

NEWSLETTER NO.8

Introduction

This is the eighth Sitmae REACH Newsletter. Six months have passed since our previous newsletter. This is too long and we apologise for the fact. The whole REACH community, including Sitmae, was however extremely busy to meet the first registration deadline.

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

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Previous Newsletters: still contain valuable information. They can be downloaded from our web site: www.sitmaereachservices.com .

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1. Registration

First REACH deadlines passes

December 1st 2010 was the first deadline for REACH registrations. The deadline applied to all substances marketed > 1.000 t/a, all CMR cat 1&2 > 1 t/a (Carcinogen, Mutagen, Reprotoxic) and all substances classified R50/53 > 100 t/a (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

In 2010, almost 25.000 registrations were submitted, for some 3.400 different substances. Of these nearly 400 were CMR cat. 1&2 and over 150 were classified R50/53. In 2008 ECHA had grossly underestimated the number of pre-registrations, but this time their prognoses were right on the dot.

There are fears that some essential substances would not be registered. Problems in the market place may be expected. Some 4.900 substances were supposed to be registered, so there are some 1.500 'missing'. And also a considerable number of the registration were only as 'intermediates' and these can only be used as feedstock in chemical manufacturing processes. The European Commission monitors closely the possible disappearance of substances from the market.

Approximately 86% of registrations were made by large companies and 14% were SMEs. Only Representatives of non-EU manufacturers made 19% of the registrations,

Sitmae submitted 27 registrations for 15 different substances. This proved to be a lot more work than envisaged; and it is not over yet. We are already working on a several late registrations and are expecting more in the months to come.

Next registration deadlines

No news, but an important reminder: the next registration deadlines are the following:

- Substances marketed between 100 and 1.000 t/a: 31st of May 2013
- Substances marketed between 1 and 100 t/a: 31st of May 2018

As with the first deadline, pre-registrations are no longer possible in the last year before these deadlines. The number of registrations for each of these deadlines will be much larger than for the 2010 deadline, but the dossiers can be simpler.

Late registrations

ECHA (the European Chemicals Agency) must report to Member State national authorities the registrations that were received after the deadline. In the first month after the deadline, already 2,000 registration dossiers, for 300 different substances, had been received. It is estimated that some 400 of these registrations are truly 'late'; they should have been submitted before December 1st 2010.

Not every 'late registration' however implies non-compliance with REACH. It is, for example, difficult to argue 'non compliance' when between the deadline and the actual moment of registration, less than 1.000 tons were imported or manufactured. The same is the case when after the deadline, REACH obligations for imports were 'transferred' from the importers themselves to an Only Representative, who then registers the substance.

Registrations in a non-EU supply chain

Non-EU formulators (producers of 'mixtures') may purchase substances that have already been registered by their non-EU supplier. Or they may buy substances that were registered by their European Manufacturer. Where this is the case, the importer or the non-EU formulator's Only representative no longer needs to register the substances.

In practice it is very difficult to obtain adequate proof of such registrations. A simple letter giving the registration number and the tonnage band could be enough. But the registrants sometimes require signatures under complicated contracts, wish their own OR to have the contact details of all the formulator's European customers and sometimes even regard their registration numbers as confidential business information. Lack of guidance and lack of knowledge of REACH makes for many different perceived problems and as many different solutions.

ORO (the 'Only Representatives Organisation'), of which Sitmae is a member, is asking ECHA and the European Commission to produce guidance on these, and many other, subjects.

How registration works

The consortium

The complex registration dossiers are generally prepared by a consortium. A consortium is a group of European manufacturers of the same substance. Sometimes non-EU manufacturers also participate. They determine the 'substance ID', which gives the specifications of the substance for which the dossier is produced. This includes for instance bandwidths for all possible impurities. They share toxicological studies already in their possession and commission additional studies if necessary.

The costs of the dossier and the management of the consortium are high. For large volume substances (i.e. > 1.000 t/a), these may vary between € 0,5 and € 3 million! These costs are however shared between registrants. Mostly according to tonnage band, because volumes less than 1.000 t/a require simpler dossiers. Sometimes the costs are shared according to actual quantities produced.

Lead registrant

One of the cooperating companies is the first to register; this is the 'Lead registrant'. The Lead Registrant is the only one to actually submit the complete dossier. This generally includes a 'Chemical Safety Report' (CSR) and 'Guidance to Safe Use'. The others submit only the individual part of the registration dossier. This part includes analytical proof that their substance answers to the 'substance ID' and proof that they have paid their share in the costs.

Letter of Access

Companies that do not actively participate in the consortium can also take part of this 'joint submission'. For the 2010 registration deadline, the average 'joint submission' was done by seven companies.

