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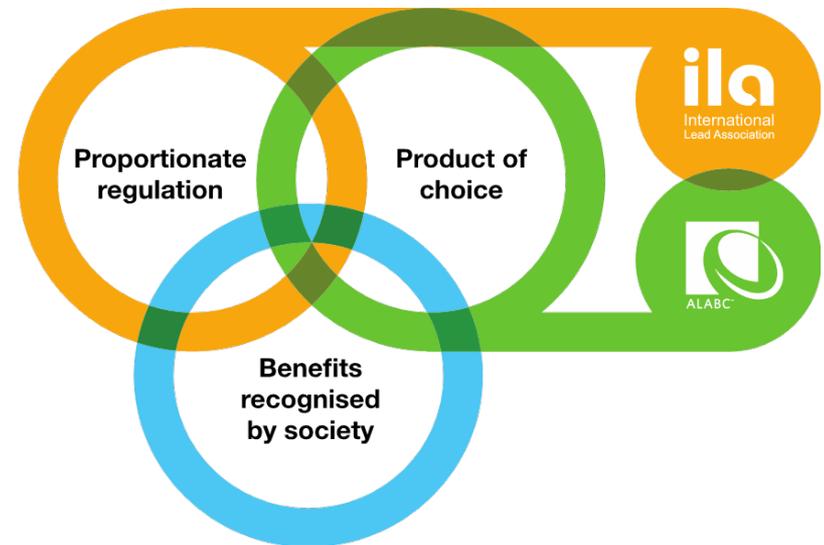
# Developments in EU Legislation Impacting Lead

The beginning of the end for lead ammunition?

Dr Steve Binks  
International Lead Association

# The International Lead Association

- **The International Lead Association is a membership body that supports companies involved in the mining, smelting, refining and recycling of lead.**
- **We represent the producers of about 3 million tons of lead and almost two thirds of lead production in the western world.**



**OUR VISION** “A sustainable global lead industry that is recognised for the positive contribution it makes to society”

# Outline- Developments in EU Legislation Impacting Manufacturing and Use of Lead

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- **EU Chemical Policy**
  - **REACH Authorisation & Restriction**
- **Classification, Labelling & Packaging**
- **Occupational Exposure Limits**
- **EFSA**
- **Conclusions**

# EU Chemicals Policy

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- REACH came into force in 2007 with provisions being phased-in over 11 years
- The Regulation calls for the **progressive substitution of the most dangerous chemicals (referred to as "substances of very high concern") when suitable alternatives have been identified.**
- SVHC defined as:
  - Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with Regulation (EC) No 1272/2008
  - Substances which are persistent, bio-accumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation
  - Substances which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation
  - Substances of equivalent concern (incl endocrine disrupting chemicals)

# REACH Authorisation

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- **Authorisation** procedure aims to
  - Ensure that **risk** resulting from SVHC's are **properly controlled**
  - Ensure these **substances are replaced by suitable alternatives where economically and technically viable**
- Substances subject to authorisation may not be placed on the market for a use or be used unless **the use** has been authorised
- All uses are covered unless
  - excluded from the scope
  - exemption is foreseen in Annex XIV
- Authorisation is linked to the applicant
- *Imported articles are not subject to authorisation*
- No volume threshold
- Time dimension: transitional periods (latest application date and sunset date), review period (general / specific)

# REACH Authorisation

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- Two “routes” to authorisation:
- **“Adequate control”**:
  - if the risks are adequately controlled as documented in CSR
  - does not apply to PBTs, vPvBs and to other substances for which it is not possible to determine a threshold
- **“Socio-economic”**:
  - if the socio-economic benefits outweigh the risk and
  - there are no suitable alternative substances or technologies
- ***Art 60(4) : .... Authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies....***

