Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package WP A.5

Human health risks related to the consumption of game meat and other meat and dairy products

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Contents

1. Description of the Work Package

1.1. Background

Food and especially game meat consumption is one potential source of lead exposure. The highest amounts of game meat are consumed in hunters' families, which are considered to be at the highest risk. Especially vulnerable are small children whose neurological development may be impaired due to lead exposure. Lead deposited next to shooting ranges may contaminate the soil and result in lead exposure of cattle grazing on land contaminated with lead ammunition. Subsistence farmers (and their families) eating meat and dairy products derived from cattle exposed to lead are at highest risk in this case.

1.2. Objectives

The following topics are covered in the present work package:

1. What is the level of exposure to lead due to game meat consumption in hunters' families?

2. What kind of risk will game meat consumption cause?

3. What is the contribution to the overall level of concern?

4. What is the prevalence and level of exposure caused by other meat or dairy products?

2. Summary of the Dossier Submitter proposal

Human ingestion of lead via the environment may occur via the intake of food and drinking water contaminated from shooting activities and may also occur via the consumption of game meat hunted with lead gunshot or other type of lead projectiles, as the existing best practices to handle hunted game meat do not eliminate the lead in the game meat.

The risks to human health via drinking water and consumption of crops and/or meat from cattle grown on agricultural soils adjacent to or within shooting areas are discussed qualitatively. The risks to human health from consumption of contaminated game meat are assessed quantitatively by the Dossier Submitter.

In terms of human risk characterisation, the Dossier Submitter has assessed the human health risks associated to game meat consumption by calculating the effect of the blood lead level increment with respect to:

- loss of IQ points in young children,

- % increase in the prevalence of chronic kidney disease (CKD) in adults, and

- increase in systolic blood pressure in adults.

The Dossier Submitter estimates that in any given year about 1 million children are vulnerable to lead exposure resulting from the consumption of game meat.

3. Relevant information from the consultation of the Annex XV restriction report

Extensive comments were submitted on human health risks associated with game meat consumption. These are summarised below.

Comments related to the lead levels in game meat and to the consumption of game meat

During the consultation, stakeholders provided information on the use of non-expanding full metal jacket (FMJ) or other non-expanding bullets such as open tip match bullets (OTM) and small calibre weapons for the hunting of special species and possible lead contamination related to these uses. The Finnish Hunting association (comment #3255) performed a field test which suggests that FMJ, OTM and .22 LR bullets do not cause lead contamination in game meat. These field tests showed that the difference of weight of FMJ, OMT and .22LR bullets before and after impact was negligible (some bullets were even reported with higher weight after impact due to meat remnants that got stuck in the bullet). This suggests that these bullets do not cause any contamination of game meat with lead and/or any secondary poisoning. Small calibres and FMJ or OTM bullets are allowed only for use in the hunting of small game or seals in some countries (Scandinavia, Baltic countries) (comments #3255, 3262).

The European Federation for Hunting and Conservation ('FACE') provided comments regarding the human health risk assessment and the EFSA (2020) input data for consumption and lead content of game meat used by the Dossier Submitter in the assessment (comment #3467).

Regarding the lead content in game meat, FACE questioned the relevance, reliability and scientific validity of the data. According to FACE, the high average value provided for game hunted with bullets (2.516 mg/kg) in contrast with the low value provided for shots (0.366 mg/kg) is not supported by the scientific literature, where it is generally observed that average lead concentrations are higher in birds than in large game species (see AESAN 2012, Food Standards Agency in Scotland 2012). Further, values provided by EFSA (2020) for deer and wild boar do not stand a comparison with other publications. For instance, the German Federal Institute for Risk Assessment found that lead content (P95) in roe deer was 0.582 mg/kg (n=2 235) and in wild boar 1.446 mg/kg (n=1 542) (Gerofke et al 2018). EFSA reported that the mean lead content in roe deer was 0.048 mg/kg (P95 0.124 mg/kg, n=733), and in wild boar 1.143 mg/kg (P95 0.67 mg/kg, n=966) (EFSA 2012a).

FACE also questioned the use of the the maximum allowable level (ML) of 0.1 mg Pb/kg set by Commission Regulation (EC) No 1881/2006[1] for meat from domesticated animals (bovine animals, sheep, pigs, and poultry) as a threshold for a "dangerous concentration" in game meat, since there is no ML established for game. Additionally, FACE expressed their disagreement with the approach followed by the Dossier Submitter for the risk assessment, where the samples with a lead concentration above 0.1mg/kg (i.e., worst case) were used as a surrogate for all game meat. In another comment (#3363), it was noted that the

[1] Commision Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1881

recommendation for setting up the same maximum lead concentration limit in game meat (mammals) as for beef, sheep, pork and poultry is impractical, because so called lead-free alternatives also contain lead which makes it impossible to ensure compliance with this value.

In relation to game consumption, FACE considered the values used by the Dossier Submitter based on the 95th percentile as an overestimation, not representing the whole hunting community of the EU 27. In their opinion, these high values are not likely to occur even amongst indigenous hunters using game as their main nutrition (Chan et al., 2017). FACE consider that as the input values used in the dietary exposure assessment are incorrect, the Dossier Submitter 's human health risk assessment fails to reliably estimate the risks resulting from game meat consumption.

Other commenters agreed with the Dossier Submitter's assessment and brought some further issues to the attention of RAC and the Dossier Submitter (comments #3209, 3494, 3485).

The German competent authority raised the issue of lead nanoparticles found in game meat and provided a publication where the topic is highlighted as an *"unattended source of lead with a largely unknown toxicological impact to humans" (Kollander et al., 2017)*. It also highlighted the fact that lead bioavailability and adsorption increases when cooking meat in acidic conditions (Schulz et al., 2021) (comment #3209).

The European Environmental Bureau (EEB, comment #3494) commented on the content of lead in game and indicated that lead levels used in the restriction proposal for some types of game animals (small game) are notably below previously reported levels. This is further supported by the recent publication by Pain et al., (2022) suggesting even 14-times higher mean game meat lead levels in small pray hunted with shotgun than the lead levels presented in the Annex XV report. EEB further questioned the Dossier Submitter's statement that 'European hunters generally follow "best practice", as advised by several wildlife authorities, when handling game meat" since there is no proof provided for such a statement.

Comment #3485 highlighted that in Italy the consumption of game meat has steadily increased over the last decades, leading to a situation in which frequent game meat consumption is no longer limited to hunter families, but has become "frequent among people living in the countryside, mainly in mountainous areas where wild ungulates are very abundant. In a large part of Alps and Apennines, the number of servings per month consumed by non-hunters can be relevant, especially during the hunting season".

The Wildfowl & Wetland Trust (#3303) as well as an individual commenter (#3460) pointed out that they believed that lead concentrations, particular in birds, could be higher than in the EFSA dataset (EFSA, 2020) and provided additional data on lead concentrations found in game meat.

Finally, WWF (comment #3446), raised the issue of the presence of lead residues and their quantification in big game meat and sausages. In this sense, Garcia Fernandez et al. (2018) evaluated the presence of lead in 86 pieces of sausages bougth across different Spanish regions and concluded that the probability of a person consuming a piece of sausage with lead levels above the legally established levels is close to 50% (one in every two pieces). In addition, the average lead concentration of the contaminated samples reached almost 0.4 mg/kg, which is four times the maximum concentration limit set up in Commission Regulation (EC) No 1881/2006 for meat from livestock.

Comments related to the qualitative risk assessment

The International Lead Association (ILA) & Pb REACH Consortium (PbRC) provided comments criticising the qualitative health risk assessment performed by the Dossier Submitter (comment #3223). In their opinion, the benchmark dose (BMD) modelling is too conservative/uncertain and does not take into account recent publications on the association between low-dose blood lead and neurological functioning (IQ) in children, as well as studies on low-dose blood lead on adult neurological function, cardiovascular disease, and kidney disease.

ILA further noted that a predicted IQ loss of 1 point associated with 12 µg/L lead blood levels may be no more than statistical “noise” and calls into question whether a change in IQ of 1 point can be considered “adverse”, given that IQ tests possess an approximate error rate of ±3 IQ points, and questioned the effectiveness of the restriction.

4. Evaluation

4.1 Indirect exposure of humans via environment: Game meat consumption

Human ingestion of lead via the environment may occur via the intake of food and drinking water contaminated from shooting activities and may also occur via the consumption of game meat hunted with lead gunshot or projectiles, as the existing best practices to handle hunted game meat do not eliminate all lead in game meat. In particular, consumption of meat from game hunted with lead ammunition is likely to be a relevant source of lead exposure since lead particles and fragments may reside in edible tissues despite best practises in handling game meat.

After hitting quarry animals, lead shot used for hunting can ‘fragment’ with small particles of lead being distributed within the tissues of an animal. Some of these fragments may reside in edible tissues away from the primary wound and remain there after butchery and food preparation (Green and Pain, 2014). According to the available evidence, it is not possible to successfully remove all embedded fragments of lead from the wound channels of shotgun hunted game as tiny lead particles would go unnoticed.

