

ENVIRONMENT, HEALTH AND SAFETY NEWSLETTER

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1° REACH Regulation

- **Thirteen New Proposals for Substances of Very High Concern**

On 28 February 2012, the European Chemicals Agency (ECHA) published new proposals to identify an additional thirteen chemicals as Substances of Very High Concern (SVHC). Some of these substances are used in the battery industry, although not as primary substances. EUROBAT's Committee on Environmental Matters (CEM) will discuss the status of these substances at its next meeting at the end of May.

- **Data on Candidate List Substances in Articles**

From 5 March 2012, the ECHA has begun publishing information on articles available for consumer use on the EU market that contain SVHCs included on the Candidate List. This is partly to remind importers and producers of their legal obligations to notify when their articles contain substances on the Candidate List.

The data is based both on the notifications that companies have submitted to ECHA and on the information contained in the registration dossiers.

- **Classification and Labelling Inventory Launched**

On 12 February, the ECHA launched the Classification and Labelling Inventory of chemicals on the EU market. The database contains classification and labelling information on notified and

registered substances received from manufacturers and importers, as well as a list of harmonised classifications. It currently contains over three million submission records covering more than 90,000 chemical substances.

- **Evaluation Report 2011**

The ECHA published its 2011 Evaluation Report in late February, which presents details and figures on its REACH dossier evaluation activities and their respective output. The report concludes that a large part of the examined registration dossiers raise compliance or quality concerns to different degrees. Resultantly, ECHA strongly encourages registrants to proactively update their dossiers, taking into account three recommendations:

- Precisely identify substances
- Improve and update Chemical Safety Reports,
- Provide testing proposals and hazard assessments in the registration dossier to satisfy information needs for read across approaches.

The report also contains recommendations on the relevance of particular tests, the test material for the specific substance, substance identity, and reproductive toxicity testing; as well as how to avoid shortcomings in other areas.

2° Quality management program for the production of Lithium cells and batteries

The UN recommendations for the determination of a quality management programme for the production of Lithium cells and batteries shall apply from 2013 within the scope of the Transportation of Dangerous Goods Regulations

This will introduce visible labelling of Lithium batteries and their packaging regarding compliance with the testing procedure in section 38.3 of the UN test manual

The recommended quality management programme for the transportation of dangerous goods will be binding from 2013. This is applicable to the transport of produced Lithium cells and batteries in the scope of the Dangerous Goods Regulations when transported by air (ICAO T.I.), sea (IMDG Code) and road/rail (ADR/RID).

During the meeting of the International Civil Aviation Organization (ICAO)'s Dangerous Goods Panel in October 2011, a related request to include the programme in the ICAO T.I.2012 was accepted. It should be noted that the inclusion of the quality management programme in the IMDG Code 2013 and ADR/RID 2013 is little more than a formality. Manufacturers of Lithium cells and batteries now have the rest of the year to develop and install the quality management programme, and integrate it into their existing quality programmes.

The quality management programme and the documents to be prepared for the safety tests will have to be presented to the competent authorities on request.

As demanded by the US Department of Transportation (DOT), EU level discussions in 2011 sought to introduce a visible labelling of Lithium batteries and their packaging, in order to comply with the testing procedure in section 38.3 of the UN test manual. Although an agreement was made to introduce the required safety labelling, the proposed symbol has since been criticized as inappropriate. It is probable that a new request – with a different and more appropriate symbol – will find a majority at the UN sometime this year. If so, the compulsory labelling provisions will be regulated by the aforementioned Transportation of Dangerous Goods Regulations; most likely from 2015.

Both the introduction of the quality management programme and visible safety labelling for Lithium batteries and their production will be of benefit to battery manufacturers and users. Firstly, their additional safety measures can be used to build confidence in Lithium battery technology during dialogue with related authorities and international committees. Secondly, it will be easier to identify the manufacturers and other market participants that – whether

consciously or unconsciously – contravene the regulations; especially regarding visible safety labelling.

EUROBAT will further highlight the necessity:

- of complying with the transport regulations and to optimize quality security within the entire battery industry (incl. assemblers)
- of independently revising the security tests (38.3 of the UN manual) regarding state-of-the-art technology by the battery manufacturer and users
- of establishing a collaborative cooperation between industry and authorities, especially after accidents or other security-relevant incidents

also, because only by this appropriate rules in the transport of Dangerous Goods Regulations can be achieved.