# REACH Authorisation- Lead & Compounds

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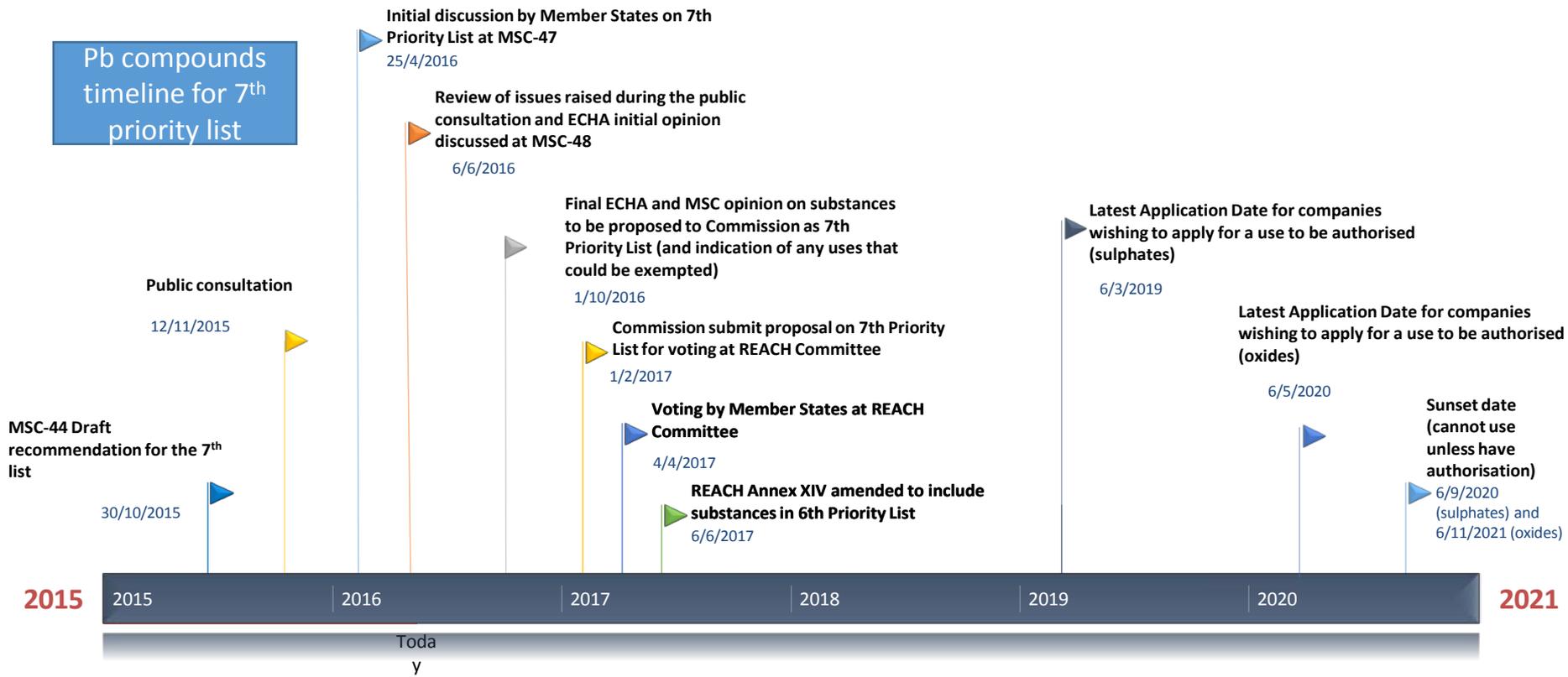
- Commission or Member States can nominate substances meeting criteria as SVHC to the “Candidate List”
- Lead compounds meet criteria as SVHCs
- Lead compounds represent 27 of the 163 substances currently included in the candidate list BUT
  - Lead Metal is NOT currently included....
- ECHA have developed so called “[PACT](#)” tool that lists the substances for which a risk management option analysis (RMOA) have been are in process of being conducted by MSCA since the introduction of the SVHC “Roadmap” in 2013
- Lead Metal listed in PACT by both Sweden & Denmark with Danes proposing;
  - Candidate listing as SVHC
  - Additional risk management measures to address lead exposure via drinking water and food
  - Additional activities at National level with Authorities providing information to citizens about risks of lead in drinking water