Hunting with bullets also results in lead transfer deep into the tissues that surround the wound. Felsmann et al. (2016) investigated the effect of lead bullets on game meat and indicated that the projectile penetrates the animal body generating a temporary cavity which is accompanied by a change in the pressure within the funnel of a wound and in the adjacent tissues. Due to this phenomenon, lead transfers deep into the tissues that surround the path of a wound. Contamination can be worsened if the bullet hits a bone and further disintegrates, contaminating a larger area of tissues with fragments of increased surface area.

The Norwegian Scientific Committee on Food Safety (Norwegian VKM, 2013) reviewed the data on the impact of different ammunition types on the lead concentration in game meat and found that expanding lead-containing bullets produce a cloud of lead particles in the meat around the wound channel. Further, Broadway et al. (2020) investigated fragmentation in deer shot with three different types of low velocity lead ammunition (rifled slugs, sabot slugs and modern muzzle-loading bullets). All radiographed deer had evidence of fragmentation, with a geometric mean of 13.1 (95 % CI = 10.3- 16.8) fragments per deer. In general, the author concluded that compared to high velocity rifle bullets, significantly fewer lead fragments are made available to humans and wildlife that consume game shot with low-velocity ammunition types.

European hunters are thought to generally follow "best practice" to handle meat as lead concentration in the wound channel can be very high. The FACE Guidance on managing risks from lead mentions the following on managing risk from ammunition:

"Attempts to remove lead ammunition from game meat can be successful at significantly reducing the levels of lead contamination. Research in Sweden has shown that proper handling of game shot with lead ammunition can effectively eliminate the risk (Swedish NFA, 2014a). The Federal Institute for Risk Assessment, Germany (BfR, 2011) states that cutting out large sections of meat around the bullet hole is not always enough to guarantee removal of lead.

Risk management options can include the application of appropriate game meat handling techniques, eating game shot with non-lead ammunition, or reducing their intake of game shot with lead ammunition."

Lead in game meat

Animals hunted with lead ammunition frequently contain lead fragments in the carcass which contaminate meals made from game meat with concentrations of lead substantially above the maximum levels set by Commission Regulation (EC) No 1881/2006. The maximum permissible levels for bovine animals, sheep, pig and poultry are 0.1 and 0.5 mg Pb/kg wet weight for meat and offal, respectively. No maximum levels for lead in wild game have been set. However, the Swedish National Food Administration (Swedish NFA, 2020) considers that game meat with lead contents exceeding this limit value should not be considered as safe according to Article 14 of Regulation (EC) No 178/2002[2]. Röschel et al. (2020) proposed that Commission Regulation (EC) No 1881/2006 should be amended to incorporate a maximum lead concentration level for game meat as a supplementary measure to the replacement of lead ammunition. This would harmonise food safety standards for lead in meat traded across and imported into the EU.

The concentration of lead in game meat will vary in relation to the distance to the wound channel. Dobrowolska and Melosik (2008) reported for 16/20 meat samples from the wound channel of wild boar and red deer, lead concentrations > 100 mg/kg wet weight, 1/20 even exceeding 1 000 mg/kg wet weight. Swedish NFA (2014a) reported median and maximum lead concentrations from the wound channel of 146 and 1 829 mg/kg wet weight. RAC notes that the measured lead concentrations are highly scattered, especially for wild boar and is probably also dependent of different parameters linked to how the bullet reaches the meat, i.e., the part of the body hit by the bullet and the distance and angle of entrance for the bullet. Table 1 (Table 1-42 of the Background Document) and Table 2 (Table 1-43 of the Background Document) presents lead concentrations at different distances from the wound channel for wild boar and red deer according to Dobrowolska and Melosik (2008) and the Swedish NFA(2014) and Forsell et al. (2014), respectively.

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178

Table 1: Lead concentration in wild boar and red deer at different distance from the bullet pathway (Dobrowolska and Melosik, 2008)

Indiv. No.	Carcass weight	Lead concentration (mg/kg wet weight)[1]						
		Wound		Distance from bullet pathway (cm)				
		entrance	exit	5	15	25	30	control
Wild boar								
1	86	**1 095.9**	**736.0**	**32.2**	**11.2**	**4.2**	**3.3**	0.3
2	82	**189.2**	**67.4**	**18.9**	**6.2**	0.2	0.2	0.2
3	78	**125.2**	**59.8**	**14.2**	**0.8**	0.2	0.2	0.1
4	76	**131.4**	**77.7**	**11.9**	**3.8**	0.2	0.2	0.2
5	43	**361.4**	**633.1**	**47.5**	**6.8**	**3.8**	**3.1**	0.3
6	34	**179.2**	**395.4**	**26.2**	**5.2**	**2.6**	**0.9**	0.1
7	32	**74.0**	**95.0**	**5.1**	**0.9**	0.1	0.1	0.1
8	32	**65.5**	**158.3**	**8.2**	**0.8**	0.2	0.2	0.2
9	29	**76.5**	**212.3**	**10.3**	**0.8**	0.2	0.2	0.2
10	26	**69.7**	**176.3**	**10.2**	**2.3**	0.1	0.1	0.1
Red deer								
1	116	**234.6**	**76.5**	**43.8**	**8.6**	**0.3**	0.1	0.1
2	113	**364.8**	**102.6**	**53.7**	**5.7**	**1.1**	**0.8**	0.2
3	110	**185.8**	**67.3**	**31.9**	**7.9**	**0.2**	0.1	0.1
4	102	**476.9**	**92.7**	**87.5**	**16.9**	**4.8**	**1.1**	0.3
5	98	**156.6**	**60.4**	**16.9**	**5.1**	0.2	0.2	0.2
6	97	**243.8**	**97.2**	**42.7**	**13.7**	**0.3**	**0.2**	0.1
7	96	**176.8**	**67.9**	**38.7**	**9.6**	**0.2**	0.1	0.1
8	93	**346.5**	**123.7**	**64.2**	**12.5**	**5.8**	**0.9**	0.3
9	89	**198.5**	**64.9**	**32.1**	**2.6**	**0.2**	0.1	0.1
10	88	**135.7**	**59.9**	**23.2**	**4.3**	0.1	0.1	0.1

Notes: [1] lead concentrations exceeding the individual control value (last column) are marked in bold

Table 2: Lead content (mg/kg) in the meat of wild boar in relation to the distance to the wound channel (Swedish NFA, 2014c, Forsell et al., 2014, Swedish NFA, 2014b)

	Sample in relation to wound channel	N	Lead concentration (mg/kg)			Samples >0.1 mg/kg [1]
			Min	Median	Max	
Wild boar	Wound channel	18	0.011	**146**	**1 829**	94 %
	0 to 5 cm	18	0.007	**9**	**1 466**	89 %
	5 to 10 cm	18	0.004	**0.11**	**18**	50 %
	10 to 15 cm	15	0.004	0.04	**29**	27 %

Notes: [1] Threshold set by Commission Regulation (EC) No 1881/2006 for lead in meat

RAC agrees that the removal of meat at a distance of 10 to 15 cm from the wound channel significantly reduces the probability to ingest meat with a high lead concentration. However, this practice does not allow to totally exclude the ingestion of meat containing lead above the limit set by Commission Regulation EC No 1881/2006, as 27 % of the wild boar samples presented a lead concentration higher than 0.1 mg/kg at a distance of 10 to 15 cm from the wound channel.

The concentration of lead will also vary depending on the type of game hunted. For animals hunted with lead shot (duck, game birds, hare, partridge, pheasant, quail and rabbit), EFSA derived lower bound and higher bound values for the lead concentration in meat intended for consumption (see Table 3 below, Table 1-45 of the Background Document).

Table 3: Concentration of lead in meat intended for consumption from game hunted with lead shot in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples > 0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
Duck	1 313	73	0.081	0.096	17.900	89 (7 %)
Game birds	48	24	0.207	0.214	1.797	14 (29 %)
Hare	341	60	0.889	0.903	104.000	50 (15 %)
Partridge	17	82	0.054	0.081	0.840	1 (6 %)
Pheasant	713	48	0.676	0.683	113.000	160 (22 %)
Quail	129	74	0.024	0.044	0.400	12 (9%)
Rabbit	11	64	0.341	0.347	1.000	4 (36%)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples > 0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
All[1]	**2 574**	**63**	**0.352**	**0.366**	113.000	**330/2574 (13 %)**

Notes: [1] this row also includes one result from pigeon and one from snipe not displayed in the table

In other studies, i.e.: Pain et al. (2010), it was found that a high proportion of meat samples from game hunted with gunshot had lead concentrations exceeding 100 ppb w/w (0.1 mg/kg w/w). For example, 56 % and 47 % of fresh meat samples from partridge and pheasant, respectively, exceeded 0.1 mg Pb/kg, 21 % and 18 % exceeded 1.0 mg Pb/kg, and 5.7 % and 2.4 % exceeded 10 mg Pb/kg. The Food Standards Agency in Scotland estimated that the mean lead concentration in pheasants equals to 1.87 mg/kg (median 0.078 mg/kg, n=58) and partridges 1.33 mg/kg (median 0.169 mg/kg, n=53). These values are above the reported values by EFSA. Further Mateo et al 2011, found that 54.7% of hunted red partridge had lead levels equal to 2.55 mg/kg, which is above the maximum residue level of 0.1 mg/kg w/w and above the value provided by the Dossier Submitter. Additionally, a recent review, submitted to RAC during opinion development (Pain et al., 2022) suggests up to 14-times higher mean lead levels in small prey hunted with shotgun than the estimates based on EFSA data (2020) used by the Dossier Submitter. Thus, there are some uncertainties related to the lead concentration in game meat for small game.

