Avenue Marcel Thiry, 204
B-1200 Brussels, Belgium
Tel: +32 2 774 96 53
Fax: +32 2 774 96 90
E-Mail: eurobat@kelleneurope.org
www.eurobat.org

EUROBAT
Association of European Storage Battery Manufacturers
Association des Fabricants Européens d'Accumulateurs
Vereinigung Europäischer Akkumulatoren-Hersteller

# Guidelines of EUROBAT

# for the Implementation of the

# European REACH Regulation

# Covering the Manufacture and Marketing

# of Batteries in the European Union

# December 2007

**These guidelines are intended to provide assistance with the implementation of the REACH regulation but not replace them.**

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**These guidelines were prepared by the Committee for Environmental Matters of EUROBAT on the basis of the best knowledge available as to the concrete requirements of REACH. The guidelines will be subject to change as the actual implications of REACH are being clarified by the EU institutions and our understanding of these requirements applied to the battery industry becomes more accurate.**

## Foreword

REACH brings with it the reversal of the burden of proof, thus offering chances to everyone involved. Let us use them jointly as partners for our mutual benefit.

**Up to now:** Where the determining of risks is concerned, the authorities and their institutions have been responsible up to now for the all-important determination of the properties of substances and the corresponding classification of these substances by their hazard characteristics. This categorization is of decisive importance because limiting values (workplace, air, water, soil, waste), production conditions and utilization restrictions all the way through to product bans are derived from them. On an EU level, the Scientific Committee on Occupational Exposure Limits (SCOEL) establishes the properties of substances and makes the appropriate classification recommendations which can then be declared as binding by the EU Commission in Directive 67/548/EEC in regard to the marketing and handling of substances.

**In future**: After REACH comes into full effect, the substance manufacturers will be responsible for establishing risk, which also means the determination of substance properties. This will be done within the scope of so-called substance safety reports which also contain the risk management measures. These substance safety reports will then be presented to the new European Chemicals Agency (ECHA) and the national authorities of the Member States for risk assessment. The decisions that result from this will be made by the EU Commission in its rules and regulations. The EU Parliament and EU Council are involved in the legislative process concerning the amendments to the media and/or product-related regulations derived from this.

**Resolving of conflicts through cooperation as partners**:

**1st Step**: To ensure scientifically sound categorization, the reversal of the burden of proof caused by REACH must have the result that "cooperation as partners" takes place when necessary between industry and science in regard to the groundbreaking legal classification of hazardous substances. It must not be allowed to happen that, once industry becomes responsible for testing the properties of substances in line with the forthcoming REACH regulation, committees such as SCOEL continue to work in parallel to this on the same topic in closed shops. Instead of the principle of report and counter-report with completely reversed premises, we must jointly achieve genuine cooperation here. Industry should not be expected to hire more scientists when it becomes necessary to determine the properties of substances. The work of those scientists and institutes which are currently responsible will remain of vital importance in this area in the future when, for example, they are commissioned by the responsible industry to carry out the studies.

**2nd Step**: In the event of scientifically proven risks in substances (e.g. carcinogenic, mutagenic or reproduction-toxic effects), these must be examined via the substance/product life cycle with the inclusion of alternative substances and alternative products. The decision must then be taken within the scope of a risk/cost/benefit analysis within the REACH authorization process (or within the framework of special regulations, such as the Battery Directive). It is to be expected that the essential decisions, such as those on the authorization to manufacture and use particularly hazardous substances in products, will be reached in ECHA. Even if the Commission formally grants the approval, it will normally comply with the recommendations of ECHA. According to Article 85 of the regulation, the ECHA committees will each be made up of 1-2 members from each Member State. This would mean that the Member States would appoint 1-2 representatives (presumably from the environment ministries) to each ECHA committee, e.g. for substitution examinations and socio-economic analyses. These representatives can seek the advice of experts for support (e.g. SCOEL or eco institutes). The official participation of representatives from industry is not planned. This results in the justified concern of industry that theoretical decisions reached by bureaucrats could be implemented without any consultation with industry. This cannot be allowed to happen with future substance and product authorizations, upon which the existence of entire industrial sectors will depend throughout Europe. The appropriate level of direct involvement of industry in the ECHA committees is therefore imperative.

