

Preparations for the 2018 REACH Registration deadline

48th Meeting of the Management Board 14-15 December 2017

Key messages

The Management Board is invited to take note of the update on REACH 2018 deadline preparations and discuss if further actions are needed to ensure that sufficient support is available at national level for companies, and particularly SMEs.

Background

The upcoming registration deadline on 31st of May 2018 is expected to be the biggest so far in terms of number of dossiers received. Furthermore, 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 attached document was prepared for CARACAL in order to provide the Member States Competent Authorities and stakeholders with an update on ECHA's preparations to manage the related workload and on the ongoing actions put in place to support companies in the coming months. The document was presented and discussed in the open session of the 25th Caracal meeting held on the 15th of November 2017. The MSCAs welcomed this update and some participants highlighted the importance of providing support to companies as well as concerns with potential latecomers. There was general agreement to continue monitoring the progress and keep the MSCAs informed.

Rationale

ECHA has in the past years undertaken major efforts to ensure that the upcoming registration deadline will be a success. The upcoming registration deadline on 31st of May 2018 will pose a number of challenges to industry, Member States, but especially to ECHA. In order to cope with the workload, ECHA has set up a cross-Agency programme in order to increase its processing capacity, strengthen the company support and prepare a contingency plan in case the number of registrations largely deviates from the estimates underlying the ECHA work programme. Monitoring systems (both internal and external) are also in place to allow all parties to follow progress.

It is important that Member States ensure that there is sufficient capacity at national level, mainly at the national helpdesks, to provide support to the many SMEs who may find issues that hamper them. ECHA will keep a strong collaboration with them during the coming months.

The Directors Contact Group has also reconvened as a body to discuss and find solutions to any critical issue identified which should help SMEs in achieving to register their dossiers. At their meeting on 27 November, the Directors issued a recommendation for companies to notify their registration intentions for the REACH 2018 registration deadline. They decided to reconvene on 15 December in Brussels to continue their deliberations on a pragmatic approach to alleviating the cost burden on registrants in the 1-10 tpa band.

The status as of mid-November 2017 is that progress is satisfactory with a 13% more dossiers for this deadline than what was expected by this date. However, the percentage of SMEs submitting remains below expectations at around 15%. There are no major issues with the workload at the moment and the preparations are on track both from the recruitment and training of additional interim staff as well as from the company support and processing. Finally ECHA will launch the final version of the ECHA Cloud Services for SMEs on 18 December.

Contribution of all stakeholders will still be needed in the last crucial months ahead of the 31 May 2018. Contingency actions are identified in case of major deviations from the forecast and may potentially affect ECHA's output on other areas in 2018 if resources need to be redeployed.

Attachment:

- Annex: CARACAL document CA/75/2017 rev.1

For questions: christel.musset@echa.europa.eu with copy to mb-secretariat@echa.europa.eu

Helsinki, 13/11/2017
Doc. **CA/75/2017 rev.1**

**25th Meeting of Competent Authorities
for REACH and CLP**

15-16 November 2017

Concerns: **Update on REACH deadline 2018 preparations**

Agenda Point: ***Point 9.1***

Action requested: **Member State Competent authorities and observers are invited to take note of this document and discuss how to ensure that sufficient support is available at national level for companies, and particularly SMEs**

For information/discussion.

1. Introduction

The upcoming registration deadline on 31st of May 2018 is expected to be the biggest so far in terms of number of dossiers received. Furthermore, 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.

This deadline will complete the data collection exercise on existing substances via the registration process, staggered over three deadlines, that was kicked off when the REACH Regulation entered into force. It involves substances manufactured or imported into the EEA in quantities of between 1 and 100 tonnes per year.

This document provides the Member States Competent Authorities and stakeholders with an update on ECHA's preparations to manage the related workload and on the ongoing actions put in place to support companies in the coming months.

Some points are also highlighted that deserve special attention by all actors, but Member States in particular, to ensure a successful registration deadline.

2. What do we expect

ECHA expects that up to 60,000 registrations for around 25,000 substances will be prepared and submitted for this deadline, three times more than for highest peak so far in 2010. Current estimates are based on the original model of the European Commission from 2006, based on extensive surveys done for the impact assessment of REACH as well as the information available to the European Chemicals Bureau at the time.

These estimates for 2018 have been reviewed by ECHA but not revised for the following reasons: 1) the number of registrations received in 2010 and 2013 were extremely close to the Commission estimates from 2006 showing the robustness of the information collected for the impact assessment; 2) The results from a number of inputs that have been collected from different sources, including registration intentions surveys at national level, have not revealed anything that would justify a revision. ECHA is currently undertaking a small validation exercise with external support to confirm whether a revision would be warranted.

