WB/ADB

Helsinki, 20. 03. 2017 D(2017)0884

Ms Emily O'Reilly
European Ombudsman
1, Avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex
France
e-mail: eo@ombudsman.europa.eu

Subject: Case 811/2016/MDC: Response to the European Ombudsman's request for further information regarding implementation of Decision 1606/2013/AN on how the European Chemicals Agency applies rules concerning animal testing

Reference: Letter dated 20/01/2017, further clarified by your letter of 20/02/2017.

Dear Ms O'Reilly,

I refer to your letters of 20 January 2017 and of 20 February 2017 seeking clarification on the implementation of one of the proposals made by you in the course of an earlier inquiry - case 1606/2013/AN.

Your clarification in your letter of 20 February 2017 was helpful as it was not apparent to us that ECEAE had made a request for a review of your decision in Case 811/2016/MDC and we were not aware of their grounds for review set out in their letter dated 21 September 2016. Furthermore, it was unclear to us that the ECEAE could rely on the new implementing provisions to request for such review given that these provisions only entered into operation on 1 September 2016 (a few months after the decision closing Case 811/2016/MDC). Indeed, Article 14 of the provisions provide that they apply "*to all inquiries opened on that date and any complaints concerning which the Ombudsman has, on that date, not yet taken a position*".

In your letter of 20 January 2017 you have asked me to reply to two questions, please find my response below, followed by a summary of the benefits of the approach currently applied by ECHA:

1. Answer to your first question

   If, after using the knowledge already in its possession, if any, and the information provided by the registrant, ECHA concludes that the registrant has not given adequate consideration to the availability of alternative methods, would ECHA reject the testing proposal?

First, it is good to bear in mind that companies are not making testing proposals on their own volition but because the REACH Regulation requires them to provide a standard set of data (hereafter "information requirements", listed in the REACH Annexes).

As already explained in our letter of 11 March 2016, ECHA cannot reject a testing proposal for a standard REACH information requirement on the ground that the registrant has not considered alternative methods. Were ECHA to be able to reject a testing proposal for lack of consideration of alternatives it would result in the registration dossier having a data gap

for a compulsory standard information requirement/ end-point listed in annexes IX and/ or X of the REACH Regulation. The registration dossier would therefore be incompliant with the REACH information requirements. Such a situation would be unacceptable given that the main aim of the REACH Regulation is to ensure a high level of protection of human health and the environment.

The rejection of a testing proposal (in accordance with Article 40(3) (d) of REACH) is legally only possible in the event that ECHA has end-point compliant data at its disposal clearly showing that the test is not needed for the end-point concerned. ECHA can also reject a testing proposal in accordance with Article 40(3)(c) of REACH and impose a different test to the one proposed in case the latter will not generate relevant information.

As you are aware, the European Commission services have confirmed to us that the rejection of the testing proposal is not the means to achieve the aim of correcting potential non-compliance of the registration due to insufficient justification of the consideration of alternatives. Indeed, according to the Commission in those cases where ECHA considers that it does not have sufficient evidence at its disposal to conclude that it is possible to avoid animal testing, ECHA should require the animal test to be performed, modified or supplemented with additional tests, if necessary. (See letter of 8 March 2016 from the European Commission to ECHA annexed to ECEA's complaint of 25 May 2016).

However, the European Commission confirmed that we can require registrants to provide their consideration of alternatives in their testing proposals in their registration dossiers and that the presence of these considerations can be assessed at completeness check.

1.1. Requirement to submit considerations in the registration dossier

As explained in our follow-up letter of 11 March 2016, since your Decision of 11 September 2015, all new testing proposals concerning vertebrate animal tests submitted by registrants must contain their considerations of alternative methods. Initially, until June 2016, all registrants that have submitted such testing proposals were contacted by letter and requested to demonstrate their considerations of alternatives by completing a template. In most cases registrants did fill in the form in a meaningful way.

As of June 2016, the presence of the consideration of alternatives forms part of the completeness check process of registration dossiers and this verification is performed manually.

