EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002437-73-07/F Helsinki, 30 July 2013

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Silver nitrate, CAS No 7761-88-8 (EC No 231-853-9), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for Silver nitrate, CAS No 7761-88-8 (EC No 231-853-9), by [redacted] (Registrant).

- Long term toxicity to soil macroorganisms: OECD Guideline 222 (Earthworm Reproduction Test, (*Eisenia fetida/Eisenia andrei)*) using the registered substance.
- Long term toxicity to terrestrial plants: Test protocol based on ISO 11269-1 (1993), ISO 11269-2 (1995) and OECD guideline 208 using the registered substance.
- Toxicity to soil micro-organisms: OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) using the registered substance.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 18 January 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the present dossier at a later stage.

On 1 March 2012, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 19 October 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 15 November 2012 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. On basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 18 January 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 submitted proposals for amendment to the draft decision.

ECHA reviewed the proposals for amendment received and did not amend the draft decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 25 March 2013, the Registrant provided comments on one of the proposed amendments. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 April 2013 in a written procedure launched on 27 March 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance:

1. Long-term toxicity on terrestrial invertebrates (Annex IX, 9.4. column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);
2. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216); and
3. Long-term toxicity testing on plants (Annex X, 9.4.6; test method: Test protocol based on ISO 11269-1 (1993), ISO 11269-2 (1995) and OECD guideline 208);
   or
   Long-term toxicity testing on plants (Annex IX, 9.4. column 2; test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (and as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **30 April 2014** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Long-term toxicity on terrestrial invertebrates

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Short-term toxicity to terrestrial invertebrates is a standard information requirement as laid down in Annex IX, section 9.4.1. of the REACH Regulation. However, column 2 of that Annex specifies that long-term toxicity testing shall be considered by the registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent. ECHA notes that the registered substance, being inorganic, is stable in the environment and therefore long-term testing is more appropriate as the condition of column 2 is met.

While, information on this endpoint is available (OECD 222) in the registration dossier the Registrant has concluded that there is a need to perform further testing since:

"The toxicity of silver ion (Ag+) and silver nanoparticles (Ag NPs) in soils is poorly understood at present compared to other metals in soils (e.g. copper, zinc). The silver ion has been found to be toxic to both plants (Wallace et al. 1977) and soil microbial processes (Johansson et al. 1998; Throback et al. 2007). While the Ag+ ion is highly bactericidal and fungicidal, on addition to soil the ion is sorbed to organic matter and clays and its bioavailability is significantly reduced (Hou et al. 2005)."

and

"the amount of information available for Ag is very small and there are no models of soil bioavailability, ageing processes, or leaching factors, and even toxicity data are limited. Data on behaviour of other metals in soil cannot be used to infer reactions for Ag+ due to the different chemistry of Ag+ compared to other metals – for example, Ag+ retention in soil (Kd value) is much harder to predict from soil properties than, for example, Zn as noted in the very recent GEMAS partitioning studies (Janik et al. 2010). Furthermore, Ag+ is affected to a greater extent by complexation reactions in soils than many other metals e.g. chloride in saline soils, which complexes Ag+ and increases mobility – effects on bioavailability in soils are unknown. This project aims to address these knowledge gaps by examining Ag+ ion behaviour across a range of soils, and determine toxicity of Ag+ to key soil microbial processes, plants and soil invertebrates."

Given the properties of the registered substance, ECHA considers that the further testing on different soil types is justified since soil properties can have a pronounced impact on the observed effects. The justifications provided are sufficient to support the testing proposed. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study:

- Long-term toxicity on terrestrial invertebrates (Annex IX, 9.4. column 2; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);

using the registered substance.

