European Ombudsman

# Decision of the European Ombudsman closing the inquiry into complaint 1301/2013/(FOR)AN against the European Chemicals Agency (ECHA)

Decision
**Case** 1301/2013/AN - **Opened on** 18/07/2013 - **Decision on** 20/06/2014 - **Institution concerned** European Chemicals Agency ( No maladministration found ) |

The complaint arose from a disagreement between the complainant (the European Coalition to End Animal Experiments) and the European Chemicals Agency regarding some aspects of the procedures for the registration of chemicals by the Agency. The complainant was concerned to minimise the extent to which registration would require safety tests involving animals. The complainant felt that the Agency was misinterpreting a factsheet it had published for the benefit of potential registrants and that, as a consequence, registrants were undertaking more testing involving animals than was otherwise necessary. Following her inquiry, the Ombudsman concluded that the agency was not misinterpreting its own factsheet and that its practices in this area were compatible with the duties laid on it by the relevant EU Regulation. Accordingly, the Ombudsman did not find any maladministration on the part of the Agency.

## The background to the complaint

**1.** The complainant is the European Coalition to End Animal Experiments (ECEAE), which has stakeholder status at the European Chemicals Agency (ECHA). ECHA is the EU specialised agency in charge of the registration, evaluation, authorisation and restriction of chemicals under Regulation 1907/2006 (the 'REACH Regulation') [1] , which aims at ensuring " *a high level of protection of human health and the environment as well as the free movement of substances...* [and] *also* [at] *promot* [ing] *the development of alternative methods for the assessment of hazards of substances* " [2] . Moreover, the REACH Regulation provides for safeguards intended to minimise new animal testing and to give practical effect to the principle that animal testing should not be performed where it can be avoided, known as the last resort principle.

**2.** ECHA is responsible for ensuring that registrants [3] have supplied the information required by the REACH Regulation relating to the safety of chemical substances which are produced in or imported into the EU. The information to be supplied depends on the tonnage of the substance that will be placed on the market [4] . A registrant wishing to place a substance on the EU market in quantities for which information is not available may be required to carry out

tests on animals in order to assess the risks the substance might pose to humans and the environment. The registrant could also be required to carry out non-animal tests.

**3.** When handling a registration, ECHA performs three main tasks: (i) completeness checks to ensure that the registrant has included in the dossier all the information required by the REACH Regulation; (ii) compliance checks in respect of at least 5% of the registration dossiers for each tonnage band, to ensure that they comply with the REACH Regulation; and (iii) evaluation of test proposals for the generation of information required for higher tonnage bands [5] .

**4.** In September 2009 **,** ECHA published a factsheet entitled " *Information requirements for repeated dose toxicity and reproductive toxicity* " (the 'factsheet') in order to aid registrants to avoid specific animal testing. The factsheet stated that the registration dossier need not contain a screening study for reproductive/developmental toxicity (the 'lower tonnage screening') if it contains the results of, or a proposal to carry out, a pre-natal developmental toxicity study [6] or a two-generation reproductive toxicity study [7] (the 'higher tonnage tests').

**5.** The complainant understood the factsheet to say that the existence of a proposal to carry out the higher tonnage tests obviates the need for lower tonnage screening, although the former would not yet have been performed. In other words, as the complainant understood it, the prospective availability of the results of higher tonnage tests is sufficient to satisfy the requirements of the REACH Regulation.

**6.** ECHA's view, maintained in correspondence and meetings with the complainant, is that the factsheet applies only to the completeness check of a registration dossier. The factsheet is not concerned with whether a dossier complies overall with the REACH Regulation. ECHA is of the view that a dossier could be complete if it contains only a proposal for higher tonnage tests, even though these tests have not yet been performed. However, it might emerge during compliance checks that this is insufficient to prove that the dossier complies with the REACH Regulation. In such a case, ECHA will demand that a lower tonnage screening be carried out too.

**7.** The complainant disagreed with this interpretation and turned to the European Ombudsman on 21 June 2013.

# The inquiry

**8.** The Ombudsman opened an inquiry into the complaint and identified the following allegations and claims.

## Allegations

ECHA:

(i) wrongly applies different legal tests to the registration of the same substance;

(ii) made untrue public statements in a factsheet and a press release; and

(iii) encouraged registrants, in contravention of the REACH Regulation, to conduct unnecessary animal tests.

