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ENVIRONMENT, HEALTH AND SAFETY NEWSLETTER

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1° REACH Regulation

- **Lead Oxides and Lead Sulphates**

As mentioned in issue 3/2012 of this newsletter, the European Commission has asked the European Chemicals Agency (ECHA) to prepare 38 dossiers nominating substances of very high concern (SVHC) to the Candidate List for Authorisation. 21 of these substances are lead-containing compounds, including a number which are widely used in the production of batteries (Lead Monoxide, Lead Tetroxide, Tetralead Trioxide Sulphate, Pentalead Tetraoxide Sulphate). EUROBAT has responded this this consultation which ended on 18 October. The files submitted as answers to the consultation are available on the members only section of our website.

On 19 December, all four Lead compounds were formally added to the Candidate List for Authorisation, due to their reprotoxic properties. Across the next year, ECHA will likely make proposals to the European Commission for the most adequate risk management option (RMOs) to be taken (authorisation, restriction or other measures) for each substance, before beginning their assessment of the four Lead compounds for prioritisation. The table below provides an idea of a tentative timetable for the evaluation of the substances. There can be additional delays or procedures in the course of the process, which may result in the timing to be delayed.

December 2012	*Four Lead compounds to be added to the Candidate List of SVHCs*
December 2012	*ECHA to publicise non-confidential responses to the public consultation*
2013	*ECHA to conduct and improve RMOs for the four Lead compounds*
February 2014	*ECHA to begin assessment of the four Lead compounds for prioritisation*
June-September 2014	*Public Consultation for ECHA's Draft Recommendations of prioritised substances*
January 2015	*Final ECHA Recommendations of Prioritised Substances for Authorisation to EC*

EUROBAT has advocated that risk managements options other than authorisation may be best suited for the said substances, and that the battery is already well covered by legislation protecting human health and the environment, thereby qualifying for an exemption from authorisation under article 58.2 of the REACH Regulation. All of these arguments are currently under further development with the support of the REACH Lead Consortium, other industry stakeholders and legal support.

- **Harmonized Classification of Lead**

ECHA - at the request of the Swedish Chemicals Agency - has launched a consultation on the harmonized classification of Lead, which closed on 7 December. EUROBAT answered to the consultation by supporting the arguments and comments put forward by the REACH Lead Consortium and International Lead Association.

- **Nickel compounds**

The French agency for food, environmental and occupation health and safety (ANSES) has been enlisted to evaluate substances to be proposed for inclusion onto the Candidate List of SVHCs by the French government. This agency is at present preparing RMO analyses for a number of Nickel compounds, including Nickel Dihydroxide, which is used in battery manufacturing.

- **Briefing of EC and Member State officials**

For all processes linked to the REACH Regulation, it is essential that European Commission and Member States officials have a fair understanding of the battery industry, its products and the use of substances considered so that they can take informed decisions. EUROBAT has therefore been dedicating efforts in the past weeks to brief the said officials:

  - A delegation of EC officials (DG Enterprise and DG Environment) visited Enersys' plant in Arras on 25 October, to get acquainted with the manufacturing process of Lead-based batteries, the implementation of EU legislation aimed at protecting human health and the environment, as well as with EUROBAT's Blood Lead Reduction Programme.

  - A group of EC officials from the same Directorates General attended part of the meeting of EUROBAT's Committee on Environmental Matters (CEM) of 6 November where they were able to exchange with EHS managers of our member companies and deepen their understanding of our industry. The meeting was also the occasion to discuss the argumentation put forward by EUROBAT in our answer to ECHA's consultation on the Lead oxides and Lead sulphates mentioned above, and to address related questions raised by officials.

  - Individual CEM members have been contacting Member State officials in the countries they operate in, to provide similar information and answer any questions on the industry and its use of substances under evaluation. Member States play an important role in the decision-making process under the REACH Regulation.

