Decision number: CCH-D-2114328799-31-01/F Helsinki, 20 April 2016

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

For Hematite, chromium green black, CAS No 68909-79-5 (EC No. 272-713-7) registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for **Hematite, chromium green black, CAS No 68909-79-5 (EC No. 272-713-7)**, submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Annexes IX/X, Sections 8.6.2. and 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 or more tonnes per year. This decision does not take into account any updates after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 4 February 2015.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 14 May 2014.

On 13 November 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt fo the draft decision.

On 19 December 2014 ECHA received comments from the Registrant on the draft decision. The ECHA Secretariat reviewed the comments and modified Section III (Statement of reasons) of the draft decision whilst Section II (Information required) was not amended.

On 3 March 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, no proposals for amendment to the draft decision were submitted.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: OECD 408) in rats; and

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

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 Article 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **29 April 2019**. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement.

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

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. Adequate information on this endpoint needs to be present in the technical dossier for the substance subject to the present decision to meet this information requirement.

The Registrant has proposed to adapt the information requirement of sub-chronic toxicity (Annex IX, Section 8.6.2. of the REACH Regulation).

In the justification of this proposed adaptation the Registrant, *inter alia*, claims that neither an oral, nor an inhalation study needs to be conducted due to chemical inertness and unreactive nature of the registered substance.

However, ECHA notes that neither column 2 of Annex IX, Section 8.6.2. nor the general rules for adaptation in Annex XI (such as Section 1 of Annex XI, which the Registrant also refers to) include the possibility to adapt the standard information requirement on the basis of the argument made by the Registrant.

The justification of the Registrant most closely relates to the adaptation possibility of Annex IX, 8.6.2. Column 2, last indent of the first paragraph, according to which no sub-chronic toxicity study needs to be conducted if "the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure."

The justification of the adaptation given by the Registrant is that the substance "can be considered chemically inert". Furthermore, according to the Registrant, the solubility and bioaccessibility of the substance is low. In gastric fluid conditions, below [redacted]% of chromium and [redacted]% aluminiun becomes bioavailable." This information suggests low solubility and also low bioavailability.

However, the Registrant has not demonstrated that the cumulative conditions of the adaptation possibility listed in Annex IX, 8.6.2. Column 2 4th indent of the first paragraph are fulfilled. In this respect, ECHA notes that no experimental data on absorption nor 28-day study record/data on substance subject to the present decision was provided in the registration dossier. Moreover, evidence of limited human exposure has not been given.

The Registrant has also not demonstrated why the testing would not appear to be scientifically necessary pursuant to Annex XI, section 1 of REACH.

Therefore, since the Registrant has not provided sufficient information to show that conditions of any adaptation in Column 2 of Annex IX, 8.6.2. or Annex XI are met, the adaptation of the information requirement suggested by the Registrant cannot be accepted. Consequently there is an information gap and it is necessary to provide information for Annex IX, Section 8.6.2.

Registrant comments

The registrant has made comments, which are relevant to both the information requirements for sub-chronic and pre-natal developmental toxicty studies.

The Registrant in his comments highlighted the information to support his claim of inertness which was provided in the registration which comprised a) physico-chemical characterisation of the substance demonstrating that the metal atoms are firmly retained in a crystalline structure, b) Transformation/Dissolution studies which show that the metals contained in the pigment do not become bioavailable to any extent above Ecotoxic Reference Values established for each metal and c) bioaccessibility studies that demonstrate that the metals are not released from the substance at levels that could pose a concern for human health, when tested in various human surrogate physiological media.

The Registrant also proposes to further substantiate his adaptation of the standard information requirement by applying a "read-across strategy to similar hematite pigments" chromium iron oxide and manganese alumina pink corundum. The Registrant considers that these analogue substances are "characterised by the same crystaline structure ("hematite"), contain similar metal elements and have similarly poor solubility/bioaccessibility". The Registrant further refers to tiered testing strategies intended to document the inertness of these analogue substances. These strategies are based on the conduct of 28-day repeated dose toxicity studies and in vivo toxicokinetic investigations on chromium iron oxide and manganese alumina pink corundum.

ECHA has considered the approach in the registrant comments. ECHA understands that the Registrant proposes to adapt the information requirement of annex IX, 8.6.2 for a sub-chronic toxicity study according to the provisions of Annex IX, section 8.6, column 2, first subparagraph, last indent. It is ECHA's understanding that the Registrant intends to read-across the conclusions from the 28-day repeated dose toxicity studies and the toxicokinetic investigations intended to be performed on the analogue substances chromium iron oxide and manganese alumina pink corundum in order to substantiate an adaptation according to Annex IX, section 8.6, column 2, first subparagraph, last indent.

