EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-006-2014
Appellant	International Flavors & Fragrances B.V., the Netherlands
Appeal received on	26 May 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH Regulation
Keywords	*Evaluation – Substance evaluation – Request for further information*
Contested Decision	Decision on substance evaluation for Hexyl Salicylate of 25 February 2014. The Decision was notified to the Appellant through the annotation number SEV-D-2114273859-29-01/F.
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- annul the Contested Decision; and
- order the Agency to refund of the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 25 February 2014 following a substance evaluation of the Substance by the Netherlands' Competent Authority.

In the Contested Decision the Agency requests the concerned registrants (among them the Appellant) to submit information for the registered substance including:

- *in vitro* dermal absorption study,
- 28-day repeated dose toxicity study in the rat, by inhalation, and
- information related to exposure assessment for Hexyl Salicylate (the 'Substance').

By means of its appeal, the Appellant contests the Contested Decision on, amongst others, the following grounds.

[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.

The Appellant claims that by requesting the studies and submission of information that is not material to the concerns identified on the list of the substances included in the CoRAP (Community Rolling Action Plan), the Agency exceeded the limits of its competence and misused its powers under the substance evaluation process. The Appellant contends that the listing of the Substance in the CoRAP identified potential carcinogenic, mutagenic or toxic for reproduction (CMR) properties as the concern to be addressed through substance evaluation. Inhalation irritation properties were however not identified, nor can they be expected to be considered '*of concern*' by reference to the other properties considered '*of concern*' in the context of the authorisation process and the expressed focus of the CoRAP listing. The Appellant concludes that by requesting additional exposure information the Agency exceeded the scope of its powers under Article 44(1) and Article 46(1) of the REACH Regulation and violated Article 11(1). The Agency cannot lawfully require further information which is related to producer specific exposure scenarios for workers and/or consumers.

The Appellant also contends that the Contested Decision is based on manifest errors of assessment related to the requirement for a 28-day repeated dose toxicity study in the rat, by inhalation.The Appellant argues that this study does not address skin irritation observed during acute exposure and will not result in another derived no-effect level (DNEL) for inhalation. By requiring a study which is not necessary to address the alleged concerns the Contested Decision does not meet the 'necessity' test in the principle of proportionality.

Furthermore, the Appellant claims that the Contested Decision lacks reasoning, in particular because it does not explained how the comments submitted by the Appellant were taken into account. In that regard, the Contested Decision does not provide sufficient justification for requesting the respective studies and the exposure information to be included in the registration dossier and, in particular, it does not explain why the arguments submitted by the Appellant on the draft decision have been rejected.

Moreover, the Contested Decision is flawed because it is not based on all relevant information that was available to the Agency. The Appellant considers that the Agency cannot artificially restrict its obligation to take comments into account from registrants, and certainly that all and any comments received from a registrant during the legal commenting period must be assessed.

Finally, the Appellant claims that when requesting the information in the Contested Decision, the Agency failed to take into account the need to avoid animal testing. The Contested Decision was therefore adopted in breach of Article 25 of the REACH Regulation.

Further information

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

The CoRAP list of substances is available here:

https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.