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REACH REPORT JUNE 2010

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1. NEW GUIDANCE AND REGULATIONS

Moratorium on the publication of ten guidance updates

ECHA has placed a six-month moratorium on the publication of ten guidance documents until the first REACH registration deadline, 30 November 2010. Industry representatives involved in the consultation processes for these guidelines must concentrate on the upcoming REACH registrations and CLP notifications. (And, although this is not given as a reason, changing the content of guidance documents such a short time before the first deadlines is not really good governance.)

The postponement applies to the planned amendments listed below. It is pointed out however that this moratorium may result in a need to update registration dossiers later on.

Regarding registration

- Amendment of Annex V guidance (e.g. on Genetically Modified Organisms)
- Amendment of Guidance on monomers and polymers1
- Guidance on intermediates (clarification of the concept of strictly controlled conditions)

Information Requirements & Chemical Safety Assessment

- Scope of exposure assessment
- Exposure based adaptation and strictly controlled conditions
- Exposure scenarios for waste life cycle stage
- Derivation of DNELs/DMELs from human data

Other

- Guidance on substances in articles
- Guidance on Safety Data Sheets
- Guidance on the CLP Regulation - application of the CLP criteria (labelling)

New guidance on waste and recovered substances

New guidance is for companies who recycle and recover. Substances that are recycled or recovered in the EU often do not need to be registered under REACH. The guidance contains advice on the obligations under REACH and clarifies the criteria that need to be met in order to benefit from the registration exemption. It also explains obligations on sharing information on recycled and recovered substances in the supply chain.

The document can be downloaded from the ECHA website:

http://guidance.echa.europa.eu/docs/guidance_document/waste_recovered_en.pdf

New translations available

ECHA published the Guidance on Exposure Scenario Formats in all 22 official EU languages.

'Slow progress' on Candidate List

Continued pressure on ECHA to include many more substances in the Candidate list comes from green Members of the European Parliament. In the background a fundamental difference of opinion exists. Green MEP's and NGO's regard inclusion in the Candidate List as useful in its own right since it triggers the obligation to inform consumers. Member State representatives and the Commission however regard inclusion in the Candidate list as a first step in an authorisation process, and they do not wish to clog up that process.

Today substances are only included in the list if a Member State submits a dossier thick enough to cover the whole authorisation process. Legally however many more substances could be included in the list without this. Hundreds of substances that are already subject to harmonised classification as CMR (Carcinogenic, Mutagenic, Reprotoxic) could be included without a dossier. The dossiers are legally only necessary for the later steps in the authorisation process.

In the mean time the NGO 'HEAL' (Health and Environment Alliance) has launched a campaign to make the general public appeal to their national governments to nominate greater numbers of substances to the Candidate List. It has provided a model letter and list of national ministries responsible for chemicals regulation. It urges people to propose chemicals from the 'SIN' list or the Trade Union's Priority List.

It is whispered in Brussels that later this year the Candidate list will be expanded to some 200 substances.

In the pipeline

A number of issues on the desk of high level Industry-Commission consultations are in the process of being solved:

- Extra time for registration by downstream users who discover that essential substances have not be registered by a manufacturer or importer.
- What is to happen if a lead registrant fails and others have to take over?
- What must happen if the legal identity of a registrant changes during the registration process?
- What if a production plant has technical problems and production must temporarily be switched to another plant.

2. REGISTRATION

ECHA challenged by unpredictable workload

According to its latest figures, ECHA is expecting 38.000 registrations, for 4.500 – 5000 different substances before November 30th. But the figure is unsure. The total number of registration may go up to 75.000. The effort to identify the lead registrants in an early stage is partially successful; most are known now, but 1.500 are still missing.

Even when the number of registration is limited to 38.000, ECHA may expect on average 200 dossiers per day. The actual number until now (June '10) is much lower. If the numbers don't pick up, the daily numbers closer to the deadline may well exceed 1.000 per day.

ECHA is preparing for contingencies.

SME's must prove their 'smallness'

SME's (Small or Medium sized enterprises) pay lower fees to ECHA than larger companies. Where registrants claim to be SME's, ECHA checks the correctness of the claim. The company is asked to submit a considerable amount of information: two years of audited annual accounts, details of the ownership structure of the company and the composition of the headcount.

Registration of monomers

Polymers are exempt from registration under REACH. The monomers that were used for their production are however not. In the recent update of the ECHA FAQs, a difficulty is addressed, that occurs when polymers are imported and the same monomer may come from different sources.

The monomer's registration dossier must include spectral data and a chromatogram of the original monomer, but generic spectral data or a generic chromatogram are not accepted. In this case the registrant is responsible for assessing the sameness of the monomers from the different sources. If he considers that they are the same, he must submit one set of spectral data and one representative chromatogram. If the monomers from the different sources have different impurity profiles, these different compositions of the substance will be referred to in the registration dossier.

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List of intended registrations

Users of chemicals have always insisted that it should be possible for them to check whether the critical substances they use are going to be registered by their manufacturer. ECHA has now published a list of all the 4441 substances that, according to ECHA, are planned to be registered in 2010. The list is informative, but does not really help much. In many cases the 'lead registrant' is unknown to ECHA and if a substance is not on the list, this may mean that it will be registered for one of the next deadlines.

