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Subject: Follow-up to the European Ombudsman Decision 1606/2013/AN on how the European Chemicals Agency applies rules concerning animal testing

Reference: Decision dated 11 September 2015 (Complaint 1606/2013/(FOR)AN))

Dear Ms O'Reilly,

I refer to your decision published on your website on 11 September 2015 closing Case 1606/2013 with the following conclusion:

> *ECHA has accepted the Ombudsman's proposals for a solution. However, in order to implement the first proposal, further measures may need to be adopted and the Ombudsman trusts that ECHA will take all the necessary steps to do so. The Ombudsman therefore invites ECHA to inform her, within six months of the date of this decision, of its position on the matter in order to enable her to review the progress made.*

I would now like to inform you of the measures taken by ECHA in order to implement the first proposal (section 1 below). Sections 2 and 3 below describe the kind of information ECHA has received as a result of the steps already taken by ECHA and the benefits of this approach. Section 4 describes the efforts we have undertaken to inform ECHA's relevant stakeholders on this issue.

1. Considerations on alternatives as part of the testing proposal examination

    1.1. Requirement to submit considerations

Since your decision of 11 September 2015, all new testing proposals concerning vertebrate animal tests submitted by registrants are subject to a new procedure requesting registrants to provide their considerations of alternative methods.

To begin implementing this a manual procedure was developed. In brief, all affected registrants are contacted by letter and requested to complete a template in a concise manner. This template lays out the possible alternative methods according to Article 13(1) of the REACH Regulation. Registrants are not limited in the amount of information they can provide. The request also extends to the specific adaptation possibilities as defined in Annexes VII to X (column 2) of the REACH Regulation as these too may mean animal testing is not necessary. For your information, I have included in Annex 1 a copy of the template letter we have been sending to registrants that have submitted testing proposals.

The registrant's considerations are published "as is", together with the vertebrate testing proposal information, on ECHA's testing proposal third party consultation webpage available to the public. Third parties therefore have the opportunity to provide their comments on these considerations.

Although already in place as of 11 September 2015, ECHA publicly communicated this new procedure in a Press Release ECHA/PR/15/13 (2 November 2015) and in its e-News (4 November 2015) (see http://echa.europa.eu/view-article/-/journal_content/title/echa-asks-registrants-to-show-how-they-considered-alternative-methods-before-consulting-on-testing-proposals). This information was also reported in other media and websites.

Please note that ECHA is now undertaking work to introduce the template requesting for considerations on alternatives into the standard registration dossier format IUCLID 6 (a planned update of an IT tool used for the preparation of registration dossiers). This means that when a registrant submits a registration dossier or updates his registration dossier with a testing proposal on vertebrate animals he will be required to include his considerations on alternatives in the actual registration dossier. If no consideration on alternatives is provided the registration or registration update will not pass the completeness check and the registrant will be provided one more chance to regularise his dossier. Failure to include considerations on alternatives will result in the rejection of the registration dossier/ registration dossier update.

The launch of IUCLID 6 is planned for spring 2016. ECHA further intends to hold specific communication activities highlighting the change and providing advice to registrants.

1.2. Assessment of considerations

The considerations as well as the third party comments are assessed, recorded, and taken into account in the evaluation. A section addressing ECHA's assessment of the considerations of alternatives has been developed in our draft testing proposal decision templates.

ECHA will reject a testing proposal in the event it has end-point compliant data at its disposal clearly showing that the test is not needed for the end-point concerned. Indeed, ECHA has already in the past rejected a testing proposal for vertebrate testing on that basis. This can be the case 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. For example, end-point compliant data may already be available in another registration dossier for the same substance held by ECHA.

However, where ECHA considers that it does not have sufficient information on alternatives at its disposal to conclude that it is possible to avoid animal testing 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 animal testing are not disregarded.

2. Analysis of testing proposals received since 11 September 2015

Since 11 September 2015, ECHA has received vertebrate testing proposals for 12 registrations dossiers. The testing proposals all concerned studies investigating human health endpoints.

ECHA therefore sent to each registrant a letter inviting for its considerations on vertebrate testing. 11 out of the 12 registrants which made testing proposals provided their considerations on alternatives within the deadline set in ECHA's letter. These considerations have been published on ECHA's testing proposal third party consultation webpage (see http://echa.europa.eu/information-on-chemicals/testing-proposals/current). Third parties can therefore comment on both the testing proposal and the considerations on alternatives.

In response to ECHA's letter, one registrant informed ECHA that it decided to withdraw his testing proposal and replaced it with a weight of evidence adaptation. ECHA therefore closed the testing proposal process for that substance.