If we proceed as outlined above in the 1st and 2nd steps, joint, risk-based decisions capable of being implemented in actual practice could be reached in future, thus ensuring sustainable consumer, employee and environmental protection with the simultaneous strengthening of the competitiveness of European industry.

Ray Kubis

President of Eurobat

Brussels, November 2007

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**Eurobat is the representative association for automotive and industrial battery manufacturers and their suppliers, the collective voice of over 30 European operations employing around 30,000 professionals in Europe.**
For questions or further information, please contact Pierre Conrath at Eurobat, email: eurobat@kelleneurope.com, tel. + 32 2 774 96 53

## 1. Introduction

The REACH regulation came into effect simultaneously and with binding force in all 27 Member States on 1 June. The acronym REACH stands for

R = Registration,
E = Evaluation and
A = Authorization of
CH = CHemical substances

REACH is the most comprehensive and significant set of legal regulations the European Union has ever produced in the field of health, environmental and consumer protection. European industry in its entirety is affected by the regulation as the manufacturers, importers or users of chemical substances. **Chemical substances also include the non-ferrous metals and their inorganic compounds which are essential for the battery industry.**

### 1.1 Main changes caused by the regulation

The following changes are of vital importance:

- **Reversal of the burden of proof**

Manufacturers and importers are now responsible for determining the properties of substances and must derive the corresponding limiting values and risk management measures from these and coordinate them with the responsible committees in order to protect consumers, employees and the environment.

- **No data no market**

Substances which are not registered by the time a particular deadline expires may no longer be manufactured or marketed subsequently. During the registration process, a comprehensive substance safety report containing all relevant health and environmental data must be presented.

- **Authorization process for particularly dangerous substances**

The use of particularly dangerous substances will be prohibited unless authorization is granted before deadlines, which have yet to be determined, have expired. The first list of substances subject to approval will probably be published in 2009 in Appendix XIV of the EU Commission regulation. Among the "candidates" for this list are known carcinogenic or reproduction-toxic substances, such as **cadmium oxide and lead oxide**. It is to be expected that the **objective of the approval process in actual practice will not be to grant authorization but to prohibit the use of a substance if suitable alternatives are available.**

### 1.2 Main objective of the regulation

The main objective of the regulation is to improve the protection of human health and the environment from a national economic point of view, too. This is to be achieved by means of a uniform evaluation and control system for new substances (substances brought into circulation from September 1981) and **old substances (on the market before September 1981)**. In particular, the gaps that exist in the knowledge of approx. 30,000 old substances will be closed here by means of subsequent examinations within the scope of the registration process. Uncontrollable risks will then be removed by means of limitation measures, substitution orders and utilization bans.

### 1.3 Area of application of the regulation

The REACH regulation covers the manufacture, marketing and use of individual substances, substances contained in preparations and substances contained in products. Manufacturers, importers and downstream users must ensure, in line with the precautionary principle, that they manufacture, market and utilize substances which do not have a negative effect on human health or the environment. **The obligations of battery manufacturers who have their headquarters in Europe and those who import substances, preparations and products into the EU market (importers) are identical.**

### 1.4 Exemptions from the regulation

The general and specific exemptions from the regulation or parts of the regulation are covered in Article 2. **Waste substances for recycling or disposal are fully exempt from the REACH regulation** (Article 2, Para. 2).

The complete exemption of substances in batteries adopted in the first reading by the EU Parliament and the exemption of substances in batteries from the REACH approval process discussed within the scope of the second reading could no longer be taken into consideration in the political agreement between the EU Parliament and EU Council. **It remains to be seen, therefore, whether the possibilities for an exemption of the substances in batteries will be granted in accordance with Article 58 (2) once the regulation has come into full effect**.

