



EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Chemicals & Biotechnology
Chemicals, Biocides and Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals – REACH
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Brussels, 20 September 2011
Doc. RRD/57/2010 (final)

Report from the

Directors' Contact Group

between Commission, ECHA and
Industry Associations on Meeting the
First REACH Registration Deadline

Achievements, Lessons Learned and
Recommendations

NOTE TO THIS REPORT

This report sets out the achievements, lessons learned and recommendations from the work of the Directors' Contact Group (DCG) between Commission, ECHA and Industry Associations on Meeting the First REACH Registration Deadline, which operated between February 2010 and March 2011.

The report is written with a multiplicity of audiences in mind. First and foremost it is intended to inform the Management Board of the European Chemicals Agency (ECHA) and the Competent Authorities on REACH And Classification And Labelling (CARACAL) of the work of the DCG. It is though also intended to provide a transparent account to other interested parties, in particular national and EU industry organisations and their members, non governmental organisations representing workers, consumers and the environment and similar organisations in third countries interested in REACH and CLP.

This report has been agreed by the members of the Directors' Contact Group.

SUMMARY

The adoption of Regulation (EC) No 1907/2006 of the European Parliament and the Council on 18 December 2006 concerning the Registration, Evaluation and Authorisation of Chemicals (REACH) marked a milestone in the modernisation of the European chemicals legislation. REACH is widely recognised as being the most ambitious and comprehensive piece of chemicals legislation in the world.

REACH set 30 November 2010 as the deadline for all manufacturers and importers of high volume substances and substances of particular concern to register their chemicals, thus subjecting a large proportion of the volume of chemicals on the EU market to the REACH rules.

Recognising that fulfilling the REACH requirements by this deadline would present significant challenges to industry, the Commission invited six industry organisations and the European Chemicals Agency (ECHA) to nominate members to and thereby set up the Directors' Contact Group (DCG). The purpose of the DCG was to monitor progress towards meeting the first registration deadline and to reduce practical obstacles to registration identified by industry.

In the course of 2010 the DCG identified and addressed in total 28 issues, contributing to the successful completion of registration by the first deadline. The practical co-operation between the Commission, ECHA and industry associations therefore proved successful, demonstrating that obstacles to registration can be reduced. This clear learning from the efforts in 2010 made the Commission decide to continue the work of the DCG with the aim of continuing the registration success story through the next major registration deadline of 31 May 2013.

1. INTRODUCTION

The adoption of Regulation (EC) No 1907/2006 of the European Parliament and the Council on 18 December 2006 concerning the Registration, Evaluation and Authorisation of Chemicals (REACH) marked a milestone in the modernisation of the European chemicals legislation. REACH is widely recognised as being the most ambitious and comprehensive piece of chemicals legislation in the world. However, it is important to recognise that it was one of several pieces of legislation initiated in the beginning of the 21st century aiming at modernising the EU chemicals policy – the regulation on Plant Protection Products was adopted on 21 October 2009, the revision of the Biocides Directive was submitted to co-decision on 12 June 2009, the CLP Regulation was adopted on 16 December 2008 to transpose the GHS requirements in the EU and a number of other pieces of sector specific legislation have been or are being revised over the last five years (toys, construction products, WEEE, RoHS).

It was acknowledged early on and has been proven time and time again, that the implementation of REACH will pose and continues to pose significant challenges for all parties concerned – be it the regulated or the regulators. The biggest changes that REACH introduced by comparison with past legislation concern industry. REACH reverses the burden of the proof from authorities having to demonstrate concern to industry having to demonstrate safety and REACH establishes fixed demanding information requirements for existing chemical substances.

The mechanism adopted in REACH to implement these changes is *registration*. Manufacturers and Importers are required to collect all available information on the chemical substance, but now with clear minimum requirements, assess the information, classify and label the substance based on the outcome of the assessment, perform a safety assessment to establish and implement safe manufacturing and use conditions and finally to document the whole process in a registration dossier. It is the activities which industry carries out and documents in the registration dossier which gives rise to the improvement in chemical safety which is expected of REACH.

The implementation of the registration requirements in REACH built on similar procedures developed under past legislation, in particular under the Existing Chemicals Regulation (Regulation (EC) 793/93) and the Notification Scheme under the Dangerous Substance Directive (Directive 67/548/EEC), but nevertheless present significant additional challenges to industry. The REACH information requirements for existing substances (called Phase-in substances in REACH) are significantly more extensive, the obligation to submit a safety assessment is new, the obligations to share data and to submit joint registrations are new. Finally REACH affects new players: there are now obligations on all actors in the supply chains and obligations on manufacturers and importers of phase-in substances in volumes between 1 and 10 tonnes.

REACH registration is therefore *the* central process in REACH for achieving its key objectives. Registration clearly represents a significant challenge for industry. It is therefore of common interest of the Commission, ECHA, Member States and Industry that this challenge is successfully met.

2. THE DIRECTORS' CONTACT GROUP

2.1. Background

During the autumn of 2009, the Commission and ECHA received indications of concerns from industry that they were facing a variety of practical problems in setting up SIEFs that they feared may reduce the quality of the registration dossiers submitted to ECHA or even prevent companies from meeting the first registration deadline. This feedback came through the regular contacts the Commission and ECHA have with industry associations and through a written request of 30 November 2009 soliciting feedback on the preparedness of industry to meet the registration challenge of 30 November 2010.

At the 15th meeting of the Management Board of ECHA held on 17-18 December 2009, the Board received and subsequently supported a note from the ECHA Executive Director concerning the creation of a group, involving the Commission, ECHA and industry, to look into the issues at stake and to seek ways of addressing the practical concerns identified by industry.

2.2. The Establishment

On 11 January 2010, the Commission selected and invited six industry organisations and ECHA to nominate members to the Directors' Contact Group (DCG) and each Director also to nominate a Sherpa. The Sherpa Group was responsible for preparing meetings, implementing their follow-up and carrying out inter-meeting work, as decided by and under the direction of the DCG.

The purpose of the DCG was to monitor progress towards meeting the 30 November deadline and to:

- reduce practical obstacles to SIEF formation and registration; and
- address foreseeable situations which a registrant may find himself, not due to his own doing, but hindering registration and which are not addressed in the legal text;

whilst staying within the legal provisions of REACH and not impinging on the objectives of REACH (in particular the protection of human health and the environment and enhancement of competitiveness and innovation).

At the first meeting of the DCG held on 5 February 2010, the group adopted its mandate (see Annex 1) and started its work to identify, prioritise and address issues of concern and to establish a system to monitor the preparedness of industry to meet the registration challenge.

The achievements of the group are set out in Section 3 of this report, whereas an overview of the meetings (Annex 2), the participants (Annex 3) and the documents prepared (Annex 4) are set out in Annexes.

2.3. The Players

The DCG comprises four of the five central players in REACH:

- The Commission responsible for REACH – represented by its DG Environment and DG Enterprise services – who in its role as guardian of the Treaty has a particular responsibility regarding the legal interpretation of REACH and the defence of the political objectives of REACH;
- ECHA whose Secretariat is responsible for managing the *registration* process in REACH;
- Industry Organisations representing Manufacturers, Importers and Distributors who are responsible for the operation of the SIEFs, the preparation and submission of (joint) registrations (and all the consequences that follow from registration);
- Industry Organisations representing Downstream Users (DU) who are responsible for communicating up and down the supply chain and reacting to registration information received through the supply chain.

