

Lead in game meat

Risk management

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ISSN 1104-70

Preface

It is the task of the National Food Agency (NFA) to protect the interests of Swedish consumers by working to ensure safe foods of good quality, fair practices in the food trade and healthy dietary habits.

Several international studies have shown that lead residues from ammunitions can occur in very high concentrations in game meat. According to the European Food Safety Authority (EFSA), almost 30 percent of the samples of game meat analysed exceeded the maximum permitted level of 0.1 mg/kg that applies to lead in meat from cattle, sheep, pigs and poultry that are offered for sale. In Sweden, it is estimated that around 10 percent of the population consume a large amount of game meat (approximately 300,000 hunters and their families). It is therefore important that the NFA investigates to what extent lead occurs in game meat, and whether there is any risk associated with the consumption of game meat.

In the autumn of 2011 a pilot study was conducted that led to NFA producing advice in respect of the consumption of meat deriving from game shot with bullets containing a lead core (Bly i viltkött – en riskhanteringsrapport [Lead in game meat - a risk management report], National Food Agency 2012). In 2012, NFA's Riksmaten [National Diet] investigation showed that consumers of game meat had higher contents of lead in their blood than other consumers (Riksmaten – vuxna [National Diet - adults] 2010-11) and a decision was made to continue studies concerning lead in game meat. The sub-reports that are hereby published answer the following questions:

- In which cuts of game meat do lead residues from ammunition occur, and how high are the concentrations?
- Can the lead residues be removed through adapted handling/cleaning?
- How much of the lead residues is available to the body through the consumption of shot game?
- How great a risk is entailed by the consumption of game meat, with respect to the effect that lead can have on the health of the consumer?
- What measure or measures are required to reduce the risk of the occurrence of lead in game meat?

These studies provide greater knowledge into the risks that can exist from the consumption of game shot with ammunition containing lead, and provide data and result for generating recommendations on how meat can be handled to minimise any possible risks.

The studies have been conducted on a collaborative basis by the National Food Agency, the Swedish Association for Hunting and Wildlife Management (SJF) and the National Veterinary Institute (SVA).

Report no. 18 *Lead in game meat* consists of four parts. *Part 1, Ammunition residues and chemical analysis*, investigates how the occurrence of lead residues from ammunition and lead contents vary between various cuts of game meat, depending on the choice of ammunition and the placement of the shot itself. This report also studies how lead residues dissolve in gastric environments. *Part 2, Lead contents in the blood of hunter families*, investigates whether the content of lead in the blood affects consumers of game meat. Parts

1 and 2 provide data for the risk assessment of consumption of game meat shot with lead ammunition that is presented in *Part 3, Risk assessment*. The latter describes the risks entailed by residues of lead ammunition in game meat. Based on this assessment, a health-based critical level for lead fragments in game meat has then been established.

The information contained in these three scientific sub-reports and in other academic literature has then been evaluated in order to assess what measures could and should be used to reduce the risks associated with the occurrence of lead in game meat. Other relevant factors have also been considered within these assessments, such as whether it is possible for consumers to follow specific advice regarding the consumption of game meat that has been shot with lead ammunition; how advice such as this would be perceived; how it could be applied by the target groups; which supervisory authorities exist for this purpose; and whether the consequences of such a measure are proportionate in relation to the risks and benefits. *Part 4, Risk management*, describes the different considerations and assessments that led to the measures that NFA deems are necessary for the handling of occurrences of lead residues in game meat, and in order to minimise the risks that consumption of such meat can entail. The report aims to clearly describe the reasoning behind the measures that NFA has determined.

National Food Agency, 7 October 2014

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Summary of the risk management

Risk management applies to

Risks relating to lead in meat from game shot with lead ammunition.

Measures for handling game shot with lead ammunition – hunters

1. The wound channel¹ created by the bullet (meat that looks affected or bloodshot) and a further minimum of 10 cm of not visibly affected meat around the wound channel(s) is to be cut away and disposed of in conjunction with the processing and the cleaning of the carcass.
2. For game shot with lead shot the affected meat should be cleaned and visible pieces of shot should be removed. When hunting with lead shot, hunting ammunition, not sports ammunition, should be used.

Measures for handling game shot with lead ammunition - consumers

1. Avoid consuming meat from the wound channel of game shot with lead ammunition, if the meat has not been cleaned as described above.

Commercial game handling measures

1. Game handling facilities (referred to below as GHF) and retail facilities are to establish procedures that ensure that game meat released for sale on the market does not contain elevated levels of lead from ammunition.

Information to be communicated in conjunction with the publishing of the reports

- For consumers who eat game meat on just a few occasions each year, it is considered that the likelihood of consuming a portion of meat that contains an elevated level of lead is small, regardless of the part of the carcass the meat has come from. The exposure to lead that may occur in such a scenario does not imply an increased risk, in respect of an elevated level of lead in the blood.
- Meat that is already in the freezer and *that could be suspected* to contain increased levels of lead need not be disposed of from a risk point of view, but consumption should be limited to a maximum of once a month. ***However, women who are pregnant, or plan to be pregnant, and children under the age of 7 should avoid consuming this meat.***
- Using lead free ammunition eliminates the risk of lead fragments in game meat and related products.

¹Meat visibly affected by bullets, gunshot or fragments, including all bloodshot meat.

Motives for the risk management

Risk assessment

Background

Lead occurs commonly throughout the environment, in the air, in the ground and in water. In Sweden, lead is mined and recycled lead is reprocessed. The spreading of lead in the environment and, consequently, the levels of lead in the blood have decreased steadily in Sweden as a result of the phasing out of lead in petrol. Car batteries and other accumulators are currently the major usage area for lead. Blood lead levels are somewhat lower in Sweden than in the rest of Europe.

Acute and severe lead poisoning (high levels of lead in the blood) cause many different symptoms, such as tiredness, constipation and loss of appetite. Lead also damages the red blood cells and this can lead to anaemia. A more serious case of poisoning can also mean the loss of nerve functions in the extremities (e.g., the arms), which can lead to partial paralysis. Even low levels of exposure to lead are thought to have negative effects on the nervous system. This is especially the case when the brain is developing in the foetus or in small children.

In epidemiological studies of children it has been estimated that blood lead levels of around 12 µg/litre can lead to a lower IQ. This effect is supposed to occur at the lowest levels of exposure.

In its risk assessment, the European Food Safety Authority (EFSA) established three reference points (RP) for exposure to lead (EFSA, 2010).

1. Reference point for developmental effects – blood lead level of 12 µg/litre corresponding to a lead intake via food of 0.5 µg/kg body weight/day. This level of exposure has been associated with a reduction in IQ of one unit at population level (4-10-year-old children). In addition to children, this RP is also considered to be applicable to infants and foetuses.
2. Reference point for chronic kidney disease in adults – blood lead level of 15 µg/litre corresponding to a lead intake via food of 0.63 µg/kg body weight/day.
3. Reference point for effects on systolic blood pressure in adults – blood lead level of 36 µg/litre corresponding to a lead intake via food of 1.5 µg/kg body weight/day.