They purchase a 'Letter of Access' (LoA). The cost for these LoA's is equal to a fair share of the total costs. Most consortia are meticulous about a fair pricing of the LoA. If not; they are in breach of EU competition law. LoA's vary very much in price, since they depend on the number of registrants. For large volume substances, an expensive LoA may cost over € 100.000 and a cheap one may cost € 10.000.

Once the LoA is available, the individual part of the registration can be prepared. Quantities imported or manufactured are listed, analytical information is collected, the CSR (Chemical Safety Report) is checked for appropriateness, etc. Once complete, the registration is submitted to ECHA (European Chemicals Agency). Here the submission is automatically checked for completeness. If it passes the automatic checks, ECHA sends its invoice.

ECHA's invoice

The ECHA invoice depends on the size of the company and the tonnage band. Large companies (employing > 250) registering > 1.000 t/a will pay € 23.250,- . A 'Micro' enterprise (employing less than 10) registering 1 – 10 t/a pays only € 120. If a company claims to be of 'Small or Medium Size'; proof must be provided. Several years of annual accounts are necessary. 'Mistakes' are seriously fined.

Once the ECHA invoice has been paid, the registration number is sent out, and the registration is complete.

2. CLP: Notification and Safety Data Sheets

... and the first CLP deadlines passes also

January 1st 2011 was the deadline for the notification of Classification. European manufacturers and importers had to tell ECHA how they classify their substances. Only companies that have themselves registered a substance under REACH are excused from this exercise. No lower threshold applies: import of a few kilograms already triggers the obligation.

By the deadline, 3.1 million of these notifications were submitted, covering well over 100.000 different substances. These figures may look impressive, but this was done by only 6.600 different companies. The actual number of European importers of chemicals must many times higher. Especially since there is no lower threshold. It looks as if there will be an almost indefinite supply of non-compliant companies for the enforcement authorities. ECHA, in the mean time, is checking whether they have not made a mistake in their statistics: 'group notifications' may have been counted as been done by one single legal entity.

At Sitmae we prepared a simple 'How to Notify Guide'. We have put this guide put this at the disposal of our customers and their clients. Readers who wish to receive this guidance, please send an e-mail to jennifer.verspoor@sitmae.com

New Safety Data Sheets

Companies that have registered a substance must now adapt their Safety Data Sheets. The results of the Chemical Safety Assessment should of course be incorporated. Also Classification and Labelling according to GHS (Global Harmonised System) should be introduced.

The biggest change however is the addition of 'Exposure Scenario's'. There must be an 'ES' covering every different use of the chemical. A system exists to group the almost infinite number of possible uses, in a workable number of categories. Still, a substance with a widespread use will need a lot of Exposure Scenario's. Ethanol for example, needs eighteen different ones. The whole Ethanol package counts thirty six pages.

The Safety Data Sheets must be provided in an official language of the country of the recipient. To make the multiple language issue manageable, only standard phrases are used. These can be translated automatically without producing nonsense. But for the Exposure Scenario's however, no agreed standard phrases yet exist. For the time being they are only produced in English.

A Safety Data Sheet with exposure scenario's is called an 'Extended Safety Data Sheet'.

At Sitmae we offer a service for producing Safety Data Sheets and Exposure Scenario's. For more information please contact Paul Verspoor at reach@sitmae.com.

'Extended' Safety Data Sheets and mixtures

Now that new Extended Safety Data Sheets for substances come available, the SDS's for mixtures may have to be adapted. The formulator (producer of a mixture) must use the

Exposure Scenarios and the other information about his ingredients, when preparing the SDS for the mixture.

With very few exceptions, there is no obligation in REACH to make separate Exposure Scenario's specifically for the mixtures themselves. With regard to the Exposure Scenario's for the substances in the mixture, the formulator is allowed different approaches:

- He may attach the relevant Exposure Scenario's for the hazardous ingredients to the SDS for the mixture.
- He may integrate the information from Exposure Scenario's of the hazardous ingredients into the Safety Data Sheet itself.

In practice the first option will often be chosen since this saves cost and time. This will likely remain so, until adequate automatic translation of exposure scenario's becomes possible.

The exceptions mentioned above are the following:

There will be an Exposure Scenario for the mixture itself, if a separate 'Chemical Safety Assessment in accordance with Art.32.2' has been done for the mixture. No guidance for such a CSA yet exists.

There are also 'special mixtures'. In these, a hazardous substance is included within the matrix of the mixture, in such a way that exposure to the hazardous substance becomes impossible. This is often the case with alloys, but it may also occur in some polymers. Special mixtures can be made subject to a CSA to substantiate the lack of exposure. As a result, they may have their own special Exposure Scenario's.

