ECHA
EUROPEAN CHEMICALS AGENCY

ECHA's REACH 2018 Roadmap

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Background

The REACH Regulation aims for a high level of protection of human health and the environment, including promoting alternative methods for assessment of hazards of substances, as well as free circulation of chemicals in the European market, while enhancing competitiveness and innovation. This ambitious piece of European legislation recognised that chemicals greatly contribute to the lifestyle of modern society and have a vital impact on the economic and social wellbeing of citizens. However, chemicals can also potentially have detrimental health effects on workers and consumers, and can sometimes severely damage the environment.

To fulfil the objectives of REACH, it is crucial to have adequate information on chemicals that are placed on the market. Accurate knowledge on properties, uses and resulting exposure to chemicals allows proper risk control measures to be designed. REACH provides a system of registration for generating, documenting and disseminating this information. Specifically, REACH was designed to harmonise the information requirements for chemicals that existed on the European market before September 1981 as well as the new chemicals put on the market after that date. These new chemicals were previously covered by different directives with different testing requirements for the chemicals.

REACH reversed the burden of proof on the safe use of chemical substances. It is now up to individual companies who manufacture or import chemicals to demonstrate how these substances can be used safely. Companies need to collect information on substance properties and their uses, and assess how workers, consumers and the environment are exposed to the substances. Companies document the conclusions in a registration dossier. ECHA and other authorities use the information in the registrations to decide whether further, European-wide, risk management measures are needed. Most of the information in the registrations is made available to the general public in publications on ECHA's website.

To allow companies and authorities to manage the workload related to registering chemicals, REACH introduced a stepwise system for substances already on the European market. The most hazardous substances and those manufactured or imported in the largest quantities were to be registered first, in 2010, followed by the registration of chemicals in 2013 that were manufactured or imported in the next largest quantities. Finally, the chemicals that are manufactured or imported between 1-100 tonnes per year per company are to be registered last, in 2018. This means that the registration of chemicals in 2018 will complete the data gathering process on substances on the European market, resulting in the most comprehensive chemicals database in the world.

REACH places the burden of proof on industry in order to protect consumers, workers and the environment from the adverse effects of chemicals. One of the difficulties in balancing the REACH objectives against costs is that while the immediate benefits of safer use of chemicals will become a reality in the workplace relatively soon, the larger scale benefits are only expected to be realised in the forthcoming decades. Nevertheless, the financial and other resource investments need to be made now. Therefore, awareness raising on the efforts for this improvement in societal well-being is needed.

Companies also ask for stability in the regulatory environment, ensuring fair and non-discriminatory treatment of SMEs in SIEFs, simplification of the registration process and tools, and making the supporting documents more easily accessible for companies.

REACH registration by 2018

Both industry and authorities have gathered valuable experience in the practical implementation of the REACH registration requirements during the two registration deadlines that have already passed. It is now known, for example, approximately how much time it takes to prepare a proper registration, what kind of communication and information flows need to be established, what the user experiences of the scientific IT tools and submission tools needed for registration are, and how the available support documentation and helpdesk services are perceived. In addition, sharing the costs of registration between companies has proven to be prone to conflicts, and

SMEs appear to contribute disproportionally more to the costs of joint submission.

However, it is expected that the registration deadline of 31 May 2018 will be quite different from the two previous ones, in terms of both the number of registrations and the type of registrants. It is expected that up to 70 000 registrations will be prepared for 2018. This is three times more than previously prepared for either of the previous deadlines. Significantly, many more of the registrants are expected to be inexperienced and located outside the chemical sector, and there will be more small and medium-sized enterprises (SMEs) than for the previous registration deadlines. The new substance information exchange forums (SIEFs) will also be small or even consist of only a single company, while at the same time, there will be less information available on the substances to be registered. Despite the reduced data requirements for registrations below 100 tonnes, this will result in the need to generate data within the companies making registrations. For the 2018 registration deadline the need for support to registrants on how and when to use suitable alternative approaches will be in high demand.

All this will happen in a totally different economic climate from that of the early 2000s when REACH was drafted. The European Commission and several stakeholders have pointed out the need to pay special attention to supporting SME registrants, which are numerous and varied. They are also vital to the European economy, its competitiveness and its capacity for innovation. When preparing for 2018, ECHA will pay specific attention to SME needs. In particular, an objective is to identify any potential practical obstacles that may prevent SMEs from making successful registrations, participating effectively in SIEFs or from being part of joint submissions. Specifically, awareness on the fair and transparent sharing of costs is needed. All resulting improvements, whether they concern clarifying obligations, procedures, support or IT tools will naturally benefit all registrants irrespective of their size.