Pursuant to Article 20 of the REACH Regulation ECHA shall undertake a completeness check of each registration dossier in order to ascertain that all elements required under Articles 10 and 12 and the registration fee have been provided. The same procedure applies to any registration update in accordance with Article 22 of the REACH Regulation (e.g. due to the tonnage upgrade).

Under this process, ECHA checks if the required information in a registration dossier is present. If the required information is missing in the registration dossier or registration update then it will not pass the completeness check (first failure) and the registrant will be provided one more chance to regularise his dossier within the set deadline. If the subsequent updated submission does not contain the required information within the deadline given, it will again fail the completeness check (second failure) resulting in the rejection of the registration dossier/ registration dossier update.

Rejection of the registration dossier means that the registrant may not place the substance on the EU market. Rejection of a registration dossier update means that a registrant cannot

place the substance at a higher tonnage band at which he has registered the substance. In both cases (rejection of registration and rejection of registration update), the registrant may not perform the proposed test as no decision has been taken on the testing proposal.

The June 2017 update of the IT tool used for the preparation of registration dossiers (IUCLID 6) contains a template requiring registrants to provide considerations on alternatives for their testing proposals. This means that when a registrant submits a registration dossier or updates his registration dossier with a testing proposal on vertebrate animals he is required to include his considerations for each alternative listed in this template. If no consideration for each alternative is provided, the registration or registration update will not pass the completeness check. This can ultimately lead to the rejection of the registration dossier/ registration dossier update.

One of the ECEAE's main concerns is apparently that under the technical completeness check the adequacy of the considerations is not assessed and that in principle *"[a] registrant could include a telephone directory in the section marked 'consideration of alternatives' and still pass the completeness stage"*.

However, the latter cannot happen and is merely a hypothetical scenario. Indeed, ECHA manually checks if the registrant has provided its considerations for each potential alternative listed in the template provided. If the registrant provides nonsense or no information this will be caught by the manual verification and the registration will be considered incomplete.

It should be noted that this process has been effective. In fact in the past 8 months 33 out of 168 dossiers had failed the initial submission, due to no or incomplete consideration of alternatives provided. Attached are examples on how registrants give this information.[1]

1.2. Assessment of considerations of alternatives

As already pointed out in previous communications, obtaining information on alternative methods is a scientifically complex exercise.

As agreed by you *"it is not ECHA's role to put forward adaptation arguments on behalf of the registrants to identify, in every case, the most appropriate alternative testing methods. This is neither feasible in terms of the available resources and the deadlines under the REACH Regulation, nor respectful of the regulation's intentions to free public authorities from the excessive burden they bore in the past."*[2] Indeed, as was indicated by you in paragraph 17 of the friendly solution proposal *"ECHA does not have to, and should not, take the place of the registrant in assessing what information is needed to demonstrate the safety of substances and how such information can be best obtained."*

To facilitate a registrant's in fulfilment of their obligation to consider alternatives ECHA has provided a number of tools for registrants to do this for their specific cases. In particular, QSAR toolbox allows registrants to find analogues and existing categories of substances. Guidance is also provided on how to build and assess read-across cases[3], which are in fact the most frequently used adaptations made by registrants. ECHA has already provided Guidance to registrants on the searching of information.

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[1] Annex 1 and 2 to the current submission.
[2] Paragraph 23 of your letter of 8/10/2014 of friendly solution
[3] ECHA is constantly developing its support for registrants by providing more concrete advice on using alternative methods to fulfil the information requirements. It has recently published the principles of the Read-Across Assessment Framework (RAAF) for UVCB substances, in addition to the previously published RAAF for monoconstituent substances.

https://echa.europa.eu/documents/10162/13643/information_requirements_r3_en.pdf/41895234-1125-4977-b058-50a98e36fa48

ECHA is also aware that scientific reviews of alternatives conclude there are no "test methods" (e.g. in vitro) that can currently replace higher tier studies (i.e. the ones which are subject to the testing proposal process).[4] ECHA will be conducting its own review on the topic this year.

