ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 29 JULY 2015 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-019-2013

(Notified substance – Statement of non-compliance (SONC) – Procedure under Article 51 of the REACH Regulation)

Factual background

The Appellant notified a substance to the Belgian competent authorities under the Dangerous Substances Directive[1].

The Belgian competent authorities requested further information from the Appellant in accordance with the national legislation implementing the Dangerous Substances Directive. In that request the Appellant was asked to provide information on a toxicokinetic study (OECD 417), and an in-vitro mammalian cell genotoxicity test (chromosomal aberration test or mouse lymphoma assay).

Pursuant to Article 24(1) of the REACH Regulation[2] such notifications are regarded as registrations for the purposes of that Regulation. Article 135(1) provides that '*[t]he requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51 of [the REACH Regulation]*'.

Following a reminder from the European Chemicals Agency (hereinafter the 'Agency') regarding the request for further information by the Belgian competent authorities, the Appellant submitted a dossier update to the Agency. Specifically, for the in-vitro mammalian cell genotoxicity test requirement the Appellant submitted the requested information using a read across adaptation. For the toxicokinetic study requirement, the Appellant provided supportive information on the intrinsic properties and the toxicological profile of the substance.

Following an examination of the dossier update, the Agency concluded that the Appellant's dossier did not contain the information requested by the Belgian competent authorities. The Agency sent a '*Statement of Non-Compliance following a Dossier Evaluation Decision Under [REACH Regulation]*' (hereinafter the 'SONC') to the Belgian competent authorities. The SONC stated that the registration dossier is not in compliance with Article 5 and that the Appellant is in breach of Article 41(4). The SONC also asked the Belgian competent authorities to address the non-compliance. An attachment to the SONC set out the Agency's conclusions on the information submitted by the Appellant in its dossier update.

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the SONC.

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[1] Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3). All references to Articles hereinafter concern the REACH Regulation.

Main findings of the Board of Appeal

The Board of Appeal found that, pursuant to Article 135(1), the competent authority's request for further information on the substance must be *'considered as'* an Agency decision *'adopted in accordance with Article 51'* and that, in effect, such a request is equivalent to an Agency compliance check decision adopted pursuant to Article 41. The Board of Appeal found further that the Agency's assessment of the Appellant's dossier update, submitted in consequence of the request of the Belgian competent authorities, falls within Article 42(1) which provides that '*[t]he Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary*'. Article 41(3) states that decisions '*…shall be taken in accordance with the procedure laid down in Articles 50 and 51'*.

The Board of Appeal then considered whether the Agency was required, in the present case, pursuant to Article 42(1), to adopt a decision in accordance with Article 41 and in turn go through the decision-making procedure foreseen in Articles 50 and 51.

The Board of Appeal observed that, pursuant to Article 42(1), the Agency would not be required to draft a new decision following the procedures foreseen in Articles 50 and 51, where that decision would merely confirm the previous decision. In this regard, the Board of Appeal, applying the case-law of the European Courts by analogy, stated that a measure is regarded as merely confirmatory of a previous decision if it contains no new factor as compared with the previous measure and was not preceded by a re-examination of the circumstances of the person to whom that measure was addressed. In particular, if the measure constitutes the reply to a request in which substantial new facts are relied on, and whereby the administration is requested to reconsider its previous decision, that measure cannot be regarded as merely confirmatory in nature, since it constitutes a decision taken on the basis of those facts and thus contains a new factor as compared with the previous decision.

The Board of Appeal then considered whether in the present case the Appellant's update of the registration dossier should be considered to be substantial new information. The Board of Appeal noted that the Appellant's update needed to undergo a scientific assessment in order for the Agency to conclude on whether the information requirements had been met. The Board of Appeal also noted that at the time of the notification of the Substance, the Dangerous Substances Directive contained no equivalent to Article 13 that requires registrants to provide information on intrinsic properties of substances through means other than vertebrate testing whenever possible. The Board of Appeal added that, in the present case, the Appellant was compelled to submit information adapting the requirements set out in the request of the competent authority if it considered that the adaptation possibilities in Annex XI to the REACH Regulation applied. The Board of Appeal also concluded that the Appellant had made a bona fide adaptation proposal, pursuant to Article 13 and Annex XI, and that this therefore required a scientific assessment. The Board of Appeal concluded that the read across adaptation submitted by the Appellant in its registration dossier update must be considered to be substantial new information. As a result, the SONC did not simply confirm the earlier request of the competent authorities and the Agency's scientific assessment of the Appellant's dossier update resulted in a fresh decision.

The Board of Appeal further noted that the Appellant did not have the opportunity to comment on the Agency's conclusions contained in the SONC dismissing the read across adaptation. In this respect, the Board of Appeal highlighted the importance of the right to be heard. The Board of Appeal also considered that, in the present case, where the request of the competent authority required testing on vertebrate animals, following the procedure set out in Articles 50 and 51 might have helped to ensure that testing on vertebrate animals is undertaken only as a last resort pursuant to Article 25(1).

The Board of Appeal concluded that, in the present case, the Agency's conclusion in the SONC was not communicated in a decision adopted in accordance with the procedures in Articles 50 and 51, thus depriving the Appellant of the procedural guarantees provided therein. The Board of Appeal therefore found that the Agency breached Article 42(1) and annulled the Contested Decision.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.
