EUROPEAN CHEMICALS AGENCY

Helsinki, 10 December 2018

Addressee: [redacted]

Decision number: TPE-D-2114450362-57-01/F
Substance name: methyl-1h-benzotriazole
EC number: 249-596-6
CAS number: 29385-43-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 25/10/2016
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

While your originally proposed tests for

- Pre-natal developmental toxicity study (EU B.31./OECD TG 414);
- Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C;
- Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222);
- Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD TG 208);
- Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216)

using the analogue substance 1H-Benzotriazole (EC No 202-394-1) are rejected, you are requested to perform:

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rats or rabbits), oral route using the registered substance.**

2. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12°C including the identification of the degradation products (Annex IX, Section 9.2.3.) using the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.**

3. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**

   Or

4. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208) using the registered substance.**

5. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation.

To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by ***17 June 2020***. You also have to update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposals submitted by you.

TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION
In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Grouping and read-across approach for toxicological and ecotoxicological information

Your registration dossier contains for multiple endpoints adaptation arguments in form of a grouping and read-across approach according to Annex XI, 1.5 of the REACH Regulation. ECHA has assessed first the scientific and regulatory validity of your Grouping and read-across approach for toxicological and ecotoxicological endpoints in general before the individual endpoints (sections 1 - 5).

You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5. of the REACH Regulation, for the endpoints:

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.);
- Biodegradation in water and sediment: simulation tests (Annex IX, 9.2.1.2);
- Toxicity to terrestrial arthropods (Annex X; 9.4.4);
- Toxicity to terrestrial plants (Annex X, 9.4.6);
- Toxicity to soil microorganisms (Annex IX, 9.4.2).

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural aspects the chemical structures have in common and the differences between the structures of the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s) and (2) Different compounds have the same type of effect(s).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

A. Description of the grouping and read-across approach proposed by the Registrant

You have provided a read-across documentation as a separate attachment.

In your read-across documentation you propose read-across between the substances:

- 1H-Benzotriazole, EC No 202-394-1 (CAS No 95-14-7, here after 'benzotriazole'),
- 4(or 5)-methyl-1h-benzotriazole, EC 249-596-6 (CAS No 29385-43-1, here after 'methyl benzotriazole'),
- Sodium 1H-benzotriazolide (EC no. 239-269-6), here after 'sodium benzotriazolide') and
- Sodium 4(or 5)-methyl-1H-benzotriazolide (EC no. 265-004-9) (here after 'sodium methyl benzotriazolide').

You claim that either of these substances can be the source substance.

In your registration dossier you have provided testing proposals to achieve compliance with the REACH information requirements for the registered substance 4(or 5)-methyl-1h-benzotriazole, EC 249-596-6 (CAS No 29385-43-1, here after 'methyl benzotriazole'), using data of structurally similar substance 1H-Benzotriazole, EC No 202-394-1 (CAS No 95-14-7, hereafter the 'source substance').

You use the following arguments to support the prediction of properties of the registered substance from data for source substance and you claim that on the basis of the following it is possible to predict the human health and ecotoxicological properties of the registered substance:

- structural similarity (similar fused rings, similar reactivity, deprotonation of Nitrogen atom leading to the conjugated base as sodium salt)
- similarity in physico-chemical properties (molecular weight, physical form, vapour pressure, Log Pow, water solubility)

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

- ecotoxicological similarity (substitution of the benzene ring (from benzotriazoles to methyl benzotriazoles) are not expected to change the fate and ecotoxicological properties significantly (supported by Verhaar and ecosar classification scheme))
- the degradation rate between the substances differ (4-Methyl-Benzotriazole is less biodegradable then 5-Methyl-Benzotriazole or 1H-Benzotriazole. This difference in degradation rate is caused by a slower reaction kinetic of the 4-Methyl-Benzotriazole), some common reaction patways are present
- toxicological similarity (based on the results from toxicological endpoints and QSAR modelling), including similarity in toxicokinetics (based on similar physicochemical properties and based on absorption, distribution, metabolism and excretion)

ECHA considers that this information is your read-across hypothesis, which provides the basis whereby you predict the properties of the registered substance from the source substance.

