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The consumption of sheep or beef liver can contribute considerably to the total intake of per- and polyfluoroalkyl substances (PFAS)

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Per- and polyfluoroalkyl substances (PFAS) are industrial chemicals that have been used for decades in several industrial processes and consumer products due to their special technical properties. They are not easily degradable and are detectable everywhere: in the environment, in the food chain and in humans.

The Lower Saxony Ministry of Food, Agriculture and Consumer Protection has written a report on PFAS concentrations in sheep and beef liver based on samples from the 2019 National Residue Control Plan. The BfR has compared these data with PFAS concentrations in sheep and beef liver samples sourced from the food control programmes of various German federal states, which were taken in the period 2007 to 2020. The BfR concludes that the concentrations of PFAS in sheep and beef liver detected in Lower Saxony do not differ significantly from the concentrations known from the investigations undertaken by the other federal states. In order to assess the health risks posed by the PFAS concentrations in sheep and beef liver, the BfR used the more comprehensive data from the federal states..

Overall, the BfR concludes that sheep or beef liver with the identified concentrations can contribute considerably to the total intake of PFAS in individuals who consume these foods. PFAS are also ingested through many other kinds of foods. At least in the case of high intakes of sheep or bovine liver, this source of exposure can lead to a comparatively high exhaustion (up to the limit) of the tolerable weekly intake (TWI) for a single food, especially for perfluorooctane sulfonic acid (PFOS). The exhaustion of the TWI for perfluorooctanoic acid (PFOA, EFSA 2018) by consumption of sheep or bovine liver is considerably lower compared to the exhaustion of the TWI for PFOS.

1 Subject of the assessment

The German Federal Institute for Risk Assessment (BfR) was asked to prepare an assessment of the health risks posed by concentrations of per- and polyfluoroalkyl substances (PFAS) in beef liver cited in a report by the Lower Saxony Ministry of Food, Agriculture and Consumer Protection (MF). In its report, the MF has analysed data including data from the 2019 Lower Saxony National Residue Control Plan (NRCP) on concentrations of PFAS in samples of sheep and beef liver. In this Opinion, the BfR compares the data from the MF's report with concentrations of PFAS in sheep and beef liver from the food control activities of the German federal states as carried out from 2007 to 2020, and assesses the health risk for the concentrations detected by the federal states' food control programmes.

2 Result

The German Federal Institute for Risk Assessment (BfR) has based its estimate of the exposure of consumers through the consumption of beef liver on concentration data of six compounds in the PFAS group (perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid

(PFOA), perfluorohexanoic acid (PFHxA), perfluorononanoic acid (PFNA), perfluorododecanoic acid (PFDoDA) and perfluorohexane sulfonic acid (PFHxS)) from food surveillance programmes conducted by the German federal states in the period 2007 to 2020.

In its report dated 14 April 2020, the Lower Saxony Ministry of Food, Agriculture and Consumer Protection (MF) published an exposure assessment based on the data for concentrations of PFOS, PFOA, PFHxA, PFNA and PFDoDA in samples of sheep and beef liver collected as part of the 2019 Lower Saxony National Residue Control Plan (NRCP).

The results of the BfR's exposure assessment indicate that these foods constitute an important source of exposure to PFAS for individuals that consume sheep or beef liver containing the identified concentrations.

Of the PFAS investigated, PFOS makes up the greatest proportion of exposure to PFAS for consumers of sheep or beef liver. In assessing this exposure, the BfR has applied the tolerable weekly intakes (TWIs) as derived by the European Food Safety Authority (EFSA) of 13 ng/kg body weight (bw) per week for PFOS and 6 ng/kg bw/week for PFOA (EFSA 2018). The EFSA Opinion (EFSA 2020) on the assessment of other compounds in the PFAS group—including some of the compounds that have been taken into account in BfR's present exposure assessment for sheep and beef liver—is currently only available in draft form.

