

Decision number: CCH-D-0000003075-80-05/F

Helsinki, 9 July 2013

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Ashes (residues), plant, CAS No 93333-79-0 (EC No 297-049-5), registration number [REDACTED]
Addressee: [REDACTED]**

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for Ashes (residues), plant, CAS No 93333-79-0 (EC No 297-049-5) submitted by [REDACTED] (Registrant).

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 23 April 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation. The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 14 April 2012.

On 21 November 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 December 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received.
On basis of the comments, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 23 April 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

- a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below; and
- b. Composition of the substance (Annex VI, 2.3.), as specified under section III.(b) below.

Taking into consideration the data currently available in the dossier, section III. below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA is not in the position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in section III. below and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **9 January 2014**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Missing information related to substance identity:

One of the key objectives of the REACH Regulation is to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH Regulation). In order to achieve this objective, the registration provisions under REACH impose to manufacturer and

importer to provide a set of information as codified in Annexes I and VI to X of the REACH Regulation that shall allow the determination of hazards and risks of substances manufactured in or imported to the European Union (Articles 10, 12 of the REACH Regulation, see as well Recital 17 of the REACH Regulation). Within these information requirements, substance identification constitutes a requirement of its own, pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation. Annex VI, section 2 lists the information requirements that shall be sufficient to identify the registered substance. The unambiguous identification of the registered substance subject to the present decision is fundamental to establish what the substance actually manufactured or imported consists of, and to set the basis around which the hazards and risks with regard to that substance shall be determined. Where the substance is not unambiguously identified, ECHA may not be able to independently verify that hazard and exposure information submitted in a registration dossier is relevant for the substance that was intended to be registered.

(a) Name or other identifier of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as UVCB. The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. According to the ECHA "Guidance for the identification and naming of substances under REACH and CLP" (Version: 1.2, March 2012) referred to as "the Guidance" thereafter, UVCB substances cannot be sufficiently identified by their chemical composition and the main identifier for UVCB substances is the description of the manufacturing process, including final or most relevant steps of the processing. ECHA observes that the description of the manufacturing process has not been provided in IUCLID section 1.1 and the brief description included in IUCLID section 3.1 is not sufficiently detailed to allow unambiguous identification of the registered substance.

More specifically, the EC entry used by the Registrant indicates that the registered substance corresponds to residual ashes formed during the burning of a combination of plants. The Registrant specified in IUCLID section 3.1 that the substance is a "residuum from the burning in Fluidized Bed or classical Combustion boilers". Furthermore, based on the information included in the dossier different fractions of ashes might be collected (fly ash, bottom ash).

However details on the different manufacturing process (combustion technologies) including identity and ratio of the fuel(s), operating parameters and relevant steps (e.g. fractionation) used in the combustion process have not been provided in the dossier. ECHA points out that according to section 4.3 of the ECHA Guidance referenced above, any significant change in the manufacturing process of a UVCB substance would be likely to lead to a different substance that should be registered separately. It is expected that such significant differences in the manufacturing process will be reflected in the composition of the final product. Hence ECHA presumes that the combustion technology (fluidized bed or classical combustion) and procedure of collection of the ashes (bottom or top part of the boiler) should be normally regarded as crucial parameters of the manufacturing process, determining the composition of the registered substance and therefore its identity. However no information how the choice of the combustion technology affects the composition of the registered substance is present in the dossier. Also, the information on the mineralogical composition of different fractions (fly and bottom ashes) provided in section 1.4 of the IUCLID dossier, is not sufficient as such to determine whether these fractions might be regarded as part of the same substance, since significant part of them is amorphous (█ respectively). ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail to understand how the combustion technology and fractionation affects the composition and therefore identity of the registered substance.

In line with the above, the Registrant is requested to provide detailed information on the process(es) used for the manufacturing of the registered substance. In particular, the identity of the fuels used, their ratio, information on the collection, storage of the ashes and their post treatment (if any), operating parameters (temperature and pressure) and any other relevant data shall be provided separately for each of the specified technologies (fluidized bed and classical combustion). Unless it is proven that different combustion technologies and fractionation steps lead to the same substance (by demonstrating at least that the composition is known and consists of the same well defined predominant constituents), the substances originating from significantly different manufacturing processes (in this case different combustion technologies) or process steps (including collection/fractionation) shall be regarded as different substances under REACH, which require separate registrations. The Registrant shall not report information which refers to multiple substances.

Regarding how to report the description of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1. Flow charts can be included in section 1.4 of the IUCLID dossier.