2. Effects on soil micro-organisms

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Effects on soil micro-organisms is a standard information requirement as laid down in Annex IX, section 9.4.2 of the REACH Regulation. Column 2 of Section 9.4. of Annex IX of REACH specifies that in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. However, ECHA considers that the intrinsic properties of soil microbial communities are not addressed through the equilibrium partitioning extrapolation method. Thus, the hazard to soil microbial communities needs to be evaluated as a standard information requirement under Annex IX, 9.4.2. Therefore, ECHA concludes that the effects on soil micro-organisms need to be ascertained by performing a relevant test.

The Registrant proposed a nitrogen transformation test (OECD 216). According to ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), Chapter R.7C, R.7.11.3.1. p112, the nitrogen transformation test (OECD 216) is considered sufficient for most non-agrochemicals.

While, information on this endpoint is available (OECD 216) in the registration dossier the Registrant has concluded that there is a need to perform further testing and has provided justifications as outlined in section III.1. above. Given the properties of the registered substance, ECHA considers that the further testing on different soil types is justified since soil properties can have a pronounced impact on the observed effects. The justifications provided are sufficient to support the testing proposed.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study:

- Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216)

using the registered substance.

3. Long-term toxicity testing on plants

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Although information on toxicity testing in plants is available in the registration dossier ECHA understands that the Registrant proposes to generate data on the long-term toxicity of the substance to plants (Annex IX, section 9.4. column 2). Short-term toxicity testing on terrestrial plants is a standard information requirement as laid down in Annex IX, section 9.4.3. of the REACH Regulation. However, column 2 of that Annex specifies that long-term toxicity testing shall be considered by the registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent. ECHA notes that the registered substance, being inorganic, is stable in the environment and therefore long-term testing is more appropriate as the condition of column 2 is met.

The OECD 208 test detailed in the registration dossier was carried out using only two different plant species. The OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing ECHA considers six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline.

Regarding the test method, the Registrant initially proposed a seedling root elongation and seedling growth test protocol based on ISO 11269-1 (1993), ISO 11269-2 (1995) and OECD Test 227 (2000).

However, in the formal comments received by ECHA on 15 November 2012 the Registrant clarified that the reference to OECD 227 test guideline was proposed in error and that toxicity testing on plants is proposed to be performed according to OECD guideline 208. Furthermore, the Registrant indicated that a higher tier risk assessment methodology is to be employed.

ECHA notes that the minimum requirement for six plant species in the OECD 208 test, as explained above in this section, to cover the long term testing requirement is based on the assumption that a standard terrestrial risk assessment is to be performed where toxicity data for a limited number of taxonomic groups is to be used. Under such assumptions, it is appropriate to carry out the OECD 208 long-term test on plants using the minimum six plant species. However, if the Registrant intends to use higher tier assessment methodology this implies that a more robust risk assessment will be performed and hence the requirement for six species in the OECD 208 test may not apply. In this instance it may be appropriate to carry out the testing as proposed by the Registrant using a test protocol based on ISO 11269-1 (1993), ISO 11269-2 (1995) and OECD guideline 208.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to perform:

- Long-term toxicity testing on plants (Annex X, 9.4.6.; test method: Test protocol based on ISO 11269-1 (1993), ISO 11269-2 (1995) and OECD guideline 208);

or

- Long-term toxicity testing on plants (Annex IX, 9.4., column 2.; test method: Terrestrial plants, growth test, OECD 208 using at least six species (and as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline))

using the registered substance.

Once the results of the test become available it is the responsibility of the Registrant to assess the use of the test results to fulfil data requirements of the REACH Regulation and the use of the test results in the chemical safety assessment.

If the current OECD 208 data in the registration dossier is to be used to fulfil the long-term toxicity testing on terrestrial plants information requirement in the context of a standard terrestrial risk assessment with toxicity data from three taxonomic groups, a minimum of 4 additional species shall be tested using the same soil type as in the available study. The Registrant shall ensure that a minimum of two monocotyledonous species four dicotyledonous species from different groups are selected according to the criteria indicated in the OECD 208 guideline.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

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

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

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 or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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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