## 2. Obligations of Manufacturers and Importers in the Registration Process

### 2.1 Pre-registration

The interim deadlines for old substances listed under 2.2, below, which apply in accordance with Article 23, can usually only be claimed if the substances have been pre-registered (Article 28). Pre-registration must take place between 1 June and 1 December 2008 and is free of charge. Pre-registration is not an obligation to register. Without pre-registration, old substances must be registered in the same manner as new substances from 1 December 2008.

The European Chemicals Agency requires the following information for pre-registration:

- Name of the substance, including EINECS and CAS number
- Name and address of the company, including a point of contact
- Scheduled deadline for registration and quantity report.

Pre-registration has the goal of facilitating the formation of consortiums for conducting the joint registration of identical substances. All companies which pre-register the same substance are automatically included in a *Substance Information Exchange Forum* (SIEF) in which the option – and in the case of animal experiments the obligation – exists of exchanging information on each substance.

## 2.2 Registration deadlines depending on quantity and classification

The following interim deadlines apply to the registration of old substances:

| | |
|---|---|
| **1 December 2010** | Ø Substances > 1,000 t/year<br>Ø Carcinogenic, mutagenic or reproduction-toxic substances (so-called CMR substances) of Category 1 and 2 > 1 t/year<br>Ø Substances categorized R50/53 (highly toxic for aquatic organisms)<br>> 100 t/year |
| **1 June 2013** | Ø Substances > 100 t/year |
| **1 June 2018** | Ø Substances > 1 t/year |

## 2.3 Registration of substances

Manufacturers and importers must include a technical substance dossier when registering substances. For those substances >10 t/year, an additional substance safety report is also required.

The technical substance dossier must essentially contain the following information in accordance with Article 10:

- Identity of the manufacturer(s)/importer(s)
- Identity of the substance
- Information on the manufacture and possible use(s)
- Classification and labelling
- Guidance on safe use
- Summary of physical-chemical, toxicological and environmental-toxicological information

The substance safety report must essentially contain the following information in accordance with Article 14:

- Assessment of the danger to human health
- Assessment of danger to the environment
- Exposure assessment and description of risks for all applications
- Measures for controlling risks, including the establishment of limiting values for human health (DNEL – Derived Non Effect Level) and protection of the environment (PNEC - Predicted No Effect Concentration).

The substance safety report documents the substance safety assessment, which has to be conducted for a substance as such or when contained in a preparation or product.

According to a preliminary cost estimate, the following prices will be charged for registration:

| Quantity Range | Basic Charge | Consortium Members | SME | SWE Consortium Members |
|---|---|---|---|---|
| in t/Year | | | | |
| 1 – 10 | € 1,200 | € 804 | € 900 | € 504 |
| 10 – 100 | € 3,257 | € 2,182 | € 2,443 | € 1,368 |
| 100 – 1000 | € 8,842 | € 5,924 | € 6,631 | € 3,714 |
| > 1,000 | € 24,000 | € 16,080 | € 18,000 | € 10,080 |

The costs for the physical-chemical, toxicological and environmental toxicological tests can amount to between one and ten million euros.

### 2.4 Registration of substances in preparations

The importer of preparations (preparations consist of 2 or more substances, e.g. pastes, paints, adhesives, cleaning agents, alloys) must register every ingredient in the preparation > 1 t/year. **The registration of the preparation itself is not necessary (Article 6, Para. 1)**.

For preparations produced within the EU, on the other hand, there is no obligation to register the substances contained in them. In this case, the producer of the preparation is a so-called "formulator" who is regarded as a downstream user and not as a manufacturer.

### 2.5 Registration of substances in products

According to Article 7, Para. 1, substances in articles > 1 t/year must be registered by the manufacturers or importers of the products if the substances contained in the products are released in the intended manner (e.g. ballpoint pens, soaps). Substances already registered for the application in question (use in the corresponding product) are not subject to registration (Article 7, Para. 6).

### 2.6 Notification of substances in products

According to Article 7, Para. 2, the manufacturers and importers of articles (e.g. finished products such as batteries, electrical devices, cars) only have to give notification of (**and not register !!!**) the following substances to the European Chemicals Agency:

- Substances which could be subject to authorization in accordance with Article 58 in regard to their classification (e.g. CMR substances Cat. 1 or 2)
- > 1 t of the substance in the product per year and per producer or importer
- > 0.1 weight % in the product.

