

5th meeting of the Directors Contact Group on Registration under REACH

25 May 2010

The Directors Contact Group on Registration held their fifth meeting on 25 May 2010. At this meeting the directors notably took stock of their progress, especially with respect to elaborate achievable actions to solve prioritised problems by the deadline of 1 June that they had set themselves for such actions to remain timely for the deadline of 30 November for registration of substances.

The Group either established solutions to six of the seven issues they had prioritised or identified such solutions to be proposed to appropriate bodies such as enforcement authorities. This further raises the number of priority issues for which they have brought their deliberations to closure since their previous meeting of 6 May. For some issues, they took note that participants are already implementing actions to which they had committed.

The Group further endorsed the ongoing work on the remaining 20 issues which had not needed to be prioritised as they were deemed either less complex or were already being addressed through actions that were being undertaken anyway. Out of these 20 issues, eleven are now solved. The timeline of 1 June 2010 is not relevant to most of them, but they remain subject of continued monitoring at Sherpa level.

In the coming months the Directors Contact Group will continue to work on the identification and implementation of solutions to these issues. They will also further communicate with stakeholders on the progress of registration and the actions they developed for the prioritised issues. Further more, they will elaborate on 'lessons learned' in addressing the key issues and develop recommendations for future registration deadlines.

A list of issues addressed by the DCG, together with their status and outline of their agreed or proposed solutions is provided in attachment.

Priority issues¹

Topic	Short description	Status	Solution – short description
SIEF operation	In the final stage of SIEF activities prior to registration, prolonged disputes e.g. on cost and data-sharing as well as late comers joining SIEF may disrupt the timely preparations to meet the registration deadline.	Solution identified	<ul style="list-style-type: none"> - Lead Registrants can freeze the lead dossier of the SIEF two months before the planned submission date. ECHA published recommendation to Lead Registrants on ECHA website on 16 April 2010. - COM asks Member States to ensure adequate support to SMEs and to strengthen the capacity of the national helpdesks - National helpdesks addressed by VP Tajani by video message - ECHA will update its Industry user Manual 7 (Joint submission) on the occasion of the next major release of REACH-IT at the end of May to reflect the possibility of a parallel submission of the Lead Registrant and the other registrants of a joint submission - Industry associations will remind their members about the importance of transparency in the cost sharing
Very late activity in the SIEF	Activity in SIEFs may be seriously disturbed if in a very late stage numerous legal entities change their status from dormant into active. Issue of inactive members becoming active at a very late stage jeopardize discussion and successful submission.	Solution elaborated	(Common solution with issue described above)
SIEF without EU manufacturer	When a substance is exclusively manufactured outside the EU, it is often difficult for an Only Representative or importer to take up the role of Lead Registrant.	Solution identified	<p>Downstream Users should pro-actively communicate up the supply chain informing of which substances are needed after 1 December 2010 and also pro-actively search for other potential suppliers. (On 16 April 2010, ECHA published list of substances for which registrations are expected by the 2010 deadline together with an appeal to Downstream Users).</p> <p>Downstream Users should consider becoming a part of a SIEF by informing the ECHA in accordance with Article 28(7) to make known the need for registration of the substance;</p> <p>Downstream Users should consider stock piling substances which are needed after 1 December 2010;</p> <p>Downstream Users should consider becoming an importer, pre-register according to Article 28(6) and register .</p>

¹ Prioritised as deserving particular attention, according to criteria agreed by the Group: these issues were deemed more complex, or having widespread impact on industry, or potential "show-stoppers" preventing registration.

Topic	Short description	Status	Solution – short description
Dependency on the LR in SIEF	A Lead Registrant can fail with his submission in the end phase, leaving member registrants in a difficult situation.	Solution identified	<p>Two scenarios have been identified:</p> <p>1) <i>The Lead Registrant submits his dossier in time, but subsequently fails technical completeness check</i></p> <p>The next major release of REACH-IT (available at the end of May 2010) will allow other registrants to submit their individual dossiers immediately after the Lead Registrant has submitted the dossier, i.e. even before the Lead Registrant has been assigned a registration number.</p> <p>2) <i>The Lead Registrant does not submit a registration dossier</i></p> <ul style="list-style-type: none"> - One of the other registrants needs to take over the Lead Registrant role in REACH-IT and submit a complete and valid lead dossier. -If the dossier cannot be totally compliant with the REACH requirements due to time constraints posed by the unexpected situation, the affected registrants should contact their national competent authorities explaining their situation and their proposed solution, putting ECHA in copy, and the national authorities subsequently inform ECHA of any agreed outcome.
Legal entity change	Need to accommodate complex mergers and splits, or change of toll manufacturing, that can be caused by unforeseen conditions, in the 12 month period before the registration deadline..	Solution identified	<p>On 25 March 2010, ECHA released a new version of REACH-IT with enhanced legal entity change functionality. This functionality will now cover most standard Legal Entity change situations.</p> <p>In case the affected company fails to submit its registration within the legal deadline due to the change in company/production structure takes place very close to the deadline, it has to immediately inform the relevant Member State Competent Authorities, putting ECHA in copy of that message. When the MSCA(s) propose a solution for that specific situation, they simultaneously should inform ECHA.</p>
Uses not covered by a registration	If the use of a Downstream User is not covered by his or another supplier, he cannot use the substance anymore or should do the CSA for it, which is difficult, especially for SMEs.	Solution established	<ul style="list-style-type: none"> - Clarification of questions related to legal interpretation - Communication activities towards Downstream Users - Elaboration of a Q&A for downstream users
Completeness of dossiers	Due to the time it takes to form SIEFs and to complete discussions within them, and the waiting period between the time a test is ordered and the SIEF gets the results, some data required in Annex VII and VIII may not be available in due time.	Solution identified	