The profile of companies registering will also be different; as more small and medium-sized enterprises (SMEs) are foreseen to register, (up to 40% of the registrants are expected to be SMEs). For large companies the deadline is also different from the two previous ones, as this time they may have tens of chemicals in their portfolios to register.

It is worth noting that high tonnage dossiers continue to arrive reflecting market turnovers, business changes, etc. Updates of existing registrations are also coming in as a steady flow, adding to the processing capacity needed.

Based on the experience of the previous deadlines ECHA expects three peaks of submissions: one before the end of 2017, another one in March 2018 because companies will get the outcome of the completeness check in three weeks if they submit their dossier before April 2018, and the biggest one right before the deadline itself. A 'tail' of submissions will likely take place right after the deadline keeping the workload high until 2019.

However, a degree of uncertainty remains on all these predictions and ECHA is counting on the possibility of deviations as explained below.

3. ECHA's preparations

Given the significant challenge that ECHA faces with this deadline, it has been crucial to properly prepare for it well in advance. Some of the key challenges identified are:

- Large number of dossiers need large processing capacity particularly as the completeness check includes a manual verification step since 2016;
- Related tasks such as invoicing, or assessment of confidentiality claims will also gradually increase as the dossiers enter ECHA's system;
- High number of inquiries to be processed following the end of the pre-registration in May 2017;
- Less experienced companies may need intense support; and
- Larger number of disputes filed due to data and cost sharing issues, which can be more prominent due to the enforcement of the OSOR principle in the submission process, i.e. companies are no longer allowed to submit individually if a joint submission exists for the same substance and registration type.

To manage this exceptional situation that impacts the whole Agency, ECHA set up an internal programme to prepare for the 2018 deadline in early 2017. Since then, this programme has been the framework to plan, implement, monitor and achieve the different activities related to the registration deadline in a coordinated way. The programme has a cross-Directorate nature as the management of the deadline affects most parts of ECHA, from the operational units taking care of the registration related processes, to the IT, human resources, legal, company support and communication units.

- The Programme includes five work packages:
- Service and support policies: to organise the support given by ECHA to companies given the large number of questions expected, and to reinforce the cooperation with the national helpdesks and stakeholders. The nature of the questions is expected to change over time from e.g. how to find my lead registrant to questions on invoicing or submission problems later on.
- Staff plan for recruitment of additional capacity: given the size of the task, the regular staff of ECHA cannot absorb it without major alteration of the operations and regulatory processes. The peak of work is therefore going to be managed with the support from additional interim workforce, as it is already the case on the manual verification process, where ECHA resources have not grown at the same time as the workload. A staff and corresponding recruitment plan have been set up including induction of the newcomers. The main tasks that will be taken care of by the interims are the processing of dossiers and the support to companies.
- Facilities and ICT: the number of staff involved in the deadline work will hit the 100 number at the highest peak. This poses a logistical challenge in terms of workspace, IT and other equipment. Most of the involved staff will move to work in the ECHA's conference centre for the largest part of 2018.
- Modelling, monitoring and reporting: a crucial part of the programme is the ability to closely monitor the submissions to be able to predict the corresponding workload. A dashboard for management is in place as well as a fee estimation model to be able to anticipate the incoming revenues.
- Contingency plan: The work is planned so that the IT tools, processes and staff are able to handle 60,000 dossiers¹ and related helpdesk questions during normal office hours. In addition, ECHA also prepares for either significantly higher or significantly lower workload. In case of significantly higher number of registrations, the redeployment of staff from other ECHA areas will be triggered. This may have an impact in ECHA's outputs next year. In case major changes are needed to the tools or the process, the necessary communication will also be in place.

¹ 50,000 deadline 2018 related registrations and 10,000 updates to be received during 2018.

4. Where are we now?

The Programme has been operating during these past months and delivered on all the areas mentioned. The recruitment of additional staff has started and the areas of dossier processing, IT support and inquiry/disputes handling have been strengthened. Registration related IT tools and Guidance are stable for registrants.

In terms of the deadline 2018 related registrations, the figures as of 2nd November 2017 are as follows:

- 12 280 registrations received and completed (this is 13% above the estimate for this date)²
- These cover 5 640 substances of which 3 550 are new
- 16% of these registrations are by SMEs (this is below estimate of 40%)
- Rate of submissions received for processing is at around 400 dossiers per week showing an up-going trend towards year end (48% initials and 52% updates)

Despite the slight deviation from the estimates, the workload is currently properly managed and all internal and legal deadlines are met.

