EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate D - Water, Marine Environment & Chemicals
ENV.D.3 - Chemicals, Biocides and Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
ENTR.F.1 - REACH
ENTR.F.2 - Chemicals Industry

Brussels, 10 January 2014

Assessment of the completion by DCG2 of the tasks identified by DCG1

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This document aims at examining the achievement of the recommendations laid out in the DCG1 Report (Document RRD/57/2010 (final)). A "traffic lights" system was used in order to track progress:

- ✓ A green check sign indicates the achievement of an identified task;
- ❖ The blue lozenge indicates a task which is still being resolved or which was partially addressed; and
- × The red cross indicates that a task was not completed due to technical reasons such as lack of resources.

Overview

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.

✓ These two points were achieved by setting up DCG2.

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.

✓ ECHA statistics proved to be satisfactory in this respect, as evidenced by the outcome of the first, second and third meetings of DCG2.

SIEF Operation

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.

- ✓ Industry associations developed ad-hoc publications and documents and ECHA focused on communication for SMEs. ECHA updated the Guidance on Data-sharing, took initiative to ask lead registrants to have their names published, held two lead registrant workshops and gave a series of webinars

- ✓ This set of actions reached a wider target audience than would have been achieved by a single document

REGISTRATION

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.

- ✓ ECHA carefully assessed the possibilities and implemented some DCG1 solutions for DCG2 (such as the Guidance moratorium). Furthermore, ECHA opened the DCG1 solutions for exceptional cases on 1 March 2013. ECHA has shown that it could deal with the exceptional cases on an ad-hoc basis.

COMMUNICATION IN THE SUPPLY CHAIN

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.

❖ The best practice guidance was not drafted but several documents were produced by industry associations. DUCC and CEFIC produced a joint position on communicating uses upstream, whereas ENES is addressing the issues for communicating downstream. Communication on uses is also being addressed in the context of the cross-stakeholder CSR/ES Roadmap which ECHA published on 17 July 2013.

✓ The intermediates issue was looked at by the Commission. In addition, in May 2012, ECHA Forum of enforcement held a workshop for enforcement authorities on intermediates. The material and outcome of the workshop have been made accessible on the ECHA website. http://www.echa.europa.eu/en/web/guest/view-article/-/journal_content/8ccfdae3-39ec-4c0f-bc1c-bdda01f25069.

✓ ECHA screened all intermediate registrations dossiers (5500) in August 2012 and found potential incompliances with regard to either intermediate status or strictly controlled conditions in over 40% of the dossier screened. Most of the dossiers were updated either to remove the observed anomalies or to full registration.

✓ The DCG solution to issue 22 on "uses not covered" offers support to deal with case (a).

ECHA Guidance Documents (and other non-IT tools)

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.

❖ The publication of guidance at recurring dates has been considered to be impracticable as this means holding up the publication of certain guidance documents as long as others are not ready. This mode of synchronisation is inefficient and the recommendation is therefore considered obsolete.

✓ ECHA maintained a guidance moratorium from 1 December 2012 until after the REACH registration deadline of 31 May 2013.

✓ Guidance documents of relevance to SMEs are regularly translated into all other official EU languages (except Irish Gaelic). These documents are available via the respective language versions of the ECHA website.

IT TOOLS

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.

✓ ECHA unveiled a new version of IUCLID and Chesar well ahead of the registration deadline (summer 2012) and REACH-IT six months before the registration deadline.

✓ ECHA developed an IT Platform to facilitate contacts between REACH registrants and CLP notifiers in order to come to agreement in cases where diverging classifications have been notified for the same substance (as required by Art. 41

of the CLP Regulation).

- ✓ ECHA coordinated and trained the national helpdesks to ensure that they can offer up-to-date advice in their national languages and conducted a feasibility and needs assessment as announced in the Agency's Work Programme 2011. ECHA launched the ECHAterm multilingual database and has populated it with hundreds of chemical terms which SMEs can (and do) use in fulfilling their obligations.

HELPDESK AND CAPACITY BUILDING

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.

- ✓ ECHA provided additional support to the registrants, similarly to what was done in the run-up of the 2010 registration deadline. This was in recognition to the smaller size of the companies involved (SMEs).
- ✓ ECHA held two Lead Registrant workshops in 2012 and thereby reimbursed the attendance of -SME Lead Registrants.

LESSONS LEARNED BY ECHA

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;

- ✓ IUCLID was improved by including the Dossier Quality Assistant to help registrants detect potential inconsistencies in their registration dossiers ahead of dossier submission.
- ✓ ECHA has implemented a new workflow to handle inquiries with a view to mitigate the effect of potentially peaking submissions next to the deadline.
- ✓ Information on the SME definition was made available on ECHA's website. Individual communication was sent to each pre-registrant of the 2013 deadline, reminding them to verify and update whenever appropriate their SME status prior to submitting their registration.

FURTHER MANDATE

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.

- ✓ The Commission informed the CARACAL of the second ToW of the DCG.
- ✓ ECHA acquainted the FORUM with the mandate and work of the DCG at the Forum-9 meeting on 1-3 March 2011.