# REACH Authorisation-Lead & Compounds

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- 4 Pb compounds (lead monoxide, lead tetroxide, tetralead trioxide sulphate, pentalead tetroxide sulphate) were recommended by ECHA for 6th priority list of substances
- Following public consultation in 2014 and review by MSC, ECHA decided to omit them from the 6<sup>th</sup> priority list submitted to Commission
- New Commission not satisfied with functioning of authorisation process and neither 5<sup>th</sup> or 6<sup>th</sup> Priority list have made it onto REACH Annex XIV
  - Interactions between OHS legislation and REACH
  - Simplified authorisation for some uses
- ECHA continue to progress with prioritisation process and public consultation on 7<sup>th</sup> Priority list scheduled for Q4 2015-several Pb compounds (but not Pb metal) will be included.
- First step in process for inclusion of lead metal into REACH authorisation regime will be harmonised classification & labelling

# Pb compounds timeline for 7<sup>th</sup> priority list



11/12/2015 - 8/2/2016

**Public Consultation**

30/10/2015 - 1/1/2017

**Advocacy at Member State & Commission possible**

6/6/2017 - 28/2/2019 (sulphates) 30/4/2020 (oxides)

**Companies prepare Authorisation applications**

# Classification, Labelling & Packaging- CLP

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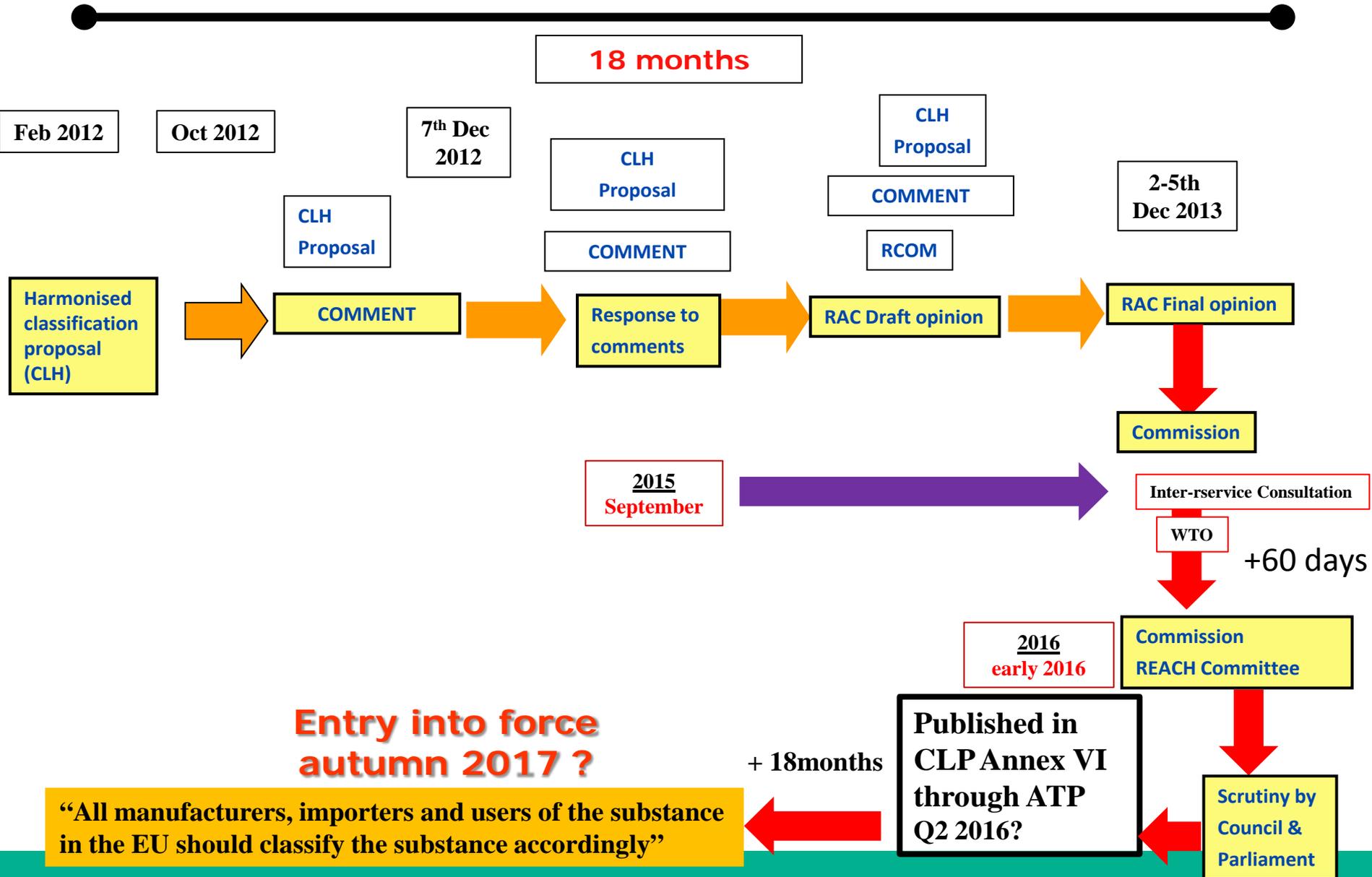
- CLP Regulation applies to substances and mixtures but NOT articles
- Classification & labelling is typically responsibility of organisation that places the substance (or mixture) onto the EU market
- However certain situations require that the classification of a substance is harmonised and made obligatory at Community level to ensure an adequate risk management throughout the European Community.
  - Where the substance is either carcinogenic, mutagenic, toxic for reproduction or a respiratory sensitiser
  - When the substance is an active substance in biocidal or plant protection products
  - When it is justified that a classification at EU level is needed
- Lead compounds but NOT lead metal already have an obligatory harmonised classification

