

Committee for Risk Assessment (RAC)

**Request by the Executive Director of ECHA under
Art. 77(3)(c) of REACH to prepare a supplementary
opinion on the restriction dossier on lead in
outdoor shooting and fishing**

ECHA/RAC/A77-O-0000007180-83-01/F

1 December 2022

SUPPLEMENTARY OPINION

Pursuant to Article 77(3)(c) of Regulation (EC) No 1907/2006, the Committee for Risk Assessment (RAC) has adopted a **supplementary opinion** on the proposed restriction on lead in outdoor shooting and fishing, taking into account the comments and supporting evidence submitted by stakeholders on:

A specific dataset concerning the presence of lead in game meat and the human intake of game meat, as provided by the European Food Safety Authority ('EFSA dataset').

This dataset used by the Dossier Submitter (ECHA) in their assessment of human health risks from lead in ammunition was not made publicly available prior to the closure of the consultation on the Annex XV restriction report.

I. PROCESS FOR ADOPTION OF THE SUPPLEMENTARY OPINION

On 21 June 2022¹, the Executive Director of ECHA requested RAC, following a three-month targeted consultation on the EFSA dataset, to re-assess their evaluation of these data in the context of the proposed restriction of lead in outdoor shooting and fishing. The Committee was requested to take into account the specific comments and supporting evidence submitted by stakeholders in the aforementioned consultation and to provide a supplementary opinion updating or confirming their conclusions on the risks posed by the intake of lead through consumption of game meat.

Rapporteur, appointed by RAC: **Tiina SANTONEN**

In accordance with the above mandate, the rapporteur developed this supplementary opinion, summarising the justifications for confirming the RAC conclusions in the opinion on the restriction proposal of lead in outdoor shooting and fishing on the risks to human health resulting from the intake of game meat.

The RAC opinion was adopted **by consensus** on **01 December 2022**.

¹ https://echa.europa.eu/documents/10162/17086/rac_mandate_follow_up_on_lead_en.pdf/fd4b33fd-c4e2-08a3-b42a-66d5178f706e?t=1656412172486

II. SUPPLEMENTARY OPINION OF RAC

THE SUPPLEMENTARY OPINION OF RAC

RAC has formulated its opinion based on an evaluation of additional information received in a targeted consultation on lead concentrations in game meat, game meat consumption among hunters and their families and potential exposure to lead through game meat consumption.

Summary of the previously adopted RAC pinion

In its original opinion on the proposed restriction of lead in outdoor hunting, sports shooting and fishing, RAC (ECHA, 2022)² concluded that consumption of game meat hunted with lead gunshot or expanding bullets resulted in a moderate to high risk for children and pregnant women from families consuming large amounts of game meat. However, for other adults, the risk from such consumption of game meat was considered as low. RAC also supported the use of the Dossier Submitter's quantitative assessment approach for IQ loss but noted significant uncertainties caused by the large variability in game meat lead concentrations and the lack of data on the blood lead (B-Pb) levels among high consumers of game meat.

RAC noted that very recently published data, reporting high lead concentrations in small game (Pain et al., 2022) suggests that the risks related to its consumption may be greater than estimated by the Dossier Submitter. Regarding the risk of chronic kidney disease in adults, RAC noted that the results of the quantitative analyses reported by the Dossier Submitter should be interpreted with caution because of the conservative nature of the EFSA Benchmark Dose Level (BMDL), and because of the need for long term exposure via highly contaminated game meat. Therefore, RAC agreed with the Dossier Submitter that the risks are likely to be significantly lower than calculated. This is in line with the low risk concluded for adults in the qualitative risk assessment.

RAC also noted the significant uncertainties in the assessment of all human health effects, which were largely due to limited information on exposure. In the case of risks arising from game meat consumption, exposure was assessed based on modelling data due to the lack of measured data. Some uncertainties related to the dose-responses and BMDLs derived based on the available human epidemiological data were also recognised. Despite the identified uncertainties in the underlying data, RAC concluded that consumption of game meat hunted with lead gunshot or expanding bullets results in a moderate to high risk for children and pregnant females. For adults, the risk caused by the consumption of game meat is low.

RAC's supplementary opinion

Based on the new data submitted in the targeted consultation, and a sensitivity analysis of its implications, RAC reiterates its conclusion that there is a moderate to high risk from game meat lead exposure for **children** (infants and toddlers) in hunter families. RAC notes that the EFSA dataset is likely to underestimate lead concentrations in small game meat and this may result in an underestimation of the total health impacts in children.

