Analysis of the:

„ECHA report – recommendation of total ban on lead ammunition“

by LEX – Czech association for protection of firearms rights – www.gunlex.cz

Source: ECHA report - identifies risks to terrestrial environment from lead ammunition ***https://echa.europa.eu/cs/-/echa-identifies-risks-to-terrestrial-environment-from-lead-ammunition*** *ECHA/PR/18/14*

1 INTRODUCTION

The ECHA report is relatively well sourced. By checking the sources, however, we found that ECHA often omitted important claims of source studies and misinterpreted many others. In addition, around half of the sources mentioned in the text of ECHA report are missing in the bibliography list. As a result, we had to find them through our own research, which was not always successful. The ECHA report therefore does not fulfill standards of scientific research.

We also doubt the objectivity of the report, as it openly prefers total ban on grounds of simple and easy enforcement, at the expense of firearms owners.

When checking the sources, we always attempted to track the chain of information back to primary data (i. e. results of actual research), and where we found it, we point to that research (with eventual comments to its faults or misinterpretation.)

2 HEALTH RISKS

2.1 Direct emissions into environment

ECHA reports the risk of pollution by deposit of lead ammunition into soil through shooting. Reported amount (21 000 tons per year) was computed from number of manufactured rounds and average lead content per round[1].

As proof of risk, ECHA report refers to Finnish study[2], which claims around one-third of Finnish shooting ranges to be risk of pollution of groundwater. However, upon more detailed review of that

1 As a source of amount of manufactured ammunition, ECHA report refers to AFEMS (Association of European Manufacturers of Sporting Ammunition) report for 2010. We could not find that report, so we could not verify it.

2 Sorvari, J., Antikainen, R., Pyy, O. (2006). Environmental contamination at Finnish shooting ranges - The scope of the problem and management options. Science of the Total Environment, 366, 21–31. https://www.sciencedirect.com/science/article/pii/S004896970500923X#bib30

study, we learned that the study simply assumes as risk any shooting range placed closer than 100 m to source of groundwater; no actual measurement of lead content in water was performed during this study. The study claims (without stating any sources) that three Finnish shooting ranges were actually detected (by measurement) as a source of lead pollution exceeding health limits, while the number of shooting ranges in Finland is estimated by the study to be between 2000 and 2500.

In relation to that, we point to a study performed on an outdoor range in Czech Republic[3], where actual measurement of lead in soil was carried out. The study found that even before the backstop where most bullets fall, lead did not penetrate deeper than 30 cm into soil.

Since we were not able to find any study, which would actually perform measurement of lead content in groundwater near shooting ranges in larger scale, we recommend performing such a study.

2.2 Health risks of lead ammunition for birds and mammals

Primary poisoning – ingesting lead projectile from environment: This phenomenon is well proven in waterfowl on wetlands, where birds often swallow lead shot with food or grit (however, use of lead shot on wetlands is already banned). ECHA report claims that terrestrial birds, especially mourning doves and gallinaceous birds (pheasants, partridges) are at the same risk as waterfowl. In case of mourning doves, we found studies which prove that claim[4] [5] [6] (around 2,5% of examined birds had one or more lead shot in its intestines). With gallinaceous birds, we found study of pheasants performed in the pheasantry[7], which has showed 3% of such occurrence.

Secondary poisoning – ingesting lead shot with prey or carcass, of ingesting lead-contaminated

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[3] ASH, C. – TEJNECKÝ, V. – ŠEBEK, O. – NĚMEČEK, K. – ŽAHOUROVÁ - DUBOVÁ, L. – BAKARDJIEVA, S. – DRAHOTA, P. – DRÁBEK, O. Fractionation and distribution of risk elements in soil profiles at a Czech shooting range. *Plant, Soil and Environment,* 2013, roč. 59, č. 3, s. 121-129. ISSN: 1214-1178. https://www.researchgate.net/publication/235217492_Fractionation_and_distribution_of_risk_elements_in_soil_profiles_at_a_Czech_shooting_range

[4] CASTRALE, J.S. 1991. Spent shot ingestion by Mourning Doves in Indiana. Proceedings of the Indiana Academy of Science 100:197–202. http://journals.iupui.edu/index.php/ias/article/view/7223/7223

