

NEWSLETTER NO.6

Introduction

This is the sixth 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:

<p><u>1. New guidance and regulations</u></p> <ul style="list-style-type: none"> • New Guidance • New Cosmetics regulation • REACH review • Substances in Articles • Registration numbers in Safety Data Sheets <p><u>2. Reach: work in progress</u></p> <ul style="list-style-type: none"> • 2010 Registration deadline • ECHA expects a huge workload • ECHA IT-system 	<p><u>3. Substances</u></p> <ul style="list-style-type: none"> • Candidate list expanded • Phthalates • Substances of ‘Similar Concern’ • Mixture Toxicity • Plant extracts from GMO (Genetically Modified Organisms) • Nano materials <p><u>4. Miscellaneous</u></p> <ul style="list-style-type: none"> • Enforcement • Importers • Sitmae member of the ‘Only Representatives Organisation’
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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. NEW GUIDANCE AND REGULATIONS

New Guidance

Two shortened versions of REACH guidance have been published in 22 different languages. It concerns 'Guidance in a nutshell' on substances in articles and 'registration data and dossier handling'. In addition translations of several factsheets and the ECHA navigator tool have been completed.

A new Technical Guidance Document on Waste and Recovered Substances is expected to be published in April. Updates of the TGD on the Use Descriptor System will appear chapter by chapter starting next April. The update of the TGD on Substances in Articles will appear later this month (February 2010) and the updated version of guidance on CLP is foreseen in October.

All the guidance documents can be downloaded from the ECHA web site.
(<http://echa.europa.eu>)

New Cosmetics regulation

The new EU Cosmetics regulation has been published. It was adopted in the European parliament and rubber stamped in the Council in November. It tightens the control on CMR's and introduces the need to define, assess and label nano-materials used in cosmetics. The new regulation can be downloaded from the Eur-lex website. (<http://eur-lex.europa.eu/en/index.htm>)

REACH review

REACH is to be revised in 2012. The preparations have started. Officially Article 138(6) of REACH mandates the Commission to carry out, by the 1st of June 2012, a review to assess the scope of REACH and the possible overlaps with other relevant EU legislation. Further to this review the Commission may, if appropriate, present a legislative proposal to amend the scope of REACH. It is however expected that the occasion will also be used for all sorts of other changes.

As always in the EU, such a procedure starts with a consultant who investigates. In this case the contract 'to provide policy, legal and technical support to the Commission' was awarded to Milieu Limited (Brussels, Belgium) with a small number of sub-contractors. Duration of the study 20 months, which means that it should be finished by 21 August 2011. Total cost almost € 200.000.

Where trade associations wish to look after the interests of their members, early contact with these consultants is of great importance.

Substances in Articles

When candidate list substances occur in articles in a concentration higher than 0,1%, this has to be declared to the recipient and, if asked for, also to the consumer. All sorts of problems now come to light. It still unclear what an 'article' is (the whole imported Korean car, or

every single nut and bolt). This issue will be surely addressed in the next revision of REACH. No doubt that it will become 'every nut and bolt', as recently proposed by the Nordic Council.

Another issue is old stock; spare parts for cars that have gone out of production and even spare parts coming from car wrecks are affected. The same sort of thing may go on in other industry sectors.

Registration numbers in Safety Data Sheets

The issue of the registration numbers on the Safety Data Sheets has been resolved. Suppliers who are either a distributor or a 'down stream user' may omit the part of the number that identifies the individual registrant. EU based formulators of preparations are 'down stream users'. The full number must be provided within seven days after a request from the Member State authorities. (In the case of a multi stage supply line, it is seven days for each step in the line).

So far so good for EU based formulators and distributors; but not for their non-EU equivalents! They are per definition not 'distributors' or 'down stream users': both definition in REACH clearly state that these must be EU based. Unless things change again, the non-EU formulators would still have to publish the full registration numbers. This means disclosing their suppliers and troublesome long lists of numbers if they have more than one supplier for the same ingredient.