Therefore ECHA has first assessed the read-across approach proposed by the Registrant in the light of the requirements of Annex XI, section 1.5 of the REACH Regulation, and subsequently assessed the validity of the adaptation according to Annex IX, section 8.6, column 2, 4th indent.

Assessment of the proposed read-across approach

ECHA has issued final decisions on the two source substances of the proposed read-across for the substance subject to this decision which recognise the Registrant's intention to follow their tiered testing strategy to document the "inert" nature –of these pigment substances as follows: (i) first, demonstrate in a 28-day oral toxicity test at the limit dose (1,000 mg/kg bw/d) that there is an absence of any toxicity; (ii) next, by conducting in vivo toxicokinetic studies document the absence of any quantitatively relevant oral absorption. However, in the final decision of the two source substances, the information requirements for sub-chronic toxicity study (90-day), oral, and pre-natal developmental toxicity study in rats or rabbits, oral, were retained, since the outcome of the studies within the testing strategy are not known and therefore, it cannot be concluded at present, whether all the specific criteria of the respective column 2 adaptations will be met. The final decisions were issued on 4 July 2014 (for chromium iron oxide) and 28 May 2014 (manganese alumina pink corundum).

The deadline given to the registrant in both final decisions was 5 June 2017. In those final decisions "ECHA therefore recognises that the Registrant may seek to justify any adaptation within his own responsibility and to follow an according testing strategy in order to demonstrate that the adaptation is justified."

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".

Annex XI, 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents the ECHA's analysis concerning the justification in both a generic and an endpoint-specific context.

ECHA recognises the merits of the scientific rationale on which the Registrant established his read-across approach for addressing the information requirements for the substance subject to this decision, however ECHA observes that the Registrant failed to provide scientific supporting evidence to justify the arguments on which the read-across approach is based. Specifically, there is significant uncertainty arising from the following:

- The Registrant states that the analogue substances and the registered substance are "characterised by the same crystalline structure". The similarity in the crystalline forms of the substances involved in the read-across approach is not adequately established. The registrant identified the analogue substances in his comments by referring to their chemical names but failed to provide scientific evidence demonstrating similarity in crystalline structure between these substances and the registered substance. According to the requirement of Annex XI, section 1.5, structural similarity is a prerequisite for the use of grouping of substances and read-across under REACH. In the absence of scientific information supporting the claimed structural similarity, the read-across approach cannot be accepted.

- The Registrant indicates in his comments that the analogue substances and the registered substance contain "*similar metal elements*". ECHA notes that no information on the composition of the analogue substances has been provided. In the absence of this information, ECHA considers that this specific argument of the read-across approach is not completely verified. The names of the analogue substances may provide some generic information on the metal elements included in the composition of these substances. However detailed information on the composition and purity/impurity profiles of the analogue substances is necessary to assess the relevance of the information obtained from these substances for predictions the properties of the registered substance. ECHA notes that the exact composition of the registered substance remains ambiguous on the basis of the information reported in section 1.1 of the registration dossier where it is stated that "*its composition may include any one or a combination of the modifiers Al_2O_3, Fe_2O_3 or Mn_2O_3*". Information on the presence of these constituents in the composition of the registered substance and the comparison with the source substances of the read-across is missing.

That comparison would be an essential part of the read-across hypothesis, however no information on their presence or absence is reported in the description of the composition of the registered substance as described in the IUCLID section 1.2. ECHA also observes that the assessment of the impact of the differences in the composition between the source substances and the registered substance, or the absence thereof, on the claimed similarity in the "inertness" of the different crystals appears not to have been accounted for by the Registrant in his comments. In the absence of detailed information on the composition of the analogue substances, ECHA considers that the Registrant failed to demonstrate that the properties of the registered substance can be predicted from the analogue substances chromium iron oxide and manganese alumina pink corundum.

- The Registrant indicates in his comments that the analogue substances and the registered substance have "*similarly poor solubility/bioaccessibility*" and in his comments highlights the information in this regard on the registered substance. Furthermore, the technical dossier also contains information on the behaviour of the registered substance in artificial physiological media. ECHA notes however that no data informing on the solubility of the analogue substances has been provided to support the claim of similar poor solubility. ECHA further points out that information on the dissolution of the substances in artificial physiological media or from transformation/dissolution studies may constitute useful information in the assessment of toxicokinetic properties of a substance. However this information alone does not address all the aspects and characteristics of in vivo exposure and does not form on its own a sufficient basis to ascertain the bioavailability of a substance. In the absence of information on the solubility and bioavailability of all the substances involved in the read-across approach, ECHA considers that this specific argument of the read-across approach is not completely verified.

