European Chemicals Agency
Board of Appeal

Announcement of appeal[1]

Case	A-005-2011
Appellant	Honeywell Belgium N.V., Heverlee (Leuven), Belgium
Appeal received on	21/06/2011
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 *Evaluation – Compliance check – Request to submit further information – Animal welfare*
Contested decision	CCH-D-0000001396-72-03/F
Language of the case	English

Remedy sought by the appellant

The appellant requests that the Board of Appeal should:

- annul the part of the contested decision that requires the appellant to conduct a 90-day repeated dose toxicity study (sub-chronic toxicity study) in the rabbit, by inhalation, and
- refund the appeal fee.

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 2,3,3,3-tetrafluoropropene (a refrigerant).

In the contested decision the Agency concluded that the registration did not comply, *inter alia*, with Articles 10(a)(vi) and 12(1)(e), and with Annex X, Section 8.6.4 of the REACH Regulation. The Agency requested the appellant to submit information following the conduct of the test method 90-day repeated dose toxicity study (sub-chronic toxicity study) in the rabbit, by inhalation (test method B.29 of Regulation (EC) No 440/2008 or OECD Test Guideline 413; hereinafter, '90-day inhalation test in rabbits'). The Agency justified this decision on the basis that:

[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.

1. The death of pregnant rabbits in the appellant's prenatal developmental toxicity testing on rabbits satisfies the criterion "toxicity of particular concern" as set-out in Annex X, Section 8.6.4;
2. The available evidence is inadequate for toxicological evaluation and/or risk characterisation because the data submitted shows that the rabbit is more sensitive to toxicity from the substance as compared with the rat; and
3. The available information on the toxicity of the substance on the rabbit is inadequate for toxicological evaluation and/or risk characterisation.

The Agency stated that the study protocol should be modified with additional clinical pathology and histopathological elements to evaluate effects on reproductive organs (specifically as described in OECD Test Guideline 416, paragraphs 29 – 32, 39, and 41 – 45).

The appellant argues that the contested decision has been adopted in breach of Article 41 and Annex X, is inconsistent with Article 13(3) and Article 13(2), and is in breach of, and inconsistent with, Article 25(1), of the REACH Regulation. Moreover, the appellant also challenges the proportionality of the contested decision. The appellant's arguments in support of its claims can be summarised as follows:

1. Information on the sub-chronic toxicity endpoint in question were satisfied by the inclusion of a 90-day inhalation test in rats in accordance with the REACH Regulation and the corresponding ECHA Guidelines on endpoint specific information requirements;

2. There is no test method laid down in a European Commission Regulation or in other international test methods as regards a 90-day inhalation study in rabbits;

3. The requested study in rabbits is almost unprecedented;

4. The results from a 90-day inhalation test in rabbits are very unlikely to be of any scientific value or to provide additional information on the safety of the substance, in part because of the problems in conducting such a test on rabbits, and therefore will only result in the unnecessary sacrifice of vertebrate animals;

5. The requirement to conduct a 90-day inhalation study in rabbits is disproportionate as other tests could and should be conducted first;

6. These other tests may provide sufficient data and therefore further consultations with the Agency are required to decide whether additional testing is necessary; and

7. The requirement for the appellant to conduct a 90-day inhalation test in rabbits has been adopted without consultation on the development of appropriate test methods.

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