Board of Appeal decisions concerning vertebrate animal testing on cosmetic ingredients

The ECHA Board of Appeal has adopted two important decisions which examine the links between REACH and the Cosmetics Regulation with regard to the requirements for testing on animals.

Helsinki, 18 August 2020 - The Board of Appeal adopted two decisions concerning compliance checks of registration dossiers for homosalate and 2-ethylhexyl salicylate, which are used exclusively as ingredients in cosmetic products (cases A-009-2018 and A-010-2018).

In the contested decisions, ECHA had required a registrant to carry out several studies on vertebrate animals on the substances to fulfil registration requirements for human health endpoints, namely a 90-day subchronic toxicity study, two PNDT and two EOGRT studies. In one of the two cases, ECHA also required the registrant to carry out a fish sexual development test.

Vertebrate animal testing on cosmetic ingredients (A-009-2018 and A-010-2018)

The registrant argued before the Board of Appeal that ECHA cannot require studies on vertebrate animals for human health endpoints because the substances are used exclusively as ingredients in cosmetic products.

The Board of Appeal found that the REACH Regulation requires registrants to perform studies on vertebrate animals even if the substance is used exclusively as an ingredient in cosmetic products. The REACH Regulation does not contain an automatic exemption from the information requirements for registration if a substance is used as an ingredient in cosmetic products. A registrant can benefit from an exemption only if it shows that the conditions for an adaptation (for example, a waiver for the studies) are fulfilled.

This conclusion is consistent with the Cosmetics Regulation. The Cosmetics Regulation contains restrictions for vertebrate animal testing on the ingredients of cosmetic products. These restrictions, however, do not prevent registrants from carrying out tests in order to comply with the information requirements of REACH.

Information requirements concerning aquatic toxicity (A-010-2018)

The registrant also argued before the Board of Appeal that ECHA cannot require a fish sexual development test because this test is not a standard information requirement for registration purposes.

The Board of Appeal held that a fish sexual development test is not a standard information requirement for registration purposes (Column 1 of Section 9.1. of Annex IX). However, ECHA has the power to require a fish sexual development test from a registrant, if necessary, as an adaptation (Column 2 of Section 9.1. of Annex IX).

In this case, ECHA had found that a fish sexual development test is necessary because existing information shows that 2-ethylhexyl salicylate may be an endocrine disruptor. As a consequence, ECHA was entitled to require the registrant to carry out a fish sexual development test.

Outcome

The Board of Appeal rejected both appeals.

Andrew Fasey, Technically Qualified Member of the Board of Appeal and rapporteur for the cases, says: "*The two decisions published today are among the most important taken by the Board of Appeal to date. The relationship between the information requirements in REACH and the marketing and testing 'bans' in the Cosmetics Regulation have been an issue for many years with several different interpretations. The two decisions adopted today are based on a rigorous analysis of the wording and objectives of the two pieces of legislation. I don't expect that everyone will agree entirely with these decisions. We have however tried to set out as clearly as possible how and why we have arrived at our conclusions.*"

Further information

The full text of the decisions can be found under the following links:

- Decision A-009-2018
- Decision A-010-2018
- REACH regulation
- Cosmetics Regulation

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

http://echa.europa.eu/web/guest/regulations/appeals