The probability to ingest lead shot pieces is higher when consuming small birds like quail for example since this bird is eaten in one piece. This means that if the breast for example was hit by shot, the probability to ingest a piece of lead is very high. The bioavailability of lead in game meat is also affected by cooking (under acidic conditions, with vinegar (Pain et al., 2010; Shulz et al 2021)) and might be affected by the time period before consumption but no data were presented on this by the Dossier Submitter. Lead particles in game meat can dissolve while cooking, producing soluble lead salts that then contaminate parts of the meat. These salts have greater bioavailability and may pose an increased risk compared to metallic lead particles (Mateo et al., 2007).

EFSA also provided data on lead concentration in game meat hunted with bullets in the EU (EFSA, 2020, Table 1-46 in the Background Document reproduced as Table 4 below). Based on common hunting practices it was assumed that chamois, deer, moose, roe deer and wild boar were hunted with lead bullets.

Table 4: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples >0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
Chamois	15	87	0.002	0.010	0.021	0

Species	**N**	**Samples below detection limit (%)**	**Lead concentration in game meat (mg/kg)**			**Samples >0.1 mg/kg (%)**
			Mean lower bound	**Mean upper bound**	**Max**	
Deer	5 034	55	1.992	2.006	5 309.000	514 (10 %)
Moose	330	48	0.026	0.035	2.720	9 (3 %)
Roe deer	314	48	10.893	10.903	588.620	*Included under "deer*
Wild boar	4 040	47	2.810	2.827	3 650.000	818 (20 %)
All[1]	**10 334**	**52**	**2.501**	**2.515**	5 309.000	**1 341 (13%)**

The data reported by EFSA for wild boar and wild deer are in a similar range as reported by ANSES (2018) for France (3.4 mg Pb/kg). However, Gerofke et al (2018), reports lower values for roe deer (0.582 mg/kg) and wild boar (1.446 mg/kg). The mean lead concentrations of the samples close to the wound channel (5.37 mg/kg) and saddle (1.72 mg/kg) exceeded 0.1 mg/kg (Gerofke et al., 2018). Lindboe et al. (2012), on the other hand, reported mean lead concentrations of 5.6 mg/kg ranging up to 110 mg/kg for 52 samples of ground meat from moose shot in Norway. The Swedish National Food Agency found a median lead level in minced moose meat of 0.03 mg/kg. As regards roe deer and fallow deer, the mean lead level in the samples was 0.25 mg/kg. In marketable meat of red deer hunted under controlled conditions and prepared by trained professionals, the mean lead concentration in meat close to the wound channel was 58 mg/kg, and in meat from the saddle and haunch < 0.1 mg/kg (Martin et al., 2019). In marketable meat from roe deer, they reported mean lead values close to the wound channel (13.96 mg/kg), saddle (0.97 mg/kg) and haunch (0.17 mg/kg), all exceeding 0.1 mg/kg.

In the consultation of the Annex XV restriction report, the analysis presented by the Dossier Submitter was challenged in terms of the representativeness of the data and its scientific validity. The use of the maximum allowable level (ML) of 0.1 mg Pb/kg set by Commission Regulation (EC) No 1881/2006 for meat from domesticated animals (bovine animals, sheep, pigs, and poultry) as the threshold for a "dangerous concentration" of lead in game meat was also put into question. It should be noted that in the restriction proposal the Dossier Submitter has not used this ML for risk assessment or proposed this to be used as a dangerous level that should be applied also for game meat, but it is rather used only as reference point. Thus, this is a misinterpretation.

RAC notes that the EFSA data presented by the Dossier Submitter includes more than 12 000 entries from 26 Member States plus United Kingdom and Macedonia. Germany, Slovakia, Check Republic, Austria and France with 3 193, 1 926, 1 637, 1 340 and 1 335 are the most represented countries. Yet other countries such as Hungary (>500 data points), Portugal (>500), Denmark (>450), Latvia (>400), Poland (>300), etc., are well represented. Other countries such as Spain, Sweden, Belgium, Lithuania, Norway account for more than 100 data points. Considering the high number of samples and recognising that the level of reporting across Member States is never equally exhaustive, RAC concludes that the EFSA data is suitable for risk assessment.

RAC further notes that data on lead concentrations in game meat vary significantly, depending on the cut of meat. Variability is also found across studies and can be explained by the degree of fragmentation of the ammunition, the path the ammunition takes, and the level of care applied to remove the flesh surrounding the wounds, among others. In this sense, non-expanding full metal jacket bullets may result in lower lead contamination of game meat as non-jacketed or partially (or semi-) jacketed expanding bullets.

However, in spite of the variability in lead concentration in meat across studies and depending on the cut of the meat, RAC considers the data provided by EFSA as the most comprehensive and exhaustive dataset available for lead concentration in game meat and supports their use for further calculations.

The data shows that, even if prepared under best practices, a relevant proportion of game meat has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg Pb/kg meat). Of specific concern are individual samples showing very high lead concentrations even above 1 000 mg/kg and the fact that a non-negligible fraction of hunter families might be exposed to high concentrations over a long period of time. In this sense, RAC recognises that using mean concentration values for the risk assessment is a conservative approach, yet it better reflects the above scenarios and therefore is deemed suitable for risk assessment. As shown in Tables 3 and 4 above, the mean lead concentration in game meat bagged with lead shot was 0.351-0.366 mg/kg, while the mean lead concentration in game meat bagged with lead bullets was 2.501-2.515 mg/kg. In both cases, 13 % of the samples presented a lead concentration above 0.1 mg/kg (EFSA, 2020).

Consumption of game meat

While other parts of the general population do consume game meat, the focus of the assessment presented in the Background Document is on game meat consumption by hunters and their families. Indeed, Green and Pain (2019) reviewed the published information on game meat consumption in the EU and concluded that the main consumers of game are hunters and their families and associates, and that a low percentage of the general population in most EU Member States may be frequent (a few times per month) or high-level (once per week or more) consumers of game meat.

For the purpose of this restriction proposal, EFSA provided recent data on the consumption of game meat in the EU via food recall surveys (EFSA, 2020). In the restriction proposal, the Dossier Submitter initially considered that the 95th percentile of chronic consumption of game meat were a good proxy of high frequency consumers such as hunter households. However, after taking into account the comments received in the consultation of the Annex XV restriction report, the Dossier Submitter updated their approach and used the median value of chronic consumption of game meat instead as a better proxy of high frequency consumers such as hunter households. The median (P50) chronic daily consumption of game meat for different age groups, as provided by EFSA, is reported in Table 5 below (reproduced from Table 1-50 from the Background Document). Of specific importance for this assessment are the data on infants and toddlers, who are specifically sensitive to lead-related IQ loss. Data from pregnant and lactating women were not considered due to their low number.

Table 5: Minimum, maximum and median across surveys of the median (P50) of the chronic daily consumption of meat from game hunted with lead gunshot and bullets in the EU (EFSA, 2020)

Population	Ammun.	N (S)[1]	Daily consumption of game meat (g/kg bw and day)[2]		
			Min P50	Med P50	Max P50
Infants	Shot	1-15 (5)	0.89	1.00	1.67
	Bullet	1-8 (3)	0.14	0.43	4.26
Toddlers	Shot	1-25 (10)	0.11	1.46	4.82
	Bullet	1-30 (7)	0.15	1.01	2.82
Other children	Shot	1-56 (13)	0.44	0.79	4.45
	Bullet	1-27 (11)	0.26	1.18	2.82
Adolescents	Shot	1-84 (14)	0.13	0.89	2.45
	Bullet	1-6 (12)	0.11	0.57	2.83
Adults	Shot	1-218 (20)	0.21	0.58	1.37
	Bullet	1-68 (16)	0.10	0.65	1.76
Elderly	Shot	1-74 (16)	0.42	0.63	1.36
	Bullet	1-27 (11)	0.09	0.58	1.53
Pregnant women	Shot	1-3 (5)	0.40	0.49	0.73
	Bullet	6 (1)	0.22	0.63	0.95
Lactating women	Shot	4 (1)	0.76	0.76	0.76
	Bullet	4 (1)	0.13	0.84	1.56

Notes: [1] range of number of subjects N in (S) surveys; [2] Some of the medians presented in this table were calculated based on information from fewer than 60 subjects and might hence not be statistically robust.