The DCG does not include representatives from (any) Member State(s). The DCG therefore has no representation regarding enforcement, which is the sole competence of Member States and it has no representation of the bodies REACH required to be established within the Member States, i.e., the Competent Authorities and the National Helpdesks. The DCG also does not include other stakeholders such as the NGOs and the trade unions representation.

2.4. The Working Method

The DCG was established as an 'informal' group, in so far as it had no legal basis in REACH or other provisions. It was established by the Commission to discuss issues of common interest with the aim of developing and agreeing on solutions to be implemented under the responsibility of the respective players in the group. The DCG thereby provided advice to the Commission, ECHA and industry, covering manufactures/importers and downstream users, on how they could carry out tasks under their respective responsibility, knowing that this would be supported by the rest of the group and notably the Commission services and ECHA.

The ECHA Secretariat led the activities in developing and maintaining an *overview* of the preparedness of industry to meet the first registration deadline. ECHA used its direct contact with potential registrants (e.g. Lead Registrants having nominated themselves on the ECHA website) and a variety of other means to collect information directly from the potential registrants and concerned downstream users. The industry organisations used their networks and established websites to collect information from the companies and national associations they represented.

The industry associations led the work in identifying and detailing issues of concern. The Commission and ECHA led the activities in developing solutions. With this general division of responsibilities, the DCG developed respective issues papers setting out the details of the concern and based on a thorough understanding of the issue developed a solution.

Where a solution did not fall under the sole responsibility of ECHA or industry and involved the responsibilities of the Member States, in particular of the Competent Authorities, the Commission and ECHA consulted the CARACAL (the Competent Authorities on REACH And Classification And Labelling) on the DCG's proposals. ECHA's Executive Director also decided to consult the ECHA Forum, when solutions involved Member States Enforcement.

Finally, there was an agreement that the representatives of the industry organisations communicate with their constituencies, both to collect information needed in the work of the DCG, but also to report on progress made and solutions developed.

2.5. 'Issues' and Their 'Solutions'

The DCG used the terminology of 'issue' and 'solution' as a means of describing the concerns raised by industry and what could be done to address those concerns. In this context, an 'issue' was seen by the DCG as being the identification and detailing of the concern raised by industry; in particular it detailed the obstacle(s) hindering or reducing the efficiency of industries activities in preparing a registration in advance of the first registration deadline.

A 'solution' was a practical proposal whose implementation would remove or reduce the obstacle(s) identified or increase the efficiency of preparing for registration. Such 'solutions' fell into two categories:

- those the DCG members could identify but not implement themselves as the solution did not fall completely within their responsibilities or those of some of them;
- those that the DCG could implement as the solution did fall completely within the responsibilities of (or some of) the DCG members.

Advice and agreement was sought from the CARACAL and the National Enforcement Authorities through the Forum if the 'solution' involved fell within the responsibilities of Member States. Also these fora were used to seek advice for a number of 'solutions' where this was not the case.

3. ACHIEVEMENTS

3.1. The Overview

Extract from the DCG Mandate

Objective[s]:

Monitor the overall preparedness of companies as to meeting the 2010 registration deadline.

Tasks:

- (1) Maintain an overview of the overall preparedness of industry as to meeting the Registration Deadline based on a bottom-up analysis of available information by 31 March 2010;
- (2) Identify key information needs for improving the overview progressively up to 1 September [2010];

The Achievements

The preparation of the overview started at the 1st DCG Meeting (5 February 2010) where each of the six DCG member industry organisations and ECHA prepared an overview document of relevant available information, which highlighted that much activity was underway, both by lead registrants and by co-registrants in preparing for registration, but also that significant information gaps existed. The DCG therefore concluded that efforts needed to be invested in obtaining more and better information.

At the 3rd DCG Meeting (8 April 2010) an overview of the overall preparedness based on all available information had been developed, although it still contained considerable gaps¹. Based on the pre-registration information, ECHA at the time expected 14,237 substances to be registered, whereas ECHA had positive feedback that 3,189 substances would be registered and an additional 527 seemed like they would. The gap however was very large.

The overview was therefore continuously improved with significant efforts by industry organisations and ECHA at every meeting of the DCG, with the most important activities being:

- ECHA and each industry organisation collecting information on which substances were expected to be registered by the first deadline and whether a lead registrant had been nominated and the results published on the ECHA website;
- ECHA and DU organisations collected information on critical substances which were not on the list of substances intended to be registered and actions undertaken by the manufacturing/importing organisations to clarify the registration status of the substances;

¹ This was highlighted in the title of the overview: "Progress report on developing the Overview"

By the 6th DCG Meeting (17 September 2010) ECHA had refined its expectations to 4,477 substances being registered (corresponding to 38,000 registration dossiers). ECHA knew the identity of 2210 Lead Registrants, and of the existence of a Lead Registrant for a total of 2701 substances. Also of the 4,477 substances, 677 had already been registered. Finally, Downstream Users had identified 11 substances not on the list of 4,477 substances but critical to their business. This indicated that good progress was being made by industry, but also a concern regarding the gap between the expected substances to be registered and those actually being registered.

By the 8th DCG Meeting (26 November 2010) 4,852 substances were expected to be registered. By the deadline, reported at the 9th DCG, 24,675 registration dossiers for 4,300 substances were registered, of which 3,400 were phase-in substances. This latter number thus falls significantly short of the expected number of phase-in substances to be registered by the first deadline. However, the industry organisations reported that they had not received information from their member companies of any last minute decisions not to register substances.

The DCG therefore chose to interpret the shortfall of registrations as it was more likely that the list of substances expected to be registered was inflated rather than this being an indication of the failure of industry to comply with the registration requirements. This interpretation was further re-enforced at the 9th (21 January 2011) and 10th DCG Meetings (25 February 2011) as no participant had heard from companies any messages to the contrary.

Nevertheless, this shortfall is currently being examined by ECHA and the different industry associations.

Conclusions

The DCGs objective of establishing and maintaining an overview was met and the timelines agreed in doing so were adhered to.

It is however evident that the accuracy of the overview did not live up to the initial expectations of the DCG. Whilst it provided reassurances that no major industry wide problems were to be expected in meeting the deadline, a significant discrepancy remained on the number of substances that were indicated as intended to be registered by the 2010 deadline in the industry and ECHA surveys in spring 2010 as compared to substances actually registered.

The successes and weaknesses of the work as well as recommendations for improvements are set out in Section 4.

3.2. The Issues

Extract from the DCG Mandate

Objective[s]:

Identify and resolve priority issues of concern in meeting obligations relevant to the registration deadline [of 30 November 2010];

Identify and resolve priority issues of concern for a secured supply of high-volume substances to down stream users;

Tasks:

- (3) Develop an inventory of issues of concern to industry in meeting obligations relevant to the Registration Deadline [of 30 November 2010] by 10 February 2010;
- (4) Prioritise the inventory to identify serious issues to be addressed by 28 February 2010;
- (5) Elaborate achievable actions to solve the prioritised problems that can be implemented by no later than 1 June 2010

The Achievements

A preliminary list of issues as well as criteria for setting priorities were discussed and agreed at the 1st DCG Meeting (5 February 2010). A list of 27 Issues including the identification of and agreement on 7 Priority Issues was agreed at the 2nd DCG Meeting (2 March 2010), as well as to not only work on the 7 Priority Issues, but in fact attempt to tackle all 27 identified issues. By 1 June 2010 the DCG had developed solutions for the 7 Priority Issues² (notably endorsing many of them at the 5th DCG Meeting (25 May 2010). All remaining issues, including one new issue identified over the summer, were addressed at or immediately after the 6th DCG Meeting (17 September 2010).