Based on data on the concentrations of PFOS in samples from food control programmes of the German federal states conducted from 2007 to 2020, the consumption of beef liver by individuals in the group of consumers of this food item leads to an exposure similar to 10% (mean weekly exposure, modified lower bound (mLB), median consumption (P50)) to 38% (mean weekly exposure, upper bound (UB), high consumption (95th percentile)) of the TWI of 13 ng/kg body weight (EFSA 2018).

In this same scenario, the consumption of sheep liver leads to an exposure of a similar magnitude as the consumption of beef liver, namely of 11% (mean weekly exposure, mLB, median consumption (P50)) to 39% (mean weekly exposure, UB, high consumption (95th percentile)) of the TWI for PFOS.

The exhaustion of the TWI of 6 ng/kg bw/week for PFOA (EFSA 2018) achieved through the consumption of sheep or beef liver is considerably lower compared to the exhaustion of the TWI for PFOS.

Consumers are exposed to PFAS through a variety of foodstuffs other than sheep and beef liver. Assuming average consumption quantities, total exposure to PFOS from food and drinking water is around 3.5 to 10.1 ng/kg bw/week (lower bound to upper bound) (EFSA 2018).

At least in cases where large quantities of sheep or beef liver are consumed, this source of exposure can result in an exhaustion of the TWI which is comparatively high for a single foodstuff, in particular with regard to PFOS.

Overall, from the BfR's view it can be assumed that, particularly for PFOS, the data from the German federal states' food control programmes from 2007 to 2020 describe the situation concerning the occurrence of PFAS in sheep and beef liver more comprehensively than the data from Lower Saxony because they are based on data from several federal states.

In summary, the results of the present exposure assessment for PFAS in sheep and beef liver, based on data from several German federal states, do not offer any reason to believe that the results from the NRCP in Lower Saxony constitute a regional outlier in terms of the concentrations of PFAS — particularly PFOS — in sheep and beef liver.

3 Rationale

3.1 Hazard characterisation

In its opinion, dated 13 December 2018, on the health risks associated with the occurrence of perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in food, EFSA derived a tolerable weekly intake (TWI) of 13 ng/kg bw for PFOS and 6 ng/kg bw for PFOA (EFSA 2018). The TWI derivation is based on the positive association between the PFOS/PFOA concentrations in human blood samples and an elevated blood serum level for total cholesterol in humans as observed in epidemiological studies. The BfR responded to this in its Opinion dated 21 August 2019 (BfR 2019). On 24 February 2020, EFSA published a draft opinion on health risks connected with the occurrence of per- and polyfluoroalkyl substances (PFAS) in food (EFSA 2020). In this draft, a TWI of 8 ng/kg bw/week was derived for the sum of four PFAS, namely PFOA, PFOS, perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic acid (PFNA). This TWI derivation is based on the results of a recent cross-sectional study and applies the negative correlation observed between the antibody titre after vaccination in children and the concentrations of these four PFAS in the blood serum of these children. The BfR has commented on the draft of this recent EFSA Opinion. EFSA announced that the Opinion would be finalised at the end of July 2020.

In order to evaluate the exposure to PFOS and PFOA from the consumption of sheep or beef liver, the BfR followed the approach of the Lower Saxony Ministry of Food, Agriculture and Consumer Protection (MF) by applying the TWI values from the EFSA Opinion (2018), since the final publication of the group TWI is still outstanding.

3.2 Exposure assessment

3.2.1 Data set

The evaluation of concentrations of PFAS in sheep and beef liver in Germany was based on current data taken from the food control activities of German federal states during the period 2007 to 2020. These data were passed to the BfR by the BVL as a result of a data request to the food control authorities of the German federal states initiated by the BfR and handled by the BVL. This data set encompasses analytical results from the states' food surveillance programmes as well as other investigations conducted by state-level authorities. Suspect samples were excluded from the evaluation.