3° Transport of new and used or waste Large Format Lithium Batteries

This section outlines the results of the international meeting of car and battery manufacturers and battery recyclers on 21/22 February 2012 in Brussels, as well as the joint industry conference call on 16 April 2012 and the resultant actions in international committees for dangerous goods

- **Transport of Lithium ion industrial batteries > 35 kg/per battery in air traffic;**
 - **Coordination and determination of safety relevant requirements in a new ICAO Special Provision (SP Axxx)**

The ICAO Working Group Meeting for Lithium batteries from 6 – 10 February 2012 in Montreal dealt mainly with the future transport regulations of Lithium portable batteries. However, the industry still outlined in a joint Working Paper (DGP-WG/LB/1-WP/6) that the current approval process is impracticable and unacceptable with regard to future production of large Lithium ion batteries for the mass market. This topic will be on the agenda during the next ICAO DGP Working Group of the Whole Meeting, which is scheduled to take place around October 2012.

The contents of a new SP Axxx in the form of a new Working Paper have to be submitted to ICAO by August 2012. The appropriate contents of the new Special Provision are scheduled to be developed in two different directions.

1. The German working group of the car and battery manufacturers will pursue the inclusion of additional requirements regarding an “**open-fire**” and a “**drop**” test.
2. The Rechargeable Battery Association (PRBA) and RECHARGE will check how additional safety (which will be gained by passing an open-fire and drop test) can be achieved through the choice of appropriate packaging.

It must then be determined whether these requirements for battery testing and packaging can be recorded as “either/or” in the new Special Provision. Doing so would increase flexibility for producers, which would have a significant impact for the different applications of large lithium batteries.

Participants will also make clear when presenting the new Working Paper that requirements – as determined in existing and coming international Standards – for the safe application of Lithium Batteries will also increase safety during their transportation.

➤ **Interpretation of the authorization according to the existing special provision A99**

As mentioned in previous newsletters, the interpretation of the authorization demands that before each individual dispatch of lithium batteries for transportation, an authorization of the respective sender state will be required. Such a requirement is not practicable for future series production and the mass transport of lithium batteries > 35 kg gross mass (incl. spare part supply).

It is unlikely that a majority for the new SP Axxx in the ICAO DGP will be found by October 2012. With this reality, it could be an appropriate solution to provide an interpretation of the authorization in the SP A99 for the benefit of the battery manufacturers and users. Related to this, Eckhard Fahlbusch prepared a draft of a second ICAO Working Paper and sent it to the participants of the aforementioned industry meeting between car and battery manufacturers and battery recyclers. This will also be submitted during the meeting of the wider ICAO Working Group in October 2012, where it should find a majority when the adoption of the new SP Axxx is again postponed. The paper's submission to the ICAO will be made via PRBA by mid-August 2012, and will follow on from the Working Paper ((DGP-WG/LB/1-WP/6) of 12 January 2012.

The adoption of the 2nd Working Paper will clarify that the batteries to be transported and the packaging would only have to be approved once. Approval would then be granted to batteries and their packaging, rather than their respective transport. The more general approval could then be used for each battery transport until its expiry date or revocation.

• **Transportation Directive for used lithium batteries (portable and industrial batteries) for road/rail and sea**

➤ **Transportation of intact/undamaged lithium batteries**

There is consensus that the transport of intact/undamaged large lithium industrial batteries (for maintenance, inspection and recycling) should be undertaken in line with Packaging Instruction 903, which is focused on the transport of new Lithium batteries. This procedure would be analogous to the transport of new and intact Lead batteries by road according to the ADR Special Provision 598.

It can be expected that above 95 % of used Lithium batteries are in an intact/undamaged condition and can be transported as described above.

➤ **Transport of damaged lithium batteries**

There is consensus that the criteria to determine “damaged” batteries shall comply with the principles of the Special Provision A154 in air traffic. This specifies that Lithium batteries are damaged when the manufacturer classifies them as damaged **because of safety reasons**; either as a consequence of malfunction, or the possibility of endangering heat generation through fire or short-circuit.

More detailed criteria shall not be legally regulated. For the transport of damaged Lithium batteries, the criteria of the Special Provision A154 have been included in the new Packing Instruction that has been applied by the industry. On the basis of these general criteria, those responsible shall decide in individual cases whether the batteries to be transported are to be classified as damaged, and accordingly transported under the new Packing Instruction.

The industry proposed in the new Packing Instruction that approved packaging shall meet the requirements of Packing Group II. When requesting an approval for the transport of prototypes according to Special Provision A88 or the transport of damaged Lithium batteries, the competent authorities determine authorized packaging which meets the requirements of Packing Group I. It is expected that this controversial difference will be discussed during the related UN meeting from 25 June – 04 July 2012. If a majority is to be reached over the

request for a new Packing Instruction, it is possible that the Packing Group I will have to be accepted.

