

Support SMEs in the registration process

44th meeting of the Management Board 13-14 December 2016

Key messages

With the third REACH registration deadline of phase-in substances a mere 18 months away, this document summarises for the Management Board the state-of-play in the Agency's support to SMEs. ECHA calls actors to join forces and ensure that the SMEs reachable via their networks find the material.

In addition, ECHA is receiving some signals that companies are rationalising their portfolios to the extent that there is a danger that some substances will not be registered at all. Honest communication on registration intentions is needed to allow downstream users to prepare accordingly.

Management Board members are requested to take note of this information as well to help identify further avenues within their national fields of responsibility to activate additional information platforms for "reaching the unreachable".

Background

Under its current best estimates, ECHA expects up to 60,000 registration dossiers to be submitted for the last phase-in REACH registration deadline. Many registrants will be SMEs and inexperienced companies. A lot of additional substances will be registered by smaller SIEFs; in a number of cases, it will be single registrants submitting dossiers. In this light, ECHA has over the last two years undertaken a multitude of actions in support of SMEs preparing for the deadline. This document summarises these activities.

Rationale

Apart from having a legal responsibility to provide advice and assistance to registrants, ECHA depends on the successful submission of dossiers by registrants with obligations for the 2018 deadline to be able to satisfactorily conclude the phase-in registration sequence foreseen by the REACH Regulation. Ultimately, success or shortcomings in reaching this important milestone in managing the implementation of the regulation will be an important factor in determining the reputation of the EU chemicals safety acquis at a crucial point in the European Union's history.

There may be phase-in substances that are not registered even in the 1-100 ton band. This may lead to the disruption of supply chains and to negative economic impacts on downstream industries. Evidently, in many cases, business decisions taken by companies in 2017 will lead to them to discontinue marketing certain substances in their portfolio. Feedback available to ECHA to date justifies some concern that such 'portfolio rationalisation' might be going quite far. It is therefore important that downstream users are alerted on the crucial nature of the REACH 2018 registration deadline for their businesses, so that they can examine their suppliers' registration intentions, and, if needed, can change supplier or start preparing their own import and registration in time.

ECHA has, over the last years, been a highly motivated driving force in designing, developing and providing enhanced IT tools for registration as well as information material to support SMEs in their registration efforts¹. The support material has been well received by the SMEs, as well as the efforts to reduce the need to invest in IT resources for registration's sake. The major

¹ See ECHA's REACH 2018 Roadmap at https://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf.

concern lies in reaching out to SMEs to make sure that all dutyholders know about their obligations, support material and available help.

ECHA's REACH 2018 support material will still be enhanced in 2017 with practical examples which have been demanded by SMEs. For the registration related IT tools the next step will be the launch of the Cloud Services offered only for SMEs. A demo of this new tool will be shown to the Board as part of the introduction to this point on the agenda.

As for the challenge on reaching out to SME registrants, more concerted efforts are called for. Importantly, national initiatives may need to be strengthened to reach still unaware companies. National and sub-national actors, be they authorities or industry associations, are more likely to enhance our collective outreach, as they constitute actors with better 'ground-level' knowledge and networks.

Attachment:

- State-of-play in supporting SMEs

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State-of-play in supporting SMEs

MB/53/2016 final annex 14.12.2016

1. ECHA preparations for the REACH 2018 deadline

Support material developed for SMEs under the REACH 2018 Roadmap

Under the REACH 2018 Roadmap which was published in January 2014, ECHA split the roll-out of support material for registering into seven phases. For six of the phases, ECHA has, by the end of November 2016, published a full support package in a format particularly designed to guide SMEs and inexperienced companies. Each package includes

- Introduction to the topic
- Web articles on relevant sub-topics
- Comprehensive collection of links to further material
- Explanatory webinar

Apart from being structured by phases, all the support material is presented in three tiers of complexity: getting started – essential reading – going deeper. The latter level mainly addresses specialists within companies and/or their consultants.

All material is written in an SME-friendly language, and is available in 23 languages (apart from the webinars) via ECHA's dedicated REACH 2018 webpages.² Phase 7 ('keep you registration up-to-date') will be published only after the registration deadline, in the second half of 2018. In 2017 ECHA will complement the existing material by adding case studies and practical examples, to illustrate the most common issues facing SMEs.