RAC also reiterates its previous conclusion that risks for **adults** are likely to be low, although the underestimation of lead concentrations in small game in the EFSA dataset means that total lead exposure including from both small and large game meat is likely to be an

² <https://echa.europa.eu/documents/10162/5e0bed8b-4421-bdfe-139d-96c6c9c07bc0>

underestimate.

RAC notes that the conclusions from the qualitative assessment on the risks posed by the intake of lead through consumption of game meat for pregnant women as presented in the previously adopted RAC opinion are unchanged by this supplementary opinion since the qualitative assessment carried out on this aspect was not influenced by the EFSA dataset.

III. OPINION JUSTIFICATION

1. Relevant information from the consultation of the EFSA datasets on lead levels in game meat and game meat consumption

Comments related to lead concentrations in game meat

Several comments raise concerns that the EFSA dataset underestimates game meat lead concentrations. These include comments #88, 89, 90, 91 and 92. The most comprehensive analysis is provided in comment #88 (from two of the authors of Pain et al, 2022, which focuses on small game meat lead concentrations and compares the EFSA data to that published by Pain et al. (2022) (this study was considered in RAC's original opinion). The analysis provides several explanations for the discrepancy observed between the Pain et al. (2022) dataset and the EFSA dataset. The former reports an up to 14 times higher arithmetic mean lead concentrations for small game meat compared to the EFSA dataset.

The main points raised in comment #88 were:

- The EFSA dataset includes samples from animals that have production methods coded in a way that suggests that the animals (especially ducks) were not hunted (e.g., industrially produced, or domestic poultry).
- Data seems to also include samples of offal rather than meat. Liver or kidney levels do not represent meat contamination by shooting and may result in an underestimation of game meat lead concentrations.
- There is a concern that in some cases, the hunting method may have been other than lead ammunition (e.g. trap, arrows/crossbows, hunted with birds of prey). This is especially the case for hares in the Czech Republic, which contain much lower concentrations of lead than hares from Germany.

Based on these observations, comment #88 suggested to use published, peer reviewed, data (including Pain et al., 2022) for the assessment of risks related to game meat consumption rather than the EFSA dataset.

A reanalysis of the EFSA data, provided in comment #88, excluding the above-mentioned data, resulted in arithmetic mean game meat lead concentrations in duck, pheasant and hare of 1.026 ppm (mg/kg), which is similar to that calculated by Pain et al. (2022) for these species (arithmetic mean of 1.08 ppm). These concentrations are approximately three times higher than the mean concentrations used by the Dossier Submitter when concluding that risks were not adequately controlled (0.366 mg/kg). The weighted arithmetic mean of the

complete Pain et al. (2022) dataset (including all species and whole observation period from 1991-2021, but excluding Denmark where lead gunshot is banned) was 2.474 mg/kg. The lead concentration tended to increase over the years with the most recent data (2011-2021) showing weighted arithmetic mean levels of 5.205 mg/kg. The reason for this increase over time suggested by Pain et al. (2022) is unknown.

Similar observations were made in comment #92 (by Wildfowl & Wetlands Trust, WWT) which also included some reanalysis of the EFSA data. This reanalysis suggests that 20% of small game exceeds the EU maximum allowable lead concentration for meat from domestic animals of 0.1 ppm instead of 13% as calculated by the Dossier Submitter. In the case of large game, a reanalysis did not result in a significant difference.

Comment number #90 (an individual) supports in principle the use of the EFSA data for risk assessment but notes the issues mentioned above, which they suggest may lead to the underestimation of game meat lead concentrations. The recent study by Pain et al. (2022) is also cited. Comment number #91 makes similar arguments.

Comment number #89 (Danish Academy of Hunting) refers to two recent studies (Kollander et al. (2017) and Leontowich et al. (2022) showing the presence of lead fragments and lead nanoparticles in meat hunted with lead bullets. Data on game meat lead concentrations from Pain et al. (2022) are referred to.

One Member State Competent Authority (comment #93), considered the EFSA data to be unrepresentative and therefore did not support the RAC conclusions on the risk associated with the consumption of game meat. They noted significant uncertainties related to the exposure assessment (i.e. data on the concentration of lead in game meat and the consumption of game meat) and that appropriate measured data on blood lead levels are not available.

Comments #94 (FACE - European Federation for Hunting and Conservation) and #95 (AFEMS - Association of European Manufacturers of Sporting Ammunition) consider that the lead concentrations in game meat used for the risk assessment are overestimates. The comments consider that some of the lead concentrations reported for game meat are not representative of the consumable parts of game hunted with bullets. According to these comments, the highest lead concentrations must have been obtained from meat close to the wound channels of the carcasses which should normally be excised and discarded before any use. In comment #95 an outlier analysis was performed and the three highest lead concentrations (out of total of 10 334 measurements) in large game were discarded. This resulted in an arithmetic mean lead concentration (upper bound) of 1.48 mg/kg, which is 59% of the arithmetic mean value calculated by the Dossier Submitter. No new data on game meat lead concentrations were provided in these two comments.

