

NEWSLETTER No.1

Introduction

This is the first Sitmae REACH Newsletter. With this newsletter we inform our customers about what is happening in the ever changing world of REACH. This new legislation it is still subject to interpretation and even to occasional change. The general principles stay the same, but in the details there is still a lot that needs to be clarified.

Sitmae will send you a newsletter whenever there is information which is of use to you. If you do not wish to receive this newsletter, please let us know by responding to this e-mail.

The subjects of this newsletter:

- Pre-registration deadline rapidly approaching
- Candidate list published
- Consequences of the candidate list
- Substitute it Now! SIN list published
- Pre-registrations under way
- Technical Guidance Notes available
- Review Annexes IV and V (Exemptions)
- Registration in non-EU supply lines
- Pre-registration and re-import
- Registration numbers
- Appendix: Candidate list (October 2008)

Pre-registration deadline rapidly approaching

At the time of writing, five more weeks remain before the pre-registration deadline passes. Any non-pre-registered substances imported into the EU after December 1st will be illegal. The European Commission has repeatedly said that there will be no extension. (Even if such an extension was wanted, it could no longer be organised: the deadline is in the law, and a European law takes a lot longer than five week to change.)

If you wish to avoid the very busy last few weeks before the deadline, we can already make your REACH ID today, even if your substance inventory is not yet ready. Once the ID exists, pre-registration can be done quickly. (Assuming of course that the information on the substances is complete and correct: chemical names, Eines numbers and CAS numbers)

Candidate list published

The Candidate list is published. It contains no more than 15 substances. This is much less than what was expected. From this Candidate list a 'priority list' will be chosen. Substances on the priority list will be the first to be evaluated for authorisation.

The first edition of the candidate list is appended to this newsletter. We suggest you check the list. If any of your substances are on it, it is time to look at the possible consequences.

Consequences of the candidate list

Under REACH, substances on the candidate list are special. Information on their occurrence in articles and preparations must for instance always be given to 'recipients' and to consumers at their request.

It is generally expected that the candidate list will work as a de-facto black list. It is likely that EU based importers will demand absolute absence of these substances in any products that they buy.

It is expected that there will be a lot of unnecessary questions from the public wanting to know whether candidate list substances are present in products. NGO's have pre-printed postcards ready.

From the 'Candidate list' a 'priority list' will be chosen. The substances on the priority list will be the first to be evaluated for their need to be subject to authorisation. There is however still a long way to go before any substances will reach the stage of appearing in the Annex XIV that will list these very special substances.

Information on substances on the candidate list needs only to be provided if the article or preparation (blend of chemicals) contains more than 0,1% w/w. Therefore the question is relevant: 'what is exactly is an article? Is it the whole car or is it every single nut and bolt?'

The European Commission has decided that the only legally correct answer is 'the whole car'. Several EU Member States however strongly disagree. Some have decided to accept the Commission's interpretation but to strive for a change in the law. Others, such as Denmark and Sweden, are intent on taking an importer to court and hope to prove the Commission wrong.

Substitute it Now! SIN list published

SIN stands for 'Substitute it Now!' The SIN list was made by environmental NGO's because they are dissatisfied with the shortness of the 'candidate list'. It contains some 300 substances. Some of these are obviously potential 'Substances of Very High Concern', many are already classified as Cat 1 or 2 CMR's (and already not permitted in articles in concentration > 0,1%) but other inclusions are debatable.

Please note that there are several European producers of consumer goods who are considering banning these substances as well as the substances on the Candidate list. It is wise to take note of this list.

The SIN list can be downloaded from <http://www.chemsec.org/list/>

Pre-registrations under way

By mid October 10.700 companies have done some 400.000 pre-registrations. This does not include a UK based firm and a German firm who both surprisingly pre-registered all the 100.000 existing substances in one go.

ECHA has now limited the number of pre-registrations to 10.000 per company and it will not take up the two super-registrants in the SIEFs.

Also there were 180 inquiries to determine if substances without the proper EINECS number are allowed the 'phase in' status, 230 notifications of new substances used for R&D (PPORD) and 5 registration dossier were submitted.

Many non-EU companies seem still to be waiting. They seem to be still investigating their options and are slow in concluding that there are not so many. The deadline of December 1st is approaching fast!

Technical Guidance Notes available

Technical Guidance Notes keep being published. These TGD's are there to ensure a good implementation of REACH. Of the TGD's intended for industry, only the TGD's on 'Classification and Labelling notification', 'Preparation of an application for authorisation' and 'How to comply with GHS' (the new C&L regulation) are still missing.

TGD's can be found at http://reach.jrc.it/guidance_en.htm

Review Annexes IV and V (Exemptions)

Annexes IV and V with their important exemptions have been reviewed. They have been streamlined but not been altered fundamentally. For those dealing with substances occurring in nature it may be wise to check if these substances are not now exempted. Annex IV is a simple list some forty substances that are exempted, Annex V is more complicated, for this annex a Guidance Note will soon be published.

If you want a copy of the official text, please send us an e-mail.

Registration in non-EU supply lines

It is now possible that non EU manufacturers may (through an Only Representative) register substances under REACH. This means that non EU formulators who are buying registered chemicals and who actually export the substances to the EU, do not have to register again. They will however have to show (on batch level) that the substances used were indeed registered.

Beware however: Although non-EU based formulators may thus not register, they will still need an Only Representative. Otherwise their customer (the importers) will still have the burden of pre-registration. There is no legal provision for the use of the pre-registration of a non-EU manufacturer higher up a non-EU supply line. The situation is not clear and legally not settled. In order to prevent mishaps, long delays at customs and trouble for the importers, ECHA strongly recommends that non-EU formulators pre-register all the substances in their

products, even if their suppliers do the same. Only when the suppliers prove that they actually have registered the substances in question is it wise to de-pre-register.

Pre-registration and re-import

Re-imported chemicals (i.e. produced and registered in the EU, exported and then imported into the EU again) do not have to be registered again by the importer or the non-EU formulator.

However, just as for registration in a non-EU supply line, exporter pre-registration is still needed. ECHA recommends that importers or non-EU formulators pre-register all re-imported chemicals. Only when the suppliers prove that they actually have registered the substances in question is it wise to de-pre-register.

Registration numbers

Registration numbers will consist of two parts: one part indicating the substance and another indicating the 'owner'. The numbers will have to appear on the Safety Data Sheets. Formulators and distributors are unhappy, since this will tell their customers where they purchase their ingredients. Also it is unclear what to do when a distributor or formulators has more than one supplier for the same substance. When a solution has been found, we will communicate this through a future newsletter.

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

Sitmae REACH Services BV
Paul Verspoor
21 October 2008

Appendix: Candidate list (October 2008)

No	Substance name	Einecs numbers	Reason
1	Anthracene	120-12-7 204-371-1	Persistent, bioaccumulative and toxic
2	4,4'- Diaminodiphenylmethane	101-77-9 202-974-4	Carcinogen, cat. 2
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 10588-01-9 234-190-3	Carcinogen, cat. 2; Mutagen, cat. 2, Toxic for reproduction, cat. 2
8	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2 201-329-4	Very persistent and very bioaccumulative
9	Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7 204-211-0	Toxic for reproduction, cat.2
10	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α – HBCDD, β -HBCDD, γ -HBCDD)	25637-99-4 and 3194-55-6 (134237-51-7, 134237-50-6, 134237-52-8) 247-148-4 and 221-695-9	Persistent, bioaccumulative and toxic
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
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