The seven priority issues identified and solutions developed by the DCG were:

- Issue 11: Functioning of the SIEF;
- Issue 26: Very Late Activity in a SIEF;
- Issue 20: Dependency on the Lead Registrant;
- Issue 21: SIEF without an EU Manufacturer;
- Issue 15: Legal Entity Change;

² Part of one of the issues was later seen as being of less priority as it concerned DUs' obligations when receiving information in the supply chain and hence this part was worked on a resolved over the summer of 2010.

- Issue 10: Completeness of Dossier;
- Issue 22: Uses not Covered by a Registration.

The first two issues (11 and 26) concerned setting out practical rules for the good functioning of a SIEF enabling the lead registrant to obtain the necessary agreements within the SIEF and prepare in an orderly fashion the lead registration dossier. These issues therefore fall within the responsibility of industry so that the DCG support of the solution helped establish these solutions as 'best practices'.

Issue 20 concerns situations where the lead registrant does not manage to submit a complete lead registration and the submissions by co-registrants, who for their part do submit a complete part of their registration, are, not due to their own conduct, deemed incomplete. Issue 21 concerns SIEFs without an EU manufacturer, and mainly outlines different ways for European downstream users to ensure the registration of the European importer or only representative before the registration deadline. In addition, the situation where a downstream user decides to become an importer and register the substance after the deadline is covered. These issues fall within the responsibility of ECHA to whom the registrations of the co-registrants are submitted and hence the DCG support serves to have the Commission backing that this is legally correct and the industry backing that this addresses their concerns.

Issue 15 concerns situations where the legal entity of a potential registrant who has pre-registered is bought, sold or merged into another legal entity. Under the assumption that the contractual arrangements comply with national laws and cover how REACH responsibilities and liabilities are carried over from one legal entity to the other, this solution sets out the technical means of implementing these contractual arrangements. Also here, this implementation falls within the responsibilities of ECHA and hence the DCG support serves the same purpose as for Issues 20 and 21.

Issue 10 sets out a practical solution for those companies affected by test houses encountering unexpected problems in conducting a test required for registration and hence not enabling the registrant to register on time with the required information. As for the previous three issues, this falls within the competences of the ECHA and hence the DCG support serves the same purposes.

Finally, Issue 22 sets out the options that downstream users have to make their uses known and the obligations which the suppliers have in acting to downstream user requests. This issue and its practical implementation lie within the scope of the legal interpretation of REACH and hence fall within the responsibility of the Commission.

The Commission and ECHA considered it helpful that the solutions to the issues falling within the ECHA competence undergo a CARACAL and Forum consultation to ensure that Member States Authorities including the National Enforcement could also support ECHA taking its responsibility in the manner suggested by the DCG. This consultation process took place over the summer resulting in CARACAL support by the end of August. Simultaneously, ECHA developed the conditions under which companies would qualify for the exceptions and what evidence they need to submit to provide justification.

An overview of the work of the DCG on the 28 issues is set out in Annex 5. A summary paper and the practical implementation of the solutions have been published by ECHA on its website in 22 languages first on 27 September 2010 and updated on 12 November 2010.

ECHA reported to the 9th DCG meeting that a very limited number of companies benefited from the exceptions.

Conclusions

The DCG's objective of establishing a list of issues and identifying and providing solutions to priority issues was not only met but considerably exceeded, as all 28 identified issues were addressed.

The ambitious timelines set at the outset of the DCG were not always met. The inventory of issues was established on 2 March (not by 10 February) and the Priority Issues identified also on 2 March (not 28 February). Moreover, while the DCG was able to identify the necessary solutions before 1 June 2010, their implementation and publication was first realised on 27 September 2010 – the timing mainly being due to the consultation processes of the CARACAL and the DCG's (in particular the Commission and ECHA) reactions to the consultations.

To conclude, the main weakness of the DCG work was that it underestimated the time it would take to consult with Member States via the CARACAL and the Forum, including the work carried out by the Commission and ECHA to seek the endorsement. This is further assessed and recommendations made in Section 4.

3.3. Transparency and Communication

Extract from the DCG Mandate

Objective:

No specific objective

Tasks:

- (6) Communication with all stakeholders on the progress of registration and the actions developed by the Contact Group for the priorities issues

The Achievements

From the second meeting onwards, the DCG issued short summary statements of the results obtained, which were distributed widely, including to CARACAL and to the press.

The DCG regularly released documents to CARACAL and to the National Enforcement Authorities via the Forum which provided insights to the work of the DCG and on some documents the CARACAL and the National Enforcement Authorities via the Forum were also requested to comment or agree to. In addition, the ECHA Secretariat gave status reports to the Forum in the plenary meetings and the Commission gave status reports of the work of the DCG at every CARACAL meeting.

An overview of all the documents prepared within the DCG is given in Annex 4 along with an indication which of these documents were released to CARACAL and why the other documents were not. The release of documents to CARACAL was timely up to the summer, whereas the summary records of most DCG meetings (after the 3rd) were first released in January 2011.

Although the work of the DCG was widely supported, doubts were frequently expressed by in particular the ECHA Management Board and the CARACAL, as these bodies did not consider themselves having a full insight of the workings of the DCG. This became apparent to the DCG during the autumn of 2010 when the possibility of extending its mandate was being discussed.

Conclusions

The task was executed as intended. A weakness in the communication was the late distribution of summary records.

Overall, though not a specific task, one of the main benefits of the DCG was that it provided a communication channel on the one hand to voice the concerns of industry regarding the preparations of the first registration deadline and on the other hand to communicate solutions to industry. The analytical approach of DCG to monitor industry preparedness, analyse the concerns, and to establish solutions promoted transparency and alleviated to a considerable extent the anxiety before the deadline.

In hindsight, it seems that while handling a remarkable number of issues it sometimes remained unclear to other bodies why for some issues CARACAL and the Forum were consulted and in other cases not. The Group should have more clearly clarified what exactly a solution identified or developed by the DCG entailed. The Group should also have realised that implementation of solutions and translation of the practical instructions require also time.

The successes and weaknesses are further assessed and recommendations made in Section 4.

3.4. Registration

Extract from the DCG Mandate

Objective:

No specific objective

Tasks:

- (7) Monitor and review the implementation and effect of the recommendations and overall registration up to 1 December 2010 and resolve ad-hoc issues as they occur;

The Achievements

The main achievement of industry and ECHA regarding the first registration deadline is that it worked. ECHA received 24,675 dossiers for almost 3,400 phase-in substances.

The DCG would like to attribute part of the success of achieving this result to the work it has done. Although in the months up to the deadline, the DCG did not identify any ad-hoc problems which needed resolution prior to the deadline, it saw:

- the 'best practice' rules elaborated to support lead registrants to stepwise compile the joint registration dossiers smoothed many of the SIEF internal workings;
- the Guidance moratorium enabled companies to focus on getting the registrations finalised, without continuously following the publications of revised Guidance documents and the thereby implied need to revise the registration dossier;
- the guidelines on the rights and responsibilities of downstream users and suppliers clarified what the different actors are obliged to do and what is voluntary.

Of the 28 issues, five could be implemented if ECHA agreed, based on the provided evidence, that the concerned company fulfilled the conditions set out in the issue and its solution. ECHA was contacted by 50 companies regarding these DCG solutions resulting in 17 companies submitting the requested documentary evidence. ECHA accepted the evidence as demonstrating the fulfilment of the respective cases for five companies.

