Case Note

The Case Notes section will identify and analyse important judgements of courts around the world that shape the interpretation and application of chemical law and regulation.

Dossier Updates During Dossier Evaluation: ECHA's New Approach

Case A-001-2018 BrüggemannChemical

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On 29 November 2019, ECHA published a short news release and amended versions of several Q&A entries as well as their *Practical guide: How to act in dossier evaluation*, describing its new approach regarding dossier updates during a dossier evaluation process. Although this seems to be a reaction to the Board of Appeal decision in the case A-001-2018 of 9 April 2019 (*BrüggemannChemical*), the published approach stands in clear contrast to the findings of the Board of Appeal in this case.

I. Introduction

Articles 40 to 43 of Regulation (EC) No. 1907/2006 (REACH) lay down criteria and rules for dossier evaluation processes.

Directly after the submission of a registration dossier by the registrant, ECHA examines each dossier in a so-called completeness check according to Article 20(2) REACH, in order to assess whether all information to be included in a registration dossier according to Articles 10 and 12 REACH are actually included. However, in the course of a completeness check, only the quantity of the provided information is subject to assessment, whereas it is not assessed whether or not the provided information is sufficient

and adequate with regard to quality of the content. The assessment of the quality of a registration dossier takes place during dossier evaluation, which can be performed as either examination of testing proposals included in the dossier or as compliance check.

Before conducting (vertebrate animal) studies listed in Annex IX and Annex X REACH, which are, as a rule, relevant for registrations in the tonnage bands over 100 t/y according to Article 12(1)(d) and (e) REACH, testing proposals have to be submitted in the registration dossier. The examination of testing proposals in dossiers by ECHA according to Article 40 REACH aims to prevent unnecessary vertebrate animal studies and leads either to the decision that the proposed tests have to be carried out as proposed or that the proposed tests have to be carried out with certain modifications or that additional or no test have to be carried out respectively.

The second form of dossier evaluation is the so-called compliance check according to Article 41 REACH, which for example may take place for registration dossiers for which the registrant(s) used the possibility to opt-out from certain data-sharing obligations according to Article 11(3) REACH or for registration dossiers of substances which are included in the Community Rolling Action Plan (CoRAP). The scope of assessment during a compliance check is much broader than during a completeness check prior to the acceptance of a registration dossier, since the quality of the provided information is under assessment and not only the mere provision of (any) information as such. In case ECHA finds a dossier not compliant with the relevant information requirements, the concerned registrant(s) are required to

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submit any information necessary to bring the registration dossier into compliance.

This article focusses on the possibility of a registrant to update its registration dossier during dossier evaluation. The first milestone in this context was the decision of the Board of Appeal of the European Chemicals Agency (Board of Appeal) of 1 August 2013 in case A-003-2012 (*THOR GmbH* - cf. paragraph II.). Following the Board of Appeal's decision, ECHA published a news alert and an update of Practical Guide 12 in which it intended to clarify its approach regarding the consideration of dossier updates during dossier evaluation procedures (cf. paragraph III.). However, the Board of Appeal found in its decision of 9 April 2019 in the case A-001-2018 (*Brüggemann-Chemical*) that ECHA failed to clarify in the necessary manner its approach regarding the consideration of dossier updates during dossier evaluation proceedings (cf. paragraph IV.). Again, following the new decision of the Board of Appeal, ECHA amended the applicable Practical Guide in November 2019, issued another news release on 26 November 2019 ECHA and updated corresponding Q&A entries on 29 November 2019, outlining its amended approach in this context (cf. paragraph V.). The question to be answered by this Case Note is, whether these updates made by ECHA are in line with the findings of the Board of Appeal in case A-001-2018 (cf. paragraph VI.).

II. Decision of the Board of Appeal of 1 August 2013 in Case A-003-2012 (*THOR GmbH*)¹

In this case, the Board of Appeal ruled for the first time on the possibility for ECHA to set a cut-off date for the consideration of dossier updates by a registrant in the course of a dossier evaluation procedure.