With inexperienced actors as a specific target audience, ECHA also launched explanatory 'Getting started'³ webpages as well as a booklet entitled 'Chemical safety in your business – introduction for SMEs'.⁴

Sector-specific support

Acting upon specific practical as well as policy needs, the Agency has so far provided especially targeted support to the dyes (provision of data older than 12 years available for registration purposes) and essential oils sectors (cooperation with industry associations to prepare sector-specific guidance on substance identification and environmental assessment). This was very well-received by the affected constituencies. Sector-specific guidance is currently being prepared in cooperation with the inorganic pigment sector.

Prompted by contacts from other sectors, ECHA is ready to collaborate with their representative bodies or companies to develop further targeted guidance to assist registrants. ECHA has already published a number of such pieces of guidance in a dedicated section on its website⁵.

ECHA's IT tools for registration

ECHA published new versions of all its registration related IT tools during the course of 2016. These include IUCLID, which is a central tool for documenting information on chemicals and creating registration dossiers, Chesar, which provides a structured way to making a chemical safety assessment, and REACH-IT, which is the secure on-line platform used for communication between companies and ECHA. All tools have significant new features in terms of both user interface and embedded help systems, and for REACH-IT in all EU languages, and the aim has been to make the tools as intuitive and user-friendly as possible, based on feedback from industry. It is noteworthy that the upgrade of tools led to a small peak of registrations submitted by companies having prepared their dossiers in the previous version of IUCLID.

² <http://echa.europa.eu/reach-2018>.

³ <https://echa.europa.eu/support/getting-started>.

⁴ https://echa.europa.eu/documents/10162/21332507/guide_chemical_safety_sme_en.pdf.

⁵ <https://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/>.

Most notably with regard to the last registration deadline, it is now possible to create a registration dossier for a member registrant completely in REACH-IT online, if they fully rely on the Lead registrant's dossier, hereby alleviating the burden of installing and learning IUCLID.

Furthermore, to minimise the burden of IT tool maintenance and support for SMEs, ECHA will launch a totally new concept to deliver its IT tools during 2017: the ECHA Cloud Services. In summer 2017 it will be possible for SMEs who need to prepare a full dossier to use the current IUCLID through the ECHA Cloud Services, without having any longer to locally install this tool and local databases on their own devices. By the end of the year, additional simplifications of IUCLID, designed to support SMEs in their dossier preparation, will be available in the ECHA Cloud.

ECHA's registration related Guidance material

The Agency updated most of its Guidance material of relevance to registration by June 2016 to provide for a two-year stand-still ('moratorium') to provide companies with a stabilised regulatory environment in the run-up to the deadline. In May 2016, the Agency published a list of relevant guidance pieces that it would, for plausible reasons, only be able to publish closer to the deadline. Of these, the updated guidance on registration was published in November, whilst other updates of the guidance documents (on data sharing and substance identification) will be ready imminently, with the exception of the guidance on nanomaterials.

ECHA has complemented available information material with practical guides, not least the 'practical guide for SME managers and REACH coordinators' on 'how to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year' published in July 2016 which not only states all information requirements but also argues their rationale in detail. In addition, ECHA has revised and updated its practical guides related to alternative methods to fulfil information requirements, and five previous guides have been merged into one document, 'How to use alternatives to animal testing to fulfil your information requirements for REACH registration' and revised the practical guide 'How to use and report (Q)SARs'.⁶ These documents take into account the latest changes in Annex VII and Annex VIII, which make the non-animal testing methods the default to fulfil certain information requirements at lower tonnages.

Enhanced mechanism to resolve data-sharing and joint submission disputes

Following the entry into force of the Commission Implementing Regulation on joint submission of data and data-sharing in January 2016, ECHA enhanced its mechanism to resolve data-sharing and joint submission disputes. If ECHA decides in favour of the potential registrant, it will provide them not only with access to the disputed information, as it was before, but will also ensure that they remain part of the same joint submission for the substance. When settling disputes ECHA has been mandated to take into consideration parties' compliance with principles of fairness, transparency and non-discrimination clarified by the Implementing Regulation.

In a meeting between MSCA Directors and ECHA on 17 November some new ideas were put forward. These include setting up national data-sharing bureaus that could advise SMEs in their own language on data-sharing complaints, and suggest data-sharing mediators, accredited by these bureaus, who would facilitate negotiations between the companies. MSCAs could be invited to share information on such initiatives and practices in CARACAL.

Easier and more transparent ways to report information required for registration

The format of the technical dossier (IUCLID format) has been reviewed based on users' feedback. It is now more structured and transparent and includes integrated help so that registrants can more easily understand how to fill in their dossiers. Furthermore, the revised completeness check tool makes it clearer which information is required in a complete dossier. Apart from the manual

⁶ See <https://echa.europa.eu/practical-guides>.

verifications done by ECHA staff, the completeness check is reproduced in the Validation Assistant of IUCLID so that SMEs can check their dossiers ahead of submission.