In another case, ECHA did not receive a reply within the deadline set. In this case, it appeared that the Registrant claimed that the testing was already underway to meet Chinese registration obligations. It is ECHA's standard practice to terminate testing proposal procedures for which the proposed test is already on-going. Thus, in this case ECHA terminated the testing proposal procedure and informed the Member State authorities of this situation. The Member State authority in which the company is based can then determine whether the registrant has breached relevant REACH and national requirements to avoid animal testing. In particular, the Member State authority should consider whether there has been a breach of national legislation implementing Directive 2010/63 on the protection of animals used for scientific purposes and whether there has been a breach of the REACH requirement to submit a testing proposal prior to testing.

With respect to the cases for which ECHA has received considerations on alternatives, ECHA is currently in the process of evaluating these considerations. However, the quality of the considerations vary from being very detailed in nature to brief statements stating that there is no alternative available. We are therefore, planning to develop further advice and guidance to raise the quality of the considerations submitted. Furthermore, ECHA's Management Board Advisory Group on dissemination will be examining whether further measures are needed to make ECHA's third party consultation on testing proposals more meaningful.

3. Benefits of the approach

The invitation to registrants to provide their considerations on alternatives has 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. Furthermore, this invitation may push registrants to further consider whether testing is really needed.

The request for considerations therefore serves the purpose of raising awareness of alternative methods with registrants where that is needed. It also allows registrants to demonstrate how they have fulfilled obligations to consider alternative methods and hence improve transparency.

In the future, as new alternative methods are developed and are adequate for REACH purposes, the request for considerations may serve as a reminder that Registrants should keep their knowledge up to date.

This approach goes hand in hand with ECHA's REACH 2018 Roadmap (see http://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf) published on 14 January 2015. The roadmap recognises that for the 2018 REACH registration deadline (i.e., for substances manufactured and imported in quantities below 100 tonnes) there is a need for support to registrants on how and when to use suitable alternative approaches. The roadmap further explains that ECHA "*will include more concrete*

advice on using alternative methods to fulfil the information requirements in the updated guidance documents as well as on the dedicated ECHA web section on the new test guidelines. ECHA will support the registrants also by publishing the principles of the Read-Across Assessment Framework (RAAF) which may be useful to understand what to aim for in a good robust read across justification".

4. Informing the European Commission, the Member States and other stakeholders

At the 18th meeting for of Competent Authorities for REACH and CLP (CARACAL) held on 12 and 13 November 2015 ECHA presented to the European Commission, Member State Competent authorities and stakeholders a paper describing the steps taken and to be taken by ECHA to implement the Ombudsman conclusion in Case 1606/2013. ECHA requested participants for provide feedback and advice.

In response, the European Commission services confirmed to us that these measures can be implemented without amending the REACH legislation.

We intend to report shortly to the CARACAL on the progress made on the further implementation of the proposal for a friendly solution.

We have also had a meeting on 7 March 2016 with representatives of the European Coalition to End all Animal Experiments (ECEAE – the complainant in Case 1606/2013). At this meeting, we had a constructive and meaningful discussion on ECHA's role and activities related to evaluation processes in view of avoiding unnecessary animal testing and the promotion of alternative methods on animal testing. We also briefly explained how we were currently implementing the proposal for a friendly solution and encouraged the ECEAE to provide systematically during the third party consultations on testing proposals their comments on the considerations of alternatives submitted by registrants in their testing proposals.

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

Yours sincerely,

Geert Dancet

Executive Director

Enclosures

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

CONSIDERATIONS OF ALTERNATIVE METHODS ON TESTING PROPOSALS IN YOUR REGISTRATION

Please complete this form and provide information for each of the points below.

If you have more than one testing proposal, please copy and paste the three bullet points within the same document and complete the details as appropriate for each testing proposal.

This document will be published on ECHA website along with the third party consultation on the testing proposal(s).

Public substance name: e_ss_public_name
EC Number (omit if confidential): e_ss_dossier_ec_no
CAS Number (omit if confidential): e_ss_dossier_cas_no

Date of considerations: Click here to enter a date.

- **Hazard endpoint for which vertebrate testing was proposed:**

  Click here to select a testing proposal endpoint **with the [registered/analogue] substance [name of analogue substance if public];**

- **Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information** (instruction: please address all points below):
  - available GLP studies
  - available non-GLP studies
  - historical human data
  - (Q)SAR
  - *in vitro* methods
  - weight of evidence
  - grouping and read-across
  - substance-tailored exposure driven testing [if applicable]
  - [approaches in addition to above [if applicable]
  - other reasons [if applicable]
- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):