

Newsletter No.9

This is the ninth Sitmae REACH Newsletter. 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 our customers.

The subjects in this newsletter:

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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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New Sitmae web site

Sitmae REACH Services have a brand new web site. REACH is explained in laymen's terms. It goes from 'REACH at a glance', via an 'Executive summary' to detailed explanation of important subjects.

All our different services are now also described. We are not just 'Only Representatives', but also full REACH service providers and experienced consultants. We run a true 'One-stop REACH shop'.

Please have look: www.sitmaereachservices.com

Registrations

Missing registrations

Some 1.500 substances that should have been registered in 2010 were 'missing'. Of some 1.000 of these, this was due to postponement of the registration 2013, a change in the substance, or simply to a mistake. For some 500 substances ECHA does not know the reason for non-registration. 'Down Stream Users' fear a lack of supply, but so far no practical examples have been encountered.

ECHA expectations for the next registration deadline

The next registration deadline is in May 2013. It affects substances marketed between 100 and 1.000 tonnes per year. ECHA expects a total of around 10,000 dossiers, covering 3.500 different substances. The figure is low compared to other predictions for this tonnage band.

For many of the substances in this tonnage band there is little data available. Potential registrants are advised by ECHA to make an early start.

Registration of intermediates

Intermediates are substances that are only used to produce other substances. Some are never even isolated from the chemical process; others are temporarily stored or transported to another plant. Registration of intermediates requires far less data than 'normal' registration and is therefore much cheaper.

Of course there is a requirement to keep these substances under the 'strictly controlled conditions'. Exposure of workers and the environment must be avoided. If these 'strictly controlled conditions' cannot be met, the substance must be registered as a 'normal' substance.

The Technical Guidance on what exactly are 'strictly controlled conditions' has been revised. The new guidance is such, that far fewer substances can be regarded as 'intermediates'. When the revision was published however, the registration of intermediates was already underway.

Confusion results and an angered industry lobby is going on. Industry representatives fear that the costs for updating an intermediate dossier or for investing in modifications to the installation will not be a viable option, especially for SME's (Small and Medium Size Enterprises).

ECHA doubts 86% of intermediates dossiers

It seems a logical result of the item above. Registrants of intermediates must prove that the substance really is an intermediate. They must also prove that 'strictly controlled conditions' are in place during the whole substance life cycle.

ECHA says that most of the intermediates dossiers screened so far do not adequately demonstrate that these two conditions are met. The registrants are ‘requested’ to update their dossiers.

Dossier database

ECHA has started the dissemination of the non-confidential part of registration dossiers. Readers are recommended to have look.

<http://apps.echa.europa.eu/registered/registered-sub.aspx> . For a good example fill in: EC number 200-578-6 (Ethanol).

An important shortcoming is that only the lead registrants’ dossier is published. In this Ethanol case the lead registrants only produces ethanol for fuel. The dossier does not mention any other uses. This very much reduces the usefulness of the information. No doubt an adaptation will follow.

Confidentiality

The amount of information from the registration dossiers that is made public will increase over time. In spite of industry protests, the registrants’ names will soon also be published. (Some companies prefer the general public not to know exactly which ‘horribly poisonous’ substances they produce). ECHA argues that if a registrant had wished to stay anonymous, he should have employed a ‘Third Party Representative’. ECHA also argues that, per definition, anything that is normally published in a Safety Data Sheet cannot be confidential.

A legally interesting issue arises, where non-EU producers have used the services of an Only Representative. ECHA proposes to publish the name of the principal rather than the name of the OR. But these non-EU producers have no legal possibility to employ a ‘Third Party Representative’. There was never a need, since anonymity was a logical consequence of using the OR in the first place. Discussions are continuing.

ECHA’s intention to increase the amount of public information is in part caused by a court case started by a number of NGO’s.

Evaluation & Authorisation

Community Rolling Action Plan (CoRAP)

The 'E' in REACH stands for Evaluation. Now that a large number of substances have been registered, the Evaluation phase kicks in. There are two kinds of evaluation:

- A compliance checks of the registration dossiers and the evaluation of testing proposals
- The substance evaluation by Member States. These will study substances of concern, on the basis of the Community Rolling Action Plan (CoRAP).

The CoRAP is being developed by ECHA. The first proposal for this list is expected in December 2011 and the final version early 2012.

CoRAP will also allocate the substances to the different Member States. The plan is to evaluate 40 different substances in 2012 and 50 in the following years. Several Member States already say that they will not have enough capacity. These may have to hire consultants, but are then faced with a confidentiality issue.