Comments related to game meat consumption

Comment #94 from FACE considers the EFSA consumption figures used by ECHA in their assessment to be overestimations. However, they mostly criticise the P95 intake estimates that were used in the original Annex XV restriction report. These P95 levels were replaced by intake estimates representing P50 levels in the Background Document revised after the consultation on the Annex XV restriction report. Uncertainties related to the EFSA game meat

consumption data especially in the case of infants and toddlers were noted. A mistake in the game meat consumption figures in Table 1-50 of the Background Document was noted (i.e. the game meat consumption figures were mixed between game meat hunted with bullets and shot) although these errors do not have any further impact on the Dossier Submitter's assessment. However, contrary to the assumption of FACE, the data provided in Tables 1-51 and 1-54 are correct.

Comment #95 (AFEMS) presents an evaluation of the EFSA dataset by Arcadis US, inc. Their report considers the consumption figures to be overestimates and provides a reanalysis of the data using lower consumption figures. Regarding **infants**, they consider that ECHA's assumption on game meat consumption is based on only 31 subjects from eight surveys. It is likely that the term "infant" does not include babies less than six months old since babies in their first six months of life should be consuming mother's milk or baby formula and not consuming meat. In addition, according to their calculations, the game ingestion rate implies that infants consume ~27% of their total protein from game hunted with lead gunshot or bullets. Based on this, they propose to omit infants as a receptor, or at least to reduce the ingestion rate to a value that assumes no meat ingestion for the **0-6-month-old** and reduce the ingestion rate for the **6 to 12-month-old** to 10% of total protein intake. According to their proposal, the median P50 ingestion rates for infants would then be 0.93 g/day for bullets, 0.4 g/day for gunshot and 1.3 g/day (total 483 g/year instead of 2.6 kg/year as estimated by the Dossier Submitter). On a body weight basis, this means 0.185 g/kg-day for bullets and 0.08 g/kg-day for shot. Assuming a game meal of 25 g for an infant, this would equal 19 game meals per year.

Lower consumption figures for **toddlers** are also proposed by Arcadis (Comment #95). They referred to published total meat consumption estimates of ~ 40 g/day from the UK and the Netherlands and noted that the Dossier Submitter's estimate of 30 g/day of game meat intake for toddlers represents 75% of their total daily meat consumption. According to the Arcadis evaluation, this can be considered an unreasonable assumption even for hunter families. The respondent proposed to reduce the ingestion rate of toddlers from a daily consumption of 30g of game meat as proposed by the Dossier Submitter to 51 game meat meals per year containing 50 g meat per meal. This corresponds to a total consumption of 1.512 kg/year, which is approximately 10-times lower than the estimate given by the Dossier Submitter (10.8 kg/year).

Similarly, the comment notes that the Dossier Submitter's proposal on game meat consumption (86.7 g/day) corresponds to 58 % of the average daily meat consumption by European **adults** (estimated as 147 g/day by Arcadis). The respondent considered that this figure was not representative and recommended to reduce the estimation of game meat ingestion to 10% of the 95th percentile of the total meat consumption rate in Europe (estimated as 319 g/day). With this modification, their calculated median P50 ingestion rates for adults would be 11.642 kg/year in total (compared to 31.4 kg/year used by the Dossier Submitter). Assuming a large game meat portion of 200 g per meal (Haldimann et al., 2002; Ferri et al., 2017), this would equate to 58 game meals per year.

The recalculations provided by Arcadis (comment #95) using lower arithmetic mean values for lead concentrations in game meat hunted with bullets and lower consumption figures are presented in Table 1 and 2 below (reproduced from the Arcadis report). No recalculations were provided by the respondent using lower consumption figures of game meat hunted with

gunshot.

