EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003415-78-02/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 from fluidized bed combustion, 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 FBC Ash, 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 present dossier at a later stage.

The compliance check was initiated on 11 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 21 December 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 31 January 2013 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received.

The newly provided information in the updated registration dossier is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

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 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 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.

As examples of hazardous constituents present in combustion residues can be named metals, polycyclic aromatic hydrocarbons and silica. Combustion residues may contain a broad range of metals, for example, arsenic, selenium, cadmium, lead, and mercury depending on the source of the fuel. Though the concentrations of these constituents are generally low, if not properly managed, they may cause a risk to human health and the environment. Incomplete combustion leads to variety of products corresponding to the content of total organic carbon (TOC) in the residues. TOC includes polycyclic aromatic hydrocarbons (PAHs), a large group of organic compounds with highly persistent properties in environment. Additionally, some of the PAHs exert toxic, mutagenic and carcinogenic effects. Besides the type or source of the burned fuel, formation of PAHs is influenced by and varies depending on the combustion conditions such as temperature, oxygen, residence time and turbulence. Furthermore, distinct fractions of ashes can differ in the PAHs content. Namely, there are studies showing that PAH levels vary between fly and bottom ash fraction. Crystalline silica (quartz, cristobalite) is classified as human carcinogen and the respirable fraction is liable to cause silicosis and lung cancer. Also broad concentration ranges for some of the constituents which cannot be linked with the source or with description of the manufacturing process raise concern for potential hazards and risks. [1]

[[1] Reference list:
Wheathley A. and Sadhra S., Polycyclic aromatic hydrocarbons in solid residues. *Chemosphere*, (2004) 743-749.
Stefanova M. *et al.*, PAHs in fly ash from lignite combustion. *Bulletin of the Geological Society of Greece*, (2007) 1499-1504
Harrison L., Respirable Crystalline Silica (RCS) – Carcinogenicity, *Advisory Committee on toxic substances, Health and Safety Executive UK*, 2008
Johansson I. and van Bavel B., Levels and patterns of polycyclic aromatic hydrocarbons in incineration ashes. *The Science of the Total Environment*, (2003) 221-231
Sulovsky P., Mineralogy and chemistry of conventional and fludised bed coal ashes. *Bulletin of the Czech Geological Survey*, (2002) 1-11
Stewens W. *et al.*, The cementitious and pozzolanic properties of fluidized bed combustion fly ash. World of Coal Ash Conference 2009, Lexington, KY, USA, Ash Library
Ennel A. *et al.*, Polycyclic aromatic hydrocarbons in ash: Determination of total and leachable concentrations. *Environmental Pollution*, (2008) 285-292
FitzGerald T., Current issuesin the regulation of coal ash. World of Coal Ash Conference 2009, Lexington, KY, USA, Ash Library
Borm P.J.A., Toxicity and occupational health hazards of coal fly ash (CFA). A review of data and comparison to coal mine dust. *The Annals of Occupational Hygiene*, (1997) 659-676
Blumenstock M *et al.*, Influence of combustion conditions on the PCDD/F-, PCB-, PCBz- and PAH-concentrations in the post-combustion chamber of a waste incineration pilot plant. *Chemosphere*, (2000) 987-993
Andersson P. and Marklund S., Emissions of organic compounds from biofuel combustion and influence of different control parameters using a laboratory scale incinerator. *Chemosphere* (1998) 1429-1443]

(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 section 3.1 is not sufficiently detailed to allow unambiguous identification of the registered substance.

More specifically, the Registrant indicated that the registered substance corresponds to ashes from fluidized bed combustion coal fired power stations with co-combustion of secondary fuels. With the update of the registration dossier in January 2013 anthracite, hard coal and lignite are indicated as the primary fuels and biomass of plant origin as an example of a secondary fuel. Initially reference was made only to not further specified secondary fuels. Furthermore different fractions of ashes are collected (fly ash, bottom ash) and a desulfurisation takes place.

However further details on the manufacturing process including identity and ratios of the secondary fuel(s) used in the combustion process (in the form of exhaustive list) have not been provided in the updated 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 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, only limited information on how the fractionation of ashes affects the composition of the registered substance (and its variability expressed by the concentration range values for each constituent in all reported compositions) is present in the dossier. The clarification provided by the Registrant in the dossier update referred to the source of primary fuels and indicated only an example of secondary fuel, i.e. remained unclear concerning further secondary fuels that may be used. As explained, the information on the sources is only one relevant element of the identification of the substance. ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail to understand how the fractionation affects the composition and its variability 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 secondary fuels used, their ratios, and any other relevant data shall be provided . Unless it is proven that different 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 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 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, with the update of the registration dossier in January 2013, the Registrant provided four compositions: *"FBC Fly Ash - Composition of Lead Registrant"*, *"FBC Bottom Ash - Composition of Lead Registrant"*, *"FBC Fly Ash – mineralogy"* and *"FBC Bottom Ash – mineralogy"*.

The concentration range values (minimum and maximum) have not been reported for any constituent in *"FBC Bottom Ash - mineralogy"*. The concentration range values for only two constituents have been reported in *"FBC Fly Ash – mineralogy"*. On the other hand ECHA observes that exceptionally wide concentration ranges have been provided for some constituents in *"FBC Fly Ash - Composition of Lead registrant"*, in *"FBC Bottom Ash - Composition of Lead Registrant"* and in *"FBC Fly Ash – mineralogy"*. 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 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 compositions potentially represent different substances that shall not be covered by one registration.

Moreover, some of the mineralogical phases identified and quantified by the X-ray diffraction analysis have not been individually reported in IUCLID section 1.2.

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.

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 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 constituent and group of constituents were obtained (i.e. information on the samples selection (including information on primary and secondary fuels), 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 constituent and 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) and the fuels used 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), the spot samples selected for the analysis shall represent the same manufacturing campaign, where the fuel, desulfurisation agent 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.

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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Jukka Malm
Director of Regulatory Affairs