ECHA observes that no toxicological data, for example from adequate studies with repeated exposures, are available to support the hypothesis that the analogue substances and the registered substance are likely to have similar toxicological properties. Furthermore, the toxicological data proposed to be read-across from the analogue substances to the registered substance does not yet exist. In the absence of these data, ECHA considers that the Registrant has not established a scientific basis according to which properties of the registered substance can be predicted from data from the analogue substances chromium iron oxide and manganese alumina pink corundum.

For the reasons above, ECHA considers that the read-across approach as currently documented fails to establish a basis according to which the properties of the registered substance can be predicted from the source substances as required in theconditions of Annex XI, 1.5 of the REACH Regulation.

Assessment of the comments on exposure considerations

ECHA notes that the Registrant indicates in his comments that "*efforts will be undertaken to document in writing a) a reasoning why no significant human exposure occurs, and ii) demonstration of the lact of any relevant inhalability, based on the results of dustiness/particle/size distribution measurement under simulated handling conditions and respirtory tract deposition modelling*". ECHA understands that the Registrant intends to undertake these efforts in order to support the adaptation possibility described in Annex IX, section 8.6, column 2, 4th indent in respect of "limited human exposure".

Since the information provided in the comments of the Registrant is not sufficient, ECHA considers that the Registrant has not demonstrated that this condition of the adaptation possibility of Annex IX, 8.6.2 Column 2, 4th indent of the first paragraph is fulfilled.

ECHA acknowledges the Registrant's comments with his explanations to support, and his agreement to, the oral route of administration.

Conclusion on the Registrant's proposed strategy

As outlined above, ECHA understands that the strategy presented by the Registrant in his comments to the draft decision was to make use of the read-across approach to substantiate an adaptation according to Annex IX, section 8.6, column 2, 4th indent. Since the read-across approach proposed by the Registrant is not aceptable as currently documented, ECHA considers that the Registrant has not provided an adequate scientific justification to adapt the information requirement of Annex IX, section 8.6.2 for a sub-chronic toxicity study according to Annex IX, section 8.6, column 2, 4th indent.

It is noted that the read-across approach is based on a prediction of an absence of effects, and in ECHAs understanding, this "prediction model" would be applied by the Registrant for both endpoints under consideration. Therefore, an observation of any sign of toxicity in the 28-day studies performed with the analogue substances chromium iron oxide and manganese alumina pink corundum would undermine the adaptation of the information requirement as this would contradict the Registrant's hypothesis as regards to the inert and unreactive nature of the substances.

ECHA considers that the Registrant has not demonstrated that the cumulative conditions of the adaptation possibility of Annex IX, 8.7 Column 2, last indent of the first paragraph are fulfilled. Therefore, the adaptation of the information requirement of Annex IX, 8.7.2 cannot currently be accepted and therefore the requirement for information from a sub-chronic toxicity study is retained.

In the light of the properties of the substance and the information provided on the uses and potential human exposure, ECHA considers that testing by the oral route is most appropriate. According to the test method OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, in the absence of a justified adaptation and pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

The results from the studies with the analogue substances, on which some of the read-across arguments are based, are not yet available, and the Registrant therefore cannot fulfill the requirements of Annex XI, section 1.5 and of Annex IX, section 8.6.2, column 2, 4th indent for the registered substance with an adaptation based on the read-across. Bearing that limitation in mind, ECHA recognises that the Registrant may seek to justify any adaptation within his own responsibility and to use the results of the testing strategy proposed in his comments to the draft decision, in order to demonstrate that the adaptation of the information requirement of is justified.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In response to the Registrant comments on the draft decision and to allow the time necessary to fulfill his new testing strategy, ECHA Secretariat considers that a reasonable time period for providing the required information in the form of an updated IUCLID dossier is 36 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has proposed to adapt the information requirement of prenatal developmental toxicity (Annex IX, Section 8.7.2. of the REACH Regulation).

The justification of the adaptation given by the Registrant is that the substance "can be considered chemically inert". Furthermore, according to the Registrant, the solubility and bioaccessibility of the substance is low.

However, ECHA notes that neither Column 2 of Annex IX, 8.7. nor the general rules for the adaptation of Annex XI include such possibility to adapt this information requirement.

The justification of the Registrant most closely relates to the adaptation possibility of Annex IX, 8.7 Column 2 last indent of the first paragraph according to which no reproductive toxicity studies need to be conducted if the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method, and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

ECHA notes that while the Registrant has provided data low solubility and low bioaccessibility of the substance subject to this decision (given also in IUCLID section 7.1.1. *basic toxicokinetics*), the Registrant has however not demonstrated that the cumulative conditions of the adaptation possibility of Annex IX, 8.7 Column 2, last indent of the first paragraph are fulfilled. In this respect, ECHA notes that no experimental data on absorption nor systemic toxicity test on the substance subject to the present decision has been provided. Moreover, evidence of no or no significant human exposure has not been given.