Table 1. Change in mean concentration of lead in game hunted with bullets recommended by Arcadis (comment #95) and its impact on health risk (reproduced from the Arcadis report)

Receptor	Lead source	Game meat consumption * g/kg bw-day	Lead conc in game meat Mean µgPb/g	Daily intake of lead µ/kg-d	IQ point loss	CDK Prev. increase %	SBP increase mmHg
Infants	Bullets	1	1.477	1.477	1.47	NA	NA
Toddlers	Bullets	1.46	1.477	2.156	2.15	NA	NA
Adults	Bullets	0.58	1.477	0.857	NA	1.37	0.068

* Median: P50

Note by RAC: Lead concentration in game meat as suggested by Arcadis, game meat consumption as presented by the Dossier Submitter in Table 1-54 of the Background Document

Table 2. Change in mean Concentration of lead in game hunted with bullets and game Intake recommended by Arcadis (comment #95) and their combined impact on health risk (reproduced from the Arcadis report)

Receptor	Lead source	Game meat consumption g/kg bw-day	Lead conc in game meat Mean µgPb/g	Daily intake of lead µ/kg-d	IQ point loss	CDK Prev. increase %	SBP increase mmHg
Infants	Bullets	0.185	1.477	0.273245	0.27	NA	NA
Toddlers	Bullets	0.204	1.477	0.301	0.30	NA	NA
Adults	Bullets	0.251	1.477	0.371	NA	0.59	0.029

Note by RAC: Lead concentration in game meat and game meat consumption as suggested by Arcadis.

Other relevant comments

Regrettably, a majority of comments were not relevant for the current consultation and many of simply opposed the restriction. Several comments referred to studies from Spain reporting

the presence of pellets in the gizzard of birds, and the concentration of lead in the liver and kidney in birds hunted either with lead ammunition or non-lead ammunition. The aim of these studies was not to study game meat lead concentrations but rather lead exposure of birds resulting from e.g. ingestion of lead pellets. Since they did not provide information of lead concentrations in game meat in birds hunted with lead ammunition, these studies are not considered relevant for the current evaluation.

FACE and AFEMS (comments # 94 and 95) also commented on the lead absorption figures used by the Dossier Submitter. They both considered the assumption that 50% of lead in game meat is absorbed in small children to be an overestimate but although they provided suggestions for alternative absorbed fractions, they did not provide new data to substantiate such alternative absorption figures. The only new study presented was Schulz et al. (2021), which reported the bioavailability of lead in pigs fed with deer meat. The results suggested a bioavailability of between 2.7% - 15% (15% was for meat marinated in acidic medium).

According to FACE, since only 13% of game meat samples hunted with bullets exceeded the limit of 0.1 mg Pb/kg (which is the maximum allowable limit (ML) for lead in domestic animal meat set in EC 1881/2006), this value can be considered as "the relative bioavailability" of lead metal ready to be absorbed in the body from all game meat consumed. Using this value and the absorption rate of 50% for children and 10% for adults, FACE proposed to apply "an absolute bioavailability" value of 6.5% (0.13×0.50) for lead metal in game meat ingested by children and 1.3% (0.13×0.10) lead metal in game meat ingested by adults.

2. RAC evaluation of the information submitted in the consultation

Lead concentrations in game meat

No new data on the concentrations of lead in game meat were provided in the targeted consultation but several comments challenged the analyses of the EFSA data performed by the Dossier Submitter as discussed above.

RAC acknowledges the reanalysis of the lead concentrations in small game meat, which gives a plausible explanation for the differences in average game meat lead levels between the EFSA data and those reported in the Pain et al. (2022) study. This reanalysis (provided in comment #88) suggests that mean game meat lead concentrations in small game hunted with gunshot may actually be several times higher than estimated by the Dossier Submitter (arithmetic mean of 2.5-5.2 mg/kg compared to the Dossier Submitter's arithmetic mean estimate of 0.366 mg/kg). According to the evaluation of the data provided in comment #88, as much as 70% of the lead concentration data for duck, pheasant and hare in the EFSA dataset may be wrongly classified or should not be considered as representative of the lead concentration in small game meat. Removing these data reduces the size of EFSA dataset significantly since they represent 65% of the whole EFSA dataset for small game. This is likely to affect also the representativeness of the dataset since the number of remaining samples are very low for some species.

In terms of large game hunted with bullets, RAC agrees that there are three values with very high lead concentrations (1 843, 3 650 and 5 309 mg/kg), which have a significant impact on the arithmetic mean levels. Those may represent parts of meat taken close to the wound channel, which – according to the current advice – should not be used for food. However, RAC

notes that the EFSA dataset is based on samples taken during normal food surveillance i.e. meat available to consumers, which suggests that the advice on the discarding meat close to the wound channel have not been always followed. Therefore, RAC considers that they cannot be totally ignored.