Game meat consumption of hunter families has been estimated to be 50 g/day for adults (ANSES, 2018, Gerofke et al., 2018, Haldimann et al., 2002) and 25 g/day for children (ANSES, 2018). Sevillano Morales et al. (2011) estimated only for wild boar and red deer an average consumption of 23 g/day and 96.7 g/day as 95th percentile. Assuming a similar amount of small game hunted with shot is consumed, a value of 193 g/day would represent the 95th percentile.

Based on EFSA data on chronic consumption of game meat, the median daily game meat consumption of high frequency consumers was set at 0.65 and 0.58 g/kg bw/day for adults consuming game hunted with gunshot and bullets, respectively. This corresponds to a daily intake of 45.6 g and 40.9 g for an adult of 70 kg body weight.

For children, only limited data is available from the EFSA database. For infants (0 to 12 months of age) the median value indicated was 0.43 and 1.0 g/kg bw/day. Assuming a body weight of 5 kg, this corresponds to a daily intake of 2.1 and 5.0 g, respectively. For toddlers (1 to 3 years), the median value indicated was 1.01 and 1.46 g/kg bw/day. Assuming a body weight of 12 kg, this corresponds to a daily intake of 12.2 g and 17.5 g, respectively.

RAC notes that these data take into account only direct consumption of meat and not meat by-products (like sausages, paté, etc.) made with game meat and sold to the general public, which could increase the daily intake of game meat in the general population. Nevertheless, RAC agrees with the Dossier Submitter that the most important consumers of game meat are hunters and their families.

Measured blood lead (B-Pb) levels related to consumption of game meat

The Dossier Submitter notes that very limited data are available on how frequent game meat consumption affects B-Pb levels in hunter families. When reviewing the published studies that report measured B-Pb levels in game meat consumers, the following is considered:

- Men usually have higher B-Pb levels compared to females;
- Shooting /hunting has a significant contribution to the B-Pb level;
- Professional or leisure activities may contribute to B-Pb levels.
- The available studies investigating B-Pb levels in hunter and/or members of hunter families usually do not separate the data with respect to sex or shooting/hunting activities. Therefore, it is difficult to draw conclusions on their influence on B-Pb levels.

The available data indicate a small increase in B-Pb level of 3 to 5 µg/L in adults that consume moose meat two to three times a week (see Swedish NFA, 2014a, Swedish NFA, 2014c, Wennberg et al., 2017, Swedish NFA, 2014a). Further, the available data suggest that subsistence hunters in the circumpolar regions have the highest levels of lead; in one study the increment for females (assumed to be non-hunters) was 6 and 15 µg/L (Tsuji et al., 2008). No reliable B-Pb level measurements in children from hunter families are available.

RAC notes that no biomonitoring data for hunter families are available.

4.2 Additional sources of indirect exposure of humans via the environment

Meat and dairy products: The risk of grazing ruminants being exposed to lead shot could be more prevalent than anticipated since clay pigeon shooting and the shooting of game birds is an increasingly popular rural business and can result in the contamination of land used for pasture, fodder or silage (Payne et al., 2013). In fact, several studies report exposure of ruminant animals to ammunition-derived lead, principally via the consumption of silage (Bjørn et al., 1982, Frape and Pringle, 1984, Howard and Braum, 1980, Payne et al., 2013, Rice et al., 1987). The risks to cattle resulting from the consumption of lead has been further assessed in the work package report WP A.1.

Root and leaf crops can be another source of exposure to lead. Concentrations of lead in the soil of a shooting range can be very high. In the sector including backstop berm, target stand and a band of land about 5 to 10 meters wide around the berm, lead concentrations normally exceed 1 000 mg Pb/kg. In the immediate surroundings of the backstop berm lead concentrations often fluctuates between 200 and 1 000 mg Pb/kg (Dinake et al., 2019). In agricultural soils close (10 m) to a trap shooting range, total lead concentrations were reported to range from 573 to 694 mg/kg (Chrastný et al., 2010).

A direct correlation between lead in soil and lead in plants has been reported (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare L.*) grown on shooting ranges, lead concentrations were 138 mg/mg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Commission Regulation (EC) No 1881/2006 limits lead concentration in cereals to 0.2 mg/kg food for human consumption.

Drinking water (via surface water or groundwater): The potential lead contamination of surface and groundwater resulting from the use of lead ammunition at sports shooting ranges has been assessed under the work package report WP A.2. Although a risk for human health can be anticipated if contaminated ground or surface water is used as drinking water, there is insuffcent information available to make any reliable human health risk assessment related to the consumption of drinking water contaminated via the environment by lead deposition on shooting ranges.

4.3 Risk Characterisation

Risks from game meat consumption

For risk characterisation, the Dossier Submitter used EFSA CONTAM Panel (EFSA, 2010) BMDL calculations to derive references points:

- $BMDL_{01}$ of 12 µg/L for developmental neurotoxicity in children (decrease in IQ by 1 point on the full scale IQ);
- $BMDL_{10}$ of 15 µg/L for 10 % increase in the prevalence of chronic kidney disease (CKD) in adults ;
- $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult.

It is recognised that that there are many caveats regarding their interpretation and the uncertainty associated with the derivation of the BMDL values. For example, the prevalence of kidney disease was compared with concurrent B-Pb levels. The EFSA CONTAM Panel noted that this effect would depend on lead exposure over a prolonged interval of time, during which such exposure was declining appreciably. Hence, the $BMDL_{10}$ intake value for this endpoint is likely to be numerically lower than necessary to protect against lead-induced CKD. In other words, the BMDL10 value may depend on earlier higher exposure levels, and if a BMDL10 value could be calculated based on those exposure levels, it might be higher.

In the absence of a threshold for the critical effects, the Dossier Submitter is reflecting the health impact by calculating the effect of the increase of B-Pb with respect to:

- IQ decrease in IQ points for children,
- % increase in the prevalence of chronic kidney disease (CKD) in adults, and
- increase in systolic blood pressure (in mmHg) in adults (this endpoint was however not used in the human health impact assessment).

RAC recognises the conservative nature and uncertainties related to EFSA BMDLs especially for CKD and SBP and especially at low B-Pb levels. Regardless of these uncertainties, RAC considers that the EFSA BMDLs are, however, acceptable estimates for use in risk characterisation.

The Dossier Submitter used the following approach to calculate the risk to humans via the environment as a result of consumption of meat from game hunted with lead ammunition:

- To calculate the daily intake of lead from game meat, the Dossier Submitter used the EFSA data on the minimum, median and maximum (across surveys) 50^{th} percentile (P50) of the chronic daily consumption of game meat in young children (infants and toddlers) and adults as a proxy for the consumption of hunter families that are high-frequency consumers of game meat (see Table 5 above).

- For the lead concentration in game meat, the Dossier Submitter used the EFSA data on the mean upper bound concentration of lead in game meat hunted with lead shot and lead bullets (see Table 6 below). According to the Dossier Submitter, the EFSA data on median lead concentration in game meat is not representative for the population at risk because this value does not reflect the consumption of game meat samples with high lead concentration. This is because when considering game meat consumption **over the whole year** hunter families will consume different parts of the game which may have very different lead concentrations ranging from no increased lead concentration to very high levels of lead for those cut of meat from the area around the wound channel. Such a scenario is best reflected by using the mean value.

- The Dossier Submitter points out that the use of the mean value to characterise the concentration of lead in game meat may be considered as a conservative approach. This is because, according to the EFSA dataset, the lead concentration in game meat is highly skewed with a median value that is orders of magnitude lower than the mean value. RAC notes that the mean value for game meat lead levels used for risk characterisation is significantly higher than the P95 level and this has an important impact on the B-Pb levels modelled for infants and toddlers.

- For the calculation of B-Pb levels resulting from daily lead intake via game meat, the Dossier Submitter adapted the dietary intake values in µg/kg bw that correspond to the BMDLs reported in EFSA (2010) to the bioavailability of metallic lead. The following assumptions were made:

For **developmental neurotoxicity in children** aged ≤ 7, EFSA (2010) concluded on a $BMDL_{01}$ (decrease in IQ by 1 point on the full scale IQ) of 12 µg Pb/L blood (1 µg/L = 0.083 IQ points). According to EFSA, 12 µg/L corresponds to a lead intake from diet containing soluble lead of 0.5 µg Pb/kg bw/day. Assuming 50 % bioavailability of metallic lead compared to lead ions for children results in the following relationship:

12 µg Pb/L blood corresponds to 1 µg/kg bw/day.