A solution might be to allow the Only Representative to keep the full numbers and provide them to the Authorities when asked. No doubt some serious lobby work will be taking place by ORO, the Only Representative Organisation.

2. REACH: WORK IN PROGRESS

2010 Registration deadline

ECHA, the European Commission and industry are now becoming seriously worried about the first registration deadline of December 1st 2010. For many substances that have been pre-registered as being manufactured or imported in a quantity exceeding 1.000 t/a, which are classified CMR's or with R50/53, there are no registration activities underway. Even if such activities were started today, it would still be almost impossible to be ready in time for the registration deadline.

A 'High Level Steering Group' will try to address the problem. They are thinking about more awareness campaigns. Whether this will be enough, may be doubted. The Commission, ECHA and several industrial trade associations participate. A serious quantification and analysis of the problem is still missing. So far only 2.300 'lead registrants', covering as many different substances have been identified by ECHA: less than 10% of the expected numbers.

A part of the problem seems to lie with substances that are not at all produced in the EU. Here importers or non-EU manufacturers should take the lead, but seem reluctant to take on the job.

For all Sitmae customers we have checked whether any of their substances need to be registered by the first registration deadline. Where this is the case we are in communication to determine the best way to address this.

ECHA expects a huge workload

After the closing date for pre-registrations in December 2008, ECHA still received 36.000 'late pre-registrations' from 1st time importers and manufacturers. By the end of 2009 some 900 registration dossiers had been submitted of which some 170 were processed all the way through to the registration number.

In 2009, the ECHA helpdesk answered over 6.000 questions. These questions came from all over the world. The ECHA web site was visited more than 400.000 times from 162 different countries, with a total of 1,7 million page views.

For 2010 ECHA expects some 25.000 registration dossiers, some 2 million notifications of Classification & Labelling and 15.000 helpdesk questions. They are however not very sure of these figures. ECHA also has a plan B for when the number of dossiers rises to 75.000. Whatever the case, in order to cope they will have to hire extra staff and outsource some of their work.

To those who still hope that REACH will collapse under it's own weight, and ECHA with it, it will be a disappointment to find that the preparations are so thorough.

ECHA IT-system

ECHA is engaged in a huge project to prepare its IT system for the expected peak in activities by the end of 2010. Not only will it have to be ready for the expected workload, but it will also introduce some improvements and additional features. Some these will address issues



like the possibility to transfer registration rights in the case of organisational changes (mergers, de-mergers etc), cease of manufacture and different methods for the notification of Classification and Labelling (substance by substance or in bulk, with or without the use of UICLID).

3. SUBSTANCES

Candidate list expanded

Another 14 substances were added to the Candidate list. The complete list now counts 29 entries. It is added as an annex. Substances on the Candidate list will be evaluated and possibly taken up in Annex XIV with authorised substances; substances for which a strict permitting system will apply. The supplier of candidate lost substances must provide information to his industrial and commercial customers and, upon request, also to consumers. (See earlier newsletters and our web site for details).

The Commission's intention was to add 15 new entries. The producers of Acrylamide however went to the European Court, arguing that this substance is only used as an intermediate and can therefore not be subject to authorisation. As a result it can also not be a 'candidate substance'. The Court has not yet passed any final judgement, but it did decide that until it would do so, Acrylamide was not to be listed as a candidate substance.

Further expansions of the candidate list are planned to take place twice per year. For the next expansion, for which the process has started, seven substances are on the list. This plan for slow expansion of the list may however be revised. The newly installed Environment Commissioner Janez Otcnik, said in the European parliament to favour a much larger number of substances on the Candidate list. He was supported by the new commissioner for Industry and Entrepreneurship, Antonio Tajani. More than 1500 substances are eligible and it is whispered that in the near future the candidate list may count over 200 substances.