B. ECHA's analysis of the grouping and read-across approach

Your proposed adaptation argument is that the similarity in chemical structure and similarity in some of the physico-chemical, ecotoxicological and toxicological properties between the source and registered substance is a sufficient basis for predicting the properties of the registered substance for other endpoints. Structural similarity is a prerequisite for applying the grouping and read-across approach. However similarity in chemical structure and similarity of some of the physico-chemical, ecotoxicological and toxicological properties does not necessarily lead to predictable or similar human health and environmental properties in other endpoints. Your justification based on structural similarity, similar physico-chemical, ecotoxicological and toxicological properties has not established why the prediction is reliable for the human health and environmental endpoints for which the read across is claimed.

Furthermore, you have indicated a difference in the degradation rates between the constituents of the registered substance and the source (4-Methyl-Benzotriazole is less biodegradable than 5-Methyl-Benzotriazole or 1-H Benzotriazole). ECHA notes that the prediction from a more biodegradable source (1-H Benzotriazole) substance to a less biodegradable substance can underestimate the persistency of the target substance. For these reasons, ECHA considers that the arguments on biodegradation properties is not a reliable basis whereby the properties of the registered substance may be predicted from data for source substance without a risk of underestimating the persistency.

Based on the information provided, the registered substance with the methyl group on the benzotriazole ring is less soluble and has a higher lipophilicity. Regarding predictions of ecotoxicity, lipophilicity may influence bioavailibility, bioaccumulation potential and toxicity.

You have not explained in your hypothesis why testing the source substance would be more appropriate. For example in your CSA you have provided a *Vibrio fischeri* tests, which shows that the registered substance is 10 times more sensitive/toxic than the source substance in the aquatic environment.

With reference to the data matrix, you only provided data for mutagenicity with results from Ames study and *in vitro* mouse lymphoma assay performed with the source substances benzotriazole (EC no. 202-394-1) and methyl benzotriazole (EC no. 249-596-6). Hence, you cannot conclude that the "*negative genotoxicity profile is also similar between the source and the target chemical*". Furthermore, from the data matrix provided it can be noted that

there are no *in vivo* studies available for any of the source or target substances and no positive *in vitro* mutagencity results. As regards the latter, the predicted negative result is solely based on the *in vitro* data (Ames, Chromosome aberration and Mouse Lymphoma Assay) with the source substance. Hence, the "*false positive alert*" (claimed under the 'Reactivity towards proteins and DNA' section) cannot be justified with the absence of data. ECHA also notes that for the other higher endpoints (sub-chronic toxicity study (90-day), fertility study and chronic long-term study (2-year)) there is only data with the source substance. Consequently, ECHA notes that you do not have the basis to conclude/assume that there are "*similarities in results...between the target and the source chemical(s) to support read-across*" since in most of the human health endpoints there are no results for the target substances. ECHA notes that as no higher tier studies are available for the target substances the presented information does not allow comparison of toxicological profiles of the substances.

Additionally, ECHA has taken into account all of your arguments together. ECHA firstly notes that you have not provided a reasoning as to why these arguments add to one another to provide sufficient basis for read-across. Secondly, the defects of each individual argument are not mitigated by the other arguments you have provided, and so ECHA considers that the arguments when taken all together do not provide a reliable basis for predicting the properties of the registered substance.

C. Conclusion on the grouping and read-across approach

Therefore, ECHA considers that this grouping and read-across approach does not provide a reliable basis whereby the human health, environmental effects and environmental fate of the registered substance may be predicted from data for source substances. Hence, this approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. of the REACH Regulation.

As described above, further elements are needed to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source and registered substances. This could be achieved (if it is possible) by a well-founded hypothesis of (bio)transformation to a common compound(s), or that the registered and source substance(s) have the same type of effect(s), together with sufficient supporting information to allow a prediction of human health and environmental properties.