All interested parties can also follow registration progress via the ECHA statistics webpages, which will soon include an interactive infographic to further facilitate monitoring the progress of the registration process. Detailed statistics will be provided on a monthly basis.

5. Company support

In 2014-2016 ECHA developed, in cooperation with stakeholders, SME friendly support material and novel awareness raising means under ECHA's REACH 2018 Roadmap. The seven-phase model of registration, from analysing the company portfolio to keeping registrations up-to-date, has proven to be an effective way of guiding the companies to a successful registration. A communications network consisting of members from Member State representatives as well as various industry associations has supported the process to ensure that awareness was raised among companies. More information can be found here: <http://echa.europa.eu/reach-2018>.

ECHA has also continued its more traditional support such as developing its IT tools and publishing Q&As as well as replying the numerous individual questions received via our contact form. In the coming months, the focus will be on this area. National helpdesks will be kept informed via the HelpNet, which is meeting virtually throughout the peak months, and face-to-face at the end of January 2018, to touch base on the preparations as well as any issue that has been identified. The document outlining ECHA's cooperation with the national helpdesks is provided in the Annex.

It is important to note that companies and particularly SMEs may need support in their national language. This is best provided by the national helpdesks. It is therefore critical that the national helpdesks are adequately resourced, and can benefit from the training on the latest registration tools and processes and available help offered by ECHA.

Whenever companies are having problems with a specific submission e.g. failure of completeness check, it is better for companies to contact ECHA directly as national helpdesks do not have visibility on the actual submission status and related problems.

ECHA has also been contributing to numerous conferences and training events often providing practical hands-on support on how to prepare and submit registration dossiers. Although resource intensive, this support is highly appreciated by companies. The closer we get to the deadline, this type of support to national events will become very challenging. Careful planning is therefore necessary in case such support is needed in the coming months.

² i.e. for phase-in substances registered <100 tonnes/year.

Pro-active support will also continue and ECHA is prepared to address frequently occurring issues quickly via most appropriate means such as webinars, Q&As, or news items. For example, ECHA may notice that companies start to fail submissions due to a particular business rule and would communicate on how to avoid the issue. Also in this area, the support of multipliers such as the national helpdesks is key to make sure that the messages are passed to the registrants in due time.

Finally, the Directors' Contact Group (DCG) has reconvened following the approach from the previous deadlines. This group provides a forum to monitor registration progress, discuss practical hurdles to registration and find solutions that can be supported by all parties and therefore communicated. The current focus is on the review of the solutions identified for previous deadlines, and on the future of SIEFs. A study recently published by ECHA showed that the price of the letter of access is one of the key hurdles for SMEs in the registration process. This is also a point that ECHA has raised and is discussed with industry associations and Commission in the context of the Directors Contact Group. The work of the DCG can be followed here: <https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group>.

6. Concluding remarks and points for discussion

As explained above, ECHA has put in place major efforts to ensure that the upcoming registration deadline will be a success, but contribution of all stakeholders is needed in the last crucial months ahead of the 31 May 2018. Contingency actions are identified in case of major deviations from the forecast and may potentially affect ECHA's output on other areas in 2018 if resources need to be redeployed.

MSCAs are invited to:

- Make sure that sufficient capacity is in place particularly at national helpdesks to be able to cope with an increased demand for support.
- Monitor the registration progress in their country via the ECHA statistics, communicate their observations to ECHA and take action if the numbers are not as expected.
- Contact ECHA if there are plans for awareness raising, or training events to be organised at national level in the coming months, in particular in case ECHA support would be needed to allow resources planning.

ECHA also invites further ideas and information from the CARACAL participants on potential issues that may arise as well as the commitment to share status and experiences on the deadline progress in future CARACAL meetings.

Annex. ECHA support for the registrants of the 2018 deadline³

Purpose

This document outlines ECHA's approach to support registrants in the run-up to the last REACH registration deadline of 31 May 2018 (hereon DL2018). ECHA is relying on lessons learnt from the two previous deadlines in 2010 and 2013, but acknowledges that the last deadline has its specificities that sets particular challenges⁴.

ECHA is committed to help companies according to the tasks given in the REACH Regulation⁵. Nevertheless, the Agency's support cannot replace the burden of proof set to industry by REACH, nor inadequate or late preparations.