[5] FRANSON et al. Ingested shot and tissue lead concentrations in mourning doves. 2009. https://www.peregrinefund.org/subsites/conference-lead/PDF/0202%20Franson.pdf

[6] KENDALL, R. & SCANLON, P. Lead concentrations in mourning doves collected from Middle Atlantic Game Management Areas. 1979. https://www.researchgate.net/publication/266330176_Lead_concentrations_in_mourning_doves_collected_from_Middle_Atlantic_Game_Management_Areas

[7] Butler DA, Sage RB, Draycott RAH, Carroll JP. Potts D, (2005). Lead exposure in ring-necked pheasants on shooting estates in Great Britain. Wildlife Society Bulletin 33(2), 583-589. https://www.researchgate.net/publication/261826356_Lead_Exposure_in_Ring-Necked_Pheasants_on_Shooting_Estates_in_Great_Britain

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meat: this phenomenon is allegedly[8] proven in raptors hunting waterfowl (affected by primary poisoning). However, this problem should be solved by already existing ban on use of lead ammunition on wetlands. This phenomenon is further well proven (by finding of projectiles in stomachs or pellets regurgitated by birds) in scavenger birds feeding on carrions, for example condors[9] or red kites[10]. We were unable to find a study with such certain proof concerning common birds of prey; lead poisoning from ammunition is usually only assumed on grounds of high blood lead level[11], which can have other sources. We recommend further research in this matter.

Risk for mammals: ECHA reports cases of lead poisoning of cattle by eating silage harvested from lead ammunition contaminated fields. We could not find any of the reported sources except for one[12], which we could not evaluate, as only an abstract of the source is available online.

2.3 Health risks of eating lead-harvested game by humans

Transfer of lead from ammunition to game meat: According to the ECHA report, this happens by embedding of lead projectile either in animal body or by fragmentation of projectile (especially when hitting a bone) and contamination of meat by microscopic fragments of lead. This is well proven by a study[13] examining content of lead in bird game meat: 65% of examined birds contained 1-18 (2,17 on average) shots. 76% of birds contained fragments of shots visible on X-ray picture.

After removal of shots from samples, lead level in game meat was measured. Maximum level

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8 The only source we found on the web is printed book unavailable to us: Pattee OH, Hennes SK (1983) Bald eagles and waterfowl: the lead shot connection. Trans 48th N Am Wildl Nat Resour Conf 48:230–237 https://pubs.er.usgs.gov/publication/5221827

9 CADE,T. J. 2007. Exposure of California Condors to lead from spent ammunition. Journal of Wildlife Management 71:2125–2133. http://www.bioone.org/doi/abs/10.2193/2007-084

10 PAIN,D.J.,I.CARTER,A. W.SAINSBURY,R. F.SHORE,P.EDEN,M.A.TAGGART,S.KONSTANTINOS,L. A.WALKER,A. A.MEHARG,AND A.RAAB. 2007. Lead contamination and associated disease in captive and reintroduced Red Kites (Milvus milvus) in England. Science of the Total Environment 376:116–127. https://www.sciencedirect.com/science/article/pii/S0048969707001003

11 Fisher IJ, Pain DJ, Thomas VG. A review of lead poisoning from ammunition sources in terrestrial birds. Biol Conser. 2006;131(3):421–432. https://www.sciencedirect.com/science/article/pii/S0006320706000802

12 RICE, D., McLOUGHLIN, M.F., BLANCHFLOWER, W.J., THOMPSON, T.R. Chronic lead poisoning in steers eating silage contaminated with lead shot-Diagnostic criteria. 1987. https://www.researchgate.net/publication/19471926_Chronic_lead_poisoning_in_steers_eating_silage_contaminated_with_lead_shot-Diagnostic_criteria

13 Pain, D.J., Cromie, R.L., Newth, J., Brown, M.J., Crutcher, E., Hardman, P., Hurst, L., Mateo, R., Meharg, A.A., Moran, A.C. (2010). Potential hazard to human health from exposure to fragments of lead bullets and shot in the tissues of game animals. PLoS One, 5(4), e10315. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0010315

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allowed by EU regulation[14] for chicken, beef, lamb and pork meat was exceed in 20 – 87,5 % of samples (depending on type of game). Of that, 0 – 25 % samples exceeded the limit ten times, in 0 – 12,5 % samples the limit was exceed hundred times.