In using this underlying data set for this present Opinion, the BfR has analysed data on concentrations for those PFAS accounted for by the results report from Lower Saxony (perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA) and perfluorododecanoic acid (PFDoA)). In addition, the compound perfluorohexane sulfonic acid (PFHxS) is also included in this evaluation, since the value derived for the tolerable weekly intake by EFSA in its current draft statement on the health risks associated with the occurrence of PFAS in foods relates to the total for PFOA, PFOS and PFNA as well as PFHxS.

Values below the limit of detection or limit of quantification are treated with the *modified lower bound* (mLB) and the *upper bound* (UB) approaches. In the first approach, values below the limit of detection (LOD) are replaced with the value '0', while values below the limit of quantification but above the LOD are replaced with the LOD. In the UB approach, values below the limit of detection (LOD) are replaced with the LOD, while values below the limit of quantification (LOQ) but above the LOD are replaced with the LOQ. Accordingly, the mLB approach is expected to yield higher averages than for the LB approach, in which all values below the limit of detection and quantification are set to '0'. Since the difference between the *lower bound* and the *modified lower bound* is very small for the present data set, only the values from the *modified lower bound* approach are presented in the following.

The data set for liver consumption by adolescents and adults was taken from the National Food Consumption Study II (NVS II) published by the Max Rubner Institute (MRI) (MRI 2008; Krebs *et al.* 2006). NVS II is currently the most recent representative study for food consumption in the German population. The study, which surveyed about 20,000 individuals aged between 14 and 80 on their eating habits using three separate survey methods (dietary history, 24-hour recall and weighing protocol), was conducted between 2005 and 2006 throughout Germany (MRI 2008).

The evaluations of long-term consumption are based on the data from the NVS II dietary history interviews: these data were collected with the aid of the 'DISHES 05' program. The dietary history method was used to survey 15,371 people, who retrospectively recorded their typical consumption over the last four weeks. Evaluations of consumption data were made as part of the 'LExUKon' project on foodborne intake of environmental contaminants (Blume *et al.* 2010) funded by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU). To calculate the quantities consumed, recipes/dishes and virtually all foods consisting of multiple ingredients were broken down into their unprocessed constituent parts, with relevant processing factors also applied in the case of drying, for example.

The BfR also commissioned a market research institution with a phone-based survey of a representative sample of the German population aged 14 and over. A total of 1005 persons were randomly selected and interviewed in the first survey round (September 2011), and 1004 persons were interviewed in the second round (November 2011). The survey was aimed at collecting data on foodstuffs rarely consumed and their consumption frequencies over the last 12 months. The results were weighted to account for the factors of age, gender, German state and town/city size (Ehlscheid *et al.* 2014). This survey was utilised in order to assign the consumption frequencies from NVS II for sheep and beef liver. This is necessary, as it is well known, that results from short-term surveys, as NVS II, tend to underestimate the consumption frequency for foods that are rarely consumed.

3.2.2 Occurrence data

Tables 1 and 2 summarise the occurrence data from the data provided by the German federal states' food control authorities for the years 2007 to 2020 for beef and sheep liver. With the exception of PFOS, the number of values above the limits of detection/quantification is low for all of the PFAS accounted for.

The average *lower bound* (LB) concentrations for PFAS in beef and sheep liver in the samples from the National Residue Control Plan (NRCP) in Lower Saxony from the period mid-August to end of December 2019, used as the underlying data set for the Lower Saxony results report, are summarised in tables 3 and 4.

Compared with the limits of quantification for the data from the Lower Saxony NRCP as presented in the Lower Saxony results report, the limits of quantification for most PFAS in the data supplied by the German federal states' food control authorities for 2007 to 2020 are considerably higher (up to one order of magnitude higher). As a result of the considerably lower limits of quantification, the difference between the concentrations estimated using the LB and UB approaches is lower in the data from the Lower Saxony NRCP than in the data supplied by the German federal states' food control authorities for 2007 to 2020. Accordingly, the results for both data sets are only comparable with limitations.

The data on beef and sheep liver supplied by the German federal states' food control authorities for 2007 to 2020 is provided by six states (Baden-Württemberg, Bavaria, Bremen, Hesse, Mecklenburg-Western Pomerania and North Rhine-Westphalia) and accordingly do not offer a nationwide picture. Nor can it be excluded that some of the foods investigated originate from regions with unusual input sources of PFAS into the environment.

