ECHA
EUROPEAN CHEMICALS AGENCY

ECHA's REACH 2018 Roadmap

Progress Report

January 2016

ECHA's REACH 2018 Roadmap - Progress Report

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Background

ECHA's REACH 2018 Roadmap, addressed to ECHA's stakeholders, was published on 14 January 2015. It is a response to the fact that the last registration deadline of phase-in substances in 2018 will affect many inexperienced and SME registrants, and it documents the Agency's commitment to:

- critically review the REACH registration process from start to finish, and
- enhance the process, support, documentation and IT tools to more effectively support companies with their obligations for the forthcoming registration deadline of 31 May 2018.

ECHA is committed to reviewing the progress made and the milestones for each phase on a yearly basis.

This is the first of those reviews and reflects the status of the roadmap implementation at the end of January 2016. The document follows the seven-phase structure introduced in the original roadmap, and should be read in relation to ECHA's REACH 2018 Roadmap, which it complements. For each phase, the following are described:

- changes affecting the scope/content of the phase;
- progress made under 2015; and
- updated milestones.

During the year, it became evident that material for all the phases needs to be monitored all the way to the registration deadline to reflect if updates due to new developments are needed.

Phase 1 – How does the REACH registration 2018 deadline affect a company?

Phase 1 was launched successfully on 24 June 2015 with new web pages aimed at inexperienced and SME registrants on how to get started with registration activities.

352 participants watched the webinar live at the phase launch, and the video recording has been downloaded over 2 300 times by the end of January 2016.

In response to the major concern of stakeholders consulted on the draft roadmap document, namely that of low level of awareness by 2018 registrants, ECHA established the 'REACH 2018 Communicators' Network' in early 2015.

Currently, 40 organisations[1] have joined the network, and as a first joint activity, it prepared a joint communication around the phase launch. The effects of these combined efforts were seen in the elevated publicity for REACH 2018 throughout the autumn.

However, feedback from the national helpdesks as well as ECHA's own observations indicate that companies – especially SMEs – are not yet active in preparing their registration dossiers for the last deadline. While

1 21 Member States, 11 stakeholder organisations, six regional contact points for Enterprise Europe Network EEN, the European Commission and ECHA.

some are deliberately postponing the business decision on registration until late 2016-early 2017, there is presumably still a large proportion of companies that have not grasped the benefits of early planning. Therefore, awareness raising activities will remain high on the agenda, and further activities will be explored in the REACH 2018 Communicators' Network in 2016.

The milestone referring to the review of ECHA's Q&A database was postponed, because it overlapped with a customer insight survey concerning the overall accessibility of information on our website. The results of this survey were received in the end of 2015 and, based on the outcome, issues concerning the Q&A database will be tackled in 2016. Nevertheless, the content of phase 1 relevant Q&As was reviewed and wording simplified for better readability.

Achievements in 2015

REACH 2018 web page (www.echa.europa.eu/reach-2018) established as ECHA's central point of information on the forthcoming deadline.

REACH 2018 Communicators' Network established, awareness-raising material developed and joint activities around phase 1 launch organised:

- REACH 2018 leaflet[2]

Phase 1 relevant material on the ECHA website revised and new material targeted to SMEs published.

Webinar on phase 1 "Know your portfolio and start preparing now" (24 June 2015).

Updated web pages and Q&As on substance identification.

Simplified language and improved to-the-point-approach in:

- Content of Q&As for phase 1
- ECHA decisions
- ECHA Helpdesk replies

Reviewed milestones

Publication of updated Guidance on Registration (2016).

Reviewed Q&A database on ECHA's website (2016).

Outreach campaign for the 2018 registration deadline, where joint information campaign together with national helpdesks and ASOs forms the backbone (activity continues from 2015).

Single point of entry for questions to ECHA (2016).

2 http://echa.europa.eu/documents/10162/22038499/reach_2018_leaflet_en.pdf. Available in 23 languages.

Phase 2 – Finding co-registrants

Phase 2 was launched successfully on 18 November 2015 with new web pages targeted to inexperienced and SME registrants on how to find the co-registrants under two possible scenarios, i.e. where there already is a registration for the substance and where no such registration has been submitted.