The information to be presented along with the notification is contained in Article 7, Para. 4. According to article 7 paragraph 7 the registration must occur from the 01.06.2011.

Notification is not necessary if the substances have already been registered for the intended purpose (use in a corresponding product).

## 3. Obligations of the Battery Industry in the Registration Process

In most cases, the battery industry is to be described as a downstream user and has therefore no registration obligations. This also applies to the manufacture and/or processing of the following substances and preparations within the EU.

### 3.1 No registration obligation for powders and pastes containing lead, nickel and zinc

When manufacturing preparations, such as powders and pastes containing lead, nickel and zinc in Europe, the individual substances in the preparations do not have to be registered. As already explained in 2.4, above, the battery producers are downstream users in this instance and not manufacturers as defined by the REACH regulation. **If these preparations are imported, the substances contained in them must be registered by the importer. If the battery manufacturer is an importer, he is responsible for the registration.**

### 3.2 No registration obligation for the manufacture of battery lead oxide

Battery lead oxide is a preparation as defined by the Chemicals Law (see the statement on this made by the Federal Environmental Protection Agency on 31 May 2006 within the scope of the implementation of the Seveso II Directive in lead battery production). Because the substances lead metal (approx. 30 %) and lead oxide (approx. 70 %) contained in the preparation have already been registered by the lead metal and lead oxide manufacturers, registration by the battery manufacturers is not necessary. The battery industry will consider battery lead oxide within the notification of lead battery paste in accordance with article 7 paragraph 2.

### 3.3 No registration obligation for the manufacture of acid and alkaline battery electrolytes

The manufacture of acid and alkaline battery electrolytes in the battery industry is not subject to the registration obligation either, because the battery manufacturers also function as downstream users in this instance. The starting substances supplied, e.g. sulphuric acid and caustic potash solution, are merely further processed. Registration is the responsibility of the manufacturers of the starting substances who supply the battery industry.

### 3.4 No registration obligation for substances in batteries

Batteries are products as defined by the European Chemicals Law. Because no substances contained in batteries are intended to be released under normal or reasonably foreseeable conditions, the registration obligation contained in Article 7, Para. 1 does not apply to batteries (see also Item 2.5 of these guidelines).

### 3.5 Notification of substances in batteries

As outlined in 3.4, above, batteries are articles as defined by the European Chemicals Law. If batteries contain substances which could be subject to authorization in accordance with Article 56 in regard to their classification (e.g. CMR substances Cat. 1 or 2, **such as lead oxide and cadmium oxide**), all that battery manufacturers and

importers have to do is notify the European Chemicals Agency of these substances (**not register them !!!**). Notification is not necessary if the substances have already been registered for the intended purpose, which in this case is use in batteries (see also Item 2.6 of these guidelines). EUROBAT will support the member companies in view of a pragmatic implementation of this notification requirement - which is valid from 01.06.2011.

### 3.6 Inventory of substances

The preparation of an inventory of substances is not an obligation arising from the REACH regulation~~,~~: it is a generally recommended tool to help fulfil the obligations resulting from REACH.

The sample substance inventory contained in the **Appendix 1** has been specially developed by the Trade Association for Batteries for the pragmatic implementation of the REACH regulation in the battery industry. After being prepared specifically for each location, this inventory of substances must always be kept up-to-date in order to guarantee that an overview of all substances, preparations and products that conform with REACH is available at all times.

### 3.7 Evaluation of the inventory of substances to establish effect

The inventory of sample substances contains all REACH-relevant information and can be evaluated easily via the selected links in the Excel file. After each material specification, the respective responsibilities in line with the REACH regulation are evaluated automatically.

## 4. Obligations of the Battery Industry as a Downstream User

### 4.1 Communication in the supply chain between suppliers and customers

REACH defines certain obligations for communication along the supply chain. These exist both on the part of the supplier toward his customer and on the part of the customer towards his supplier. Accordingly, a supplier of hazardous substances and preparations must communicate an EC safety data sheet to his customer. The customer must check the essential safety-relevant contents and notify the supplier of any deviations, under consideration of customer-specific requirements.

