

Agreed Findings and Recommendations of the Lead Ammunition Group

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Executive summary

This report has been authored by John Batley, Stephen Crouch, Mark Tufnell and Barney White-Spunner, ex-members of the Lead Ammunition Group, with support from Richard Ali, British Association for Shooting and Conservation. It has been produced separately from any produced by the Chairman of the LAG because of our significant concerns over the LAG process.

This report reviews evidence provided to the LAG and makes recommendations to address existing and new potential risks identified.

The risk assessments undertaken as part of the process are summarised as follows:

1. The wildlife risk assessment indicates no wildlife population impacts of spent lead ammunition in England.
2. The human health (game meat) risk assessment provides no new evidence to supplant the FSA (2012) advice to consumers of game meat.
3. The human health (livestock products) risk assessment indicates no additional management issues.

This report identifies mitigation options appropriate to the identified risks as follows:

1. Wildlife risk assessment:
 - a. Communicate existing best practice on the disposal of lead-shot carcasses to reduce the availability of spent lead ammunition.
 - b. Improve compliance with the lead shot legislation to further reduce potential exposure.
2. Human health (game meat)
 - a. With the support of the FSA provide advice to shoots and game-processing establishments on game handling and processing to minimize lead entering the human food chain through game meat.
 - b. Advice to consumers on domestic game meat preparation/culinary practice to reduce lead exposure through their game meat meals.
 - c. Advice to consumers at heightened risk of health impacts on frequency of game meat consumption to reduce potential lead exposure from this source.
3. Human health (livestock products)
 - a. Given the demonstrable low level of risk identified by the risk assessment from consumption of livestock products potentially affected by spent lead gunshot, existing regulations and guidelines are sufficient. We have no further recommendations.

1. Background

In response to specific calls by a group of stakeholders over possible impacts of spent lead ammunition, the Department for Environment, Food and Rural Affairs (Defra), and Food Standards Agency (FSA), in March 2010, set up a Lead Ammunition Group (LAG) to address the issues and advise accordingly.

1.1. LAG terms of reference

The purpose of the Lead Ammunition Group (the Group) is to bring together relevant stakeholders and experts to advise Defra and the FSA on:

- (a) the key risks to wildlife from lead ammunition, the respective levels of those risks and to explore possible solutions to any significant risks;*
- (b) possible options for managing the risk to human health from the increased exposure to lead as a result of using lead ammunition.*

The scope will be limited to England (though relevant research and evidence may be drawn from anywhere) and focused on safety aspects for human food, impacts on wildlife and issues surrounding possible alternatives to lead. The Group will be established for an initial 12-month period, after which progress will be reviewed by Defra & FSA.*

Aims

- To advise Defra/FSA on what the significant risks to wildlife from the use of lead ammunition are and what levels of risk these pose in the short, medium and long term. Also any perceived risks which the evidence indicates are not significant.*
- To advise Defra/FSA on possible options for managing the risk to human health from increased exposure to lead resulting from the use of lead ammunition notably in terms of food safety (including game shot with lead ammunition and spent lead shot deposited on agricultural land).*
- To advise Defra/FSA of any significant knowledge gaps that may hinder the identification or assessment of risks, the development of technical solutions or the development of government policy.*
- To advise Defra/FSA on any communication issues, and possible solutions, concerning the relaying of balanced information on issues surrounding the use of lead ammunition to the media, general public and stakeholders.*
- To advise DEFRA/FSA of any significant impacts of possible advice or solutions on shooting activity and associated recreational, wildlife management, economic and employment impacts.*

The LAG comprises individuals with knowledge and/or expertise relating to the conservation, animal welfare, environment, human food safety, gun and ammunition makers/traders, and shooting and deer management sectors.

We, the authors of this report, supported this initiative as it promised to produce a thorough, balanced and evidence-based assessment of any significant risks to wildlife and human health from spent lead ammunition in this country, together with potential management options for those that, by consensus, needed to be addressed.

