

## **NEWSLETTER NO.4**

### **Introduction**

This is the fourth 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:

- Languages for Safety Data Sheets
- Early registration obligations
- Classification and Labelling Inventory
- List of pre-registered substances
- Overburdened SIEFs (Substance Information Exchange Forum)
- Harmonised Classification & Labelling (C&L)
- New Cosmetics Regulation
- Nano-materials
- Candidate and Priority List
- Trade Union Priority List
- Call for lower ECHA Fees
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  - ECHA and EFSA cooperation
  - Only Representative for non-EU distributors?

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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## **Languages for Safety Data Sheets**

According to REACH Art 31.3, Safety Data Sheets must be provided in an official language of the country in which the product is sold; unless the Member State provides differently. The obvious question for product marketed in many different EU countries is whether one single SDS in English could be acceptable.

Sitmae performed a survey of the provisions in all the thirty countries in which REACH applies. So far 26 countries have responded. The results:

- Almost all the countries demand the SDS in one of their official languages (For example in Belgium: Dutch or French). Finland demands the SDS in both Finnish and Swedish. Malta allows three different languages (Maltese, Italian and English) and Liechtenstein 'informally' allows English if agreed between supplier and recipient.

The list with the results of the survey is attached to this newsletter.

*Sitmae customers: At Sitmae we are currently testing a company that offers translation of Safety Data Sheet at reasonable cost. Results will be communicated to Sitmae customers who may need this service.*

## **Early registration obligations**

The first registration deadline is 1 December 2010. This deadline mainly applies to substances marketed in quantities > 1.000 t/a. The deadline however also applies to some substances that are marketed in much smaller quantities:

- Substances classified as Cat 1 or 2 CMR (Carcinogen, Mutagen, Reprotoxin) > 1 t/a
- Substances classified R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) > 100 t/a.

*Sitmae customers: Sitmae customers who are affected by this REACH obligations have been contacted by us directly.*

## **Classification and Labelling Inventory**

A Classification and Labelling Inventory will be set up. ECHA will make a publically accessible database. (REACH Art.112-116)

Manufacturers and importers will have to notify ECHA of their Classification and Labelling of the dangerous substances that they put on the market. For phase-in substances, the deadline is 1 December 2010. (There is talk of extending this deadline to 1 January 2011) For importers this applies not only to 'Substances on their own', but also to substances in preparations! (But only for ingredients that lead to a classification as dangerous of the preparation)

For substances that will be registered by November 2010 there is no need for a separate notification. This will be included in the registration dossier.

*Sitmae customers: Sitmae customers who are affected by this REACH obligations will be contacted by us directly in due time.*

Notification will be a cumbersome activity implying the use of IUCLID; the complicated software package necessary for registration. Luckily REACH foresees the notification by 'groups' of manufacturers and importers. To use the SIEFs (Substance Information Exchange Forum) for this purpose seems obvious. CEFIC (European Chemical Industry) is hoping to make a 'bulk-upload tool' available in time

An additional complication is that there is no lower threshold. This means that also substances imported or manufactured below 1 t/a must be notified.

Unavoidably there will be different notifications for the same substance. REACH calls upon industry to avoid this complication as much as possible (Art 113.2: 'notifiers and registrants shall make every effort...'). What procedures will be put in place to help the 'notifiers and registrants' to make this effort is as yet unknown. Guidance is said to be on its way. A major problem is expected to be the issue of substance identity.

ECHA expects some 3,4 million (!) notifications. CEFIC (European Chemicals Industry) expects a few more: 5 million. There is little that the Commission can do to reduce this avalanche. When the REACH proposal was in its final stages, the potential problems were pointed out to the Council and the European parliament. These both insisted however on the procedure as found in REACH today. Since the 'co-legislators' have spoken, there is little room for the Commission to improve the situation.

### **List of pre-registered substances**

The December list of pre-registered substances consisted of 146,014 distinct substances. It included 17,087 substances pre-registered using only CAS numbers. These were verified and the correct CAS names were provided, and missing EC numbers or CAS numbers were added if they could be found.

A further 10,223 substances that were pre-registered using only chemical names. Of these CAS numbers were identified for 1,359 substances.