- **REACH in Brief**

  - ECHA has published company names and registration numbers from REACH registration dossiers. For more information, please visit: http://echa.europa.eu/view-article/-/journal_content/4d3d287d-0d31-47c8-8468-75b2c51e3de9

  - Companies had until 1 December 2012 to update their SDSs for substances and mixtures to comply with the amendments of the REACH Regulation. The respective REACH consortia have provided their members with that information. For more information, please visit: http://echa.europa.eu/web/guest/view-article/-/journal_content/eca0d8de-be4d-4e28-a68b-47fd3c01d079

2° EUROBAT Blood Lead Mitigation Workshop – 7 November 2012

EUROBAT introduced a Blood Lead reduction programme for the battery industry in 2001, the target values of which were revised in 2006. Blood Lead levels in the industry have decreased steadily since then. In order to envisage the next steps for this programme, EUROBAT held a workshop on 7 November, where participants could discuss the latest best practices for reducing the exposure to Lead of workers on the basis of presentations and examples provided by Exide, Johnson Controls and Hoppecke.

The workshop proposed new target values and items to be considered for the future of EUROBAT's Blood Lead reduction programme. The CEM will now further build on these suggestions and make a proposal to the EUROBAT Board for amending or updating the programme.

3° Revision of Annex X of the Water Framework Directive

In line with a proposal tabled by the European Commission, EUROBAT has supported advocacy efforts towards the European Parliament by Eurométaux and the International Lead Association to avoid a non-scientifically based classification of Lead as a "Priority Hazardous Substance" under Annex X of the Water Framework Directive. On 28 November, the European Parliament's Environment, Public Health and Food Safety Committee supported industry's argumentation and rejected amendments asking for the classification of Lead as a "Priority Hazardous Substance". The Committee's report is now scheduled for vote in the Parliament's plenary, most likely in April 2013.

4° Transportation of Large-Format Lithium Batteries

- **>35 kg/per battery in air traffic**

The revised Working Paper to remove the weight limitation of 35 kg per battery was welcomed at the ICAO DGP meeting from 15 – 19 October 2012; however not accepted in its present form

The application will be revised by the German ICAO Delegation for the next ICAO DGP meeting in April 2013 – the limitation of the state of charge could play a major role

Dr. Peter Lamp, head of storage technologies at BMW, represented the car and battery industry as an official member of the German ICAO delegation during the ICAO DGP meeting in Montreal. His report informed that:

- There was consensus that it is necessary to increase the weight restriction of 35 kg per battery.
- It was also agreed that a new Special Provision with specific requirements for the battery and the packaging is better than having to grant numerous approvals – especially in regards to the emerging mass market.
- A principle agreement was recorded. The German Working Paper is not yet accepted, and so again has to be revised.
- The discussion made apparent that a limitation of the state of charge (e.g. SOC 50%) will likely be the decisive criteria for achieving the necessary majority of the ICAO DGP members.
- Intermediate steps suggested for the weight increase between 35 kg and 400 kg are not practicable and will likely be refused by the car and battery industry
- The definition of the packaging as 'flame retardant' or 'non-combustible' needs further elaboration or should take presiding standards as the reference. This could lead to the requirement for a metal box.

In summary the meeting took the industry's proposals one step further, with good chances of success to achieve the required majority during the next meeting. Progress has been facilitated by the constructive cooperation with Mark Rogers (Chairman of the Dangerous Goods Committee of the International Pilots Association (IFALPA)) since summer 2011 and his influence at the ICAO DGP.

The head of German Delegation, Herman Brockhaus - German Federal Office of Civil Aviation (LBA) - intends to revise the German application and submit in time for the next meeting of the ICAO DGP Working Group (most likely April 2013). He will coordinate the amendments with the joint working group of the car and battery manufacturers.

In regards to the amendments (e.g. SOC restriction) it has to be taken into consideration that the transport of Lithium batteries > 35 kg per piece **without approval** for the worldwide air traffic can only occur when time is short and it is not possible to wait weeks to get an exemption – e.g. **when transporting replacement batteries.** It can be expected that the majority of Lithium batteries > 35 kg in the international sea traffic will be transported according the Packing Instruction 903 of the IMDG Code.

The existing ICAO special provision A99 shall remain. This means that Lithium batteries >35 kg can be transported with the packaging of the **packaging group II** from 01 January 2015 – **provided that the necessary approvals have been granted**.

- **UN Sub-Committee adopts proposals on Waste Lithium Batteries Transportation and Damaged/ Defective Lithium Batteries Transportation**

During the 3-11 December 2012 meeting of the UN Sub-Committee of Experts on the Transport of Dangerous Goods, industry proposals were successfully adopted on Waste Lithium Batteries Transportation – SP377 (new) and P909 (new) – and Damaged and Defective Lithium Batteries Transportation – SP 276 (new), P908 (new) and LP904 (new).

The provisions adopted for shipping waste batteries and damaged/defective batteries provide a reasonable approach for packaging these batteries, in line with industry requests. The provisions adopted for waste batteries include an exemption from UN testing requirements and several other battery design requirements that are impossible for shippers of waste batteries to verify when offering these batteries for transport.

Industry attention now turns to the acceptance of these proposals in the International Maritime Organisation (IMO) and International Civil Aviation Organisation (ICAO).

5° Implementation of the German risk concept for carcinogenic substances like Cadmium, Cobalt and Nickel compounds as well as Lead and its compounds

According to its Risk Concept for carcinogenic substances, Germany will determine Exposition-Risk-Relationships (ERBs) as workplace limits. ERBs regarding the acceptance risk are already defined for the not-occupationally-exposed general population. ERBs will be correlated with corresponding low Biological Guidance Values (BGVs), based on the background concentration of the general population. The goal of the German concept is that professional exposure - when handling verifiable carcinogenic substances - should not be higher than for the general population.

The following ERBs are in the Pipeline:

- **Cadmium:** Tolerance value: 1,6 µg/m³, Acceptance value: 160 ng/m³
- **Nickel:** Tolerance value: 2 µg/m³, Acceptance value: 0,8 µg/m³
- **Cobalt:** Tolerance value: 5 µg/m³, Acceptance value: 0,5 µg/m³
- **Lead:** Tolerance value: 30 µg/m³ (with a corresponding Blood Lead Level of 250 µg/l),
  Acceptance value: 2 µg Cd/m³ (with a corresponding Blood Lead Level of 15 µg/l).

The tolerance values must be fulfilled (comparable with an OEL) and the acceptance values must be strived towards (targeted value).

Regarding the discussion about Lead and its compounds, German industry is fighting against the determination of the above ERBs and the corresponding Blood Lead Levels, because Lead and its compounds are currently not classified as carcinogenic 1A or 1B.

With cooperation between ZVEI`s battery association and the WirtschaftsVereinigung Metalle, the industry was successful in achieving the implementation of the German risk concept for carcinogenic substances within a new binding Technical Rule for Metals and its compounds, combined with industry sector rules of the employers' liability insurance associations ("combined model").

This is an agreeable solution for the battery industry, provided that the combined model would have a comparable liability to the presumption of conformity of a substance specific Technical Rule (TRGS) according to § 7 (2) German Ordinance on Hazardous Substances.

Below the TRGS, a regulation with protective measures will be developed from accident insurers together with the battery manufacturers for the handling of Cadmium, Nickel and Cobalt during battery production. The advantage of this solution is a possible focus on the pure battery-specific uses of substances in a regulation below a legally secure roof of the framework TRGS. Having a substance-specific TRGS would mean that all uses of the substance need to be regulated in detail. According to experience, the development of a substance-specific single TRGS will be very complex and the implementation for the user often confusing.

The framework TRGS and the battery sector rule shall be completed within the next two to three years.

The German government has initiated a process to also establish the AGS risk concept in regards to carcinogenic substances on an EU level. A pragmatic implementation of the "combined model" in Germany could also be pioneering for other EU member states and potentially would have a positive influence on the procedure of future REACH approval procedures.

6° Implementation of the new Seveso III Directive

The new Seveso III Directive (2012/18/EU) to control the risks during major accidents with hazardous substances came into force on 13 August 2012 and shall be applied from 01 June 2015 in the EU member states.

The production of Lead batteries is not subject to the complex and cost-intensive extended obligations of the new Seveso III Directive.

The same applies to the production of Lithium, NiCd and NiMH Batteries, as far as the tonnage threshold of 200 tonnes for Nickel hydroxide and mixtures containing Nickel hydroxide (present on-site) will not be exceeded or achieved.

