

Announcement of appeal¹

Case A-008-2012

Appellant Przedsiębiorstwo Produkcyjno-Handlowe (PPH) UTEX Spółka z

organiczoną odpowiedzialnością, Rybnik, Poland

Appeal received on 2 October 2012

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 Evaluation – Compliance Check – Substance identity – Substance

composition - UVCB - Annex VI requirements

Contested decision CCH-D-0000002552-79-03/F

Language of the case English

Remedy sought by the Appellant

In submitting the appeal the Appellant applies 'for a change of the contested decision in the section regarding separate registrations for "pure SDA" and "mixture SDA"

Pleas in law and main arguments

The contested decision was adopted on 4 July 2012 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the substance 'Product of Semi-Dry Absorption method of Flue Gas Desulphurization'.

In the contested decision, pursuant to Articles 41(1)(a), 41(3) and 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): a description of the manufacturing process of the UVCB substance to identify the name of the registered substance; and
- Composition of the substance (Annex VI, 2.3.): information to establish and verify the composition and the name of the registered substance.

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

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chemical name and the more detailed description of the manufacturing process. In this case the Registrant provided a detailed description of the technological processes used for desulphurization of exhaust gases from coal-fired power plants. Based on this information, the description covers not only the desulphurization manufacturing process carried out with the preliminary dust (ash) extraction step but also the desulphurization with partial or no dust extraction. As a result, substances referred to in the registration dossier as "pure SDA" or "mixture SDA Product and ash" can be obtained. The Agency notes that significant differences in the composition of the "pure SDA" and the "mixture SDA Product and ash" can exist depending on whether the preliminary dust extraction step is applied or not. Accordingly the Agency regards the substance referred to as "pure SDA" and the "mixture SDA Product and ash" as different substances under REACH which require separate registrations. Accordingly, the Registrant is requested to remove from the dossier any information which does not refer to the registered substance (i.e. SDA product, obtained by the desulphurization process with preliminary dust extraction; "SDA Product"). The Registrant is also requested to ensure that the chemical name and the description of the manufacturing process take into account the dust extraction steps and that the chemical name and the description of the manufacturing process shall be representative for the registered substance.

2. Regarding the composition of the registered substance (Annex VI, 2.3) the Agency stated that the registration dossier contains three different compositions but the registered substance ("SDA Product") can be obtained only in the desulphurization process with preliminary dust separation step. Furthermore the composition in the registration dossier is not specific for the registrant but only contains constituents and their corresponding concentration ranges as they were agreed within the SIEF. The Registrant is requested to revise the composition information and provide information that is specific to the manufactured substance and to support this information by the provision of analytical data. The Registrant is requested to submit the missing description, and results, of the analytical method(s) used for the identification and quantification of the registered substance ("SDA Product") including its constituents.

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. The registration dossier complies with the requirements of the REACH Regulation including correct identification of the registered substance. The description of the manufacturing process of the substance is very detailed and exact and should not give any doubts as to the identity of the UVCB substance.
- 2. The REACH Regulation defines that only chemical substances are subject to registration. The documentation provided is therefore sufficient for both kinds of SDA, provided that companies having the mixture of SDA and ash have registered both pure SDA and ashes from coal. The Appellant accepts the requirement for the registration dossier to only include information regarding "pure SDA". However, they cannot agree with the grounds for separate registration of the 'mixture' as they possess tests, analyses and expert opinions confirming their position that the mixture of ashes with SDA is only a mixture of two substances which do not react with each other and is therefore not subject to registration.
- 3. Obtaining "pure SDA" and "mixture of SDA and ash" only depends on the place of dust extraction in the coal combustion process. The components of the "mixture of SDA and



- ash" are only connected by the fact that they are manufactured at the same time and place and cannot be isolated from each other as a result.
- 4. The Appellant states that the toxicological and ecotoxicological properties of the mixture of ash with the products of flue gas desulphurization are not worse than those of pure SDA. The Appellant's strategy regarding the identification of the registered substance is correct and they see no reasons for submitting a separate registration for the mixture of SDA and ash as this is a mixture of two substances both of which have already been registered.

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