All companies need to think ahead about the impact of registration on downstream users of chemicals. The registrants should take a proactive role and communicate their registration intentions or the lack thereof early and openly, and downstream users should inform registrants on their need to have certain substances on the market. Awareness raising by all stakeholders is needed in this regard.

ECHA is committed to supporting industry to compile and improve the quality of their registrations, and its SME-targeted approach may demand completely innovative methods to be developed together with the stakeholders. It is important that stakeholders inform ECHA as early as possible on specific sectors or group of actors that might have distinctive issues related to the 2018 registration deadline, for example, essential oil or complex inorganic pigments producers. At the same time, it needs to be ensured that the objective to ensure high protection of human health and the environment is not undermined. If the registration of all chemicals put on the European market is successfully carried out, REACH will result in a large scale improvement of human health and the environment in Europe. This is realised through the increased knowledge used by companies in their everyday operations and stored in ECHA's database for authorities to use in regulatory risk management actions. In addition, the increased knowledge on chemicals and their uses form the basis for future innovations.

Construction and review of the 2018 Registration Roadmap

This roadmap is addressed to ECHA's stakeholders, and it documents the Agency's commitment to critically review the REACH registration process from start to finish and to enhance the process, support and documentation to more effectively support companies with their obligations for the forthcoming registration deadline of 31 May 2018. This review is carried out in cooperation with the stakeholders.

The basis for this roadmap is the extensive documentation of the experience of both authorities and industry with REACH implementation so far (see Annex 1). In addition, it takes into account the feedback received by ECHA through its helpdesk and guidance consultation mechanism, as well as through

contact with its stakeholders. It is clear that both authorities and industry will need to invest resources in REACH implementation in the forthcoming years.

ECHA has consulted the competent authorities for REACH and CLP (Caracal), HelpNet, the Forum and the Agency's accredited stakeholder organisations to make sure that it has correctly identified the currently known obstacles for registrants and to gain insight into how the stakeholders plan to prepare their support for the registrants with a view to 2018.

The consultation turned out to be successful as it helped ECHA to better understand the underlying issues for the 2018 registrants and provided interesting ideas on how to support them better. Altogether, six Member State competent authorities, 11 national helpdesks, eight accredited stakeholders and two Forum members provided comments to the draft version of the roadmap. From the feedback, 122 individual comments could be drawn. The comments were further divided into three different classes: 1) comments that suggested a change in the roadmap document, 2) comments that suggested an ECHA action in one of the phases, and 3) other comments, i.e. comments outside the scope of the 2018 registration roadmap and/or outside the remit of ECHA.

Finally, the roadmap was discussed with ECHA's accredited stakeholders in the annual Accredited Stakeholder Workshop on 9 October 2014[1]. The stakeholders agreed on the following shared recommendations, not all addressed to ECHA, with regard to preparations towards the 2018 registration deadline:

1. Establish a clear, uniform and multilingual information campaign;
2. Involve Chambers of Commerce in the information campaign;
3. ECHA should create material that can be adapted by Member States and others to reach the target audiences;
4. Mobilise Member States to use multiple channels to reach SMEs that are not members of professional bodies;
5. Reinforce national helpdesks for 2018;
6. Speed up the provision of simplified guidance and tools for SMEs in 23 languages;
7. Provide good, simple guidance on Annex III (including read-across and grouping);
8. Give downstream users the possibility to check registration intentions;
9. Encourage the Commission to screen potential sources of financial help for SMEs and contribute to explaining their existence;
10. Look for best practice in training and mentoring to see if it can be promoted among the Member States and professional bodies.

[1] Accredited stakeholders are organisations that ECHA has selected according to eligibility criteria adopted by the Management Board on 13 February 2008. All accredited stakeholders have a legitimate interest in ECHA's work, have activities at European Union level, are representative of their field of interest and are non-profit making. For the current list, see: http://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations.

ECHA foresees that it will review the roadmap annually to ensure that the most recent developments are accounted for in the planned actions. Specifically, the milestones will be reviewed on a yearly basis in line with the review of ECHA's Multi-Annual Work Programme milestones, taking into account the best knowledge on ECHA's resources at the time.