In both data sets, PFOS stands out with the highest concentrations detected in sheep and beef liver compared with the other PFAS. In the data set supplied by the German federal states' food control authorities for 2007 to 2020, comparatively high concentrations of PFNA can also be seen in beef liver (table 1).

The concentrations of all PFAS accounted for in beef liver are higher in the data set supplied by the German federal states' food control authorities for 2007 to 2020 than in the data set from the Lower Saxony NRCP.

For sheep liver, both the mean values and the 95th percentile of LB concentrations in the Lower Saxony NRCP are higher for all PFAS (same high value for PFDoA) than the mLB concentrations in the data set supplied by the German federal states' food control authorities for 2007 to 2020; an exception is the 95th percentile of PFOS concentrations. Due to the considerably higher limits of quantification in the test results from the German federal states' food control programmes for 2007 to 2020, however, the mean values and 95th percentile of UB concentrations are higher than in the Lower Saxony NRCP, with the exception of the mean value for PFOS concentrations.

BfR generally assumes that, particularly for PFOS, the data from the German federal states' food control programmes from 2007 to 2020 describe the situation concerning the occurrence of PFAS in sheep and beef liver more comprehensively because of the availability of data from several states — even when accounting for the limitations due to higher limits of quantification/detection.

Table 1: Concentrations of various PFAS in beef liver, data from the food surveillance activities of German federal states during the period 2007 to 2020

Beef liver	PFAS	Number Samples	Samples above the limit of quantification (LOQ)		Concentration, modified lower bound [$\mu\text{g}/\text{kg}$]		Concentration, upper bound [$\mu\text{g}/\text{kg}$]		
			Number	%	Mean LOQ [$\mu\text{g}/\text{kg}$]	P95	Mean value	P95	
	Perfluorododecanoic acid (PFDoA)	53	1	2	2.34	0.09	0	1.56	2.00
	Perfluorohexanoic acid (PFHxA)	77	9	12	1.56	0.25	2.26	1.04	2.26
	Perfluorohexane sulfonic acid (PFHxS)	67	1	1	1.54	0.03	0	0.93	1.00
	Perfluorononanoic acid (PFNA) ¹	67	11	16	1.70	0.72	5.70	1.55	5.70
	Perfluorooctanoic acid (PFOA)	127	18	14	1.39	0.33	2.07	1.00	2.50
	Perfluorooctane sulfonic acid (PFOS)	127	60	47	1.39	4.05	16.70	4.42	16.70

Table 2: Concentrations of various PFAS in sheep liver, data from the food surveillance activities of German federal states during the period 2007 to 2020

Sheep liver	PFAS	Number Samples	Samples above the limit of quantification (LOQ)		Concentration, modified lower bound [$\mu\text{g}/\text{kg}$]		Concentration, upper bound [$\mu\text{g}/\text{kg}$]		
			Number	%	Mean LOQ [$\mu\text{g}/\text{kg}$]	P95	Mean value	P95	
	Perfluorododecanoic acid (PFDoA)	14	0	0	3.0	0	0	2.09	2.00
	Perfluorohexanoic acid (PFHxA)	17	0	0	1.7	0	0	0.86	1.00
	Perfluorohexane sulfonic acid (PFHxS)	17	0	0	1.7	0	0	0.86	1.00
	Perfluorononanoic acid (PFNA)	17	0	0	1.7	0	0	0.86	1.00
	Perfluorooctanoic acid (PFOA)	27	2	7	1.1	0.02	0.14	0.59	1.00
	Perfluorooctane sulfonic acid (PFOS)	27	11	41	1.1	4.30	16.10	4.45	16.10

¹ 10 samples with a limit of quantification of 800 $\mu\text{g}/\text{kg}$ were not accounted for during the evaluation, since they dominated the result. All are from 2012 and a value above the limit of detection was not detected in any of these samples.

