ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003537-70-04/F Helsinki, 30 June 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For vinasses, residue of fermentation, List No 932-215-9, 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 for vinasses, residue of fermentation, List No 932-215-9, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 6 March 2014, 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.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 2 August 2013.

On 13 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

On 27 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision and asking for an extension of the given deadline to provide the requested information up to 6 months.
The ECHA Secretariat considered the Registrant's comments and request to extend the deadline to provide the requested information and amended Sections II and III of the draft decision.

On 6 March 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, 2.1.);
2. Composition of the substance (Annex VI, 2.3.);
3. Spectral data (Annex VI, 2.3.5.);
4. High-pressure liquid chromatogram or gas chromatogram (Annex VI, 2.3.6.);
5. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **7 January 2015.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1) Name or other identifier of the substance (Annex VI Section 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2. 1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient information on the manufacturing process, as explained thereinafter.

The registered substance corresponds, according to the chemical name assigned by the Registrant in section 1.1 of the IUCLID dossier, to vinasses obtained as a residue of fermentation. For this substance, the Registrant provided, in the same section of IUCLID, a description of the manufacturing process consisting of two main stages: fermentation and downstream processing [redacted]. However, both stages are not considered sufficiently detailed.

- The fermentation

  The description of the fermentation stage is not sufficiently detailed for different reasons.

  Firstly, the micro-organism used is described by the Registrant as having a "[redacted]" However, no further information on the identity of the micro-organism is included. ECHA notes that the Registrant also submitted, in section 13 of the IUCLID dossier, a document entitled "[redacted]" which mentions that "[redacted]" (see chapter 4.1 of the document). Moreover, even if the micro-organism is not a constituent of the substance, it has an impact on the fermentation products and therefore its identity is normally expected to be one of the determinants for the final composition of the registered substance and must accordingly be specified for the identification of the UVCB substance manufactured by the Registrant.

  Secondly, the fermentation medium used for the manufacturing of the registered vinasses is described by the Registrant as a "[redacted]". However, no further information is included on the identity of the substrates and [redacted]. Moreover, the list of families of substrates and fermentation [redacted] provided in the "[redacted]" (see chapter 4.2 of the document) does not establish the substrates and [redacted] effectively used by the Registrant himself as it is neither exhaustive nor registrant-specific. ECHA takes note that the document also states that "[redacted]". However, in chapter 5.2 of the same document, it is indicated that the residues of the fermentation feedstock and [redacted] are present in the vinasses. The identity and the ratio/concentration of the starting materials therefore are one of the determinants of the composition of the registered substance and must accordingly be specified for the identification of the UVCB substance manufactured by the Registrant.

  Finally, the fermentation parameters have not been reported in the dossier.

- The downstream processing

  The manufacturing process description provided by the Registrant specifies that the fermentation is followed by [redacted]. For the [redacted] the Registrant did not provide any information regarding the methods used. Additionally, for the [redacted], chapter 4.4 of the attachment "[redacted]

[redacted]" specifies that this process corresponds to the [redacted] solvent [redacted] without any change in the composition of the vinasses [redacted] However, the document also specifies that "[redacted]". It follows that the addition of these processing aids normally results in a change of the composition between the [redacted] itself. However, the Registrant did not specify the chemical identity of these processing aids. The chemical nature of these processing aids cannot be derived from the composition of the registered substance currently reported in the dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the missing information on the description of the process used for the manufacturing of the registered substance. The description shall include:

- the relevant parameters for the fermentation: the identity of the micro-organism, the raw material used as starting material, incubation control parameters (such as temperature, pH, pressure, time, nutrients, agitation, airflow, redox), the identity of the solvent(s) and identity of the processing aid substances such as pH controlling agents and defoamers; and
- the relevant methods and parameters used in the [redacted] step; and
- the relevant parameters for the [redacted] of the downstream processing, more specifically the actual technique used ([redacted]) and the identity of the relevant processing aid substance used (e.g pH controlling agents and defoamers).

The Registrant shall ensure that the information is consistent throughout the dossier. Where the Registrant covers different grades of the substance in a registration, the Registrant shall report separately the source, manufacturing process of each grade. ECHA highlights that grades for which a manufacturing process description is not provided may eventually not be considered being covered by the registration.

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

2) The composition of the substance (Annex VI, 2.3.)