Actions for the 2018 registration deadline

Preparations for successful registration under REACH can be divided into seven phases:

1. Understanding if and how the REACH registration 2018 deadline affects a particular company;
2. Finding co-registrants;
3. Co-operating with co-registrants;
4. Assessing hazards and risks;
5. Preparing the registration dossier in IUCLID;
6. Submitting the registration dossier in REACH-IT; and
7. Keeping the registration up-to-date.

These phases are explained in more detail below. For each phase there is an explanation of:

- what the phase is about;
- what the known identified issues for companies that make the phase difficult are;
- what kind of actions are foreseen to improve the situation; and
- what the anticipated milestones for the phase are.

As it is also essential to provide targeted company support during all the phases of the roadmap, the following support package (i.e. deliverables) will be considered and the most suitable ones selected for each phase. ECHA sees that both the support and communication strategies will involve Member State competent authorities, national helpdesks and accredited stakeholder organisations.

- A joint information campaign together with ECHA, national helpdesks and accredited stakeholder organisations on the topic of the particular phase;
- Regular checks with the HelpNet members on topical issues;
- Advance notice on the REACH 2018 web pages on relevant topical items;
- Promotion of relevant Practical Guides and other support material, including observations in the annual Evaluation Report;
- Scoped REACH FAQs (agreed among HelpNet members) or Q&As;
- Trainings on relevant topics;
- Exemplification of complex issues; and
- One-to-one sessions focusing on the issues relevant to the particular phase offered at ECHA events.

For all phases, it will be considered whether the actions and/or support documents need to be separated for 1-10 tonnes registrants and 10-100 tonnes registrants.

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

As a first step in preparing for the REACH 2018 registration, companies need to know whether and how the REACH registration 2018 deadline affects them. Recent studies and events have indicated that the bottlenecks identified by SMEs include:

- a lack of awareness;
- difficulties in accessing information;
- inadequate understanding of cost implication;
- a need for sector specific/tailor-made information; and
- difficulties in approaching ECHA.

Although a vast amount of information is already available both on ECHA's website and elsewhere, the relevant information is not always easy to find in a manner that is targeted to the roles of the reader under REACH. The aim of this phase is to make sure that companies are aware of and have the information that they need, and that the amount, format and level of complexity of the information is appropriate to the specific situation of the company. Specifically, companies should already at this stage be able to perceive the approximate costs of registration, which requires early communication on cost sharing of both data and joint submission. Industry stakeholders are in a key position to provide this type of information. With regard to accessibility of support material ECHA will investigate the possibility of providing material for the basic webinars in all EU languages, potentially in cooperation with the national helpdesks.

The support provided to companies during this phase is enhanced by providing e.g. a checklist for selecting a good consultant, simplified/scoped ECHA Helpdesk replies, one-to-one sessions for companies at ECHA events and a "single point of entry" for all incoming questions to ECHA. The awareness of companies on the REACH 2018 registration requirements is increased with enhanced collaboration with the ECHA accredited stakeholder organisations, arranging joint information campaigns together with national helpdesks and accredited stakeholder organisations, organising training events and reviewing the Q&A database on ECHA's website with an enhanced ability to find relevant information for REACH 2018. The possibility to offer more interactive support will be explored.

ECHA will also review its existing documents that support companies that need to take action before the 2018 deadline, especially potential registrants and SMEs who have registration obligations or other duties before the deadline. The scope of the review will include Guidance documents and manuals as well as other related ECHA publications.

The review will especially cover the "accessibility" of the documents, where accessibility here means the ease of finding the documents in the first place, whether the documents are at the correct level of complexity for the reader's needs, whether they are written in sufficiently simple language and whether translations are available where necessary.

ECHA will also analyse how its support to registrants can be enhanced either directly through the ECHA Helpdesk or indirectly by improving interactions with national helpdesks, industry associations and other groups, such as the Enterprise Europe Network. Targeted support on selecting consultants has been compiled within the Directors' Contact Group (DCG)[2].

Communication on REACH in general and on the 2018 registration obligations in particular is essential to:

- remind companies of their obligations and need to analyse, at this stage, whether or not they need to invest in registration;
- remind companies to verify if they fully meet the criteria for SME status; and
- remind companies to make sure that they have adequate resources for REACH even though the last registration deadline is still a few years ahead.