1. Summary of the Facts

On 21 October 2010, ECHA initiated a compliance check of the appellant's registration dossier and notified the draft decision to the appellant on 14 July 2011 with the information that comments on the draft decision would be possible within 30 days of receipt of the draft decision. The comments provided by the

appellant lead however not to an amendment of the draft decision and thus, on 2 September 2011, ECHA notified the Member State Competent Authorities (MSCAs) and on 17 October 2011 the Member State Committee (MSC) about the draft decision. The MSCA proposed for an amendment of the draft decision and on 5 October 2011, ECHA informed the appellant about this proposal and invited it to provide its respective comments. Following ECHA's invitation, the appellant submitted its comments on 4 November and updated its registration dossier on the same date. Finally, on 28 February 2012, ECHA adopted the decision and informed the appellant in the accompanying cover letter that the dossier update was not considered, since the decision-making process was at its final stages.²

The appeal against this decision was lodged by the appellant on 25 May 2012.

2. Findings of the Board of Appeal

Based on the fact that the REACH Regulation does not foresee a deadline for registration dossier updates during dossier evaluation proceedings, the Board of Appeal assessed, whether ECHA has clearly, precisely and in a timely manner communicated such a cut-off date to the appellant and/or to the public so that the appellant would have had the obligation to be informed about such a cut-off date. In a nutshell, this was negated by the Board of Appeal and thus the application of a cut-off date was considered to infringe the principle of legal certainty in this individual case.

However, it is notable that the Board of Appeal did not reject the possibility as such for ECHA to establish a cut-off date in published guidance documents, in general news publications and/or in individual letters to registrants. Such a cut-off date could be admissible if communicated clearly, precisely and in due time to the affected registrant(s) or more generally to the broader public.³

1 ECHA, 'Decision of the Board of Appeal of the European Chemicals Agency' (1 August 2013) <<https://echa.europa.eu/documents/10162/3ed8b4e6-0381-4746-8bfe-81127ca3eb02>> accessed 1 February 2020.

2 *ibid* paras 8 - 19.

3 *ibid* paras 97 - 99.

III. Tightening of Relevant Rules by ECHA in 2015

About one and a half years after the Board of Appeal Decision in Case A-003-2012 was published, ECHA published a news alert on 28 January 2015⁴ and updated the respective Practical Guide 12 in July 2015.

In the news alert, ECHA announced that dossier updates will not be taken into account ‘after the draft decision on a compliance check has been sent to the registrant for comments’, in order to shorten processing times for the evaluation procedure.

In the revised version of Practical Guide 12 however, ECHA communicated a different approach. According to the relevant paragraph, ECHA informed that it won’t ‘normally’ take into account dossier updates during the evaluation procedure, in case ‘no reference is made in the registrant’s comments’ on the draft decision. In other words, ECHA communicated the opportunity for registrants to mention in their comments that a dossier update has taken or will take place and that such a dossier update will be considered in the evaluation process. The wording ‘does not normally take into account’ dossier updates without reference in the registrant’s comments even indicates that there might be situations in which a dossier update would be taken into account even without any reference in the registrant’s comments on the draft decision.

IV. Decision of the Board of Appeal of 9 April 2019 in Case A-001-2018 (BrüggemannChemical)⁵

In this case, the Board of Appeal had to decide about another decision of ECHA in a compliance check pro-

cedure regarding the possibility for a registrant to update its registration dossier after receiving the draft decision.

1. Summary of the Facts

On 14 December 2015 the appellant received a draft decision by ECHA in an ongoing dossier compliance check procedure. The draft decision requested the appellant to perform certain vertebrate animal studies and include them into its registration dossier. The draft decision was accompanied by a cover letter, received by the appellant together with the draft decision on 14 December 2015, in which ECHA included another explanation of its approach regarding dossier updates during compliance check procedures. In this context, ECHA informed the registrant that it ‘*does not take into account any dossier updates after the notification of this draft decision*’⁶ [author’s emphasis] to the registrant.

