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EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 27 OCTOBER 2015 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-006-2014

(Substance evaluation – Misuse of powers – Scope of substance evaluation – Exposure information – Proportionality – Duty to state reasons – Article 25(1))

Factual background

Following the substance evaluation of hexyl salicylate (hereinafter the 'Substance') by the Netherlands (the evaluating Member State), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting additional information from registrants of the Substance (hereinafter the 'Contested Decision'). The information requested was intended to clarify a concern regarding local toxicity via the inhalation route and determine the risk of worker and consumer exposure to the Substance.

One of the registrants of the Substance, International Flavors & Fragrances B.V. (hereinafter the 'Appellant'), requested the Board of Appeal (hereinafter 'BoA') to annul the Contested Decision.

Main findings of the Board of Appeal

In its Decision of 27 October 2015 the BoA observed that the Substance had been included in the Community Rolling Action Plan (hereinafter 'CoRAP') 2012 on the basis of a different concern (i.e. reproductive toxicity) than the one which formed the basis for part of the Contested Decision (i.e. local toxicity by inhalation). In consideration of the objectives of the substance evaluation process and of Regulation (EC) No 1907/2006 (hereinafter the 'REACH Regulation') the BoA held that the assessment of a substance included in CoRAP is not limited to the concerns that led the Agency to include that substance in CoRAP in the first place.

The Appellant further claimed that the Agency could not request information relating to exposure from individual registrants by means of a substance evaluation decision. In its decision, BoA observed that, despite the fact that the Agency could have requested exposure information through a compliance check of individual registration dossiers, such information is not standard information in the context of registration and would not necessarily be requested during a compliance check. Moreover, substance evaluation may be an appropriate procedure for requesting exposure information. This is due to the fact that during the course of a substance evaluation the Agency may take into account 'all information submitted' rather than the contents of a single registration dossier and this more holistic view may make it apparent that further information on exposure is needed. Finally, it would be inefficient for the Agency to have to conduct compliance checks of several registration dossiers in order to adopt decisions to help clarify the potential risk identified during a substance evaluation. On that basis, the BoA rejected the Appellant's argument that exposure information should, in the present case, have been requested through separate decisions following compliance checks.

The Appellant also claimed that the Contested Decision was disproportionate in so far as

it requested a 28-day repeated dose toxicity study in rats (hereinafter the 'RDT study'). The BoA considered that, under substance evaluation, in order to request additional information consistent with the proportionality principle, the Agency must amongst other things be able to demonstrate the necessity of the requested measure by setting out the 'grounds for considering that a substance constitutes a risk to human health and the environment'. The Agency must also be able to demonstrate that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures.

The BoA found that the Contested Decision set out with sufficient clarity the objective pursued by the request for the RDT study, namely to clarify the concern for short-term inhalation toxicity in light of the possible exposure of workers and consumers to the substance and, if appropriate, establish an inhalation Derived No-Effect Level (hereinafter 'DNEL') for local effects. Moreover, the BoA Decision held that the Agency had established the necessity of the measure in question. First, the available data on eye and skin irritation indicated a respiratory irritation concern which needed to be clarified. Secondly, there was prima facie a significant exposure of consumers and workers to the substance. Thirdly, no inhalation DNEL had been established.

The BoA found that the requested RDT study was appropriate to achieve the objective pursued, in particular, because any local effects in the respiratory tract due to either irritation or sensitisation reactions should be seen in a well-conducted 28-day RDT study. Finally, the BoA held that the Appellant had not established that a less onerous measure was available. The BoA consequently dismissed the Appellant's plea relating to the lack of proportionality of the 28-day RDT study as unfounded.

In light of its examination of the claims outlined above, the BoA also dismissed the pleas put forward by the Appellant that the Contested Decision was partly based on a manifest error of assessment, that it lacked reasoning and that it breached Article 25 of the REACH Regulation by requiring unnecessary animal testing.

In light of the above considerations, having dismissed all the Appellant's pleas, the BoA dismissed the Appeal in its entirety as unfounded.