Apart from the general communication on REACH 2018 registration objectives and progress, ECHA has established a "one-stop-shop" for 2018 registrants on its website[3]. The latter will provide a compilation of all the relevant documentation for the 2018 registration deadline in three layers of increasing complexity. Forthcoming improvements to ECHA's scientific IT tools, processes and documents will be announced on the web pages.

The awareness raising efforts need to be made jointly by ECHA and all stakeholders to reach all the duty holders. Development and communication of sector-specific support is also called for, to make sure that the approach to registration is coherent within sectors.

Milestones to support this phase

Publication of one-stop-shop web page, in all EU languages, for 2018 registration information on the ECHA website (2014).

Checklist for selecting a good consultant (with the DCG) (published on 11 June 2014).

Simplified/scoped ECHA Helpdesk replies (2015).

Reviewed Q&A database on ECHA's website with an enhanced ability to find relevant information for phase 1 (2015).

Webinar "How does the REACH 2018 registration deadline affect you?" giving clear advice to companies to assess whether the deadline affects them and how (2015).

Outreach campaign for the 2018 registration deadline, where joint information campaign together with national helpdesks and ASOs forms the backbone (2015-2017).

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

[2] See http://echa.europa.eu/about-us/partners-and-networks/directors-contact-group
[3] See http://echa.europa.eu/reach-2018/

Phase 2 – Finding co-registrants

When a company has established that it needs to register its substances by the 2018 deadline, the next phase is to find its co-registrants. REACH foresees only one registration per substance, and companies registering the same substance are expected to share their data and to submit their registration jointly. To bring potential registrants of the same substance together, fit-for-purpose IT tools and further guidance on substance sameness will be crucial.

To start this phase, companies first need to identify their substance in a consistent manner that is fit for regulatory purposes and can be shared with potential co-registrants. Well-documented, unambiguous substance identification is essential for a solid registration, and all other information in the registration will be mirrored against it. Therefore, appropriate guidance/support material must be made available to registrants well before the registration deadline.

Furthermore, it is recognised that substance identity guidance/support material, as a whole, is lacking information for certain complex substance types, such as UVCB substances (unknown or variable composition, complex reaction products or biological materials). What is available varies between substance types. To the extent its resources allow, ECHA will continue collaboration with sector-specific groups (representative bodies or companies) to develop sector-specific substance identification guidance to assist registrants. Where relevant, it will do this within the framework of the OECD.

Secondly, companies will need to find out who intends to register or already has registered the same substance. It will be made easier for potential registrants to find their co-registrants, so that discussions on submitting jointly can start in good time.

Information on the ECHA website about the progress towards registration for individual substances will also be increased. Specifically, the aim is to assess the possibilities of improving the pre-SIEF forum in REACH-IT and the information on the ECHA website related to:

- how to find out if the substance has been registered and who is the (lead) registrant;
- how to become a (candidate) lead registrant and find the members; and
- how to find co-registrants if the substance was not pre-registered.

Thirdly, when in contact with each other, companies need to conclude whether they are indeed intending to register the same substance. The ECHA Guidance for identification and naming of substances under REACH and CLP has a section on substance sameness. However, the text is currently limited in its scope and depth, in particular for UVCB substances.

ECHA is developing possible solutions for a further structured approach on substance sameness that were discussed amongst key stakeholders in a workshop in October 2014. The international chemicals management arena may also need to be considered in the discussions to try to move some way to an internationally harmonised system.

Milestones to support this phase

Methodology established for substance sameness (2015).

Potential review of the Guidance on Substance Identification and Naming or other types of material for addressing substance sameness (2015).

Improved accessibility to finding co-registrants (2016).

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

Phase 3 – Cooperating with co-registrants

At the core of REACH lies the principle that companies registering the same substance should not duplicate tests involving vertebrate animals but instead share the available data. These companies are typically competitors on the European market, but nevertheless they have to come to an agreement on sharing the data to avoid unnecessary animal tests. While the legislation foresees that industry self-regulates this aspect of the registration process, ECHA can provide advice targeted to the needs of SMEs to facilitate their work.

Therefore, as a third phase for preparing a registration, once a potential registrant has clearly identified their substance in a way that allows them to comply with the regulatory requirements (see Phase 2), they need to get in contact with other potential and/or existing registrants of the same substance to discuss the need for data and the sharing of available studies in the respective SIEF. This also serves to comply with the joint submission obligation. While REACH does not foresee any role for ECHA in SIEF formation and management or data-sharing negotiations, the Agency can help companies by providing understandable and accessible information and guidance, as well as through the data-sharing dispute process.