The list can be found on the ECHA website:

http://echa.europa.eu/chem_data/list_registration_2010_en.asp

3. SUBSTANCES

First new restrictions under REACH expected

Restrictions to marketing and used have existed for a long time in the EU. The existing restriction can be found in Annex XVII, making up almost half of the regulation. For the first time since it's coming into effect new restrictions will be added to this annex. Two proposals have been made by France: lead and its compounds in jewellery and the use of Dimethylfumarate (DMFu) in consumer articles.

Lead is to be restricted because children may suck or ingest jewellery. DMFu is used as an anti-moulding agent. Consumer articles containing DMFu such as furniture, clothing and shoes can cause dermatitis. There is already a temporary ban on articles containing DMFu. The proposed restriction will make this permanent. ECHA now calls for information on these two proposals.

Eight new substances on the Candidate list

The Candidate List, with substances that may in the future be subject to authorisation, has been expanded with eight new substances. It now lists 38 different substances. The eight new additions are:

- Trichloroethylene
- Boric acid
- Disodium tetraborate anhydrous
- Tetraboron disodium heptaoxide hydrate
- Sodium chromate
- Potassium chromate
- Ammonium dichromate
- Potassium dichromate

All of these substances are either carcinogenic, mutagenic or reprotoxic (CMR) substances.

See the annex of this newsletter for the complete Candidate list, complete with EINECS numbers.

For the obligations resulting from inclusion in the Candidate List see the Roadmap.

Acrylamide back on Candidate List

Inclusion of Acrylamide in the Candidate list was postponed when the European Court needed time to come to a final conclusion. Producers had argued that as it is an intermediate it is subject to authorisation, and therefore not eligible for the Candidate list. The Court has now decided otherwise and Acrylamide is back on the list. The producers are not happy. They state that the inclusion is "an idiosyncrasy with no safety implications for the use of Acrylamide and only creates the potential for confusion, casting unfounded doubts on the safety of this unique intermediate".

Greenpeace seeks further REACH restrictions on NPEs

The use of Nonylphenols (NPs) and their ethoxylates (NPEs) is restricted through REACH Annex XVII. There is evidence that NPs are endocrine disrupters and that in the environment NPEs can degrade to alkylphenol, which is persistent, bioaccumulative and toxic to aquatic life. NPs and NPEs are also classed as priority hazardous substances under the water framework Directive (WFD). This means that all emissions, discharges and losses must be phased out by 2020.

NPEs have been used as surfactants, dispersants and wetting agents in industrial and institutional cleaning products. Smaller amounts were used as emulsifiers, textile and leather finishers and as components of pesticides and water-based paints.

Greenpeace examined emissions data in the UK, Slovakia, the Czech Republic, Spain and Germany. All five countries seem not to be ensuring the phase out. Greenpeace calls for REACH implementation to be “speeded up” and that a restriction for articles containing traces of NPEs should be included in annex XVII.

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4. MISCELLANEOUS

CLP notification and imported substances

According to the CLP regulation (Classification, Labelling and Packaging of chemicals) all manufacturers and importers of chemicals must notify to ECHA the classification and labelling that they propose for their substances. Their proposed classification will be listed in a huge database. Of course there will be conflicting entries. The regulation says that the notifyers must make every effort to reach agreement amongst themselves. How they must do this is not described however.

A huge complication is that there is no lower threshold! It also applies to imports below 1 ton/year! Life is not made simple either: UICLID 2, the software for registration of substances must be used to provide information about the notifying company.

For EU based manufacturers and importers of substances 'on their own' it is may be cumbersome, but maybe doable. It 'only' applies to substances with registration deadlines in 2013 and 2018. Those who register a substance by December 2010 do not need to notify separately, since the proposed classification and labelling is part of the dossier.

For importers of preparations (mixtures) it is a different story. A small relief will be that they must 'only' notify the substances that render the preparation 'dangerous'. But the lack of a lower threshold means that may need to notify even substances that they have even not pre-registered under REACH. Happily there is an exemption for cosmetic products

The regulation offers the possibility for joint notification of 'groups of companies'. This would be a typical task for the REACH Only Representative: he knows the substances and the importers and can he get information from the non-EU based producer. It is however not to be because the OR is not at all mentioned in the regulation. They were forgotten …

A 'solution' is suggested by the authorities. The OR is to import himself a small bottle of ever substance and preparation on his files. This would give him the obligation to notify, and as he must than notify anyway, he could than do it also for the other importers. Assuming of course that he has first obtained their written consent for whatever classification or notification he will propose. Industry representatives have already classified this solution as a joke.

There is some fierce last minute lobbying going on, to get the rules changed into something more practical. If that lobby does not succeed it may be doubtful that ever a high rate of compliance with this regulation will be reached.

Enforcement: Results and Plans

The EU Member States align their REACH enforcement efforts. The first phase of enforcement concentrated on pre-registrations and safety data sheets. Between May and December 2009 almost 1,600 inspections were carried out in 23 Member States and in Norway and Iceland. In total 878 manufacturers, 666 importers, 83 only representatives and 858 downstream users were inspected.

