ChemicalWatch
GLOBAL RISK & REGULATION NEWS

EU industry questions 'effectiveness' of REACH authorisation

Lead and borate associations concerned with recommendations

4 September 2014 / Europe

European industry associations are questioning the regulatory effectiveness of the REACH authorisation process, after Echa launched its consultation on the 22 substances recommended for inclusion in the authorisation list. The list includes four borates, seven lead substances and seven phthalates (CW 1 September 2014 (http://chemicalwatch.com/21026/echa-consults-on-22-substances-for-reach-authorisation)).

Commenting on the recommendation process, Roger Doome, secretary general of the European Borates Association (EBA), says Echa's decisions are "very automatic". He says it is not part of the agency's mandate to see that its part in the procedure is "efficient, proportional or has regulatory effectiveness". "Echa makes a list and passes the list to the Commission," he adds. The agency says it is required to recommend priority substances from the candidate list for inclusion in the authorisation list. These substances are presented to the European Commission, taking into account the opinion of Echa's Member State Committee. The final decision is taken in a comitology procedure with scrutiny involving EU member states and the European Parliament.

Dr Doome says that downstream users of the proposed borates are more interested in the Commission's parallel consultation, facilitated by Echa, on the possible socio-economic impacts of authorisation on the substances. It is the first time this type of consultation has been conducted at this stage of the authorisation process. He says this is the most important aspect of the decision on borates, and points out that the substances have been included, for the first time, in the Commission's triennial report, *Critical raw materials for the EU*, released in June.

A restricted supply could impact the economy, says Dr Doome. He adds that there are essential uses of borates that if restricted could impact some of Europe's major industries. "For example, many EU countries use nuclear plants for energy production – it's impossible to operate a nuclear plant without boric acid," he adds.

For safety reasons, it is essential because the plants require boron isotope to control radiation and contain nuclear waste, he adds. "Producers of nuclear energy are likely to be granted authorisation but the authorisation period is only granted for seven years, whereas the life of a nuclear plant is around 40 years. The concern is around how they can guarantee the safety of these plants," says Dr Doome. However, Echa points out that seven years is not an automatic or maximum review period. There are several considerations which may lead to a longer review period, or up to 12 years, such as the length of an applicant's investment cycle, the costs of using alternatives or the socio-economic benefits being higher than the risks.

Expressing its own concerns, the lead industry opposes the recommendation of four of the lead compounds, lead monoxide, lead tetroxide, tetralead trioxide sulphate and pentalead tetraoxide sulphate, which are used to make certain batteries. International Lead Association (ILA) regulatory affairs director, Dr Steve Binks says: "ILA believes that authorisation is not the most proportionate and effective risk management option for the four lead compounds used in the manufacture of lead batteries."

He says this is because there are no proven alternative substances, and the compounds are not present in batteries placed on the market. "REACH authorisation would be restricted to workplace exposures and this phase of the lifecycle of a lead-acid battery is already extensively covered by existing EU workplace legislation, including a Europe-wide binding occupational exposure limit value (BOELV) and biological limit value (BLV)," he adds.

The trade group European Council for Plasticisers and Intermediates (ECPI), says it is less concerned by the recommendation of the seven phthalates, used in a number of plastics applications. The proposed phthalates are classified and “very well-known for their reproduction toxicity effects”, it says.

Over the last 20 years, European manufacturers have progressed in the development of alternatives to the classified phthalates with other non-classified plasticisers, it says. “As an example, 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters has been replaced by high molecular phthalate DINP, di-isononyl cyclohexane dicarboxylate DINCH or mono or di benzoate in flooring applications.”

Industry and other interested stakeholders have until 30 November to submit comments on the substances through both Echa and the Commission's consultations.

Leigh Stringer

Further Information

Report on critical materials (http://ec.europa.eu/enterprise/policies/raw-materials/files/docs/crm-report-on-critical-raw-materials_en.pdf)

Echa consultation (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list)