Irrespective of the information in the cover letter that no dossier updates will be taken into account after the notification of the draft decision, the appellant included in its comments on the draft decision that a dossier update will be performed as soon as possible, since the version of the registration dossier on which the draft decision was based did not reflect the actual uses of the registered substance.⁷

On 8 June 2017, ECHA notified the MSCAs the draft decision for their comments. Since the MSCAs proposed amendments to the draft decision, the appellant received the opportunity to comment on the proposed amendments and once again emphasized on 14 August 2017 that certain uses included in the dossier are obsolete and thus will be removed in a dossier update.⁸ As announced, the appellant updated its dossier on 16 August 2017 by amending the descriptions of uses of the substance.⁹

However, on 10 November 2017, after unanimous decision of the MSC, ECHA adopted its decision which required the appellant to submit the same studies as already mentioned in the draft decision. The decision was once again accompanied by a cover letter in which ECHA stated that the ‘decision was adopted without considering any dossier update submitted after the draft decision was notified’¹⁰ to the appellant.

The appeal against this decision was lodged by the appellant on 12 February 2018.

4 ECHA, ‘e-News’ (28 January 2015) <https://echa.europa.eu/de/view-article/-/journal_content/title/echa-e-news-28-january-2015> accessed on 1 February 2020.

5 ECHA, ‘Decision of the Board of Appeal of the European Chemicals Agency’ (9 April 2019) <<https://echa.europa.eu/documents/10162/a78aee88-e3c7-c8c7-9a03-ae93a51fd917>> accessed 1 February 2020.

6 *ibid* para 51.

7 *ibid* para 9.

8 *ibid* paras 10 and 11.

9 *ibid* para 12.

10 *ibid* paras 14 and 15.

3. Findings of the Board of Appeal

The findings of the Board of Appeal can be divided in two lines of argumentation. In the first line, the Board of Appeal focused on the inconsistent and confusing communication of ECHA (cf. paragraph a)). In the second line, the Board of Appeal assessed whether a cut-off date at the point in time the draft decision is notified to the registrant can be admissible at all (cf. paragraph b)).

a. Inconsistent and confusing communication

First and foremost, the Board of Appeal came to the conclusion that the cut-off date ‘was expressed inconsistently and confusingly by the Agency in the news alert, in Practical Guide 12 [and] in the cover letter (...).’¹¹ The latest information available to the appellant before the notification of the draft decision to the appellant together with the cover letter, was Practical Guide 12 implicitly stating that dossier updates will be taken into account after the notification of the draft decision to the appellant in case reference is included in the comments on the draft decision. Therefore, the Board of Appeal stated that the appellant could rely on the taking into account of its dossier update as announced in its comments on the draft decision.¹² The information in the news alert, stating that a dossier update won’t be taken into account are older information and this not relevant for the registrant anymore. The information in the cover letter, as well stating that dossier updates won’t be taken into account after the notification of the draft decision, were notified to the registrant together with the expiry of the deadline and thus not in a timely manner.

b. Notification of the Draft Decision as Cut-off Date

Irrespective of these arguments with regard to the failure of ECHA to meet the fundamental requirements of legal certainty by failing once again to clearly, precisely and in a timely manner communicate the foreseen cut-off date to the appellant and/or the general public, the Board of Appeal assessed whether or not the cut-off date could be set at all at the point in time when the draft decision is notified to the registrant.

ECHA claimed that for reasons of simplification and acceleration of the underlying administrative

compliance check procedures, a cut-off date at the point in time when the draft decision is notified to the registrant must be legitimately possible. First of all, ECHA argued that a registrant has to keep its registration dossier constantly up-to-date according to Article 22(1) REACH, irrespective of ongoing dossier evaluation procedures.¹³ The introductory sentence of the cited Article 22(1) REACH states that ‘following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency’ and thus can be said to encompass a general update obligation at all times.