Conclusions

The work of the DCG has contributed to the success of registration prior to the first registration deadline. It is difficult to measure the impact of the work of the DCG, but clearly the establishment of a forum for a dialogue to address problems played a significant role in reducing the worries of industry in how they are expected to meet the registration requirements. Also many of the solutions (eg on SIEFs and Guidance moratorium) contributed to creating a predictable environment for the companies to do their registration work.

Finally the fact that only a few companies utilised the exceptional solutions and contacted ECHA may be due to at least three factors:

- the situations for which the solution was developed were indeed exceptional and hence only of relevance to a few companies;
- the opportunity to use such solutions was not widespread knowledge;
- the registrants in situations identified by the DCG submitted their registration dossiers without seeking prior agreement from ECHA.

The successes and weaknesses are further assessed and recommendations made in Section 4.

3.5. This Report

Extract from the DCG Mandate

Objective:

No specific objective

Tasks:

- (8) Elaborate on 'lessons learned' by the Contact Group in addressing the key issues and develop recommendations for future registration deadlines by 28 February 2011;

The Achievements

This report elaborates the 'lessons learned' from the work of the DCG. Although the DCG did not meet its self imposed deadline for finalising the report, it nevertheless provides a comprehensive and timely input to the work needed in advance of the next registration deadline.

4. LESSONS LEARNED CONCERNING THE OVERVIEW

Lessons Learned

From the first meeting of the DCG onwards ECHA coordinated the development and updating of the overview, giving indications as to industry's preparedness for meeting the first registration deadline.

Although this overview gave confidence that registration was progressing and that major difficulties in meeting the deadline were not to be expected, significant knowledge gaps did prevail. The DCG assumed this deficiency to be due to a composite of factors, including:

- Manufacturers and Importers were spending all efforts on finalising the registration dossiers and hence had little resources left to communicate down the supply chain;
- Downstream Users became active relatively late in communicating up the supply chain, putting extra strain on resources of suppliers of many substances;
- ECHA and industry associations made several attempts to contact companies, resulting on some companies being contacted through multiple channels for the same information, also putting additional strains on resources.

The DCG with ECHA in the lead is further assessing these issues under the new mandate of the DCG. The preliminary observation is that it seems that feedback collected by online surveys sent directly to pre-registrants is not conclusive, but, this needs to be analysed further.

Recommendations

ECHA and industry associations should further assess the shortcomings of the information collection methods applied by the DCG.

ECHA and industry associations should develop and implement a coordinated action plan in advance of the next registration deadline for collecting the relevant information.

This recommendation is addressed to ECHA to take the lead, with the necessary support of the Commission. It need only be implemented three months prior to the next deadline, i.e. by 1 March 2013.

5. LESSONS LEARNED CONCERNING MEETING THE 1ST REGISTRATION DEADLINE

5.1. SIEF Operation

Lessons Learned

SIEFs represent a significant new challenge to industry. They require a new way of working between the involved companies and pose significant workability challenges. The pre-registration by thousands of companies without intention to register also created difficulties for each pre-SIEF in forming a SIEF and agreeing on the lead registrant.

REACH provides little legal foundation for the smooth functioning of SIEFs leaving each individual SIEF up to establishing its own working practices, transparency schemes, time schedules, legal agreements and cost sharing mechanisms. Significant resources have therefore been devoted in the main industry associations to provide tools and guidance to SIEFs, including developing IT solutions for improving transparency and communication within SIEFs. Many large manufacturers of substances have also put together large teams to undertake the SIEF work as lead registrants or members.

SIEFs also present specific additional challenges to SMEs. They generally have fewer resources and hence are more vulnerable to unequal treatment and language barriers³. As SMEs generally cannot invest as much time in the SIEFs as bigger companies, they are subject more easily to misunderstandings.

The solutions developed by the DCG give a number of important elements to a more common framework for how SIEFs should function, but much more can be done to create better economies of scale, to disseminate standard texts for SIEF agreements, to establish common rules of transparency, timelines and data sharing and develop common IT support tools.

³ It seems that most SIEFs use English as the common language.

Recommendations

Building on the relevant DCG solutions, it is recommended that a more comprehensive 'best practices' guidance or tools should be developed. Clearly such guidance should be sufficiently flexible to ensure that currently well functioning SIEFs are not hindered.

This recommendation is addressed to the Commission and ECHA to take the lead, with significant support by industry and Member State Competent Authorities. The work to implement this recommendation should start in 2011 in order for it to be ready by 1 June 2012, well in advance of the 1 June 2013 deadline.

5.2. Registration

Lessons Learned

The DCG solutions addressing situations where a company encounters difficulties in submitting the registration by the deadline due to no fault of its own proved to have a value for a (very) limited number of companies.

This confirms indeed the exceptional nature of the cases the solutions sought within the frame provided by the REACH legislation to address, but could also be the result of limited awareness of the availability of such solutions.

It should also be noted that as the issues relevant for meeting the registration deadline are now identified the registrants for the next deadlines should be able to better prepare for them in time. It may therefore be that some of the solutions established and identified by the DCG for the 2010 deadline are not relevant for future registrants.

Recommendations

Using the relevant DCG solutions already implemented by ECHA for the next deadlines, ECHA should investigate their relevance for the next registration deadline and if necessary improve their accessibility, possibly modifying the conditions for qualifying as an 'exceptional case' and developing further the guidance for companies to apply for using the 'exceptional cases'.

This recommendation is addressed to ECHA to take the lead, with the necessary support of the Commission. It need only be implemented three months prior to the next deadline, i.e. by 1 March 2013.

5.3. Communication in the Supply Chain

Lessons Learned

The DCG solutions to improve communication in the supply chain and in particular to lend support to the Downstream Users' rights established under REACH were of help to Downstream Users. Concerns however remain that Downstream Users can not effectively take advantage of these rights, in particular to make their use known and hence having it covered by the suppliers CSR.

The DCG also identified that due to insufficient communication in the supply chain supply of crucial substances to DUs may cease resulting in significant negative

effects. This issue was not finalised under the first DCG mandate and will therefore be further developed under the new DCG mandate.

Recommendations

Building on the relevant DCG solution, it is recommended that a more comprehensive 'best practices' guidance should be developed for communicating up and down the supply chain.

This recommendation is addressed to the Commission and ECHA to take the lead, with significant support by industry and the Member State Competent Authorities. The work to implement this recommendation should start in 2011.

The particular case of a substance having been registered as a strictly controlled intermediate whilst a downstream user uses the substance in other ways than as a strictly controlled intermediate presents problems. The source of the problem could be (a) the refusal of the registrant to cover the non strictly controlled intermediate use in the registration dossier; (b) due to different interpretations of what constitutes a strictly controlled intermediate or (c) the non intermediate use is covered by manufacturers or importers of volumes below 1000 tonnes. This specific issue needs urgent attention. It is recommended that the Commission and ECHA take the lead.

5.4. ECHA Guidance Documents (and other non-IT tools)

Lessons Learned

The stability and predictability of the availability of the ECHA guidance is essential for a company's efficient planning for and preparing of a registration dossier. It is therefore of the utmost help if updates and new releases of guidance are planned and announced significantly in advance of their publication.

During the work of the DCG the recommendation to ECHA was developed and implemented that guidance updates and new releases should only take place at set fixed times in a year. The six month moratorium in publishing new guidance proved very helpful for companies' preparations in advance of the first registration deadline. However this moratorium would have been even more useful for industry had it been in place for a longer time prior to the registration deadline. This ensures that no changes in the guidance would occur during the active period of preparing a registration dossier.