Potential registrants are faced with a number of challenges, which may differ based on what the situation of the SIEF is and the level of involvement the company wishes to have in its SIEF. While these challenges are already known from previous registration deadlines, the upcoming 2018 registration deadline might require ECHA to develop some of the following measures to minimise the burden especially in the light of the expected high number of SMEs affected:

- SIEF management

  ECHA will increase efforts to raise awareness regarding the responsibilities in SIEFs. Currently, industry practice regarding the role of the lead registrant expects the lead registrant to take the overall responsibility and initiative for all issues related to the registration. This approach might not be the most suitable for registrants for the 2018

deadline. ECHA will focus on two areas:

- To find a volunteer for the role of lead registrant within a SIEF: enhanced information will be made available regarding (i) the shared/common responsibilities of all members of a joint submission, (ii) the limits of the role of the lead registrant, and (iii) the possibilities to outsource the workload to a consultant.
- To find a volunteer in a SIEF to perform a missing study. ECHA will raise awareness concerning the procedure to assign the responsibility to perform missing studies to individual SIEF members, as laid out in Article 30(2).

- Data and cost-sharing negotiations

  Negotiations with the lead registrant/consortium of an existing joint submission might seem overwhelming from the viewpoint of an inexperienced SME. To help ensure transparency, fairness and non-discrimination in the data and cost-sharing negotiations, ECHA will provide information (e.g. publishing best practice) to support potential registrants in their negotiations. This should also cover negotiations between data owners and potential registrants in the SIEF before the submission of their registration dossier.

- Data and cost-sharing disputes

If data or cost-sharing negotiations fail, REACH foresees the possibility to lodge a data-sharing dispute with ECHA. Information on the assessment criteria and the process will be published to increase transparency regarding ECHA's procedures. At the same time, it is hoped that this will trigger a learning process within industry, leading to improved negotiation practices.

In addition, parallel work in the European Commission to explore the possibility for an Implementing Act on data and cost sharing and of the Directors' Contact Group (e.g. on best practice for cost sharing and SIEF management) is on-going and is expected to contribute to addressing the above-mentioned aspects. Hence, one part of the identified issues for registrants can be proactively tackled by ECHA by improving and developing related communication and information material, e.g. on its website, and this work has been kicked off in 2014. On the other hand, for those areas where input is required from stakeholders, such as the Directors' Contact Group, concrete implementation will only be developed once a decision is taken or a recommendation is issued by the respective bodies.

Milestones to support this phase

Publication of ECHA data-sharing dispute decisions and assessment criteria (2014).

Publication on task sharing and practices in a SIEF, including promotion of the DCG document 'Recommendation on sound SIEF management' (2015).

Publication of support material (2015) and provision of online training (2016) for data-sharing negotiations.

Publication of DCG recommendations (2014-2017).

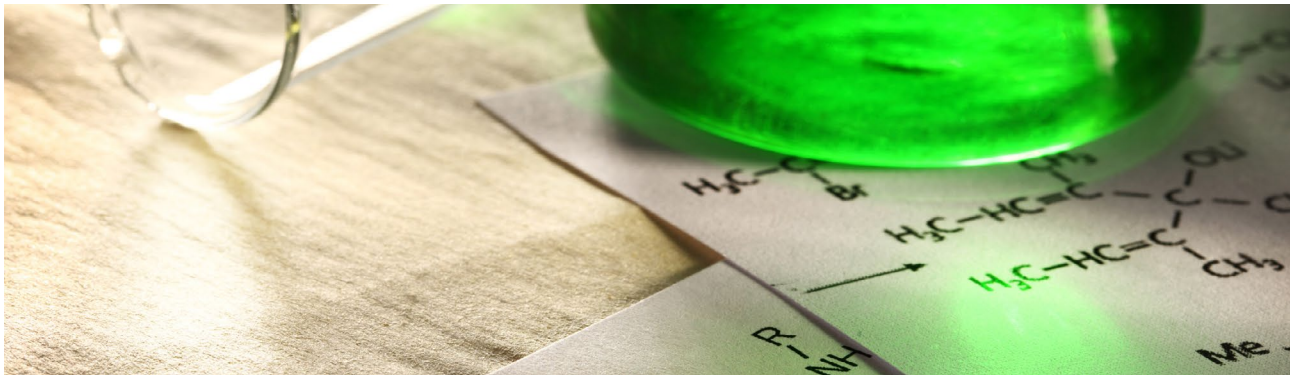
Phase 4 – Assessing and documenting hazard and risk information in the registration dossier

