NUCLEAR MEDICINE EUROPE
the industry association

Transport Experts
Nuclear Medicine Europe working group

Official Statement from Nuclear Medicine Europe and the Transport Experts Working Group

Nuclear Medicine Europe and the Transport Experts Working Group fully support the continued development and adoption of alternative materials to lead, wherever and whenever feasible. However, it is crucial to acknowledge that lead is currently indispensable for the safe transport of radioactive materials; without lead, transport in the nuclear medicine sector would not be possible.

We urge stakeholders to engage with their respective national authorities to raise awareness of this critical issue, especially as the European Commission has yet to vote on the REACH recommendation, with a decision expected in 2025. Although a ban on lead appears unlikely, it remains essential to keep authorities informed about the ongoing need for lead in the transport of radioactive materials to safeguard the operations of the nuclear medicine industry.

We refer to the previously published position paper (key points here below) by the Working Group on the potential ban of lead in the transport of radiopharmaceuticals. This paper outlines the significant challenges posed by such a ban and provides recommendations aimed at ensuring patient care is not compromised.

Key points

- Nuclear Medicine Europe recognizes the urgent need to reduce lead usage but emphasizes the nuclear medicine community's ongoing commitment to **maintaining stringent safety measures** during lead use, ensuring no direct contact with individuals.
- The European Chemicals Agency proposes **banning lead metal**, while raising concerns for the Nuclear Medicine community.
- Lead plays a **crucial role in radiation shielding**, ensuring safety during **transport of radiopharmaceuticals**.
- Existing lead production installations may become obsolete, leading to **delays or shortages, and increased costs**.
- Alternatives pose very **complex practical and economic challenges**.
- Recommendations include **exemptions for nuclear medicine**, advocating for a circular economy, engaging with legislators, and collaborating with patient associations to ensure safety and accessibility.

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Position Paper on the Ban on Lead for the Transport of Radiopharmaceuticals

The European Chemicals Agency's (ECHA) 11th recommendation to include lead metal in the REACH Authorization List* raises significant concerns within the Nuclear Medicine community

While the intention behind such regulations is undoubtedly to enhance safety and environmental protection, it is crucial to consider the potential challenges and consequences that may arise from the implementation of this ban.

*(https://echa.europa.eu/-/echa-recommends-eight-substances-for-reach-authorisation)

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CHALLENGES AND CONSIDERATIONS

1. Critical Role of Lead in Radiation Shielding

Lead has been a cornerstone material in the nuclear medicine industry for its unparalleled efficiency in shielding against radiation, ensuring the safety of both professionals and the environment.
The ban on lead for transport may compromise the industry's ability to uphold rigorous safety standards during the transportation of radiopharmaceuticals.

Furthermore, a potential ban of lead usage in nuclear medicine and a replacement by other materials may increase complexity of transport and use of radiopharmaceutical products. Ultimately such decision and norms may prevent patient access to a large array of diagnosis and therapies across Europe.

2. Longevity of Existing Lead Installations

Many facilities within the nuclear medicine community have invested in lead-lined walls, machines, and packages, designed to last for decades without posing any risk to individuals. Implementing a lead ban could render these existing installations obsolete, necessitating replacements or modifications, leading to extensive delays in providing radiopharmaceuticals to patients.

3. Impact on Treatment Costs

The prohibition of lead for transportation could lead to drastic increased costs associated with the treatment of patients, as alternatives may be more expensive or less efficient in ensuring the necessary protection during transport.

4. Practicality and Viability of Alternative Materials

Alternative materials such as steel or concrete are often impractical due to their bulkiness, making regular transport to hospitals much more challenging.
Tungsten, while effective, is extremely scarce and expensive, posing economic challenges for widespread adoption in the industry.
Materials like depleted uranium, while having shielding properties, introduce concerns regarding radioactivity, creating a new set of safety, regulatory and environmental issues.

POSITION AND SUGGESTIONS

1. Exception or exemption for nuclear medicine

Given that the use of lead in the nuclear medicine industry accounts for only a small percentage (1 to 2%) of the total lead consumption, we propose that this specific community be granted an exception or complete exemption from the lead ban.
This exception could be based on the industry's commitment to **maintaining and enhancing safety standards** through other means, such as advanced packaging technologies or additional safety measures during transport.

2. Advocacy for a circular economy

The nuclear medicine community actively pursues a circular economy approach, emphasizing **the smart use of lead-containing packages**.
Implementing effective recycling programs for lead-based shielding materials ensures environmental sustainability while mitigating the impact of a potential lead ban on the industry.

3. Engagement with Legislators

Every national association related to nuclear safety must **engage with national legislators** on radiation protection, articulating the concerns and challenges posed by the proposed lead ban. By fostering open dialogue, the nuclear medicine community can work collaboratively with regulators to find practical solutions that balance safety, environmental responsibility, and economic viability for the benefit of the patient.

4. Collaboration with Patients' Associations

The radiopharmaceuticals associations should actively **collaborate with Patients' Associations** to ensure that any regulatory changes do not compromise the accessibility and affordability of treatments.
Inclusion of patient perspectives in discussions can provide valuable insights into the real-world impact of proposed regulations on the patient experience.

CONCLUSION

Nuclear Medicine Europe’s Members are committed to prioritizing safety and environmental concerns while safeguarding accessible patient care. Striking a delicate balance between these priorities, Nuclear Medicine Europe remains dedicated to collaborative efforts with legislators, Patients' Associations, and regulatory bodies.

