ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 27 April 2018

Addressee: [redacted]

Decision number: CCH-D-2114407685-46-01/F
Substance name: 1,2-dihydro-5-nitro-3H-1,2,4-triazol-3-one
EC number: 213-254-4
CAS number: 932-64-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 08/09/2017
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:[1]

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

2. **Robust study summary for available short-term toxicity data on aquatic invertebrates (Annex VII, paragraph 2 of Introduction and Section 9.1.1. in conjunction with Annex I, Sections 1.1.4 and 3.1.5. and Chapter 4 and Article 22(1)) provided that permission to refer to this study can be secured;**

3. **Robust study summary for Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.; test method: ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum) reported in the Section 6.1.5. of the registration dossier;**

4. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**

5. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

6. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: generate an environmental exposure assessment including exposure scenarios for all the identified uses and revise the risk characterisation accordingly.**

[1] No testing for endpoints listed in Annexes IX or X to the REACH Regulation may be started or performed at this moment: A decision only becomes legally effective and binding for you after it has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

You have to submit the requested information in an updated registration dossier by **6 May 2019**. You also have to update the chemical safety report, where relevant.

The reasons of 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[2] by Kevin Pollard, Head of Unit, Evaluation E1

[2] 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

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

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.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

a) Information provided

You have provided the following justification under endpoint record 7.8.2: *weight of evidence based on the extended one-generation reproductive toxicity study, the reproductive and developmental toxicity screening study and reproductive and developmental toxicity studies with similar substances (RDX, amitrole and TNT).* In addition, you have further explained "*a teratogenicity study is not necessary. In the Extended One-Generation Reproductive Toxicity study, NTO did not affect mean litter size (14.41–14.9 pups litter), number of live births (13.63-14.44 per litter), still births (0.25-0.68 per litter), or the percentage of pups in each litter that were male (45.3%-53.5%). Pre- and post-implantation loss and corpora lutea number were unaffected by NTO. In the reproductive and developmental toxicity screening study, gross external abnormalities were not observed in the litter examined after either 24 hours of parturition or on postpartum day 4. Moreover, Amitrole, RDX and TNT, which are structurally similar substances to NTO, are not developmental toxicants at non toxic doses*".

To support your justification you have provided the following sources of information in IUCLID section 7.8.1:

- Key study: "*screening for reproductive/developmental toxicity*", rat, oral (OECD TG 422; GLP) with the registered substance, [redacted], 2014 (study report), rel. 1.
- Key study: "*extended one-generation reproductive toxicity - with developmental immunotoxicity (Cohorts 1A, 1B without extension, and 3)*", rat, oral (OECD TG 443; GLP) with the registered substance, [redacted], 2016 (study report), rel. 1.

ECHA understands that you have sought to adapt the information requirement according to Annex XI, 1.2. (weight of evidence) and Annex XI, 1.5. (read-across). ECHA has first evaluated the information you provided on read-across and then the information you provided on weight of evidence.

Read-across

ECHA notes your statement that "*reproductive and developmental toxicity studies with similar substances (RDX, amitrole and TNT)*". ECHA understands that you have considered the information from the source substances "*RDX, amitrole and TNT* "to predict the properties of the registered substance with respect to pre-natal developmental toxicity according to the provision of REACH Annex XI, Section 1.5.

Grouping of substances and read-across approach

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 similarities and differences between the source and registered substances[3]. 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 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 and degradation 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.

[3] 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 ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[4]- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

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

Evaluation approach and conclusion on read-across

ECHA notes that there is no documentation for the read-across. Therefore, your dossier is lacking a basis for predicting relevant human health properties of the registered substance from data for the source substances.

In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substance.

Hence, you have not established that relevant properties of the registered substance can be predicted from data on the analogue substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected.

Consequently, ECHA has not considered the read-across information in the evaluation of the weight of evidence.

Weight of evidence

ECHA's evaluation and conclusion of the information provided

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

Your weight of evidence adaptation needs to address the specific dangerous (hazardous) properties of the registered substance with respect to a pre-natal developmental toxicity study (EU B.31/OECD TG 414). Relevant elements are in particular exposure route, duration and levels, sensitivity and depth of investigations to detect pre-natal developmental toxicity (including growth, survival, external, skeletal and visceral alterations) and maternal toxicity.

However, the available OECD TG 422 screening ([redacted], 2014) and OECD TG 443 ([redacted], 2016) studies with the registered substance does not provide information on pre-natal developmental toxicity. Because, it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement is rejected.

[4] 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).

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated that "*A quantitative environmental risk assessment will be conducted if a suitable basis for calculated PNECs may be determined following the review of the ecotoxicity studies*. ECHA notes that the comment is not relevant for pre-natal developmental toxicity.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers 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 5.0, December 2016) 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a first species (rat or rabbit) by the oral route.