In addition, ECHA submitted that the substance at issue was included in the CoRAP according to Article 44(2) REACH in 2015, indicating that the substance as such, not the registration dossier, will be evaluated within the next three year. However, since Article 41(5) (c) REACH states that the listing of a substance in the CoRAP should be considered as a criterion for the selection of respective substance dossiers for a compliance check, ECHA argues that the appellant ‘should have been aware that a compliance check may follow and update its dossier before the draft decision was received.’¹⁴

Both arguments were completely rejected by the Board of Appeal, since it holds that the registrant cannot know the concrete date on which he will be notified with a draft decision excluding the further update of its registration dossier. ‘Even if the Appellant had clearly understood in advance that the cut-off point was the date it received the draft decision, it did not know when it would receive the draft decision. Therefore, it had no way of knowing in advance the date of the cut-off point.’¹⁵

First of all, the Board of Appeal emphasizes, by referring to its decisions in the cases A-001-2014 of 10 June 2015 (*CINIC Chemicals Europe*)¹⁶ and

11 *ibid* para 64.

12 *ibid* para 54.

13 *ibid* para 36.

14 *ibid* para 37.

15 *ibid* para 55.

16 ECHA, ‘Decision of the Board of Appeal of the European Chemicals Agency’ (10 June 2015) <<https://echa.europa.eu/documents/10162/1c4b9834-9057-4191-9998-5d8baa8267d4>> accessed 1 February 2020.

A-017-2014 of 7 October 2016 (*BASF SE*),¹⁷ that in general ECHA is obliged to take into account all information available and circumstances present at the time of the adoption of its final decision. However, the Board of Appeal acknowledged in these cases that for reasons of administrative efficiency the setting of a cut-off date at the point in time when the draft decision was notified to the MSCAs might be admissible in case at least substantial new information will be taken into account irrespective of a cut-off-date. In the light of these decisions, an absolute cut-off-date, as applied by ECHA in the case at hand is not admissible, since, as a minimum, substantial new information must be taken into account¹⁸

In a next step, the Board of Appeal hold that the fact that each registrant has to keep its registration dossier up-to-date all the time according to Article 22(1) REACH cannot justify an absolute cut-off date. Since a registrant might assume that its registration dossier is complete and up-to-date prior to the notification of a contrary draft decision regarding its dossier, there would be no reason for such a registrant to update its dossier. Only in the point in time when the registrant receives a draft decision in a dossier evaluation procedure, it might become aware of the missing of certain information in its registration dossier leading to the understanding of the registrant that an update of the dossier is necessary. This line of argumentation is supported by fact that the final decision taken by ECHA, the MSCAs and MSC in a dossier evaluation procedure is not completely determined by the REACH Regulation but leaves aspects of discretion. Therefore, the registrant itself can in no point in time definitely determine whether or not ECHA will require a dossier update and thus, the mere statutory update obligation according to Article 22(1) REACH cannot justify an absolute cut-off date.¹⁹

Finally, the Board of Appeal also rejected ECHA's argument that at least the inclusion of the substance in the CoRAP should have sufficiently informed the appellant that its registration dossier will become subject to a compliance check and thus make him to update its dossier.²⁰ Since the inclusion of a substance in the CoRAP does not automatically lead to a compliance check of all registration dossiers for these substances and since, based on the aforementioned string of argumentation, the compliance of a registration dossier cannot be determined by the registrant with absolute certainty, the inclusion of a substance in the CoRAP cannot justify an absolute cut-off date at the point in time the registrant receives a draft decision in a dossier evaluation procedure.

