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Report Summary 2011

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The Operation of the REACH and CLP Regulations

Following seven years of extensive consultation, the REACH regulation was adopted in December 2006. It is the most ambitious piece of chemicals legislation in the world. At the beginning of 2009, REACH was complemented by an updated Classification, Labelling and Packaging regulation (CLP).

This document summarises the report that the European Chemicals Agency (ECHA) has prepared for the European Commission on how these two regulations have worked to date.

REACH requires the Agency to report on the operation of the legislation, to the European Commission every five years. This report is the first of its kind since REACH came into effect. It reviews the Agency's initial experiences of working with the new legislation, highlighting the workability of REACH and CLP including the key strengths and weaknesses in their implementation.

THE LEGISLATION IS WORKING

In its infancy, critics feared that REACH was too ambitious: it was complex; placed heavy responsibilities on companies; and set demanding deadlines for industry and the regulators. The overarching message of ECHA is that the REACH and CLP regulations are working successfully and that the various actors responsible for the work are responding as required. To a large extent the success of the legislation can be attributed to the effective collaboration between the key actors - industry, other stakeholders, the Member States, the European Commission and the Agency.

DEADLINES

The legislation set challenging deadlines: for pre-registration in December 2008; registration in November 2010; and notification of classification and labelling in January 2011. Those deadlines were successfully met by tens of thousands of companies, the Member States Competent Authorities and the Agency, which met the demands placed on it to provide companies with support and guidance and the means to register and notify.

NUMBER OF REGISTRATIONS AND CLP NOTIFICATIONS RECEIVED

Submission type	Number
Full registrations	26 337
Registrations: intermediates	5 455
Notifications	3.2 million

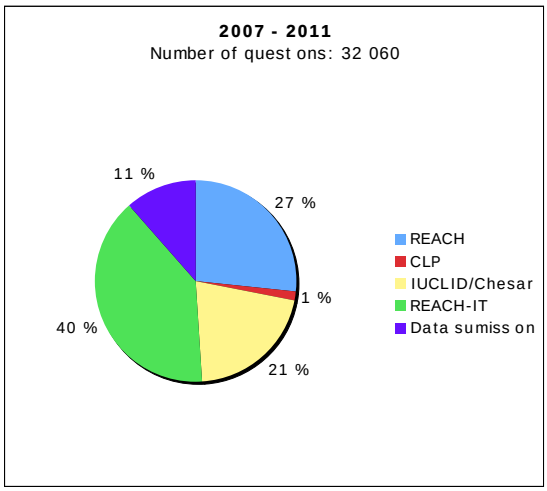
LESSONS LEARNT

Implementing a new and unique piece of legislation is challenging. Lessons are learnt quickly as each hurdle is encountered. The first, significant challenge for all actors was uncertainty.

For companies manufacturing and importing chemicals, for example, there was uncertainty in the interpretation of the legal text, how best to comply, how to work with fellow manufacturers, how best to share data and what agreements to put in place. For users of chemicals, so called downstream users, uncertainty occurred in how to ensure that their substances have been registered for their uses. For the Agency there was uncertainty in how best to provide the clarity and guidance that industry needed and how to plan and prepare resources for an unknown volume of registrations.

In fact, the Agency has assisted companies by providing advice, guidance, training and IT tools (often in 22 EU languages) and by stabilising these tools by not issuing updates in the six months prior to the first deadline.

The second challenge was the need for new, collaborative working relationships – between companies; between the Member State Competent Authorities, their Helpdesks and enforcement authorities; and between the Agency, the European Commission, industry and other stakeholders. These relationships have been built and have borne fruit in terms of producing working relationships that are deepening and will last.



QUESTIONS RECEIVED BY THE ECHA HELPDESK BY TOPIC.

A third challenge occurred in the inter-relationship between various aspects of REACH and CLP. For example, differences in the identification of

substances have led to difficulties in the development and implementation of substance information exchange fora (SIEFs); platforms for companies to share data on their substances.

Also, as a result of these fundamental differences on substance identification, there have been knock-on implications for dossier evaluation, classification and labelling and risk management activities that need to be addressed. This is an area in which the Agency needs to work in partnership with industry and the Commission.