Toxicity of lead in human organism: ECHA report claims (without presenting any sources to that effect) that lead is considered to be "non-threshold substance", i.e. harmful in any amount, therefore any limitation is desirable and justified by itself.

However, ECHA-referred sources state only one condition where lead is actually harmful in any amount – toxicity for developing nervous system of children. In this case, even micrograms per deciliter of blood is associated with slight decrease of intellect (in children up to 10 years, raise of blood lead level from 2,4 µg/dl to 10 µg/dl correlates with decrease of IQ by 3,9 point[15]). We found no study, which would prove health issues in adults with blood lead levels of micrograms/dl. By U.S. standards, acceptable blood lead level is set at 5µg/dl[16], for adults 10 µg/dl[17]. Average blood lead level for Americans is 2,58 µg/dl[18] (therefore, this is amount of lead collected by human through normal life in developed country).

Transfer of lead from game meat to human organism: this issue is not addressed by ECHA at all. The report only inquires into amount of game meat consumed in certain EU member states. ECHA explicitly writes that actual research of influence of game meat harvested by lead ammunition on human health was not performed at all, because lead is a known non-threshold substance. ECHA reports to decision of CONTAM panel (EFSA) as a source. We find quite unusual to establish such factor by agency decision, instead of scientific research.

We have very serious issues with this claim. A study performed on Italian hunters[19] found that game eating hunters actually have a blood lead level higher (0,9 – 6,1 µg/dl) than people who do

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[14] COMMISSION REGULATION (ES) No. 1881/2006 of Dec.19 2006, which establishes maximum limits of certain contaminants in food, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:CS:PDF

[15] Lanphear, B. P., Hornung, R., Khoury, J., Yolton, K., Baghurst, P., Bellinger, D. C., Canfield, R. L., Dietrich, K. N., Bornschein, R., Greene, T., Rothenberg, S. J., Needleman, H. L., Schnaas, L., Wasserman, G., Graziano, J., Roberts, R. (2005). Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives, 113(7), 894-899. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257652/

[16] Center for Disease Control and Prevention, https://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm

[17] Center for Disease Control and Prevention, https://www.cdc.gov/niosh/topics/ables/description.html

[18] HITTI, M. Lead in Blood: 'Safe' Levels Too High? 2006 https://www.webmd.com/a-to-z-guides/news/20060918/lead-in-blood-safe-levels-too-high#1

[19] FUSTISTONI, S., SUCATO, S., CONSONNI, D., MANNUCCI, P.M., MORETTO, A.: Blood lead levels following consumption of game meat in Italy. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28189071

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not eat game meat (1,0 – 5,3 µg/dl); however, this is still safely under limit of 10 µg/dl for adult. On top of that, study found that hunters themselves had higher blood lead levels, but their friends and family members who also eat game meat had not. The study speculates that higher lead levels in hunters' blood could have other sources than game meat, possibly handling ammunition or inhaling fumes produced by shooting.

Since ECHA lists Italy as one of countries with high consumption of game meat, we consider these findings very important.[20].

Another such a study was performed on American hunters[21]. It also found blood lead level increased by 0,30 µg/dl – to total average of 1,27 µg/dl, which is still almost four times less than maximum level allowed for *children.*

Similar study performed in Switzerland[22] did not find significant difference in blood lead level between hunters consuming game meat and control group of blood donors, nor any significant correlation between blood lead level and frequency of game meat intake.

Another study performed in Sweden[23] found (by X-ray and computer tomography examination of wild boars killed by lead bullet) that fragments of lead are concentrated in distance to 4,5 cm from wound channel, with smaller concentrations up to 10 cm of distance. This meat is removed with common meat processing methods. The study also performed experiment with simulated digestion process and found that bioavailability of metallic lead is under 1%, i.e. less than 1% of metallic lead is absorbed into human body in digestive system.