As a result, the appeal has been upheld in its entirety because of several breaches of the principle of legal certainty.²¹

V. ECHA's New Approach

As a reaction to the decision of the Board of Appeal ECHA published another news release on 26 November 2019,²² with the following heading and introductory statement:

'ECHA does not consider dossier updates during evaluation decision making

Once ECHA has sent a draft decision to registrants, it does not consider dossier updates during evaluation decision making. Registrants need to keep their registration dossiers up to date at all times.'

ECHA argues that each registrant is on its own responsible for the submitted registration dossier and has to keep it up-to-date at all time. Since the dossier has to be up-to-date, ECHA states that the dossier has to comply with the information requirements set out in Articles 10 et seq. REACH at the time the dossier evaluation procedure is opened and that 'the initiation of a compliance check should not be a trigger for updating your dossier.'

Against this background, ECHA concludes the following regarding the point in time and possible mechanisms to provide information during the dossier evaluation procedure.

'If new information becomes available after that, registrants must submit this through their comments to the draft decision. The Agency will consider the information in the comments and may amend the decision accordingly.

17 ECHA, 'Decision of the Board of Appeal of the European Chemicals Agency' (7 October 2016) <<https://echa.europa.eu/documents/10162/659d9855-0ff3-33ca-6675-859516e69ec4>> accessed 1 February 2020.

18 *ibid* para 73.

19 *ibid* para 76 and 77.

20 *ibid* para 78.

21 *ibid* para 82.

22 ECHA, 'ECHA does not consider dossier updates during evaluation decision making' (26 November 2019) ECHA/NR/19/42 <<https://echa.europa.eu/de/-/echa-does-not-consider-dossier-updates-during-evaluation-decision-making>> accessed 1 February 2019.

Furthermore, ECHA does not take new information on tonnage, uses and exposure into account after it has sent the draft decision to registrants for comments.’

In the corresponding Q&A entry 1577, modified on 29 November 2019 – ‘Until when can I update my dossier so that the update is considered in the dossier evaluation process?’²³ – ECHA clarified that the start of a dossier evaluation process can be monitored at the Dossier evaluation status page on its website.²⁴ Hence, ECHA claims that each registrant has ‘the opportunity to verify and (if necessary) update [its] dossier especially regarding use and tonnage information before a draft decision is issued.’ In addition, ECHA gives a clear statement that the downgrade of the registered tonnage band or the removal of certain uses after the notification of the draft decision, either in the form of a dossier update or in the comments on the draft decision, won’t be taken into account in the decision-making process at all.

The same approach is outlined in the revised ECHA Practical Guide ‘How to act in dossier evaluation’ of November 2019.²⁵ Only in this Practical Guide the possibility for the registrant to be contacted by ECHA – ‘ECHA may contact you’ – giving the opportunity for dossier update during the assessment prior to the notification of the (draft) decision is mentioned; however, only with regard to ‘a (draft) decision targeting substance identity.’

VI. ECHA’s New Approach in the Light of the Board of Appeal Case Law

In a nutshell, the new approach by ECHA regarding the treatment of dossier updates during a dossier evaluation procedure can be considered as a frontal attack on the jurisprudence and authority of the Board of Appeal.

The Board of Appeal clearly stated that an absolute cut-off date at the point in time the draft decision is sent to the registrant is not legally permissible, since this is the first point in time a registrant might learn that its dossier is considered not to be compliant. According to the decision of the Board of Appeal, it is irrelevant whether or not the registrant had or has the possibility to foresee that its dossier is or will be selected for evaluation. Therefore, the remark by ECHA that each registrant may find out on the Dossier evaluation status page whether or not its

dossier is currently subject to evaluation, cannot justify the cut-off-date. In addition, the information provided on the Dossier evaluation status page does not enable the registrant to clearly foresee when the draft decision will be issued. On the Dossier evaluation status page, the first status to be displayed is the status ‘under assessment’ which means that ‘the evaluation of the dossier has formally started’. The next status on the timeline is the status ‘ongoing’ which means that ‘the registrants have received the draft decision’. Since neither the REACH-Regulation nor applicable guidance documents and the Dossier evaluation status page as such lay down a (mandatory) timeframe between the formal start of the evaluation procedure by ECHA and the notification of the draft decision to the registrant, the registrant has no legal certainty about the time span available for performing a dossier update. This is in clear contradiction to the ruling of the Board of Appeal and its corresponding argumentation regarding the inclusion of a substance in the CoRAP. The Board of Appeal clearly set the requirement that a registrant has to be aware of the concrete date of the cut-off point which is not at all ensured by ECHA’s new approach.