ECHA carried out a further breakdown:

- Approximately 10% of all the pre-registrations are described as 'multi-constituent'. This includes a number of reaction masses. Many were probably errors however. Perhaps preparations or lists of substances which should have been pre-registered individually.
- Some 6% of the substances were identified only by a name. Amongst these are natural material extracts, substances identified only as colour index, reaction masses, reaction products or simply 'products'. There are also polymers, oils including natural and mineral oils, ethoxylates, probable trade names and UVCBs (Unknown Variable Composition) and there even was the pre-registration of a 'cow'.
- For over 50.000 substances at least one of the pre-registrants has indicated that the deadline is 1 December 2010.

EC numbers have been assigned to many substances that did not have any. A 600 number was allocated to all substances pre-registered with a CAS number, and a 900 number to the others.

## **Overburdened SIEFs (Substance Information Exchange Forum)**

ECHA is seriously worried about the way many SIEFs are functioning, or better not functioning at all. It has developed tips for helping SIEFs along. These can be downloaded from: [http://echa.europa.eu/sief\\_en.asp](http://echa.europa.eu/sief_en.asp)

Some self appointed 'facilitators' are still blocking the process. For many substances no SIEF has yet been formed and the communication by some facilitators is incomplete since they have not reached all the pre-registrants for their substances, or have missed that there substance has been pre-registered under more than one EC number.

The response to serious facilitators is very low. In many cases not more than 10% of all the pre-registrants react. This is a result of the many pre-registrations by companies that do not intend to actually register, such as importers of preparations.

An awareness campaign has been started by ECHA under the slogan: 'The clock is ticking'. Also all lead-registrants are asked to make themselves known to ECHA. They will receive additional help in the form of workshops and, if industry gets what it wants, a special 'hot line'.

In the case of joint submissions, the latest submission date for the lead registrant is three months before the official deadline. That is the time that ECHA needs to check the correctness of the dossier. The other registrants may only submit after this check has been performed. In practice this puts the deadline forward by three months. The European Commission is presently studying the possibility of making correction to a dossier after the deadline. This would 'hand back' these disparately needed three months.

*Sitmae customers: We at Sitmae are keeping track of all the SIEFs that are being formed. We get into active contact with the SIEFs for substances of which our customers have indicated that they wish to register them.*

## **Harmonised Classification & Labelling (C&L)**

Next to the C&L Inventory, the old system for 'Harmonised Classification and Labelling' still exists. Member States may ask legally binding C&L for CMR substances, active ingredients in biocidal or plant protection products and for substances where there is a need for harmonisation because suppliers classify the same substance in different ways.

So far six dossiers have been submitted by member States. They are in their official 'consultation phase':

Substance identification			Proposed by	Proposed classification
Substance name	CAS number	EC number		
Di-tert-butyl peroxide	110-05-4	203-733-6	France	Muta Cat 3; R68* (Muta 2 - H341)
Gallium arsenide	1303-00-0	215-114-8	France	T; R48/23 Repro. Cat. 2; R60 Carc. Cat 3; R40 (STOT Rep. 1 - H372 Rep. 1B - H360F Carc. 2 - H351)
Indium phosphide	22398-80-7	244-959-5	France	Carc. Cat 2; R45 Repro. Cat.3; R62 T; R48/23 (Carc. 1B - H350 Rep. 2 - H361f STOT Rep. 1 - H372)
Trixylyl phosphate	25155-23-1	246-677-8	Netherlands	Repr. Cat.2; R60 (Repr. 1B - H360)
Epoxiconazole	133855-98-8 (formerly: 106325-08-0)	406-850-2	Sweden	Repro Cat. 2, R61* (Repr 1B; H360D)
Diantimony trioxide	1309-64-4	215-175-0	Sweden	Xi; R38* (Skin Irrit. 2, H315)

*Sitmae customers: Sitmae customers who export any of these substances or are planning to do so, should be aware that once the classification has been harmonised, most of these substances will have an early registration obligation.*

## New Cosmetics Regulation

The new European Cosmetics Regulation will soon be formally adopted. The European Parliament and the Council reached a 'common position' in March and the Plenary of the European parliament has voted in favor of the package deal. The Regulation will replace the 1976 cosmetics Directive.

