

# PRESS MEMO

This memo focuses on the first REACH deadline of 30 November 2010. It provides background information on the statistics available immediately after the deadline on the morning of 1 December.

Hesinki, 01 December 2010

# The outcome of the First REACH Registration Deadline

# **Overview**

As of 24:00, 30 November 2010, ECHA had received 24,675 registration dossiers, submitted for nearly 3,400 phase-in substances. The final number of registrations and substances will be available when all submitted dossiers have been processed within the coming weeks.

Registrations were received from all member states, the highest percentage being from Germany at 23%, almost double the 12% received from the United Kingdom which submitted the second highest number of registrations.

The overall number of registrations accepted for processing is in line with what was originally forecast by the European Commission. The numbers of registrations increased steadily throughout the year, but from September 2010, the trend changed. Numbers soared dramatically - incoming registrations in a single month totalled four times the number of dossiers previously registered. The increase became more gradual again in October – an increase of 7% percent - with statistics increasing again over the last month.

In the last six months, the ECHA Helpdesk dealt with in excess of 5 500 enquiries from companies. Of these, 27% were minor technical issues concerning REACH-IT that were easily resolved. A further 22% concerned more complex submission activities such as for example, data sharing, invoicing and business rules. During 2010, ECHA has also provided a series of training sessions and 16 webinars which attracted over 10,000 participants. Finally, during the last quarter, ECHA has proactively contacted more than 500 companies (30% of them SMEs) by phone or e-mail to help with their specific submission problems. As a result of this and the availability of specific IT tools to pre-check the content of the dossiers, the success rates of submitted dossiers increased steadily.

During 2010, the Directors Contact Group identified 28 different scenarios in which companies might face impediments to registration and measures to help such companies were set up. A total of 17 such cases were submitted to ECHA by the deadline.

ECHA received registrations for nearly 400 substances which are listed as CMRs<sup>1</sup> and more than 150 as R50-53<sup>2</sup> from Annex VI of the CLP regulation. Of those, 27 are already on the Candidate List of Substances of Very High Concern.

In this document, the numbers provided reflect the registrations of phase-in substances required by the 2010 deadline.

<sup>&</sup>lt;sup>1</sup> CMR: Category 1 or 2 Carcinogenic, Mutagenic or Reprotoxic substance from CLP Annex VI Table 3.2 (Annex I of DSD).

R50-53: Very toxic to aquatic organisms substances from CLP Annex VI Table 3.2 (Annex I of DSD) or by selfclassification in the dossier

# 1. Number of registration dossiers Accepted for Processing (AfP) and successfully completed

Based on information gathered from various industry sources early in 2010, ECHA expected to receive registrations for up to 4,700 substances and between 25,000 and 38,000 registration dossiers.

The final number of substances registered by the first REACH deadline will only be available after all registration dossiers have been processed. The majority of the registration dossiers will be processed by 28 February, while the remainder (i.e. the small minority who failed the technical completeness check and need to submit further information via an updated dossier) will be processed during 2011. ECHA's website will be updated regularly with the latest statistics.

#### Submissions

Dossier type	Accepted for Processing	Successfully Completed		
	Total*	For the 2010 deadline**	Total*	For the 2010 deadline**
Registration	19,702	17,174	14,265	12,312
Transported Isolated				
Intermediate	3,544	2,692	2,699	1,979
On-Site Isolated				
Intermediate	1,429	857	1,037	492
Total	24,675	20,723	18,001	14,783

<sup>\*</sup>Total includes dossier updates during the period.

# 2. Dossier submissions split by Joint Submission (Lead and Member Registrants) or Individually

Information exchange is one of the main principles of the REACH regulation. Joining a Substance Information Exchange Forum (SIEF) is a legal obligation for all registrants of phase-in substances pre-registered or registered before the deadline. SIEFs are formed by companies that intend to register the same phase-in substance. The SIEFs are established to facilitate the sharing of information, avoid the duplication of new studies, avoid unnecessary animal testing and agree on classification and labelling if necessary.

Normally, each substance has a Lead Registrant who submits the joint registration dossier. Other SIEF members submit their dossier as member registrants. For substances submitted jointly, there is an average of 6.5 members for every Lead Registrant.

#### 2. Breakdown of Submissions

	% Accepted for Processing	Ratio Member/Lead**
Joint - Lead Registrant	12%	
Joint - Member Registrant	82%	6.7
Individual Registrant*	6%	

<sup>\*</sup> Includes individual submissions for non-phase in substances

<sup>\*\*</sup>Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

<sup>\*\*</sup> Number of Member Registrants for every Lead Registrant

#### 3. Dossier submission failure rates

Business Rules and related failures (e.g. file format) decreased dramatically during the year and stabilised in recent months (an average of 15%) and the Technical Completeness Check (TCC) failure was very low (approx 1-2%) once registrants were using the TCC check tool.

# 3. Technical Completeness Check Failure Rates

Dossier type	For the 2010 deadline*	
Registration	1%	
Transported Isolated Intermediate	2%	
On-Site Isolated Intermediate	1%	

<sup>\*</sup> Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

# 4. Dossier submissions by country

Reflecting the European chemicals market, the largest number of dossiers submitted came from Germany. Iceland, Norway and Lichtenstein are included in the list because they are part of the European Economic Area and are implementing REACH.