Table 3: Overview of average LB concentrations of PFAS in beef liver in samples from the Lower Saxony NRCP (LAVES, 2019)

Beef liver	Number Samples	Samples above the limit of quantification		Mean LOQ [$\mu\text{g}/\text{kg}$]	Concentration, lower bound [$\mu\text{g}/\text{kg}$]		Concentration, upper bound [$\mu\text{g}/\text{kg}$]	
		Number	%		Mean value	P90	Mean value	P90
Perfluorododecanoic acid (PFDoA)	75	1	1	0.27	0.02	0	0.29	0.27
Perfluorohexanoic acid (PFHxA)	75	26	35	0.32	0.09	0	0.39	0.32
Perfluorononanoic acid (PFNA)	75	26	35	0.16	0.12	0.39	0.22	0.39
Perfluorooctanoic acid (PFOA)	75	13	17	0.15	0.04	0.18	0.17	0.18
Perfluorooctane sulfonic acid (PFOS)	75	42	56	0.49	2.38	3.30	2.59	3.30

Table 4: Overview of average LB concentrations of PFAS in sheep liver in samples from the Lower Saxony NRCP (LAVES, 2019)

Sheep liver	Number Samples	Samples above the limit of quantification		Mean LOQ [$\mu\text{g}/\text{kg}$]	Concentration, lower bound [$\mu\text{g}/\text{kg}$]		Concentration, upper bound [$\mu\text{g}/\text{kg}$]	
		Number	%		Mean value	P90	Mean value	P90
Perfluorododecanoic acid (PFDoA)	5	0	0	0.27	0	0	0.27	0.27
Perfluorohexanoic acid (PFHxA)	5	1	20	0.32	0.13	0.33	0.39	0.49
Perfluorononanoic acid (PFNA)	5	5	100	0.16	0.32	0.41	0.32	0.41
Perfluorooctanoic acid (PFOA)	5	3	60	0.15	0.17	0.34	0.23	0.34
Perfluorooctane sulfonic acid (PFOS)	5	5	100	0.49	5.51	9.91	5.51	9.91

3.2.3 Data on consumption

Table 5 presents the consumption quantities for beef and sheep liver for adults, based on the DISHES interviews from NVS II.

Table 5: Average quantities consumed per day by individuals aged from 14 to 80 years of age, relative to body weight (g/body weight per day) (basis: consumers only)

Food	Number of consumers	Consumer proportion [%]	Median	95th percentile
Beef liver	823	5.40	0.046	0.162
Sheep liver	6	0.04	0.074	0.102

For both, sheep and beef liver, the proportion of consumers among the study participants is relatively small. In the survey on rarely consumed foods, the proportion of consumers, covering to the last 12 months, was determined as 41% for the consumption of pork, beef or calf

liver and 7% for the consumption of lamb or sheep liver. When considered over the long term, this indicates a higher proportion of consumers in the population compared with the data from NVS II.

Since data from only six consumers of sheep liver are present in NVS II, uncertainties are also significant in terms of quantity estimates. In the present opinion, the data for consumption quantities of beef liver were therefore utilised within the scope of a pragmatic approach. As an additional step to better represent the potential range of consumption, an estimate of consumption from an earlier BfR opinion — based on an estimate of portion sizes and consumption frequencies (BfR 2009) — was compared with the data from NVS II. The approach applied there is more conservative and therefore results in higher consumption quantities.

If the consumption data for beef liver are converted into average consumption per week, this results in weekly consumption values of 24 g (median) and 88 g (95th percentile). In comparison, the estimates from the earlier opinion for the consumption of sheep liver, based on assumptions for portion sizes and consumption frequencies, are 40 g per week for normal consumption (i.e. of average frequency) and 250 g per week for frequent consumption (95th percentile).

