EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 23 SEPTEMBER 2015 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-005-2014

(Substance evaluation – Risk – Proportionality – Data gap – EOGRTS – Compliance check)

Factual background

Following the substance evaluation of carbon tetrachloride (hereinafter the 'Substance') by France, the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting the Appellants to provide information on an extended one generation reproductive toxicity study (hereinafter 'EOGRTS') by inhalation (OECD Test Guideline 443). The Appellants requested the Board of Appeal to annul the Contested Decision.

Main findings of the Board of Appeal

In its Decision of 23 September 2015, the Board of Appeal considered that, under substance evaluation, in order to request additional information the Agency must be able to, firstly, demonstrate that there is a potential risk to human health or the environment. Secondly, the Agency must be able to show that the potential risk identified needs to be clarified. And thirdly, the Agency must be able to demonstrate that the information requested has a realistic possibility of leading to improved risk management measures.

With regards to the first criterion, the Board of Appeal observed that demonstrating a potential risk is based on a combination of hazard and exposure information. As a result of the restrictions in place, there is no suspected consumer, or widespread, exposure to the Substance. According to the information available to the Board of Appeal, the only possible exposure is to workers and that risk is currently managed on the basis of a derived no-effect level (hereinafter 'DNEL') obtained from information on systemic liver toxicity. There are also strict safe handling measures in place to protect workers, such as the requirement to wear protective equipment and for appropriate exhaust ventilation at facilities.

The Board of Appeal found that the Agency had not rebutted the Appellants' assertion that the existing DNEL ensures that there will be no exposure to the Substance at levels at which there is a realistic possibility of reproductive toxicity. Furthermore, no evidence was presented to the Board of Appeal which would support the conclusion that the current risk management measures are inadequate to address the concerns for systemic liver toxicity and therefore for reproductive toxicity.

The Board of Appeal also observed that two other substance evaluation decisions had been sent to certain individual registrants requesting information on exposure for specific uses. The Board of Appeal noted that the information submitted in response to those decisions may indicate that there is potentially a level of worker exposure which could require additional risk management measures. However, as that information had not been received by the time the Contested Decision was adopted the Agency's conclusion regarding worker exposure was premature.

In relation to a hazard concern the Board of Appeal considered that the Agency's evidence supporting a concern for reproductive toxicity was weak, in particular at doses at which workers can reasonably be expected to be exposed. The Board of Appeal noted further that

there is no indication that the Substance causes reproductive toxicity at dose levels that would not be associated with significant systemic liver toxicity.

The Board of Appeal also found that the Agency did not demonstrate that the risk management measures already in place, consequent to the various regulatory requirements and the DNEL developed as a result of systemic liver toxicity, will not ensure the protection of workers from harm caused by possible exposure to the Substance.

The Board of Appeal concluded that, in this particular case, the Agency had not demonstrated that there is a potential risk that needs to be clarified and that the requested information had a realistic possibility of leading to improved risk management measures. The Agency had not demonstrated that the requested information is necessary to meet real information needs regarding the protection of human health and the environment. The Board of Appeal considered that under the substance evaluation procedure greater clarity regarding the potential risks to human health and the environment are required in order to substantiate a request for further information.

The Board of Appeal also found that a perceived gap in the standard information requirements cannot, in itself, justify a request to fill such a data gap pursuant to substance evaluation. A data gap does not constitute on its own evidence of a potential risk for human health or the environment.

The Board of Appeal also observed that in the present case one of the Appellants had proposed a waiver in its registration dossier as a means to fill the relevant information requirement. In this regard, the Board of Appeal observed that a conclusion regarding the adequacy of a waiving argument should ordinarily be reached under the compliance check procedure.

The Board of Appeal considered, however, that the Agency may be able to provide sufficient reasoning to justify in certain cases, in light of the objectives of the REACH Regulation and substance evaluation and in particular the protection of human health and the environment, requesting under substance evaluation information that should have, ordinarily, been requested following a compliance check procedure. In the present case, however, no such justifications were found.

In light of the above considerations, the Board of Appeal concluded that the Contested Decision is disproportionate on the grounds that an EOGRTS is not, based on the Contested Decision and the submissions in the present proceedings, necessary to clarify a risk to human health or the environment. In addition, the Agency had not adequately justified requesting information that was standard for one registrant from all the Appellants under the substance evaluation procedure. The Contested Decision was therefore annulled and the case remitted to the Agency for further action.