### 4. Dossiers Accepted for Processing by Country

Country	For the 2010 deadline*	
Country	Number	Percentage
Germany	4727	23%
United Kingdom	2430	12%
The Netherlands	1922	9%
France	1838	9%
Belgium	1676	8%
Italy	1504	7%
Spain	1251	6%
Poland	705	3%
Sweden	582	3%
Finland	546	3%
Czech Republic	444	2%
Austria	392	2%
Greece	313	1.5%
Romania	302	1.5%
Norway	289	1.4%
Ireland	227	1.1%
Portugal	217	1.0%
Bulgaria	212	1.0%
Hungary	212	1.0%
Slovakia	170	0.8%
Denmark	161	0.8%
Luxembourg	141	0.7%
Cyprus	105	0.5%
Lithuania	101	0.5%
Slovenia	86	0.4%
Estonia	77	0.4%
Latvia	66	0.3%
Iceland	16	0.08%
Malta	8	0.04%
Liechtenstein	3	0.01%
Total  * Possiers submitted by companies indicating a phase-in substance mee	20,723	100%

<sup>\*</sup> Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

#### 5. Dossier submissions by company size

The 2010 deadline concerns chemicals manufactured or imported in the highest volumes and the most hazardous substances. This tends to be reflected in the size of the companies that submitted their registration dossiers.

### 5. Dossiers by Company Size

Company size	Accepted for Processing For the 2010 deadline*
Large	86%
Medium	9%
Small	4%
Micro	1%

<sup>\*</sup> Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

### 6. Dossier submissions as an Only Representative (OR)

Almost a fifth (19%) of all dossiers that were accepted for processing were submitted by Only Representatives. Only Representatives are those legal entities representing non-EU manufacturers. This figure demonstrates the ability of non-EU companies to participate successfully in REACH.

#### 6. Dossiers submitted by an Only Representative

	Accepted for Processing For the 2010 deadline*
Only Representative	19%

<sup>\*</sup> Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline

# 7. Number of DCG issues

The Directors' Contact Group (DCG) was set up in January 2010 and is made up of the European Commission, ECHA and Industry Associations. As a result of the DCG's work, solutions were found for 28 issues of concern to industry of which 4 required notifications to ECHA. By the deadline, a total of 17 companies had identified themselves as being affected by those 4 issues.

### 7. Registrants Making Use of the Directors' Contact Group Solutions

Issue	Description	Number
10	Completeness of dossiers	13
15	Legal entity change	2
20	Dependency on the lead registr	0
21	SIEF without EU manufacturer	2
Total		17

Number of companies that uploaded their evidence.

### 8. Number of testing proposals

Before performing tests to fulfil info requirement listed in Annex IX and X of the REACH Regulation, the company must submit a testing proposal. Any test proposed on animals will be subject to public consultation during the coming months.

# 8. Number of Testing Proposals Received

Process step	Accepted for Processing
Dossiers with testing proposal(s)	580
Testing proposals	1,548

### 9. ECHA Helpdesk statistics in the last 6 months (Jun-Nov)

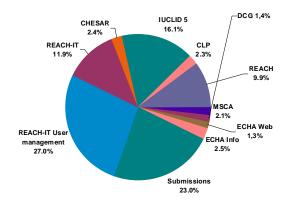
The ECHA Helpdesk dealt with in excess of 5500 questions from companies. Of these, 27% were minor technical issues concerning REACH-IT that were easily resolved. A further 22% concerned more complex submission activities such as for example, data sharing, invoicing and business rules.

## SPECIAL SERVICE FOR REGISTRANTS

ECHA Helpdesk

1. Incidents received (June - November 2010)

Topic	Total Incident Count	Percentage
REACH	573	9.9%
CLP	133	2.3%
IUCLID 5	932	16.1%
CHESAR	141	2.4%
REACH-IT	689	11.9%
REACH-IT - User management	1561	27.0%
Submissions	1332	23.0%
ECHA Info Support	144	2.5%
ECHA Web Support	77	1.3%
Directors' Contact Group (DCG)	79	1.4%
Member State Competent Authority		
. ,	119	2.1%
Total received	5,780	100.00%



#### **NEXT STEPS**

#### **Processing**

Information on the registered substances is published on ECHA's website at: <a href="http://apps.echa.europa.eu/registered/registered-sub.aspx">http://apps.echa.europa.eu/registered/registered-sub.aspx</a>

#### Dissemination

Non confidential information provided by companies in their dossiers will be published on ECHA's website over the coming months.

Information is already provided from the earliest successful dossiers at <a href="http://apps.echa.europa.eu/registered/registered-sub.aspx">http://apps.echa.europa.eu/registered/registered-sub.aspx</a>

#### **Evaluation**

ECHA will evaluate 5% of dossiers in each tonnage band and all dossiers which include testing proposals relevant to Annexes IX and X.

#### **Next Legal Deadlines**

Manufacturers and importers must notify the classification and labelling of their substances to ECHA by 3 January 2011 (if they have not already done so in their registration dossier). This includes the classification and labelling of hazardous substances of any volume as well as non-hazardous substances subject to registration after 2010.

The next REACH deadlines are in 2013 and 2018:

- 31 May 2013 for phase-in substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer in the Community or per importer at least once after 1 June 2007;
- 31 May 2018 for phase-in substances manufactured in the Community or imported in quantities of 1 tonne or more per year per manufacturer or per importer at least once after 1 June 2007.

# **Further information**

ECHA's Press Release on 1 December 2010 including Executive Director Geert Dancet's video message

Frequently Asked Questions on REACH

### **ECHA** website

**European Commission DG Enterprise REACH pages** 

**European Commission DG Environment REACH pages** 

### **ECHA Press Office**

press@echa.europa.eu