3.2.4 Estimate of long-term intake

Tables 6 and 7 show the exposure to individual PFAS for the median and frequent consumption of sheep or beef liver, when applying either the mLB or the UB approach, as well as mean concentrations. The great difference between the mean concentrations when applying the mLB approach versus the UB approach also has a significant effect on exposure assessment. As a consequence of the low proportion of samples above the limits of quantification, major differences in the results for the mLB and the UB estimate exist for PFDoA, PFHxA, PFNA and PFOA, both for median as well as for frequent consumption quantities. For these PFAS, the exposure assessment therefore includes major uncertainties.

PFOS makes up the greatest proportion of exposure to PFAS following the consumption of sheep or beef liver.

Table 6: Long-term average exposure for adults to various PFAS from the consumption of beef liver at average concentrations; occurrence data from the food surveillance activities of German federal states during the period 2007 to 2020. See table 5 for consumption data.

Beef liver	Average weekly exposure [ng/kg body weight/week]			
	Modified lower bound		Upper bound	
PFAS	Median consumption (P50)	Frequent consumption (P95)	Median consumption (P50)	Frequent consumption (P95)
Perfluorododecanoic acid (PFDoA)	0.03	0.11	0.50	1.80
Perfluorohexanoic acid (PFHxA)	0.08	0.29	0.33	1.20
Perfluorohexane sulfonic acid (PFHxS)	0.01	0.03	0.30	1.10
Perfluorononanoic acid (PFNA)	0.23	0.82	0.50	1.80
Perfluorooctanoic acid (PFOA)	0.10	0.37	0.32	1.10

Perfluorooctane sulfonic acid (PFOS)	1.31	4.60	1.42	5.00
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Table 7: Long-term average exposure for adults to various PFAS from the consumption of sheep liver at average concentrations; occurrence data from the food surveillance activities of German federal states during the period 2007 to 2020. See table 5 for consumption data.

Sheep liver	Average weekly exposure [ng/kg body weight/week]			
	Modified lower bound		Upper bound	
PFAS	Median consumption (P50)	Frequent consumption (P95)	Median consumption (P50)	Frequent consumption (P95)
Perfluorododecanoic acid (PFDoA)	0.00	0.00	0.64	2.27
Perfluorohexanoic acid (PFHxA)	0.00	0.00	0.28	0.97
Perfluorohexane sulfonic acid (PFHxS)	0.00	0.00	0.28	0.97
Perfluorononanoic acid (PFNA)	0.00	0.00	0.28	0.97
Perfluorooctanoic acid (PFOA)	0.01	0.03	0.19	0.67
Perfluorooctane sulfonic acid (PFOS)	1.38	4.87	1.43	5.05

If the values for consumption quantities are taken from the BfR Opinion on sheep liver consumption (BfR 2009), consumption quantities are 1.7 times (median) to 3.6 times (95th percentile) higher—and the exposure assessments results are therefore also higher—than when using beef liver consumption data as a surrogate for the consumption of sheep liver.

3.2.5 Uncertainties

Since the limits of quantification in the data set supplied by the German federal states' food control authorities for 2007 to 2020 are comparatively high, this produces significant uncertainties in the results for exposure to PFAS by the consumption of sheep or beef liver. Results from the Lower Saxony report show, the limits of quantification in the most recent investigations are considerably lower.

For sheep liver in particular, the low sample count and application of the mLB approach, which yields more realistic values for the exposure assessment than the LB approach, limits the potential for a comparison between the occurrence data from the data set supplied by the German federal states' food control authorities with those from the Lower Saxony results report. A comparison between LB and mLB in the data set supplied by the German federal states' food control authorities for 2007 to 2020 does show very small differences, however.

The data on beef and sheep liver supplied by the German federal states' food control authorities for 2007 to 2020 is provided by six states (Baden-Württemberg, Bavaria, Bremen, Hesse, Mecklenburg-Western Pomerania and North Rhine-Westphalia) and accordingly do not offer a nationwide picture. Nor can it be excluded that some of these samples originate from regions with unusual input sources of PFAS into the environment.

The consumption data used in this assessment – although the most recent data available for Germany--were collected over ten years ago. Therefore, it cannot be excluded that consumption habits for liver have changed since then — which could conceivably lead to an underestimation or an overestimation.

