EUROPEAN CHEMICALS AGENCY

Decision number:CCH-D-0000003077-76-04/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), nonhazardous municipal solid waste, CAS No to be determined (EC No to be determined), 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), nonhazardous municipal solid waste, CAS No to be determined (EC No to be determined) 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 registration at a later stage.

The compliance check was initiated on 02 November 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.

By 21 December 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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;
b. Composition of the substance (Annex VI, 2.3.), as specified under section III.(b) below and
c. Description of the analytical methods (Annex VI, 2.3.7.), as specified under section III.(c) 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 09 October 2013.

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" thereinafter, 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 included in IUCLID sections 1.1 and 3.1 is not sufficiently detailed to allow unambiguous identification of the registered substance.

More specifically, the Registrant indicated different types of waste as a starting material for the registered substance. In the chemical name of the registered substance ("Ashes (residues), nonhazardous municipal solid waste"), the Registrant indicated that the source material used for the manufacturing of the registered substance is a "nonhazardous municipal solid waste". This is not consistent with the information on the manufacturing process provided in IUCLID sections 1.1 and 3.1. In the description field in section 1.1 of the IUCLID dossier the Registrant indicated that the registered substance corresponds to residual ashes formed during the combustion of a "municipal and non-hazardous industrial waste", while in section 3.1 of the dossier "[redacted]" is indicated as the source material used. Thus, the nature and identity of wastes used as starting materials, as well as their selection criteria/limitations remains unknown. It is also not mentioned whether other secondary fuels are used in the combustion.

Furthermore, the description of the manufacturing process provided in IUCLID sections 1.1 and 3.1 indicates that two different fractions ([redacted]) are collected. One of these ([redacted]) is further processed (extracted), while the other ([redacted]) is cooled in a water bath. Finally both fractions are mixed. 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 would be reflected in the composition of the respective fractions [redacted]

[redacted], respectively. However, no information on how the fractionation and post processing affects the composition of the registered substance is present, as only one composition representing a mixture of both fractions is provided in section 1.2 of the IUCLID dossier (see section III.(b) below). In addition it is not clear whether the mixing step of different fractions of ashes is an inherent part of the same manufacturing process. ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail in order to understand how the 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 and mixing of ashes and their post treatment, operating parameters (temperature and pressure) and any other relevant data shall be provided. In order to unambiguously identify wastes used as raw materials, the specific index number from the EC harmonized list of wastes (Commission Decision 2000/532/EC of 3 May 2000) should be provided. If different fractions are isolated on their own from the process, the description of the manufacturing process shall be provided separately for each fraction. The manufacturing processing steps shall be provided in the order they occur. Unless it is proved that different fractionation steps lead to the same substance (e.g. by having the same well defined predominant constituents), products originating from significantly different process steps (including collection/fractionation and post-treatment) shall be normally regarded as different substances under REACH, which shall be covered by separate registrations. In addition ECHA underlines that the substances originating from other combustion technologies than specified in section 3.1 of the IUCLID dossier ("[redacted]"), shall be normally also regarded as different substances under REACH.

The Registrant shall also ensure that the registered product does not meet the criteria of mixtures as defined in Article 3(2) of the REACH Regulation. ECHA underlines that despite of the fact that a mixture as such is not the subject of registration under REACH, the registration obligation applies to the substances forming the mixture as per Article 6 of the REACH regulation. The Registrant shall not report information which refers to multiple substances or mixtures in one registration dossier.

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 cornerstone 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 two compositions for the registered substance: composition based on X-Ray diffraction analysis (mineralogy) and an elemental composition expressed as (hypothetical) oxides. Both of these compositions refer to the mixture of bottom and fly ashes. ECHA observes that exceptionally wide concentration ranges have been provided for some constituents. This may potentially lead to the situations when one constituent or group of constituents is predominant in some compositions, while in the others this constituent is minor or even absent. 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 perfectly acceptable, compositions referring to different fractions of the ash shall normally be regarded as different substances, as explained under section III.(a). ECHA therefore concludes that the reported composition covers fractions which may differ significantly by their composition and appear thus not to be manufactured under the same process conditions.

In addition, the mineralogical composition indicates the presence of amorphous phase (as a major constituent) which is represented by the generic constituent "[redacted]. This EC number should however not be used as an identifier for that constituent. The EC entry associated with EC number [redacted] refers solely to the specific chemical substances formed during the production of inorganic glasses. This entry is therefore not appropriate identifier for other constituents/substances, such as ashes, which are manufactured using different raw materials and technological process. Furthermore, concentration ranges for four other mineral constituents ([redacted]) have not been provided. The analytical report indicates also the presence of some volatile constituents (e.g. "loss by ignition", "loss by drying") which have not been included in the composition of the registered substance.

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) separately in the registration dossier.

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 ≥ 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 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. The EC entry [redacted] shall not be used as an identifier of the amorphous part of this kind of UVCB substance.

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. total organic carbon), 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 group 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 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.

c) Description of the analytical methods (Annex VI, 2.3.7)

ECHA notes that the description of some of the analytical methods used for the chemical analysis of the registered substance is not sufficient, as only a reference to the standard operating procedures (ref. [redacted]), which are not available publicly, is provided.

Therefore the Registrant is requested to provide a description of the analytical methods used for the chemical analysis (ref. [redacted], listed in the table included on the page 3 "Used test procedures" and page 4 "Test results" of the attached document "[redacted]") of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. If the description is not sufficient for the method to be reproduced by any third party laboratory, ECHA will consider the description insufficiently detailed. In that case, the information requirement under Annex VI section 2.3.7 will not be fulfilled.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

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.

[redacted]
Jukka Malm
Director of Regulatory Affairs