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REACH

Chemicals

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34th Meeting of Competent Authorities for REACH and CLP

31 March – 1 April 2020

Concerns: **Nanomaterials and REACH – An ECHA Update**

Agenda Point: **Point 9.2**

Action Requested: **Competent Authorities and observers are invited to comment on this document. Written comments should be sent by 8 May 2020 to:**

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This paper summarises the first quarter of implementation of the nanomaterial-specific amendments in REACH. It also outlines ECHA's ongoing activities related to development of further support to aid companies in their efforts to comply with the modified REACH Annexes in relation to nanomaterials.

ECHA Update - Introduction

The updated REACH information requirements for nanoforms of substances apply as of 1 January 2020[1]. Beyond this date, companies must have a registration compliant with these requirements to manufacture or import nanoforms of substances that fall within the scope of REACH.

ECHA's priority leading up to this date has focused on raising awareness among potential registrants and to support successful registration of nanoforms in line with the updated requirements. This was manifested by e.g. amending IUCLID to facilitate a transparent structure of information in the dossier submissions of the new information requirements. The amendment of the Annexes demanded development of additional fields for e.g. characterisation and justification of sets of nanoforms in IUCLID. The use of these changes was explained for potential registrants in a well attended webinar in November 2019.

It is evident that a successful implementation of the new information requirements continues to require a steep learning curve for both authorities as well as industry.

A. Current status of implementation since January 2020

Despite efforts undertaken last year, ECHA notes a lower than expected number of registration updates. Consequently, there is still a lack of the anticipated additional nanomaterial-specific information that the updates were supposed to provide. Noting that the situation is complex and the reasons for the lower numbers may be multiple, ECHA would like to raise the attention and awareness of the current situation.

By 1 January 2020, 86 unique submissions for 34 substances covering nanomaterials were received. A further 19 submissions[2] have been received so far in 2020 (i.e. by the deadline of the submission of this document), resulting in a total of 39 substances covering nanoforms that have been registered according to the updated REACH requirements. Of the received submissions, 45% failed the completeness check and were issued the standard four months deadline to rectify the incompleteness. The most frequent shortcoming detected at completeness check is the incomplete justification for registering separate nanoforms as sets of similar nanoforms. In addition, several joint submission member dossiers for which the Annex VI information requirements have been considered complete are still pending the submission of a complete lead dossier that would provide the Annex VII-X information requirements according to the amended requirements for nanoforms.

The number of substances with nanoforms on the EU market today is uncertain. Nevertheless, a number of estimates exists, including in the impact assessment accompanying the proposal for the amendment of the REACH regulation for nanomaterials (375 nanomaterials)[3], the 2nd Regulatory review on nanomaterials (ca. 200 nanomaterials)[4], and an estimate by CEFIC/RPA

[1] Get ready for new requirements for nanomaterials, *ECHA news release, 8 October 2019*

[2] Status on 12 March 2020

[3] COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Commission Regulation amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, X

[4] The figure of "ca. 200" nanomaterials is attributed to the 2nd Regulatory Review in the Staff Working Document on Impact Assessment. However, this specific number is not found within the Second Regulatory review itself Communication on the Second Regulatory Review on nanomaterials, COM(2012) 572 final or the Staff Working Paper on Types and Uses of Nanomaterials.

(500-2000 nanomaterials)[5]. ECHA's own estimates (ca. 300 nanomaterials) based on the information gathered by the European Union Observatory for Nanomaterials (EUON[6]) is within the range of these estimates. Regardless of the estimate used, and the uncertainties surrounding each estimate, it is clear that the number of registrations containing substances in the nanoform received to date is far below the estimates.

ECHA has offered bilateral discussions to registrants to provide advice in the updating process. Starting end of 2019 and up to now, 6 of such bilaterals took place and provided more insight into practical hurdles that registrants faced. For example, some of the registrants who were aware of their registration obligations indeed face difficulties in creating their submission jointly e.g. due to confidentiality issues linked to the specific aspects of their nanoforms. Some consortia have set up a 'trustee' system to alleviate such hurdles, however, this has also created some complications in terms of (slow) communication. It also seems that some registrants are currently still in the process of characterising their forms and are awaiting the outcome of the test laboratories. Such factors may have contributed to the low submission numbers received so far.