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity. More specifically, ECHA notes that one generic reference substance covering all constituents of the UVCB substance has been reported in the IUCLID section 1.2. No specific information was provided on the constituents and groups of constituents expected to be present in the composition of the registered substance such as metabolic side products, major organic components (e.g. organic acids, alcohols, sugars, proteins, phenolic compounds etc.) and inorganic components (e.g. inorganic salts).

According to section 4.3 of the Guidance, the Registrant shall 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 known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. Regarding the unknown metabolic side products and major organic components, these constituents shall be grouped by their nature and molecular weight:
    - low molecular weight organic compounds: acids, alcohols, sugars, phenolic compounds, polyols, peptides;
    - high molecular weight organic compounds: proteins, carbohydrates (polysaccharides, glycans), nucleic acids, lipids.

For each constituent and group of constituents, the minimum, maximum and typical concentration, shall be reported.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the the identity and concentration values of the constituents and groups of constituents required to be reported in the composition.

The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA underlines that, for the reporting of the [redacted] constituents, the Registrant shall, as a baseline, report individually each [redacted] present in the composition of the substance. For those [redacted] for which the speciation can technically not be determined, the Registrant shall report instead the individual [redacted]. The Registrant shall include a scientific justification as to why the speciation of any reported [redacted] can technically not be determined. The Registrant shall ensure that the information is sufficient for ECHA to have a compositional representation of the [redacted] constituents in the registered substance.

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

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. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

3) The spectral data (Annex VI, 2.3.5. of the REACH Regulation)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain any spectral data. Instead, the Registrant includes justifications for not providing this information. According to the justifications, the Registrant considers the required spectral data as not helpful to scientifically identify such complex substance. ECHA however points out that spectral data is a standard requirement of Annex VI, Section 2.3.5. Contrary to the Registrant's justifications, ECHA regards the required spectral data as scientifically necessary for the identification of the registered substance since the substance has organic constituents and therefore contains functional groups which can be detected by spectral analytical methods. These spectra can furthermore be used to fingerprint complex substances such as the registered UVCB substance.

Accordingly, spectral data required to be provided pursuant to Annex VI, 2.3.5. of the REACH Regulation (including the Ultra Violet and Infra-Red and Nuclear Magnetic Resonance (such as a ^{1}H-NMR) spectra or, as an alternative to the NMR spectrum, mass spectra from a mass spectroscopic analysis of the registered substance) is considered necessary for the identification of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct spectral data as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

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

4) The High-pressure liquid chromatogram or Gas chromatogram (Annex VI, 2.3.6.)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain High-pressure liquid chromatogram (HPLC) or Gas chromatogram (GC). Instead, the Registrant includes justifications for not providing a GC. According to the justifications, the Registrant considers the required GC as not helpful to scientifically identify such complex substance. ECHA however points out that HPLC or GC chromatogram is a standard requirement of Annex VI, Section 2.3.6. Contrary to the Registrant's justifications, ECHA regards the required chromatograms as scientifically necessary for the identification of the registered substance since these techniques provide valuable fingerprints of the registered substance.

Accordingly, appropriate chromatographic data required to be provided pursuant to Annex VI, 2.3.6. of the REACH Regulation is considered necessary for the identification of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the correct chromatographic data. The information shall include the

report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area.

The Registrant shall ensure that the information is consistent throughout the dossier.

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

The Registrant shall ensure that the description of the analytical method used for the chromatographic analysis, including the experimental set-up (i.e. the column type, length and diameter; injection volume; mobile phase/carrier gas; GC temperature programme; flow rate; concentrations of HPLC standard solutions; detection technique; and run time) and preparation of solutions and identity of standards, is specified, in line with the requirements of Annex VI section 2.3.7.

5) The description of the analytical methods (Annex VI, 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

More specifically, ECHA notes that the Registrant provided an analytical report in section 1.4 of the IUCLID dossier where analytical methods used for the quantitative analysis of the substance are described by a reference code. The results presented in the report however do not enable to establish the composition of the registered substance to the level of detail specified in section III.A.2 of this decision and required for the identification of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition 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.

The Registrant shall ensure that the information is consistent throughout the dossier.

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

6) Deadline for submitting of the requested information

When submitting comments on the draft decision, the Registrant asked to extend the deadline for submitting requested information to 6 months. The Registrant's justification for this request was the need for additional time for investigation of the appropriate methods and conditions of analyses which will allow generation of the required analytical data. ECHA evaluated the justification provided and decided to change the deadline from 3 to 6 months.

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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Leena Ylä-Mononen
Director of Evaluation