The margin between the blood lead levels measured in pregnant women and children and the levels where effects that are quantifiable at group level can be detected is relatively small. In its latest risk assessment of lead, EFSA state that in Europe, the exposure of pregnant women (foetuses) and children to lead is at a level close to or above the health-based reference value of 0.5 µg lead/kg body weight/day. It is therefore important that exposure to lead continues to decrease, both in food and in the environment in general. In general, basic foods such as fish, meat, cereal products, root vegetables and dairy products contain low levels of lead. However, the majority of lead exposure comes from cereals, drinks and vegetables, despite the fact that they have low levels, since relatively speaking, we consume a large amount of these food groups. Other foods that may contain

elevated levels of lead are shellfish, liver from game and certain wild mushrooms. In its latest (2010) risk assessment of lead, EFSA has assessed that Europeans who consume a large amount of game meat (considered in this calculation to be consumption of 200 grammes per week) have a higher intake of lead than consumers who do not eat game meat. According to surveys conducted by the National Food Agency in 1999 and 2012, the mean intake of lead from all food groups was 7 µg and 11 µg per person per day, respectively (Becker et al. 2011, Matkorgen 2012). However, these surveys do not take into account the problems with lead fragments from ammunition in game meat. Eleven microgrammes per person per day corresponds to an exposure of 0.2 µg/kilo body weight per day for a person weighing 60 kg, and this can be compared with the health-based reference values of 0.5-1.5 µg/kilo body weight per day that EFSA established in 2010. In the body, lead is deposited in the bone tissue and in the blood. The half-life for lead is 10-30 years in the bone tissue and 20-40 days in the blood.

Pregnant women who do not have a sufficient intake of calcium during the pregnancy mobilise calcium from the bone tissue, which means that lead which is deposited to the bones is also released into the blood, resulting in higher levels of lead in the blood. The same applies for women who are breast-feeding.

Children eat more than adults in relation to their body weight (i.e., high exposure) which means that children are exposed to more lead than adults from food. Small children also probably ingest more lead from sources other than food than adults due to their "hand in mouth" behaviour (e.g., toys, dust).

There are several studies that indicate that consumption of game and blood lead levels are positively correlated. Significant differences have been shown in the level of lead in the blood of people who consume game meat compared with those who do not (Iqbal et al. 2009, Tsuij 2008, Meltzer et al. 2013). Pigs fed with game meat containing lead fragments have also been found to have elevated levels of lead in their blood (Hunt et al. 2009).

Tolerable levels of lead in game meat

The National Food Agency's risk assessment in this project constitutes the basis for the establishment of an adjusted critical level for lead in game meat, which means that game meat with lead levels lower than this adjusted critical level may be consumed without an unacceptable exposure to lead. This approach differs to that employed in the pilot study in lead in minced moose meat, where scenario calculations were used in respect of exposure. Subsequently, in the risk assessment, EFSA's health-based reference points are used, but other relevant parameters are also taken into consideration (part 3):

- EFSA's health-based reference points (RP) 0.5 and 0.63 µg/kg body weight/day for children and adults respectively. These values have been divided by 10, as EFSA considers that at 0.05 and 0.063 µg/kg body weight/day there is a negligible risk of negative health effects in children or adults respectively.
- Ten per cent of the total exposure to lead via food is considered to be acceptable to come from game meat.

- The body weight that have been used in the calculations of lead exposure are 30 kg for children and 70 kg for adults. The consumption level is set at 27 grammes per day (raw meat), which is the estimated median level of game meat consumed by hunter families.
- The dissolution of lead fragments in the stomach has been set at 10 per cent (part 1).

These calculations and adjustments for various conditions mean that the adjusted critical level that can be accepted in game meat is 0.06 mg per kilo game meat for children and 0.16 mg per kilo game meat for adults. The mean value for these adjusted levels is 0.11 mg per kilo. Since the National Food Agency considers that it is difficult, from a consumer point of view, to have different adjusted critical levels for children and adults respectively, the mean value of 0.1 mg of lead per kilo of game meat will be used as the highest lead level that can be tolerated from a risk perspective.

Blood lead levels in Swedish consumers of game meat

In a study conducted during 2013-2014, levels of lead in the blood have been examined in relation to the life style and dietary habits of hunter families. This is in order to investigate whether people who consume a large amount of game meat have elevated levels of lead in their blood as a result of exposure to the lead fragments found in game meat. The families participating in this study consisted of men and women (18-65 years old), where at least one of the parents hunts regularly, and their children, if they were still living at home (3-17 years old). Another criterion for participation was that at least one person in the family ate game meat at least twice a month. The participants were recruited from five Swedish regions (Nyköping, Stockholm, Umeå, Uppsala and Östersund) (National Food Agency 2014, part 2).

- Adults who consume game meat had significantly higher levels (48 per cent; $p < 0.01$) of lead in their blood compared with randomly selected adults who never eat game meat (16.3 $\mu\text{g/litre}$ compared with 11.0 $\mu\text{g/litre}$ among adults recorded as not consuming game meat in the previously conducted dietary habits survey, Riksmaten – adults 2010-11).
- Adults who consume moose meat 1 time/week or 2-7 times/week had significantly higher blood lead levels compared with a group of consumers who never consumed game meat (Riksmaten – (adults) 2010-11): blood lead levels were 53 per cent and 31 per cent higher, respectively (part 2).
- For adults who consume moose meat 1-3 times/month, the blood lead level was 23 per cent higher than the group of consumers in Riksmaten – adults 2010-11 who never eat game meat. This difference was not statistically significant.
- No *significant* trend between bloods lead levels and the amount of game meat consumed could be observed on the *whole* of the material in this hunter study (i.e., all participants and all amounts of consumption). This is probably due to the fact that the blood lead level is largely affected by the number of shots fired and that all of the hunters consumed comparatively large amounts of game meat.
- For adults in the hunter study, the blood lead level was statistically significant increased in relation to the number of shots fired over the course of the last six months ($p < 0.01$).

- Blood analyses of women who stated that they never shoot, but do eat game meat, showed that they had significantly elevated blood lead levels (30 per cent increased; $p < 0.05$) compared with a group of women in the Riksmaten – adults 2010-11 survey who stated that they never eat game meat (part 3).
- The level of lead in the blood of children in hunter families is the same as that of children in other previous Swedish surveys (in the hunter study, part 2, there was no control group for children).
- Blood lead levels in this study are, on the whole, high in relation to EFSA's health-based reference points (RP). Out of the men, 70 % have blood lead levels that exceed the reference points; for children, 40-50 % have levels that exceed the reference points; and for women, the corresponding figure is 30 % (part 3). The corresponding figures from the Riksmaten – (adults) 2010-11 survey for men and women who stated that they never consume game meat were 33 and 15 per cent over the RP respectively.
- Consumption of game meat and blood lead levels have previously been investigated by the National Food Agency. Using data from the Swedish survey of dietary habits, Riksmaten – adults 2010-11, it has been shown that randomly selected adults (18-80 years old) who eat game meat once or more a month have higher levels of lead in their blood than those who do not consume game meat (Bjermo et al. 2013).
- Previous studies in USA and Canada have shown significant differences between blood lead levels measured in people who consume game meat and those who do not (Iqbal et al. 2009, Tsuji et al. 2008). A Norwegian study also showed that consumers who eat game meat, especially minced game meat, at least once a month, have higher blood lead levels (Meltzer et al. 2013, VKM 2013).

Uncertainties in the blood lead study

The regular consumption of game meat normally involves consumers who hunt, and the members of their family. Several studies show that the level of lead in the blood can be affected by factors other than the consumption of game meat. The number of shots fired is an example of this, and this may partly explain why men who *hunt* and eat game meat have much higher levels of lead in their blood than women who eat game meat but who do not hunt.