Thus, there are in reality only two realistic alternative methods to address higher tier information requirements, i.e., by providing a valid read-across argument meeting the conditions set out in Annex XI section 1.5 of the REACH Regulation or by providing a weight of evidence argument in accordance with Annex XI section 1.2 of the REACH Regulation.

In fact, registrants often waive the testing requirements under Annexes IX and X by applying these adaptations. This is confirmed by ECHA's reports under Article 117(3) of the REACH Regulation on the status of implementation and use of non-animal testing methods and testing strategies published in 2011 and 2014[5].

However, it would be difficult for ECHA to verify whether such adaptations could apply in cases where a registrant claims in his testing proposal that no such adaptations are available unless there is publicly available information that addresses this. Information on assessments done in the EU and other jurisdictions are also available from public sources such as the OECD eChemportal which ECHA has financed.

During the evaluation of testing proposals ECHA checks the consideration of alternatives made by the registrant, third party comments submitted during the consultation of the testing proposal and the results of public information (e.g. international reviews or from other regulatory assessments) on the substance. ECHA also checks if it has any other ongoing activities on the substance which could provide additional considerations. This may lead to the conclusion that testing is not needed. In such cases, the proposed testing can be avoided either by an update of the dossier with the valid alternative or by rejection of the testing proposal.

1.3. Regulatory outcomes in the testing proposal process resulting from considerations of alternatives

- Acceptance of the testing proposal

ECHA has so far not seen an example where the considerations of alternatives have been inadequate. As explained above, this is probably because the possibilities for adapting higher tier information requirements are relatively limited.

ECHA would accept a testing proposal if there is no information at ECHA's disposal sufficient to address the information requirement.

- Termination of the decision making process

[4] JRC report: Alternative methods for regulatory toxicology – a state of the art review. Worth et al. (European Union, 2014).
[5] Published at ECHA's website at, respectively: https://www.echa.europa.eu/documents/10162/13639/alternatives_test_animals_2011_en.pdf/9b0f7e93-4d61-401d-ba2c-80b3b9faaf66 ; and https://www.echa.europa.eu/documents/10162/13639/alternatives_test_animals_2014_en.pdf/587d000c-688e-4cdd-9f59-f7d7aacc677b . The third report under Article 117(3) is planned to be published by June 2017.

When it happens that ECHA on its own or via third party comments becomes aware of the availability of an adaptation possibility (e.g. obvious case of read-across or non-EU guideline study on the substance and endpoint in question) it passes such information to the registrant for its own consideration and further action. To use these adaptation possibilities the registrant must acquire legitimate access to the data in question. If this is done then the registrant provides the data in its registration dossier and can remove the testing proposal – as he has no longer a need to generate new data.

In such cases, the testing proposal process is therefore terminated. It also happens, as indicated to you in our follow-up letter of 11 March 2016, that registrants considered that they have actually alternative data available and provided a weight of evidence data, or that the test is already being performed for the purposes of other regulatory regimes. Consequently, ECHA did not need to take a decision on the testing proposal and the process was terminated.

Termination of the testing proposal process before a decision requesting studies is adopted happens for about a quarter of testing proposals, most of which concern vertebrate animal testing.[6]

- Rejection of the testing proposal

As explained above and indicated in our letter of 11 March 2016 ECHA will reject a testing proposal in the event it has endpoint compliant data at its disposal clearly showing that the test is not needed for the endpoint concerned. This has already been done for some cases, for example, if the substance already is classified for the hazard endpoint in question, or if ECHA already holds or has access to the information concerned (such as data already available in another registration dossier for the same substance held by ECHA).

- Acceptance of a read-across testing proposal

ECHA has accepted on numerous occasions the proposal of a registrant to carry out the test on an analogue substance and to fulfil the relevant endpoint of the registered substance by a read-across adaptation. It has been done on a one-to-one read-across basis, as well as for the whole category of substances, where instead of e.g. 27 tests, one per endpoint on each of the registered substances, testing of only 5 substances was required.

1.4. Conclusion

As described above, ECHA currently has processes in place that allow consideration of alternatives or actual needs for testing. The efficiency of these processes is demonstrated by the numbers provided above (e.g. 33 failed TCC, 25% of Testing proposal cases are terminated, several testing proposals are rejected, many read-across adaptations accepted in TPs).