For the increase of prevalence of **CKD in adults**, EFSA (2010) concluded on a $BMDL_{10}$ (10 % increase in the prevalence of CKD) of 15 µg Pb/L blood (1 µg/L = 0.667 % increase in the prevalence of CKD). According to EFSA, 15 µg/L corresponds to a lead intake from diet containing soluble lead of 0.63 µg Pb/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

15 µg Pb/L blood corresponds to 6.3 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood corresponds to 1 µg/kg bw/day.

For the increase in **systolic blood pressure in adults**, EFSA (2010) concluded on a $BMDL_{01}$ (1 % change in SBP corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult) of 36 µg Pb/L blood (1 µg/L = 0.033 mmHg). According to EFSA, 36 µg/L corresponds to an intake of diet containing soluble lead of 1.5 µg/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

36 µg Pb/L blood corresponds to 15 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood corresponds to 1 µg/kg bw/day.

In Table 6 (reproduced from Table 1-54 from the Background Document) the calculated mean values for daily intake of game meat for the 95 percentile population (used as proxy for hunter families), incremental B-Pb levels and the resulting health impacts are summarised for children (infants and toddlers) and adults. The results indicate that the median consumption of game hunted with lead shot results in a low impact with IQ losses of well below 1 for infants and toddlers, respectively, whereas the median consumption of game meat hunted with bullets has a much higher impact with IQ loss of 2.51 and 3.66 IQ points for infants and toddler, respectively. For adults, the mean increase in the prevalence of CKD is 0.38 and 2.35% for game hunted with shot and bullets, and the mean increase in systolic blood pressure would be 0.02 and 0.12 mmHg for game hunted with shot and bullets.

RAC notes that to take into account the strongly skewed underlying distribution, the Dossier Submitter took forward the full distribution of predicted B-Pb levels to quantify the baseline risks and to monetise such risks.

Table 6: Calculated mean values for daily intake, incremental B-Pb levels and health impacts from the consumption of meat from game hunted with lead bullets and shot in the EU based on data from EFSA (2020)

Popu-lation	Type of ammu-nition	Game meat consumption (g/kg bw and day; P50[1]		Lead conc. in game meat (µg/g meat; mean upper bound)[2]	Daily intake of lead (µg/kg bw/d; mean)	PbB level increment (µg/L: mean)	IQ point loss in children	Incr. preval. of CKD (%) in adults	Incr. in SBP (mmHg) in adults
Infants	Shot	Min	0.14	0.366	0.051	0.615	0.05	—	—
		Med	**0.43**	**0.366**	**0.155**	**1.864**	**0.16**	**—**	—
		Max	4.26	0.366	1.558	18.694	1.56	—	—
	Bullet	Min	0.89	2.516	2.241	26.891	2.24	—	—
		Med	**1.00**	**2.516**	**2.508**	**30.095**	**2.51**	—	—
		Max	1.67	2.516	4.193	50.315	4.19	—	—
Toddlers	Shot	Min	0.15	0.366	0.056	0.670	0.06	—	—
		Med	**1.01**	**0.366**	**0.371**	**4.450**	**0.37**	—	—
		Max	4.82	0.366	1.031	12.369	1.03	—	—
	Bullet	Min	0.11	2.516	0.286	3.432	0.29	—	—
		Med	**1.46**	**2.516**	3.663	**43.953**	**3.66**	—	—
		Max	4.82	2.516	12.130	145.562	12.13	—	—
Adults	Shot	Min	0.10	0.366	0.035	0.084	—	0.06	< 0.01
		Med	**0.65**	**0.366**	**0.238**	**0.571**	—	**0.38**	**0.02**
		Max	1.76	0.366	0.645	1.548	—	1.03	0.05
	Bullet	Min	0.21	2.516	0.520	1.247	—	0.38	0.04
		Med	**0.58**	**2.516**	**1.469**	**3.525**	—	**2.35**	**0.12**
		Max	1.37	2.516	3.437	8.250	—	5.50	0.27

Notes: 1 – See Table 5; 2 – See Table 3 and Table 4

A robustness check of the lead intake values obtained in the above calculations can be made by comparison to a study by Lindboe et al. (2012) that investigated the lead content of ground (minced) meat from moose (*Alces alces*) from 52 samples intended for human consumption in Norway and predicted human exposure through this source. In 81 % of the batches, lead concentrations were above the limit of quantification of 0.03 mg/kg, ranging up to 110 mg/kg. The mean lead concentration was 5.6 mg/kg, i.e., 56 times the EU limit for lead in meat. The lead intake from exposure to moose meat over time, depending on the frequency of intake and portion size, was predicted using Monte Carlo simulation. For consumers eating a moderate meat serving (2 g/kg bw), a single serving would give a lead intake of 11 µg/kg bw on average, with maximum of 220 µg/kg bw. Using Monte Carlo simulation, the median (97.5th percentile) predicted weekly intake of lead from moose meat was 12 µg/kg bw (27 µg/kg bw) for one serving per week and 25 µg/kg bw (45 µg/kg bw) for two servings per week. A weekly intake of 27 µg Pb/kg bw would result in a daily intake of 3.86 µg Pb/kg bw/day. This value corresponds well with the EFSA data for median game meat consumption by adult members of hunting households (3.9 µg Pb/kg bw/day). RAC notes that the best data for robustness check would be biomonitoring data on B-Pb levels of these hunter families, but this is not available for infants and toddlers.

Another sensitivity check was made by applying the All Ages Lead Model (AALM, v. 2.0), which is a simulation model developed by U.S. EPA that predicts lead concentration in body tissues and organs of hypothetical individuals based on simulated intake and lifetime lead exposure[3]. According to U.S. EPA, “the purpose of the model is to provide risk assessors and researchers with a tool for rapidly evaluating the impact of possible sources of lead in a specific human setting where there is a concern for potential or real human exposure to lead”. When applying the AALM model to simulate steady state B-Pb levels in high-frequency game meat consumers, the Dossier Submitter found a close agreement with the values predicted for infants and toddlers based on the EFSA (2010) relationship between chronic dietary intake and B-Pb level (12 µg Pb/L blood ↔ 1 µg/kg bw/day). For adults, B-Pb levels simulated with the AALM model were roughly a factor of two larger than those obtained with the EFSA relationship (2.4 µg Pb/L blood ↔ 1 µg/kg bw/day).

These data indicate that game meat consumption by hunter families can have a relevant impact on the neurodevelopment of young children. The performed calculations may be underestimates because they do not include lead exposure *in utero*. Furthermore, even if the estimate includes infants (under the age of 12 months), the mobilisation of the lead accumulated in the body of the lactating female hunter family member and its elimination with milk might be underrepresented.

The available data also indicate that game meat consumption by hunter families can have an impact on the incidence of chronic kidney disease in adults (males and females).

The impact of game meat consumption and the accumulation of lead in the body of female hunter family members at reproductive age and on offspring during pregnancy and the mobilisation of lead with elimination via the milk during lactation is of concern. Consequently,

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[3] The software is downloadable under: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=343670

advice is provided from national authorities such as French ANSES[4] or German BfR[5] that children and women at childbearing age should not consume game meat.

Based on national statistics of the number of hunters, the Dossier Submitter calculated that there are 6 million hunters in the EU-27 (Röschel et al., 2020). According to Eurostat data, the average household size in the EU-27 is 2.3. Thus, hunter families comprise about 13.8 million individuals (3.1 % of the EU-27 population). The number of female hunter family members at reproductive age were estimated to be 2.1 million.

As the share of the EU-27 population aged 7 or younger is approximately 8 % of the total population and assuming an equal age distribution in hunter families as in the general EU population, the Dossier Submitter estimates that about 1.1 million children aged 7 or younger are particularly vulnerable to lead exposure.

RAC considers that the Dossier Submitter's approach to use mean game meat lead values may result in a conservative estimate of the risks because of the highly skewed distribution of the lead levels in game meat (leading to a very high mean value). Uncertainties are also due to the limited biomonitoring data available from hunters' families to support these high lead exposures in children. On the other hand, the use of e.g., median level may underestimate the risk. It should be noted that some game meat samples present lead concentrations which are 10-fold higher than the average levels. If this game meat is consumed by young children, it will result in significant increases in B-Pb levels. For example, if a toddler consumes highly contaminated game meat with a lead content of 19 mg/kg (representing 99th percentile of large game meat lead levels) in 12 meals per year (i.e. once per month, 100 g meat/meal) and otherwise lead levels in the consumed meat remain at median level or below (having only minor impact on total exposure), the average lead intake of the toddler would result about the same (close to 5 µg/kg/day) as in the Dossier Submitter's scenario.