When a new or revised guidance is published, industry would need time, the length of which would be dependent on the guidance, to study the new guidance and implement it in its registration. For some issues it might be relatively easy to update an existing registration or modify a registration in preparation while for others industry might implement more extensive changes, perhaps even preparing a whole new registration from scratch.

It can also be assumed that the more guidance is available in all Union languages the easier it is for companies, in particular SMEs, to prepare their registration dossiers.

In the run-up to the 1st registration deadline industry as well as ECHA was publishing guidance, which in some cases turned out to be inconsistent with one another.

Recommendations

Building on the DCG solutions regarding guidance, it is recommended that:

- new and revised guidance for registration be published on fixed recurring dates;
- to issue a guidance moratorium similar to 2010 moratorium well before the next registration deadline of 31 May 2013;
- further guidance documents, in particular those most relevant to SMEs, be translated into all EU languages.

These recommendations are addressed to ECHA to take the lead, supported by the Commission and Member State Competent Authorities. The work to implement this recommendation should start in 2011.

In addition it is recommended that industry and ECHA work together in developing consistent guidance which compliments each other but does not conflict with one another.

5.5. IT Tools and Support

Lessons Learned

As with guidance, the stability and predictability of updates to the existing software systems is of key relevance to companies planning of and preparation for registration.

Also the availability of the relevant (parts of the) IT tools in all EU languages may be of importance to ensure accessibility by companies, in particular SMEs, to the tools needed for fulfilling REACH and CLP requirements.

In addition, the continuous round the clock availability of REACH-IT in the period close to the deadline gives companies additional work time to meet the deadline.

It should be noted that the effects of any change in interpretation or implementation of the legislation, or in the content of the guidance on REACH-IT was always considered and hence putting constraints on the work, as generally any necessary change would require time and resources to change.. One of the reasons why the DCG solutions were workable was because it was carefully verified that they did not conflict with the implementation in REACH-IT, which had been developed over a number of years.

Recommendations

Building on the DCG solutions regarding IT tools, it is recommended that:

- new or revised IT tools for registration be released on fixed recurring dates;

- no new or revised IT tools for registration be released between 1 December 2012 and 1 June 2013;
- REACH-IT be available round the clock in the period close to the registration deadline;
- ECHA will conduct a feasibility and needs assessment with regard to enhancing SME accessibility to communication with the Agency, including via REACH-IT, in different languages;
- Any further solutions developed include consultations on the limitations of the IT system and the software development cycle;
- vulnerabilities in REACH-IT used by fraudulent or malevolent users be examined and, if need be, remedied.

This recommendation is addressed to ECHA to take the lead, supported by the Commission and Member State Competent Authorities. The work to implement this recommendation should start in 2011.

5.6. Helpdesks and Capacity Building

Lessons Learned

Companies greatly appreciated the increase in direct communication between ECHA and companies in advance of the first registration deadline. It would be very helpful if this practice would continue, in particular in advance of the second registration deadline.

There were also examples of high impact national programmes to assist companies to prepare for registration, in particular in France and Belgium. These and other initiatives and approaches (e.g. pooling consultants for multiple companies) should be compiled and wider recommendations made as to how to support industry better and broader in the preparation for the next registration deadline.

Recommendations

Building on the positive experience in the run-up towards the first registration deadline, it is recommended that ECHA re-establishes close to the next deadline the practice of contacting companies directly in certain cases.

This recommendation is addressed to ECHA to take the lead. The work to implement this recommendation should continue.

Furthermore it is recommended that the Commission set out to develop a compendium of past exercises implemented by Member States or industry organisations to support registrants and develop recommendations for the second deadline for discussion with ECHA, Member State Competent Authorities and industry.

Finally it is recommended that ECHA, together with the relevant industry associations, consider how to improve the support to SMEs in preparing their registrations in advance of the second registration deadline.

5.7. Lessons Learned by ECHA

Lessons Learned

From the viewpoint of submitting registration dossiers to the Agency it seems that the technical and administrative checks done by ECHA to ensure that the dossier can be processed by the REACH-IT system, also known as business rules, form a major hurdle for inexperienced registrants to successfully submit their dossiers. Although failing this step has no legal consequences as such, it may prove to be critical if the submission is done very close to the registration deadline. It appears that every batch of registrants needs to be trained separately in this regard, as ECHA could notice that another round of webinars was required in early November when the member registrants started to submit their registration dossiers in larger numbers.

During the final months up to the first registration deadline ECHA could also notice that worryingly many companies did not respect the joint registration obligations set in Article 11 of REACH.

In the last quarter of 2010 ECHA received a growing number of inquiries for phase-in substances for which the companies had not pre-registered. This could be an indication that companies first realised close to the registration deadline that a registration was due in order to continue manufacturing and import. This situation should be further investigated in advance of the next registration deadline.

In October 2010 ECHA announced that it would check the status of companies who claim to benefit from reduced REACH fees due to being SMEs. ECHA learned during the pilot exercise towards SMEs that there is a clear need for more communication about the factors determining the SME status under the Union legislation as many claimed SMEs examined did not fulfil the SME criteria and ECHA charged an administrative fee for incorrect notification of the SME status.

Recommendations

It is recommended that ECHA review the support mechanisms provided to the registrants on business rules in order to provide best possible tools, e.g. including as many business rules to ECHA's Technical Completeness Check tool as possible, to future registrants to successfully pass the business rules.

Furthermore, it is recommended that ECHA take the lead, supported by the Commission and industry to:

- Investigate further the reasons for the significant increase in inquiries of phase-in substances and, if necessary and possible, propose remedies;
- Raise awareness among the future registrants on the joint submission obligations and the related legal consequences for breaching it;
- Raise awareness among the future registrants on the determinants of the SME status;

5.8. A Further Mandate for the DCG

Lessons Learned

Although the work of the DCG provided solutions to the issues identified and there is consensus that the work should continue under a new revised mandate, the communication with in particular the CARACAL, the Member State Enforcement Authorities via the Forum and the ECHA Management Board was not optimal.

The roles and responsibilities of the individual players, in particular the role of ECHA under registration, and the role of the Commission, ECHA, and industry in the DCG had not been clearly established and discussed in these bodies.

Recommendations

Building on the experiences of consulting CARACAL and Member State Enforcement Authorities via the Forum on the DCG solutions, it is recommended that the Commission prepare a discussion document for the CARACAL and Member State Enforcement Authorities via the Forum plenary clearly setting out the working methods of the DCG and the division of responsibilities regarding registration issues between ECHA, Commission, Member States and industry.

This recommendation is addressed to the Commission regarding CARACAL and ECHA regarding the Member State Enforcement Authorities via the Forum to take the lead. The work to implement this recommendation should start as soon as possible.

6. CONCLUSIONS

The work of the Directors' Contact Group between Commission, ECHA and Industry Associations on Meeting the First REACH Registration Deadline identified and developed solutions to a number of issues, which helped smooth the way to a successful completion of registration or facilitate registration in exceptional circumstances that would otherwise inhibit it. During its work many lessons have been learned and many pointers shown as to what can be done by the Commission, ECHA, Member States and industry to make the route to the next registration deadline even smoother. To accompany the work along this road, the Commission and ECHA have decided to continue the work of Directors' Contact Group between Commission, ECHA and Industry Associations under a new mandate, with extended participation and focusing on meeting the second REACH registration deadline (see Annex 6 for the mandate)

Annex 1

Mandate of the Directors' Contact Group between Commission, ECHA and Industry Associations on Meeting the First REACH Registration Deadline

1. OBJECTIVE

The objective of the Contact Group between Commission, ECHA and Industry Associations on Meeting the REACH Registration Deadline (called 'the Directors' Contact Group') is to:

- (1) Monitor the overall preparedness of companies as to meeting the 2010 registration deadline;
- (2) Identify and resolve priority issues of concern in meeting obligations relevant to the registration deadline;
- (3) Identify and resolve priority issues of concern for a secured supply of high-volume substances to downstream users.