In your comments you have accepted the rejection of your initial testing proposals using the analogue substance 1H-Benzotriazole (EC# 202-394-1). You indicated that you accept the decision to perform the proposed tests using the registered substance.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to OECD TG 414 by the oral route with the analogue substance 1H-Benzotriazole (EC No. 202-394-1).

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with the analogue substance 1H-Benzotriazole (EC No. 202-394-1). As already addressed above, in the section on *Grouping and read-across approach for toxicological and ecotoxicological information,* ECHA does not accept the read across approach.

ECHA considers that a study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent. On the basis of this default consideration, ECHA considers testing should be performed with rats or rabbits as a first species.

You proposed testing by the oral route. ECHA agrees that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

Outcome

Therefore, pursuant to Article 40(3) (d) and (c) of the REACH Regulation, you are requested to carry out the additional study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rat or rabbit), oral route (test method: OECD TG 414) while your originally proposed test for a pre-natal developmental toxicity study (test method: OECD TG 414) with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.6.2.3.2.

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Simulation testing on ultimate degradation in surface water" is a standard information requirement as laid down in Annex IX, Section 9.2.1.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the analogue substance 1H-Benzotriazole (CAS: 95-14-7 / EC: 202-394-1) for a Simulation biodegradation study in surface water (OECD TG 309 / EU C.25) with the following justification: *"In accordance with Annex XI 1.5 further testing has not been proposed as simulation study according to OECD guideline 309 with 1H-Benzotriazole is proposed. Results are considered to be adequate for assessment of Tolyltriazole."* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.2.1.2. of the REACH Regulation. However, as already addressed above, in the section on *Grouping and read-across approach for toxicological and ecotoxicological information,* ECHA does not accept the read across approach and therefore requests this test to be done with the registered substance.

The information currently available in the technical dossier and the Chemical Safety Assessment (CSA) is not sufficient to conclude on the biodegradation potential and consequently the persistence of the registered substance or its degradation products in water and thus, it is necessary to generate additional information for this endpoint.

ECHA notes that the information from the simulation study may also be needed for the purposes of the PBT, vPvB assessment.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In the testing proposal you have not specified the temperature at which the test shall be performed. One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

According to Section 9.2.3 in Annex IX of the REACH Regulation identification of degradation products is a standard information requirement. You have not justified an adaptation of this requirement. Consequently, there is an information gap and it is necessary to provide information for this information requirement. The identification of degradation products should therefore be included in the requested degradation simulation test. It is also noted that the OECD TG 309 Test Guideline features the formation and identification of the degradation products.

Therefore, pursuant to Article 40(3)(d and c) of the REACH Regulation, you are requested to carry out the additional study using the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25/OECD TG 309) at a temperature of 12°C including the identification of the degradation products (Annex IX, Section 9.2.3.) The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study. While your originally proposed test for simulation testing on ultimate degradation in surface water (EU C.25/OECD 309) with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. The Registrant is also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11.1.3. and Figure R. 11-1 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

3. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 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.

The information on "long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (OECD Guideline 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)) on analogue

substance: 1H-Benzotriazole / 95-14-7 / 202-394-1) with the justification of the proposed read-across in the read across justification document.

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance is considered as not readily biodegradable since there was 4% degradation of the substance over 28 days in an OECD 301 F test on ready biodegradability using the registered substance. The registered substance must therefore be considered as very persistent, which is the default setting for not readily biodegradable substances when value of the half-life in soil is not available.

Therefore, ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1., column 2.

However, as already addressed above, in the section on *Grouping and read-across approach for toxicological and ecotoxicological information,* ECHA does not accept the read across approach and therefore requests this test to be done with the registered substance.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

ECHA notes that the strategy pursued by you is not based on the integrated testing strategy. Therefore, ECHA would like to note that as only one confirmatory long-term soil toxicity test is necessary you may choose to perform one of the tests requested under points 3 or 4. Consequently you may adapt the other testing requested under the points 3 or 4 - according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation.