Loading one's own ammunition could also be related to higher blood lead levels, but this relationship was not statistically significant following adjustment for the number of shots fired. Similar connections have also been reported by Meltzer et al., 2013.

It should be noted that there is a relatively large difference between the blood lead level of women and men in the hunter study: 12.3 and 20.4 $\mu\text{g/litre}$ respectively. For individuals in the Riksmaten – (adults) 2010-11 survey who did not consume game meat, the corresponding figure was 10.1 $\mu\text{g/litre}$ for women and 12.5 $\mu\text{g/litre}$ for men. The difference in levels between men in the respective studies (20.4 in relation to 12.5) is therefore the main reason for the total differences between the groups (hunter study vs. Riksmaten – (adults) 2010-11).

A weakness of the study is that there is no control group that does not eat game meat. The hunter families proved to have a relatively high and even level of game meat consumption. In order to be able to make a comparison with a group of adults with "no reported

game meat consumption”, the results from Riksmaten – (adults) 2010-11 have therefore been used for this statistical comparison.

Summary of blood lead levels in Swedish game meat consumers

When game meat is consumed once or more a month, there is often a greater probability that the blood lead level is significantly increased. Results from recent studies show that the blood lead levels of this group of consumers are around 30-50 per cent higher, and that the differences are statistically significant when compared with consumer groups who eat game meat less than once a month, or not at all.

Levels of lead in meat from game shot with lead ammunition

Levels in minced moose meat

Fifty-four samples of minced moose (*Alces alces*) meat have been collected, forty-eight from the private freezers of hunters in various parts of the country, and six purchased in food stores (part 1). In this study it is not known which parts of the carcass have been used for the minced moose meat, but the results give a good picture of the level of lead in the ready-to-eat minced moose meat. The results showed a wide range, with lead levels from under the detection limit (0.02 mg/kg) up to 31 mg/kg. In 33 per cent of the samples (18/54), the lead level exceeded the tolerable limit (0.1 mg/kg). 54 per cent of the samples (29/54) contained a quantifiable level of lead, i.e., more than 0.02 mg/kg. The major differences in lead levels probably indicate the variation that exists in respect of the origin of the meat that is subsequently used for minced meat. When minced game meat is produced, both meat from the proximity of the wound channel and from further away is used.

Levels in wild boar

These results refer to 17 wild boars shot in the front shoulder and the number of individual cuts of meat analysed from these animals is 69 (part 1).

Bullet wound cavity

In meat directly connected to the wound cavity channel (meat that would normally be trimmed away or meat that is visibly affected or bloodshot) the levels of lead are high; the median is: 146 mg/kg (min: 0.011; max: 1829), (Figure 1; part 1). In 94 per cent of the samples (17/18) the level of lead exceeded the tolerable limit (0.1 mg/kg).

Meat intended for consumption close to the wound channel

The meat that is not visibly affected by the shot, 0-5 cm outside of the wound channel, also has very high levels of lead; the median is: 9 mg/kg (min: 0.007; max: 1466) (Figure 1; part 1). In 89 per cent of the samples (16/18) the level of lead exceeded the tolerable limit (0.1 mg/kg).

The two regions further from the wound channel, 5-10 cm and 10-15 cm away, has median values of 0.11 mg/kg (min: 0.004; max: 18) and 0.04 mg/kg respectively (min: 0.004; max: 29) (Figure 1; part 1). In 50 (9/18) and 27 (4/15) per cent of the samples respectively, the level of lead exceeded the tolerable limit (0.1 mg/kg).

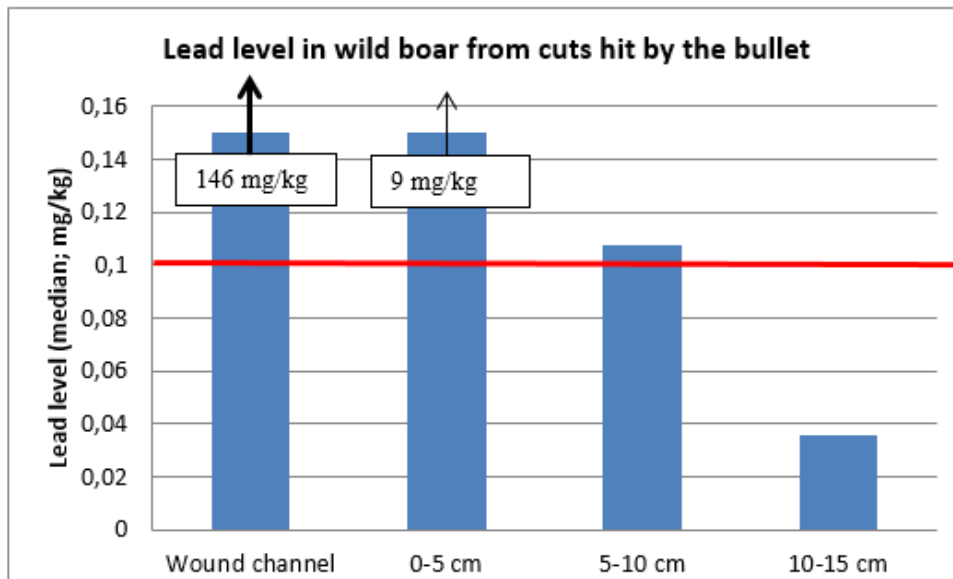


Figure 1.

Median level of lead in wild boar from cuts hit by the bullet. Note that the two columns "wound channel" and "0-5 cm" have median values that extend beyond the boundary of the Y axis, 146 mg/kg and 9 mg/kg respectively. Wound channel = meat where the shot is cleaned from visibly affected meat, traditionally not for consumption; 0-5 cm = meat 0-5 cm outside of the visibly affected meat that is cleaned, will probably be consumed; 5-10 cm = meat 5-10 cm outside of the visibly affected meat that is cleaned, will probably be consumed; 10-15 cm = meat 10-15 cm outside of the visibly affected meat, will probably be consumed. The red line denotes the level of lead that is tolerable: 0.1 mg/kg.

Levels in roe deer and fallow deer calves

These results refer to 8 roe deer and 11 fallow deer calves and the number of individual cuts of meat analysed from these animals is 57 (part 1).

Wound channel

In meat directly connected to the wound channel + "0-5 cm" (meat that would normally be trimmed away according to the SJF's 2012 recommendation) the levels of lead are high; the median is: 121 mg/kg (min: 10.2; max: 439) (Figure 2; part 1). In 100 per cent of the samples (18/18) the level of lead exceeded the tolerable limit (0.1 mg/kg).

Meat for consumption from cuts hit by the bullet

The meat (shoulder meat in this survey) that was not visibly affected by the shot also had increased levels of lead, the median was: 0.08 mg/kg (min: 0; max: 235) (Figure 2; part 1). In 47 per cent of the samples (7/15) the level of lead exceeded the tolerable limit (0.1 mg/kg).

Other meat for consumption from roe deer and fallow deer calves

Meat (loin, tenderloin, saddle, haunch) from the parts of the carcass that were not hit by the shot had considerably lower or non-detectable levels of lead (Figure 2). Meat from the loin had a median level of 0.01 mg/kg. In 25 per cent of the loin samples (4/16) the level of lead exceeded the tolerable limit (0.1 mg/kg). Meat from the tenderloin had a median level of 0.009 mg/kg, and none of the samples (0/4) exceeded the tolerable limit. In the saddle and haunch, the median level was 0.004 mg/kg, and none of the samples exceeded the tolerable limit (0/3 and 0/3 respectively).