The issue of individual high measurements which will raise the mean lead concentration above the P95 level was recognised by RAC in their previous opinion although no reanalysis excluding those samples were performed. This was because the mean lead concentrations were not used for the human health impact assessment. The Dossier Submitter used instead the full distribution of the EFSA data of lead concentration in game meat which is based on 10 334 data points for lead concentration in large game meat. If the three values identified as statistical outliers in the Arcadis report are removed from the dataset, no changes in the distribution will follow except at the very highest end of the curve. In the impact assessment for children, the Dossier Submitter capped the exposure to game meat level corresponding to 1 IQ point and assumed 0 IQ point loss below that threshold. Since the impact assessment ignores the high end of the measured values, RAC estimates that the effect of these three high individual lead concentration values in the calculation of the IQ loss for children is nil.

In the case of small game, the removal of those values from the EFSA dataset that may not correspond to game meat hunted with gunshot and have significantly lower lead concentrations has a significant impact on the arithmetic mean of the lead concentration (as shown in comment #88). RAC has not been able to assess the impact of removing these data as the distribution function of the lead concentration in small game meat excluding these values is not available. However, it can be expected that, due to the significant number of samples in the EFSA dataset that may not be representative of the lead concentrations in small game meat, the quantification of human health effects performed by the Dossier Submitter would lead to an underestimation of the impacts. Removal of 65% of samples from the dataset has a significant impact on the size of the EFSA dataset, potentially also affecting its representativeness. The recent literature analysis by Pain et al. (2022) also does not provide information on the distribution of the small game meat lead concentrations and this prevents its use in health impact assessment as an alternative data source to the EFSA dataset.

Overall, the mean lead concentration calculated by the Dossier Submitter for large game based on the EFSA data is impacted by three extremely high values and may therefore be an overestimate of typical exposure but not potential exposure if consuming one of these samples, as they may reflect inadequate butchering of meat and cannot so easily be discarded.

Based on the data provided in Pain et al. (2022) and the above reanalysis of the EFSA data submitted during the targeted consultation, the mean small game lead concentration calculated from the EFSA dataset appears to be an underestimate and should be in the same range as the mean value calculated for the large game. This would also be in line with the general observation from the existing literature that average lead concentrations are usually higher in birds than in large game species. Therefore, overall, mean game meat lead concentrations as calculated by the Dossier Submitter may rather represent an underestimate rather than an overestimate of the lead content in game meat hunted with lead ammunition.

Game meat consumption

No new data on the consumption of game meat in hunter families were provided in the consultation but the assumptions used for meat consumption by the Dossier Submitter were challenged by several respondents as already discussed in section 1. Recalculations based on alternative assumptions on game meat consumption in hunter families were provided.

In the case of **infants** (0 to 12 months old), it is recognised that infants below six months old do not usually consume meat since it is generally recommended to start giving meat (typically in the form of puree) to infants only from the age of six months (although in some cases earlier). However, RAC notes that infants below six months may be exposed to lead via mother's milk. An exposure assessment for lactating females was not performed by the Dossier Submitter and therefore, this exposure route is missing from the assessment. The Dossier Submitter's estimate of total game meat consumption of 2.6 kg/year for infants (based on the data from eight food recall surveys provided by EFSA with a range from 1 to 15 respondents) can be calculated to correspond to 100 game meat meals during the first year of life (assuming meat consumption of about 25 g/meal as proposed in comment #95). This would mean four game meat meals per week if it is assumed that infants below six months old do not consume meat. Although this can be considered as a conservative estimate of the game meat consumption in infants, RAC does not consider it to be unrealistic. The focus of this assessment is on hunter families, which are considered to be heavy consumers of game meat. If this meat is used for baby food in these families, larger amounts of puree, sufficient for several meals, might be batch-prepared at one time.

In addition, the conservativeness of this assessment is reduced if we include the potential for exposure via lactation before the age of six months, which is not otherwise considered. However, as a sensitivity analysis, RAC has made some calculations using the 'min. P50 level' from the EFSA survey data (total consumption 1.03 g/kg/day = 5.15 g/day = 1 880 g/year) which corresponds to about 75 game meals during the first year of life if the meat content of 25 g/meal is retained. The data are presented in Table 3 under section 3.2. Comment #95 proposes to use only 19 game meat meals as a proxy for infants. RAC considers that this estimate is not likely to sufficiently represent heavy game meat consumer families. In any case, it should be noted that the data on the game meat (or any meat) consumption of infants is very limited.

Regarding exposure of **toddlers**, the current assessment (based on the data from 17 food recall surveys provided by EFSA with a range from 1 to 30 respondents) assumes consumption of 10.8 kg/year of game meat, which corresponds to more than 200 meals/year (4 meals/week) of 50 g/meal. On the contrary, comment #95 (Arcadis) proposed to use consumption figures corresponding to 51 meals/year of 50 g/meal for toddlers. RAC considers that this proposal does not represent reasonable worst-case conditions for hunter families. Previous assessments from France and Germany (Gerofke et al., 2018) have used game meat consumption estimates of above 1 meal/week and 91 meals/year for adults and children, respectively. In line with these estimates, for the purposes of this supplementary opinion, RAC made a sensitivity analysis for toddlers using 100 meals/year of 50 g/meal as an estimate of game meat consumption. This will result in average consumption of 13.4 g/day with 40% being small game and 60% large game. These calculations are presented in Table 3 in section 3.2, below.