1.2. The LAG process

The LAG, in turn, set up the Primary Evidence and Risk Assessment Subgroup (PERASG), with the following terms of reference:

- (a) *To gather and list sources of evidence for assessing the risks of lead in ammunition under the categories outlined below*
- (b) *To advise on the quality, applicability and therefore inclusion of such evidence for risk assessment*
- (c) *To propose a risk assessment method*
- (d) *To use the proposed evidence sources to prepare an initial risk assessment under the categories outlined below:*
 - (1) *Risks to wildlife from ingested lead from ammunition. This will include welfare considerations, individual and population level risks.*
 - (2) *Risks to human health from the ingestion of lead from ammunition. This will include both risks associated with the ingestion of lead gunshot/bullets or fragments thereof in game animals, and the ingestion of animals that have themselves ingested and assimilated lead from ammunition. (It may also include any other perceived risks arising from lead ammunition).*
 - (3) *Risks to human health through livestock feeding in areas of lead shot deposition. This will include risks from lead deposited through inland shooting, including clay-pigeon and other target shooting.*

The respective terms of reference for both the LAG and its PERA Sub-group indicated that the LAG process sought assessment of risks from exposure to spent lead ammunition for:

- a) wildlife in England
- b) human health from game meat consumption
- c) human health from livestock products

Advice to Defra/FSA was then to address:

- a) significant risks to wildlife and possible solutions
- b) managing risks to human health
- c) communicating balanced information on issues and possible solutions
- d) assessing possible impacts of advice or solutions on shooting and related activities.

In November 2013, four risk assessments were presented by PERASG to the LAG: two relating to wildlife (resulting from failure of consensus within the Sub-group), one for human health impacts of game meat consumption, and one for human health via consumption of livestock products.

Only the last reflected endorsement of all PERASG members.

A process of developing possible mitigation options for identified risks, via a separate sub-group, then began within the LAG. This was to inform the LAG report to Defra/FSA. Regrettably, this process rapidly became problematic.

These and other issues led us to express dissatisfaction with aspects of the LAG process, that could result in conclusions and mitigation recommendations which are not necessary, not appropriate or not proportionate in relation to real risks.

1.3. LAG report to Defra/FSA

We do not support the report which the Chairman shared with the Group in light of the issues and concerns outlined below. It is unsatisfactory as it does not reflect the concerns and inputs of all LAG members. Furthermore, this report, is unbalanced over the reality, scale and impact of significant risks to wildlife and human health from spent lead ammunition in this country. By including unnecessary, inappropriate and disproportionate risk management

options/recommendations, without an adequate evidence base, it is weighted in favour of stakeholders seeking to achieve substantive reductions in the use of lead ammunition.

This report fails to address some of the requirements made of the LAG under its terms of reference and consensus-based advice has not been given. These include “communication issues, and possible solutions, concerning the relaying of balanced information on issues surrounding the use of lead ammunition to the media, general public and stakeholders, and significant impacts of possible advice or solutions on shooting activity and associated recreational, wildlife management, economic and employment impacts.”

Finally, there have been significant procedural failings in the preparation of this report. These include:

- Advanced circulation of the report to an unknown number of individuals at least four months before circulation to the wider Lead Ammunition Group
- A failure to include three members of the Primary Evidence and Risk Assessment Subgroup in the circulation of the draft report
- Refusal to change the date of what turned out to be the last meeting, so 3 key members could not attend
- Failure to circulate the minutes or the final draft to the one of us who stayed as a member of the group until after the last meeting

Taken together these failings mean that this report cannot be taken to represent a LAG consensus report.

2. Risk assessments

This section summarises the main findings and/or conclusions as reported in each of the prepared risk assessments.

2.1. Wildlife

The wildlife risk assessment, requested by and prepared for the PERASG, concluded that there is no evidence of significant lead ammunition wildlife impacts at the population level in England. Evidence does indicate adverse effects at the individual level, including welfare impacts and death, from lead ingestion. There is potential for lead exposure of wildlife types inhabiting high-density spent-shot sites, but such losses may not impact populations overall due to localisation or compensatory mortality mechanisms.

The LAG sought one wildlife risk assessment from PERASG and this was produced by two members on behalf of the Sub-group, both of whom have expertise in the area. It followed agreed scientific protocols and procedure, particularly with respect to the selection and use of published evidence. However, it was rejected by two other members of PERASG. They produced their own risk assessment, which did not follow the procedure recommended at the onset of the process. By drawing extensively on literature from outside the UK it presented a number of risk scenarios unsupported by the UK evidence base.

