Briefing Note – Exemptions from Authorisation and REACH Article 58(2)

ECHA and Member State Committee Position

According to Article 58(2) of the REACH Regulation, "u*ses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*".

When assessing proposals for exemptions from the authorisation requirement in accordance with Article 58(2) that are submitted during the public consultation on the draft recommendation ECHA considers the following elements:

- There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed.

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV. Generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria.

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece(s) of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper. This can include EU legislation that allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only the aim of imposing measures (e.g., EU legislation which provides Member States the possibility to impose less

stringent requirements than that suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

On the basis of these elements, ECHA has concluded that:

i. Only existing EU legislation is relevant in the context to be assessed (not national legislation);
ii. Minimum requirements for controlling risks to human health or/and the environment need to be imposed in a way that they cover the life-cycle stages that are exerting the risks resulting from the uses in question;
iii. There need to be binding and enforceable minimum requirements in place for the substance(s) used.

In deliberations with the MSC Committee concerning the 6th and 7th Priority lists and lead compounds, ECHA has interpreted "proper control" to require that "*the existing EU legislation provides a binding substitution regime with timeline or review process*".

The MSC has agreed with ECHA's interpretation and has, in its opinion on the 7th draft recommendation on priority substances for inclusion in REACH Annex XIV concluded that *"there could possibly be grounds for exemption from authorisation for uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate that are regulated under the RoHS and ELV legislation*". However, they have highlighted that neither legislation covers the entire lifecycle of a battery and as such may not offer the same level of protection of human health and the environment that could be afforded by the REACH authorisation scheme.

As such the MSC Opinion is that the use in the production of lead batteries covered by ELV, but not other automotive or industrial batteries, may have grounds for exemption under REACH Article 58(2).

We still await ECHA's formal recommendation to the European Commission, which was due for end October; ultimately, the Commission is responsible for assessing grounds for granting REACH Article 58(2) exemptions from authorisation in any draft legislative text.

To date only one REACH Article 58(2) exemption has been granted by the Commission: for the use of certain phthalates in the immediate packaging of medicinal products (Regulation 143/2011) on the basis that there was "*specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of risks*".

Industry's Response

The use of the four lead compounds is industrial and restricted to the workplace as the compounds are transformed into other lead compounds (lead metal and/or lead dioxide) during the manufacturing process. Less than 0.1% of the four lead compounds are present in the battery that is placed on the market. Moreover, batteries are sealed articles where consumer and environmental exposure during use is not possible and they operate in a closed-loop with a very efficient collection and recycling system. We believe that this is an important element in defining the scope of the analysis required to address the use (or categories of use) that is proposed to be exempted.

EU legislation should always be considered holistically. Given the principle of proportionality, additional regulation should only be added where there are existing measures if it has a demonstrated added value, to avoid double regulation. We therefore believe that when one considers the wealth of existing lead-specific EU legislation that exists to control risks to human health and the environment, in addition to substitution drivers in the EU Batteries and ELV Directives, it is not an efficient or proportionate regulatory action to include use of the four lead compounds in battery production in Annex XIV of REACH and that Commission should consider applying REACH Article 58(2) to exempt this use.

1. There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted [i.e. lead battery

production]. This legislation establishes minimum requirements for controlling risks to human health or/and the environment and specifically refers to lead and lead compounds.

a. The existing EU legislation consists of a binding biological and occupational exposure limit as specified in the Chemicals Agents Directive (supported by mandatory requirements to conduct medical surveillance on lead exposed employees).
b. Pregnant and breastfeeding workers are also specifically protected under Directive 92/85/EEC, which in Article 6 ("*cases when exposure is prohibited*") stipulates that they may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardise safety or health. In Annex II, in the context of Article 6, the Directive refers explicitly to lead and lead derivatives. The Directive therefore sets specific risk management measures to protect pregnant and breastfeeding workers from exposure to lead and thus supplements and supports the risk management measures provided by the binding exposure limit and substitution requirement stipulated in the Chemical Agents Directive.
c. Battery manufacturing and recycling operations are in scope of the Industrial Emissions Directive and accompanying non-ferrous metals Best Available Technique Reference Document (BREF). The latter includes binding Associated Emission Values (AELs) for lead (and other hazardous substances) that reflect best available technique and ensures the same minimum level of control of risks throughout the EU.
d. Any residual risk of lead exposures resulting from release of lead from battery manufacturing and recycling operations as a result of man via the environment concerns are also covered by existing EU legislation that establishes maximum levels of lead in ambient air, drinking and surface water, food etc.

2. We do not agree with ECHA and the MSC that REACH Article 58(2) requires that the existing EU legislation provides a binding substitution regime in order to demonstrate proper control of risk. However, notwithstanding this, we have highlighted that in the context of industrial use of the four lead compounds, the Chemicals Agents Directive includes a provision for substitution in its hierarchy of controls. Moreover, the battery itself is regulated either by the requirements of the End of Life Vehicles Directive and/or the EU Batteries Directive. Both legislative acts include provisions for encouraging substitution of lead batteries.

a. The Batteries Directive (2006/66/EC) includes a substitution provision that requires Member States with battery manufacturers established on their territory to "*promote research and encourage improvements in the overall environmental performance … throughout their entire life cycle as well as the development and marketing of batteries and accumulators which contain smaller quantities of dangerous substances or which contain less polluting substances, in particular* ***as substitutes for mercury, cadmium and lead***." It also includes several other provisions aimed at substituting heavy metals (e.g. Article 4 – Prohibitions), which should be seen as specific risk management measures.

b. The End of Life Vehicles Directive (2000/53/EC) was adopted in September 2000 with the aim of reducing waste from end-of-life cars as well as at the improvement in environmental performance of all the economic operators involved in the lifecycle of vehicles by ensuring that the constituent parts of a car can be recycled. As a key component in the functioning of a car, this directive also applies to car batteries. Under Article 4(2)(a) a number of substances, including lead may not be used in cars. Annex II provides for exceptions to these restrictions, including the use of a number of these substances in batteries.

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