At this particular point, we must note omission in ECHA report that almost looks like an intentional misleading. One part of often-cited study *Pain et al. 2010*[24], looks into bioavailability, i.e. computes how much lead would be transferred into human organism from lead-contaminated meat, and

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20 FERRI, M., BALDI, L., CAVALLO, S., PELLICANO, R., BRAMBILLA, G.: Wild game consumption habits among Italian shooters: relevance for intakes of cadmium, perfluorooctanesulphonic acid, and ^{137}cesium as priority contaminants. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28271815

21 Iqbal S., Blumenthal W., Kennedy C., Yip F.Y., Pickard S., Flanders WD., Loringer K., Kruger K., Caldwell K.L., Jean Brown M.: Hunting with lead: association between blood lead levels and wild game consumption. 2009. https://www.ncbi.nlm.nih.gov/pubmed/19747676

22 Intake of lead from game meat – a risk to consumers' health? HALDIMANN, M., BAUMGARTNER, A., ZIMMERLI, B. 2002. https://link.springer.com/article/10.1007/s00217-002-0581-3

23 LEAD IN GAME MEAT - Bio accessibility of fragments of metallic lead. QUARFORT, U., HOLMGREN, CH. 2012. https://www.leadinammunition.com/independent-studies-011/

24 See 13.

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whether such amount would exceed the maximum allowed daily dose for children, set by WHO[25] at 25 µg per kg of body weight. The study claims that this limit would be exceeded only in two of eight types of game meat, *through daily consumption*. If consumed once per week, no type of game meat would exceed allowed dose. ECHA ignored and omitted these findings, substituting them by claims about absolute harmfulness of lead. Note that precisely these claims about "non-threshold substance" and research-unsupported claims of harmfulness of game meat for human health is what ECHA declares as legal basis for EU action and total ban on lead ammunition.

Findings of the above-mentioned studies show that while contamination of game by lead ammunition is indeed high, this effect is largely negated by very low bioavailability of metallic lead in human organism and amount of lead actually absorbed through human digestive system is safely under daily dose for adult human. The only point where we can agree with ECHA claims is a recommendation for children and pregnant women to avoid game meat (or eat only game harvested with lead-free ammunition) due to high toxicity of lead for developing neural system.

The ECHA study points to fact that, unlike chicken, pork etc., game meat does not have any limit of lead contamination set; we must however point to the fact that these limits were set in regard to water-soluble compounds of lead, where bioavailability is much higher.

We definitely recommend performing an actual study on blood lead level among hunters, in order to base further decision-making on facts and not on mere assumptions.

2.4 Health risks accompanying sport shooting

A complex study[26] referred to by the ECHA report found a serious air pollution by lead on shooting ranges, with corresponding high blood lead levels in present persons, up to 125 µg/dl for firearms instructors. On the other hand, another cited study[27] found that this pollution can be lowered by 95 – 97% through use of lead-free primers and jacketed bullets. Considering that mentioned technology went into widespread use since execution of study (1989), we recommend performing a study that would test a current situation in this field.

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[25] http://www.euro.who.int/__data/assets/pdf_file/0004/97042/4.4.-Exposure-of-children-to-chemical-hazards-in-food-EDITED_layouted.pdf

[26] Laidlaw, M.A., Filippelli, G., Mielke, H., Gulson, B. and Ball, A.S., 2017. Lead exposure at firing ranges—a review. Environmental Health, 16(1), p.34. https://ehjournal.biomedcentral.com/articles/10.1186/s12940-017-0246-0

[27] SARAH E. VALWAY, JOHN W. MARTYNY, JEFFREY R. MILLER, MAGDALENA COOK, ELLEN. J. MANGIONE: Lead Absorption in Indoor Firing Range Users. 1989. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1349901/

3 ALTERNATIVE AMMUNITION

For the proposed ban on lead shot and its replacement with lead-free shot, no impact assessment study was carried out by ECHA. In place of it, the ECHA report refers to an AMEC study[28] considering such replacement, performed in 2012. This study expects costs of 190 mil. € per year. In 25 years, it expects one-time and yearly costs together as 2,7 billion €.

Another study, which ECHA substitutes for impact assessment, is a COWI study[29] from 2004. This study expects costs of 220 – 370 mil. € per year while explicitly declaring that in the end, firearms owners shall pay it all through higher ammunition prices. The study also notes that with some considered alternatives to lead, like tin, bismuth and tungsten, no studies were performed in regard of their toxicity in water and soil.

