~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001715-74-03/F Helsinki, 21/10/2011

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

For Cyanuric acid, CAS 108-80-5 (EC 203-618-0); 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 Cyanuric acid, CAS No.108-80-5 (EC No. 203-618-0) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 14 April 2011.

On 8 June 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 27 June 2011 the Registrant provided to ECHA comments on the draft decision.

On 29 July 2011 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. 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.

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

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 12(1)(e), 13(3) and Annex VII of the REACH Regulation the Registrant shall submit the information on using the test method as indicated below

1) *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. *E. coli WP2* uvrA, or *E. coli* uvrA (pKM101), or *S. typhimurium TA102*, following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

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 **22 October 2012**, 12 months from the date of the decision.

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 per year or more in accordance with Articles 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annex VII 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.

1) Missing information related to mutagenicity

According to Annex VII, section 8.4, *in vitro* gene mutation study using bacteria (Ames test) is a standard information requirement at the present tonnage level.

ECHA notes that for the endpoint required by section 8.4.1 of Annex VII, *in vitro* gene mutation study in bacteria, the Registrant provided data from two *in vitro* gene mutation studies in bacteria performed according to proposed guidelines for registering pesticides in the U.S.: Hazard Evaluation: Humans and domestic animals, Section 163.84-1 (43 FR 37388) (1980) and a scientific publication with no guideline (1985).

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA. Other tests may be used if the conditions of Annex XI are met.

In the present case, the tests submitted were carried out with no reference to the test methods recognised by the Commission or ECHA, which means that the studies do not meet the requirements in current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

The version of the EU Test Method B.13/14/OECD TG 471 in force since 1997 introduces the need to perform the test in at least five strains of bacteria. The required fifth bacterial strain, i.e. *Escherichia coli WP2* strains or *S. typhimurium TA102*, has the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which the four bacterial strains used in the studies may not detect.

The Registrant indicated in his comments to the draft decision to accept the information requests for the above-mentioned test.

Consequently, the Registrant is required to complete the data set on mutagenicity by performing an *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1) using one bacterial strain which may detect mutagens, such as cross-linking agents or oxidising mutagens, i.e. *E. coli WP2* uvrA, or *E. coli* uvrA (pKM101), or *S. typhimurium TA102* , following recommendations of EU Method B.13/14 laid down in Commission Regulation (EC) No 440/2008 or OECD Test Guideline 471.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> "Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

V. 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs