EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-001-2012
Appellant	Dow Benelux B.V., Terneuzen, Netherlands
Appeal received on	24 January 2012
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Evaluation – Compliance check – Request to submit further information – Rejection of suggested read-across approach*
Contested decision	CCH-D-0000001716-72-04/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests that the Board of Appeal should:

- annul the contested decision obliging the Appellant to submit the following information for the registered substance on:
  - *in vitro* gene mutation on mammalian cells, and
  - pre-natal developmental toxicity study, in the rat, by the oral route; and
- refund the appeal fee.

The Appellant also seeks access to the complete files of the Agency and the Member State Committee (the 'MSC') related to the compliance check in question.

Pleas in law and main arguments

The contested decision was taken by the Agency pursuant to Article 41(3) of the REACH Regulation following a compliance check, under the dossier evaluation procedure, of the registration submitted by the Appellant for the substance dipropylene glycol methyl ether acetate (DPMA).

In the contested decision the Agency concluded that the registration did not comply with the requirements of Articles 10, 12 and 13, and with Annexes VIII, IX and XI of the REACH

[1] Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency.

Regulation. The Agency requested the Appellant to submit the information for the registered substance on: *in vitro* gene mutation on mammalian cells (using test method B.17 of Regulation (EC) No 440/2008) and pre-natal developmental toxicity study, in the rat, by the oral route (using test method B.31 of Regulation (EC) No 440/2008).

The Agency's reasoning can be summarised as follows:

1. regarding its request to submit the missing information on *in vitro* gene mutation in mammalian cells (Annex VIII, 8.4.3 of the REACH Regulation), the Agency stated that this information is required as negative results were obtained in the tests specified in Annex VII, 8.4.1 and Annex VIII, 8.4.2;
2. regarding its request to submit the missing information on pre-natal developmental toxicity (Annex IX, 8.7.2 of the REACH Regulation), the Agency concluded that the read-across of information, from dipropylene glycol methyl ether (DPM) to DPMA, as suggested by the Appellant is not acceptable. This is because, contrary to the Appellant's suggestion, the Agency considered that whilst DPMA hydrolyses to DPM, toxicokinetic data suggests that DPMA will still be available in the body for significant amounts of time. Furthermore, the Agency stated that the basis for establishing similarity for grouping of substance and read-across approach, as provided for in Annex XI, 1.5(1) of the REACH Regulation, is not met as DPMA contains an acetate functional group that is not present in DPM.

The Appellant contests the Agency's decision requiring it to submit the above-mentioned missing information for the registered substance. The Appellant's claims and arguments supporting them can be summarised as follows:

1. The contested decision is illegal in so far as it requests that the Appellant performs the *in vitro* gene mutation study on mammalian cells. The Agency ignores the fact that the Appellant already performed the study and submitted the respective information in September 2011. There is therefore no need for such a request.
2. Regarding the pre-natal developmental toxicity study, in the rat, by the oral route, the Appellant raises the following arguments:
   - Assignment of decision-making powers to the Agency within the framework of the dossier and substance evaluation is unlawful as a result of incompatibility with the principle of institutional balance and constitutes an inadmissible transfer of responsibility from the Commission to an institution not governed by the European Treaties. Both the Agency and the MSC abused their competence and infringed EU primary law by taking a discretionary decision;
   - The MSC's change to the Agency's draft decision is incompatible with primary law and the Comitology Regulation and must be deemed unlawful as the MSC should have only been able to either consent to the draft decision or reject it;
   - The Agency violated the Appellant's right to be heard by not clearly expressing the information on which it intended to base the contested decision and without taking into account the profound scientific argumentation of the Appellant;
   - The contested decision is illegal, since the Agency's reasoning and the fact that it – together with the MSC – has not considered the Appellant's profound and substantial scientific argumentation, violate the Agency's duty to give a statement of reasons for a measure adversely effecting its addressee;
   - The Agency had no sufficient argument and thus no right to oblige the Appellant to submit further information for the registered substance using the test method in question, in particular since the Appellant provided stringent argumentation and proof (e.g. OECD [Organisation for Economic Co-operation and Development] study,

PMA [Propylene Glycol Methyl Ether Acetate], PM [propylene glycol methyl ether], DPM, DPMA comparison); and

- The Agency disregarded its margin of discretion by rejecting the Appellant's justified read-across deduction and obliging it to perform further testing. Moreover, the Agency misused its margin of discretion by requiring the Appellant to conduct a pre-natal developmental toxicity study in the rat, while neglecting the principle of animal welfare and failing to weigh that principle against the need to undertake the study at issue.

Further information

The rules for the appeal procedure and other background information are available on the "Appeals" section of ECHA's website:

http://echa.europa.eu/appeals/app_procedure_en.asp