Please note: The information above is based on the second draft of the Guidance on the compilation of Safety Data Sheets (October 2010). Later versions may differ.

3. Substances of Very High Concern

Candidate List

For the complete Candidate List see annex 1 to this newsletter.

The Candidate List of Substances of Very High Concern has been updated again. It now lists more than 45 entries. Additionally there are today (January 2011) some 13 substances likely to be moved to the Candidate List soon. The political aim of the Commission is still to add well over 100 substances to the candidate list by 2012. Whether they will succeed, depends on the efforts of the Member States: the proposals for inclusion must be based upon a lengthy scientific report.

When a Candidate List substance occurs in a mixture or an article, information must be provided to the recipients. As a minimum the name of the substance and, if necessary, also guidance for safe handling and use. Upon their request, consumers must also be informed. (Under REACH, ‘consumers’ are not ‘recipients’.)

An early warning for plans for additional listings can be obtained from the ‘registry of intentions’ on the ECHA web site: http://echa.europa.eu/chem_data/reg_intentions_en.asp

New obligations

From June 1st 2011 a new obligation kicks in for articles that contain Candidate List substances. In some cases, the producer or importer of articles will have to notify the use of a Candidate List substance to the European Chemicals Agency.

This obligation applies if the concentration of the substance in the article exceeds 0,1% and if the total quantity per producer or importer is over 1 t/a. The obligation to notify does not apply if: “... *the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.*”

It is interesting to note that the only the ‘recipient’ must receive the ‘appropriate instructions’, since under REACH, a ‘recipient’ is per definition not the consumer. It will be important to substantiate and document any decision that ‘*exposure can be excluded*’. Why there is still a need for ‘appropriate instructions’ when exposure can be excluded, is not explained.

Substances earmarked for Authorisation

Fifteen of the substances on the Candidate List have been prioritised and will be subject to authorisation soon. The first six are expected to officially feature in Annex XIV in the next few days.

When a substance is listed in Annex XIV and is thus subject to authorisation, it will be very difficult to be allowed to use it. A permit needs to be obtained, and that will be no easy task. Not only must it be demonstrated that the use is without dangers, but also that there is no substitute available. In practice, most uses for these substances will probably be made impossible.

4. Clarifications

Who is the importer?

At Sitmae, we have customers with complicated supply chains in the EU. Some have agents and others have large warehouses under customs supervision. Sometimes Swiss (non-EU) companies own stocks of commodities in Rotterdam and some goods are transported through the European Union and only customs cleared at their final destination. The REACH definitions of 'Import' and 'Importer' are such that in these complex situations, they do not obviously indicate who must be regarded as the importer.

For many reasons it is necessary to be able to determine and allocate importership under REACH in a consistent manner. The method of allocation should be acceptable to the non-European suppliers and their EU based clients, to the transporters of the goods and the service providers in the transportation chain, and of course to the enforcement authorities.

We at Sitmae have researched many national REACH helpdesks and the ECHA website. There is not one single simple solution, but we found one that will not be disputed, and should be workable in most cases:

Default rule: The importer under REACH is the 1st EU based legal entity who actually owns the imported goods. An agent is the importer only if he is the first owner of the goods.

Administrative requirements:

- 1) The contract between non-EU supplier and the first EU based owner of the goods must contain a clause allocating importership under REACH to this first EU based owner.
- 2) The papers accompanying the transportation of the goods should preferably mention both the importer and the Only Representative with their contact details.

As mentioned above, this is not the only solution. Other possibilities are equally defensible. It would for instance be possible to allocate importership to the shipping company that takes the goods into European territorial waters, or the airline that takes them into European airspace. Possible, but in most cases not very useful.

Intermediates

Intermediates are substances that are used solely to produce other substances. They require a smaller registration dossier than other substances if 'strictly controlled conditions' apply. (Monomers however do not enjoy this lighter regime). ECHA has published a draft Guidance on Intermediates. This draft is much more restrictive than acceptable to industry.

Intermediates are for example strictly defined: substances used to react while an article is produced, are not seen as intermediates and the 'strictly controlled conditions' are almost impossible to achieve.

The European Chemical Industry Council (CEFIC) protests heavily. It obtained legal opinions from two separate law firms that thoroughly disagree with the EU institutions' interpretation

of the legal text. Especially batch producers are seen to be in difficulty. The last word on the subject has not been spoken.

Substances in stock

Can pre-registered substances, that were manufactured or imported before the registration deadline, be placed on the market after that deadline, without having been registered? The European Member States did not agree on the answer, and the European Commission was asked for an opinion.