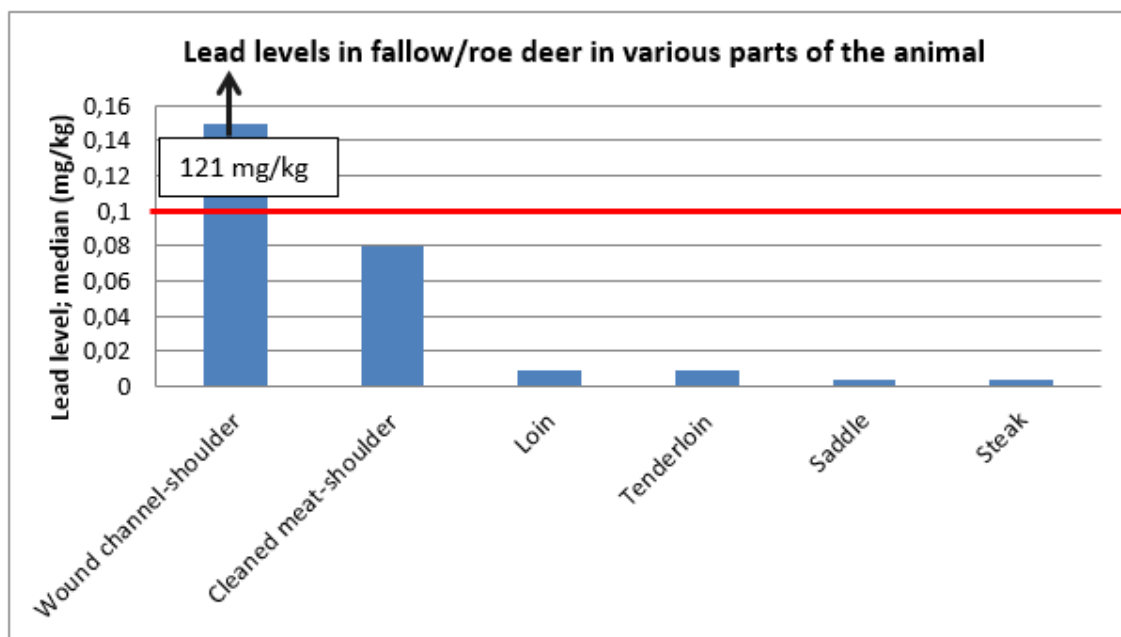


Figure 2.

Median level of lead in fallow deer and roe deer from various cuts of the animal. Note that the column "Wound channel - shoulder" has a median value that extends beyond the boundary of the Y axis, 121 mg/kg. "Wound channel – shoulder"= cleaned meat from the cut where the bullet hit with visibly affected meat, not for consumption; "Cleaned meat – shoulder" = meat that is cleaned outside of the meat visibly affected by the shot, from cuts where the bullet hit, will probably be consumed; "Loin" = meat from a cut not hit by a bullet, meat for consumption; Tenderloin = meat from a cut not hit by a bullet, meat for consumption; "Saddle" = meat from a cut not hit by a bullet, meat for consumption "Steak" = meat from a cut not hit by a bullet, meat for consumption; The red line denotes the level of lead that is tolerable: 0.1 mg/kg.

Levels of lead in meat from game shot with lead shotgun ammunition

Levels in crow breast muscles

A total of 20 crows were shot with shotguns in order to study fragments from the lead shot and lead levels in the meat. Ten crows were shot with hunting cartridges and ten with sport shooting cartridges. Hunters sometimes use sport shooting cartridges when hunting smaller game.

a) Hunting cartridges

Wound channel

In the meat directly connected to the wound channel (the wound channel where single pieces of shot have impacted, and bruised areas) and which is often used for consumption, the levels of lead were somewhat increased, the median was: 0.02 mg/kg (min: 0.006; max: 1835) (part 1). The maximum level (1835 mg/kg) is a sample containing a whole piece of a shot. These are normally removed prior to cooking, or alternatively when being consumed. In 30 per cent of the samples (3/10) the level of lead exceeded the tolerable limit (0.1 mg/kg).

Meat for consumption close to the wound channel

The meat that is not visibly affected by the shot (the area around the wound channel and bruising which is cut away) and which is used for consumption also had somewhat increased levels of lead, the median was: 0.01 mg/kg (min: 0.01; max: 0.9) (part 1). In 10 per cent of the samples (1/10) the level of lead exceeded the tolerable limit (0.1 mg/kg).

b) Sport shooting cartridges

Wound channel

In the meat directly connected to the wound channel (the wound channel where single pieces of shot have impacted, and bruised areas) and which is often used for consumption, the levels of lead for pooled samples were somewhat higher: 39.3 mg/kg (part 1). The level reported here is based on an analysed pooled sample consisting of trimmed meat from all 10 crows shot with sport shooting cartridges.

Consumption of meat close to the wound channel

The meat that is not visibly affected by the shot (the area around the wound channel and bruising which is cut away) and which is used for consumption also had somewhat increased levels of lead, the median was: 0.49 mg/kg (min: 0.04; max: 6.1) (part 1). In 80 per cent of the samples (8/10) the level of lead exceeded the tolerable limit (0.1 mg/kg).

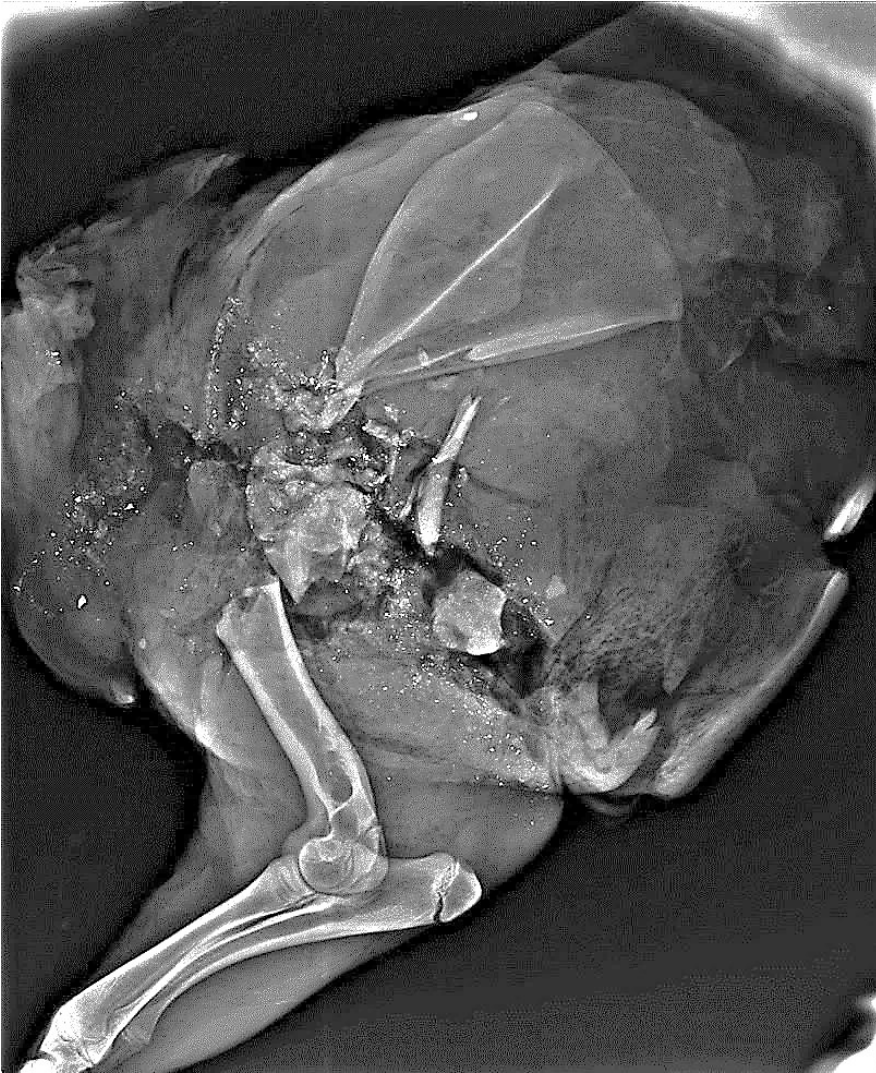
Other game shot with lead shot ammunition