Notes for your consideration

ECHA notes that a revised version of OECD TG 414 may be adopted later on this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. After the adoption of the revised version of the OECD TG 408 you should test in accordance with that version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788.

Even if you start testing before the guideline is published, it is appropriate to consider including these endocrine-sensitive parameters in your testing protocol in accordance with the proposed revised version of the draft guideline (see http://www.oecd.org/env/ehs/testing/section4-health-effects.htm).

2. Robust study summary for available short-term toxicity data on aquatic invertebrates (Annex VII, paragraph 2 of Introduction and Section 9.1.1. in conjunction with Annex I, Sections 1.1.4 and 3.1.5. and Chapter 4 and Article 22(1));

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.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

You have provided a study record for "Aquatic toxicity of 3-nitro-1,2,4-triazole-5-one", ([redacted] 2009), together with an ECOSAR prediction for the phenol class in order to meet the standard information requirement of Annex VII, Section 9.1.1. ECHA, however, notes that there is an existing study for the registered substance "Aquatic toxicity of photo-degraded insensitive munition 101 (IMX-101) constituents", Kennedy et al., 2017 (link as on 14 September 2017): http://onlinelibrary.wiley.com/doi/10.1002/etc.3732/abstract. This study suggests that toxicity of the registered substance is attributed to the toxicity of the photodegradation products, presumably ammonia ions.

Thus ECHA considers, that the results of this study give rise to a higher concern on aquatic toxicity than the data reported in your registration dossier. ECHA notes that according Article 22(1) of the REACH Regulation " *Following registration, a registrant shall be responsible on his own initiative for updating his registration dossier without undue delay with relevant new information*" (see also Annex I, Section 1.1.4 and Annex VII, introduction, paragraph 2). However, you did not consider this data in your chemical safety assessment of the registered substance.

ECHA also points out that according to STEP 1 of Annex VI of the REACH Regulation '*The registrant should gather all existing available test data on the test substance to be registered, this would include a literature search for relevant information'.* ECHA observes that the study by Kennedy et al., 2017 contains references to:

- Nitrotriazolone (NTO, CAS No. 932-64-9)—Acute toxicity to water fleas (Daphnia magna) under flow-through conditions, following OPPTS draft guideline 850.1010. Sayers LE. Springborn Smithers Study 13949.6107, report to BAE Systems, Arlington, VA, USA. 2009, and

- Environmental fate and ecological impact of NTO, DNAN, NQ, FOX-7, and FOX-12 considered as substitutes in the formulations of less sensitive composite explosives. Ampleman G, Thiboutot S. Annual report 2010-2011, NRC# 53363. National Research Council, Ottawa, ON, Canada. 2011.

These studies may also contain relevant information on the aquatic toxicity of the registered substance and thus you should consider including them into the chemical safety assessment if available to you.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated that you agree to the request and that you will attempt to obtain the use rights to the data indicated in the publication of Kennedy (2017) and that you will also investigate the relevance of the papers of BAE systems (2009) and Canadian NRC (2011). You have agreed to update your CSR accordingly.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for existing short-term toxicity data on aquatic invertebrates ("Aquatic toxicity of photo-degraded insensitive munition 101 (IMX-101) constituents", Kennedy et al., 2017), provided that permission to refer to this study can be secured. If this is not possible, you shall consider testing on your own initiative.

3. Robust study summary for Growth inhibition study aquatic plants (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5.

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.

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment.

In the technical dossier you have provided a study record for "ISO 10253 (Water quality – Marine Algal Growth Inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum*)" study. However, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment. In particular, the following elements are missing:

- Purity of the test material
- Details on sampling and analytical monitoring
- Test conditions
- Details on fulfilment of validity criteria

Therefore, you need to provide a complete robust study summary with the above missing elements for this study.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated your agreement to provide this information.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for the [ISO 10253 (Water quality – Marine Algal Growth Inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum*)(Analycen Ecotox AS)]. If this is not possible, you shall consider testing on your own initiative.

4. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

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.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Column 2 of Annex VIII, Section 9.1.3 specifies that long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement based on Annex XI, Section 1.3. by submitting results obtained from the application of a quantitative structure activity relationship model ((Q)SAR): *"Based on ECOSAR v.1 (EPISUITE, 2009), the test substance, NTO, was predicted to have LC50 of 1760.072 mg/L after 96 hours exposure...This value is predicted for Phenols class." Test material information:* [redacted]".

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.3 where it is indicated that the results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied model is provided.

You did not provide the adequate and reliable documentation of the applied model referred to under the fourth bullet point above. Without such documentation, ECHA is not in a position to assess whether the conditions outlined in the first three bullet points are fulfilled. As you have not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, ECHA cannot accept the adaptation.