Dossier selection criteria

For the selection of substances to be evaluated there are three different groups of criteria:

Hazard related criteria:

- PBT and vPvB (PBT: Persistent, Bioaccumulative and Toxic, vPvB: Very Persistent and Very Bioaccumulative). Both known and suspected.
- Suspected endocrine disrupters;
- Suspected CMR's (Carcinogenic, Mutagenic and Reprotoxic)
- Skin and respiratory sensitisers. Both known and suspected.

Exposure related criteria:

- Wide dispersive use.
- Number of using sites if emissions are due to industrial use.
- Consumer use and exposure of sensitive subpopulations such as children.
- Aggregated tonnage.

Risk related criteria:

- A high risk characterisation ratio for human and/or environmental exposure.
- Cumulative exposure from structurally related substances with hazardous properties such as endocrine disruption.

Authorisation procedure

A permit for the use of substances in Annex XIV (subject to Authorisation) can only be obtained for specific uses. Manufacturers, importers or downstream users may apply; either individually or as a group. Applications must be in by certain dates, specified in annex XIV. The whole authorisation process is governed by a strict time line.

A fee is to be paid to ECHA. An individual application of a large company will cost € 50.000 plus € 10.000 per substance and € 10.000 per use. Group applications are somewhat cheaper and very small companies pay considerably less. In addition of course the dossier needs to be drafted. Some estimate that this may be as costly as a complex registration dossier.

Two ECHA committees with Member State expert, review the application. The Risk Assessment Committee (RAC) assesses the risk to human health and environment from the requested uses. This includes the proposed risk management measures and, if relevant, the risks of possible alternative substances. The Socio- Economic Analysis Committee (SEAC) looks into the socio-economic factors and into the availability of alternatives. The committees work in parallel and have ten months to reach a draft opinion.

The draft opinions are sent to the applicants. The applicants may to comment. The comments are considered by the committees. If they think necessary, they may revise the draft opinion. Once the drafts are adopted, the European Commission takes a final decision.

REACH Lists

Authorisation list

Annex XIV (Substances subject to authorisation) already contains six substances.

The following eight substances will be added soon. The decision has been taken. The legal act is expected early 2012:

- Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)
- 2,4-Dinitrotoluene
- Diisobutyl phthalate
- Lead chromate
- Lead chromate molybdate sulphate red (C.I. Pigment Red 104)
- Lead sulfochromate yellow (C.I. Pigment Yellow 34)
- Tris(2-chloroethyl)phosphate
- Diarsenic pentaoxide
- Diarsenic trioxide

Consultations are now underway for the next set of thirteen substances;

- Chromium trioxide;
- Chromic acid, Oligomers of chromic acid and dichromic acid;
- Sodium dichromate;
- Potassium dichromate;
- Ammonium dichromate;
- Potassium chromate;
- Sodium chromate;
- Trichloroethylene;
- Cobalt(II) sulphate;
- Cobalt dichloride;
- Cobalt(II) dinitrate;
- Cobalt(II) carbonate;
- Cobalt(II) diacetate

After being 'promoted' to annex XIV, these substances remain on the candidate list. The communication obligations remain in place. All authorised substances have 'sunset' date. The earliest is in August 2014. After that date the substance may not be used without an appropriate permit.

New additions to the Candidate List

Seven new substances have been added to the Candidate List:

- 2-Ethoxyethyl acetate
- Strontium chromate
- 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
- Hydrazine
- 1-Methyl-2-pyrrolidone
- 1,2,3-Trichloropropane
- 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich

There are now 53 substances on the Candidate List. For the complete Candidate List see the ECHA web site:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Plans for the Candidate list

The European Commission intends to have 136 substances on the candidate list by the end of 2012. Most of the proposals, including a scientific dossier, must however come from the Member States. Germany plans to make 40 contributions before the end of 2012. Whether other Member States will be as active remains to be seen.

The substance **4-tert octylphenol** will probably be the first ‘substance of similar concern’ (i.e. with endocrine disrupting properties) on the Candidate List. Germany is preparing the scientific dossier.

New SIN list

The NGO’s responsible for the SIN List (SIN: ‘Substitute it Now’) have expanded their list with a twenty-two suspected endocrine disruptors. They call for swift action.

These 22 substances are found in toys, food packaging and cosmetics. Some are used as preservatives in personal care products, as UV filters and as plasticisers.