## Claims

ECHA should:

(i) apply a single legal test for completeness and compliance checks;

(ii) correct misleading statements in the factsheet and accompanying press release;

(iii) desist from encouraging registrants to ignore the clear wording of REACH in relation to animal tests.

**9.** In the course of the inquiry, the Ombudsman received the opinion of ECHA on the complaint and, subsequently, the complainant's observations in response to ECHA's opinion. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

# Alleged wrong application of different legal tests to the registration of the same substance, and related claim

## Arguments presented to the Ombudsman

**10.** The ECEAE argued that the ECHA has created a false distinction between the requirements applicable in order for a registration application to be considered complete and the requirements to be met in order to satisfy the compliance check. According to the ECEAE, registrants are required to submit dossiers that are both complete and compliant. Submitting a complete dossier, that is, a dossier which contains the information required for the relevant tonnage, but which is not compliant because the data are insufficient, means that registrants have not fulfilled their obligations under the REACH Regulation at the time of registration. Therefore, in fact, there is but a single set of obligations for registrants, so it makes no sense to apply different legal tests to completeness checks and to compliance checks.

**11.** According to the ECEAE , the relevant provisions of the REACH Regulation allow the lower tonnage screening to be avoided if information from the higher tonnage tests is available. In this regard, the ECEAE contends that the term "available" must be understood in the sense that the information will be obtained from a proposed test at a later stage. Otherwise, a dossier cannot

legitimately be considered complete if it refers to a proposed test. This interpretation should prevail both for completeness and for compliance checks, making lower tonnage screening unnecessary when higher tonnage tests are proposed.

**12.** In its opinion, ECHA stated that completeness and compliance checks serve two different purposes and that the REACH Regulation clearly differentiates between the two. The aim of completeness checks is to verify in an automated way that all mandatory fields in the registration dossiers are completed. In the compliance check, ECHA performs a scientific assessment of the adequacy of the information provided and may request further testing from the registrant in order to render the dossier compliant. In particular, a dossier may be complete if it contains a testing proposal meant to provide required information, but it will only be compliant once the test has been performed and the information has been obtained.

**13.** According to ECHA, the factsheet refers only to the completeness stage; it does not, and cannot, guarantee that the information contained in a registration dossier is compliant until ECHA actually verifies it. However, the factsheet discourages unnecessary animal testing, as there may be cases in which a registrant will be able to justify why there is no need to provide the test results in the registration dossier.

## The Ombudsman's assessment

**14.** The relevant provisions of the REACH Regulation [8] state that the lower tonnage screening " *does not need to be conducted if...* [one of the higher tonnage tests] is available ." The Ombudsman takes the view that this leaves no doubt as to the legislator's intention that the higher tonnage tests need to have been performed in order to be " *available* ", as the Regulation requires.

**15.** Reasonably, there is a significant difference between the " *availability* " to which the REACH Regulation refers and the 'prospective availability' for which the complainant argues. An available study actually proves something: either that the substance is safe, and can thus be marketed, or that it is unsafe, and thus cannot be marketed. A study that will be carried out at a later stage says nothing about the safety of the substance at present; nor does it allow any inferences to be drawn on the safety of the substance, since its results cannot be known in advance. It cannot therefore be concluded that, when referring to " *available* " tests, the legislator intended to allow ECHA to declare a substance safe at the compliance check stage, based on the hope that future tests might prove its safety.

**16.** In the Ombudsman's view, the legislator intended to allow ECHA to register substances prior to actually checking their safety. This initial registration would be done on the basis of an automatic and purely formalistic verification that every mandatory field of the registration dossier has been completed. This formalistic verification, known as "completeness check", does not " *include an assessment of the quality or the adequacy of any data or justifications submitted* " [9] . This was a necessary compromise in view of the limited resources at ECHA's disposal, the numerous registrations it receives and the need to avoid paralysing the registration procedure,

and thus the entire industry, through extensive checks from the very beginning.

**17.** It is only at a later stage, during compliance checks, that ECHA verifies that " *the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules...* " [10] . At that point, ECHA can actually check whether the higher tonnage tests are " *available* ", within the meaning of the term in Annex VIII of the REACH Regulation, and that they demonstrate the safety of the registered substance.