The webinar was watched live by 283 participants, and the video recording has been downloaded over 500 times by the end of January 2016.

The REACH 2018 Communicators' Network activities were slightly less intensive around this phase as fewer members took up the joint communication task. This also affected the amount of publicity for the REACH 2018 campaign, reflecting the importance of synchronised joint activities in the awareness raising.

The basis for finding appropriate co-registrants is relying on the identification of the substance to be registered. Over the year, it became evident that a generic all-encompassing substance sameness methodology or criteria would be difficult to establish. Rather, ECHA focused on cooperating with industry sectors to support them in developing advice for sector-specific issues related to substance identification.

Furthermore, ECHA introduced the idea of including the substance identification profile (SIP), into improvements in REACH IT/IUCLID 6. SIP was developed by Cefic in 2010 to support registrants to transparently document their sameness criteria during SIEF formation. Now registrants will be able to use new fields in IUCLID 6 to report the scope of the registered substance that their Annex VII-XI data refer to.

Finding the co-registrants depends on REACH-IT. As a new generation of this tool will be released in 2016, ECHA plans a review of the materials developed for phase 2 to reflect the changes in REACH-IT.

Achievements in 2015

Phase 2 relevant material on the ECHA website revised and new material targeted to SMEs published.

Sector-specific substance identification issues were elaborated in cooperation with several industry organisations and the following guidelines were published:

- Industry guidance on substance identity of essential oils
- OECD guidance for characterising hydrocarbon solvents for assessment purposes

Substance identity workshop for the national REACH helpdesks.

Webinar on phase 2 "Find your co-registrants" (18 November 2015).

Reviewed milestones

Improved accessibility to finding co-registrants (2016).

Revised support material for phase 2 (2016).

Industry led drafting and publication of sector-specific guidance on substance identification with support from ECHA (2014-2018):

- Industry guidance on substance identification of Complex Inorganic Pigments (CIPs) (2016).

Phase 3 – Cooperating with co-registrants

Data and cost sharing have been recognised as one of the key areas where inexperienced and SME registrants are facing difficulties. Therefore, ECHA took early actions in the area of phase 3. Further advice on SIEF management and sharing of data within SIEFs will be provided in 2016 with the phase launch.

The Implementing Regulation on joint submission of data and data sharing put forward by the European Commission was adopted on 5 January 2016[3]. It contributes to a better understanding of the notions of fairness, transparency and non-discrimination in the data-sharing process, and lays down that ECHA shall ensure that all registrants of the same substance are part of the same registration. This regulation will affect the advice ECHA develops for inexperienced and SME registrants and impacts the Directors' Coordination Group (DCG) recommendations that will need to be reviewed.

Finally, phase 3 concentrates on organisational aspects of data gathering (e.g. performing in-depth literature research from other sources than those of the co-registrants, respecting copyright law when using data from the public domain, getting aware of the availability and applicability of non-testing methods, as well as the shared responsibility to first consider alternative methods, and testing on animals only as a last resort). The scientific aspects of data assessment will be the subject of phase 4.

Achievements in 2015

Publication of new support material for data-sharing negotiations:

- What to take into account in data-sharing negotiations
- Overview of various possible cost-items

Publication of dedicated web pages explaining the REACH data-sharing dispute mechanism in practice.

Reviewed milestones

Review of all ECHA support material in the light of the Commission Regulation (2016/9) on the joint submission of data and data-sharing.

Publication of support material for new SIEFs (2016).

Publication of video material on joining an existing registration through data-sharing negotiations (2016).

Webinar on Phase 3 (2016).

Review of DCG recommendations on data-sharing and SIEF cooperation (2016).

Updating the Guidance on Data Sharing with the aim to incorporate provisions of the Implementing Regulation on joint submission of data and data-sharing (2017).

Publication of DCG recommendations (2014-2017).

3 Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Phase 4 – Assessing and documenting hazard and risk information in the registration dossier

In 2015, several actions affecting either the information requirements or support for their understanding were taken. In general, ECHA contributes to the development of new in vitro methods at the OECD level.