### 4.2 Adaptation of the safety data sheet

The directive on EC Safety Data Sheets 91/155/EEC was rescinded on 01 Jun. 2007 when the REACH regulation came into effect. The changes made to the requirements for EC Safety Data Sheets (SDS) in the REACH regulation (Article 31) compared to the requirements previously contained in Directive 91/155/EEC are purely editorial. For this reason, the amendment of all existing SDS purely on the basis of the editorial changes made in REACH is not necessary.

According to Art. 31 (9), the SDS are to be updated:

- as soon as new information which may affect the risk management measures, or new
  information on hazards becomes available;
- once an authorization has been granted or refused or
- once a restriction has been imposed.

SDS must contain exposure scenarios and/or utilization and exposure categories in an appendix if the manufacturer and/or an actor in the supply chain has to prepare or already has prepared them for a substance safety report. The contents of the SDS must match up with the information contained in the substance safety report. The enclosure of an exposure scenario with the SDS is only required for old substances once the registration deadline for the quantity band in question has expired.

**What will remain unchanged no matter what is that in the future too, no EC safety data sheets will be required for products such as batteries. Instruction leaflets on the safe handling of batteries therefore remain a service for customers of the battery industry, provided on a voluntary basis. An adjustment to the requirements of the REACH Regulation will be carried out on time.**

### 4.3 Use of a standard questionnaire for communication in the supply chain

Communication along the supply chain is a central element of the REACH regulation. As already mentioned, all actors in the supply chain have communication obligations to fulfil, both upstream and downstream. To limit the level of bureaucracy within trade and industry, trade associations have developed and coordinated standard questionnaires at EU level which should serve to make communication in the supply chain as efficient as possible.

Regarding the use of this standard questionnaire (**Appendix 2**), it is recommended that it be used exclusively for your own preparations initially and that no inquiries be launched with suppliers yet. Basically, it does not make sense to send out the questionnaires for all substances. On the contrary, the questionnaires should only be used if, after internal examination of an individual case, questions remain open in regard to a specific substance. Otherwise there is the risk that suppliers and customers will be swamped by the large number of questionnaires received.

What is important initially is that no information on use or exposure is required for pre-registration by 1 December 2008. This information will only be required later for actual registration. More intensive communication between the supplier and the customer may only be necessary when preparing for actual registration.

**Under observation of each registration deadline, the battery manufacturers are checking the information contained in the SDS and/or substance safety report they have received, with particular regard to the details on use, classification,**

**limiting values, exposure and risk management measures. If different views exist on the contents of the SDS and/or substance safety report, communication with the supplier will be necessary for the purpose of reaching an agreement. Special consideration must be given to the type of use of each substance in the battery industry.**

## 5. Evaluation of the Registration Dossier

Evaluation means the examination of the registration dossiers. A difference is made between "dossier evaluation" and "substance evaluation".

### 5.1 Dossier evaluation by the European Chemicals Agency

The main purpose of dossier evaluation is the quality assurance of the data and the avoidance of unnecessary tests on animals. The documentation submitted is checked for completeness and plausibility. Efforts are being made to ensure that the Chemicals Agency examines at least 5% of the registration dossiers from each quantity band.

### 5.2 Substance evaluation by the national authorities of the Member States

A substance can be examined if it is suspected of causing a risk to human health or the environment. If necessary, the corresponding examination data will be requested subsequently from the registering companies. **The substance evaluation is conducted by the national authorities of the Member States**. A list of those substances which are to be subjected to a substance evaluation is prepared in cooperation with the Chemicals Agency.

## 6. Authorization Process for the Use of Particularly hazardous Substances

Substances with particularly hazardous properties can be subject to a separate authorization process. According to current estimates, a total of approx. 1,500 different substances could be affected by this.

According to Article 55, the authorization process "is intended to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorizations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution."

The fee due for the authorization process alone amounts to € 58,000.