**18.** In sum, the legislator established a presumption that a substance is safe, and thus can be marketed, if its registration dossier is complete [11] . But this presumption is rebuttable: it will apply only for as long as a subsequent compliance check does not prove it wrong or unwarranted. To prove either of the two, the appropriate data must have been generated by then.

**19.** The complainant is right to state that registrations need to be fully in line with all the requirements of the REACH Regulation, in terms of both completeness and compliance, from the moment of their submission. Strictly speaking, this would mean that registrants should have already performed either the higher tonnage tests (which require a lengthy prior authorisation procedure) or the lower tonnage screening. From ECHA's perspective, however, there would be no point in requiring registrants to make that data available from the beginning, if it is not in a position to verify it at that stage, in any event.

**20.** The Ombudsman thus considers that ECHA's nuanced interpretations of the term " *available* ", in the context of completeness and compliance checks, is not manifestly erroneous or arbitrary. Moreover, it appears to be the approach which, while not departing from the intentions of the legislator, best respects the last resort principle. Therefore, the Ombudsman finds that no instance of maladministration has occurred as regards the complainant's first allegation and related claim.

## Alleged untrue public statements and related claim

### Arguments presented to the Ombudsman

**21.** The complainant pointed out that ECHA " *trumpeted* " that its factsheet avoids unnecessary animal tests and saves costs for industry. However, the complainant says it is obvious to it that ECHA does neither of these two things, since at the compliance check stage, it requires registrants to perform a lower tonnage screening if the proposed higher tonnage tests have not yet been carried out. Only by interpreting "available" studies as including prospective availability, according to the complainant, would ECHA indeed save animals' lives and registrants' money, as the factsheet claims. Similarly, only by adopting this interpretation of "available" would the REACH Regulation's aim of reducing animal testing be attained. The press release is therefore highly misleading and, although ECHA is aware of this, it has done nothing to correct this state of affairs.

**22.** ECHA took the view that its factsheet clearly mentions that it applies to completeness checks only and that it is not misleading in this regard. Moreover, ECHA said that it has applied the factsheet information consistently and maintained the distinction between the two types of checks. ECHA explained in detail how it applies the factsheet, depending on the different possible scenarios (higher tonnage tests data available at the time of registration, higher tonnage tests proposed, but not yet available, etc.). It maintained its view that clarifying its stance concerning the meaning of " *available* " in section 8.7.1 of Annex VIII to the REACH Regulation has led to animals' lives and registrants' money being saved.

**23.** In its observations, the complainant disagreed with ECHA's explanations as regards how it applies the information contained in the factsheet in practice. It acknowledged that there may have been " *some limited saving in animal tests and associated costs* ", but claimed that the factsheet and subsequent press release " *are still misleading because the saving should have been immeasurably greater* " had ECHA followed the complainant's interpretation.

## The Ombudsman's assessment

**24.** Having reviewed the text of the factsheet, the Ombudsman has ascertained that it states clearly that it applies only to the completeness check. Therefore, ECHA has not misled registrants into believing that it also applied to compliance checks.

**25.** Moreover, the Ombudsman notes that the complainant agrees that the factsheet did lead to animals' lives being saved and to a decrease in industry costs. The fact that the complainant considers that a different interpretation of the factsheet would have led to more animals being saved and to a further decrease in costs is not sufficient to conclude that the factsheet was misleading. Therefore, the Ombudsman finds that no maladministration has occurred as regards the second allegation and claim.

# Alleged encouragement to perform unnecessary tests and related claim

## Arguments presented to the Ombudsman

**26.** The complainant stated that, in reality, ECHA requests or encourages registrants to carry out a lower tonnage screening even where data from higher tonnage tests have already been generated, contrary to the REACH Regulation requirements and its own factsheet.

**27.** In the opinion, ECHA pointed out that the Annexes to the REACH Regulation contain only the minimum information requirements for a registration dossier. Registrants may have to go beyond these requirements in order to demonstrate the safety of their substance. In accordance with its obligations under Article 77(2)(g) of the REACH Regulation, ECHA provides guidance to

registrants regarding how to fulfil the minimum information requirements, how to avoid animal testing and how to determine whether they need to go beyond the minimum requirements.