ECHA has observed a limited number in questions received via the Helpdesk (23 questions so far in 2020).

B. Further actions taken to support the implementation

Following the low submission rate and the high failure rate in the technical completeness check of incoming dossiers, ECHA organised a webinar on 24 February[7]. The webinar provided an opportunity to raise further awareness among industry and to support registrants in the process of preparing their submission. The webinar contained a presentation where ECHA addressed the most common shortcomings observed in the dossiers received so far, and a questions and answers session where participants could send questions to the ECHA experts.

The ECHA is in contact with Cefic and plan a joint workshop on 30 March to understand the current issues of their members and to propose specific advice where possible. In addition, it will help to probe further into the reasons behind the low number of received dossier updates. The workshop was originally thought to be organised as a face-to-face meeting but will now be held with remote access.

Currently, ECHA has no view on to what extent the lack of certain test methods is a hurdle in the registration process. For those endpoints in REACH Annex VII and VIII, where there is currently no internationally agreed test method available, ECHA has established a temporary approach for registrants to document in the registration dossier their efforts to comply with the information requirement and commitment to address the requirement once suitable test methods become available[8]. For Annex IX and X endpoints, we have foreseen to receive testing proposals for nanoforms. However, up to now, ECHA has not received any such proposals,

[5] Risk and Policy Analysts (RPA) Impact Assessment of the REACH Implementation Project on Substance ID for Nanomaterials. The full study report is not publically accessible, but the figure of 500-2000 is referenced in a number of publications on the topic nanomaterials, including the REACH impact assessment report.

[6] EU nanomaterials observatory (EUON) – search for nanomaterials

[7] Registering nanoforms: practical advice, *ECHA webinar 24 February 2020*

[8] https://echa.europa.eu/documents/10162/13567/Template+to+document+practical+constraints+for+fulfilling+REACH+Annex+VII+and+VIII+information+requirements_en.pdf/90aa45da-8db3-2f63-10c9-4094c1b2384d

even for those endpoints where such internationally agreed test methods are lacking. Whether this means that registrants are currently mainly focusing on their specific nanoform characterisation (for which ECHA has provided a new, dedicated guidance document) and not (yet) on the hazard information (for which an update of the guidance is to be developed) remains to be seen.

In addition we are planning several short-term actions to help improve compliance and to support industry in meeting their obligations. These include:

1. Revision of the mandate of the ECHA Nanomaterials Expert Group to allow for operational support in decision-making
    i. CARACAL consultation of revised mandate through written procedure Q2 2020
    ii. Virtual meeting Q2 2020
    iii. Physical meeting Q4 2020
2. Update of guidance for human health (indicative timeline)
    i. Stakeholder consultation (from Q2 2020 to Q1 2021)
    ii. Expected publication Q2 2021
3. Update of guidance for environment endpoints (indicative timeline)
    i. Stakeholder consultation 2021
    ii. Expected publication Q4 2021
4. Based on feedback and identified needs, ECHA will continue to update manuals and instructions for preparation of registration dossiers covering nanoforms to ensure best possible advice for registrants is provided.

C. Discussion points at CARACAL meeting

Given the low number of updates ECHA would like to discuss the following with Member States and stakeholders:

1. Did we overestimate the number of substances having nanoforms on the internal market? We invite Member States and Stakeholders to share their views on the potential reasons why:

a) The number of updates received so far is low;

b) The number of expected updates was maybe too high.

2. To what extent is the current situation a reflection of difficulties faced by registrants in meeting the new information requirements? What additional action would be needed to mitigate such challenges?

3. Or, is the current situation due to a lack of awareness by registrants? If so, what initiatives seem appropriate to further increase awareness, e.g. at national level?

ECHA looks forward to work closely with CAs and industry associations to understand the current situation and to further offer help where needed.