In 2015, new alternatives to animal testing were approved at the OECD in the areas of skin sensitisation, eye irritation, skin corrosion and screening of potential endocrine disrupting chemicals[4].

The legislative process to partly amend Annexes VII and VIII of REACH was accordingly completed at EU level in December 2015. These changes, affecting mainly eye irritation, skin corrosion, and acute dermal toxicity will come into force in early 2016. In contrast, the changes to Annex VII for skin sensitisation have not yet been adopted.

In another area, the EU Ombudsman issued a decision[5] requiring ECHA to request proof from the registrants, in the context of testing proposals, that they have considered all alternative methods before proposing a test involving testing on vertebrate animals. This also has an impact for those 2018 registrants who need to submit a testing proposal as part of their registration dossier (column 2 of Annex VIII, point 8.4, mutagenicity).

The possible changes to Annexes VII to X addressing nanomaterials will not affect the requirements relevant for the 2018 registration deadline.

On the support side, ECHA submitted its proposal for supporting registrants in deciding whether they could benefit from reduced information requirements for their substances ("Annex III criteria") to CARACAL. In parallel, ECHA has generated an inventory of substances for which the reduced information requirements criteria will likely not apply unless demonstrated otherwise by the registrants. The strategy as well as the support for the 2018 registrants will be published in 2016.

ECHA also contracted out the preparation of a practical guide outlining the information requirements for substances manufactured or imported at 1-10 tonnes per year and 10-100 tonnes per year. The target audience of this guide are business managers, and the guide is foreseen to support them in understanding the requirements, the duration of a required test and identifying which level of expertise will be required.

Finally, ECHA finalised, together with the stakeholders, a format for use maps and related exposure assessment inputs for worker, consumer and environmental exposure. With the use maps, it is expected that the sectoral organisations will compile information on the typical uses and conditions of use for their members, therefore providing more practical information to the registrants' chemical safety assessment.

4 http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en

5 http://www.ombudsman.europa.eu/cases/decision.faces/en/60909/html.bookmark

Achievements in 2015

Publication of guidance updates:

- Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) - Chapter R.7.7: Mutagenicity
- Guidance on IR&CSA - Chapter R.7a, R.7.2: Skin and eye Corrosion/irritation
- Guidance on IR&CSA - Chapter R.7.6: Reproductive toxicity
- Guidance on IR&CSA - Chapter R12: Use description

Strategy for supporting the 2018 registrants in relation to REACH Annex III submitted to CARACAL.

Publication of the principles of the human health read-across assessment framework (RAAF).

Reviewed milestones

Publication of relevant Guidance updates (2016):

- Guidance on IR&CSA, Part D and R.14: regarding ES building and exposure estimation (including workers exposure estimation)
- Guidance on IR&CSA, Part E: Risk Characterisation
- Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA), Chapter R.7a, Section R.7.3: Sensitisation
- Guidance on IR&CSA, Chapter R.7a Section R.7.4: Acute Toxicity
- Guidance on IR&CSA, Chapter R.7b: Sediment compartment
- Guidance on IR&CSA, R.15: Update of parts of the IR&CSA regarding consumers exposure estimation
- Guidance on IR&CSA, Chapter R.16: Environmental exposure assessment

Review and update of relevant Practical Guides (2016):

- Practical Guide 1: How to report in vitro data
- Practical Guide 2: How to report Weight of evidence
- Practical Guide 3: How to report robust study summaries
- Practical Guide 4: How to report data waiving
- Practical Guide 5: How to report QSAR
- Practical Guide 6: How to report read-across and categories
- Practical Guide 10: How to avoid unnecessary testing on animals
- Practical Guide 14: How to prepare toxicological summaries in IUCLID and to derive DNELs

Publication and implementation of the strategy as well as the support for the 2018 registrants in relation to REACH Annex III (2016). Publication of a new Practical Guide for managers of SMEs registering chemical substances at 1-10 tonnes and 10-100 tonnes per year (2016).