➤ **Transport of used prototypes/sample batteries**

The ADR Special Provision 310 is applicable when transporting not tested or incompletely tested new prototypes/sample batteries by road. There is consensus that the transport of used prototypes/sample batteries (intact or damaged) is permissible when meeting the requirements of the ADR Special Provision 310. When necessary, there are additional safety measures to be determined or made independently.

4° Implementation of the Seveso Directive in connection with the CLP-GHS-Regulation

The final Hydrotox reports from 8 March 2012 confirm an effect level of > 10 mg/l regarding the algae toxicity of the mixture “Battery Lead Oxide”.

This result will mean that Lead battery production in EU Member States is not subject to the expensive and cost-intensive extended obligations of the Seveso Directive; therefore saving costs in a double-digit million euro range for Europe’s Lead-acid battery production industry.

Assuming that these results for Battery Lead Oxide can be transferred to Lead Battery Paste and Lead containing waste, there will be the following classifications:

- Battery Lead Oxide = preparation/mixture = H412 (corresponds R52/R53 on basis of the Hydrotox results in 2006 and 2012) = **not relevant for Seveso** and no labeling with the symbol “environmentally hazardous”.
- Lead Battery Paste = preparation/mixture = H412 (corresponds R52/53 (on basis of the Hydrotox-results of 2006 and 2012) = **not relevant for Seveso** and no labeling with the symbol “environmentally hazardous”.
- Waste containing Lead whose composition is dominated through Battery Lead Oxide and Lead Battery Paste = H412 (corresponds R52/53) = **not relevant for Seveso** and no labeling with the symbol “environmentally hazardous”.
- Lead metal in compact forms (e.g. Lead bars) = substance = H412 (corresponds R52/53) = **not relevant for Seveso** and no labeling with the symbol “environmentally hazardous”.
- Red Lead = substance = H400/410 (corresponds R50/53) = **relevant for Seveso** and labeling with the symbol “environmentally hazardous”.

Currently ZVEI’s battery association is preparing a position paper with the following conclusions and recommendations:

- Legally secure implementation of the Seveso Directive for the Lead battery production in compliance with the European Test Method Regulation.
- Until 01 June 2015 Battery Lead Oxide will be classified, labeled and packed as mixture according to Directive 1999/45/EG (article 64 of the CLP-GHS Regulation). The resulting unnecessary labeling of Battery Lead Oxide as “environmentally hazardous” refers to the European CLP-GHS-Regulation and the Dangerous Goods Regulations.

After finalisation, EUROBAT will adopt this position paper for respective lobbying activities in the relevant member states.

The Preparation Directive (1999/45/EC) will be repealed on 01 June 2015. From this date, mixtures including Battery Lead Oxide and Lead Battery Paste will be subject to the scope of the CLP-GHS-Regulation (on the classification, labelling and packaging of substances and mixtures). The second ATP (adaption to technical progress) of the CLP-GHS-Regulation leads to many amendments for their environmental classifications.

In parallel, work is in progress to adapt the Seveso Directive to the CLP-GHS Regulation (Seveso III Directive). This requires an evaluation of how the changed evaluation methods for the chronic toxicity (long term tests for 7 or 28 days according to the GHS transformation protocol) and the chronic aquatic toxicity (considering the degradability and/or bio-availability of metals) will apply to mixtures including Battery Lead Oxide and Lead Battery Paste. **This evaluation incl. of possible further evaluations has to be finalized before 01 June 2015.**

According to the current draft of the Seveso III Directive, substances and mixtures of category 3 – specified as “chronic” (H412, corresponding with R52/53) - are no longer relevant for Seveso.

It should also be noted that an extension of the scope of the Seveso Directive in regards to chronic effects of substances (so-called classification as STOT RE Specific Target Organ Toxicity - **Repeated** Exposure) will not occur, as the Major Accidents Ordinary is focused on acute danger. Otherwise, inorganic Lead and Nickel compounds such as Lead Oxide and Nickel hydroxide – according the classification (STOT RE1 (H372)) - have to be classified as toxic regarding the Seveso II Directive. There would be a tonnage threshold of 200 t (present in an establishment) when applying the extended obligations.

The compliance with the CLP-GHS-Regulation – incl. corresponding documentation – is of major impact with regard to the Seveso Directive. This is especially the case when – for example – fire administrative investigations are carried out which also scrutinize formal aspects regarding the application of the extended obligations.