The Nuclear Medicine community's focus on innovation and patient-centric care stand resolute in the commitment to advancing nuclear medicine while placing patients' well-being at the forefront of every decision and action.

STATEMENT FOLLOWING ECHA 11TH RECOMMENDATION

Progressing the European Chemicals Agency's (ECHA) recommendation to include lead metal in the REACH Authorisation List would have severe consequences for a broad range of strategically important European industries and applications – including non-ferrous metals manufacturing, lead battery production, automotive, machinery and mechanical engineering industries, the marine sector, aeronautics, space, and defence, healthcare, clean energy – including solar, nuclear and offshore wind – the use of lead in the shielding of ionising radiation, to protect workers, patients, and members of the public, as an alloying agent, and many more for which lead is an essential raw material that does not have any technical or socio-economically viable alternatives.

In many economically and socially important applications the use of lead is not only unavoidable it is essential and extensively regulated. Many products and applications that rely on lead underpin the EU's policy objectives for the twin transitions and for a strategically autonomous, sustainable future.

Lead is a raw material that plays a key role in transportation, electrification, technological diversity, green energy and supply chain security, and to achieving recycling targets. In being sourced predominantly from the recycling of EU waste products it is strategically autonomous and reduces the need to seek critical raw materials from other regions, virtually eliminating any supply chain risks. Lead metallurgy is key to urban mining and the Circular Economy philosophy, and the EU's lead production and recycling technology is world leading. In short, lead plays a significant role in the EU industrial economy.

A move to include lead in the REACH Authorisation List will have the very real effect of stifling innovation and withdrawing investment from those critical EU Industries that still rely on its use.

And for what benefit? The EU already has a comprehensive framework of lead-specific legislation designed to manage risk to human health and the environment. ECHA itself has acknowledged that the minimum requirements to protect worker health appear to be set via the binding limit values for lead, with more stringent values already anticipated under the Carcinogens, Mutagens and Reprotoxic Substances Directive. Moreover, a broad range of product and end-of-life restrictions already strictly regulates the use of lead in automotive vehicles, electronics, consumer goods, and more – uses which represent 90+% of the volume of lead used in the EU.[1] And data shows that the majority of industrial emissions of lead now result from activities which are NOT in scope of REACH Authorisation.[2]

REACH Authorisation Listing for lead will simply add unnecessary bureaucratic burden, block investment and is not the best option to improve risk management, stimulate faster substitution, or reduce exposure. It would do little more than create uncertainty which undermines the financial viability of successful European companies. It effectively reduces the productivity and competitiveness of successful EU value chains, potentially opening the door to non-EU competitors that will continue to use lead to manufacture products that still have a societal need.

[1] International Lead Association, First Uses of Lead Metal in the EU.

[2] Arche Consulting Ltd, Pb Emission Inventory for the Environment.

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And there are equally unpalatable consequences for the regulator. The complexity of existing value chains means that inclusion of lead metal in REACH Annex XIV would result in an unprecedented number – many thousands – of Applications for Authorisation which would swamp ECHA and its committees, and the Commission's own REACH Committee and its decision-making process.

Adding lead to the REACH Authorisation List with prior knowledge of these consequences for Industry and regulators makes no sense, especially considering the ongoing review of the REACH regulation that is designed to make it more efficient.

We therefore urge the Commission to reject ECHA's recommendation, support EU businesses and continue discussions on what could be a more effective and proportionate risk management measure to address any residual concerns with lead exposures.

Statement issued on behalf of the International Lead Association and the Lead REACH Consortium, representing companies in the lead and lead value chain, supported by:

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EN
E-003016/2023
Answer given by Mr Breton
on behalf of the European Commission
(17.1.2024)

Lead is a very high concern substance due to its hazardous properties as toxic for reproduction. To protect human health and environment, lead is regulated in several sectors such as batteries[1], electronic equipment[2], end of life vehicles[3], toys[4] and chemicals[5]. Workers are trained to handle it safely and about other preventive measures and protected by the binding occupational exposure and biological limit values[6] (under revision)[7]. In parallel, the Commission continues assessing available risk management measures to identify remaining risks in non-regulated uses of lead and possible needs for targeted measures.

In response to the first question, the Commission does not intend to ban the use of lead. The European Chemicals Agency included lead in a recommendation on substances that should be subject to authorisation under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)[8]. The Commission is not obliged to follow this recommendation and does not intend to include lead in the authorisation list.

As regards the second question, the Commission promotes substitution of lead where feasible, and maintains regular contacts with stakeholders on progress to replace lead by less hazardous substances or technologies. However, regarding lead for sectors such as cultural heritage, conservation and creation of objects and buildings, offshore wind and energy infrastructure and high voltage submarine cables, there seem to be no available technically and economically feasible alternatives.

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[1] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 28 July 2023 concerning batteries and waste batteries.
[2] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
[3] Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles.
[4] Directive 2009/48/EC of the European Parliament and of the Council. of 18 June 2009 on the safety of toys.
[5] Including substances or mixtures for consumer uses (REACH Annex XVII Entry 30), paints (REACH Annex XVII Entries 16 and 17), consumer products (REACH Annex XVII Entry 63, paragraphs 1-10), gunshot (REACH Annex XVII Entry 63, paragraphs 11-14) and PVC (REACH Annex XVII Entry 63, paragraphs 1-20).
[6] Council Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC).
[7] Proposal for a Directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0071
[8] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of chemicals (REACH).