SIZE DISTRIBUTION OF SIEFS (BASED UPON PRE-REGISTRATION INFORMATION)

No of companies	Substances	% of total
> 500	438	0.3
100 - 499	3 061	2.1
50 - 99	3 780	2.6
10 - 49	37 515	25.5
< 10	101 985	69.5

INDUSTRY RESPONSIBILITY

The Agency's practical experience indicates three main areas in which the operation of REACH could be improved by the proactive action of companies. Firstly, REACH has placed an increasing responsibility on companies to ensure the safe use of chemical substances. This shift of responsibility, from the regulator to industry, requires a fundamental change in mindset that is not yet fully there. Industry and industrial associations need to continue to promote this change in mindset if industry is to fully shoulder its responsibilities for safer chemicals.

Secondly, in some circumstances, it is possible to predict the effects of substances on humans and the environment without conducting new tests on vertebrate animals. However, companies have to justify their use of alternatives to testing on animals in their registration dossiers. To date, the quality of justifications has fallen short of what the legislation requires. (The Agency has produced a parallel report to this one on the use of alternatives to testing chemicals on animals).

Finally, the quality of some of the chemical safety assessments is of concern. This is crucial to the ultimate success of the REACH regulation in improving the safe use of chemicals. Companies need to improve the quality of their dossiers in this regard.

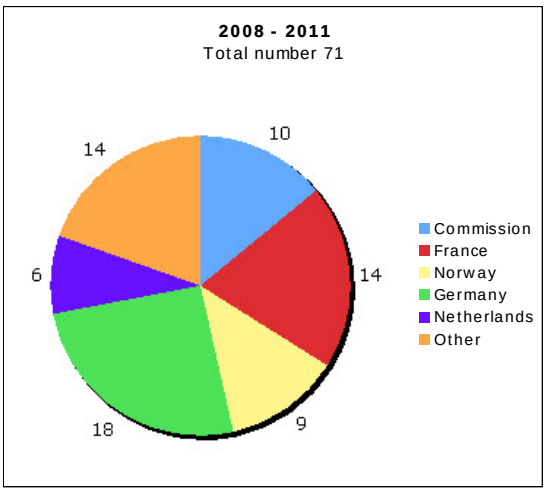
INFORMATION TO USERS

The provision of information on substances and their safe use along the supply chain to downstream users and consumers is also an aspect that requires more attention. Companies need to communicate safety information down the supply chain in a comprehensible and user-friendly form. To facilitate this communication, tools and practices need to be further developed.

The Agency itself publishes non-confidential information from registration dossiers on its website. This allows easily accessible information on hazards and safe use of chemicals, for all.

PRIORITISATION BY AUTHORITIES

In order to use resources effectively, the Agency and Member States are currently planning how to use the data from the registration dossiers to select and prioritise which chemical substances should be worked on in the authorisation, restriction or harmonised classification processes.



INTENTIONS TO SUBMIT DOSSIERS ON SUBSTANCES OF VERY HIGH CONCERN.

Note: Other includes Austria, Belgium, Denmark, Spain, Sweden and the UK.

NEXT STEPS

To ensure the success of the 2013 registration deadline the Agency, industry, the Member States and the European Commission need to build on and learn from their experiences so far. An awareness raising campaign will be organised from 2011 to 2013 to promote best practice in SIEFs and to motivate lead registrants to register early.

To create stability for the next registration deadline the Agency is not arguing for urgent changes in REACH. Thereafter, certain adjustments of the legislation would be beneficial. For example, the principles of how companies can decide if their substances are the same need to be clarified. Also the deadlines for some REACH processes should also be reviewed to ensure that the three scientific committees of the Agency can successfully manage their workload.

The Agency will continue to develop and carry out actions to improve the preparation and the quality of dossiers submitted by companies and the Member States for the REACH and CLP processes.

In the coming years, the Agency will capitalise on its successful start up period and continue to work in partnership with the European Commission, the Member States and with its stakeholders to further improve the understanding and safe use of chemicals in Europe. For this, sufficient resources are needed to ensure the continued success and coherence of the work of the Agency.

LINKS

This report summary is available in 22 EU languages.

The Operation of the REACH and CLP Regulations report can be downloaded from the website of the European Chemicals Agency. The 60-page report is available in English. It was published on 30 June 2011.

REACH Regulation EC No 1907/2006

Article 117(2)