2. TASKS

The Contact Group will:

- (1) Maintain an overview of the overall preparedness of industry as to meeting the Registration Deadline based on a bottom-up analysis of available information by 31 March 2010;
- (2) Identify key information needs for improving this overview progressively up to 1 September;
- (3) Develop an inventory of issues of concern to industry in meeting obligations relevant to the registration deadline by 10 February 2010;
- (4) Prioritise the inventory to identify serious issues to be addressed by 28 February 2010
- (5) Elaborate achievable actions to solve the prioritised problems that can be implemented by no later than 1 June 2010;
- (6) Communication with all stakeholders on the progress of registration and the actions developed by the Contact Group for the prioritised issues;
- (7) Monitor and review the implementation and effect of recommendations and overall registration up to 1 December 2010 and resolve ad-hoc issues as they occur;

- (8) Elaborate on ‘lessons learned’ by the Contact Group in addressing the key issues and develop recommendations for future registration deadlines by 28 February 2011

The Directors’ Contact Group can create technical working groups to facilitate the progress.

3. PARTICIPATION

A maximum of three representatives – of which at least one at Director level - from each Commission service and from ECHA will participate in the Directors’ Contact Group, as well as a maximum of three representatives from each of the following Industry organisations:

- CEFIC
- Eurométaux
- REACH Alliance
- Concawe
- FECC
- UEAPME

The Contact Group can be opened to other associations having a direct interest in the registration deadline of December 2010, whilst keeping the size of the Contact group to a manageable size.

4. PREPARATION OF MEETINGS.

A Sherpa for each organisation, one from each Commission service and one from ECHA will be nominated to support the preparations of the meetings of the Directors’ Contact Group and to monitor the work to be carried out.

5. CONDUCT OF THE MEETINGS

The Directors’ Contact Group will meet every month. These meetings will be chaired by the Commission. The Commission will also be in charge of the secretariat of meetings organised in this context.

6. TERM

The Directors’ Contact Group will operate until 31 March 2011.

Annex 2

Participants of the DCG

European Commission

- Gustaaf Borchardt – DG Environment
- Bjorn Hansen – DG Environment
- Gwenole Cozigou – DG Enterprise
- Graham Willmott – DG Enterprise

European Chemicals Agency

- Geert Dancet
- Andreas Herdina
- Christel Musset

Industry

- Colette Alma-Zeestraten – CEFIC
- Lena Perenius – CEFIC
- Martin Kayser – CEFIC
- Joeri Lennaers - Eurométaux
- Michele Wyart –REACH alliance
- Patrice Rollet – FECC
- Fabrice Delhaise - FECC
- Michael Lane – CONCAWE
- Patrick Peuch - CONCAWE
- Thomas Fischer – UEAPME
- Paul Verspoor - CheMI Platform
- Anne-Claire Rasselet – Orgalime
- Véronique Scailteur - DUCC

Annex 3

Meetings of the DCG

1st meeting – 5 February 2010

2nd meeting – 2 March 2010

3rd meeting – 8 April 2010

4th meeting – 6 May 2010

5th meeting – 25 May 2010

6th meeting – 17 September 2010

7th meeting – 22 October 2010

8th meeting – 26 November 2010

9th meeting – 21 January 2011

10th meeting – 25 February 2011

Annex 4

Documents of the DCG

Documents			CIRCA Nr.	Comment
RRD/SR	1	Summary Record of 1st DCG Meeting (05-02-10)	4	
RRD/SR	2	Summary Record of 2nd DCG Meeting (02-03-10)	20	
RRD/SR	3	Summary Record of 3rd DCG Meeting (08-04-10)		To be finalised
RRD/SR	4	Summary Record of 4th DCG Meeting (06-05-10)	23	
RRD/SR	5	Summary Record of 5th DCG Meeting (25-05-10)	24	
RRD/SR	6	Summary Record of 6th DCG Meeting (17-09-10)	25	
RRD/SR	7	Summary Record of 7th DCG Meeting (22-10-10)		To be finalised
RRD/SR	8	Summary Record of 8th DCG Meeting (26-11-10)	26	
RRD/SR	9	Summary Record of 9th DCG Meeting (21-01-11)	27	
RRD/SR	10	Summary Record of 10th DCG Meeting (25-02-11)		
RRD	2	Mandate of the Directors' Contact Group	1	
RRD	5	Criteria for Setting Priorities	2	
RRD	8	Issue 24: Stability of Guidance	21	Completed CARACAL consultation
RRD	11	Communication on the Work of the DCG	3	
RRD	15	Issue 21: SIEFs without EU Manufacturer	8	Completed CARACAL consultation
RRD	17	Issue 20: Dependency on Lead Registrant	9	Completed CARACAL consultation
RRD	18.1	Issue 22: Uses not Covered by a Registration (1)	N.A.	Final Version as "Summary Paper" released via ECHA website
RRD	18.2	Issue 22: Uses not Covered by a Registration (2)	N.A.	Final Version as "Summary Paper" released via ECHA website
RRD	19	Issue 15: Legal Entity Change	10	Completed CARACAL consultation
RRD	20	Issue 10: Completeness of Dossiers	11	Completed CARACAL consultation
RRD	21	Status Report: 15 Issues	N.A.	Status as of 31-05-2010 released as RRD/33/2010 (final)
RRD	22	Status Report: Remaining 5 Issues	12	
RRD	23	Communiqué: Outcome of 3rd Meeting (08-04-10)	5	
RRD	26	Issue 11 and 26: SIEF and Very Late Activity	14	
RRD	27	Issue 16: ECHA Hotline	15	
RRD	28	Communiqué: Outcome of 4th Meeting (06-05-10)	6	
RRD	30	Issue 5: RIPs on Nano-materials	16	
RRD	31	Issue 17: Abuse of REACH-IT	17	
RRD	32	Key Messages for 2010	N.A.	CARACAL document CA/64/2010
RRD	33	Communiqué: Outcome of 5th Meeting (25-05-10)	18	
RRD	35	Issue 25: Inclusion of CSR in Joint Registration	19	
RRD	55	Later Lead Registrants	N.A.	Released as part of an ECHA Press Release
RRD	53	Downstream User Concerns	N.A.	CARACAL document CA/39/2011
RRD	56	Mandate of Extended DCG	N.A.	CARACAL document CA/38/2011
RRD	57	Lessons Learned		This document
RRD	61	SIEF Guidance and Tools	N.A.	CARACAL document CA/10/2011
RRD	X	Communiqué: Outcome of 2nd Meeting (02-03-10)	7	
RRD	X	Issue 1: C&L Inventory	22	Released to CARACAL

All other documents were preparatory working documents which either did not result in agreements or resulted in one of the documents in the list above or in information being posted on the ECHA website.

Annex 5

Overview of the 28 Issues

Summary Paper:

Issue No. 1

C&L notifications

Companies should be able to claim confidentiality for the IUPAC name of the substance they have to notify to the C&L inventory. This is of particular concern for substances that do not have to be registered by 1 December 2010 or before they can be placed on the market, e.g. because they are manufactured/imported in volumes of < 1 tpa.