Both risk assessments were presented to the LAG, which then requested a consensus document summarising common ground between the two assessments. With difficulty such a document was produced but it appears to have had no further utility within the LAG process.

The areas of agreement were:

1. Lack of studies in the UK of any/all possible spent lead ammunition/receptor pathways in wildlife does not necessarily mean they do not exist

2. Deaths and impaired reproduction of individual animals, caused by direct and indirect ammunition lead poisoning, will affect death rates and birth rates and therefore population processes. Therefore there is potential for effects on population size, although detailed studies have not been undertaken in the UK. As lead poisoning mortality may be compensated by other factors affecting survival, population size may not actually be affected.

We believe, and are concerned, that a separate risk assessment appears to have been accepted by the chairman, but not by the LAG itself.

2.2. Human health (Game meat)

It should be noted that this is not a consensus risk assessment from the PERASG.

The risk assessment concludes that for the general population eating wild game infrequently, risks are low. It concluded that there are “non-trivial” risks to some high-level (UK) consumers of wild game, the number of those consumers at non-trivial risk being estimated as tens to hundreds of thousands. The report further reported adverse effects for high-level consumers include reduced intelligence/cognitive function of children, spontaneous abortion in pregnant women, and cardiovascular effects and chronic kidney disease in adults. It considers that risks from venison are lower than from gamebirds but are more variable according to the cuts of meat eaten. Finally, for a consumer to be considered “high-level” they would need to replace their entire average daily consumption of red (86g) and white meat (43g) with game meat (91g-149g).

Significant concerns were raised by members of the LAG itself, including that the risk assessment had been carried out by two PERASG members who had little expertise in human health and lead toxicology.

The assessment was not produced through a standard, transparently-robust evidence-based process. Reference was made within it to “Green Leaves III Guidelines for Environmental Risk Assessment and Management” (Cranfield University/Defra, 2011). The guidelines, however, do not apply to human toxicological risk assessment.

Concerns about the processes used in preparing this risk assessment led us to feel compelled to commission an independent review by the Support Unit for Research Evidence (SURE) at Cardiff University (November 2014).

This independent review concluded that, based on the methodological detail provided within the document, the use of literature for the risk assessment would not meet any of the criteria for a systematic review other than the provision of a clearly-focussed and answerable overall question, and sub-questions. The critical evaluation focused solely on this aspect and so did not seek any evidence that the findings of the risk assessment were biased or inaccurate.

The independent review further concluded that “a reader may have less confidence in the risk assessment since no evidence was provided that:

- a) All relevant research studies were identified and included.
- b) The included studies were appraised to identify any flaws in how the data were obtained.
- c) Reliable data from the included studies were appropriately summarised to provide an accurate answer to the question(s).
- d) Any potential conflicts of interest relating to the authors of the review and its component studies were identified.

The risk assessment itself was not subjected to comprehensive uncertainty analysis, a key requirement particularly for quantitative risk assessments, to enable readers to judge the confidence applicable to each of its conclusions.

More importantly, and particularly in light of its specialist complexity and overall contentiousness, the risk assessment has not been subjected to external independent specialist review.

The lack of human health and lead toxicology expertise within the PERASG prevented the endorsement of the risk assessment by all its members.

Most recently, its conclusions dependent on human low-level exposure to lead in game meat, and potential impacts on human health, have been thrown into further doubt by newly-available information.

Since the risk assessment was submitted to the LAG (2013), the Australian Government National Health Medical Research Council, in 2014, published findings from its study into the effects of low-level lead exposure on human health. They raise questions about both the methodology used in identifying and using appropriate published evidence for the LAG human health risk assessment (hence the SURE assessment reported above), and the risk assessment workings and conclusions relating to low-level human exposure to ammunition lead and its neurodevelopment, cardiovascular, nephrotoxic, and spontaneous abortion impacts from game meat consumption.

The NHMRC report was prepared by an expert working committee and based on independent systematic review of recent evidence (2004-13). It focused on health effects of low blood lead levels (under 5ug/dl and under 10ug/dl) in children and adults, from all sources, which included game meat consumption.

