

## **NEWSLETTER NO.3**

### **Introduction**

This is the third Sitmae REACH Newsletter. With this newsletter we inform our customers about the ever-changing world of REACH. We will send you a newsletter whenever there is information which is of use to you.

The subjects in this newsletter:

- Pre-registration: the final results
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- Generic Exposure Scenario's for solvents
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  - Registration Numbers on Safety Data Sheets

Previous Newsletters: still contain valuable information. They can be downloaded from our web site: [www.sitmae.eu](http://www.sitmae.eu).

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### **Pre-registration: the final results**

During the pre-registration period more than 65.000 companies (82% SME's) submitted 2.750.000 pre-registrations covering almost 150.000 substances. The largest REACH country was Germany with almost 1 million pre-registrations. The smallest was Iceland with some two hundred pre-registrations by some thirty different companies. (*Sitmae REACH Services alone has pre-registered more substances, on behalf of more companies, than Iceland and Malta, the second smallest country*).

Almost half of all the pre-registrations were submitted in the last two weeks before the deadline. Twenty two companies pre-registered more than 10.000 substances.

Of the 146.000 substances, 41.000 were identified without an EC number. Of these 17.000 had a CAS number, 9.500 were identified only by their chemical name and 14.500 were 'multi-constituent' substances. (*'Multi-constituent substances': chemically manufactured mixtures of substances*).

Since December 1<sup>st</sup> it is only possible to pre-register as a 'first time manufacturer or importer'. The date of first time manufacture or import must then be indicated, and of course this date must be later than December 1<sup>st</sup> 2008.

### **Overburdened SIEFs**

As a result of the enormous number of different substances that were pre-registered, there will also be some 146.000 SIEFs. (*SIEF: Substance Information Exchange Forum*). In many case it will be quite a task to get the SIEFs of the ground. Some 3.500 of them will have more than 100 members. There are even 141 SIEFs with over 1.000 members, of which two even have more than 5.000. Managing these large SIEFs is a major challenge.

At this moment the SIEF facilitators send e-mails to other pre-registrants. (*SIEF Facilitator: a pre-registrant volunteering to coordinate the start up of the process*). They aim to find out which of the many pre-registrants actually intend to register the substances. This will not nearly be so many. Many importers and non-EU based producers of preparations have pre-registered their many substances for legal purposes only. They intend to leave the actual registration to their suppliers: the manufacturers of the substances.

A nasty problem is caused by the fact that these SIEF facilitators are self appointed. Amongst them are a lot of consultants who hope gain research and coordination work. There are also consultants who offer complete dossiers at a fixed price. How they intend to do so without knowing how many registrants there will be and without knowing whether the necessary data are available is a mystery. There are also software publisher who use this method to try selling IT systems designed to organize the complicated information exchange for joint submissions of REACH dossiers.

For a manufacturer or importer who is seriously interested in the registration of his substance, it is very difficult to establish which of these self offered facilitators are acceptable at all.

At Sitmae we are doing the following:

- We are keeping record of all the invitations to join a SIEF that we receive.
- For those customers who actually manufacture the substances themselves, we are entering into a discussion with the SIEF facilitator, trying to find out how serious they are about their proposals.
- For substances that are used only in ‘preparations’, such as cosmetics, and not actually manufactured by our customers, we are simply keeping track of the developments.
- We are keeping the SIEF information available for our customers. They may for instance wish to give it to their suppliers; the manufacturers of the substances.

In our role as Only Representative we have done more than 550 pre-registrations. By mid March we have received invitations regarding approximately half of these.

**Small hope for polymers**

Four large EU based companies have managed to get to the European Court to express itself on the validity of Article 6.3 of REACH. This is the article that specifies, that all the monomers that are used to manufacture a polymer, should be registered; even if they are no longer present as such in the polymer.

The issue was originally laid before a UK High Court. The claims being that the REACH requirement for registration of monomers in polymers is unlawful on the grounds that it is irrational, discriminatory or disproportionate.

The High Court judge decided that the issue should be referred to the European Court of Justice for an opinion. Normally very slow, the European Court saw that a decision was needed in good time before the first registration deadline in 2010. The hearing before the court was on January 27<sup>th</sup>.

The preliminary ruling by Advocate General however rejects the claim. This is a set back, because the Court very often follows the opinion of the Advocate General. The Courts final judgment is expected by the end of 2009.

**Candidate and Priority List**

The first Candidate List of substances, earmarked for authorisation, was published late 2008. Out of these fifteen substances, nine now feature on the ‘Priority list’. These nine substances will be the first to be subject to the official authorisation procedure. The complete Candidate list, including the prioritisations is annexed to this document. Consultations on the priority substances have started. More information on the ECHA web site. (<http://echa.europa.eu/>)

## **Generic Exposure Scenario's for solvents**

Exposure Scenarios will be an essential element in the registration dossiers. This is where the toxicological conclusions are compared to the actual use of the chemicals. The appropriate 'Risk Management Measures' will be based on that comparison. It can be seen that for chemicals with many different uses, this work has to be structured and simplified where possible.

