



Joint industry position on the RMOA proposal on Li salts proposed by ANSES

Key messages

- Lithium is essential for the global energy transition. While its use in lithium-ion batteries is the most known, uses in other products are also essential and often irreplaceable.
- International disagreements remain on the classification as toxic to reproduction.
- Important data gaps should be filled before reaching conclusions on other endpoints and on the actual risks. The lithium industry is ready to cooperate to fill those data gaps.
- Appropriate safety measures can and should be developed now to tackle risk where it may occur.
- Risk management measures should be based on sound and robust scientific data, as disproportionate risk management measures based on incomplete data would undermine the decarbonization effort of the EU and its competitiveness.

Our industries, representing companies active in the value chains of lithium production, non-ferrous metals, grease and lubricants, electric vehicles, batteries, mining and frits for ceramics, welcome the opportunity to comment on the proposal for a Risk Management Option Analysis (RMOA) on the uses of lithium metal and three of its salts (carbonate, chloride and hydroxide) developed by ANSES¹. Developing an RMOA early in the process is good regulatory practice, which helps the industry in anticipating and planning appropriate RMOs to protect workers and the environment while reducing regulatory uncertainty. However, considering the limited available scientific and exposure data, we believe that some of the measures proposed in the ANSES draft could have significant impacts on the development of the EU lithium industry, on EU's strategic autonomy and its overall competitiveness in several crucial sectors.

¹ French Agency for Food, Environmental and Occupational Health & Safety

Lithium is essential for the global energy transition. Lithium is recognized as a strategic raw material under the Critical Raw Materials Act, mostly because it is essential and irreplaceable in battery energy storage systems. Lithium-ion batteries are increasingly being used in small portable devices, stationary energy storage applications, and of course electric vehicles. Different lithium salts are also used in other key applications, such as grease thickeners for lubricants (used for instance for wind power turbines), ceramic frits and complex inorganic color pigments, specialty glass (cooktop stoves, electronic device covers), semiconductors, pharma (i.e., for mood disorder treatment), purification systems, military, medical devices (breathing assistance systems), cement, building products for insulation, and many more. Some of these uses obviously fit the conditions highlighted in the EUC communication².

Given the current very limited footprint of lithium production and use in Europe, it can be assumed that, in general, the presence of lithium in the environment in Europe is of almost exclusive natural origin. Lithium occurs in the environment at very different concentrations depending on the geological characteristics of each region. In developing Environmental Quality Standards (EQS) at EU level, it will be important to take into account the wide variability of natural background levels.

Three lithium salts have been evaluated by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) for their presumed negative effects on human reproduction. RAC proposed a repro 1A classification for the three salts, based mostly on data from the medical field. These exposure conditions in the latter are not comparable to the normal use of lithium compounds, whether in industrial conditions, by professionals or consumers, or even for general population (e.g., in terms of doses and exposure routes). Internationally, there are differing opinions (e.g. UK, Australia, Canada, Argentina, USA) on the causality between lithium exposure and negative health effects. In the absence of a global scientific consensus, it is unlikely that other countries/regions will adopt the same classification despite using the same criteria of the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This could result in a competitive disadvantage for EU companies on the global market.

Concerns are also raised on possible adverse effects as an endocrine disruptor, environmental effects on aquatic life, and other health effects at very low exposure levels (environmental concentration), even for the general population. These concerns are relatively new, and their reliability suffers from limited availability of robust datasets and studies. ANSES recognizes that little data is available in general, and that gathering additional data will be needed to assess actual risks and develop proportionate safety measures. Data gaps are particularly relevant to the effects at low exposure levels.

Considering these limitations, additional data should be gathered before drawing conclusions on actual risks for human health, the environment, and general population. The lithium industry is ready to cooperate with authorities to fill those data gaps, assess actual risks, and develop appropriate safety measures to protect workers, the general population, and the environment. For instance, study proposals on effects on aquatic life could be launched relatively soon to refine the environmental dataset.

The industry supports the prioritization of lithium among the substances for which an Occupational

² <https://op.europa.eu/en/publication-detail/-/publication/90926c62-0365-11ef-a251-01aa75ed71a1/language-en>

Exposure Limit (OEL) should be derived in the coming years. In addition, we note that some mining activities and large battery manufacturing plants have been added to the scope of the Industrial Emissions Directive, which result in the development of Best Available Technologies.

However, we would like to stress that setting up unreasonably low limits based on unproven concerns would be disproportionate, and it would unnecessarily harm an industry that is fundamental for the decarbonization effort of the EU. At this stage, the only possible conclusion on the effects of low exposure levels is that further studies are needed.

Risk management measures should be based on sound and robust data. A key limitation in the development of risk management measures is the actual number of existing, running plants and mines in the EU. Regarding lithium, significant focus is on ongoing and future projects, which intrinsically affects the available actual data that can be provided now, e.g., on exposure. This data limitation, and the resulting reliability and completeness aspects will be crucial to discuss, and expertise on processes (or analogy with processes developed elsewhere) to be brought in.

If new classification proposals are to be launched, a parallel assessment of appropriate risk management measures should be undertaken to facilitate implementation. Similarly, restrictions on uses or even Substance of Very High Concern (SVHC) identification and authorization proposals under REACH would be disproportionate compared to the actual risks, also considering the regulatory precedents of other metals and shortcomings of the authorisation process highlighted in the framework of the upcoming REACH revision.

Socio-economic considerations are not part of the hazard assessment of substances. However, this RMOA proves that a classification does have socio-economic consequences. Besides, the setting up of risk management measures must take into account the socio-economic impact. In the case of lithium and its salts, there is a concrete risk of further disadvantaging the EU lithium industry against other regions, but also the downstream sectors and their security of supply. More generally, there is a high risk of stigmatization of lithium, with negative effects on the achievements of the targets on mining, refining, and recycling strategic raw materials in the EU included in the Critical Raw Materials Act. These measures could also negatively impact the mandatory recycled content targets and material recovery rates set out in the Batteries Regulation, and potentially on electrical vehicle (EV) adoption.

In conclusion, risk management measures should be based on sound and robust scientific data, as disproportionate risk management measures based on incomplete data would be detrimental to the decarbonization effort of the EU, and it would be in direct contradiction with the need to boost the EU competitiveness, as recently highlighted by the Draghi report, the mission letters of the new Commissioners, the Antwerp Declaration, and the French President Emmanuel Macron. The final recommendations of ANSES should therefore take these elements into account, and refrain from suggesting risk management measures not supported by adequate data on risks, exposure, and emissions. The lithium industry acknowledges the limitations of some datasets and remains ready to cooperate with ANSES and authorities at large to generate more data to assess the actual risks and set up appropriate risk management measures. Industry is also carrying out its own industry RMOA exercise and will share the main outcomes.

A3M (Alliance des Minerais, Minéraux et Métaux)

ATIEL (The Technical Association of the European Lubricants Industry)

AVERE

CEFIC (European Chemical Industry Council)

ELGI (European Lubricating Grease Institute)

ERGTC (European Reach Grease Thickener Consortium)

Eurobat (Association of European Automotive and Industrial Battery Manufacturers)

Eurometaux (Association Européenne des Métaux)

Euromines

Frit Consortium

ILiA (International Lithium Association)

RECHARGE (The Advanced Rechargeable & Lithium Batteries Association)

UEIL (The Union of the European Lubricants Industry)

VSI (Verband Schmierstoff-Industrie e.V., the German Lubricant Manufacturers Association)

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