It was based largely on 112 studies most of which were included in two major US reviews – US Department of Health and Human Services’ National Toxicological Program (2012) and US Environmental Protection Agency (2013). Both reviews were judged comprehensive and well-conducted, but of moderate quality, as they included studies not of high quality (well designed, well conducted, well reported).

It is noted with some concern that there was virtually no overlap between the literature reviewed for and deemed suitable for use in this NHMRC study and that used for the LAG human health risk assessment.

The NHMRC Lead Working Committee found little high-quality evidence to judge possible health effects of low-level lead exposure, and reported¹:

¹ NHMRC (2015) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. www.nhmrc.gov.au/guidelines/publications/eh5

“Based on the current available evidence, it is not possible to conclude that lead was the direct cause of any of the reported health effects in individuals with blood lead levels less than 10 micrograms per decilitre. While the results from some studies indicate that blood lead levels less than 10 micrograms per decilitre may be associated with some health effects, the available cross-sectional studies do not provide the type of convincing evidence that would enable public health experts and statisticians to make confident conclusions about cause and effect.”

In particular, while children with less than 5ug/dl and less than 10ug/dl blood lead showed reduced academic achievement and IQ, and more behavioural problems, it was not possible to tell whether the low-level lead exposure or other factors, such as lifestyle, environment, behaviour measurement etc, were the cause.

Adults with up to 10ug/dl blood lead showed higher blood pressure but it was not clear whether that has any important effect on individuals' health.

Overall, the Committee concluded that:

- a) It is unclear whether blood lead levels under 10ug/dl have meaningful health effects for individuals, because available studies (cross-sectional) do not provide reliable evidence needed to draw confident conclusions.
- b) Evidence from studies in other countries may not directly apply to a specific country's people.
- c) Findings from population data cannot be applied directly to individuals (e.g. individual blood lead higher than the national average does not mean reduced IQ).
- d) A small difference in a group's average for a specific health measure may not be health effects a doctor could diagnose for a person exposed to lead.

Based on the poor quality of evidence on the effects of lead at blood lead levels below 5µg/dl the NHMRC recommends that “*If a person has a blood lead level greater than 5 micrograms per decilitre, it is recommended that the source of exposure should be investigated and reduced, particularly if the person is a child or pregnant woman*”. The recommendation by the NHMRC is the same as that now used by the CDC.

The worst case scenario from Green & Pain was an estimated blood lead level of 6.0-9.6µg/dl in individuals consuming 161g of game meat every day (1.121kg game meat per week). This requires a complete substitution of all meat in the diet (including red meat, white meat, and processed meat). Other methodological considerations, such as the lack of consideration of game meat handling, mean these estimates are likely to be an absolute upper limit at best, and it is therefore very unlikely that typical game consumers are likely to approach the 5µg/dl threshold.

However, it is noted with concern that the NHMRC conclusions with respect to low-level lead exposure do not appear to be consistent with the use of blood lead levels below 10ug/dl (actually sub-5ug/dl) to predict specific health impacts, as used in the LAG human health risk assessment, based on the EFSA (2010) study.

Assessing the impact of low blood lead levels is clearly linked to baseline lead exposure across the population as a whole. The 1995 health survey of England (the most recently available) measured median blood lead levels of 2.7-3.5µg/dl for adults (P95 from 6.8-10.2 µg/dl) and 1.7-2.3µg/dl (P95 from 3.3-5.6µg/dl) for 11-15 year olds. With, for example, the P95 for adult males exceeding 10µg/dl, it is difficult to draw robust conclusions about effects of low level lead exposure whilst effectively accounting for the many confounding factors that can also affect blood pressure and kidney function. Furthermore, except for effects on chronic kidney disease, the median blood levels were in excess of the Benchmark Dose Levels

(BMDLs) established by EFSA (1.2ug/dl for developmental neurotoxicity; 3.6ug/dl for systolic blood pressure; 1.5ug/dl for chronic kidney disease).

The reliability and use of the EFSA (2010) values for low-level blood lead and specific health impacts in this LAG risk assessment needs to be reviewed in light of the Australian NHMRC 2014 study findings.

Until the issues raised particularly by the SURE appraisal and the NHMRC findings can be addressed by appropriate expertise and agreed, and any ramifications for the outputs of the risk assessment understood, the reliability of the current human health risk assessment conclusions has to remain in some doubt, due to the high level of uncertainties affecting their production.