The ECHA report further contains some more interesting thoughts:

- There is a problem that steel shot loses energy quickly at longer distances and may not have enough power to ensure quick and humane killing of bird. ECHA report "solves" this problem by recommendation not to shoot at longer distances.
- One of ECHA presented reasons for total ban on lead ammunition is that hunters prefer it if it is available.
- ECHA report considers that in place of total ban on lead ammunition, lack of alternatives shall be solved by "market mechanism", i.e. that hunters shall be forced to buy unwanted lead-free ammunition because better lead ammunition shall not be available, and manufacturers shall be forced to make lead-free ammunition, because they shall be forbidden to make anything else.

3.1 Soft steel

Shotgun ammunition with steel shot is quite widely available on market now, and its cost is comparable to lead shot.[30]. However, a lesser efficiency is expected both at longer ranges (as ECHA report admits, see above) and shorter ranges (steel is lighter than lead, therefore manufacturers recommend using a larger steel shot rather than a lead one. Consequently there is

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[28] AMEC Environment & Infrastructure UK Limited, Abatement Costs of Certain Hazardous Chemicals, Lead in shot – Final Report, 2013 https://echa.europa.eu/documents/10162/13580/abatement+costs_report_2013_en.pdf/6e85760e-ec6d-4c8a-8fcf-e86a7ffd037d

[29] REACH studies - Lead - Advantages and drawbacks of possible market restrictions in the EU - Final report http://ec.europa.eu/DocsRoom/documents/13043/attachments/1/translations

[30] See price list of Czech firearms retailer: http://www.9mm.cz/naboje.html

a smaller amount of shots in a single round, and at certain range the quarry may not be hit with enough shot to ensure quick killing – five hits are considered to be a reliable minimum.)

The AMEC study estimates that 95% of shotguns shall need reproofing to steel shot. Further it estimates that about 15% of shotguns shall not pass such reproofing (and very probably shall be damaged in the process, we add). ECHA report omits this and simply states that *"some firearms might need reproofing"*. That is possible – ECHA report claims that according to statement of (unnamed) large shotgun manufacturers, shotguns manufactured after 1970 are able to shoot steel shot without reproofing. We recommend asking national proofhouses for opinion.

The COWI study mentions another disadvantage – in the woods, steel shot penetrates deep into trunks of trees, damage wood by soaking rust and damage woodcutting tools. Many forest owners therefore prohibit use of steel shot on their lands. ECHA report omits this disadvantage entirely.

Further possible disadvantage of steel shot, also entirely omitted by ECHA report, is higher potential of steel shot for ricochet. According to COWI study, this may mean more injuries for hunters and a necessity to rebuild some shooting ranges.

3.2 Bismuth

Bismuth shot has density of 9,7g/cm^3, therefore it is a bit lighter that lead (11,3 g/cm^3) but heavier than steel (7,9 g/cm^3). Hardness of bismuth is comparable to lead, therefore bismuth shot does not cause problems with wear and tear of barrels and with ricochets, like steel shot has. Main disadvantage is 3 – 5 higher cost.

3.3 Tungsten

Tungsten shot is manufactured from plastic filled with tungsten dust. From both weight and hardness criteria, it can be equivalent replacement for lead shot. However, the price can be up to ten times higher.

3.4 Tin

Tin is even lighter than steel (7,3 g/cm^3). It is considered as substitute only in 22 cal. rimfire cartridges and airgun pellets (COWI). In both cases, lighter projectile would mean significantly shorter range and lesser accuracy. Cost of tin projectiles would be 1,5 – 6 times higher than lead.

3.5 Copper and copper alloys

Copper and copper alloys have already been used as material for monolithic hunting bullets for some time. This technology is already quite developed and some hunters prefer these bullets to

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leaden ones. There are disadvantages, however – lesser accuracy at longer ranges, lower energy especially with smaller calibers, and higher penetrative power caused by harder core material. COWI report also claims that toxicity of copper in water is comparable to lead, and toxicity in soil is even higher that lead.