These scenarios with infrequent intake of highly contaminated meat instead of constant consumption of game meat with arithmetic mean levels of lead are perhaps more likely. In these scenarios, accumulation of lead into the body after infrequent peak exposures differs from the accumulation of constant exposure, with high peak levels resulting in rapid increase in B-Pb levels followed by decrease close to background levels within two weeks. ATSDR (2020) modelled B-Pb levels after ingestion of a 0.9 mg dose of soluble lead (with assumed 100% absorption) after single or repeated peak exposures in a 30 month old child (Figure C-1 in ATSDR 2020, https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf). After a single peak exposure, the levels declined rapidly within the first month returning to approximately 120% of the baseline in approximately 35 days following the dose. After the six repeated exposures, B-Pb returned to approximately 120% of baseline in approximately 570 days after the last exposure event reflecting the accumulation of lead in bone and the slow transfer of lead from bone to blood after exposure ceases. It should be noted that this modelling was made for soluble lead assuming 100% bioavailability and, therefore, the absolute values do not correctly reflect game meat scenarios. However, the intention of this example is only to show the kinetics of B-Pb after peak exposures. The role of single peak exposures in the long-term

[4] https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead

[5] http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf

neurological effects of lead in children is unknown. However, if these peak exposures are repeated, they will result in gradual long-term increase in B-Pb levels.

Available data show that hunter families frequently eat game meat (up to 1-2/week), but there is no data on how lead levels vary between these meals. The Dossier Submitter has assumed similar levels in all meals but a higher variation between the meals is likely. The example above assuming consumption of high lead levels via game meat once per month, and otherwise lower levels in the meat, also supports a concern for children in hunter families.

Regarding adults, RAC notes the Dossier Submitter has not quantitatively characterised the risks related to the increment of prevalence of chronic kidney disease (CKD) and the increase of systolic blood pressure (SBP) as done for IQ loss in children. Yet, Table 6 reports small increases of CKD and SBP for adults based on the consumption of game meat bagged with shot and bullets, respectively. However, the clinical relevance of especially those small increases in SBP is unclear.

Nevertheless, some biomonitoring data for adults presented in the Background Document suggests that B-Pb levels in adults might not be affected by the consumption of game meat (except in some native populations practising subsistence hunting). This is in line with the modelled B-Pb levels showing only small increases in B-Pb levels with median consumption of game meat even when using the conservative mean values for the game meat lead levels. Even though it is possible to speculate that there might be cases where hunters that need to maximise their income from selling game meat are consuming the most contaminated parts, and will be exposed to even higher levels, it is not possible to verify this.

In addition to the quantitative assessment of the risks, the Dossier Submitter further assessed the risks in a qualitative manner by combining the potential for exposure with the frequency of exposure*.*

Based on data from the EFSA database on lead concentration in game meat and on the intake of game meat (50th percentile used as a proxy for persons of a hunter household), assuming lead metal bioavailability of 10 % for adults and 50 % for children and considering that there is no evidence for a threshold of lead for developmental neurotoxicity in children, the Dossier Submitter estimated that for children a blood lead level increase will result in a high risk. For adults, low risk was concluded based on the assessment described above.

Overall, considering 1) the sensitivity of small children to the effects of lead and 2) the possibility of high levels of lead in some pieces of game meat, RAC agrees that there is a risk for children resulting from the consumption of game meat. Yet the Dossier Submitter's scenario based on the constant daily consumption of game meat with lead levels corresponding to the arithmetic mean of all measurements may overestimate the risk. Further, how probability of exposure vs severity of effects are weighted in the Dossier Submitter's qualitative approach is not clear. For this reason, RAC applied a best practice approach to qualitative risk assessment, based on a conceptual model, considering the potential sources of exposure, the receptor, the pathway and their probability and severity of effects (EC 2010, ISO 21365:2019) (see Annex 1).

For children, exposure modelling suggests that up to medium increases in B-Pb levels are highly likely in high game meat consumption scenarios (representative of hunter families). In some cases, even severe increases (>30 µg/l) are possible if highly contaminated meat is consumed. Overall, based on RAC's assessment, this scenario results in moderate to high risk for children. Developmental neurotoxic effects are relevant also in the case of offspring of pregnant females.

In the case of adults, modelling shows only minor increases in B-Pb levels even in high consumption scenarios. This is in accordance with the limited biomonitoring data showing no clear association between game meat consumption and B-Pb levels. Therefore, using qualitative risk assessment, RAC concluded for adults the risk from game meat consumption is considered low. However, RAC would like to highlight the risks of game meat consumption for females at fertile age, and especially pregnant females. Although in adults increases in B-Pb levels due to game meat consumption are lower than those expected in small children, there is no threshold for the developmental neurotoxicity of lead, and therefore for pregnant females the risk is considered at least moderate since at least mild increases in B-Pb levels are expected in case of frequent game meat consumption.

For the purpose of **impact assessment and to evaluate the effectiveness and risk reduction of the restriction,** rather than mean values, the Dossier Submitter used the empirical cumulative distribution function of the EFSA data on the lead concentrations in game meat and estimated the blood lead levels and the corresponding IQ loss and increase of CKD values for the whole distribution (see Figures 1 and 2 below). This approach was followed since the mean value is not a robust measure of centrality for strongly skewed distributions.

For the impact of lead in game meat on **IQ loss**, the Dossier Submitter estimated that about 1.1 million children were at risk of high exposure and built the cumulative empirical distribution function showed in the figure below. The results suggest that 50 % of the population is at risk to lose > 0.05 IQ points and 6% to lose > 1 IQ point.

For monetising the health impact in children, the Dossier Submitter used either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points. It should be noted that both these approaches ignore the upper end of the curve, which may include some exceptionally high (and therefore rather unlikely) lead exposures.

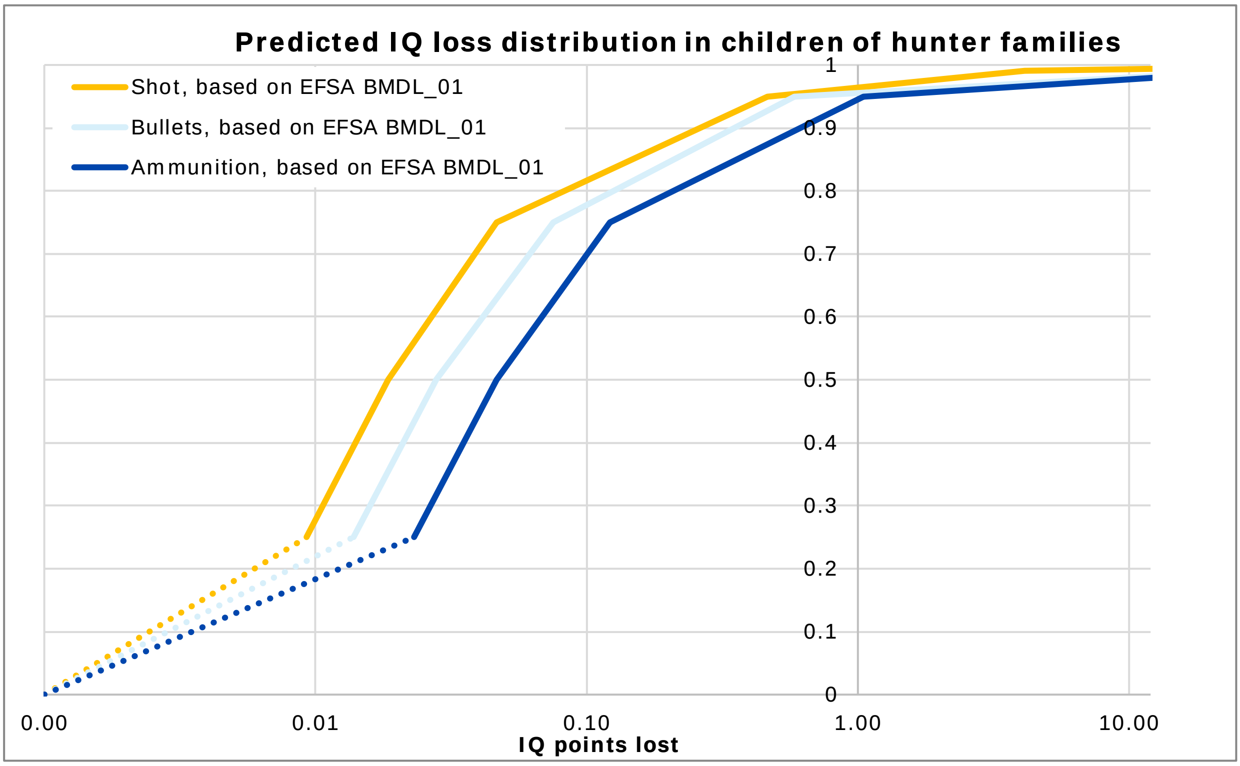

Figure 1: Empirical cumulative distribution functions (ECDFs) of IQ loss in high-frequency game meat consumers (Figure 2-4 in the Background Document)

Although the association between B-Pb levels and **increased CKD risk** in adults is less established than the one between B-Pb levels and neurotoxic effects in children, the Dossier Submitter considers that it might still be relevant at the population level since the group of exposed individuals is larger in the adult population than in the child population. The Dossier Submitter estimated that the size of the exposed adult population is about 10 million individuals.