Therefore, pursuant to Article 40(3)(d) and (c) of the REACH Regulation, you are requested to carry out the following study using the registered substance subject to the present decision: Earthworm reproduction test (OECD TG 222), while your originally proposed test for long-term toxicity to terrestrial invertebrates with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is rejected.

4. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-

organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Column 2 of section 9.4 of Annex IX 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.

The information on "long-term toxicity to plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a long-term study with plants (OECD 208) on analogue substance: 1H-Benzotriazole / 95-14-7 / 202-394-1). You claimed that: *"According to Annex XI 1.5 as Tolyltriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts and a long-term study with plants (OECD 208) for 1H-Benoztriazole has been proposed further testing with other group members is considered to be not necessary."*

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. ECHA notes that, according to the evidence presented within the Registration dossier, the substance is considered as not readily biodegradable since there was 4% degradation of the substance over 28 days in an OECD 301 F test on ready biodegradability using the registered substance. The registered substance must therefore be considered as very persistent, which is the default setting for not readily biodegradable substances when value of the half-life in soil is not available.

ECHA considers based on the substance properties as discussed under point (2) above, that there is indication for high persistence of the substance in soil. High persistence of the substance indicates the need for long-term testing to be performed (Column 2 of Section 9.4. of Annex IX). At this tonnage level, according to column 2 the registrant shall consider long-term testing. No argument has been provided as to why long-term testing is not appropriate. Furthermore, ECHA Guidance on information requirements and chemical safety assessment Chapter R10, section R.10.6.2. (version May 2008) allows the potential application of a lower assessment factor (AF) if information on additional long-term terrestrial toxicity test of two trophic levels were available. In contrast, the Guidance does not allow for a lower AF to be applied if information on a short-term study were to become available in addition to the long-term invertebrate study, which ECHA accepted under subsection (3) above. Therefore ECHA concludes that considering the properties of the substance only a long-term toxicity test on plants (and not the short-term) will provide the necessary information.

Therefore, ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3., column 2. However, as already addressed above, in the section on *Grouping and read-across approach for toxicological and ecotoxicological information,* ECHA does not accept the read across approach and therefore requests this test to be done with the registered substance.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version

3.0, June 2017), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

ECHA notes that the strategy pursued by you is not based on the integrated testing strategy. Therefore, ECHA would like to note that as only one confirmatory long-term soil toxicity test is necessary you may choose to perform one of the tests requested under points 3 or 4. Consequently you may adapt the other testing requested under the points 3 or 4 - according to the specific rules outlined in Annexes VI to IX and/or according to the general rules contained in Annex XI to the REACH Regulation.

In your testing proposal you do not indicate the number or type of plant species to be tested.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and 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. 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 TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(d) and (c) of the REACH Regulation, the Registrant is required to carry out one of the additional studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030). While your originally proposed test for long-term toxicity to terrestrial plants with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is rejected according to Article 40(3)(d) of the REACH Regulation.

5. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for "effects on soil micro-organisms" according to OECD 216 with analogue substance: 1H-Benzotriazole (CAS: 95-14-7, EC: 202-394-1). You provided the following justification: *"According to Annex XI 1.5 as Tolyltriazole is registered in a group approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts and a study testing the Nitrogen transformation (OECD 216) with 1H-Benoztriazole has been proposed further testing with other group members is considered to be not necessary."*

ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test. However, as already addressed above, in the section on *Grouping and read-across approach for toxicological and ecotoxicological information,* ECHA does not accept the read across approach and therefore requests this test to be done with the registered substance.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

Therefore, pursuant to Article 40(3)(d) and (c) of the REACH Regulation, you are requested to carry out the additional study using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216. While your originally proposed study for effects on soil micro-organisms (OECD 216) with the analogue substance 1H-Benzotriazole (EC No. 202-394-1) is rejected.

Notes for your consideration

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 15 April 2016.

ECHA held a third party consultation for the testing proposals from 16 December 2016 until 30 January 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **3 January 2018**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests 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 or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests 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 tests to be assessed.