

## Cefic's feedback on a draft Implementing Regulation on duty to update dossiers

Article 22(1) of REACH define the cases when an update of a REACH registration dossier is needed. Via an implementing regulation, the EU Commission is seeking to clarify how the provisions of article 22(1) should be understood.

Cefic is fully behind this initiative. All actors involved will benefit from having a clearer understanding of the different elements of art. 22(1).

At the Caracal meeting of 21-22 November 2018<sup>1</sup>, the EU Commission presented timeframes clarifying the notice 'without undue delay'. Cefic fully supported this proposal.

Last Caracal meeting (1-2 July 2019)<sup>2</sup> revised timeframes were presented. The November 2018 timings significantly changed.

Latest timeframes would be extremely challenging to meet. They merely seem to fit easy, straight forward updates of dossiers. In reality this kind of updates are rather exceptional. Dossier updates are typically complex, simultaneous touching upon different elements and/or involving multiple actors.

On the next pages we are suggesting alternative timeframes for updating dossiers triggered by art. 22(1). Our proposal builds upon practical experiences (see added justification) and reinforces the timings originally presented by the Commission in November 2018.

We're convinced that our proposal strikes the right balance between workability and securing timely updates of dossiers.

Beside on timings, we also suggest a few additional changes to avoid introducing a new layer of uncertainties via the implementing regulation.

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<sup>1</sup> CA/114/2018

<sup>2</sup> CA/55/2019

## Alternative proposal on timeframes

Reference draft Implementing Regulation on duty to update dossiers	Original proposed timeframe for submitting updates <sup>(a)</sup>	Current proposed timeframe for submitting updates <sup>(b)</sup>	Our proposed timeframe for submitting updates	Justification
Updates triggering a need to update the chemical safety assessment / chemical safety report (art. 1§2)	1 year	6 months	1 year	<p>An update of a CSA/CSR is typically triggered by other changes in the dossier like change of classification, new identified uses etc. Meaning you first sort out these elements, before you start reviewing a CSA/CSR. As a result the overall time needed to update a CSA/CSR is more or less the sum of: (1) time linked to deal with the changes triggering the need for updating a CSA/CSR and (2) time actually needed to review the CSA/CSR.</p> <p>The latter alone will easily take more than 6 months depending upon:</p> <ul style="list-style-type: none"> <li>- Complexity of the review. Some changes might trigger a full hazard re-assessment and a risk re-assessment.</li> <li>- Is the CSR part of the joint submission or not? If so, time is needed to discuss and agree within the joint submission.</li> <li>- Are third parties like consultants involved?</li> <li>- Activating consultants requires getting quotations, placing orders, ... which as such takes several weeks.</li> </ul> <p>A combined deadline of 12 months can therefore be considered as reasonable allowing to cover also more complex combined updates.</p>
Update in case of changes in registrant's status or in his identity (art. 3)	6 months	1 month	6 months	<p>Changes in status or identity require typically multiple dossiers updates. Updating tens of dossiers is practically not manageable within 1 month. Drafting and adoption of relevant REACH related contracts is time consuming and often only starts after identity changes.</p> <p>Alignment with deadline of art. 4 needed to cover situations where change in status is combined with changes in composition of the registered substance. Potentially relevant when status is expanded from manufacturer to importer of the same substance. Composition of the imported substance is not necessarily identical to the one manufactured (and has already been registered).</p>