Description

Services covered

ECHA is estimating that up to 36 000 questions on REACH and CLP would be sent to ECHA in 2018, of which most would be DL2018 relevant. This is three times more than received by ECHA in 2016, and approximately as much as replied by all the national helpdesks in 2016. In 2017 ECHA has received 3 400 enquiries by the end of May.

For supporting companies for DL2018, ECHA is making preparations to be able to reply to the following type of questions:

- 1) Regulatory advice: registration obligations, tonnage calculation, information requirements, joint submission, sharing of data and costs, legal entity change
- 2) Account management e.g. unblocking of accounts
- 3) Advice on IUCLID
- 4) Advice on REACH-IT
- 5) Advice on Chesar
- 6) Solving technical issues related to IUCLID and REACH-IT
- 7) ECHA Cloud Services support
- 8) Submission support: Business rules check
- 9) Submission support: Completeness check
- 10) Submission support: Invoicing
- 11) Submission support: Decisions

³ This document was presented and discussed in the HelpNet meeting on 7 July 2017.

⁴ See ECHA's REACH 2018 Roadmap, p. 5

https://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf/.

⁵ REACH Articles 77(2)(h) and 77(2)(j).

Apart from recruiting and training an adequate number of staff to be able to reply to questions, ECHA is also strengthening its infrastructure for handling the questions, namely the processes of receiving enquiries, distributing them, identifying frequent issues and communicating on frequently occurring issues. ECHA is also establishing multidisciplinary teams that can efficiently handle a bulk of incoming enquiries on known, registration related topics.

Availability of ECHA's IT tools and support

REACH-IT opening hours

REACH-IT is normally open for industry from Monday 10:00 throughout the nights until Friday 22:00, when external access is automatically blocked. This is called the "weekend closure". If Monday or Friday happens to be an ECHA holiday, the closure is normally extended accordingly. The application is running in an unattended, unsupported mode during weekday nights, when external access remains open.

Acknowledging that companies may have the need to work outside normal office hours close to the deadline, ECHA will monitor the traffic in REACH-IT and the demand for longer opening hours, and prepares for the readiness to keep REACH-IT open without any closures in the last weeks before the deadline in May 2018.

ECHA Cloud Services availability

ECHA Cloud Services are available to the registered users 24/7, with the provision of a maximum 12 hours maintenance window per month and outside or prime working hours. A maximum repair time of 4 hours is targeted.

Planned or unplanned maintenance activities or disruptions for this service will be communicated via ECHA Cloud platform portals. Maintenance of the ECHA Cloud Services (including upgrades, updates, fixes) is expected to be transparent to the users, i.e. not cause service interruptions.

Enquiries to ECHA

Under normal operations, ECHA is committed to reply to the enquiries within 15 working days. Despite the expected threefold increase of enquiries in 2018, ECHA will do its utmost to be able to keep this commitment in 2018. Among DL2018 relevant questions, ECHA aims at prioritising those which have a clear obligation fulfilment and/or deadline meeting/missing implications.

The prioritisation of DL2018 related questions in spring 2018 means that the response time to other enquiries might be compromised. ECHA is preparing to minimise the effect.

Languages covered

Enquiries to ECHA are generally sent in English, and to enable most efficiently the best experts to contribute to the replies and to reply as quickly as possible, replies are typically provided in English. If a company approaches ECHA in another EU language that expert ECHA staff members do not sufficiently master to provide a reply, ECHA will resort to its close cooperation, via the HelpNet Secretariat, with the relevant national helpdesk to solicit an appropriate reply to the enquirer to be provided in their own language by their own national helpdesk.

If ECHA assesses that a phone call would be the most efficient means to explain the

issue to the customer (see 2.4), ECHA will, to the extent possible, try to find a staff member who can explain the issue to the customer in their own language.

Support means

ECHA typically replies in writing by email. However, ECHA can also call the customer if it is assessed as being the most efficient way of solving the issue. Furthermore, customers can call ECHA's switchboard if they are unsure where to turn to for advice, or if they want to enquire about the status of a question they have already submitted to ECHA.

ECHA monitors the incoming questions to identify frequently occurring questions for which answers are not publicly available, and communicates these through the existing communication channels, i.e.

- the Weekly newsletter (under a separate REACH 2018 header);
- special e-News, when necessary;
- direct mailing to contacts from REACH-IT;
- news on the REACH 2018 web page (<http://echa-europa.eu/reach-2018>);
- social media (Twitter, REACH 2018 page in LinkedIn); and
- dedicated webinars.