For the adaptation to be acceptable, you would have to provide the above mentioned documentation and to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. The general form of the (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF), are described in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6: (Q)SARs and grouping of chemicals (ECHA, May 2008). Under REACH, reporting formats can be submitted to ECHA as attached files in an IUCLID dossier.

Furthermore, ECHA indicates, that publicly available literature data referred in the Section 2 of the present Appendix, suggests that toxicity of the registered substance is attributed to the toxicity of the photodegradation products, presumably ammonia ions. If this is the case, calculated toxicity values for the parent substance will not be reliable. ECHA further notes that in the Section 5.1.3. of the technical dossier you have indicated that ammonia ions are amongst photodegradation products of the registered substance. Thus, ECHA observes that you need to take into account toxicity of the degradation products identified according to the request in the Section 5 of the present decision.

Consequently, ECHA considers that results of the above mentioned prediction are not adequate for the purpose of classification and labelling and/or risk assessment.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) fish acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have agreed to provide QMRF and QPRF for the QSARs included in the dossier. You have also indicated your intention to generate QSAR-predictions for the photodegradation

products identified in report "*Environmental Fate and Ecological Impact of NTO, DNAN, NQ, FOX-7, and FOX-12 Considered as Substitutes in the Formulations of Less Sensitive Composite Explosives*", National research council of Canada, Annual Report 2011-2012 NRC # 53412. ECHA notes that not only documentation on the model applied and on the specific predictions (provided respectively in the QMRF and QPRF documents) is necessary, but also that you need to demonstrate that the predictions are scientifically reliable and adequate. In particular, ECHA notes that the degradation products of the substance likely include inorganic compounds (e.g. ammonia), for which a reliable prediction of the ecotoxicity may not be possible from QSAR models.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

Notes for your consideration

Due to the suspected potential to form toxic degradation products you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

5. Identification of degradation products (Annex IX, Section 9.2.3.)

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.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

While you have not explicitly claimed an adaptation, in the Section 5.1.3. of the technical dossier you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.1.2.: *"NTO was found to photo-degrade at wavelengths within the range of solar irradiation via hydrolytic denitration and photo-rearrangement; ammonia, nitrite and nitrate were detected as final products. after 7 days, >90% of NTO had degraded."*

ECHA considers that in your adaptation you propose that this information is sufficient to cover standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable as indicated in the Biodegradability in Seawater - Closed Bottle Test (degradation 3% after 28 days).

Furthermore, as described above in the Section 2 of the present Appendix, photo-induced toxicity was observed for the registered substance. In your technical dossier, you have provided a study record for a non-guideline indirect photolysis study. However, in contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard assessment. In particular, purity of the tested material, description of the test method and sampling, identification and quantification of the degradation products as well as validity criteria are not adequately specified. In addition, the predicted degradation half-life of the registered substance is not available in the summary you provided for this study.

Therefore, ECHA considers that the results of indirect photolysis study reported in the technical dossier are not adequate for the purpose of classification/labelling and risk assessment and further information on the relevant degradation products is required and your proposed adaptation is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You will need to provide a scientifically valid justification for the chosen method.

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated your intention to prepare a weight of evidence approach suitable to satisfy this information requirement.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

6. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires the Registrant to characterize the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH Regulation.

In the CSR you provided, the exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that *"Based on the aquatic toxicity data, the test substance is not classified as hazardous to the environment in accordance with Regulation (EC) No 1272/2008".*

ECHA observes that the registered substance has a self-classification as Expl. Div. 1.1, Skin Irrit. 2, Eye Irrit. 2 and STOT Single Exp. 3. and is thus fulfilling the criteria set out in Article 14(4) of the REACH Regulation for exposure assessment. Consequently, it is required to conduct an exposure assessment including the generation of exposure scenarios and a risk characterisation in the chemical safety assessment covering both human health and the environment. Furthermore, adverse effects were observed in the recent study on the *C. Dubia*, referred in the Section 2 of the present Appendix indicating LC50(48h) = 14.5 mg/L, NOEC(48h) = 5.9 mg/L.

In addition, according to *ECHA's Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R.16, Section R-16.1.3. if*

"transformation products (or degradation products" or "metabolites") are stable and/or toxic they should be taken into account in the environmental assessment."

In your comments following the procedure set out in Article 50(1) of the REACH Regulation you have indicated your agreement to conduct a quantitative environmental exposure assessment and risk assessment if a suitable basis for deriving PNECs is determined following the review of ecotoxicity studies.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate an environmental exposure assessment including exposure scenarios for all the identified uses and revise the risk characterisation accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 24 July 2017.

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 mainly 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present 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 your Member State.

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.