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/view-article/-/journal_content/title/confidentiality-of-iupac-names-in-the-c-and-l-inventory).

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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates).

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/view-article/-/journal_content/title/recommendations-to-lead-registrants). 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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates). 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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates). 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://echa.europa.eu/documents/10162/13632/intermediates_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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates).
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.

A downstream user may only realise upon receiving the SDS from his supplier that his use is not covered by the registration of that supplier. In that case the downstream user has in principle four different options: 1) he can communicate the missing conditions of his use to the supplier upstream and request him to provide an exposure scenario that covers his use; 2) change his use or his conditions of use of the substance to one that is covered by the SDS provided by his supplier; 3) change supplier to one whose SDS covers his use or 4) report his condition of use to ECHA and prepare a chemical safety report himself.

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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates).
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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates)

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/view-article/-/journal_content/title/new-manual-how-to-jointly-submit-chemical-safety-reports).

Issue No. 26

Very late activity in SIEF

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/view-article/-/journal_content/title/moratorium-on-the-publication-of-ten-guidance-updates).
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.