In almost 6% of the companies the pre-registrations were incorrect. Safety data Sheets were missing in 11% of the companies, they were in the wrong language or format in 20% of the companies. Of all the safety data Sheets inspected, 15% were verifiable incorrect.

The inspection activities will be extended until spring 2011 and will include compliance with the first registration deadline of 30 November 2010.

Big difference in national REACH fines

The Commission study comparing penalties for non compliance with REACH was finished end 2009. The most common form of sanctions are fines. They are generally set between €50,000 and €1 million. The lowest maximum fines can be found in Latvia (€ 5.000). The highest in Belgium (€ 55 million). In the UK there is no maximum to the fines.

The report stresses that it does not give a full picture of the enforcement regimes, because it does not examine how penalties are implemented in practice.

The penalties were compared to the costs of compliance. The conclusion was that where fines are capped fines at a €200,000 maximum, this was not enough to override the cost of compliance in the case of 1.000+ t/a substances.

Indeed a dossier of such a substance may cost millions. Since the cost is however generally shared between consortium members, there the discrepancy between maximum fine and compliance cost is not as large as the report suggests. Also the cost of not being able to market a substance for a great while needs to be taken into account.

Dutch take “mailbox ORs” to court

Netherlands REACH authorities are taking their first ‘bogus’ or ‘mail box’ Only Representative to court. The EU legal entities of these OR’s have usually been set up by local accountants, consultancies or banks. The directors normally reside outside the EU, and they do not comply with the minimum requirements for OR’s. They are not suitably qualified for the job and create business risks for the non-EU companies that employ them. The Dutch authorities estimate that some 40 bogus OR’s operate from the Netherlands.

Nordic Council promotes the SIN-List chemicals

Denmark, Sweden, Norway Finland and Iceland form the Nordic Council. This Council agreed to advise its constituent governments to make avoidance of hazardous chemicals a part of their public procurement policies. They explicitly mention the substances on the SIN-List.

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June 2010

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Candidate List June 2010

Substance name	EC (CAS No.)	Date of inclusion	Reason for inclusion
Aluminosilicate Refractory Ceramic Fibres *(see remark below)*	-	13.01.2010	Carcinogenic (article 57a)
Zirconia Aluminosilicate Refractory Ceramic Fibres *(see remark below)*	-	13.01.2010	Carcinogenic (article 57a)
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)
Bis(tributyltin)oxide (TBTO)	200-268-0	28.10.2008	PBT (article 57d)
Trichloroethylene	201-167-4	18.06.2010	Carcinogenic (article 57 a)
Acrylamide	201-173-7	30.03.2010	Carcinogenic and mutagenic (articles 57 a and 57 b)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	28.10.2008	vPvB (article 57e)
Diisobutyl phthalate	201-553-2	13.01.2010	Toxic for reproduction (article 57c)
Dibutyl phthalate (DBP)	201-557-4	28.10.2008	Toxic for reproduction (article 57c)
Benzyl butyl phthalate (BBP)	201-622-7	28.10.2008	Toxic for reproduction (article 57c)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	28.10.2008	Carcinogenic (article 57a)
Tris(2-chloroethyl)phosphate	204-118-5	13.01.2010	Toxic for reproduction (article 57c)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	28.10.2008	Toxic for reproduction (article 57c)
Anthracene	204-371-1	28.10.2008	PBT (article 57d)

2,4-Dinitrotoluene	204-450-0	13.01.2010	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)
Disodium tetraborate, anhydrous	215-540-4	18.06.2010	Toxic for reproduction (article 57 c)
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	13.01.2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))
Cobalt dichloride	231-589-4	28.10.2008	Carcinogenic (article 57a)
Lead chromate	231-846-0	13.01.2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Sodium chromate	231-889-5	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium dichromate	231-906-6	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Lead hydrogen arsenate	232-064-2	28.10.2008	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Potassium chromate	232-140-5	18.06.2010	Carcinogenic and mutagenic (articles 57 a and 57 b).
Ammonium dichromate	232-143-1	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Boric acid	233-139-2 / 234-343-4	18.06.2010	Toxic for reproduction (article 57 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)
Tetraboron disodium heptaoxide, hydrate	235-541-3	18.06.2010	Toxic for reproduction (article 57 c)
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	13.01.2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Pitch, coal tar, high temp.	266-028-2	13.01.2010	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)

Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	28.10.2008	PBT and vPvB (articles 57 d and 57 e)
Anthracene oil	292-602-7	13.01.2010	Carcinogenic[1)], PBT and vPvB (articles 57a, 57d and 57e)
Anthracene oil, anthracene paste	292-603-2	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene-low	292-604-8	13.01.2010	Carcinogenic[2)], mutagenic[3)], PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	13.01.2010	Carcinogenic[2)], mutagenic[3)], 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)
Triethyl arsenate	427-700-2	28.10.2008	Carcinogenic (article 57a)

Remark: See ECHA original list for extensive description

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).]