Phase 4 in the registration process concerns the collecting of information on hazardous properties and uses of substance, assessing the resulting exposure, and documenting all this in the registration dossier. The following regulatory, scientific and technical challenges may be encountered by the registrant:

- Collecting information on uses and current conditions of use from the supply chain;
- Understanding the information requirements triggered by the properties, hazards, tonnage and uses of the substance;
- Assessing the amount (coverage) and quality of the hazard information available within the SIEF;
- Developing a strategy to fill any resulting data gaps, taking into account the obligation to use animal testing only as a last resort (e.g. commissioning of new studies or justifying missing information by scientifically solid read across, data waivers etc.);
- Using these hazard data to arrive at an agreed classification within the SIEF;
- Documenting the hazard data and classification in the registration dossier in a REACH-compliant manner; and
- Where required, carrying out the chemical safety assessment and documenting it in a REACH-compliant chemical safety report.

Although ECHA already provides a considerable amount of guidance and related material on this topic, a proportion of the current registration dossiers have been found to be incompliant with one or more information requirements. Addressing these deficiencies is a key to the overall effectiveness of REACH in ensuring the safe use of chemicals. In addition, offering enhanced support to registrants (and particularly SMEs) in this context would help to make sure that they are able to confirm safe use and minimise the need for them to be faced with regulatory requests from ECHA and other authorities.

The 2018 registration deadline will also bring some information requirements that are only applied to phase-in registrations of 1-10 tonnes, and are hence implemented for the first time. These include assessing whether the substance is such that only physico-chemical information on its properties



needs to be included in the registration (i.e. whether the substance falls into the scope of Annex III or not), and documenting the use and exposure information for substances for which a chemical safety report is not required. Support for companies faced with these situations will be developed. The European Commission has launched a study to analyse whether the information requirements for 1-10 tonne registrations need to be amended. The results of this study may affect the work needed for this phase, e.g. in the form of respective support to companies.

In addition, the work to support registrants over this phase will involve a review of the existing guidance, training material and other support offered to registrants for these activities, particularly in the context of accessibility of this information for SMEs. It will also incorporate the ongoing work in relation to the cross-stakeholder Chemical Safety Report/ Exposure Scenario Roadmap (CSR/ES Roadmap), where processes and tools for harmonising communication on the uses in the supply chain are being developed.

The development of best practice for the assessment of complex substances, notably substances of complex composition and substances transforming on the use, will be reflected in related supporting documentation.

More concrete advice on using alternative methods to fulfil the information requirements will be included in the updated guidance documents as well as on the dedicated ECHA web section on the new test guidelines. ECHA will support the registrants also by publishing the principles of the Read-Across Assessment Framework (RAAF) which may be useful to understand what to aim for in a good robust read-across justification.

Finally, the OECD QSAR Toolbox facilitates using quantitative structure–activity relationship (Q)SAR methodologies to group chemicals into categories in order to fill gaps in (eco)toxicity data. It will be explored how (Q)SAR models and the OECD QSAR Toolbox could be used to support the 2018 registrants in the most effective way.

Milestones to support this phase

Publication of relevant updated Guidance (2015-2016).

Strategy for supporting the 2018 registrants in relation to REACH Annex III (2015).

Publication of the principles of the human health Read-Across Assessment Framework (RAAF) (2015).

Practical Guide for registrants of chemical substances of 1-10 tonnes (2016).

Chesar 3 and related training activities (2016).

Simplified access to Guidance helping SMEs (2016).

Phase 5 – Preparing registration dossier in IUCLID

After compiling all the information needed, the company has to enter the information in IUCLID. IUCLID is a mandatory format for data submission to ECHA, and IUCLID software, developed by ECHA in cooperation with the OECD, has had an integral role towards the successful practical implementation of REACH. However, ECHA's stakeholders have highlighted the complexity of IUCLID as one of the main challenges when registering substances. Since there is a much larger number of dossiers expected for 2018 and this deadline concerns many more SMEs than the previous ones, ECHA will pay special attention to further assisting the registration process by developing the user experience of first-time IUCLID users.