5° Intended OELs and BLvs for Cadmium, Lead and Nickel

This item regards the implementation of the risk-acceptance-concept of the German Committee for Hazardous Substances (AGS) publication 910 and the resulting “risk values and exposition-risk-relationship (ERB)” at work. There are different outcomes for each substance:

- **Cadmium:** the probable preparation of a new technical rule (TRGS) Cadmium in the AGS – for the benefit of the industry
- **Lead:** there will be a classification of lead as carcinogenic and derivation of ERB values in the AGS, probably by 2012/2013, and focusing on the limit value for Lead in particulates of 0.5 µg/m³. After that, there will probably be revision of the TRGS 505 (Lead) from 2013.
- **Nickel:** there will be ERB values of 2 µg/m³ (tolerance risk), 0.8 µg/m³ (acceptance risk until 2013), and 0.08 µg/m³ (acceptance risk after 2013 – from 2018 at the latest) before adoption in the sub-committee III of the AGS in 2012
- There is intended inclusion of substance specific biological equivalents for the acceptance and tolerance risk in the AGS publication 910
- The “presumption of conformity” of a substance specific TRGS is the most important criterion for a final validity of the TRGS

Cadmium: It can be expected that the ERB values for Cadmium will be decided in the AGS in 2012, with a recommendation to finalize a TRGS Cadmium in order to implement the risk-acceptance concept in the new AGS publication 910. During finalization and implementation of

a new TRGS Cadmium, the ERB value for Cadmium in regards to the tolerance risk of 1.6 $\mu\text{g}/\text{m}^3$ would be the basis for the threshold limit value. **From the industry's point of view, the biological parameter is of higher priority for assessing employees' health.**

During a meeting with EUROMETAUX and the international Cadmium Association (ICDA) on 17 January 2012, Eckhard Fahlbusch reported on the possible impact of the German risk-acceptance-concept being adopted by the EU. The European industry associations (incl. EUROBAT) support the initiative of the German industry to finalize a new TRGS Cadmium. Following a decision of the AGS in consensus with its social partners, this technical rule could be applied at EU level if necessary.

Lead: The German authorities have recognised the urgent need for a revision of the TRGS Lead. This comes alongside the ongoing discussion in the AGS about the implementation of the German proposal to classify Lead and inorganic Lead compounds as carcinogenic (category 1B), and the resulting derivation of ERB values for Lead.

The German proposal from 2006 is comparable to the classification of the IARC (International Agency for Research on Cancer) regarding inorganic Lead compounds as "*probably carcinogenic to humans (Group 2A)*". Following the results of the meetings of the AGS sub-committee III on 14/15 February 2012 and its Working Group for metals on 16 February 2012, ERB values for lead are set to be determined by summer 2012. This implies that the AGS sub-committee II will decide upon the aforementioned classification of Lead as carcinogenic.

It must be expected that the derivation of ERB values in the AGS regarding the acceptance risk will focus on the limit value for Lead in particulates of 0.5 $\mu\text{g}/\text{m}^3$ (European Ambient Air Quality Standard for Lead). On the basis of corresponding AGS decisions in 2012/2013, a revision of the TRGS Lead from 2013 could be necessary. The representatives of the industry are intending to prevent this unilateral approach in Germany in cooperation with EUROBAT and ILA.

Nickel: 75-80 % of Europe's Lead and Cadmium is produced and used for the manufacture of batteries. Accordingly, the influence of the battery industry regarding the revision of the TRGS Lead and the development of a new TRGS Cadmium is relatively strong. For Nickel however – where a similar approach to that taken with Cadmium is beginning to emerge – a more passive observation of the discussion on its debated ERB values is required. This will be conducted between a much wider group of concerned parties, with the Steel Industry playing an especially important role. At the latest, dialogue will begin after the decision of the AGS sub-committee III (limit values); if necessary before the end of 2012.

Substance specific biological equivalents: The ERB values at work - regarding the acceptance risk - focus on the risk of the non-occupationally exposed population. Resultantly, substance-specific biological equivalents regarding the acceptance risk will be included in the AGS publication 910. Biological Equivalents for the acceptance risk are based on the system of the risk-acceptance concept of human biomonitoring values from which the German Research Council (DFG) derived their BAR values (background concentration of the general population). In discussion are: **for Lead 90 $\mu\text{g}/\text{l}$ blood, for Cadmium 1 $\mu\text{g}/\text{l}$ blood respectively 0.8 $\mu\text{g}/\text{l}$ urine and for Nickel 3 $\mu\text{g}/\text{l}$ urine.**

This development makes clear that the common understanding of social partners in the AGS is that neither ERB values nor biological equivalents are binding limit values. There remain appropriate discretions which are indispensable for pragmatic solutions in technical regulations.