The following substances are newly listed:

- 3-benzylidene camphor
- 4-methylbenzylidene camphor
- 4-nitrophenol
- 4,4’-dihydroxybenzophenone
- Benzophenone-1
- Benzophenone-2
- Benzophenone-3
- Butylparaben
- Dicyclohexyl phthalate (DCHP)
- Diethyl phthalate (DEP)
- Dihexyl phthalate (DHP)
- Ethylhexyl methoxycinnamate
- Metam natrium
- Methyl tertiary butyl ether (MTBE)
- Pentachlorophenol
- Perchloroethylene
- Propylparaben
- Quadrosilan
- Resorcinol
- Tert-butylhydroxyanisole
- Thiram
- Zineb

The SIN list seems to gain political importance, since the European Commission says it will consult the list for new additions to the Candidate List.

To consult the SIN list and its recent additions see: <http://www.chemsec.org/list/sin-list-20>

Substances in Articles

Notification of ‘Substances in Articles’

Producers and importers of articles containing Candidate List substances had to notify the use of these substances to ECHA by June 1st 2011. This notification may however be omitted if the exposure of humans and the environment can be fully excluded or when someone has registered the substance for the use in question.

ECHA reports to have received 175 notifications by the deadline. This remarkably low number may be caused by the fact that this notification is extremely complicated. It requires the use of IUCLID; the same software package as used for making registration dossiers. ECHA intends to remind producers and importers of their obligation and hopes to make a simple IT tool for the notifications available later this year.

Guidance revised

The Technical Guidance document on ‘Substances in Articles’ has been revised. The new version is somewhat more lenient towards suppliers of articles. These may be unaware that their products contain Candidate List substances. Previously, article producers were expected to actively demand information from their suppliers. The revised version describes this as an optional action. The guidance now only states that if the information on Candidate List substances is available, it should be passed on.

The 0,1% rule

Where an article contains more than 0,1% of a Candidate List substance, REACH obligations kick in. The question remains: what is an article? The whole Korean car, or every single nut and bolt. The European Commission legal opinion is clear: the whole Korean car. Several Member States (Austria, Belgium, Denmark, France, Germany, Sweden, plus Norway) actively object. Most other Member States sympathise with the objections.

The short version of the dissenting Member States opinion is; ‘once an article, always an article’. The individual parts of an assembled article were themselves articles before they were assembled. They don’t cease to be articles, simply because they have been assembled.

France has decided to enforce the dissenting approach and has officially published this. Industry is counting on the Commission to defend its legal opinion.

French aim to ban all Phthalates

The French national assembly has voted in favour of banning all products containing phthalates, parabens or alkylphenols. These substances are feared to be endocrine disruptors.

Industry is protesting angrily. They argue that the proposed massive ban runs contrary to the scientific approach established with REACH, and is scientific, technical and legal nonsense.

The French Senate must also vote. No date has been set yet. If the proposal passes, the European Commission will have determine whether it is consistent with the REACH. Only then can it become French law.

Denmark limits itself to four phthalates

Denmark plans to ban four phthalates (DEHP, BBP, DBP and DIBP) from use indoors or coming into contact with mucous membrane. Denmark has also proposed a restriction of exactly the same content for inclusion in REACH Annex XVII.

The substances in question are listed in Annex XIV REACH (subject to authorisation). This means that their use in de EU will automatically be severely restricted in the near future. The reason behind this Danish action is that REACH authorisation only affects substances and mixtures used in the EU. It leaves imported articles alone. With an Annex XVII restriction, imported articles can be made subject to the same rules as articles produced in the EU.

An important Danish argument is the cumulative negative effect that these substances may have. If accepted by the EU, this would be the first time that such a cumulative effect of a group of substances from different source forms the basis for legislation. It would be a Danish breakthrough.

Classification & Labelling

Notification of Classification & Labelling

All producers and importers of non-registered substances had to notify their classification of the substances to ECHA earlier this year. So far ECHA has received 3.1 million notifications. Many of these are conflicting. For registered substances the classification according to the registration dossier was provided to the notifyers. But in spite of this, many nonsensical notifications have been made.

ECHA must make the resulting database public. This was postponed due to the many conflicting entries. It will now be released in the fall of 2011. Which information will be released exactly, has not yet been decided.

Labelling and packaging guidance

ECHA has published a new Technical Guidance Document on Labelling and Packaging. The document replaces a few sections from the TGD on the application of CLP criteria. The new the guidance clarifies issues like: how to determine label size, where to place supplemental information, the small packaging exemptions, interaction with transport labelling rules, the most appropriate precautionary statements and transitional provisions for chemical products already on the market.