Companies can keep the IUPAC name confidential in certain cases (non-phase-in substances, substances used only as intermediates, in research and development or in product and process oriented research and development). Indications that the IUPAC name shall be kept confidential can only be made using IUCLID as a notification tool, as there are no facilities to do this in other notification submission tools. In the IUCLID dossier, companies are requested to provide a justification for their claim as well as an alternative name for dissemination for their substance. ECHA has issued a News Alert on this on 13 August 2010 (http://echa.europa.eu/doc/press/na_10_45_confidentiality_claims_CLP_20100813.pdf).

Issue No. 2

SDS Guidance

Industry sought clarification on ECHA's intention to publish this guidance.

The Guidance on Safety Data Sheets will only be made available after the REACH registration deadline of 30 November 2010 (see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf).

Issue No. 3

Enforcement, in particular on registration and information requirements

Pragmatic, well-equilibrated and uniform enforcement of REACH needed, taking due account of the solutions identified by DCG to specific issues.

The Forum for Enforcement has been informed of the DCG solutions.

Issue No. 4

C&L IT possibilities

Companies should have other options than individual IUCLID submission to submit their C&L notification to the inventory.

ECHA published an Excel tool to enable the creation of a bulk C&L notification on 19 April 2010 and an updated multilingual version covering 22 languages on 19 May 2010.

Issue No. 5

RIP nano and REACH

Clarification on how to report information on nano-materials in registration dossiers and the phase-in status of the nano-materials is needed.

Nano-materials can either be (a) substances on their own and thus registered as such substances, or they can be (b) forms of a substance. In case (a), nano-materials that are listed in EINECS and have been pre-registered can benefit from the phase-in registration deadlines. If not, they are non-phase in substances. In case (b), the information on the nano-material should be included in the registration dossier for the respective substance. Which of the cases (a) or (b) applies, needs to be determined by applying the criteria on substance sameness.

Issue No. 6

Steering/monitoring platform

A platform to follow-up SIEF activities, identify urgent problems and discuss solutions and strategies is needed.

The DCG launched its work on 5 February 2010 and has taken onboard this task, assisted by a “Sherpa group”.

Issue No. 7

Availability of REACH-IT in 2010

REACH-IT is not available during the weekends.

ECHA monitors REACH-IT user activity; once user traffic increases to a volume that merits extending its availability beyond work days only, ECHA will make the system continuously available for industry.

Issue No. 8

Introduction of IUCLID 5.2 and REACH-IT 2.0

No major updates should be made six months before the registration deadline as these could mean additional workload to companies having to transfer their dossier from one version to another.

IUCLID 5.2 was released in February 2010 and the last major REACH-IT release for industry before the registration deadline was made at the end of May 2010; ECHA does not envisage any further releases for industry ahead of the registration deadline.

Issue No. 9

Problem of substance identity

Industry has many problems related to substance identity.

Issues have been clarified through a dialogue between ECHA and industry for specific groups of substances, and under issue No. 10, Completeness of dossiers.

Issue No. 10

Completeness of dossiers

Industry may have, in spite of their best efforts, some difficulties in providing some data required in Annex VII and Annex VIII in due time.

There may be cases where the importer of a mixture cannot obtain from his supply chain compositional and analytical data of each substance present in the mixture. Even in that case, the importer must be provided by the formulator at least with the identity and concentration of all the substances present in the mixture which are subject to registration. Exceptionally, the importer may be in a position to derive the actual compositional and analytical data of these individual substances from data relating to the mixture itself. This would allow him to meet the data requirements for the registration of the substances themselves. However, this possibility would be only acceptable subject to valid scientific justification

If companies have ordered tests in a timely manner but have not received the results in due time to complete their dossier, ECHA may take this into consideration when setting a reasonable deadline to complete their dossier as per Article 20(2) of REACH.

Issue No. 11

SIEF operation

In the final stage of SIEF activities prior to registration, prolonged cost and data-sharing disputes and latecomers joining SIEF may disrupt the timely preparation to meet the registration deadline.

ECHA issued a News Alert on 16 April 2010 recommending that the Lead Registrant freezes the dossier and the steps leading to it two months before the submission (http://echa.europa.eu/doc/press/na_10_19_dcg_lr_20100416.pdf). The REACH-IT release of 31 May 2010 allows the member registrants to submit their dossier as soon as

the Lead Registrant has passed the Business Rules check. This does not affect data sharing discussion with other potential registrants, which shall not be set aside.

Issue No. 12

CSA tool

A timely release of the tool would enable a uniform Chemical Safety Report and Exposure Scenario, and offer major help to SMEs to fulfil their requirements.

ECHA's CSA tool CHESAR was rolled out on 12 May 2010 and an updated version allowing full CSR report creation on 7 July 2010.

Issue No. 13

Scope of CSA guidance

It is unclear what needs to be covered in the exposure scenario if only health or only environmental hazards are concluded.

The Guidance on Information Requirements and Chemical Safety Assessment will only be made available after the REACH registration deadline of 30 November 2010 (see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf). In preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage.

Issue No. 14

Guidance on Strictly Controlled Conditions for Intermediates and Exposure-based Waiving

Industry was concerned that it wouldn't have time to respond to updated ECHA Guidance. Existing Guidance on "Information Requirements and Chemical Safety Assessment" describes qualitative justification for exposure-based waiving only in general terms. The publication of the revised Annex XI to the REACH Regulation in February 2009 also necessitated an update of the existing Guidance.

The Guidance update on Intermediates will only be made available in December 2010, after the REACH deadline. (see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf). In the Press Release however, ECHA reminded readers of the existing definition of “strictly controlled conditions”.

ECHA also clarified the definition of intermediates as agreed by the European Commission, Member States and ECHA on 4 May 2010 (see:

http://guidance.echa.europa.eu/docs/guidance_document/clarificationintermediates_201005_en.pdf)

In preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage.

Issue No. 15

Legal Entity change

Need to accommodate complex unforeseen mergers/splits of enterprises (legal entities) or change in manufacturing conditions taking place within the last twelve months before the registration deadline.

ECHA released a legal entity change functionality as part of the 25 March 2010 version of REACH-IT which covers the standard legal entity change scenarios. If a company finds itself in a situation where it cannot submit a late pre-registration any longer, in principle, it shall not be entitled to manufacture or import the substance concerned. However, companies will be offered the opportunity to declare their situation to the Agency via the ECHA Helpdesk in order to make it transparent. This self declaration may be taken into account by the national enforcement authorities in case of control.

Issue No. 16

No direct communication possible with ECHA for companies/LR

Companies may have urgent questions concerning their specific submission. ECHA should be able to react rapidly to support timely submission.

The ECHA Helpdesk treats questions related to a specific submission as a priority. If warranted, ECHA staff may contact the registrant directly by phone. ECHA launched an outbound Special (telephone) Service for Registrants in June (first serving Lead Registrants and later in 2010 member registrants, also).

Issue No. 17

Misuse of REACH-IT

Information in REACH-IT is misused for commercial purposes by some companies.

Member State helpdesks can report such abuse to ECHA in order to have the feedback collected in one place. Companies are encouraged to use alternative dispute resolution mechanisms to resolve the cases. ECHA will investigate the possibility to improve REACH-IT pre-SIEF functionality with regards to personal data protection in 2011.

Issue No. 18

Guidance on Annex V

Annex V provides exemptions from registration and thus clarity is needed.

ECHA issued the Guidance on Annex V on 31 March 2010.