Shot had fragmented (x-ray analysis) when it hit bone, both for a hare and a roe deer shot with lead shot. Both animals had lead levels in meat near the point of impact that were 10-100 times over the tolerable limit: 0.1 mg/kg (part 1). The statistical material for furred game is too small for any conclusions to be drawn, although it demonstrates that increased levels of lead can also occur in areas close to the wound channel of furred game shot with lead shot.

X-ray results of the cuts of meat

The analyses of x-ray images showed that game shot with expanding bullets with a lead core regularly contained hundreds of visible lead fragments of varying size in the meat around the wound channel (Figure 3). X-ray results from the wild boar samples from the region 0-5 cm from the wound channel often contained 5-10 visible fragments, whilst samples from 5-10 and 10-15 cm often lacked fragments visible with x-ray. The results also show that, despite the fact that visible lead fragments cannot be identified in the x-ray analysis, the chemical analysis shows that significantly increased levels of lead can occur in the cuts of meat investigated within the study.

A



B

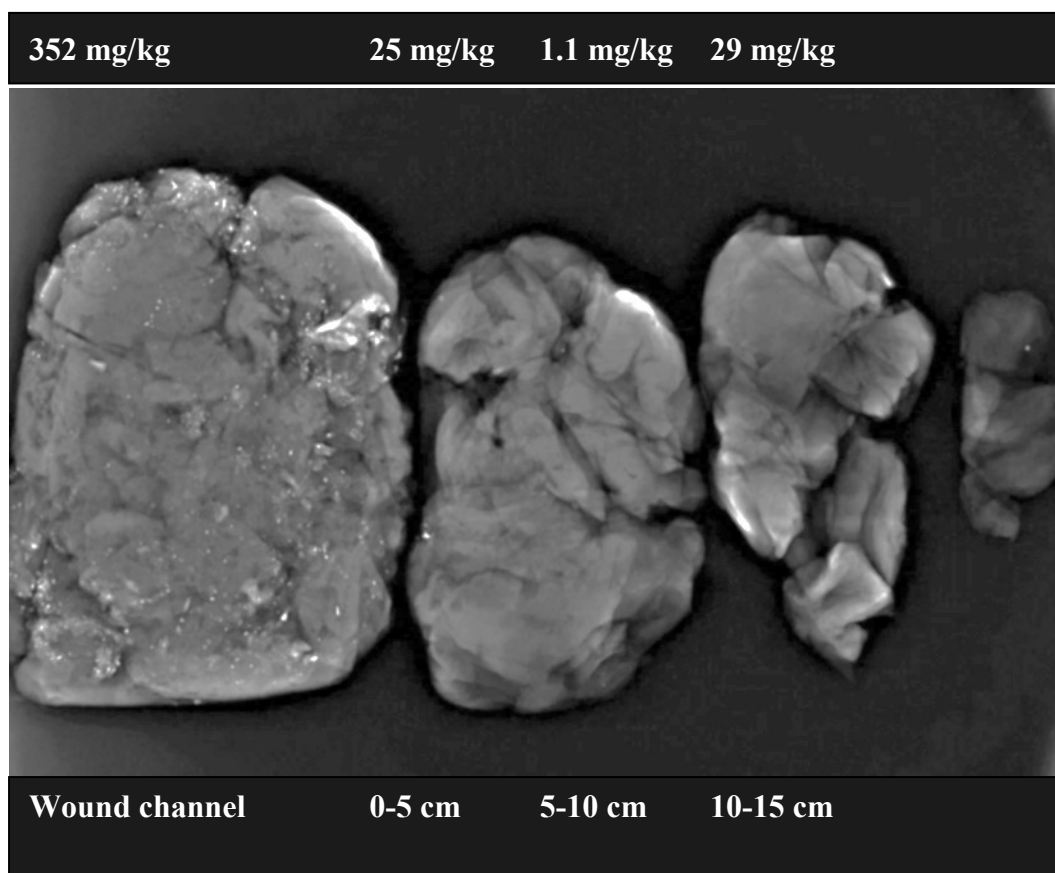


Figure 3. (a) Wild boar shoulder (individual sample V1) where a conventional, unbonded bullet hit the humerus and fragmented extensively. (b) Cleanly cut samples from the same shoulder prior to grinding. The samples from the wound channel contained many small fragments, the sample taken from 0-5 cm contained isolated fragments, the sample from 5-10 cm lacked visible fragments whilst there was one visible fragment in the sample taken from 10-15 cm.

Summary regarding lead levels in game meat

The results from the investigations show that there are significantly higher levels of lead in *game meat intended for human consumption* in the area outside of the wound channel, despite visibly (without x-ray) affected meat having been cleaned (part 1). Shot intended for sport shooting can also result in a higher level of lead in the meat (0.5 mg/kg, median, cleanly cut), despite the fact that the wound channel has been cleaned.

Options for cleaning game meat in order to reduce the lead level

The results show that it is possible to clean the area around the wound channel and in doing so, considerably reduce the risk of lead fragments in game meat. The amount a bullet expands and the amount of lead fragments released from the bullet depends on the bullet's construction, its velocity and the resistance it encounters. For example, if the bullet hits a bone, then the number of fragments will be greater than if it only hits soft tissue. There is therefore great variation in the lead levels measured in various different cuts of meat.

Cutting away a margin of at least 10 cm from visibly affected meat reduces the level of lead by up to 1,000 times. For lead shot, the corresponding figure is 100 times.

Wild boar

The results show that cleaning must be done at least 10 cm outside of the wound channel (meat that looks affected or bloodshot) in order to significantly reduce the amount of lead fragments in the meat. If this cleaning procedure is employed, the level of lead will be reduced to a median level of 0.04 mg/kg. This is approximately half of the level (0.1 mg/kg meat) that the National Food Agency consider as being tolerable from a health perspective (Figure 1 and part 3).

Roe deer and fallow deer calves

The lead levels in the wound channel, cleaned shoulder meat and loins for fallow deer calves and roe deer showed significant differences (part 1). The results show that also the cleaned meat from cuts hit by the bullet (the shoulder in this investigation) have median levels of lead close to (0.08 mg/kg) the tolerable level (0.1 mg/kg) that the National Food Agency considers acceptable (Figure 2). The results show that almost half of these samples had levels in excess of the tolerable limit. These results and the results from the wild boar study above imply that, for ungulates (moose, roe and other deer, wild boar) it is necessary to cut away at least 10 cm outside of the visibly affected area adjacent to the wound channel.