In the case of **adults**, the Dossier Submitter's proposal on game meat consumption is based on 36 food surveys with a range from 1 to 218 respondents, which is a significantly more

comprehensive dataset that is available for the other population groups. The consumption figure used by Dossier Submitter was about 31 kg/year. As a sensitivity analysis, RAC has used an assumption of 100 game meat meals per year with 200 g/meal resulting in a consumption of 20 kg/year which is in line with consumption figures used in some earlier risk assessments (Gerofke et al., 2018, ANSES 2018) and corresponds to an average consumption of 54 g/day. Half of this consumption is considered to consist of small game and half of large game. These calculations are presented in Table 4 reported in section 3.2 below. The consumption parameters provided in comment #95 (Arcadis) result in a total consumption of 11.6 kg/year, which is not considered to represent a reasonable worst-case game meat consumption for hunters.

Overall, RAC considers that the EFSA survey data on consumption of game meat in hunter families is very limited especially in the case of children. However, the targeted consultation did not bring any new information on game meat consumption that could be used for risk assessment. In the absence of valid alternative data on game meat consumption, RAC agrees to base its opinion on the EFSA dataset.

Other relevant information

The data provided during the consultation related to the absorption of lead from game meat is not considered sufficient to change the absorption estimates used by the Dossier Submitter. The new study by Schulz et al. (2021) can be considered to support the use of an absorption estimate of 10% for adults but does not provide data to support lowering the absorption estimate for small children.

RAC considers that the approach suggested by FACE of combining absorption and percentage of samples exceeding the ML of 0.1 mg/kg (as explained in section 1) is not appropriate. This approach takes into account only the lead concentration values of those samples above 0.1 mg/kg for the exposure assessment. The Dossier Submitter, on the other hand, estimated the average lead concentrations based on the full dataset and used the whole data distribution for the human health impact assessment. In the case of children, the Dossier Submitter considered an IQ point loss of 1 for those exposure levels resulting in an IQ point loss of 1 or above and assumed 0 IQ point loss below that threshold, i.e. both high and low exposures are not taken into account in the estimation of IQ loss. RAC supports the Dossier Submitter's approach for the human health impact assessment.

3. RAC conclusions on the risks posed by the intake of lead through consumption of game meat

3.1. RAC conclusion(s):

- RAC reiterates its earlier conclusion that the lead concentrations in small game (game hunted with gunshot) calculated by the Dossier Submitter based on the EFSA dataset are likely underestimated. This underestimation in small game meat may result in an underestimation of the health impacts in children although the magnitude of this underestimation cannot be assessed.

- In the case of large game (game hunted with bullets), the EFSA dataset contains three extremely high game meat lead concentration values, which increase the arithmetic mean of the game meat lead concentrations. However, since for the estimation of the health impacts in children the Dossier Submitter uses only children prone to lose ≥ 1 IQ points and ignores the impact of extremely high lead concentrations by considering all IQ point losses above 1 as 1, the inclusion/exclusion of the three highest lead concentration values for large game does not have any effect in the impact assessment.
- RAC acknowledges that the EFSA survey data on the consumption of game meat in hunter families is very limited especially in the case of children. However, the targeted consultation on the EFSA dataset did not bring any new information on consumption that could be used for risk assessment.
- RAC concludes that although the consumption rates used by the Dossier Submitter for infants and toddlers in hunter families are conservative, they are not unrealistic. RAC does not consider that the assumptions on game meat consumption rates submitted as part of targeted consultation represent reasonable worst-case conditions. They are therefore considered not suitable for use in risk assessment. However, a series of sensitivity analyses were performed by RAC using alternative assumptions on lead consumption to test the impact of varying consumption figures and game meat lead concentrations on the health risk in children and adults. These were used to support the RAC opinion.
- **Thus, RAC reiterates its conclusion that there is a moderate to high risk from game meat lead exposure for children (infants and toddlers) in hunter families.** Exposure of infants comes both from mothers' milk and from the direct game meat consumption starting typically at the age of six months.
- With regards to adults, although consumption estimates can be considered conservative, this may be compensated by the Dossier Submitter's underestimation of lead concentrations in small game.
- **RAC reiterates its conclusion that risks for adults are likely to be low.**