To download the Guidance on labelling and packaging in accordance CLP, see:

http://guidance.echa.europa.eu/docs/guidance_document/clp_labelling_en.htm?time=1302516904

Cosmetics

Cosmetic substances

The Scientific Committee on Consumer Safety has recently been asked to give its opinion on the following substances used in cosmetic products:

Substance	Requested opinion
Soytrimonium chloride	The safety for use in hair dye and cosmetic applications other than as a preservative
Kojic acid	The safety for use in cosmetic products.
4-Formyl-1-methyl quinolinium salt with 4-methylbenzenesulfonic acid salt	The safety for use in hair dyes.
Benzoisothiazolinone,	Industry request to allow it in cosmetic products.

The European Cosmetics industry is worried about the inclusion of butylparaben and proylparaben, (widely used as preservatives) in the SIN list as ‘Endocrine disruptors’. (See elsewhere in this newsletter).

Animal testing

Colipa, the European Cosmetics Associations, announces that animal testing will have to go on beyond 2013. No adequate alternatives are presently available. The alternative tests, both existing and known to be under development, are not comprehensive and lack validation.

On the other hand, the UK animal welfare group PETA is funding research work to develop commercially viable alternatives for animal testing. The recipient of the funding is an American company called CeeTox. The test to be developed and validated is intended to be a full replacement for animal tests, giving quicker results at lower cost.

Denmark examines natural cosmetic products

A Danish study examined 89 cosmetic products that were marketed as ‘non-preserved’ or ‘naturally-preserved’. Some 460 different substances were identified in the products. Of these 60 have antimicrobial, antibacterial or antiseptic properties. Also several products contained ingredients that are ‘preservatives’ according to EU legislation. Almost half the products contained one or more of the fragrances citral, geraniol, limonene and linalool. These are substances that may cause allergic reactions.

Norway registers adverse reactions to cosmetics

For two years now Norway has a national register for adverse effects of cosmetic products. So far 96 notifications were received. The most serious adverse effects were from the use of permanent hair dye, with reactions including blistering and swelling. Norwegian authorities are calling for more notifications, claiming that this will allow assessment and even warnings against certain products.

Miscellaneous

REACH Review

Twelve different studies will be commissioned for the REACH review. As mentioned in our previous newsletter: a review does not necessarily lead to a 'revision'. The European Commission is very reluctant to change anything in REACH. As it stands, REACH is already the result of a very difficult compromise.

The following studies are planned.

Study Name	lead DG	Contractor	Planned for
Technical assistance related to the scope of REACH and other relevant community legislation to assess overlaps	Environment	Milieu	Oct. 11
Functioning of the European Chemical market after the introduction of REACH regulation	Enterprise	CSES	Dec. 11
Inspections requirements for REACH and CLP	Environment	Milieu	Dec. 11
Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006	ENTR	PWC	Jan. 12
Implementation and enforcement of restrictions in Member States	Enterprise	Milieu	Jan. 12
Impact of the REACH regulation on the innovativeness of EU chemical industry	Enterprise	CSES	Feb. 12
The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH)	Eurostat	Öko – Institut	Feb. 12
Technical assistance to prepare the Commission report on the operation of REACH	Environment	RPA	March 12
Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information	Environment	JRC	Sep 11 / Nov. 12
Assessment of health and environmental benefits of REACH	Environment	Not yet commissioned	Dec. 11
The REACH contribution to the development, commercialization and uptake of products of emerging technologies	Enterprise	Not yet commissioned	Jan. 12
Review of the registration requirements for 1 to 10 tonnes substances and polymers	Environment	Not yet commissioned	March 12 / Jul. 12

Commercial use of ECHA data

A German company was selling ECHA pre-registration information, which it obtained from another company that had pre-registered some 100.000 different substances. ECHA began legal proceedings to stop this activity. It was considered contrary to the ECHA IT terms of use and of ECHA's copyright. The case was settled before it came to court. The companies have stopped this activity and deleted the pre-registrations that they now no longer need.

Custom supervision exemption clarified

Substances under customs supervision do not need to be registered. As always, such a simple rule does not work in real life. The criteria have been clarified:

- The substance must of course be 'under customs supervision'.
- The substances may not undergo any treatment or processing. This includes anything that would run counter to the safety of human health and environment.
- The substance must be in temporary storage, in a free zone or in free warehouse with a view to re-exportation.

Just storing a substance in free zone or warehouses is not enough to exempt it from registration.

Registration numbers in customs declarations

REACH enforcement authorities and customs authorities are together developing a REACH enforcement project for imports. One of the issues is the REACH information that should feature in the customs declarations. The registration number of imported substances may have to be included. This could bring about very complex situations; for instance when mixtures of numerous substances are imported. Industry representatives are developing proposals for workable alternatives.

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