(b) Composition of the substance (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, the Registrant provided a composition for the registered substance where the major constituents are expressed as (hypothetical) oxides. However the composition of the registered substance is not in line with the results of the analysis attached in section 1.4 as it is based solely on the selected results of the elemental analysis. Namely, some of the mineralogical phases identified and quantified by the X-ray diffraction analysis (e.g. feldspar minerals, arcanite) and also hypothetical oxides determined by elemental analysis (e.g. Al_2O_3 , P_2O_5) have not been individually reported in IUCLID section 1.2. The residual organic part (TOC) has also not been reported in section 1.2. Furthermore, the XRD analysis was recorded on both upper (sample BMA/P/2008) and bottom (sample BMA/Š/2008) fraction of ashes, however it is not clear on which fraction of the ashes (upper or bottom) the elemental analysis was performed (sample BMA/F/2009). Also, it is not clear whether this composition (and related result of elemental analysis) refer to the substance obtained by the Classical or Fluidized Bed Combustion technology.

In addition ECHA observes that exceptionally wide concentration ranges have been provided for some constituents. The origin of these variations in composition is not justified by the manufacturing process circumstances due to its lack of detail (see section III.(a)). Therefore it is not clear whether these variations are related to the variability in the source used or to the specific process condition. While inherent variations due to the composition of the raw materials are acceptable, compositions referring to substances obtained by significantly different technological processes shall normally be regarded as different substances, as explained under section III.(a). ECHA therefore concludes that the reported composition potentially covers substances which may differ significantly by their composition and appear thus not to be manufactured under the same process conditions.

For other constituents reported in IUCLID section 1.2 the concentration ranges have not been provided. The identity of the first listed constituent (silicon dioxide) is ambiguous as the EC and CAS numbers refer to a generic substance, whereas in the remarks field the specific form of SiO₂ is indicated ("Quarz").

In line with the above, the Registrant is requested to provide the composition(s) of the registered substance representative for different fractions (fly and bottom ash) originating from different combustion techniques (classical and fluidized bed combustion). Hence:

- The composition of fly ash and composition of bottom ash from the classical combustion; and
- The composition of fly ash and composition of bottom ash from the fluidized bed combustion

shall be reported separately in the registration dossier. If any other technology is applied for combustion, composition of respective ashes shall be reported accordingly to the example given above.

Following section 4.3 of the Guidance, the Registrant should note that for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of $\geq 10\%$ shall be identified and reported individually;
- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
- Any other known constituent shall also be specified; and
- Unknown constituents shall, whenever possible, be identified by a generic description of their chemical nature.

For each constituent and group of constituent, the typical, minimum and maximum concentration levels shall be specified.

For this kind of substance ECHA usually expects a differentiation between crystalline constituents reported as such (i.e. respective minerals) and amorphous constituents (reported as hypothetical oxides) unless more specific information is known.

As already pointed out in Section III.(a) of this decision, the Registrant shall ensure that compositions originating from significantly different manufacturing processes or process steps (including collection/fractionation) still refer to the same substance under REACH. The Registrant shall delete from the registration any reference to compositions which do not refer to the specific substance which is the subject of this registration. The Registrant shall also ensure that the compositional information refers to one substance and that is representative of the substance as it is manufactured.

Regarding how to report the information in IUCLID, the following applies:

- Any composition shall be reported in IUCLID section 1.2.
- For each constituent required to be reported individually (known constituents), the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.
- For the other constituents to be reported under a generic description (e.g. TOC), a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.
- The concentration range values must be representative for the registered substance as manufactured and it shall be stated how the minimum and maximum values for each groups of constituents within one composition were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.), as

without this information ECHA is not able to conclude on the specificity and representativeness of these values. Details of the protocol followed to determine the different concentration values of each group of constituents shall be provided in the Remarks field of the corresponding repeatable block for that group.

Each composition listed in IUCLID section 1.2 must be supported by the relevant analytical data (e.g. elemental analysis and XRD). For each reported composition the combustion technology and origin of the fraction (fly/bottom) shall be stated in the Brief description field for that composition in IUCLID. In order to understand the similarities/differences between different fractions of ashes (fly and bottom) within one combustion technology, the spot samples selected for the analysis shall represent the same manufacturing campaign, where the fuel and process parameters (e.g. temperature) are common for bottom and fly ashes until the separation point.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website. The analytical information that is necessary to verify any composition of the registered substance shall be reported in IUCLID section 1.4.

In its comments submitted in accordance with Article 51(1) of the REACH Regulation, the Registrant expressed commitment to provide the chemical and mineralogical composition of fly and bottom ashes together with a justification of concentration ranges in comparison to the chemical composition of used fuels in the update of the registration dossier. Additionally, the Registrant requested an extension of the period to provide the information from three to five months. The Registrant justified the additional time needed by the necessity to communicate with the other registrants of the substance subject to the present decision in order to get precise and detailed information on all differences of the production process, to obtain representative samples of ashes and fuels, and to have sufficient time for analyses, evaluation and explanation. ECHA found the justification for the deadline extension adequate and amended the current draft decision accordingly.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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