

Decision number: TPE-D-2114350280-62-01/F

Helsinki, 20 December 2016

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For Cashew (*Anacardium occidentale*) Nutshell Extract, Decarboxylated, Distilled., CAS No NS (List No 700-991-6), 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)(e) thereof for Cashew (*Anacardium occidentale*) Nutshell Extract, Decarboxylated, Distilled, CAS No NS (List No 700-991-6), submitted by [REDACTED] (Registrant):

- Bioaccumulation aquatic/sediment (OECD 305);
- Long-term toxicity to aquatic invertebrates (OECD 211);
- Sediment toxicity (OECD 218);
- Repeated dose toxicity: oral (OECD 408) in rats;
- Developmental toxicity/teratogenicity (OECD 415).

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 21 July 2016, 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 registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 28 February 2014.

ECHA held a third party consultation for the testing proposals from and from 15 July 2014 until 29 August 2014. ECHA did not receive information from third parties.

On 14 November 2014, ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [REDACTED].

On 19 December 2014, ECHA received comments from the Registrant on the draft decision. On 19 February 2015, the Registrant updated his registration (submission number Nr [REDACTED]) as agreed with ECHA.

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

On 21 July 2016, 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 for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposal(s) for amendment to the draft decision were submitted.

On 26 August 2016, ECHA notified the Registrant of the proposal(s) for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal(s) for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal(s) for amendment received and amended the draft decision.

On 5 September 2016, ECHA referred the draft decision to the Member State Committee.

By 26 September 2016, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 25–27 October 2016, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 27 October 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305);
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211);
3. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218);
4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats.

The Registrant shall carry out the following additional test pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation, using the indicated test method and the registered substance subject to the present decision:

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route;

while the originally proposed test for a "One-generation Reproduction Toxicity Study" (test method: OECD 415), proposed to be carried out using the registered substance is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Note for consideration by the Registrant

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **3 January 2019** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

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. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

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.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. 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.

Originally the Registrant has submitted a testing proposal for testing the registered substance subject to the present decision for bioaccumulation in aquatic species (Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD 305) with the following justification: *"To clarify the potential for bioaccumulation of Cashew Nutshell Extract, Decarboxylated, Distilled (Distilled Grade) it is proposed that, if technically feasible, a fish bioaccumulation study is conducted according to OECD Test Guideline 305 "Bioconcentration: Flow through Fish Test" and to GLP."* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.3.2. of the REACH Regulation.

Given the nature of the registered substance as an extract of unknown or variable composition, complex reaction products or biological materials (UVCB), analytical challenges can be expected. More specifically, from the testing proposal description referring to the "technically feasible" as a condition to perform the study, it is not clear if the Registrant will include all of the constituents in the study. Bearing this in mind the bioconcentration factor should be related to single constituents rather than to the overall UVCB substance to allow for the interpretation of the results.

Given the physicochemical properties of the registered substance (log Kow close to 6.2) and its low water solubility (0.3 mg/L), the Registrant is reminded that the most appropriate route of exposure according to the provisions outlined in the OECD 305 test guideline has to be chosen.

In the comment to the draft decision, the Registrant has indicated acceptance of ECHA's view and the intention to focus on different forms of cardanol for the analysis of water and fish tissue samples. With regard to choice of constituent(s) to be tested as addressed by the Registrant, all constituents with high bioaccumulation potential need to be addressed depending on their bioaccumulation potential. The Registrant has also acknowledged the need to consider the most appropriate route of administration with the testing facility.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014), bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

ECHA's Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decide to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. Data obtained from a dietary study will also need to be used to estimate BCF values.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2 Bioaccumulation in Fish: Aqueous or Dietary Exposure Bioaccumulation Fish Test, OECD 305).

Notes for consideration by the Registrant

Before conducting testing, the Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.11., PBT/vPvB assessment, which provides further guidance on what should be considered as relevant constituents for UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials).

In addition, the Registrant is advised to consult the ECHA Guidance on the standard information requirements and chemical safety assessment, Chapters R.4, 5, 6, R.7b and R.7c., where the Registrant decides to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. Also, ECHA refers the Registrant to the advice provided in the practical guide on "[How to use alternatives to animal testing to fulfil your information requirements for REACH registration](#) and on [How to use and report \(Q\)SARs](#)".

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

The Registrant has submitted a testing proposal for testing the registered substance subject to the present decision for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, OECD 211 with the following justification: "*In order to refine the PNECwater values and confirm the Toxicity (T) element of the PBT assessment it is initially proposed to conduct a long-term Daphnia magna reproduction study. This test is proposed rather a long-term fish toxicity test to avoid unnecessary animal testing.*" ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates.

In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

In the comment to the draft decision, the Registrant has indicated acceptance of ECHA's view.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

Notes for consideration by the Registrant

As further explained in section IV of this decision, it is important to ensure that the particular sample of substance selected to be tested in the study is appropriate to assess the properties of the registered substance. Hence, it is critical that those constituents which are most relevant should be present at appropriate concentrations in any sample tested.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Due to the low solubility of the substance in water, OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, which the Registrant confirmed they would use for the long term toxicity testing on *Daphnia* study in their comments on the proposals for amendment, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose. Due to the low sensitivity of the Total organic carbon analysis observed in the acute aquatic toxicity testing, this method is not recommended.

3. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

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.

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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.

The Registrant has submitted a testing proposal for testing the registered substance subject to the present decision for long-term toxicity testing on sediment organisms Sediment-water Chironomid toxicity test using spiked sediment (OECD 218) with the following justification: *"It is proposed that the study is carried out according to OECD Test Guideline 218 "Sediment-Water Chironomid Toxicity using Spiked Sediment" and to GLP. This study will assess the effects of prolonged exposure of Cashew Nutshell Extract, Decarboxylated, Distilled (Distilled Grade) to the sediment-dwelling larvae of the freshwater dipteran Chironomus sp."*

ECHA considers that the proposed study is appropriate to further investigate long-term toxicity to sediment organisms (Annex X, Section 9.5.1. of the REACH Regulation).

In the comment to the draft decision, the Registrant has indicated acceptance of ECHA's view.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance subject to the present decision: Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218).

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

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.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats via the oral route (EU B.26/OECD 408) to be performed with the registered substance subject to the present decision, with the following justification: *"it is proposed that a subchronic oral toxicity study be conducted for Cashew Nutshell Extract, Decarboxylated, Distilled (Distilled Grade) according to OECD Guideline for testing of chemicals 408 "Subchronic Oral Toxicity – Rodent: 90-day study" and to GLP. On the grounds of animal welfare, it would have to be conducted using an oral route of exposure even though this is not the likely route of human exposure. For this study, the preferred species is the rat and at least three dose levels and a control group should be used with 20 animals (10 females and 10 males) at each dose level. The animals will be treated for 90 days with observation. Appropriate clinical examinations (ophthalmological, haematology, clinical biochemistry and urinalysis when appropriate) and pathology (gross necropsy and histopathology) will be carried out and reported with interpretation."*

ECHA considers that the proposed study via the oral route is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation because the proposed route is the most appropriate route of administration having regard to the likely route of human exposure due to the following reasons.

The Registrant proposed testing by the oral route. In light of the physico-chemical properties of the substance (liquid with very low vapour pressure classified as irritating to the skin and damaging to the eyes) and the information provided on the uses and human exposure (i.e., uses with spray application), ECHA considers that testing by the oral route is most appropriate.

The Registrant proposed testing in rats. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In the comment to the draft decision, the Registrant has indicated acceptance of ECHA's view.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, by oral route (test method: EU B.26/OECD 408).

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(c) and (d) 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.

The Registrant has submitted a testing proposal for a "one-generation reproductive toxicity study according to OECD 415" to fill the pre-natal developmental toxicity endpoint, to be performed with the registered substances with the following justification: *"on a precautionary basis the Consortium has developed a vertebrate testing proposal in order to further assess any human health related hazards of the substance (if required) and to reduce the uncertainty associated with current Derived No Effect Level (DNEL) values for use in exposure estimates. Combined with this [OECD 408] study would be a reproductive and development toxicity study conducted according to OECD Guideline for testing of chemicals 415 "One-generation Reproduction Toxicity Study". This combined study would be the best for animal welfare while yielding the information required for an appropriate assessment of the potential reproductive and developmental toxicity of Cashew Nutshell Extract, Decarboxylated, Distilled (Distilled Grade). In addition to the requirements of the 90-day test outlined above, which would give the appropriate level and duration of dosing of male and female animals, mating would occur and observations made on dams, live pups and litter sizes. The clinical examination and pathology would be carried out as outlined above for the 90-day test but would include gross necropsy of dead or moribund pups and detailed pathological examination of the reproductive organs of adult animals. The results would be reported with interpretation."* ECHA notes that it has examined the testing proposal for a one-generation reproductive toxicity study according to OECD 415 only in relation to the information requirement of Annex IX, 8.7.2. of the REACH Regulation.

ECHA considers that the proposed study is not appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation, as the proposed test guideline does not meet the standard information requirement pursuant to Annex IX, Section 8.7.2. The proposed study has a different exposure duration and termination time of the study. Furthermore observation of parameters in offsprings are omitted under the test proposed, clarifying whether the registered substance would exert a hazard. Hence the proposed test cannot be accepted.

Instead, in accordance with Article 40(3)(c), a pre-natal developmental toxicity study according to EU B.31/OECD 414 is suitable to meet the information requirement of Annex X, 8.7.2. of the REACH Regulation in a first species.

The Registrant did not specify the species to be used for and did not specify the route for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used. In the comment to the draft decision, the Registrant has indicated acceptance of ECHA's view.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the following study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, by oral route (test method: EU B.31/OECD 414) while the initially proposed study has to be rejected pursuant to Article 40(3)(d) of the REACH Regulation as not appropriate.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, Section 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for adaptations are not fulfilled, they should include in the update of their dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, they should update his technical dossier by clearly stating the reasons for proposing to adapt the standard information requirement of Annex X, Section 8.7.2. of the REACH Regulation.

IV. Adequate identification of the composition of the tested material

The process of examination 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 examination of the testing proposal.

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 grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such 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://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised^[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

^[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.