Phthalates

The European Commission must, according to REACH, evaluate the existing restrictions on six different phthalates and if necessary adapt the restrictions. It has asked ECHA to do the work. The phthalates in question are: DNOP, DINP, DIDP, DEHP, BBP and DBP. Priority is given to articles used by children but not being toys, and the phthalates that are not yet classified (DNOP, DINP and DIDP). The first screening process has started.

Substances of 'Similar Concern'

Amongst the 'Substances of Very High Concern' that are eligible for authorisation is a group called 'Substance of Similar Concern'. 'Similar concern' means as bad as Cat 1 and 2 CMR's. This is aimed mainly at the Endocrine Disruptors, for which no adequate criteria yet exist. In spite of the lack in criteria, work on endocrine disruptors has started. The first substance seriously considered to get this status of 'similar concern' seems to be a flame retardant called DecaBDE (Cas 1163-19-5).

Mixture Toxicity

A report titled 'State of the Art Report on Mixture Toxicity' was published. The report was commissioned by the European Commission. It looks into the unwanted adverse effects of exposure to mixtures of chemicals. Politically, the main issue is the simultaneous exposure to

endocrine disruptors. It is expected that in the 2012 review of REACH there will be an attempt to regulate this phenomenon. Industry fears the fact that adequate criteria to establish endocrine disruption are missing and that any form of regulation could lead to an enormous number of additional assessments.

Plant extracts from GMO (Genetically Modified Organisms)

Several Member States wanted plant extracts from GMO's to be excluded from the exemptions in Annex 5 for 'substances obtained from natural sources'. The Commission has taken position: GMO's are 'natural source' and when the extracts are not chemically modified and not dangerous, they remain exempted. The discussion is not over, but it seems to be going in the way of the Commission interpretation.

Nano materials

A RIP (Reach Implementation Project) is underway regarding nano materials. The kick-off meeting was in October and the first results are expected mid 2010. Most REACH Technical Guidance Documents are the result of such projects. Experts from national authorities and industry cooperate intensively. Four case studies have started: CNT's (Carbon Nano Tubes), TiO₂, silver and CaCO₃.

Other subjects regarding nano materials are being addressed, though not necessarily in this RIP. Some of them are: communications in the supply line, nano-materials information in IUCLID (the software package used for the REACH registration of substances), alternative testing methods etc.

The main issue is whether nano materials can be addressed in the same registration dossier as they non-nano brethren. And if this is not the case, how should they be handled. This issue has not yet been resolved.

4. MISCELLANEOUS

Enforcement

REACH Enforcement is the duty of the National authorities in the Member States. Language problems arise where multinational companies have all their data at head office; in English generally. Also some Member States require detailed information about imports. Romania is for instance reported to require excel sheets with information about all the substances even in imported articles; which are exempt from REACH.

In the Netherlands, a first court case against an Only Representative is soon expected. The OR did not provide the services required of him.

The Commission study into the fines and other punishments in case of REACH infringements was finalised. Large variations were found to no-ones surprise. Very high fines can be found in the UK, Belgium, Poland, Ireland and Portugal. Low fines in Austria, Latvia, Lithuania, Malta and Romania.

Importers

The discussion on the REACH definition of ‘importer’ seems to come to a reasonable conclusion. According to REACH the importer is the legal or natural person responsible for the import, where ‘import’ is the physical introduction into the customs territory of the EU.

A narrow interpretation of this definition would put freight forwarders, logistical companies and customs agents in the position that they might be considered to be ‘importers’ under REACH. They would have to assume all sorts of responsibilities for which they are not equipped.

The consensus now seems to be that when another company (i.e. for instance the first EU based owner of the goods) assumes, in writing, the responsibility for the import, this other company will be considered to be the importer under REACH. The service companies would thus not be affected, other than as a distributor or a down stream user.