## 6.1 Authorization criteria and substances requiring approval

Substances with the following properties may be subject to the authorization process in accordance with Article 57:

- Substances classified as carcinogenic, mutagenic or reproduction-toxic category 1 or 2 (CMR substances),
- Persistent and/or bioaccumulative substances with toxic properties or very persistent and/or very bioaccumulative substances (PBT and vPvB substances) or
- Substances determined on a case-by-case basis with very worrying properties (e.g. endocrine disrupting substances).

## 6.2 Sequence of the authorization process

Substances requiring authorization will be included in a list which will be extended gradually, and given a so-called "sunset date" (Appendix XIV of the REACH regulation, which does not yet have any contents). The first entries of substances requiring authorization in Appendix XIV will be made at the earliest two years after the regulation has come into effect.

Upon expiry of the sunset date, the substance in question may not be placed in the market or used without an authorization. Companies should have submitted an appropriate application for authorization no later than 18 months prior to the expiry of the sunset date. Only then does the possibility exist of continuing to use the substance or place it on the market after expiry of the deadline. Applications for authorization should be submitted to the Agency. Manufacturers, importers and downstream users can make the application. The decision on authorization applications is reached by the EU Commission.

The bar that has to be crossed to acquire authorization has been set high: the applicant must prove that the risks of the substance are properly controlled when the substance is used. If necessary, the applicant must also provide evidence that the socio-economic benefits outweigh the risks and that no suitable alternative substances and/or technologies are available. If they are, the application for authorization must include a substitution plan showing the ways and means by which the substance requiring authorization is to be replaced in the long term.

Authorization can be combined with other stipulations regarding the monitoring of the substance in question. In addition to this, a review deadline is established individually for each authorization. To receive the authorization, a review report must be resubmitted no later than 18 months prior to the expiry of this deadline. Irrespective of this, the EU Commission can demand a review of the authorization – when new information on substitute substances becomes available, for example – which can result in the revocation of the authorization under the appropriate outline conditions. **Alternative recommendations can be submitted by all interested groups during the substitution review.**

The authorization of a substance with its permitted applications is given an authorization number and published in a public database. If substances requiring authorization are placed in the market in a preparation, the authorization number must be applied to the label. Downstream users who use substances within the scope of an already authorized application are required to notify the Agency to this effect.

### 6.3 Possible exemptions from the authorization process for the use of substances in batteries to avoid double regulation

In accordance with Article 58 (2), certain uses of substances requiring authorization can be exempted from the authorization requirement if, on the basis of existing specific legal regulations, the risk to human health and the environment is sufficiently under control.

The following specific regulations for the safe use of substances in batteries already exist:

- Battery Directive
- IVU Directive (for environmentally friendly production)
- Chemicals and employee protection guidelines
- Water Framework Directive
- Waste Framework Directive

including the substance-specific limiting values contained therein and their implementation on a national level (e.g. BattV, BImSchG, GefstoffV, WHG, KrW-/AbfG in Germany).

The new Battery Directive of 26 Sep. 2006 in particular now contains, as its main objective, a ban on the marketing of batteries which contain hazardous substances (Article 1 (1) Battery Directive). With this realignment of the Battery Directive, all aspects concerning the risks of substances, handling risks and substitution options can be regulated as required in future for all battery ingredients within the scope of further revisions of the Battery Directive. The exemptions granted in accordance with Article 58, Para. 2 relate purely to the use of substances in batteries and not the manufacture thereof. The manufacture of battery ingredients today is regulated by the REACH regulation in all cases and will remain so in future. This means that the manufacturers (including importers) of battery ingredients (this can also be the battery industry itself) are committed under all circumstances to register these substances under REACH and assess them in regard to their intrinsic properties so that no gaps open up here. The actual risks that exist when using them are then examined under the Battery Directive. If the substances are put to a use other than in batteries, the REACH regulation applies to its full extent.

The exemption proviso in accordance with Article 58, Para 2 is fulfilled on the basis of the specific regulations mentioned above, thus justifying the granting of a corresponding exemption for the use of substances requiring authorization in batteries by the European Commission to avoid double regulation.