Some important features:

- Nano-materials can be used in cosmetics, unless the European Commission's Scientific Committee on Consumer Products (SCCP) concludes otherwise. However, nano-materials used as colorants, preservatives or UV filters will have to be approved before the Regulation comes into force, three years after its adoption. Nano-materials must be identified as such on the list of ingredients on the label. *(See also next item of this newsletter: nano-materials under REACH)*
- Some widely used substances, such vitamin A, may through REACH be classified as carcinogens despite general acceptance that they are safe to use in cosmetics. Category 3 CMRs can be used if an evaluation by the SCCP concludes that it is safe. Category 1 or 2 CMRs will require SCCP's specific approval, taking into account overall exposure from other sources and a particular consideration of vulnerable groups. The applicant will also have to show that there are no alternatives.

- With regard to endocrine disruptors, the regulation will be reviewed when agreed criteria for identifying these substances are available. (Or at the latest five years after the Regulation has entered into force).

Meanwhile, two bans related to animal testing of cosmetics sold in the EU came into force on 11 March. Both were included in the old cosmetics Directive when it was revised in 2003. The first prohibits the testing in the EU of cosmetic ingredients on animals. The second bans the sale in the EU of cosmetic products containing ingredients that have been tested on animals anywhere in the world. This second ban is phased in, and becomes a complete ban in March 2013. Scientific progress on certain complex safety tests for which alternative methods do not yet exist will be taken into account.

Both bans may seriously conflict with REACH. This is because REACH applies also to substances that are used both for cosmetics and for non-cosmetic purposes. Under REACH some animal test are compulsory for these non-cosmetic uses. As a result these substances would no longer be available for cosmetics, which may seriously hamper the cosmetics industry. How this conflict will be resolved is not yet known.

*Sitmae Customers: Sitmae customers affected by this new Cosmetics legislation may wish to contact us. We can put them into contact with a specialist consultant who was actively involved during the drafting of this new regulation.*

## **Nano-materials under REACH**

A new REACH Implementation Project (RIP) has been set up specifically for nano-materials. Industry experts will be invited to participate. The project has been split up in three parts:

Substance identification: How to establish the substance identity of nano-materials. The guidance will be based on 3 or 4 case studies. The first case study will address carbon nano-tubes.

Information Requirements: The information requirements on intrinsic properties of nano-materials.

Chemical Safety Assessment: How to do exposure assessment for nano-materials and ideas for how to conduct hazard and risk characterisation. Also through a number of case studies.

The work will start in September 2009 and will be finished by the end of 2010. Interim reports are foreseen and the results of case studies will be published as soon as they are available.

In the mean time work on nano-materials continues elsewhere. RIVM (the Netherlands Institute for Public Health and Environment) is making a hypothetical dossier for nano-silver. They are trying to show that there is no difference between bulk silver and the nano version. In practice this is difficult, since very little data is available for specific nano-material end-points, such as the leaching of silver from textiles. These may show to have more effect on the environment than previously thought.

A European Commission official complains about scary messages sent out by lobbyists. By these he means NGO's who claim that health risks of nano-materials are similar to those of asbestos. This, according to the Commission, stands in the way of acceptance of these materials by the general public and the enjoyments of the benefits of these materials. The NGO's in the mean time demand pre-market approval of nano-materials.

### **Candidate and Priority List**

Of the nine substances that were 'promoted' from the candidate list to the 'priority list', seven have now been recommended by ECHA for inclusion in Annex XIV (Authorisation). These seven substances are:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- 4,4'-Diaminodiphenylmethane (MDA)
- Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)
- Hexabromocyclododecane (HBCDD)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)

The ECHA recommendation, including all the background documents is available on the ECHA web site [http://echa.europa.eu/chem\\_data/authorisation\\_process/annex\\_xiv\\_rec\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp)

A complication in the authorisation process is that it does not apply to imported articles (!). It only applies to the marketing of substances in the EU. The Member States have therefore asked ECHA to initiate also a restriction process for some of these substances (Phthalates, SCCP, HBCDD). This would lead to a general prohibition to certain uses of these substances and thus also apply to imported articles.