Our key concern over the LAG human health risk assessment is that it was prepared by individuals with little human health or lead toxicology expertise, themselves publicly antagonistic to lead ammunition. They made uncertain and non-transparent use of only some of the relevant literature. They based much of their workings on data from an EFSA study which appear not consistent with the more recent findings from a major Australian study. From this they concluded adverse impacts of spent lead ammunition on human health, which appear to require significant mitigation measures to control. However, the whole assessment is subject to many uncertainties which have not been evaluated.

In view of the risk assessment's many uncertainties and likely biases, an independent review is essential in order to validate the claimed health impacts and recommended management responses.

2.3. Human health (Livestock)

The human health risk assessment via consumption of livestock products proved straightforward and uncontentious, with all Sub-group members endorsing its conclusions. This risk assessment concluded that the potential pathways of lead into the human food chain of products derived from livestock exposed to spent lead ammunition created only a very low level of risk.

3. Risk registers

Once risk assessments had been submitted to the LAG, consideration of management options and action planning in response to identified risks to both wildlife and human health in this country, as required by the LAG terms of reference, began. A Mitigation Sub-group (MSG) was set up. The MSG sought to develop risk registers, modelled on a Defra template, to focus on key risks and possible management options and action planning appropriate to each one, to help inform the LAG advice to Defra/FSA on risks from spent lead ammunition.

This process proved unsatisfactory for a number of reasons. Despite being required by the LAG, no standardised, agreed format for risk scoring was produced to develop the risk registers. A single worst-case register, which included previously unseen and unverified information and estimates of risk and risk impacts in both wildlife and humans, was produced by two PERASG/MSG members. This was used, without wider endorsement, for completion of the whole task.

Two other risk registers submitted to the MSG were disregarded and the wildlife risk assessment consensus document was not used as the basis for the wildlife risk register/mitigation options. Consequently, many of the listed management/mitigation options proved inappropriate and/or disproportionate.

Ultimately, there has been no agreement by the MSG on a risk register, nor has one been submitted to the LAG for discussion and agreement. This key stage of the LAG remit has not been satisfactorily achieved.

4. Advice to Defra/FSA on risks and management measures

It was hoped that the process put in place through the Lead Ammunition Group would prove effective, with consensus among its members, and sub-groups, over each of the issues put before it, and their associated work programmes and outputs. That being so, the final stage of providing Defra/FSA with well-founded and appropriate advice on key risks identified with management options for addressing them, should have been relatively straightforward and supported by stakeholders.

As time has passed, and particularly over recent months, it has become increasingly clear that the process has been less than satisfactory and the likely outputs unacceptable.

We believe it is crucially important, for the credibility of the Defra/FSA initiative and the effectiveness of any future management measures, that the risks are significant and founded on sound evidence, and the measures themselves appropriate and proportionate. With respect to human health concerns any such measures should also be consistent with other official food-consumption advice where human health risks are known or suspected.

Discussions on measures which meet these requirements must also be informed by clear assessment of possible wider impacts - economically, socially and environmentally. The communication of balanced information on the issues involved and possible solutions is also crucial to help gain understanding and acceptance of necessary management measures by affected stakeholders. These requirements of the LAG clearly have not been fulfilled.

Another important issue, addressed in the LAG terms of reference, is the information lacking in each of the risk assessments, both identified and evident. This hinders full assessment of exposure risks and impacts for wildlife and human health in this country. Lack of evidence does not necessarily mean there is a problem. It should not be presumed that there are significant wildlife or human health impacts from spent lead ammunition in the absence of research evidence supporting their reality. This is especially so given that informed concerns over wildlife population or specific human health impacts are not being expressed.

New research to fill at least the most important information gaps might well be the appropriate response to help remove some of the considerable uncertainty prevailing as a result of the current risk assessments. If a precautionary management response is considered appropriate in the absence of sound evidence or new research, then any such response should still meet the requirements of better regulation, as endorsed by Her Majesty's Government.

5. Appropriate management measures

Based on the findings of the risk assessments to date, but also taking into account the many uncertainties both identified and yet to be addressed, we propose a number of management responses. These are considered to be appropriate, proportionate, accountable, consistent, transparent and targeted.