Quality and consistency of support

ECHA allocates the incoming questions to dedicated support groups that are specialised in certain topics and act as guardians of consistency. All replies are recorded in the Agency's ticketing system. ECHA maintains a knowledge base and standard replies libraries that support consistency. Both tools are referred to regularly by all teams involved in the registration deadline, ensuring that the content is correct and up to date. The quality of the replies is also ensured by quality checks performed by more experienced staff members.

Cooperation with the national helpdesks and stakeholder organisations

Member States are obliged to provide advice on registration⁶. Also many industry associations have set up helpdesks or other means to support their members in REACH related issues. ECHA's cooperation with these actors, fostered from the first moments of entry into force of REACH, has been central in making the Regulation a success so far.

In the run-up to the DL2018, the role of the national helpdesks and industry associations will be pivotal, as being closer to the companies and speaking their language, they offer the natural first point of contact especially to the inexperienced and SME registrants.

For efficiently managing the support for DL2018 registrants it is important to have a common understanding on how the work is divided between ECHA, national helpdesks and industry associations, and how to enhance communication between the three in the critical period of the anticipated registration peak in spring 2018.

⁶ REACH Article 124(2).

Dividing the support work between ECHA, national helpdesks and industry organisations

According to the agreement in HelpNet, national helpdesks are the first contact point for companies on regulatory advice. If companies approach ECHA on these type of questions, they are requested to approach their national helpdesk instead.

ECHA replies to questions regarding the registration related IT tools (IUCLID, Chesar, and REACH-IT). The support regarding ECHA Cloud Services has been outsourced but ECHA acts as a contact point for companies to ask their questions and sends out the replies.

ECHA is willing to provide additional support material on IT tools functionalities that enable national helpdesks and industry organisations to reply to customers on the questions about basic functionalities of the tools. Such support material is already available on the ECHA web site⁷, and ECHA can consider further support targeted to the national helpdesks based on identified needs.

Furthermore, ECHA replies to questions concerning specific submissions, as replying to these requires access to the Agency's databases to investigate the specific case of the customer.

Industry organisations that provide support to their members should advertise this in the run-up to the registration deadline. Many registration related issues such as substance identification and uses documentation can have sector specific features where the industry organisation is best placed to provide support on them.

Ensuring effective communication between ECHA, national helpdesks and industry organisations

Currently, the national helpdesks and ECHA communicate on individual questions via dedicated discussion fora for REACH, CLP or BPR questions on the HelpEx tool, and during the HelpNet meetings and workshops on wider policy issues, news, and tricky issues. Industry organisations that are observers to the HelpNet can participate in HelpNet events as well. However, they have no access to the REACH, CLP or BPR discussion fora on HelpEx.

Industry organisations can submit questions related to REACH implementation to ECHA, which ECHA will take to HelpEx for harmonisation discussion if needed. In addition, ECHA has informal conference calls with industry organisations to exchange views on topical issues. Finally, ECHA, industry organisations and the European Commission participate in the work of the Directors' Contact Group, which is a high-level group monitoring the progress of registration and identifying potential practical obstacles for companies along the way.

For the successful management of DL2018 it is critical to ensure that information travels swiftly between all organisations that can gather information on the problems that the registrants are facing and about solutions to frequently occurring issues. National helpdesks and industry organisations are in a key position to efficiently spread the topical news about REACH registration to their contacts. At least the following actions can be foreseen:

⁷ REACH-IT: Discover REACH-IT

(https://echa.europa.eu/documents/10162/22308542/discover_reach_it_en.pdf/, available in 23 languages); IUCLID: Functionalities of IUCLID 6.

(https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf/, available in 23 languages); Chesar: Chesar 3 User Manual.

(https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf/).

- ECHA will comment on HelpEx questions related to the DL2018 within five working days in spring 2018.
- ECHA will post information on known issues affecting DL2018 to HelpEx, so all NHD are informed promptly and at the same time.
- Information exchange Webex sessions are organised both with the national helpdesks and industry organisations during the DL2018 peak, expected from mid-February to 31 May 2018. The frequency of these will be decided *ad hoc*, depending on the number of agenda items.

It could also be explored whether the national helpdesks contact web form⁸ could be used for DL2018 communication in addition to HelpEx. Dedicated ECHA staff could monitor the enquiries so that hot topics can be timely brought to the information exchange Webex sessions, relevant information posted in HelpEx, related published information in ECHA's website is update or other necessary action is taken.

⁸ https://comments.echa.europa.eu/comments/cms/MSCA_ITsupport_form.aspx, choose topic "HelpNet – services to national helpdesks".