The data utilised from the dietary history interviews allow reliable estimations of the long-term intake of substances in foods that are regularly consumed. Diet history data are less reliable for foods that are not part of the daily diet and only consumed sporadically. This may lead to an underestimation of the actual intake for rarely consumed foods.

It should also be mentioned that the calculated exposure applies only for the group of consumers of the food in question—which in the case of sheep liver in particular make up only a small proportion of the total population.

The quantities and frequency of sheep liver consumption in specific population subgroups (such as persons with migration background) may be higher compared to the average population in Germany (BfR 2009; Schmid 2003). In these subgroups, the levels of exposure may therefore be higher.

3.3 Risk characterisation

PFOS

When considering an exposure assessment based on data on the concentrations of PFOS from food surveillance activities of the German federal states conducted from 2007 to 2020, the consumption of beef liver by individuals in the group of consumers of this food item leads to an exhaustion of the TWI for PFOS (13 ng/kg bw per week, EFSA 2018) of 10% (mean weekly exposure, mLB, median consumption (P50)) to 38% (mean weekly exposure, UB, high consumption (P95)).

In this same scenario, the consumption of sheep liver leads to an exhaustion of the TWI for PFOS of a similar magnitude as the consumption of beef liver, namely of 11% (mean weekly exposure, mLB, median consumption) to 39% (mean weekly exposure, UB, high consumption (P95)).

PFOA

When considering an exposure assessment based on data on the concentrations of PFOA in samples from food control programmes of the German federal states conducted from 2007 to 2020, the consumption of beef liver by individuals in the group of consumers of this food item leads to an exhaustion of the TWI for PFOA (6 ng/kg bw per week, EFSA 2018) of 2% (mean weekly exposure, mLB, median consumption) to 18% (mean weekly exposure, UB, high consumption (P95)).

In this same scenario, the consumption of sheep liver leads to a lower exhaustion of the TWI for PFOA of 0.2% (mean weekly exposure, mLB, median consumption) to 11% (mean weekly exposure, UB, high consumption (P95)).

It has to be considered that the uncertainties are high in terms of quantities consumed. For the exposure assessments as presented (tables 6 and 7), consumption quantities for beef liver have been used as a surrogate for the consumption quantities for sheep liver. In order to be able to estimate the influence of these uncertainties on the result, the exposure has been

assessed on an estimate of plausible portion sizes and consumption frequencies for the consumption of sheep liver (BfR 2009). Under this assumption, a higher exhaustion of the TWI values would result, ranging from 1.7 times as high (median) to 3.6 times as high (95th percentile).

Consumers are exposed to PFAS through a wide variety of foodstuffs other than liver from livestock. Assuming median consumption quantities, the total exposure to PFOS and PFOA from food and drinking water is around 3.5 to 10.1 ng/kg bw/week for PFOS and 2.1 to 10.6 ng/kg bw/week for PFOA (lower bound to upper bound) (EFSA 2018).

The results of the BfR's exposure assessment indicate that, for individuals that consume sheep or beef liver containing the identified concentrations, these foods can constitute a significant source of exposure to PFAS. At least in cases where large quantities of sheep or beef liver are consumed, this source of exposure can result in an exhaustion of the TWI which is comparatively high for a single foodstuff, in particular with regard to PFOS.

As a result of the comparatively high limits of quantification, only a few analytical results above the limits of quantification are available in the data set from the federal states' food surveillance programmes conducted from 2007 to 2020 for the target compounds (with the exception of PFOS, especially for sheep liver). For these compounds, the BfR does not consider it possible to make a conclusive assessment of exposure to PFAS from the consumption of sheep or beef liver based on the data set available.

The BfR notes further that on application of the TWI of 8 ng/kg bw/week for the sum of PFOS, PFOA, PFNA and PFHxS, as has been derived in the current EFSA draft (2020), the intake of PFOS to be assessed as tolerable would be lower than on application of the TWI of 13 ng/kg bw/week (EFSA 2018). Moreover, as the sum of the concentrations of PFOA, PFOS, PFNA and PFHxS would be assessed, the comparatively high concentrations of PFNA in beef liver in the data set analysed here would also contribute a higher exhaustion of the TWI.