In order to improve transparency of the scope of substance identity covered by the joint registration of a substance, ECHA has implemented the substance identity profile (SIP) concept in IUCLID. The SIP documents the boundaries of the substance identity for which the hazard data (Annex VII-XI) of the joint registration apply, and makes it easier for SMEs to decide whether their substance is covered by the joint registration.

Gathering market intelligence on registration intentions

ECHA has started to refine its registration estimates for the last deadline. However, contacts with industry in late 2015 and early 2016 resulted in very little concrete information available at that time on substances to be registered, the main message being that it was still too early to ask. ECHA will restart its efforts in this area in 2017 by trying to intelligently analyse the pre-registration information and by contacting pre-registrants directly.

Effectiveness of these preparations

ECHA appreciates the generally positive feedback that various audiences have provided on the roll-out of the above-mentioned information material as well as IT tools. However, there is a continuous demand for more practical examples. Even with the improved installation functionalities of IUCLID, using the IT tools for registration, is still a hurdle for SMEs. To respond, ECHA will publish case studies and illustrative examples in 2017, and roll out ECHA Cloud Services.

The information gathered so far on registration intentions of companies is fairly limited. Therefore the Agency is also interested in gathering input from further sources willing to volunteer any market intelligence.

2. ECHA's REACH 2018 outreach activities

ECHA publications

Apart from providing information on the six phases on the ECHA website, ECHA's Newsletters (four issues p.a.) and weekly e-news have over the past two years consistently contained articles and news items on the REACH 2018 registration process, including company examples. ECHA's communications activities have also increasingly made use of social media to promulgate information. A REACH 2018 awareness raising video⁷ has sought to draw readers to the ECHA REACH 2018 webpages.

De-centralised workshops and information events

Whereas ECHA held a series of workshops during 2015 to identify SME needs in terms of information, support and upgraded IT-tools (held in France, Germany, Ireland, Italy and the UK), it is now engaging in a sequence of de-centralised workshops – at the invitation of various hosting organisations – to help promulgate the afore-mentioned information and support, particularly to SMEs and their representatives.⁸ Further such opportunities may still arise, and in order to anticipate the needs and coordinate the efforts, ECHA has called the REACH 2018 Communicators' Network and HelpNet members to inform ECHA about their forthcoming REACH

⁷ <https://www.youtube.com/watch?v=d4-WI6DLBI8>.

⁸ REACH 2018 events with ECHA participation have recently taken place e.g. in Paris (February 2016), in Cambridge (August 2016), in Hamburg and Helsinki (October 2016), and in Castellon, Stockholm and Dublin (November 2016). Forthcoming events are taking place in London in February 2017, in Vienna for Central and Eastern Europe in March 2017 (co-hosted by UEAPME); in Berlin in April 2017, in Prague in April 2017, in Cambridge in August 2017 and in Vienna in December 2017.

2018 events by the end of the year. ECHA has also used national events with a wider scope to present its REACH 2018 support material.⁹

ECHA's REACH 2018 outreach in social media

Social media presence has been an integral part of the Agency's communication strategy on REACH 2018, and the publication of each of the phases has been accompanied by campaigns on ECHA's LinkedIn and Twitter accounts¹⁰. Due to the multiplicative nature of social media, these campaigns help the REACH 2018 message to reach those that do not regularly follow ECHA. In October, due to paid pushes of information on phase 5 of the REACH 2018 Roadmap, ECHA reached more than 860,000 people via social media.

Effectiveness of these activities

From the sheer numbers, it can be appreciated that ECHA is reaching out to quite a wide audience. However, it is difficult to assess the impact of the activities above, i.e. will the messages be read and understood. Therefore ECHA will enhance its outreach activities in 2017 by multilingual campaigns and engaging social media influencers who follow ECHA and have a lot of followers that the Agency would not reach otherwise. In addition, ECHA will commission a study that will segment the market of potential registrants, in order to better identify possible communication channels and target its communication, especially for promoting the new Cloud Services.

3. ECHA networks and bodies relevant for the 2018 deadline

REACH 2018 Communicators' Network

ECHA established the REACH 2018 Communicators' Network in early 2015 to alleviate concerns voiced by stakeholders regarding the low level of REACH 2018 awareness that became apparent during the REACH 2018 Roadmap consultation. Currently, the network comprises 45 organisations as members, and it has been active in designing joint communication products as well as in joint communication activities around the launch of the information packages providing orientation on the six afore-mentioned phases in preparing registration dossiers. ECHA is currently gathering feedback from the network members to assess the effectiveness of its communication activities so far. Furthermore, a joint ECHA/Commission communication strategy is being launched.

