

4th meeting of the Directors Contact Group on Registration under REACH

The Directors Contact Group on Registration met for the fourth time on 6 May 2010. At this meeting the directors made further progress in resolving issues identified as being of concern for industry to meet their obligations relevant to the registration deadline.

In the group's previous work, they had agreed on seven priority issues that should particularly be solved in good time before the first registration deadline. They had therefore agreed to elaborate achievable actions by 1 June to solve these prioritised issues. Whilst solutions for three of these issues could already be found at their last meeting on 8 April (see previous communiqué), they endorsed solutions for a further two such priority issues at their meeting of 6 May. Thus, nearly a month ahead of their chosen deadline, progress made so far clearly indicates that all seven issues can be resolved in the timeframe foreseen.

The Group has also made good progress on the other 20 issues that they had identified. 13 of these issues will very probably be solved for the 1 June deadline. The remaining seven issues do not require a solution by that deadline but work is at hand to resolve them.

In parallel, they also made good progress in monitoring the overall preparedness of industry as to meeting the 2010 registration deadline. The survey performed in this context allows confidence about the registration of about 4400 substances for this deadline. This figure is being further refined, in particular, with regard to the corresponding overall number of dossiers that legal entities are expected to submit.

This survey and the practical solutions found to the issues of concern should further secure the supply of high-volume substances to downstream users.

The next meeting of the Group is planned for 25 May, allowing to finalise all solutions proposed for the priority issues of concern before the deadline of 1 June. Beyond this date, the Group will focus on following up on the implementation of actions they recommended (those planned for implementation for after 1 June), and harvest lessons to be learnt and formulate further recommendations that are relevant to ease the process for the next registration deadlines.

The list of issues they are working on is provided below.

Priority issues¹

Topic	Short description	Status
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 elaborated
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
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 elaborated
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 elaborated
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 elaborated
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.	Expected to be solved by 1 June
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.	Expected to be solved by 1 June

Other issues

C&L notifications	There are problems with notifying substances marketed in very low volumes (< 1 tonne) to the C&L inventory, in particular when used for research: - High numbers of notifications - It should be possible to claim confidentiality for IUPAC names	Expected to be solved 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
RIP nano and REACH	Provide clarification on the phase-in status of nano-materials.	Expected to be solved by 1 June

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.

Steering/ monitoring Platform	DCG to follow up SIEF activities, identify urgent problems and discuss solutions and strategies	Solved
Availability REACH-IT in 2010	Make REACH-IT available during weekend if needed.	Solved
Introduction IUCLID 5.2 and REACH-IT 2.0	No additional major updates are foreseen after the February and April releases	Expected to be solved by 1 June
Problem of substance identity	Many problems are related to substance identity. Multiple aspects: IUPAC naming, application of guidance	Expected to be solved by 1 June
CSA tool	A CSA tool is still being developed by ECHA	Expected to be solved by 1 June
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	Expected to be solved by 1 June
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
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	1 June deadline not relevant here
Waste and REACH	Guidance to be published, clarifying issues concerning recycling and waste	Expected to be solved by 1 June
Stability guidance documents	Many guidance updates or new guidance are still being developed, but the first REACH registration deadline is drawing close	Expected to be solved by 1 June
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	1 June deadline not relevant here