As usual, the answer is not a simple yes or no. Still, this one seems workable: First the Commission clarifies that downstream users, distributors and suppliers are not required to register anything at all. So, if the substances is placed on the market by one of these; no registration. And manufacturers or importers who no longer manufacture or import the substance have become downstream users, distributors or suppliers for that substances. As a result they do not need to register it.

This logically leaves an obligation to register for only the 'active' manufacturers and importers: those that continue their production and import after the registration deadline. They must register before putting the substances on the market. This of course they would have done anyway.

5. Articles and REACH

REACH obligations for articles

The main impact of REACH is of course on substances and mixtures of substances. ‘Articles’ are exempt from the obligation to register and pre-register any components.

There are however some important REACH provisions that affect ‘articles’. First there is the obligation to inform the recipient if the article contains substances from the Candidate List. And soon there will be substances subject to authorisation, which if they are present in an article lead to obligations with a much higher impact. And there is Annex XVII, with some sixty different restrictions to marketing and use.

On top of this, it is not always obvious whether a product qualifies as an ‘article’ or must be regarded as for instance ‘a mixture in a sophisticated container’. The REACH definition is, we have heard this before, not as clear as it should be. Guidance on the subject exists but is complicated.

Sitmae Article Certification Service

More and more European importers of articles demand ‘certified REACH compliance’ from their non-EU suppliers. This often leads to an uncontrolled and expensive testing of the products for Candidate List substances. Products are tested for even the most unlikely ingredients. The tests become worthless of course as soon as the Candidate List is expanded again.

As an answer to this situation, Sitmae has developed an ‘Article Certification Service’; especially for non-EU producers. We first substantiate that their product is indeed an article, with the REACH regulation and the Technical Guidance in hand. We then check all the substances that are used for its manufacture against the Candidate List and against Annex XIV (authorisation) and we determine whether any restriction to marketing and use apply.

If we find that any of the listed substances are used, we advise the customer of his obligations and on how to be compliant with REACH. If everything is OK, we issue a certificate of REACH compliance. We also put ourselves at the disposal to the producers’ EU customers. We will explain what we have done and if necessary we help them in case of inspections.

The service is limited to products for which all the ingredients known and traceable and to producers who keep adequate track of their suppliers and production processes. Because of the complexity of the service, only rather straightforward products can benefit. Some examples are plastic foils and other plastic object, metal foils and other metal objects, yarns, fabrics, rubber tyres, etc.

For further information on the Sitmae Article Certification Service please contact Jennifer Verspoor (Jennifer.verspoor@sitmae.com)

The 0,1% rule

The European Commission is working hard to achieve consensus between all the Member States on the ‘0,1% rule’. When articles contain more than 0,1% of a Candidate List substance

or an authorised substance, information and reporting obligations kick in. The question arises: ‘what is the article?’: the whole Korean car or every single tyre? At present the Commission interpretation is ‘the whole Korean car’. But seven Member States, amongst which Germany, disagree: they argue that every nut and bolt is a separate article.

The issue is subject to a lot of legal hassling. It is important to resolve it quickly, since from June 1st the use of Candidate List substances in articles may have to be notified to ECHA. (See the separate section on the Candidate List).

6. Miscellaneous

REACH review

Over the coming two years, REACH will be reviewed; its performance will be evaluated.

A large number of studies are planned. To name a few of the subjects: REACH effect on human health and environment, on the functioning of the chemical market, on innovation, on new technologies, REACH overlap with other legislation (106 other laws at the last count!), the requirements for registrations in the 1-10 t/a range, the alleged toxicological cocktail effect of mixtures and nano-materials. Most of the studies still need to be tendered and many don't even have an official name yet.

A 'review' is not the same as a 'revision'. It is not certain that the process will result in a change of the legislation. And if the legislation is to be changed, this will certainly not be before 2013. The next registration peak, early 2013, will happen under the present rules.

The European Commission is reluctant to initiate any changes in REACH. They are afraid to 'open a can of worms'. REACH as it stands is a very complex compromise. Opening the possibility of change, will trigger every Member State, every industrial association, every NGO and not to forget the European Parliament, to come back with their previously unfulfilled wishes.

Inspections

In 2009 European inspections focussed on pre-registrations and safety data sheets. Almost 1,600 inspections were carried out, in 25 different countries where 878 Manufacturers, 666 Importers, 83 Only Representatives and 858 Downstream Users were inspected.

Non compliance with REACH obligations was found in 24% of the inspected companies. In 5.6%, of the cases the content of the pre-registration was incorrect. The required SDS were not available in 11% of the companies and in 20% the SDS were not in compliance with the language and format requirements.