The REACH 2018 Communicators' Network designed topical leaflets for national operators to use for REACH 2018 awareness raising that do not deal with REACH registration in their daily work but who are in direct contact with potentially affected companies. The REACH 2018 Communicators' Network has also compiled an inventory of potential country specific activities, so that best practice examples can be sources of inspiration for designing national campaigns on REACH 2018.

ECHA is still seeking to widen the membership of the network as well as considering to merge it with the network of Accredited Stakeholder Organisations' communicators, now that the roll-out of the supportive information has been concluded.

The REACH HelpNet

For the past two years, the agendas of the HelpNet Steering Group meetings as well as the HelpNet REACH workshops have kept the correspondents from national REACH helpdesks

⁹ E.g. Annual seminar of *essencia* (Brussels) in October 2016, as well as *Federchimica* Annual Conference on REACH and CLP (Milan), meeting of the UK Chemicals Stakeholder Forum (London) and VCI REACH Information Conference (Frankfurt), all in November 2016.

¹⁰ ECHA's REACH 2018 showcase page in LinkedIn: <https://www.linkedin.com/company/reach-2018>. ECHA's Twitter account: https://twitter.com/EU_ECHA, #REACH2018.

abreast with developments regarding information and support material, ongoing information campaigns and IT developments. These workshops have also included hands-on training on the IT tools. Furthermore, ECHA provides all HelpNet correspondents with current information by means of a HelpNet Update, circulated five times per year.

ECHA's own Helpdesk provides answers to enquiries on registration issues. The Agency's Single Programming Document (SPD 2018-2020) reflects the estimated rising number of such enquiries ahead of the deadline.

ECHA's regular REACH Stakeholders' Days

Equally, ECHA's annual REACH Stakeholders' Days have regularly included agenda items touching upon the REACH 2018 registration. Hundreds of companies have either attended physically in Helsinki or via web-streaming. In the course of these events, ECHA has provided one-to-one sessions to reply to individual company queries. The forthcoming next Stakeholders' Days (4-5 April 2017 and January 2018) will be focused on the deadline.

Other ECHA networks

Since summer 2016, ECHA is an Associate Member of the European Enterprise Network (EEN). This status allows ECHA to directly address EEN advisors directly via that network's intranet. Already in the past, ECHA worked closely with EEN advisors and HelpNet correspondents in publishing a guide for SME advisers entitled 'EU chemicals management rules and your clients' business'.

ECHA's Forum has coordinated the delivery of registration information to companies in the course of inspections.

ECHA's SME Ambassador

Whilst the catalytic function of ECHA's SME Ambassador in the period after his appointment in 2013 was instrumental in providing input to the REACH 2018 Roadmap and to the design of ECHA's phased and tiered webpages, this summary documents that SME support is in the meantime sufficiently 'mainstreamed' to have allowed his involvement to be reduced. Together with the Director of Registration, he is currently focused on trying to reach new audiences via social media (@christel_musset and @Andreas_Herdina via #REACHingSMEs and #REACH2018 on Twitter). The SME Ambassador will remain available for targeted interventions in support of SME interests as appropriate. Recently, he has engaged in monitoring the practices of companies in relation to data and cost sharing to see that the rights of SMEs are respected in SIEFs.

Directors' Contact Group (DCG)

This high-level group composed of relevant Directors of ECHA, the European Commission and industry organisations was established in 2010 to monitor progress towards the first registration deadline of REACH and to find practical solutions to any hurdles to successful registration. The group compiled a list of 28 issues and solutions to them. The chairmanship of the DCG has since moved from the Commission to ECHA, and the Agency plans to re-activate the group in 2017 to, for instance, assess the extent of risks emanating from 'portfolio rationalisation', to validate the continued relevance of some selected so-called 'SME issues' also for 2018, or to solicit the involvement of more associations in joint communications' efforts.

Effectiveness of these networks

As companies mainly receive their information via industry associations or directly from ECHA as well as via the National Helpdesks that further spread ECHA's information material, the outreach of these networks is limited by the boundaries of their membership or subscribers. SMEs outside these networks are difficult to reach. In particular in the realm of downstream users, there is an unknown quantity of still unaware SMEs that should be informed. Whilst the size of the problem is speculative, the fact that it exists makes "reaching the unreachable" all the more important in the run-up to 2018. National operators will be crucial in this.