Exposure to lead from game meat

The exposure of hunter families to lead from game meat

The results from the hunter study show that, on average, hunter families consume game meat 2-3 times/week (the median value is estimated at around 27 grammes per day). The cuts of game meat close to the wound channel that are traditionally used for consumption (wild boar, 0-5 cm and 5-10 cm and cleaned shoulder meat from roe deer and fallow deer calves) have levels that exceed the tolerable level for lead, and there is therefore a risk of elevated blood lead levels (Figures 1 and 2; part 3). Game shot with lead shot also have higher levels in the area close to the wound channel, so hunting cartridges, rather than sport shooting cartridges, should be used when hunting game.

The increased levels of lead in these cuts of meat, in combination with the elevated blood lead level in those who consume large amounts of game meat, make it reasonable to conclude that parts of this lead will be accessible for uptake into the gastrointestinal tract of human consumers. This is also backed up by our own and other solubility studies of metallic lead in acid gastric environments (part 1).

Summary of the risks

The results from the investigations show that there is a high probability of high levels of lead in game meat in the area around the wound channel, and in at least a further 10 cm of visibly affected meat, when lead ammunition is used. The studies of blood lead levels of Swedish game meat consumers show that consumption of game meat can result in a 30-50 per cent higher blood lead level. The problem with lead fragments in cuts of meat far away from the affected areas around the wound channel has probably been unknown to the majority of people. This means that social groups who eat a relatively large amount of game meat, for example hunters and their families, are at risk having an elevated level of lead in their blood. According to the calculations in the National Food Agency's risk assessment, the estimated lead intake from these cuts of meat within these groups of consumers can in many cases exceed the health-based reference points that exist for exposure to lead. Consumption of these cuts of meat is a significant source in respect of the *total* lead exposure of the consumer groups addressed within the Agency's risk assessment.

Uncertainties in the risk assessment

Statistical uncertainties of the data used have been taken into consideration with regard to the calculation made within the risk assessment report. Other uncertainties that could probably be considered to underestimate and/or overestimate the results from the risk assessment are, for instance, the amount of the various cuts of meat that is consumed, naturally occurring uncertainties in data from surveys of dietary habits, the preparation of the game samples and the bioaccessibility of lead fragments. Nor has the impact that cooking has to the bioaccessibility of lead fragments been addressed in the estimation of exposure; this could mean that there has been some underestimation, as far as the calculated intake is concerned.

Legislation and control

Legislation

Regulation (EC) No 178/2002 ("the EU's food law")

Regulation (EC) No 178/2002 of the European parliament and of the Council² (contains rules that are directed at authorities, food businesses and, to a certain extent, private consumers. The portal regulation of the food legislation's general requirements is Article 14, which applies to the whole chain, from primary production to consumer. This means that hunters are also responsible for not placing food that is unsafe on the market. Food that can be considered a risk to health is not safe. The obligations that apply to the food businesses operators (FBOs) are stated in Article 17 of 178/2002 and these imply that the FBOs are responsible for ensuring that their food satisfies the requirements of food law. Furthermore, this Article states that Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by FBOs at all stages of production, processing and distribution.

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

Regulation 178/2002 rules that, in special cases where there may be a risk to life or health, but where scientific uncertainty persists, the precautionary principle can be used as a means of establishing risk management measures or other initiatives in order to guarantee the high level of health protection chosen within the EU.

Article 7 The precautionary principle in 178/2002

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

As far as lead is concerned, EFSA has revised its evaluation (The EFSA Journal (2010) 8(4), 1570, www.Efsa.europa.eu) and recommends an ongoing, general reduction in the population's exposure to lead. This means that there is no scientific uncertainty in respect of lead and that the precautionary principle is therefore not applicable.

Regulation (EC) No 1881/2006 – Contaminants in food stuffs

The term "contaminants" refers to each substance that has not intentionally been added to a foodstuff but which is found in it as a result of production (including measures connected with agriculture, cattle farming and veterinary treatment), manufacture, refinement, preparation, treatment, packaging, wrapping, transportation or ownership of this foodstuff, or as a result of contamination of an environmental nature.

The maximum permitted levels for heavy metals in foodstuffs are currently established in the Commission's Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. As a result of EFSA's latest statement, the maximum permitted levels for lead in foodstuffs are under review.

In Annex 3 to the Regulation, the maximum permitted level for lead is stated for 17 different categories of foodstuffs. There is no maximum permitted level for lead in game meat, although category 3.1.3 contains a limit for lead in meat (excluding offal) from bovine animals, sheep, pigs and poultry (6) of 0.10 mg/kg wet weight. Bearing in mind the elevated levels of lead that the National Food Agency has noted in minced moose meat, the consumption within affected social groups and other circumstances, the Agency considers it reasonable that the same risk assessment be applied to game meat as exists for lead in beef. In the Agency's view, game meat that contains levels of lead in excess of 0.10 mg/kg wet weight should therefore be deemed not safe, in accordance with Article 14 of Regulation No 78/2002.

The EU Commission's expert working group is currently working to revise these maximum permitted levels. EFSA's latest recommendation to reduce the population's exposure to lead is the main reason for this. Furthermore, new data concerning lead levels has also been submitted by the Member States and this needs to be considered within the review process. The lead intake from beef can be used when estimating the risks for persons who consume large amounts of game meat. In other words, the regulations in respect of beef can be used as a starting point.

Hygiene legislation and private households

The hygiene regulations (852/2004 and 853/2004, see below), that apply for food businesses, are not to be applied to primary production, for example hunting, or to private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption.

Private persons are however covered by certain rules within Regulation (EC) No 178/2002, see Article 14, regarding requirements in respect of food safety, and Article 18 in respect of traceability.

Regulation (EC) No 852/2004

Regulation (EC) No 852/2004³ applies FBOs in primary production, including hunting. Within primary production, the county administrative board is the competent authority that registers and supervises food businesses. Furthermore, there are rules within the Regulation that apply for food businesses in the stages that follow primary production, for example, retail facilities (game handling establishments, food stores, restaurants, etc.). FBOs that conduct operations in the stages that are after primary production and which mainly comply with the rules found in Regulation (EC) No 852/2004 are to be registered and controlled by their municipal board.

Regulation (EC) No 853/2004 on the hygiene of food of animal origin

Specific rules regarding food of animal origin can be found in Regulation (EC) No 853/2004⁴. The Regulation is directed to FBOs that have been approved by a competent authority to conduct the production of food of animal origin. The Regulation contains rules for the operation of for example game handling facilities but there are also certain rules that apply to hunting (within primary production). The National Food Agency is the competent authority for approval and control of the Game Handling Establishments (GHE)

The main rule within Regulation (EC) No 853/2004 is that killed game is to be transported unskinned/unplucked to a game handling facility approved by the competent authority for processing and for veterinary controls. Approved carcasses from a game handling facility can be placed on the whole EU market. .

According to the Article 1, point 1.3 e) this Regulation is not to be applied on hunters who supply small amounts of game or meat from game direct to consumers or to local retail establishments directly supplying the final consumer. In this case, there is no official control of the game. Carcasses of wild boar, bear and other wild animals that are susceptible to trichinosis, and game from an enclosure that has not been declared free from tuberculosis shall, in accordance with national legislation, always be transported to a game handling establishment (GHE). The retail establishments that receive game and/or game meat from hunters are controlled by their municipal board, mentioned above.

³REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs

⁴REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin

Control legislation

The control regulations are primarily aimed at the competent authorities (control authorities).

Regulation (EC) No 882/2004⁵ on the control of feed and food stuffs

The basic legislation regarding the competent authority's controls can be found in Regulation (EC) No 883/2004 on official controls. This Regulation applies for the control of all food businesses, including game handling establishments and the retail establishments that receive small amounts of game and/or game meat directly from hunters.

Regulation (EC) No 854/2004 on the control of products of animal origin

Rules regarding the control of food of animal origin can be found in Regulation (EC) No 854/2004⁶. The Regulation contains rules regarding the official controls to be conducted at game handling establishments.

Article 5 of the Regulation states that the official veterinarian shall carry out certain inspection tasks in game handling establishments that place fresh meat on the market. These tasks include post-mortem inspections and laboratory testing. The veterinarian shall also, where applicable, make decisions concerning meat. These decisions may refer to parts of a carcass or to the whole of a carcass, with or without related organs.

Control – how is the risk of lead in game meat currently managed?

The national control programme

The programme for heavy metals in game meat proceeds from the EU Commission's "Control Directive" 96/23/EC and the maximum permitted values established in the Commission's Regulation 1881/2006/EC. The programme consists of around 100 tests. The results are reported to the Commission. The National Food Agency analysed lead in the livers of moose and roe deer in 2009 and also previously. In 2011 the Agency took samples and analysed muscles taken from 106 wild animals (moose, roe deer, wild boar) (National Food Agency's report 9/2012). The results show that the contents of lead (min-max) for moose (n=71), roe deer (n=16) and wild boar (n=19) are 0.008-0.143, <0.008 and <0.008 mg/kg wet weight respectively. The results show that all samples apart from one (0.143 mg/kg wet weight) lie under the maximum permitted value for lead in meat, 0.1 mg/kg wet weight. This shows that the environmental impact of lead in game is low, and that it lies below the relevant permitted level for lead in meat. However, it should be noted that neither the sampling model nor the analysis method within the control programme are constructed to find any possible contamination of game meat with lead fragments from lead ammunition (i.e., the isolated occurrence of lead fragments in the meat and a subsequent sampling and analysis of large, 500 - 1,000 gramme, amounts of meat).

Information for consumers

Updated information regarding hunting and health risks associated with game meat, etc. can be found at the National Food Agency web site (Link:

⁵ REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

⁶ REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

http://www.slv.se/sv/grupp1/livsmedelsoforetag/sa_kontrolleras_din_verksamhet/Pri-marproduktion/Jakt/#Bly. This information text contains information and advice on problems associated with lead in game meat originating from lead ammunition.

Hunters

The vast majority of hunters are not food businesses in the sense of the food legislation and, as a result, they are not registered with the control authority - their county administrative board. This means that the county administrative board cannot conduct controls on a hunter. However, the county administrative board must react if it suspects that a hunter has supplied food that is not safe, see Article 14 of Regulation (EC) No 178/2002.

Game and game meat may be conveyed direct from a hunter to a consumer or a retailer who, in turn, supplies it direct to the consumer. If the hunter is not considered as a food business, then control of him/her cannot be conducted in this context. However, the exemption for direct deliveries from hunters does not apply to wild boar, bear, other animals susceptible for *Trichinella* infection and deer and other animals together within enclosures that have not been declared free from tuberculosis.

The hunter can themselves mitigate the risk of lead in game meat, both by choosing to use lead-free ammunition or by efficiently cutting of the meat along and surrounding the bullet wound cavity.

Risk management at food businesses

During the 2011-2012 hunting season, around 90,000 moose were shot (Swedish Association for Hunting and Wildlife Management (SJF)). It is estimated that around 10,000 of these animals were delivered to approved game handling establishments. According to the SJF's estimations, 97,000 wild boar were shot in 2013. Approximately 13 per cent of these were delivered to game handling establishments.

When it comes to the hunter's direct deliveries of small amounts of unskinned game and game meat to food stores, restaurants and other retail establishments, the volumes involved are largely unknown to the National Food Agency. The fact is that, due to the risk of trichinosis, it is forbidden for hunters to supply wild boar and meat from wild boar direct to consumers or retail establishments. Likewise, deer and other accompanied animals may not be delivered direct to the consumer/retailer from enclosures that have not been declared free from tuberculosis.

It is the FBO that is responsible for ensuring that the food that it places onto the market is safe, and this should happen through the business establishing permanent procedures or routines that prevent, eliminate or reduce the dangers identified to an acceptable level (Article 5 of Regulation (EC) No 852/2004). The role of the control authorities is to check that the FBOs introduce such procedures for relevant hazards and that the FBOs implement their procedures.

If ammunition other than lead ammunition is used then the hazard of ammunition lead in meat from hunted game can be entirely eliminated. However, it is as yet unknown whether the use of alternative types of ammunition may result in the introduction of new hazards.

The cutting clean the wound channel and the surrounding tissue is currently conducted as the primary objective of removing bleeding and contaminants. The amount that is cut-off differs however between the various FBOs (and from hunter to hunter) and as a result, the amount of lead residue that remains after cutting also varies. As far as ammunition lead residues are concerned, a FBO should establish specific procedures in order to remove residues from the area around the wound channel.

Using x-ray examination to reduce the danger could be a way forward. The spread pattern of lead fragments in shot animals can vary however, due, for instance to the distance of the shot, the extent to which the projectile hits bone or the angle from which the animal is shot. Furthermore, the size of the lead fragments vary randomly; some are visible under x-ray, some are not. The varying spread pattern means that x-ray examination must be carried out for every package of game meat that could contain lead residues. It is unclear whether, in this way, the hazard can be reduced to a level whereby the tolerable limit is not exceeded. Examinations using x-ray would probably only be feasible in relation to the further processing of game meat and then only for pre-packed foods.

The monitoring of hazards in products, by x-ray for example, could theoretically be conducted in food stores, restaurants and other retail establishments, but it would probably be very expensive. In the view of the National Food Agency, the handling of risk should occur earlier in the chain. It has also been noted that x-ray examination only discovers larger fragments of lead, which means that the ammunition lead level can still be high even if no visible fragments are detected.

Supplementary risk management

The risk of lead from the environment in game meat is currently handled via the national control programme, at food facilities and via continually updated information communicated to consumers on the National Food Agency's web site (Link; <http://www.slv.se/grupp2/livsmedel/foretag/Regler-for-olika-typer-av-livsmedel/Primarproduktion/Jakt/?amp;epslanguage=sv>)

When considering further risk management measures, attention should be paid to the *Principle of Proportionality* (cf. Article 7 of EU Regulation No 178/2002). The measures taken should be in proportion to the objective and they should not restrict trade more than which is necessary to achieve the high level of health protection chosen in the Community, with consideration of the technical and financial feasibility and other factors that are considered justified for the matter in hand.

In point 19 of the introduction to the Regulation, it is stated, as background to Article 7, that it is generally recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

The costs for the control, the costs for businesses and the possibility to carry out control are significant factors in the question of how risks are to be managed.

Advice to Swedish consumers and other risk management measures

Consumers who may be subjected to a high level of exposure to ammunition lead in game meat are hunters, their families and consumers who frequently purchase game meat direct from hunters or in stores.