3.2. Key elements underpinning the RAC conclusion:

Infants and toddlers

The sensitivity analysis by RAC, presented below, uses mean game meat lead concentrations calculated by Dossier Submitter and those reported by Pain et al. (2022) for small game (comment #88) and alternative estimates of game meat consumption for infants and toddlers. For large game, a mean game meat lead concentration of 1.477 mg/kg, which excludes three high values as suggested in the consultation by Arcadis (comment #95) have been also considered. RAC calculations have been made following the methodology explained in Section 1.6.4.6 of the Background Document to the Opinion on the Annex XV restriction dossier on lead in outdoor shooting and fishing. The IQ point decrease calculated by the Dossier Submitter corresponds to the values presented in Table 1-54 of the Background Document.

RAC has performed these calculations using the arithmetic mean of game meat lead concentrations to demonstrate the impact of changing different parameters on IQ loss. The results can be compared to the calculations provided by Arcadis (comment #95) using lower consumption figures, which, in the opinion of RAC are not considered to represent reasonable worst-case assumptions for hunter families and are not therefore considered appropriate for risk assessment (see Table 2). It should be noted that for the human health impact, the Dossier Submitter used the full distribution of lead concentration in game meat and IQ losses above 1 were quantified as 1 in the impact assessment. Similarly, IQ losses below 1 were not considered in the human health impact assessment.

Table 3. Sensitivity analysis for infants and toddlers using modified mean game meat lead concentrations and consumption rates. Modified parameters are shown in red.

Age group	Lead source	Assessment	Game meat consumption (g/kg/day)	Lead concentration (arithmetic mean)(ug/g)	Daily intake of Pb (ug/kg/d)	IQ point loss
Infant	Gunshot	Dossier Submitter	0.43	0.366	0.155	0.16
		RAC Sensitivity analysis using lower consumption estimate ¹	0.14 ¹	0.366	0.05	0.05
		RAC Sensitivity analysis using Pain et al 2022 mean Pb concentration. ³	0.43	2.474 ³	1.06	1.06
		RAC Sensitivity analysis using Pain et al Pb conc.+ lower consumption ¹⁺³	0.14	2.474 ³	0.35	0.35
	Bullet	Dossier Submitter	1.00	2.516	2.508	2.51
		RAC Sensitivity analysis using lower consumption estimate ¹	0.89 ¹	2.516	2.24	2.24
		Arcadis Inc analysis using modified mean Pb conc. ⁴	1.00	1.477 ⁴	1.48	1.48

Age group	Lead source	Assessment	Game meat consumption (g/kg/day)	Lead concentration (arithmetic mean)(ug/g)	Daily intake of Pb (ug/kg/d)	IQ point loss
		RAC Sensitivity analysis using lower consumption and Arcadis mean Pb concentration ¹⁺⁴	0.89 ¹	1.477 ⁴	1.38	1.38
Toddler	Gunshot	Dossier Submitter	1.01	0.366	0.371	0.37
		RAC Sensitivity analysis using lower consumption estimate ²	0.46 ²	0.366	0.17	0.17
		RAC Sensitivity analysis using Pain et al 2022 mean Pb concentration. ³	1.01	2.474 ³	2.48	2.48
		RAC Sensitivity analysis using Pain et al Pb conc.+ lower consumption ²⁺³	0.46 ²	2.474 ³	1.14	1.14
	Bullet	Dossier Submitter	1.46	2.516	3.663	3.66
		RAC Sensitivity analysis using lower consumption estimate ²	0.68 ²	2.516	1.72	1.72
		Arcadis Inc analysis using modified mean Pb conc. ⁴	1.46	1.477 ⁴	2.16	2.16
		RAC Sensitivity analysis using lower consumption and Arcadis	0.68 ²	1.477 ⁴	1.01	1.01

Age group	Lead source	Assessment	Game meat consumption (g/kg/day)	Lead concentration (arithmetic mean)(ug/g)	Daily intake of Pb (ug/kg/d)	IQ point loss
		mean Pb concentration ²⁺⁴				

¹Using minimum P50 levels from EFSA consumption data for game meat consumption in infants. Corresponds to 75 game meals of 25 g during the first year of life.

²Assumes 100 game meat meals of 50 g as an estimate of game meat consumption, which will result in average consumption of 13.7 g/day with 40% being small game and 60% large game.