In 2011 the registration obligations and the new Safety Data Sheets will be the main subjects of the inspections.

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Candidate List January 2011

Please note: This is a simplified version which is just intended for quick reference. Please see the Candidate list on the ECHA website for details, before taking any business decisions.

Candidate List for authorisation under REACH Prioritised: Some of these substances will soon be subject to authorisation	EC Number	CAS Number
2,4-Dinitrotoluene	204-450-0	121-14-2
Diisobutyl phthalate	201-553-2	84-69-5
Lead chromate	231-846-0	7758-97-6
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2
Tris(2-chloroethyl)phosphate	204-118-5	115-96-8
Diarsenic pentaoxide	215-116-9	1303-28-2
Diarsenic trioxide	215-481-4	1327-53-3
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	85535-84-8
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: (<i>Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane</i>)	247-148-4 221-695-9	25637-99-4 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7

Dibutyl phthalate (DBP)	201-557-4	84-74-2
Candidate List for authorisation under REACH Not yet prioritised	EC Number	CAS Number
Trichloroethylene	201-167-4	79-01-6
Boric acid	233-139-2 234-343-4	10043-35-3 11113-50-1
Disodium tetraborate, anhydrous	215-540-4	1303-96-4 1330-43-4 12179-04-3
Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1
Potassium dichromate	231-906-6	7778-50-9
Ammonium dichromate	232-143-1	5-9-7789
Potassium chromate	232-140-5	7789-00-6
Sodium chromate	231-889-5	3-11-7775
Acrylamide	201-173-7	79-06-1
Aluminosilicate Refractory Ceramic Fibres <i>(These are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al₂O₃ and SiO₂ are present within the following concentration ranges: Al₂O₃: 43.5 – 47 % w/w, and SiO₂: 49.5 – 53.5 % w/w, or Al₂O₃: 45.5 – 50.5 % w/w, and SiO₂: 48.5 – 54 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).)</i>	-	Extracted from Index no.: 650- 017-00-8
Anthracene oil	292-602-7	90640-80-5
Anthracene oil, anthracene-low	292-604-8	90640-82-7



Anthracene oil, anthracene paste	292-603-2	90640-81-6
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	91995-15-2
Anthracene oil, anthracene paste, distn. lights	295-278-5	91995-17-4
Pitch, coal tar, high temp.	266-028-2	-
Zirconia Aluminosilicate Refractory Ceramic Fibres <i>(These are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al₂O₃, SiO₂ and ZrO₂ are present within the following concentration ranges: Al₂O₃: 35 – 36 % w/w, and SiO₂: 47.5 – 50 % w/w, and ZrO₂: 15 - 17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).)</i>		Extracted from Index no. 650-017-00-8
Anthracene	204-371-1	120-12-7
Bis(tributyltin)oxide (TBTO)	200-268-0	56-35-9
Cobalt dichloride	231-589-4	7646-79-9
Lead hydrogen arsenate	232-064-2	7784-40-9
Sodium dichromate	234-190-3	7789-12-0 10588-01-9
Triethyl arsenate	427-700-2	15606-95-8
Cobalt(II) sulphate	233-334-2	10124-43-3
Cobalt(II) dinitrate	233-402-1	10141-05-6
Cobalt(II) carbonate	208-169-4	513-79-1
Cobalt(II) diacetate	200-755-8	71-48-7
2-Methoxyethanol	203-713-7	109-86-4
2-Ethoxyethanol	203-804-1	110-80-5
Chromium trioxide	215-607-8	1333-82-0

Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid	231-801-5 236-881-5	7738-94-5 13530-68-2
Under consultation for Candidate List	EC Number	CAS Number
Cobalt(II) sulphate	233-334-2	10124-43-3
Cobalt(II) dinitrate	233-402-1	10141-05-6
Cobalt(II) carbonate	208-169-4	513-79-1
Cobalt(II) diacetate	200-755-8	71-48-7
2-Methoxyethanol	203-713-7	109-86-4
2-Ethoxyethanol	203-804-1	110-80-5
1,3,5 Trichlorobenzene	203-608-6	108-70-3
1,2,3 Trichlorobenzene	201-757-1	87-61-6
1,2,4 Trichlorobenzene	204-428-0	120-82-1
Chromium trioxide	215-607-8	1333-82-0
Acids generated from chromium trioxide and their oligomers		
<i>Group containing:</i>		
Chromic acid	231-801-5	7738-94-5
Dichromic acid	236-881-5	13530-68-2
Oligomers of chromic acid and dichromic acid	-	-