ESIG (*European Solvent Industry Group: producers*) and ESVOCCG (*producers & users of solvents*) are preparing Generic Exposure Scenario's for solvents. These will be used as a basis for specific Exposure Scenarios for the many different uses of specific solvents.

With the help of the Generic Exposure Scenarios, the specific scenario's can be drafted, when a few data are available such as a PNEC/OEL, the volatility of the solvent and a use category.

The generic system is based on exposures as estimated by a computer model. The outcome of the model must of course be checked against practical experience. The generic scenarios will be put in Excel, together with all the standard phrases that might be needed. The developers stay as close as possible to existing good H&S practices, arguing that solvents have been handled safely for many decades. As the chairman (Chris Money, Shell) put it: "*We must have been doing something right, since we do not have a major solvent caused epidemic on our hands*". The method distinguishes between consumers and workers and between professional and industrial use. It addresses both human exposure and the environment.

## **Guidance on Annex V**

Annex IV and V of REACH contain an important number of exemptions to the REACH legislation. They have recently been reviewed. Annex IV simply lists a number of substances, but Annex V is much more descriptive.

Although the text of annex V has been clarified, guidance on the interpretation was still considered useful. The draft for this guidance has been published. It can be downloaded from the Commission web site.

([http://ec.europa.eu/enterprise/reach/docs/reach/com\\_rev\\_anx\\_v\\_guidance\\_081010\\_en.pdf](http://ec.europa.eu/enterprise/reach/docs/reach/com_rev_anx_v_guidance_081010_en.pdf))

## **REACH baseline study**

The European Commission wants to monitor the positive effects of REACH on the chemical risks for the European consumers, workers and the environment, in a scientifically sound manner.

For this purpose, criteria had to be developed, a baseline (the situation before the implementation of REACH) had to be established and also autonomous trends towards risk reduction that have nothing to do with REACH had to be identified.

A 'REACH Baseline study' was commissioned. The work started in January '06 and the results have recently been published. 'Risk and Quality Indicators' have been developed and were tested on more than 100 different chemicals. The authors are confident that the system will be able to show the future results of REACH objectively.

## **Nano-materials**

The discussions on nano-materials continue. These discussions seem to become more and more complicated. The main issue is whether a nano-material is just a different form of a bulk substance or whether it is a completely different substance. The consequence of the latter approach might even be that they are not 'phase-in' substances and that they should be registered immediately. There is some indication that the answer will not be the same for all the different nano-materials, but will have to be given on a case by case basis. Criteria for such a decision do not yet exist.

## **Sanctions & Enforcement**

Early March there were still eight Member States who had not informed the Commission of their penalties for non-compliance with REACH. (Austria, Belgium, Greece, Estonia, Italy, Latvia, Luxemburg and Portugal). The European Commission is in the process of launching an infringement procedure against these countries.

The Commission has also launched a study on Member State penalties for non-compliance. It is aimed at helping the Commission to make an overview of provisions and penalties. The result is expected by the end of 2009.

The difficulty of relating non-compliance to a regulation like REACH with penal provisions in existing national legislation must not be underestimated. It completely depends on the structure of the national environmental or chemicals legislation whether this can be done with any ease.

According to a publication in Chemical Watch a shipload of chemicals was recently stopped from being unloaded by Belgium customs authorities. There was said to be a demand for instant proof of pre-registration. A Brussels based trade association however investigated the matter and could not find any proof that this ever actually happened. It would indeed have been strange, since Belgium still has difficulty in even deciding which authorities in the country will be charged with the enforcements of REACH.

## **Technical Guidance on Classification & labelling (C&L)**

The CLP Regulation (*Classification Labelling and Packaging*) has been adopted, specifying the rules for the introduction of GHS (Global harmonised System) in the EU. Now guidance on C&L can finally be published. The long awaited Technical Guidance Document will be available for endorsement by the Member States in June '09 and will be published on the ECHA web site shortly afterwards.

## **REACH IT**

REACH IT continues to be improved. For 2009 the functionality will be expanded with online submission of most of the REACH dossier types, online creation of simple dossiers such as C&L notifications and submission of information by down stream user who are not familiar with IUCLID 5. (*IUCLID: the software necessary to register substances*)

There will also be a tool to perform a 'completeness check' on registration dossiers that will be provided as an add-on to IUCLID and there will be additional functionalities for SIEFs.

## Pending issues

### Multi-constituent substance or preparation?

A 'multi-constituent substance' is the term used in REACH guidance notes to describe a mixture of chemicals resulting from a chemical process. In the legal text however, the term is not used anywhere. The German Chemical industry has taken the position that these mixtures also answer to the definition of a 'preparation'. The result of this position would be that most of the registration dossier for these 'multi-constituent substances' can be simply compiled using the dossiers for the individual substances. Also the relevant tonnage band would be that of each individual component. In many cases this would lead to an easier to compile registration dossier.

The European Commission was not pleased with this approach and asked the opinion of the Commission's Legal Service. As always, the legal Service choose the most complicated solution: a Multi-constituent substance is a substance and not a preparation. A preparation is only an intentional mixture of chemicals.

