of sheep liver.

Unlike sheep liver, lamb, sheep and mutton meat can still be safely eaten. Much lower levels of dioxins and PCBs are accumulated in the flesh.

4 References

Van den Berg, M., Birnbaum, L. S., Denison, M., De Vito, M., Farland, W., Feeley, M., Fiedler, H., Hakansson, H., Hanberg, A., Haws, L., Rose, M., Safe, S., Schrenk, D., Tohyama, I. C., Tritscher, A., Tuomisto, J., Tysklind, M., Walker, N., Peterson, R. E. (2006): The 2005 World Health Organization Reevaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-Like Compounds. *Toxicol Sci* 93(2), 223–241.

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