Figure 2 below shows the resulting empirical cumulative distribution functions for excess CKD risk. The distribution function suggests 50 % of the population at risk faces an excess risk larger than 0.04% and 3.1 % of the population bears an excess CKD risk of ≥ 10 %.

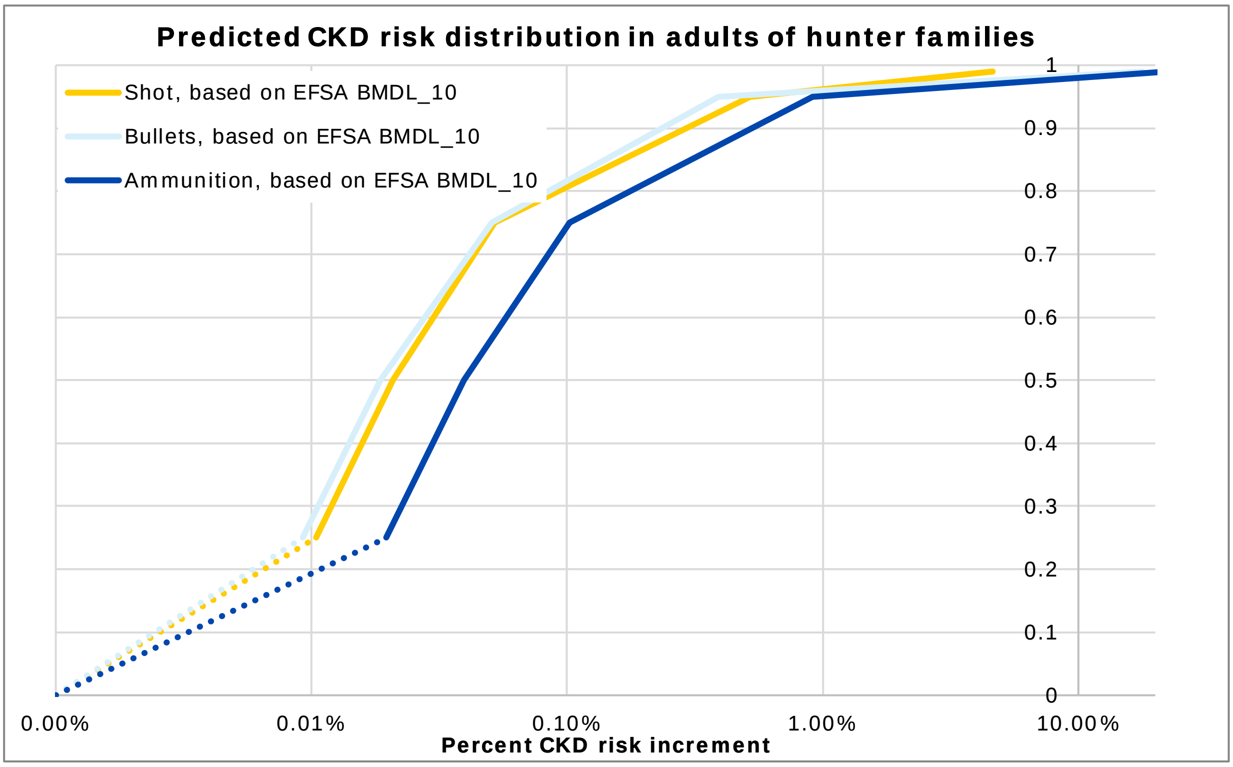

Figure 2 : Empirical cumulative distribution functions (ECDFs) of excess CKD risk in adult high-frequency game meat consumers

According to the Dossier Submitter, one may expect 1 085 additional cases of CKD (stages 3-5) in this group of extremely exposed individuals. This value might however be overestimated, as it is based on EFSA's BMDL10 which has been recognised as a worst-case value. In addition, long term repeated exposure to highly contaminated game meat (with lead levels >5 000 mg/kg) is needed to result in an excess CKD risk of >10%. Considering the distribution of lead in game meat, this might occur only in rather rare cases. Accordingly, for monetisation, the Dossier Submitter assumed that the number of attributable cases of CKD across the EU is between 100 and 1 000.

RAC agrees with the Dossier Submitter's approach to take the whole distribution of blood lead levels forward for the human health impact assessment. This approach is likely to give a more realistic overview of the variability of lead exposure from game meat consumption than a single point estimate. RAC notes that, for IQ loss, the Dossier Submitter used either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points for monetising the risks. Both these approaches ignore the upper end of the curve including some exceptionally high (and therefore rather unlikely) lead exposures. RAC agrees with this approach but notes significant uncertainties caused by large variability in game meat lead levels and lack of data on the B-Pb levels among high game meat consumers.

Regarding CKD risk for adults, RAC noted that the results of Dossier Submitter analysis should be interpreted with caution because of the conservative nature of EFSA BMDL, and because of the need for long term (>5 years) constant exposure via highly contaminated game meat. Therefore, RAC agrees with Dossier Submitter that the real numbers of CKD cases are likely to be significantly lower than predicted by the model.

Risk from consumption of contaminated food and drinking water

In the work package report WP A.1 the risks to the environment are assessed for livestock (ruminants) grazing in shooting ranges and areas used as agricultural land. Risks to humans from the consumption of lead contaminated food may also originate from the deposition of lead on and in soil of shooting ranges used as agricultural land with consequent uptake of lead by plants used for human consumption as well as by grazing ruminants delivering milk and meat for human consumption.

A direct correlation between lead in soil and lead in plants has been reported (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare* L.) grown on shooting ranges, lead concentrations were 138 mg/mg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Commission Regulation (EC) No 1881/2006 limits lead in cereals to 0.2 mg/kg food for human consumption, demonstrating that there is a risk for human health resulting from the consumption of food grown on shooting ranges.

It is also reasonable to assume that there is potential for cattle, and their products, containing elevated lead concentrations to enter the food chain, but only if they do not display overt clinical symptoms of lead poisoning that would otherwise result in their removal from the herd and disposal.

The potential exposure of humans to lead via the diet would be higher for subsistence farmers (and their families) eating meat and dairy products derived entirely from a cattle herd with sub-clinical lead poisoning following exposure to lead ammunition via grazing on land used for shooting or the consumption of silage contaminated with lead shot. To assess the significance of exposure via this route a 'worst-case local scale'[6] exposure assessment was performed considering the scenario of an adult farmer and a young child consuming all their meat and dairy products from sub-clinically poisoned cattle.

Dietary exposure is typically calculated based on representative consumption rates for a variety of foodstuffs. Meat and dairy products are of most relevance in this scenario and consumption rates are taken from the EUSES model, which uses the highest country-average

[6] Local scale is a typical worst case since all food products are derived from the vicinity of a point source (EUSES guidance)

consumption rate from the EU Member States for each food as input to the assessment of exposure to chemicals from the diet.

- Adult daily intake of meat is 0.301 kg/d ww in EUSES; and
- Adult daily intake of dairy products is 0.561 kg/d ww.

Children are commonly the most sensitive receptors in the assessment of dietary exposure as they consume more in relation to their body weight and they may also be more sensitive to the toxic effects of the substance under assessment. This is a particular issue with lead as neurobehavioural effects in children (as measured by IQ score) are the most critical health effect (Lanphear et al., 2005). EFSA Scientific Committee (2012) guidance on parameter values for dietary exposure assessment indicates that a young child consumes 52.3% of an adult diet[7], which can be applied to modify the adult consumption values for meat and dairy products given in EUSES, i.e.:

- Child's daily intake of meat is 0.157 kg/d ww; and
- Child's daily intake of dairy products is 0.293 kg/d ww.

Cattle are only likely to show clinical signs of lead poisoning at B-Pb levels higher than 250 to 400 µg/L; a B-Pb level of 300 µg/L in cattle exposed to lead from ammunition is therefore unlikely to alert a farmer to the possibility of poisoning and result in its removal from the food chain. Blood lead level is the most common metric to represent lead poisoning but equivalent concentrations in meat and milk are required for dietary exposure assessment. Bischoff et al. (2014) presents a correlation between milk and blood lead concentrations that suggests a cow with a blood lead level of 300 µg/L would produce milk containing 0.3 mg/L lead. Data from APHA (UK Animal & Plant Health Agency) indicates that the lead content of animal tissue from cattle with a similar blood lead level would be 10 - 20 mg/kg lead dw (for a mid-range value of 15 mg/kg dw this would equate to approximately 5 mg/kg ww based on water content of roughly 70 %). These calculated concentrations in meat and milk (including milk used for the manufacture of dairy products) are an order of magnitude higher than the maximum levels permitted for lead, which are 0.10 mg/kg ww in meat (0.50 mg/kg ww in offal) and 0.020 mg/kg ww in milk, according to Commission Regulation (EC) No 1881/2006.