In case ECHA intended to comply with the rulings of the Board of Appeal in cases A-001-2014 and A-017-2014 by allowing certain new information to be provided in the comments on the draft decision but completely excluding updates of the tonnages, uses and exposure scenarios from the update opportunity, this cannot be successful. The Board of Appeal clearly stated that substantial new information has to be taken into account in all stages of a dossier evaluation process. Although the term ‘substantial new information’ is neither defined in the REACH-Regulation nor in the cited Board of Appeal decisions,

23 ECHA, ‘Q & As – REACH Evaluation’ <https://echa.europa.eu/de/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Evaluation?_journalqadisdisplay_WAR_journalqaportlet_INSTANCE_70Qx_backURL=https%3A%2F%2Fecha.europa.eu%2Fde%2Fsupport%2Fqas-support%2Fbrowse%3Fp_id%3Djournalqadisdisplay_WAR_journalqaportlet_INSTANCE_70Qx%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_pos%3D2%26p_p_col_count%3D3> accessed 1 February 2020.

24 See ECHA, ‘Status der Dossierbewertung’ (11 February 2020) <<https://echa.europa.eu/de/information-on-chemicals/dossier-evaluation-status>> accessed 11 February 2020.

25 ECHA, ‘How to Act in Dossier Evaluation’ (November 2019) <https://echa.europa.eu/documents/10162/13643/pg_dossier_evaluation_en.pdf/5788b5ee-f6c0-df56-c7ea-c693740acf87> accessed 1 February 2020.

tonnages, uses and exposure scenarios are crucial for the applicable information requirements and thus for compliance of the registration dossier with Articles 10 et seq REACH.

Finally, the possibility for the registrant to be contacted by ECHA prior to the notification of a draft decision (regarding substance identity) is not suitable to eradicate the deficit in clearly inform the registrant about a upcoming draft decision in a dossier evaluation procedure, since ECHA did not oblige itself to contact all concerned registrants prior to the notification of a draft decision and thus a major uncertainty remains. In addition, ECHA itself explicitly limited the scope of such a pre-information to cases about substance identity, which is only a minor aspect in case of dossier evaluation procedures.

VII. Conclusion

The Board of Appeal clearly predefined the conditions for ECHA to be eligible to set a cut-off-date for taking into account dossier updates during dossier evaluation procedures, although such a cut-of-date is not established in the REACH-Regulation. As a first

requirement, the cut-off-date has to be communicated to the registrant and/or the general public respectively, in a clear, precise and timely manner. Secondly, an absolute cut-off-date in such a way that no new information will be considered at all when a certain stage of the dossier evaluation procedure has been reached, is inadmissible without exemption, since substantial new information has to be taken into account at all stages.

The new approach by ECHA neither communicates clearly and precisely the concrete cut-off-date to the registrant nor does accepts to consider substantial new information at all stages of the decision making process, since crucial information as tonnages, uses and exposure scenarios are excluded from being taken into account from the point in time the draft decision has been notified to the registrant.

In the light of ECHA's refusal to comply with the case-law of the Board of Appeal, the story of Board of Appeal decisions concerning cut-off-dates for dossier updates seems not to be told yet. Without going too far out on a limb, it can be predicted that it is more than probable that the Board of Appeal won't accept ECHA's new approach in a potential upcoming action brought by a registrant.