³Mean game meat Pb concentration from Pain et al. 2022 during 1999-2021 (comment#88)

⁴Excludes three extremely high game meat Pb concentration values from EFSA data as suggested by Arcadis (comment #95)

RAC's conclusions based on this sensitivity analysis:

- The Dossier Submitter's estimate of lead exposure for both infants and toddlers resulting from consumption of small game (game hunted with gunshot) may result in an underestimation of health risk.
- In case of game meat hunted with bullets, consumption figures used by the Dossier Submitter may result in an overestimation of exposure in toddlers. In other cases (infants and consumption of small game meat by toddlers), the lower consumption figures used by RAC for the sensitivity analysis had only minor effect in the lead exposure and health risk.
- Since the Dossier Submitter used the total lead distribution in the impact assessment, the inclusion/exclusion of three high lead concentration values in the large game dataset has no effect on the human health impact assessment. The underestimation of lead concentrations in small game may result in the underestimation of human health impacts. However, the magnitude of this underestimation cannot be estimated based on the current data.

Adults

Regarding adults, RAC has used the game meat lead concentration values from Pain et al. 2022 and a game meat consumption of 20 kg/year comprising of 100 meals of 200 g/meal as a sensitivity analysis. This results in an average game meat consumption of 0.78 g/kg/day divided evenly between game hunted with gunshot and with bullets. Table 4 shows the results of this sensitivity analysis. Calculations have been made as explained in Section 1.6.4.6 of the Background Document to the Opinion on the Annex XV restriction dossier on lead in outdoor shooting and fishing. The CKD (Chronic Kidney Disease) risk increase calculated by the Dossier Submitter has been reproduced from Table 1-54 of the Background Document.

Table 4: Sensitivity analysis for adults using modified mean game meat lead concentrations and consumption rates. Modified parameters are shown in red.

Age group	Lead source	Assessment	Game meat consumption (g/kg/d)	Lead conc. (arith. mean) (ug/g)	Daily intake of Pb (ug/kg/d)	Increase in B-Pb levels (ug/l)	Predicted excess CKD risk
Adult	Gunshot	Dossier Submitter	0.65	0.366	0.238	0.571	0.38
		Sensitivity analysis by RAC using lower consumption estimate ¹	0.39 ¹	0.366	0.14	0.336	0.22
		RAC Sensitivity analysis using Pain et al 2022 mean Pb concentration ²	0.65	2.474 ²	1.61	3.860	2.57
		RAC Sensitivity analysis using Pain et al Pb conc.+ lower consumption ¹⁺²	0.39 ¹	2.474 ²	0.96	2.29	1.54
Adult	Bullets	Dossier Submitter	0.58	2.516	1.469	3.525	2.35
		RAC Sensitivity analysis using lower consumption estimate ¹	0.39 ¹	2.516	0.98	2.35	1.57
		Arcadis Inc analysis using modified mean Pb conc. ³	0.58	1.477 ³	0.86	2.06	1.37

Age group	Lead source	Assessment	Game meat consumption (g/kg/d)	Lead conc. (arith. mean) (ug/g)	Daily intake of Pb (ug/kg/d)	Increase in B-Pb levels (ug/l)	Predicted excess CKD risk
		RAC Sensitivity analysis using lower consumption and Arcadis mean Pb concentration ¹⁺³	0.391 ¹	1.4773 ³	0.58	1.38	0.93

¹Assumes 100 game meat meals of 200 g as an estimate of game meat consumption, which will result in average consumption of 0.78 g/kg/day with 50% being small game and 50% large game.

²Mean game meat Pb concentration from Pain et al. 2022 during 1999-2021 (comment#88)

³Excludes three extremely high game meat Pb concentration values from EFSA data (comment#95)

RAC's conclusions based on the sensitivity analysis:

- Although consumption figures used by the Dossier Submitter can be considered conservative, the underestimation of the lead concentration in the small game dataset used by the Dossier Submitter means that, overall, the total lead exposure of adults, including from both small and large game meat, is not likely to be overestimated.
- Increases in B-Pb levels are likely to remain < 10 µg/l even when using higher estimates for small game meat lead concentrations. This is in line with the available biomonitoring studies that have not shown clear increases in B-Pb levels in adults related to game meat consumption.
- RAC reiterates its conclusion that risks for adults are likely to be low.
- Although the use of higher estimates for lead concentrations in small game meat may result in somewhat higher CKD risks in adults, RAC notes that the human health impact assessment for adults includes in any case large uncertainties also 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.

4. Additional References

Kollander et al. (2017). Anal Bioanal Chem 409, 1877–1885.

Leontowich et al (2022), PLoS ONE 17(8): e0271987.

Pain et al. (2022). *Ambio* 2022, 51:1772–1785.

Schulz, K (2021) *Journal Of Nutritional Science* 10: e24, 1-9.