3.4 Conclusion

The German Federal Institute for Risk Assessment (BfR) has based its estimate of the exposure of consumers to PFAS through the consumption of beef liver on concentrations of six compounds in the PFAS group (perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorohexanoic acid (PFHxA), perfluorononanoic acid (PFNA), perfluorododecanoic acid (PFDoDA) and perfluorohexane sulfonic acid (PFHxS)) from the German federal states' food control programmes in the period 2007 to 2020.

In its report dated 14 April 2020, the Lower Saxony Ministry of Food, Agriculture and Consumer Protection (MF) has conducted an exposure assessment based on data for concentrations of PFOS, PFOA, PFHxA, PFNA and PFDoDA in samples of sheep and beef liver collected as part of the 2019 Lower Saxony National Residue Control Plan (NRCP).

The results of the BfR's exposure assessment indicate that these foods can constitute a significant source of exposure to PFAS for individuals that consume sheep or beef liver containing the identified concentrations.

Of the PFAS investigated, PFOS makes up the greatest proportion of exposure to PFAS for consumers of sheep or beef liver. In assessing this exposure, the BfR has applied the tolerable intakes as derived by EFSA (2018) of 13 ng/kg body weight (bw) per week for PFOS and

6 ng/kg bw/week for PFOA. The EFSA Opinion (EFSA 2020) on the assessment of other compounds in the PFAS group—including some of the compounds that have been taken into account in this present exposure assessment for sheep and beef liver—is currently only available in draft form².

Based on data on the concentrations of PFOS in samples from food control programmes of the German federal states conducted in 2007 to 2020, the consumption of beef liver by individuals in the group of consumers of this food item accounts for an exhaustion of the TWI of 13 ng/kg body weight (EFSA 2018) of 10% (mean weekly exposure, mLB, median consumption (P50)) to 38% (mean weekly exposure, UB, high consumption, that is the 95th percentile).

In this same scenario, the consumption of sheep liver accounts for an exhaustion of the TWI for PFOS of a similar magnitude as the consumption of beef liver, namely of 11% (mean weekly exposure, mLB, median consumption (P50)) to 39% (mean weekly exposure, UB, high consumption (95th percentile)).

The exhaustion of the TWI of 6 ng/kg bw/week for PFOA (EFSA 2018) achieved through the consumption of sheep or beef liver is considerably lower compared to the exhaustion of the TWI for PFOS.

Consumers are exposed to PFAS from a wide variety of foodstuffs other than sheep and beef liver. Assuming mean consumption quantities, total exposure to PFOS from food and drinking water is around 3.5 to 10.1 ng/kg bw/week (lower bound to upper bound) (EFSA 2018).

At least in cases where large quantities of sheep or beef liver are consumed, this source of exposure can result in an exhaustion of the TWI which is comparatively high for a single foodstuff, in particular with regard to PFOS.

BfR's overall conclusion is, that particularly for PFOS, the data from the German federal states' food control programmes from 2007 to 2020 describe the situation concerning the occurrence of PFAS in sheep and beef liver more comprehensively because of the availability of data from several federal states.

In summary, the results of the present exposure estimation for PFAS in sheep and bovine liver, based on data from several German federal states, give no reason to assume that the results of the NRKP in Lower Saxony represent a regional anomaly with regard to levels of PFAS, especially PFOS, in sheep and bovine liver.

² The EFSA draft has been published as an open public consultation at <https://www.efsa.europa.eu/de/consultations/call/public-consultation-draft-scientific-opinion-risks-human-health>

Further information on per- and polyfluoroalkyl substances (PFAS) is available from the BfR website

https://www.bfr.bund.de/en/a-z_index/poly_and_perfluoroalkyl_substances_pfas_pfc_-_130146.html



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About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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