Issue No. 19

GMO and fermentation

Interpretation related to GMO-derived substances and the results of fermentation process needs to be finalised.

The update on Guidance on Registration will only be made available after the REACH registration deadline of 30 November 2010.

(see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf).

In preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage.

Issue No. 20

Dependency on the Lead Registrant

The Lead Registrant may fail his submission leaving the member registrants in a difficult situation.

In such a case, one of the member registrants needs to become the Lead Registrant and submit a complete and valid registration. If the dossier cannot be totally compliant with the REACH requirements due to unexpected circumstances, companies should contact ECHA via ECHA Helpdesk as soon as they become aware of the situation.

Issue No. 21

SIEF without an EU manufacturer

If a substance is manufactured only outside EU, it is often difficult for an Only Representative or importer to take up the Lead Registrant role.

Downstream users should take proactive measures to ensure that there is a continuation of supply for them. In case their supplier fails to register, a downstream user may consider taking up the role of an importer and submitting a registration. If the dossier cannot be totally compliant with the REACH requirements due to unexpected circumstances, companies should contact ECHA via the ECHA Helpdesk as soon as they become aware of the situation.

Issue No. 22

Uses not covered by registration

If the use of a downstream user is not covered by the registration of his supplier or another supplier, he cannot use the substance anymore. Alternatively, he needs to do a CSA for his use, which may be difficult for especially SMEs.

4

Issue No. 23

Waste and REACH

Issues around recycling and waste need to be clarified.

The Guidance on Information Requirements and Chemical Safety Assessment will only be made available after the REACH registration deadline of 30 November 2010. (see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf).

In preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage.

Issue No. 24

Stability of guidance

Work on guidance updates and drafting takes up too much industry resources during the critical year of 2010. Guidance documents issued late in 2010 leave too little time for industry to adapt their dossiers accordingly.

ECHA issued a moratorium on the publication of ten guidance updates on 2 June 2010 (http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf)

⁴ A description of the established solution will be inserted into this document as soon as the DCG will have finalised its work on the issue

Issue No. 25

Inclusion of CSR in joint submission

Practical problems arise, as some parts of CSR may be valid only for the Lead Registrants and others for member registrants.

It is possible to submit CSR either jointly or separately. ECHA issued a manual on how to do this on 7 July 2010 (http://echa.europa.eu/doc/press/na_10_37_dsm_20100707.pdf).

Issue No. 26

Very late activity in SIEF

See issue 11.

See issue 11.

Issue No. 27

Two generation reproductive toxicity study

There is new information on the two generation study in comparison to the extended one generation study.

The Guidance on Information Requirements and Chemical Safety Assessment will only be made available after the REACH registration deadline of 30 November 2010. (see: http://echa.europa.eu/doc/press/na_10_31_moratorium_of_ten_guidance_updates_20100602.pdf).

In preparing their dossier submissions, registrants can resort to existing guidance when applying their own best judgement on their most appropriate action to fulfil their obligations under REACH. They also need to be aware of the potential need to update their registration dossier at a later stage.

Issue No. 28

Implementing risk management measures

Companies may only at a very late stage become aware of the enhanced risk management measures they need to implement and may therefore not be able to declare in part A of the CSR that these measures are [already] implemented.

The registrant needs to declare what risk management measures are implemented, and implement and declare interim risk management measures (when feasible). In addition, he should declare for identified but not-yet-implemented risk management measures what they are and when they will be implemented.

This table provides a summary overview of the issues discussed by the Directors' Contact Group. More details on any practical arrangements that ECHA will put in place to support registrants in complying with their obligations will be made available on ECHA's website.

Annex 6

Mandate of the Directors' Contact Group between Commission, ECHA and Industry Associations on Meeting the Second REACH Registration Deadline

TERMS FOR THE WORK

OF THE DIRECTORS' CONTACT GROUP

ON MEETING THE REACH REGISTRATION DEADLINE OF 2013

BETWEEN

COMMISSION, ECHA AND INDUSTRY ASSOCIATIONS

1. Objectives:

The Directors' Contact Group (DCG) is an informal group whose objectives are to:

- Provide a platform for the informal exchange of views and information between the Commission, ECHA and participating Industry Associations on meeting obligations relevant to the second REACH registration deadline of 31 May 2013;
- Monitor the overall preparedness of companies as to meeting the 2013 REACH Registration deadline;
- Follow-up the recommendations it made under its mandate of 5 February 2010, RRD/02/2010, which expired on 31 March 2011;
- Follow-up on work on issues of concern in relation to the registration deadline of 30 November 2010, especially with regard to registration-related concerns of Downstream Users;
- Identify issues of concern for manufacturers, importers and down stream users in regard of the 2013 registration deadline, formulate recommendations on how to approach them, and monitor the progress made by all relevant actors in addressing them.
- Follow-up on issues of concern in relation to the notification of the classification & labelling of substances and the C & L Inventory;

2. Tasks:

The DCG will:

Monitoring

- Maintain an overview of the overall preparedness of industry as to meeting the second REACH registration deadline of 2013 based on a continuous bottom-up analysis of available information;
- Monitor SIEF formation and management as well as data and cost sharing within SIEFs ahead of the 2013 registration deadline;
- Monitor developments regarding communications in supply chains concerning registered or non registered substances;
- Regularly take stock on the progress made by the institutions and bodies implementing REACH (i.e., the European Commission, ECHA, national competent authorities and national enforcement authorities) in resolving the related issues of concern.
- Monitor progress in agreeing unifying the entries for the same substances in the C&L Inventory
- Draw lessons from the 2010 deadline preparations and DCG activities for the next registration deadline.

Promotion of Best Practice

- Promote best practice regarding SIEF formation and management as well as data and cost sharing;
- Promote best practice regarding communications in supply chains concerning registered or non-registered substances.

Issues of Concern

- Follow-up the recommendations made by the DCG on the basis of its original mandate (doc. RRD/02/2010) of 5 February 2010;
- Keep an inventory of issues demonstrated as being of concern to manufacturers and importers of chemical substances as well as only representatives and downstream users, particularly to small and medium-sized enterprises, in relation to the registration obligations under the REACH Regulation and the agreement of entries in the C & L Inventory under the CLP Regulation;
- The DCG may formulate proposals for addressing the identified issues of concern which then may be taken to the bodies concerned.

Communication

- The DCG will elaborate, when necessary, a communiqué after every meeting for use in external communication.

3. Participation:

A maximum of three representatives – of which at least one at Director level – from Directorate General Environment, and Enterprise and Industry of the Commission, from ECHA and from Cefic will participate in the Directors' Contact Group, as well as a maximum of two representatives from each of the following Industry organisations: Eurométaux, REACH Alliance, CONCAWE, FECC and UEAPME; and representatives of Orgalime (representing also the interests of ASD, ACEA and Eurocommerce) and DUCC to represent the interests of Downstream Users, along with a representative of CheMI Platform.

4. Preparation of meetings:

The Directorate-General for Environment will chair and be in charge of the secretariat of the meetings.

Two Sherpas from ECHA and one from each other member will support the preparation of the meetings of the DCG and monitor the work carried out. Sherpas may be assisted by members of the staff of their organisations, as needed.

The Sherpas will screen issues claimed to be of concern for their relevance for the work of the DCG. The Sherpas may describe issues identified as meriting discussion within the Group in the form of discussion papers. All DCG papers are for internal use within the member organisations only and not meant for publication unless otherwise agreed by the DCG.

5. Term:

From 1 April 2011 until 30 September 2013.