The Legal services did however not address the question whether a dossier for a Multi Constituent substance could be compiled 'as if it were a preparation'. It seems that the wrong question was answered. No doubt the German industry will further pursue the matter.

### Transitional dossiers

Under the old Existing Chemicals legislation, the European Chemicals bureau was charged with issues like harmonised Classification & Labelling, Identification of CMR's etc. When REACH entered into force, this changed, but there were still a number of dossiers in process. These dossiers have now been transferred to ECHA who will take over. In total 26 dossiers were transferred. The list and the accompanying non-classified information will in the near future be published on the ECHA web site.

### Guidance review and 0,1% rule

Several Technical Guidance Documents (*TGD*) are already up for a review. The most relevant one for industry are the TGD's on Registration, on Information Requirements and Chemical Safety Assessment and the TGD on Requirements for Substance in Articles.

For the TGD on 'Substances in Articles', (very important to the tape making industry) a consultant has been hired to prepare the review. Interim reports are expected in April and August. Finalisation is planned for October '09.

The study will focus on the issue of the 0,1% threshold, where the question is: 0,1% of what? The whole Korean car or every single nut and bolt? The Commission Legal Services are of the opinion that it is the whole car. Several Member States however have a dissenting view.

Already a 'lighter' version of this TGD has been produced. This factsheet is available on the ECHA web site in 22 languages ([http://echa.europa.eu/reach/fact\\_sheet\\_en.asp](http://echa.europa.eu/reach/fact_sheet_en.asp)).

### **Registration Numbers on Safety Data Sheets**

According to the legal text of REACH, the registration numbers of substances should feature on the Safety Data Sheet. This is more or less OK for substances, but it is not such a good idea for preparations. The numbers would enable the reader of the SDS to identify which substances were used to produce the preparation and, perhaps more importantly, also the identity of the original supplier of these ingredients. This is considered proprietary information. Also it might make the SDS very complex. What if an ink contains 30 substances and for half of them the ink maker has three different suppliers? Must he change the SDS with every batch change of his raw materials?

Severe discussions are going on between industry, the Commission and representatives of the Competent Authorities of the Member States. Industry now proposes to list the numbers, but leave out the last four digits. It would keep that information available for the authorities. This would identify the substance, but not the supplier. The opinion of the Commission Legal Services is probably to be asked. The outcome can easily be predicted.

We at Sitmae REACH Services hope that this information is of use to you. If it raises any questions, please do not hesitate to contact us. Other comments are also welcome.

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**Appendix: Candidate list (October 2008) & Priority list (January 2009)**

In the table below **Pr:** means 'on the ECHA priority list established January 14<sup>th</sup>'.

| <b>Pr</b> | <b>No</b> | <b>Substance name</b>   | <b>Einecs numbers</b>  | <b>Reason</b>  |
|-----------|-----------|---|--|--|
|           | 1         | Anthracene  | 120-12-7 204-371-1   | Persistent, bioaccumulative and toxic  |
| yes       | 2         | 4,4'- Diaminodiphenylmethane  | 101-77-9 202-974-4   | Carcinogen, cat. 2   |
| yes       | 3         | Dibutyl phthalate   | 84-74-2 201-557-4  | Toxic for reproduction, cat. 2   |
|           | 4         | Cobalt dichloride   | 7646-79-9 231-589-4  | Carcinogen, cat. 2   |
|           | 5         | Diarsenic pentaoxide  | 1303-28-2 215-116-9  | Carcinogen, cat.1  |
|           | 6         | Diarsenic trioxide  | 1327-53-3 215-481-4  | Carcinogen, cat.1  |
|           | 7         | Sodium dichromate   | 7789-12-0 10588-01-9<br>234-190-3  | Carcinogen, cat. 2; Mutagen, cat. 2, Toxic for reproduction, cat. 2            |
| yes       | 8         | 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)  | 81-15-2 201-329-4  | Very persistent and very bioaccumulative                                       |
| yes       | 9         | Bis (2-ethyl(hexyl)phthalate) (DEHP)  | 117-81-7 204-211-0   | Toxic for reproduction, cat.2  |
| yes       | 10        | Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified ( $\alpha$ – HBCDD, $\beta$ -HBCDD, $\gamma$ -HBCDD) | 25637-99-4 and<br>3194-55-6 (134237-51-7,<br>134237-50-6,<br>134237-52-8) 247-148-4<br>and 221-695-9 | Persistent, bioaccumulative and toxic  |
| yes       | 11        | Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)   | 85535-84-8 287-476-5   | Persistent, bioaccumulative and toxic Very persistent and very bioaccumulative |
|           | 12        | Bis(tributyltin)oxide   | 56-35-9 200-268-0  | Persistent, bioaccumulative and toxic  |
|           | 13        | Lead hydrogen arsenate  | 7784-40-9 232-064-2  | Carcinogen, cat. 1 Toxic for reproduction cat. 1                               |
| yes       | 14        | Benzyl butyl phthalate  | 85-68-7 201-622-7  | Toxic for reproduction, cat.2  |
|           | 15        | Triethyl arsenate   | 15606-95-8 427-700-2   | Carcinogen, cat. 1   |