

Announcement of appeal¹

Case	A-001-2013
Appellant	Infineum UK Ltd
Appeal received on	8 February 2013
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	<i>Evaluation – Compliance check – Requirements related to substance identity – Substance composition - UVCB substance – Annex VI requirements</i>
Contested decision	CCH-D-0000002759-61-02/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- annul the contested decision requiring the Appellant to submit additional information on the substance identity related to identifiers, composition and analytical methods; or, should the Board of Appeal not annul the contested decision;
- partially annul and replace the contested decision by a new decision giving the Appellant reasonable and sufficient time for the submission of the additional information required.

Pleas in law and main arguments

The contested decision was adopted on 19 November 2012 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the 'registered substance' (Phenol, alkylation products with C10-15 branched olefins derived from propene oligomerization, calcium salts, sulfurized, carbonates, overbased).

In the contested decision the Agency considers that the registration did not comply with the requirements of Article 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation. The Agency requested the Appellant to submit the following information:

- Name or other identifier of the substance (Annex VI, Section 2.1);
- Composition of the substance (Annex VI, 2.3.); and

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.

- Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7).

The Agency's reasoning can be summarised as follows:

1. Regarding the name or other identifier of the substance (Annex VI, 2.1), the Agency stated that the naming of substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) shall consist of two parts: the chemical name and a more detailed description of the manufacturing process. The Agency concluded that the chemical name assigned by the Registrant to the registered substance is not sufficiently representative of the substance. In that regard, the Agency noted that the Registrant modified the chemical name of the registered substance in an updated registration dossier. The modified chemical name does not however reflect other substance information contained in the registration dossier. More specifically, the assigned chemical name did not reflect a significant presence of a 'lubricating oil', which according to the Agency cannot be regarded as a stabiliser, in line with Article 3(1) of the REACH Regulation, as proposed by the Registrant, but should be considered to be a constituent of the registered substance. In addition, the Agency considered that the chemical name should reflect the exact identity of the starting materials and 'oil' used. The Agency also concluded that information on the manufacturing process was missing, in particular the exact ratio of the different starting materials.
2. Regarding the composition of the registered substance (Annex VI, 2.3), the Agency stated further that the registration dossier does not contain appropriate information for establishing the composition of the registered substance. The Agency considered that, as the 'lubricating oil' cannot be considered to be a stabiliser, the constituents of the 'oil' ending up in the composition of the registered substance should be regarded as constituents of that substance and reported as such in its composition. Additionally, the identity and concentration level of the constituents originating from the 'lubricating oil' have not been specified to a sufficient level of detail. Further information on the identity and concentration level of the different hydrocarbon classes within the reported groups of constituents is necessary for an unambiguous identification of the 'oil'.
3. Regarding the description of the analytical methods (Annex VI, 2.3.7), the Agency noted that the Registrant has not provided any description of the analytical method(s) used for the quantification of the registered substance including its constituents. In this respect, the Agency pointed out that the justification on its own of the quantification of the constituents and groups of constituents, without submission of the analysis and calculations, is not sufficient to demonstrate how the compositional values were derived.

The Appellant contests the Agency's decision requesting it to submit the above-mentioned information for the registered substance. The Appellant's claims and arguments can be summarised as follows:

1. In relation to the information requested by the Agency, the majority of the information has already been submitted to the extent that is, first, technically and practically possible, second, required in the Article 10(a)(ii) of the REACH Regulation and Annex VI Section 2 and, third, elaborated in the Agency's Guidance on Substance Identification and Naming.

2. The contested decision errs in law by failing to recognise the 'lubricating oil' as a stabilising additive in accordance with the definition in Article 3(1) of the REACH Regulation. The Agency incorrectly focuses solely on the preservation of stability following the formation of the registered substance. The 'oil's presence, to preserve the stability of the registered substance, is however necessary during, as well as following the formation of the registered substance. The test established by the definition provided in Article 3(1) is whether an additive is necessary to preserve stability; the function of the additive is crucial and not the time at which it is introduced.
3. In the alternative, should the Board of Appeal consider that the 'lubricating oil' is not a stabiliser, the Agency's requirement for a high degree of detailed compositional information breaches the following principles of European Union law:
 - principle of legal certainty: by requesting detailed information on the identity of the substance that goes beyond the Agency's Guidance and also constitutes a breach of the legitimate expectation created by the Guidance;
 - principle of proportionality: considering the requirements in the Guidance for UVCB substances, the Agency infringed the principle first, by requesting detailed compositional information given the difficulties relating to UVCB substances and, second, by requesting that such detailed information is provided within three months', while at least 12 months would be required for method development and analysis; and
 - principle of equal treatment: by, without objective justification, not treating the Registrant consistently with other registrants of the same or similar substances, in relation to the level of compositional detail required, first, as regards the registered substance in comparison with other members of the SIEF; second, as regards the 'oil' in comparison with other registrants of the same substance and, third, as regards both, the registered substance and the 'oil' in comparison with registrants of other UVCB substances.
4. The Agency breached Article 51(1) of the REACH Regulation, by not communicating the Registrant's comments on the draft decision to the Member States, thus denying the Registrant the possibility of receiving supportive comments to the Registrant's position and beneficial proposals for amendment of the draft decision.

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>