With the planned revisions of REACH-IT and IUCLID during 2014-2015, the user friendliness and intuitiveness of these IT tools will be enhanced, to aid their use by companies lacking IT and regulatory expertise, as is this case for some SMEs.

The ECHA Validation Assistant provides a tool for registrants to screen their registration dossier for the most common anomalies and inconsistencies before submitting it to the Agency. This Validation Assistant consists of two sets of rules: one set checks the dossier for completeness of the information and the second set includes dossier quality related rules. These rules will be revised, taking stock of the experience gathered from registration since 2008 and will especially address inconsistencies related to the identification of the substance in the dossier.

The following outputs are foreseen:

- Dossier creation in IUCLID
    - Easier workstation installation of the software; and
    - Simplifying the use of IUCLID by providing specific data entry forms for cases where data requirements are low (e.g. low tonnage band, member dossier only).
- Revised Validation Assistant.

Industry stakeholders will be involved in the development of these functionalities. Specifically, SME focus groups will be consulted on the planned new functionalities that are meant to enhance the user experience.

ECHA aims to publish the revised version of IUCLID in 2016. This will enable early registrants to prepare their dossiers well in advance with the new version of IUCLID and, simultaneously, will allow inexperienced registrants to familiarise themselves with the tool well ahead of the deadline. ECHA's ambition is to construct such intuitive tools with "embedded" help text (including multilingual aspects) and therefore reduce as much as possible the need for extensive software manuals.

Milestones to support this phase

New version of IUCLID specified for improved data structure (2014).

New and revised dossier preparation tools (IUCLID 6, Validation Assistant (including completeness check) and manuals (2016).

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

Phase 6 – Submitting registration

In the final phase of the registration, after compiling all the information needed, and having prepared the registration dossier in IUCLID, the company has to send the dossier to ECHA through REACH-IT. REACH-IT will also undergo a revision ahead of the 2018 registration deadline. The identified challenges include e.g. managing own submissions and joining the joint submission.

The following outputs are foreseen:

- REACH-IT user interface
    - Improving the user experience in REACH-IT for all types of registrations, including the issue of multilingual support.
- Registration procedure
    - Streamlining and simplifying REACH-IT messages, letters and other communications related to registration (multilingual support will be considered).

Industry stakeholders will be involved in the development of these functionalities. Specifically, SME focus groups will be consulted on the planned new functionalities that are meant to enhance the user experience.

The revised version of REACH-IT is planned to be published in 2016. This will enable early registrants to submit their dossiers well in advance and, simultaneously, will allow inexperienced registrants to familiarise themselves with the tool well ahead of the deadline. As with IUCLID, ECHA's ambition is to construct such intuitive tools with "embedded" help text (including multilingual aspects) and therefore reduce as much as possible the need for extensive software manuals.

Milestones to support this phase

Implementation of the plan regarding the completeness check tool and process, as appropriate, in particular for checking safety information (2015).

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

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

Phase 7 – Keeping registration up-to-date

Registering a substance under REACH is not a one-time exercise, but the registrants have the obligation to keep their registration dossiers up-to-date. The need for updating the dossier may arise either from a regulatory action, such as dossier or substance evaluation, or spontaneously if e.g. circumstances related to the registration change. An example of the latter is a new use for a substance to be assessed or a change in the tonnage manufactured/imported.

ECHA shares its experience on the most typical deficiencies detected in the registration dossiers in its yearly reports on evaluation. Based on its observations, ECHA can also target its support for registrants to the areas where improvements seem to be needed.

Milestones to support this phase

Evaluation reports (2015-2018).

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.

Consultations

As outlined above, ECHA's actions for the 2018 registration deadline will include a thorough assessment of existing support material, IT tools and procedures, which will be enhanced based on the outcome of the analysis. To ensure that the proposed changes will be beneficial from the SME viewpoint, the Agency has established contacts with SME focus groups with the help of Member State competent authorities throughout the EU.

These groups will be consulted when deemed necessary to gather feedback on a draft version of a tool, a document or a concept prepared by ECHA, and their feedback will be considered before publication. An example of a set of questions prepared by ECHA to support the discussions with the focus groups is presented in Annex 2. In addition, accredited stakeholder organisations will also be consulted where appropriate.