The substances not recommended for Annex XIV may still be subject to restrictions. One substance (sodium dichromate) is put on hold, until easy substitutes that are just as harmful can also be addressed. In the future all the relevant substances in such groups may be prioritised at once.

Publication in the official Journal is expected by the end of 2009.

For the coming few years, deadlines have been set for member States to hand in dossiers for new substances on the Candidate list. (2009: August, 2010: February & October).

An informal Member State working group has developed criteria to help Member States decide which substances merit such a dossier. The criteria include current hazard classification, volume, worker exposure, consumer exposure, environmental exposure and widespread use.

### **Trade Union Priority List**

There was already the NGO's 'SIN' list. Now there is also the 'Trade Union List'. ETUC (Confederation of European Trade Unions) have published a list of substances which in their opinion should be included in the Candidate list. It contains 306 entries, covering approximately 465 different substances, of which 243 cause occupational diseases, or are at least suspected to. There is only little overlap with the SIN list.

The Trade Union List can be downloaded at: <http://www.etuc.org/a/6023>

Neither the SIN list nor the trade Union list has any legal value under REACH. Both may however be used by customers or other interested parties.

### **Call for lower ECHA Fees**

Industry is calling for a reduction of the ECHA fees. Both the economic crisis and the fact that there will certainly be more registrations than originally budgeted seem to warrant a decrease. ECHA is trying to re-estimate the number of expected registrations. Considering the difficulties in the SIEFs, this must be an almost impossible task. The results, if any, will be known by the end of June 2009.

Payment in three or four stages, as also proposed by industry, is legally impossible. According to REACH, payment of the ECHA invoice means that registration is fact. This implies that either after the first invoice there is not yet a registration, or that payment of the second and third invoice is not enforceable. Also ECHA fears the need for a large department solely chasing unpaid invoices.

### **Market Surveillance**

The AMS Regulation (765/2008) sets out requirements for accreditation and market surveillance of products marketed in the EU. This is a very general regulation, applying across the entire internal market. It entered into force in September 2008 and starts to apply from 1 January 2010.

Only parts of AMS apply to REACH. Mainly the market surveillance provisions will have implications. Member states will have to perform appropriate check, alert users of identified hazards and cooperate with 'economic operators' to prevent or reduce risks and ensure recalls where necessary. For imported products that present a serious risk, the Member States will have the obligation to prohibit placing the product on the market and for other non-complying products they must take 'appropriate action', which may also include prohibition.

There will be a system for information exchange between Member States.

The first Member State action is to make a 'Market Surveillance Programme' and to communicate this to the European Commission by 1 January 2010

## **Business Europe Top Priorities**

Business Europe (Confederation of EU industry) has published a position paper with their 'lessons learnt for two years of REACH'. It includes the following seven priority areas for action:

1. The financial burden on companies should be reduced. Phased payment of registration fees first and lowering of fees in the longer term is required.
2. Consistent European chemicals legislation needs to be guaranteed. Chemicals rules must be set using uniform criteria and consistently in one place. REACH must be this place.
3. The quality of guidance about industry's REACH obligations should be improved to avoid legal uncertainty. A strong and timely representation of industry in Partners Experts Groups and translation of Technical Guidance Documents into all EU languages will help improve the situation.
4. Truly harmonised REACH rules across Member States should be ensured, especially in terms of enforcement activities. Attention should be given to industry's practical experiences.
5. The efforts of the European Chemicals Agency (ECHA) and the Commission to involve industry are much appreciated. The REACH Helpdesk Correspondents' Network should involve industry better.
6. Impacts of REACH on international trade should be looked at very carefully. Clarity about non-European companies' obligations and full compliance with WTO rules must be ensured with a view to a real level playing field.
7. ECHA's online platform to submit data and dossiers on chemical substances (REACH-IT) must be fully operational. Making the system available in all EU languages is worth close consideration, especially for facilitating SMEs' work.

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## **Pending issues**

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

The discussions about the obligation to put the registration number of substances on safety data sheets is still going strong. Obvious conflicts of interest between enforcement authorities and industry have not yet been reconciled. Industry is concerned with workability ('a new safety data sheet for preparations, every time an ingredient is bought from a different supplier') and confidentiality ('everybody can see where I buy my raw materials').