EFSA's latest risk assessment includes recommendations regarding reducing exposure to lead at population level. Within the expert group at the EU Commission suitable measures have been discussed at several meetings. But the EU Commission has no intention of discussing whether or not lead ammunition should be prohibited or replaced. On the other hand, the Commission will attempt to acquire a better picture of the lead exposure of various populations within the EU. Pending this, the Commission advises those member states more aware of the risks to provide their consumers with advice.

Other factors that the decision has taken into account

- In Sweden there are around 300,000 licensed hunters, which means that an estimated 600,000 - 900,000 persons (approximately 7-10 per cent of Sweden's population) are potential consumers of privately hunted game.
- The amount of game meat produced in Sweden each year corresponds to around 12 per cent of the amount of beef production.
- Game meat is nutritious food and advice to consumers could have a negative impact on the consumption of game in general. However, there are other equally nutritious foods that can replace game meat.
- Hunting is a positive leisure activity for its practitioners. It contributes to a good quality of life and promotes physical activity.
- There are probably cuts of meat and minced meat in private freezers (intended for human consumption) where the level of lead can be expected to be similar to those described in these studies.
- As a consumer, it is difficult to know which type of meat could contain high levels of lead, since knowledge regarding the large spread of lead contamination is probably limited.
- Depending on the method of cooking (the recipe) the solubility of lead from fragments can vary. The addition of acidic ingredients such as wine, vinegar and tomato have been shown to increase the solubility of lead.
- The lead that contaminates game meat has been shown to come from the ammunition used in hunting. Since the source of the contamination is known and can be remedied, the National Food Agency considers that the level of acceptance of lead residues in meat for consumption should be very low.
- Alternatives to lead ammunition are available, and this would eliminate the risk of lead occurring in game meat.

Conclusion

The National Food Agency considers that it is reasonable to make this source of lead exposure known and that this exposure should be reduced by giving advice to hunters and businesses that handle game and meat from game. The advice regarding the processing and cleaning of carcasses of game shot with lead ammunition is that the wound channel (meat that looks affected or bloodshot) and an additional 10 cm of unaffected meat around the wound channel(s) is to be cut away and disposed of.

Increased levels of lead in certain cuts of meat are a problem that must be solved by those handling the meat. The occurrence of lead fragments in game meat means that groups that eat a large amount of game meat, for example hunters and their families, risk an increased intake of lead. If the meat of game shot with lead ammunition is not adequately trimmed, then the consumption of game meat can be a significant source in respect of the total exposure to lead of hunters, their families and consumers who have regular access to game meat.

The blood lead levels in Europe, including Sweden, today have little effect on an individual level, but they are considered to be significant on a population level. This blood lead level is, in principle, the level that EFSA has established as a health-based reference value and this is used in the risk assessment data as the reference point that should not be exceeded. In its risk assessment of lead, EFSA makes the recommendation that exposure to lead should therefore be further reduced at population level.

Reasons/rationale for the risk management measure chosen

- The results from the investigations show that there is a high probability of high levels of lead in game meat in the area around the wound channel, and in at least a further 10 cm of visibly affected meat, when lead ammunition is used.
- The studies of the blood lead levels of Swedish game meat consumers show that consumption of game meat can lead to a blood lead level that is 30-50 per cent higher compared with consumers who seldom or never eat game meat.
- The problem with lead fragments in cuts of meat relatively far away from the affected areas around the wound channel has probably been unknown to the majority of people. This means that social groups who eat a relatively large amount of game meat, for example hunters and their families, risk having an elevated level of lead in their blood.
- According to the calculations in the National Food Agency's risk assessment, the estimated lead intake from these cuts of meat within these groups of consumers can in many cases exceed the health-based reference points that exist for exposure to lead.
- Consumption of these cuts of meat is a significant source in respect of the *total* lead exposure of the consumer groups addressed within the Agency's risk assessment.
- The National Food Agency has observed an unacceptable source of lead exposure via a specific food group in Sweden.
- Advice to those who handle (slaughter, cut) game meat is judged to have the quickest and, at present, the largest impact on public health.
- The aim of the advice is to substantially limit the exposure of relatively large social groups to lead from game shot with lead ammunition.

- In this context, limiting occasional/seldom exposures is of no major significance to health.

Hunters and their families, and those who often eat game meat

The National Food Agency considers that it is reasonable to advise hunters, their families and other social groups to avoid consuming meat from game shot with lead ammunition if it is not known whether the meat has been handled in accordance with this recommendations. There is often a great probability that meat, for example minced meat and stewing steak meat, has come from the area around the wound channel. Other parts of the animal (parts that are further away from the wound channel, for example the hind, neck, thigh or tenderloin) are not considered to have increased levels of lead as a result of lead ammunition and can therefore be consumed. For cuts of game meat already in the freezer, see below.

Comments concerning advice on meat already cut up

- Meat that is already in the freezer and *that could be suspected* to contain increased levels of lead need not be disposed of from a risk point of view, but consumption should be limited to no more than 12 times/year. ***However, women who are pregnant, or plan to be pregnant (3 months prior to pregnancy), and children under the age of 7 should also avoid consuming this meat in the future.*** Since there is a long history of consumption of this type of meat in Sweden and overseas, it is considered that the risk of consuming also this meat already cut up being slight, so there is no reason to advise that this meat be disposed of. This reasoning is motivated by both economic and social considerations, but also from a risk point of view since this relatively *short-term* consumption of pre-cut meat (*that could be suspected* to contain high levels of lead) is not thought to constitute a significant risk as far as elevated blood lead levels are concerned.
- Several studies have shown that the level of lead in the blood increases when game is consumed around one or more times per month.
- The National Food Agency considers it unacceptable that one food source can contribute so much to the level of lead in the blood. Consumption of meat that can contain increased levels of lead should therefore be kept to a minimum.

Comments concerning risk management at commercial game facilities

- The use of lead-free ammunition would eliminate the occurrence of ammunition lead in game meat. However, as a public authority, the National Food Agency cannot influence the hunter's choice of ammunition.
- A certain amount of cutting around the wound channel is conducted even today, but with the intention of removing blood and other contaminants. This study has shown, however, that at least 10 cm of unaffected meat (in addition to the wound channel and affected meat) must be cut away in order to reduce the level of ammunition lead in the meat.
- The National Food Agency's Control Department will be requesting that game handling establishments (GHEs) put on place procedures that ensure that game meat placed on the market does not contain increased levels of lead from ammunition. The national guideline now being developed will state how the cutting and trimming of

game are to be conducted in order to reduce the risk of increased levels of ammunition lead in game meat.

- The National Food Agency's Control Department will be conducting targeted controls at GHEs in order to control the procedures, their implementation and their efficiency.
- The National Food Agency encourages municipal control authorities to request that the retail establishments that handle game meat put in place procedures that ensure that game meat supplied from these establishments direct to the consumer or to other nearby retail establishment does not contain heightened levels of lead from ammunition.
- Retail establishments (e.g, restaurants and food stores) that handle game should implement procedures for control of their suppliers for game meat if the carcasses have been trimmed in accordance with recommendations from NFA.
- The National Food Agency may consider introducing a Swedish maximum level for ammunition lead in game meat.
- The National Food Agency realises that the GHEs and other FBOs that handle game and game meat will need a certain transitional period to adapt their procedures.

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