Implementing the roadmap towards the 2018 registration deadline

The roadmap covers the time span of 2015-2018, with some deliverables of 2014 also mentioned. The currently foreseen actions and milestones are outlined in this document. The actions will be explained in more detail in the forthcoming annual work programmes of the Agency, highlighted as "2018 registration relevant". ECHA will maintain regular communications regarding the milestones towards the 2018 registration deadline throughout the roadmap implementation.

It is expected that many of the actions in this roadmap will be implemented in cooperation with the European Commission, the Member States and ECHA's stakeholders. Importantly, as extensive efforts are needed to reach the 2018 registrants and to make sure that they can successfully compile and submit a registration that properly documents the substance properties and conditions of safe use, it is expected that all other actors will complement ECHA's activities with their own efforts to achieve this goal.

Annex 1. Literature review

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Annex 2. Feedback on the registration process – an example for a questionnaire to support the discussion with the focus groups

PART 1. ECHA COMMUNICATION/TOOLS SUPPORT IN DIFFERENT PHASES OF THE REGISTRATION PROCESS.

Below, the registration process is split into six different phases (as numbered in the table below). We would like to know for each phase which items (a-g) on the left-side column you used during your registration process, and what your experience on it was. NB: We do not expect you go into this material, but just to recall your past experience.

	1. HOW DOES THE REACH 2018 REGISTRATION DEADLINE AFFECT ME?	2. FINDING YOUR CO-REGISTRANTS	3. COOPERATING WITH CO-REGISTRANTS	4. ASSESSING AND DOCUMENTING HAZARD AND RISK INFORMATION IN THE REGISTRATION DOSSIER	5. SUBMITTING YOUR REGISTRATIONS	6. FOLLOW-UP ACTIONS
a. ECHA website						
b. ECHA publications (Guidance, manuals etc.)						
c. ECHA IT tools						
d. ECHA company-specific communication through IT tools						
e. ECHA generic communication (News Alerts, e-News)						
f. ECHA Helpdesk support						
g. National helpdesk support						

PART 2. SPECIFIC QUESTIONS RELATED TO DIFFERENT REGISTRATION PHASES.

1. How does your company decide/define how to describe and name its substance for REACH purposes?
    A. Is ECHA support material needed/helpful for the decision?
    B. What other support was needed?
2. How were the pre-SIEF discussions organised?
    A. Getting pre-SIEF activated. Were REACH-IT pre-SIEF functionalities helpful?
    B. Concluding on substance sameness.
    C. Agreeing on the lead registrant.
3. How are different SIEF management aspects handled within the SIEF?
    A. Managing communication and transparency.
    B. What languages have been used? What would be the most appropriate approach to the multilingual environment in SIEF?
    C. Cost-sharing discussions.
    D. Granting letters of access.
    E. SIEF agreements.
    F. How to accommodate newcomers to SIEF.
    G. Arrangements/agreement in the SIEF on who is responsible for keeping the dossier up-to-date. For how long?
    H. How were disputes resolved?
    I. How are the interests of smaller members of SIEF respected?
4. The process for collecting information for the dossier and pulling it together in IUCLID
    A. Agreeing on the dossier content.
    B. Agreeing on the new information needed.
    C. Agreeing on the alternative approaches to use. Was available support material adequate?
    D. Company staff or consultant? If latter, how to manage that?

E. What tool did you use for conducting your CSR?

F. IUCLID as a tool to store the information – what are the challenges from the company perspective?

G. Did you use IUCLID plug-ins to anticipate fees, disseminated information and the completeness of your dossier? If yes, how did you find them?

5. Submitting the dossier to ECHA

A. Understanding the submission process – what are the steps?

B. REACH-IT as a submission tool – what are the challenges from the company perspective?

C. Clarity of messaging through REACH-IT during the submission process.

D. Was submission support received from ECHA when requested?

6. Follow-up actions/keeping the dossier up-to-date

A. Did you claim some information confidential in your dossier? If yes, how did you find the assessment process?

B. Managing changes in the dossier upon authorities' request (dossier/substance evaluation)?

C. Managing changes in the dossier for spontaneous updates (uses added etc.).

PART 3. GENERAL/HORIZONTAL ISSUES.

- Do you foresee a different approach for 2018 registrations for any of the registration phases? If yes, what will be done differently?
- Was there a clear gap in ECHA guidance/support for any of the registration phases? If yes, where did you turn to for additional support? Did you find the support there?
- How have you organised REACH-related communication within your company?
- Style and vocabulary in our communication – is it understandable? How is it perceived from the company perspective?

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