# Classification, Labelling & Packaging- CLP

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- At end 2013 RAC issued their opinion on CLH for lead metal
  - Rep 1A (H360DF-May damage fertility or the unborn child, H362-May cause harm to breast-fed children)
  - Designated a “potent reproductive toxicant” and a SCL of 0.03%
  - Classification applies to ALL forms of lead metal
- SCL has significant socio-economic implications for other metals
- High level advocacy campaign developed at Eurometaux level
- Commission recognised that would not gain sufficient support from Member States and decided to omit the lead metal CLH from the 7<sup>th</sup> ATP to CLP
- Activities underway to develop protocol (“bio-elution”) for assessing bioaccessibility of metals
  - allows classification of mixtures to be derived from “bioaccessible” metal content rather than “total metal”
- Commission will propose a compromise CLH for lead metal in 9<sup>th</sup> ATP
  - Will only relate to the SCL

# SUMMARY- CLH Process for Pb Metal: update



# Classification, Labelling & Packaging- CLP

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- On 28th March 2014 Denmark submitted an Annex XV dossier for lead metal concerning harmonisation of Environmental Classification
  - Proposal is that Lead metal (in all forms) be classified as
    - Aquatic Acute 1; H400
      - M-factor 10
    - Aquatic Chronic 1; H410
      - M-factor 10
- Current Pb Consortium Classification for lead massive is: Not classified
- Current Consortium Classification for lead powder is: Aquatic Acute 1; H400 M-factor 10; Aquatic Chronic 1; H410 M-factor 1
- Public consultation expected by end of 2015 and review at ECHA RAC during 2016

# Occupational Exposure Limits

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- Objective in establishing OELs is to set limits for exposure via the airborne route such that exposure, even when repeated on a regular basis throughout a working life, will not lead to adverse effects on the health of exposed persons and/or their progeny at any time
- Council Directive 88/642/EEC, on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, introduced into EU legislation the objective of establishing occupational exposure limits (OELs) agreed by Member States
  - Binding OEL
  - Indicative OELs
- Lead currently has a Binding OEL of 150mcg/m<sup>3</sup> (8hr TWA) and an associated Binding biological exposure limit of 70mcg/dL
- Range of OELs and biological exposure limits exist in Member States (OELs, 150-50mcg/m<sup>3</sup>, BLV 70-20mcg/dL)

# Occupational Exposure Limits- So what's changed?

- Significant events:
  - 2003 SCOEL recommend “health based” limit of 30mcg/dL, 100mcg/m<sup>3</sup>
  - 2006 IARC concludes inorganic lead compounds as “probable human carcinogens” (Group 2A) and metallic lead as a “possible human carcinogen” (Group 2B)
  - 2007 Expert panel propose medical removal at 30mcg/dl or two consecutive readings above 20mcg/dL- later supported by American College of Occupational and Environmental Medicine
  - 2010 US NTP publish report on low level effects of lead citing effects seen <10mcg/dL
  - 2012 US EPA publishes “Integrated Science Assessment for Lead”
  - 2012 US National Research Council publishes report on effects of lead on potential health risks from recurrent lead exposure of firing-range personnel
  - 2014 Safework Australia consult on lowering Australian OEL to 30mcg/m<sup>3</sup> and to establish a blood lead removal limit of 20mcg/dL
  - 2014 SCOEL requested to review existing health based recommendation
  - CalOSHA proposes removal from lead exposure if two BLLs at or above 20 µg/dL, or one BLL at or above 30 µg/dL and PEL of 0.5 – 2.1 µg/m<sup>3</sup>
  - 2014 Germany initiates OEL review (latest proposal is for health based limit of 15mcg/dL)