Tables 7 and 8 (Tables 1-55 and 1-56 of the Background Document) detail the dietary exposure assessment for a subsistence farmer and a young child consuming meat and milk/dairy produce from cattle with a blood lead level of 300 µg/L. It should be noted that this assessment may underestimate the potential exposure from dairy produce as the concentration of lead in products such as cheese will be higher than that in milk.

Table 7: Dietary exposure assessment for subsistence adult (farmer)

[7] An average European toddler (1-3 years) weighs 12 kg and has a total mean food consumption rate of 114.4 g/kg bw/day; an average adult weights 70 kg and consumes 37.5 g/kg bw/day EFSA SCIENTIFIC COMMITTEE 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. *EFSA journal,* 10**,** 2579.

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.301	1.5	70	0.021
Milk/dairy	0.3	0.561	0.17	70	0.002
Total					0.023

The predicted dietary exposure to lead for an adult subsistence farmer under this scenario is 23 µg/kg bw/d, which is 15 times higher than the $BMDL_{01}$ established by (EFSA, 2012) for cardiovascular effects in adults (1.5 µg/kg bw/d) and 37 times higher than the $BMDL_{10}$ for nephrotoxicity effects (0.63 µg/kg bw/d).

Table 8: Dietary exposure assessment for the child of a subsistence farmer

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.157	0.785	12	0.065
Milk/dairy	0.3	0.293	0.088	12	0.007
Total					0.072

Under this scenario, predicted dietary exposure to lead for a toddler is 72 µg/kg bw/d, which is more than 140 times higher than the $BMDL_{01}$ of 0.5 µg/kg bw/d established by (EFSA, 2012) for developmental neurotoxicity in young children.

This scenario illustrates that worst-case exposure estimates do not correspond with negligible potential exposure.

However, in the absence of evidence that this scenario could reasonably occur in practice in the EU, the Dossier Submitter considers this to be a hypothetical and illustrative scenario, which is not part of the main analysis.

Risks for the consumption of lead contaminated drinking water may originate from the deposition of lead on and in the soils of shooting ranges using lead gunshot or lead bullets, with corrosion of lead and its mobilisation to surface water and groundwater as drivers. The potential lead contamination of ground and surface waters resulting from the use of lead ammunition at sports shooting ranges has been assessed under the work package report WP A.2. As in the case of food, no further information is available to assess potential health risks from the consumption of drinking water contaminated via the environment by lead deposition on shooting ranges. Based on the available information, the Dossier Submitter has estimated the risk for humans due to indirect exposure via food and drinking water to vary between low (+) to high (+++) depending on the shooting frequency and risk management measures at the shooting range.

RAC notes that there is no data on the human exposure via food or drinking water and agrees with the Dossier Submitter that the situation may vary depending on the shooting frequency and the risk management measures in place at the shooting range. When there is no agricultural land adjacent to the shooting range and groundwater contamination is unlikely (soil not favorable for the transfer of lead to groundwater) the probability of exposure can be considered unlikely. Higher probability (high concern) for environmental contamination is related to shooting ranges with high intensity of shooting, adjacent to agricultural land, and with soil favorable for lead movement to surface water and groundwater. Considering the apparent lack of evidence supporting this exposure route, this is not considered a frequent case and is therefore judged to be a low probability resulting in low-moderate risk, the highest risks being related to the exposure of children and pregnant females.

5. Uncertainties

There are several uncertainties associated with the derivation of the BMDL values.

There are uncertainties in relation to the estimation of lead concentrations in hunted animals. Sampling from larger animals may be misleading because it is possible to obtain both highly contaminated and completely uncontaminated samples from the same animal. The analysis of a sample that is close enough to the wound channel may lead to very high maximum lead concentrations.

In addition, according to the EFSA dataset, the amount of lead in game meat hunted with bullets is much higher than the amount of lead in game hunted with gunshot. A possible reason might be related to the temporary cavity phenomenon of bullets, especially pressure fluctuations in adjacent tissues. This phenomenon may be responsible for lead transfer deep into the tissues that surround the path of a wound. On the other hand, a recent study (Pain et al., 2022) suggests up to 14-times higher mean lead levels in small prey hunted with shotgun than the estimates based on EFSA data (2020) used by the Dossier Submitter.

There are uncertainties in relation to the daily consumption of meat from game hunted with lead gunshot and bullets in the EU for sensitive groups such as pregnant and lactating women, since very few data are available. The Dossier Submitter considered as most relevant for risk assessment the data on infants and toddlers as the most sensitive group for developmental neurotoxicity and the data on adults in general in regard to the risks for chronic kidney disease and increase in blood pressure without sex division. No relevant measured data on B-Pb levels are available from infants and toddlers in high game meat consuming families either.

Very limited data are available on how frequent game meat consumption affects B-Pb levels in hunter families. The data presented in the report is modelled and cannot be compared with real measured values.

There is very limited data available to assess exposure and potential health risks from the consumption of food or drinking water contaminated via the environment by lead deposition on shooting ranges.

6. Conclusions

1. Data related to the amount of lead in game meat is available from various studies where the concentration of lead in meat intended for consumption was measured. It is, however, noted that there is a large variability in the game meat lead levels. However, the available data indicate that even if prepared under best practices a relevant proportion of game meat has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg /kg meat).

2. Information received in the consultation of the Annex XV restriction report indicates that non-expanding bullets (FMJ) and small calibre pistols used for the hunting of small game or seals may not result in similar lead contamination of the game meat as observed with expanding ammunition.

3. The data on the concentration of lead in game meat and game meat consumption allows for an estimation of the risk of lead for sensitive population groups such as toddlers and infants, as well as for getting general conclusions for adults.

4. The risks for neurodevelopmental effects in children and for CKD in adults associated with incremental B-Pb levels from the consumption of meat from game hunted with lead bullets or gunshot are quantitatively estimated. B-Pb values are, however, based on modelling and only limited crosschecking (for adults) can be done with real data adding uncertainty to the results.

5. RAC considers that the Dossier Submitter's approach to use the mean values for game meat lead levels in the risk characterisation (in contrast to the impact assessment; see point 9 below) may result in a conservative estimate of risks due to the highly skewed distribution of the lead levels in game meat. On the other hand, higher lead levels in small game meat reported in some studies compared with the data used by the Dossier Submitter reduce the possible overestimation caused by this. In addition, since some pieces of game meat may contain more than one order of magnitude higher amounts of lead when compared to the mean levels used by the Dossier Submitter, similar total intakes of lead may follow even after few meals/year of this highly contaminated meat. This may result in significant increases in B-Pb levels in children.

6. RAC concludes that there is a moderate to high risk for neurodevelopmental effects in children.

7. In adults, the effect on B-Pb levels are smaller, and there is no biomonitoring data available from European hunters consuming game meat to contradict this smaller effect. However, some effects on CKD and some cardiovascular effects are possible, but the level of adversity of these effects is not clear, so a low risk is concluded.

8. It should be noted that developmental neurotoxic effects are relevant also in the case of pregnant females. Although in adults increases in B-Pb levels due to game meat consumption are lower than those expected in small children, since there is no threshold for the developmental neurotoxicity of lead, also for pregnant females the risk for developmental neurotoxicity is considered relevant.

9. Instead of single point estimate of game meat lead levels and B-Pb levels in hunters and their families, the Dossier Submitter took the whole distribution of blood lead levels forward for the human health impact assessment. RAC agrees with this approach, which gives a more realistic overview of the variability of lead exposure from game meat consumption.

10. Limited evidence is provided to substantiate the risk of lead from contaminated food or drinking water. Yet, the evidence provided indicate potential risks which can be a concern in permanent shotgun areas with no environmental risk management measures or in intensive shooting areas.

11. RAC therefore concludes that human exposure to lead via the environment is an important concern for game meat consumption in hunting with lead gunshot and bullets, and for lead contaminated food in case of sports shooting ranges with no environmental risk management measures or in intensive shooting areas.

7. References

Additional references not included in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing:

García-Fernández Antonio J., Isabel Navas Ruíz, Pedro María-Mojica, Irene Valverde Domínguez, Eduardo A. Hernández Hernández. 2018. Plomo en productos cárnicos de caza mayor: estimación de riesgos por su consumo.

Chan L, Receveur O, Batal M, Sadik T, Schwartz H, Ing A, Fediuk K, Tikhonov C. 2017. First Nations Food, Nutrition and Environment Study (FNFNES): Results from Saskatchewan. Ottawa: University of Ottawa.

Pain et al. (2022). How contaminated with ammunition-derived lead is meat from European small game animals? Assessing and reducing risks to human health. Ambio https://doi.org/10.17863/CAM.83511

Food Standards Scotland, 2012, ‘Risk to human health from exposure to lead from lead bullets and shot used to shoot wild game animals‘.