4 FISHING WEIGHTS

Health risks for waterfowl: ECHA report sufficiently documents poisoning of waterfowl, especially loons[31] and swans[32] by fishing lead. Report states that swallowing of even one lead may cause acute poisoning and death, due to larger size of fishing lead compared to shot.

Health risks for humans: ECHA report claims (without reporting any sources) possible risk for humans by inhaling lead vapors during homemade casting of fishing lead.

Reason for EU intervention: ECHA states necessity to complete protection of waterfowl by ban on fishing lead along with (already existing) ban on lead shot on wetlands as reason for EU intervention.

Alternative materials: COWI study refers to tin, tungsten, steel, zinc and bismuth as possible alternatives. Unfortunately, zinc was also already proven to be toxic[33], while toxicity of bismuth, tungsten and tin is not sufficiently scrutinized, as was mentioned above. ECHA report also claims that according to EFTTA (European Fishing Tackle Trade Association), there is no acceptable replacement for smallest types of fishing leads.

Costs: Costs of fishing weights from alternative materials would be comparable to projectiles costs.

5 SOCIO-POLITICAL ASPECTS

ECHA report dismisses any alternatives to total ban on lead ammunition (for example, limited restrictions or support of voluntary use of lead-free ammunition) and explicitly prefers total ban as most simple and easy solution. In contrast, COWI study even claims explicitly that there is no legal

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31 Grade, T. J., Pokras, M. A., Laflamme, E. M. and Vogel, H. S. (2018), Population-level effects of lead fishing tackle on common loons. Jour. Wild. Mgmt., 82: 155-164. doi:10.1002/jwmg.21348 https://wildlife.onlinelibrary.wiley.com/doi/full/10.1002/jwmg.21348

32 Kirby, J., Delany, S. and Quinn, J., 1994. Mute Swans in Great Britain: a review, current status and long-term trends. Hydrobiologia, 279(1), pp.467-482. https://link.springer.com/article/10.1007/BF00027878

33 Steel Shot, Proposed Use for Hunting Waterfowl: Environmental Impact Statement, https://books.google.cz/books?id=bjA3AQAAMAAJ&pg=SL36-PA46&lpg=SL36-PA46&dq=zinc+shot+toxicity&source=bl&ots=viCyBMKzGY&sig=kTLIxRSPy5gcrbz6Wn_sdacnbhw&hl=cs&sa=X&ved=2ahUKEwi76p6Yn63eAhXEiiwKHd3QAqwQ6AEwCXoECAIQAQ#v=onepage&q=zinc%20shot%20toxicity&f=false

the basis for EU intervention in case of shooting ranges, because lead pollution in this case stays limited locally and can be solved at national level. ECHA report basically denies this with explanation that EU-wide ban would be simplest and most easily enforceable.

Quite interestingly, the ECHA report recommends leaving the enforcement of the ban on fishing lead to the member states.

One of the main arguments for restrictions presented by the ECHA report is the protection of health of shooters themselves – i.e. protection of people from themselves, whether they like it or not. ECHA report goes so far in this aspect that it recommends to consider even ban on home casting of fishing weights.

ECHA report states that there could be possibility for exemption from lead ammunition ban for professional shooters of Olympic sport disciplines, for muzzleloaders and antique firearms, as well as maybe for someone else who can justify his exemption.

6 CONCLUSION

ECHA report is strongly biased towards restriction of lead ammunition, with open preference for total ban. In all its aspects, it selectively omits important information contained in cited sources (for example, low bioavailability of metallic lead in human organism) and reports only aspects, which support this goal.

Also, it interprets some of the sources in a misleading way (for example, cites source claiming that one-third of Finnish shooting ranges were found to be water pollution risk, omitting fact that cited study based this claim solely on proximity of shooting ranges to water).

In addition, some of sources are seriously outdated (like 1989 study on lead in shooting fumes on ranges).

On top of that, roughly half of sources mentioned in the text are not listed in bibliography at the end. A student who would perform such a sloppy job on his thesis would not be even allowed to take the exam.

For those reasons, we strongly recommend to MEPs not only to demand full impact assessment, but also to ask for verifying independent study, which would ensure that evaluation would be fair and complete. Only then, European Parliament can responsibly decide whether proposed total ban is in accord with the basic rules of lawmaking, especially principles of legal basis, subsidiarity and proportionality.

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