Sitmae member of the ‘Only Representatives Organisation’

Sitmae REACH Services has become a member of the ‘Only Representatives Organisation’: ORO. This is a trade organisation of some 20 specialised REACH Only Representatives. The goal of ORO is to set quality standards for its members and to be an advocate not only for its members, but also for their customers. Web site: <http://www.onlyrepresentatives.org/>

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Candidate List February 2010

<u>Substance name</u>	<u>EC or CAS Number</u>	<u>Date of inclusion</u>	<u>Reason for inclusion</u>
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	28.10.2008	Carcinogenic (article 57a)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	28.10.2008	vPvB (article 57e)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	28.10.2008	PBT and vPvB (article 57d - e)
Anthracene	204-371-1	28.10.2008	PBT (article 57d)
Benzyl butyl phthalate (BBP)	201-622-7	28.10.2008	Toxic for reproduction (article 57c)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	28.10.2008	Toxic for reproduction (article 57c)
Bis(tributyltin)oxide (TBTO)	200-268-0	28.10.2008	PBT (article 57d)
Cobalt dichloride	231-589-4	28.10.2008	Carcinogenic (article 57a)
Diarsenic pentaoxide	215-116-9	28.10.2008	Carcinogenic (article 57a)
Diarsenic trioxide	215-481-4	28.10.2008	Carcinogenic (article 57a)
Dibutyl phthalate (DBP)	201-557-4	28.10.2008	Toxic for reproduction (article 57c)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9 (134237-50-6) (134237-51-7) (134237-52-8)	28.10.2008	PBT (article 57d)
Lead hydrogen arsenate	232-064-2	28.10.2008	Carcinogenic and toxic for



			reproduction (articles 57a and c)
Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	28.10.2008	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)
Triethyl arsenate	427-700-2	28.10.2008	Carcinogenic (article 57a)
2,4-Dinitrotoluene	204-450-0	13.01.2010	Carcinogenic (article 57a)
Aluminosilicate Refractory Ceramic Fibres 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) Al ₂ O ₃ and SiO ₂ are present within the following concentration ranges: <ul style="list-style-type: none"> • Al₂O₃: 43.5 – 47 % w/w, and SiO₂: 49.5 – 53.5 % w/w, or <ul style="list-style-type: none"> • 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).	-	13.01.2010	Carcinogenic (article 57a)
Anthracene oil	292-602-7	13.01.2010	Carcinogenic1), PBT and vPvB (articles 57a, 57d and 57e)
Anthracene oil, anthracene-low	292-604-8	13.01.2010	Carcinogenic2), mutagenic3), PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste	292-603-2	13.01.2010	Carcinogenic2), mutagenic3), PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	13.01.2010	Carcinogenic2), mutagenic3),

			PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, distn. lights	295-278-5	13.01.2010	Carcinogenic ² , mutagenic ³ , PBT and vPvB (articles 57a, 57b, 57d and 57e)
Diisobutyl phthalate	201-553-2	13.01.2010	Toxic for reproduction (article 57c)
Lead chromate	231-846-0	13.01.2010	Carcinogenic and toxic for reproduction (articles 57a and c)
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	13.01.2010	Carcinogenic and toxic for reproduction (articles 57a and c)
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	13.01.2010	Carcinogenic and toxic for reproduction (articles 57a and c)
Pitch, coal tar, high temp.	266-028-2	13.01.2010	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
Tris(2-chloroethyl)phosphate	204-118-5	13.01.2010	Toxic for reproduction (article 57c)
Zirconia Aluminosilicate Refractory Ceramic Fibres 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) Al ₂ O ₃ , SiO ₂ and ZrO ₂ are present within the following concentration ranges: <ul style="list-style-type: none"> • Al₂O₃: 35 – 36 % w/w, and • SiO₂: 47.5 – 50 % w/w, and • ZrO₂: 15 - 17 % w/w, 	-	13.01.2010	Carcinogenic (article 57a)

b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm).			
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- 1) The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)
- 2) The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5) and less than 0,1 % w/w benzene (EINECS No 200-753-7).]
- 3) The substance does not meet the criteria for identification as a mutagen in situations where it contains less than 0,1 % w/w benzene (EINECS No 200-753-7).]