Reference draft Implementing Regulation on duty to update dossiers	Original proposed timeframe for submitting updates <sup>(a)</sup>	Current proposed timeframe for submitting updates <sup>(b)</sup>	Our proposed timeframe for submitting updates	Justification
Submitting an inquiry in case a next tonnage threshold is reached (art. 5§1)	-	Immediately	1 month and as far as information requirements are not yet covered by the joint submission	The text <i>'as from the moment the registrant becomes aware of ... shall submit immediately...'</i> creates by definition an incompliant situation. You cannot immediately submit an inquiry. Some time is needed to compile the inquiry before submission. Making it a conditional requirement: an inquiry is not necessary for a member of a joint submission who wants to increase his individual tonnage band when the joint submission already covers that higher tonnage band. In such case the member contacts the lead company directly and pays his share for the additional data requirements.
Update in case a higher tonnage band is reached - submitting new data generated for an update to Annex VII or Annex VIII (art. 5§2 – 2 <sup>nd</sup> indent)	6 months after completion any additional study	6 months after receiving final test reports	6 months after receiving the final required test report	Update to Annex VII or VIII may require multiple additional testing. Dossier updates only to be submitted after <u>all required</u> testing is completed. Only once all required testing is completed one will have the full picture on classification and labelling, safe use conditions, etc. Intermediate updates are purely administrative.
Update in case a lower threshold is reached (art. 5§3)	3 months	1 month	No mandatory update	Updating a dossier when a lower threshold is reached, brings no added value. Existing dossier contains all info to assess safe use. Having a registration of a higher tonnage band in place - even if not strictly needed – allows industry to deal with fluctuating market demands without continuously having to update dossiers.
Update in case of cease manufacturing or import (art. 5§4)	3 months	1 month	3 months on the condition there are no legitimate reasons to assume manufacturing/import will resume	Manufacturing of many chemicals and import takes place in batches. Long interruptions between two manufacturing campaigns or imports can occur (sometimes even taking more than 1 year). Making it a conditional update secures cease of manufacturing/import is notified when it actual happens.
Update in case of new identified uses and new used advised against	3 months (in case no CSR or new use covered by existing CSR)	1 month 6 months if update CSR?	3 months (in case no CSR or new use covered by existing CSR)	In many cases new uses trigger an update of the CSR. Article is not clear on whether the general deadline of art. 1§2 would apply or not.

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(art. 6)	1 year in case new use triggers update CSR		1 year in case new use triggers update CSR	For the sake of legal clarity, the deadline is suggested to be aligned with the one set for updating the CSR (art. 1 (2) and art. 9 draft IR). 3 months versus 1 is suggested to allow proper discussions within the SIEF. E.g. agreeing on a use advised against can be very sensitive as it has market implications linking it to antitrust and legal issues. One month is far from sufficient to decide on all this. Note: having a deadline of 3/12 months does not preclude meeting the deadlines set by art. 37 (3).
Update in case of new knowledge (art. 7)	1 year	6 months	6 months (in case update SDS without update CSR) 1 year (in case update CSR)	Deadline to be aligned with deadlines set by art. 1(2) and art. 9. According to art. 22§1-e) an update is only needed if new knowledge on risks leads to changes of the SDS or CSR. For the sake of legal certainty conditions of art. 22§1-e) need to be included in the implementing regulation.
Update in case of change in classification and labelling (art. 8)	1 year	1 month	6 months (in case no update CSR) 1 year (in case update CSR)	Deadline to be aligned with deadlines set by art. 1(2), art. 7§3 and art. 9.
Updates or amendments of the chemical safety report (art. 9)	1 year	6 months	1 year	See justification given for deadline art. 1§2.

Reference draft Implementing Regulation on duty to update dossiers	Original proposed timeframe for submitting updates <sup>(a)</sup>	Current proposed timeframe for submitting updates <sup>(b)</sup>	Our proposed timeframe for submitting updates	Justification
Updates of dossiers by co-registrants in case of joint submissions (art. 12)	-	1 month	6 months	<p>Communication between lead registrants and co-registrants requires time. Documents need to be circulated and discussed, letters of access to be obtained etc. Processes can be optimised, but any minor hiccup in the communication will lead to an exceedance of the deadline of 1 month. On top consultants can be involved, particularly in case of SMEs. Activating consultants requires getting quotations, placing orders, ... which as such takes several weeks.</p> <p>Finally member registrants need to update their CSR in case no joint CSR is submitted. Alignment with the deadlines set in art. 1 (2) and art. 9 is warranted.</p>

## Suggestions to avoid new layers of uncertainty

Reference draft Implementing Regulation on duty to update dossiers	Current text	Our proposal	Justification
Tracking changes specified in art. 22(1) (art. 2)	... registrants shall have monitoring and tracking systems in place that enable them to identify if any of the cases ...	Delete art. 2	<p>In our view the proposed text is not related to clarifying the different elements of art. 22(1). It imposes a new, explicit obligation on registrants.</p> <p>What 'monitoring and tracking systems' should entail is open to interpretation, creating legal uncertainties.</p>
Update in case of new identified uses and new used advised against (art. 6)	... updates pertaining to new uses, <b>uses that are no longer relevant</b> , or uses advised against shall be made ...	Delete reference to no longer relevant uses	<p>'No longer relevant uses' are not mentioned in art. 22(1). No longer relevant uses are not defined in REACH. Concept is open to interpretation. Creates legal uncertainty.</p>