In January 2009, the European CLP Regulation came into force which replaces the current European system for the classification and labeling of substances and mixtures. As a consequence, other legislation has to be amended to reflect its requirements, including especially the Seveso II Directive.

The Seveso II Directive (96/82/EC) was adopted in December 1996 and replaced the first Seveso Directive of 1982. The Seveso II Directive applies to all companies which have dangerous substances available or that could arise during an accident which correspond to or exceed the mentioned amounts of its Amendment I. The Seveso II Directive refers to the classification of dangerous substances: up to now to the Directive 67/548/EWG (Substances Directive) and 1999/45/EG (Preparations Directive).

In revising the Seveso II Directive, the goal has been to keep its existing protective level while not causing an unnecessary extension of the application level. The revision has also sought for metals besides the pure substance classification also to include the risk-based effects. **Furthermore, it was very important to regulate for a differentiation between the acutely and the chronical toxicity.**

The Seveso III Directive was published on 24 July 2012 in the Official Journal of the European Union (attachment 1) and came into force on 13 August according to article 33. The Member States have until 31 May 2015 to implement the required legislative and administrative Acts to fulfill this Directive. The Member States will apply the Acts from 1 June 2015. The Seveso II Directive will be repealed on 1 June 2015.

- **No tightening when using lead-containing preparations (battery lead oxide and lead battery paste)**

According to the new Seveso III Directive, substances and mixtures of category 3 "chronic"(H412 corresponds R52/53) are further not relevant for Seveso.

An extension of the scope of the Seveso III Directive in regards to chronic effects of substances (so-called classification as STOT RE Specific Target Organ Toxicity - **Repeated** Exposure) shall not occur, as the Major Accidents Legislation is focused on acute danger. Otherwise, inorganic Lead compounds like Lead Oxide – according to the classification (STOT RE1 (H372)) – would also have to be classified as toxic regarding the Seveso II Directive, and respectively the Major Accidents Ordinance. There would be a tonnage threshold of 200 tonnes (present in an establishment) when applying the extended obligations.

- **No tightening when using Nickel compounds**

As mentioned above, an extension of the scope in regards to chronic effects of substances (so-called classification as STOT RE Specific Target Organ Toxicity - **Repeated** Exposure) has not occurred. Thus, Nickel Hydroxide with the classification (STOT RE1 (H372)) is not relevant for Seveso.

In the Seveso III Directive, some inhalable powdery Nickel compounds are **finally** mentioned. These are Nickel Monoxide, Nickel Dioxide, Nickel Sulphide, Trinickel Sulphide and Dinickel Trioxide. However, again no amendments were made. The originally planned classification of numerous Nickel compounds which have been classified as carcinogenic Category 1 since 01 December 2012 (among others Nickel Hydroxide) could be prevented by the industry as carcinogenic effects are chronical. **This is of highest importance for the production of Nickel-based Lithium batteries as well as NiCd and NiMH batteries, as the threshold tonnage for the application of the expensive and cost-intensive extended obligations for the above mentioned Nickel compounds is very low: 1 tonne (present in an establishment).**

Nickelhydroxide and Nickelhydroxide-based preparations are subject to Seveso because of the aquatic toxicity (H400) with threshold tonnages of 100 tonnes (obligation for **lower-tier establishments)** and 200 tonnes (extended obligations for **upper-tier establishments**).

Important !

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**. ZVEI's Battery association will prepare the relevant activities in coordination with EUROBAT's CEM and Hydrotox.

7° Battery Directive

- **Recycling Efficiency**: The European Commission has set-up a working group composed of representatives of EU Member States and industry to work out guidelines for the implementation of Regulation 493/2012/EC on the calculation of recycling efficiencies of batteries. Issues considered include definitions of “breaking batteries” or of battery packs as well as the exclusion of water content for Lead-based batteries or the application of the rules of the Regulation to emerging battery technologies. EUROBAT participated in the work of the working group by submitting a position paper providing input into all these issues.

- **Export of Waste Batteries**: The same working group has been discussing a Commission Working Document aimed at establishing rules for the assessment of recycling operations of batteries outside of the European Union. EUROBAT participated in the discussion by insisting that recycling operations outside the EU to which batteries are exported should operate under the same conditions as similar facilities located in the EU.

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