On the contrary, there is no evidence, and particularly none provided by ECEAE, that since the entry into operation of the REACH Regulation unnecessary testing would have been required. Especially, there is no evidence that the animal tests imposed for relevant endpoints of specific registered substances, as a result of an ECHA testing proposal decision, led to any unnecessary testing i.e. that there were, in those circumstances, other acceptable alternatives to animal testing which have not been duly considered.

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[6] ECHA Report on the Operation of REACH and CLP 2016, page 60; https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf/4c958d7a-3158-447b-9e81-d8bae9a7e7f9

In fact, the ECEAE is under the mistaken impression that registrants always want to test animals rather than apply alternative methods to fulfil REACH obligations. However, the reality is that ECHA has received much less testing proposals than expected because in many cases registrants have considered, rightly or wrongly, that they can address the higher tier REACH information requirements with an adaptation argument.[7] This is obviously also financially more interesting to companies as testing is costly. The validity of such adaptation argument is assessed by ECHA under the compliance check process under Article 41 of the REACH Regulation.

Nevertheless, in cases where ECHA considers that it does not have necessary information for the hazard end-point, including convincing information on alternatives at its disposal, it will require the animal test to be performed. This will ensure that both the main aim of the REACH legislation, which is to ensure a high level of protection of human health and the environment as well as the objective to avoid unnecessary animal testing are fulfilled.

2. Answer to your second question

Does ECHA take into account third party comments when using the knowledge in its possession to conclude whether the registrant has given adequate consideration to the availability of alternative methods?

Yes, it does.

ECHA publishes every testing proposal that involves vertebrate animals and the registrant's considerations on alternatives. This enables third parties to assess and provide comments on these considerations on alternatives during the public consultation on a testing proposal. The considerations as well as the third party comments are assessed by ECHA, recorded, and taken into account in the evaluation. They are presented, together with ECHA's assessment in the draft decision on the testing proposal for the registrant's considerations and comments.

In 2016, third party consultations were launched for 54 substances. ECEAE has not responded to any of them. As a response to these consultations, ECHA received only one single third party comment.[8] This may be explained by the fact that third parties are now aware of the considerations made by registrants on the potential alternatives and they therefore no longer consider it necessary to comment on the testing proposal.

3. Benefits of the approach

The newly reinforced obligation for registrants to provide their considerations on alternatives in all testing proposals serves the purpose of raising awareness of alternative methods with registrants where that is needed. It also successfully requires registrants to demonstrate how they have fulfilled obligations to consider alternative methods, as any dossier submission will not pass the completeness check without it.

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[7] See in particular ECHA's Second report under Article 117(3) of the REACH Regulation, p.32-33, https://www.echa.europa.eu/documents/10162/13639/alternatives_test_animals_2014_en.pdf/587d000c-688e-4cdd-9f59-f7d7aacc677b

[8] ECHA, Evaluation under REACH – Progress Report 2016, page 21, https://www.echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8

This obligation to provide considerations on alternatives has also improved transparency as it allows third parties to better understand why a registrant considers that no alternatives are available for the testing he has proposed. Although it is difficult to measure, it may be that knowledge on alternatives already considered by the registrant has led to a much lower number of third party comments provided than in any of the previous years.

Finally, it also improves ECHA's understanding of registrants' considerations, facilitates the assessment of testing proposal and any further assistance or regulatory outcome – as presented in sections 1.2. and 1.3. above.

I trust that this information has clarified to you ECHA's position on the matter and the efforts ECHA has undertaken to implement your Decision. Please do not hesitate to contact me should you have any further questions.

Yours sincerely,

Geert Dancet
Executive Director

Enclosures: Annex I – Examples of failed justifications concerning considerations of alternatives during TCC.

Annex II – Examples of corrected justifications concerning considerations of alternatives during TCC.

Copy: Ms Katy Taylor, ECEAE, katy.taylor@crueltyfreeinternational.org