# A Word on EFSA

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- The 2010 scientific opinion on lead in food issued by the European Food Safety Authority has had wide ranging effects
- Panel identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for risk assessment and that the PTWI of 25 µg/kg b.w. is no longer appropriate as there is no evidence for a threshold for critical lead-induced effects
- Determined the 95th percentile lower confidence limit of the benchmark dose (BMD) of 1 % extra risk (BMDL01) of 1.2 µg B-Pb/dL (0.50 µg/kg b.w. per day) as a reference point for the risk characterisation of lead when assessing the risk of intellectual deficits in children measured by the Full Scale IQ score.
- This BMDL01 is  $\leq$  background and 1/10<sup>th</sup> of this was used as reference dose by RAC in recent REACH restrictions pertaining to childhood exposure to jewellery and consumer articles and in the REACH authorisation application for Lead chromate

# Summary

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- **REACH Authorisation/Restriction**
  - Current authorisation activities relating to lead compounds have no direct impact on lead use in ammunition (but may set precedent for later lead metal reviews)
  - Most uses of lead metal will in future require REACH authorisation but LAD >>2025
  - Availability of alternatives and cost-benefit of restricting/banning lead use for hunting will be key in the argument
  - **AMEC** report prepared for ECHA in 2012 estimated that
    - Total costs of hunting ban at net present value, over twenty five years, are estimated at €2.7 billion (cf €45 million wetland ban)
    - Abatement costs were estimated to be in order of €9K/tonne cf steel as alternative

# Summary

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- **Classification & Labelling**
  - Harmonised EU classification for reproductive toxicity for lead metal will be in force by end 2017
  - Ammunition considered an article and thus not directly affected
  - Implications for manufacturing limited as existing workplace legislation concerning handling & use of lead already establishes health & safety standards.
    - May be potential implications for SEVESO status of sites if ENV classification of massive lead is passed
  - Major implication of harmonised classification will be inclusion of lead metal in REACH candidate list and then ultimately REACH Annex XIV (Authorisation)
  - Once on candidate list will be [REACH article 33 requirements](#) for ammunition

# Summary

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- **Occupational Exposure Limits**
  - Expect to see significant reduction in occupational exposure limits and lower blood lead removal requirements over the next 5 years
  - May have cost implications for manufacturing of lead ammunition and implications for professional use (especially in firing ranges)
- **EFSA**
  - The EFSA BMDL01 and conclusion of lack of demonstrable threshold for some health effects associated with lead will continue to have wide ranging implications in field of food safety, water quality, factory discharge limits, soil remediation, and general childhood health and wellbeing etc
  - Expect to see reductions in EU wide limits and additional risk management options being considered to limit exposure over the next decade.

# Conclusion- Does this legislation spell the beginning of the end for use of lead ammunition ?

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- **Amendments to EU CLP and OEL legislation are unlikely to have any significant impacts on use of lead in sporting ammunition but are likely to push up manufacturing costs.**
- **However there is no doubt that opinions such as those published by EFSA and recent reviews on health effects of lead will increase calls for substitution in remaining applications that result in wide dispersive use.**
- **EU REACH Authorisation requirements for use of lead metal will impact the sector sometime in the mid 2020's and EU manufacturers will need to be in a position to demonstrate safe manufacturing and use, make strong arguments that there are no alternatives and demonstrate that socio-economic benefits of use of lead in sporting ammunition outweighs cost to human health and the environment.**
- **There is the possibility that Member States that have already banned use of lead shot for hunting and sport shooting may push for full or partial EU wide restrictions through REACH**

# THE NEW STORY FOR LEAD



Essential



Sustainable



Innovative