5.1. Wildlife

Few “significant” risks from spent lead ammunition have been identified for wildlife in England.

From what is known, some groups of avian predators and scavengers appear to be the most exposed wildlife groups (aside from waterfowl). There are some management options that will reduce risks to such birds. However, the identified risks appear to be at an individual, rather than population, level and so any proposed mitigation should be targeted to ensure it is appropriate to the need.

With respect to the evident risks to waterfowl, these should be addressed by improving the effectiveness of existing legislation rather than by introducing further restrictions on lead ammunition. Current failures in law enforcement should not be used to justify further legislation.

In summary:

- a) Communicate existing best practice on the disposal of lead-shot carcasses to reduce the availability of spent lead ammunition.
- b) Improve compliance with the lead shot legislation to further reduce potential exposure.

5.2. Human health via game meat

There is lack of agreement within the LAG over the assessment of risks for human health and, consequently, associated potential management measures. We do not believe new substantive risks serious enough to warrant curtailment of the use of lead ammunition have been adequately identified.

In 2012 the FSA published advice to consumers of game meat following its own risk assessment. That awareness-raising of likely and possible risks, and practical advice on game handling and culinary practice, appear appropriate and proportionate management measures, enabling consumers to make their own informed choices.

They are also consistent with government guidance on frequency and/or quantity of consumption of other foods with their own risk factors for human health, especially for particularly vulnerable members of society.

The FSA continues to give specific advice, often based on EFSA studies, for example, that shark, marlin and swordfish, and to a lesser extent, tuna, all of which can contain potentially health-impacting levels of mercury, should be avoided by pregnant women, and eaten no more often than one portion per week by other adults. Oily fish, such as tuna, herring and game fish, should be limited to less than 240g/week for pregnant or breast-feeding women. Similarly, red and processed meat is advised to be limited to 490g/week for all adults.

Reviewing and increasing the profile of the existing FSA advice on game meat consumption, and not treating it differently from other foods also subject to consumption advice, would contribute substantially to mitigating any potential risk.

A data modelling exercise has shown that removing the 5% of samples with the greatest lead

levels could reduce the average lead level in game meat by 95%. This clearly demonstrates the protective role that appropriate game meat handling techniques could have on mitigating against any remaining risk after consumers have applied the FSA guidelines.

In summary:

- a) Advice to shoots and game-processing establishments on game handling and processing to minimize lead entering the human food chain through game meat.
- b) Advice to consumers on domestic game meat preparation/culinary practice to reduce lead exposure through their game meat meals.
- c) Advice to consumers at heightened risk of health impacts on frequency of game meat consumption to reduce potential lead exposure from this source.

5.3. Human health via livestock

Given the demonstrable low level of risk identified by the risk assessment from consumption of livestock products potentially affected by spent lead gunshot, existing regulations and guidelines are sufficient. We have no further recommendations.

5.4. Knowledge gaps

A significant knowledge gap exists over the application of modeled data to the real world, and therefore we propose the following actions:

- a) Survey blood lead levels within the UK population and sub-populations to ascertain and quantify the extent of any real risks to consumers
- b) Encourage the shooting and conservation community to further participate in the Predatory Bird Monitoring Scheme to ascertain and quantify the extent of any real risk to birds of prey.

6. Conclusions

We have concerns about the LAG process and hence the conclusions and recommendations of LAG's forthcoming report to Defra/FSA.

The wildlife risk assessment indicates no wildlife (non-waterfowl) population impacts of spent lead ammunition in England. Exposure of individual avian predators and scavengers to spent lead ammunition in their prey/food can be reduced by promoting the safe disposal of lead-shot game and other carcasses. Improving the enforcement of the lead shot regulations with respect to waterfowl will further reduce exposure of waterfowl to spent lead gunshot and of avian predators/scavengers to exposure through their food.

We have great concerns about the validity of the human health (game meat consumption) risk assessment and do not believe it provides new evidence to supplant the current FSA (2012) advice to consumers of game meat.

The human health (livestock products) risk assessment indicates no additional management issues.

Mitigation options for the identified risks, complying with the Government's principles of better regulation, have been identified.