Other issues

Topic	Short description	Status	Solution – short description
C&L notifications	There are problems with notifying substances marketed in very low volumes (< 1 tonne), in particular when used for research, to the C&L inventory: - High numbers of notifications - It should be possible to claim confidentiality for IUPAC names	Solution expected by 1 June	
Guidance SDS	Guidance under approval process.	Work on-going. 1 June deadline not relevant here	
Enforcement, in particular on registration & information requirements	Ensure that a pragmatic, uniform and well equilibrated enforcement of registration requirements takes place, taking due account of the solutions developed by the DCG to specific issues.	Work on-going. 1 June deadline not relevant here	
C&L IT possibilities	Without bulk upload possibility, companies have to enter all the information in IUCLID 5. The legal text offers the possibility to enter the notification by group of M/I	Solved	A C&L bulk generation tool was released on 19 April. An updated multi-lingual version covering 22 languages was released on 19 May 2010. A group notification tool is planned to be released
RIP nano and REACH	Provide clarification on the phase-in status of nano-materials.	Solved	A document was produced, clarifying the issue.
Steering/ monitoring Platform	DCG to follow up SIEF activities, identify urgent problems and discuss solutions and strategies	Solved	Directors Contact Group
Availability REACH-IT in 2010	Make REACH-IT available during weekend if needed.	Solution established	ECHA is monitoring activity and will make REACH IT available during week-ends closer to the registration deadline, if activity confirms need.
Introduction IUCLID 5.2 and REACH-IT 2.0	No additional major updates are foreseen after the February and April releases	Solution expected by 1 June	IUCLID 5.2 was released in February 2010 REACH-IT 2.1 will be released before the end of May 2010
Problem of substance identity	Many problems are related to substance identity. Multiple aspects: IUPAC naming, application of guidance	Solved	The issues related to the substance ID were clarified through dialogue between ECHA and industry on specific groups of substances.

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CSA tool	A CSA tool is still being developed by ECHA	Solved	The Chesar tool was released on 12 May 2010. The use of Chesar is not mandatory, but it provides a structured way of carrying out Chemical Safety Assessments (CSA) and preparing Chemical Safety Reports (CSR).
Scope CSA guidance	What has to be covered in the ES if only health or only environmental hazards are concluded	Work on-going. 1 June deadline not relevant here	
SCC for intermediates and EBW	Guidance is still under development and thus forthcoming before the 2010 deadline	Work on-going. 1 June deadline partially not relevant here	
No direct communication possible with ECHA for companies/LR	Companies may have specific questions on practical problems encountered during use of REACH-IT and IUCLID 5	Solution established	ECHA's system for relaying and addressing specific questions from registrants, together with guidance, manuals, webinars and practical guides.
Abuse REACH-IT	Information from REACH-IT is abused for commercial purposes by companies	Expected to be solved by 1 June	
Guidance on Annex V	Annex V provides exemption of registration and clarity is needed	Solved	Guidance issued on 31 March 2010
GMO and fermentation	The results of a fermentation process (e.g. vinasses) can't be seen as natural substances that are exempted under REACH. Ongoing discussion on vegetable oils obtained from GMO plants	Work ongoing, 1 June deadline not relevant here	
Waste and REACH	Guidance to be published, clarifying issues concerning recycling and waste	Solved	Guidance on waste was published on 12 May 2010
Stability guidance documents	Many guidance updates or new guidance are still being developed, but the first REACH registration deadline is drawing close		
Inclusion of CSR in joint submission	Some practical problems exist, because some parts may be LE related and not valid for all SIEF members	Expected to be solved by 1 June	
Two generation reproductive toxicity study	There is new information on the two generation study versus the extended one generation study	Work on-going. 1 June deadline not relevant here	