One proposal is to leave out the last four digits, which identify the registrant. The producers would be obliged to come up with the full number within 45 days of a request from the enforcement authorities. The 45 days may however be too short for long supply lines.

Even though the obligation to put registration numbers on the safety data sheet is in the legal text, there is some room for manoeuvre. The legal text does not at all describe what information the registration number should contain; that is ECHA's prerogative. Another solution might be to simply use random numbers.

### **Technical Guidance under development**

A completely new guidance document for CLP (Classification Labelling and Packaging) is on its way. A new guidance factsheet on Authorisation has been published. Factsheets can be downloaded from: [http://guidance.echa.europa.eu/guidance3\\_en.htm](http://guidance.echa.europa.eu/guidance3_en.htm)

Shortened versions of lengthy guidance documents will be provided in the near future in many different languages. These shortened documents are currently under preparation for the 'Guidance on Requirements for Substances in Articles' and the 'Guidance on Registration'.

The European Commission has finalised and published draft guidance for Annex V (exemptions) and on Waste and Recovered Substances. The two documents have been handed over to ECHA

For the 'Guidance on Waste and Recovered Substances' however, a number of subjects still need further elaboration. They all have to do with the stipulation that substances recovered in the EU do not need to be registered if an 'Extended Safety Data Sheet' (ESDS) is available. For example: What are the obligations when a substance is recovered but does not need an SDS? How will a recovery operator know if the concerned substance has been registered? How to deal with situations where the recovered substance is used for a use that does not feature on the ESDS?

Some points in other Technical Guidance Documents will also be revisited, such as the 'Use Descriptor System', the 'Exposure Scenario Format', the 'Tier 1 Exposure Estimates', the 'Scope of exposure assessment', the 'Extended Safety Data Sheets', the 'Exposure scenarios describing strictly controlled conditions', the 'Exposure assessment for the waste life cycle stage', and the workability of the 0,1% threshold for substances in articles. REACH apparently remains complicated; even to those who have drafted it.

### **Cumulative risks from Endocrine Disruptors**

Denmark, supported by Sweden, calls attention to the 'cocktail effect' caused by mixtures of endocrine disrupting chemicals. They are advocating a cumulative risk assessment of such substances. These include the phthalates currently on the Candidate List.

For the moment ECHA and the Commission mainly see legal and practical problems for such a new approach. According to the NGO's they are 'overly focussing on the barriers to action'.

### **ECHA and EFSA cooperation**

ECHA and EFSA (European Food safety Agency) have signed a MoU (Memorandum of Understanding) to formalise their cooperation. They will cooperate on 'the assessment of the hazards and risks of chemical substances and the development of risk assessment methodologies'. They will also intensify their exchange of information and scientific data.

**Only Representative for non-EU distributors?**

REACH does not allow non-EU based distributors to appoint an Only Representative. Only non-EU manufacturers and formulators have this possibility. The Commission does not recognize that this is a real problem. They argue that basically REACH addresses the importers and REACH can also be complied with without an 'Only Representative'. The earliest that a change is possible is in 2012, when REACH is to be reviewed and revised.

Sitmae Consultancy BV  
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24 June 2009

**Annex: SDS Languages**

Country	Language 1		Language 2		Language 3	English?
Austria	German					no
Belgium	Dutch	or	French			no
Cyprus	Greek					no
Czech Republic	Czech					no
Denmark	Danish					no
Estonia	Estonian					no
Finland	Finnish	and	Swedish			no
France	French					no
Germany						
Greece	Greek					no
Hungary	Hungarian					no
Iceland						
Ireland	English					yes
Italy						
Latvia	Latvian					no
Liechtenstein	German					Mutual agreement
Lithuania	Lithuanian					no
Luxemburg	French	or	German			no
Malta	Maltese	or	English	or	Italian	yes
Netherlands	Dutch					no
Norway	Norwegian					no
Poland						
Portugal	Portuguese					no
Romania	Rumanian					no
Slovakia	Slovakian					no
Slovenia						
Spain	Spanish					no
Sweden	Swedish					no
United Kingdom	English					yes