**28.** ECHA denied that it requires registrants to carry out lower tonnage screenings even when higher tonnage test data are available. It merely provides them with information to be taken into consideration in deciding whether the lower tonnage screening is necessary. In any event, it is up to registrants to decide whether to avail themselves of the possibility of avoiding lower tonnage screening or whether, due to considerations regarding the safety of the substance, they want to carry out such screening.

**29.** In its observations, the complainant acknowledged that the REACH Regulation lays down minimum requirements. It also acknowledged that registrants are ultimately responsible for the safety of their substances and that they might have to go beyond such minimum requirements in order to prove that their substances are safe. There is nothing wrong with ECHA making recommendations to registrants in this regard, where the particular circumstances warrant such recommendations. However, ECHA routinely strongly recommends that further tests be carried out. This goes against the choice that the legislator clearly made in the REACH Regulation, namely, to exempt registrants from performing certain tests if others are available. Even if ECHA limits itself to making recommendations in this regard, it is more than likely that registrants will not feel comfortable ignoring them, and this in fact converts those recommendations into requirements.

## The Ombudsman's assessment

**30.** The Ombudsman notes that the debate between the complainant and ECHA with regard to this allegation and claim is essentially scientific. On the one hand, ECHA gave a detailed description of its policy of recommending to registrants that they consider carrying out further toxicological tests, although the REACH Regulation does not explicitly oblige them to do so. On the other hand, the complainant convincingly argued why such tests may not be necessary and explained that there is scientific disagreement between toxicologists on this specific point. The Ombudsman's mandate does not extend to settling scientific disputes between EU agencies and complainants. Her assessment in the present case is concerned only with the question of whether, by " *encouraging* " registrants to perform additional tests, ECHA has exceeded its mandate under the REACH Regulation.

**31.** Both the complainant and ECHA agree that the REACH Regulation lays down minimum requirements which might need to be supplemented in practice in order to ensure the actual safety of the registered substances. Under the REACH Regulation, registrants, not ECHA, have ultimate responsibility to prove that their substances are safe and, as the complainant acknowledged, they could incur liability should this not be the case. Taking into account the complainant's argument that toxicology is " *an uncertain science* ", the Ombudsman considers it reasonable that ECHA supports registrants, through recommendations, to consider performing other tests to assess the safety of their substances. Issuing guidance is, moreover, one of ECHA's tasks in accordance with Article 77(2)(j) of the REACH Regulation. In any event, the

Ombudsman also notes ECHA's position that it is ultimately up to registrants to decide whether or not to follow its recommendations.

**32.** It is true that, as the complainant states, when a regulator systematically recommends a particular course of action, this might lead the industry to believe that it should follow such recommendations at all times in order to be on the safe side. This could have the consequence of converting the recommendations into rules. However, from the complainant's observations, it appears that " *the vast majority of registrants only conduct the minimum requirements* ". The complainant's fears thus seem to be unfounded.

**33.** Therefore, the Ombudsman does not find any instance of maladministration as regards the third allegation and claim.

# Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

**There has been no maladministration in the present case.**

The complainant and ECHA will be informed of this decision.

Emily O'Reilly
Done in Strasbourg on 20 June 2014

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[2] Recital 1 of the REACH Regulation.

[3] A registrant is the person submitting a registration for a substance with ECHA (Article 2, definition 7 of the REACH Regulation).

[4] The tonnage will determine which of Annexes VII to IX to the REACH Regulation will apply. The requirements of the various Annexes are cumulative, meaning that a substance marketed in larger quantities will have to fulfil the requirements of the Annex governing its tonnage band, as well as those laid down in the Annexes concerning lower tonnage bands.

[5] Test proposals are made by registrants when there is an information gap concerning the

safety of the registered substance that cannot be filled otherwise than by animal tests.

[6] Pre-natal developmental toxicity refers to any possible interference with normal development of the foetus resulting from exposure of either parent prior to conception.

[7] Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females as well as developmental toxicity in the offspring.

[8] Annex VIII, section 8.7.1, column 2.

[9] Article 20(2) of the REACH Regulation.

[10] Article 41(1)(b) of the REACH Regulation.

[11] This is known as staggered compliance, that is, the possibility that a dossier will become fully compliant with the REACH Regulation, in substantive terms, after its submission.