EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003880-73-03/F Helsinki, 16 December 2013

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

For Subtilisin, CAS No 9014-01-1 (EC No 232-752-2), 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 Subtilisin, CAS No 9014-01-1 (EC No 232-752-2), submitted by Novozymes A/S (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI) or those of Annexes VII to IX relating to aquatic toxicity.

This decision is based on the registration 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 submitted after 5 September 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.

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 10 May 2013.

On 28 June 2013 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 2 July 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 5 September 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), 10(a)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Title I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- the hazard classification of the registered substance for chronic aquatic toxicity Category 1 based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (b)(i) or (ii) and 4.1.4), as specified in section III below. In the alternative, the Registrant is required to provide reasons why no such classification is given.

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 **16 March 2014**.

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 requirement. The scope of the present decision is limited to classification and labelling for aquatic toxicity (Annex VI, Section 4.1 and 4.2 of the REACH Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the dossier:

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In addition, for each entry, reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes the following:

The technical dossier includes aquatic chronic toxicity studies indicating a NOEC or equivalent value equal to or lower than 0.01 mg/l which is considered reliable by the Registrant (Klimisch score 1 or 2). However the Registrant has not classified the substance as Aquatic Chronic Hazard Category 1 and used the resulting hazard statement "H410: Very toxic to aquatic life with long lasting effects", which would be in line with the criteria set out in Part 4 of Annex 1 of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. (b)(i) or (ii) and 4.1.4 of the CLP Regulation).

In the comments submitted 2 July 2013, the Registrant stated that in order to obtain a better safety factor for PNEC estimation and due to poor recovery and clear indications from acute aquatic toxicity studies that Daphnia are the most sensitive species towards the registered substance, the Registrant had decided to repeat the Daphnia reproduction test. The Registrant proposed to update their registration dossier with the new long-term Daphnia study also verifying classification and other relevant parts of their dossiers accordingly as soon as the study is completed. The Registrant indicated to submit an updated technical dossier in October 2013 and wished ECHA to postpone the decision making process until then.

ECHA considers that acquiring new data does not affect the Registrant's ability to comply with the request in the draft decision as the Registrant, based on available information in the technical dossier, is able to either classify or to provide reasons why no such classification is given. The Registrant was informed of ECHA's decision to proceed with the decision making process.

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP Regulation as specified above and is consistent with the data on aquatic toxicity available in the registration dossier. The Registrant shall also provide resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (b)(i) or (ii) and 4.1.4). In the alternative, the Registrant is required to provide reasons why no such classification is given.

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

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]
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