The importance of substance specific TRGS: When dealing with the 2006 revised TRGS Lead (provided that TRGS regulations are complied with), it is deductible that the requirements of the legislation on hazardous substances are fulfilled when handling hazardous substances containing Lead. This increases the legal certainty for the production of Lead batteries.

During any future revision of the TRGS Lead, the battery industry will fight to preserve the presumption of conformity at all costs. Analogously, equivalent provisions should be established during negotiations for the TRGS Cadmium and Nickel. This is achievable by determining appropriate mandatory protective measures (technically, organizationally, personally) in the TRGS. For these cases, the contents of the TRGS when handling the included substances would be decisive. Once achieved, the risk-acceptance-concept of the AGS publication 910 is considered to be implemented and will be replaced by the contents of the respective TRGS. This would also be an appropriate solution at European level.

6° Battery Directive

Commission Regulation 1103/2010/EU on a.o. the capacity labeling of automotive batteries will enter into force in the course of May.

During a recent meeting with the European Commission, EUROBAT highlighted that standard EN 50342-1, which the Regulation refers to for automotive batteries, does not cover motorcycles batteries used in starting, lighting and ignition functions (which is the definition of automotive batteries under the Battery Directive). As a result, the rules laid down in the Regulation for the calculation of the capacity of automotive batteries cannot apply to these batteries. The European Commission is aware of the issue and promised to issue a clarification on this matter in the coming months.

In addition, EUROBAT is still in discussion with the European Commission on the fact that the tolerance for the labelling of the capacity and cold cranking current for automotive batteries (+/- 10%) goes way beyond what the revised standard EN 50342-1 authorizes. In order not to create confusion for aftermarket batteries, battery manufacturers request that only the tolerance set in the standard be accepted. There also, the European Commission promised to look into the matter should this increased tolerance indeed create confusion for aftermarket batteries.

Finally, the European Commission is currently preparing draft rules on the export of waste batteries and accumulators. A first draft should be submitted to representatives of EU Member States in the coming months.

7° ECHA Guidelines for the provision of Safety Data Sheets for substances and mixtures

The effective exchange of information in the supply chain for the use of substances and mixtures is of highest importance for the implementation of REACH. The central communication instrument for this exchange has become the Safety Data Sheet according to Annex II of the REACH Regulation.

The European Chemical Agency (ECHA) announced that the new guideline is now available in 22 EU languages. All are available by following the link below:

<http://echa.europa.eu/de/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach>.

It is probable that competent national authorities will take the ECHA Guideline as basis for the review of data safety sheets of substances and mixtures. With this in mind, battery manufacturers should inform their supplier of which body will be responsible for the provision of the safety data sheets of their supplied substances and mixtures.

Importantly, it remains true that according to the new ECHA Guideline for implementation of REACH, **no safety data sheets are necessary for articles or products like batteries**. The information according to Article 33 about substances in products from the candidate list will also not be transferred into a safety data sheet.

The legal importance and the requirements regarding content and quality of safety data sheets have increased considerably according to Annex II of REACH regulation. **Even if in practice**

the customers would like to have safety data sheets, none for batteries should be issued. The leaflets described under 8° for the safe handling of batteries remain a service for customers of the battery industry on a voluntary basis.

8° Leaflets for safe handling of Lead batteries and Lithium batteries

ZVEI's battery association has revised the leaflet for safe handling of Lead batteries and prepared a new leaflet for safe handling of Lithium batteries. The leaflet for Lead batteries can be used as a sample for an organization's own leaflets or as direct customer information. In addition, it is an appropriate document – among others – for transport of Lead batteries as dangerous goods in air traffic.

The leaflet for Lithium batteries is not directed towards the customer/user of Lithium batteries. **Instead, it is a manual or guideline for Lithium manufacturers to set up industry- or product-specific leaflets themselves.** Once completed, it will describe the main components of the battery system or battery technology and its key features. Because the range of different Lithium battery technology substances and technologies is still increasing, the leaflet is only able to contain general information for primary and rechargeable Lithium battery systems – e.g. for fire-fighting.

In order to avoid misunderstandings and confusion, users should clearly state that this information is not a safety data sheet but “voluntary product information on the basis of the format of the safety data sheet”.

EUROBAT will adopt the leaflets in English language as soon as possible.

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