Publication of updated Q&As on information requirements, using the information on annual evaluation reports (2016).

Release of Chesar 3, with related training activities (2016).

Webinar launch of Phase 4 (July 2016).

Extension to the RAAF principles for environmental endpoint assessments (2017).

Phase 5 – Preparing registration dossier in IUCLID

For the purpose of registration, the information on the properties, the classification, and the use and exposure information, gathered in the previous phases, are reported and documented in a registration dossier using IUCLID software. For the 2018 deadline, the mandatory version of the software will be IUCLID 6.

In 2015, the development of IUCLID 6 reached the testing phase. The beta version of the software was published in July 2015 so that interested companies could already start getting familiar with it.

Substantial improvements are foreseen in IUCLID 6 (in comparison to IUCLID 5), such as:

i) an embedded help system reviewed and Dossier Submission Manuals integrated;

ii) a new format (update of OECD Harmonised Templates, improvement of substance identity reporting);

iii) an improved desktop version installation, and

iv) an online IUCLID dossier creation using REACH-IT (for members of a joint submission).

A much larger number of dossiers are expected for the 2018 deadline than for the 2010 and 2013 deadlines, and many more SMEs are concerned now than were previously. Therefore, ECHA has been paying special attention to assisting the registration process developing the user experience of first-time IUCLID users.

This includes:

- Visiting SMEs to exchange and collect feedback/requirements that help ECHA to improve the IUCLID 6 software and to better adapt the training and support material to the users' needs;
- Preparing a clear and consistent help system for IUCLID 6;
- Encouraging users to clarify any doubts and problems through the ECHA Helpdesk; and
- Offering video tutorials and webinars.

Achievements in 2015

Release of the IUCLID 6 beta version on a new IUCLID 6 website.

Reviewed milestones

Official release of IUCLID 6 (2016).

Publication of support material.

Webinar on Phase 5 (2016).

Training (update) of national helpdesk correspondents on dossier preparation (2016-2017).

Phase 6 – Submitting registration

The final phase towards successful registration is to send the dossier to ECHA through REACH-IT. In 2015, the development work towards an enhanced REACH-IT continued.

Importantly, the development needed to anticipate the adoption of the Implementing Regulation on joint submission of data and data sharing which lays down that ECHA shall ensure that all registrants of the same substance are part of the same registration. Furthermore, the decision in ECHA's Management Board in summer 2015 to include a manual check of certain information in the completeness check process was taken into account in the software development.

The revised version of REACH-IT (REACH-IT 3) will be published in 2016. Due to the inter-dependency of the tools, REACH-IT and IUCLID 6 will be published in a coordinated manner. Once the new version of REACH-IT is out, it will only accept IUCLID 6 files.

Apart from the more conceptual changes outlined above, the main focus of the development has been on improving the user interface and overall user experience of REACH-IT, resulting e.g. in a considerable reduction in the number of manuals necessary for using the tool.

Achievements in 2015

Implementation of the plan regarding the completeness check tool and process, as appropriate, in particular for checking safety information.

Introducing the changes regarding manual completeness checks into the REACH-IT development.

Reviewed milestones

Release of REACH-IT, ready for the 2018 registration deadline (including multilingual support as appropriate) (2016).

Publication of support material.

Training (update) of national helpdesk correspondents on dossier submission (2016, 2017).

Webinar on Phase 6.

Phase 7 – Keeping your registration up-to-date

No specific activities were carried out regarding this phase in 2015 under ECHA's REACH 2018 Roadmap. However, each year ECHA has the duty to publish a report on the evaluation and progress made towards providing the information in compliance with REACH.

In particular the report "shall include recommendations to potential registrants to improve the quality of future registrations". The lessons learnt from dossier evaluation are available here: http://echa.europa.eu/support/how-to-improve-your-dossier/lessons-learnt-from-dossier-evaluation.

Reviewed milestones

Evaluation reports (2016-2018).

Webinar on phase 7 (2018).

Milestones for the post-2018 period will be defined later, as part of the process to build the ECHA Multi-Annual Work Programme for 2019-2023.

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