Registrant comments

ECHA has considered the approach in the registrant comments which are relevant to both the information requirements for sub-chronic and pre-natal developmental toxicty studies.

The Registrant in his comments highlighted the information to support his claim of inertness which was provided in the registration which comprised a) physico-chemical characterisation of the substance demonstrating that the metal atoms are firmly retained in a crystalline structure, b) Transformation/Dissolution studies which show that the metals contained in the pigment do not become bioavailable to any extent above Ecotoxic Reference Values established for each metal and c) bioaccessibility studies that demonstrate that the metals are not released from the substance at levels that could pose a concern for human health, when tested in various human surrogate physiological media.

In his comments to the draft decision, the Registrant also proposes to further substantiate his adaptation of the standard information requirement by applying a "read-across strategy to similar hematite pigments" chromium iron oxide" and "manganese alumina pink corundum". The Registrant considers that these analogue substances are "characterised by the same crystaline structure ("hematite"), contain similar metal elements and have similarly poor solubility/bioaccessibility". The Registrant further refers to tiered testing strategies intended to document the inertness of these analogue substances. These strategies are based on the conduct of 28-day repeated dose toxicity studies and in vivo toxicokinetic investigations on chromium iron oxide and manganese alumina pink corundum.

ECHA has issued final decisions on the two source substances of the the proposed read-across for the substance subject to this decision which recognise the Registrant's intention to follow their tiered testing strategy to document the "inert" nature –of these pigment substances as follows: (i) first, demonstrate in a 28-day oral toxicity test at the limit dose (1,000 mg/kg bw/d) that there is an absence of any toxicity; (ii) next, by conducting in vivo toxicokinetic studies document the absence of any quantitatively relevant oral absorption. However, in the final decision of the two source substances, the information requirement for sub-chronic toxicity study (90-day), oral, and pre-natal developmental toxicity study in rats or rabbits, oral, was retained, since the outcome of the studies within the testing strategy are not known and therefore, it cannot be concluded at present, whether all the specific criteria of the respective column 2 adaptations will be met. The final decisions were issued on 4 July 2014 (for chromium iron oxide) and 28 May 2014 (manganese alumina pink corundum). The deadline given to the registrant in both final decisions was 5 June 2017. In those final decisions "ECHA therefore recognises that the Registrant may seek to justify any adaptation within his own responsibility and to follow an according testing strategy in order to demonstrate that the adaptation is justified."

Assessment of the comments on the proposed read-across approach

ECHA has assessed the read-across approach proposed by the Registrant in this comments to the draft decision. For the reasons described in section III.1 above, ECHA considers that the read-across approach as currently documented fails to establish a basis according to which the properties of the registered substance can be predicted from the source substances as required in the conditions of Annex XI, 1.5 of the REACH Regulation.

Assessment of the comments on exposure considerations

ECHA notes that the Registrant indicates in his comments that "*efforts will be undertaken to document in writing a) a reasoning why no significant human exposure occurs, and ii) demonstration of the lact of any relevant inhalability, based on the results of dustiness/particle/size distribution measurement under simulated handling conditions and respirtory tract deposition modelling*". ECHA understands that the Registrant intends to undertake these efforts in order to address the adaptation possibility described in Annex IX, 8.7 Column 2, 3rd indent of the first paragraph in the respect that "...there is no or no significant exposure". Since the information referred to by the Registrant is not provided, ECHA considers that the Registrant has not demonstrated that this condition of the adaptation possibility of Annex IX, 8.7 Column 2, 3rd indent of the first paragraph is fulfilled.

ECHA acknowledges the Registrant's comments with his explanations to support, and his agreement to, the oral route of administration.

Conclusion on the Registrant's proposed strategy

Since the Registrant has not provided sufficient information to show that the cumulative conditions of an adaptation in Column 2 of Annex IX, 8.7., 3rd indent of the first paragraph are met, the adaptation of the information requirement suggested by the Registrant cannot be accepted. Therefore, the adaptation of the information requirement of Annex IX, 8.7.2 cannot be accepted. 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 414, as referred to in in Annex IX, Section 8.7.2. of the REACH Regulation, 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.

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

The results from the studies with the analogue substances on which some of the read-across arguments are based are not yet available, and the Registrant therefore cannot fulfill the requirements of Annex XI, section 1.5 and of Annex IX, section 8.7, Column 2, 3rd indent for the registered substance with an adaptation based on a read-across. Bearing that limitation in mind, ECHA recognises that the Registrant may seek to justify any adaptation within his own responsibility and to use the results of the testing strategy proposed in his comments to the draft decision in order to demonstrate that the adaptation of the information requirement is justified.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In response to the Registrant comments on the draft decision and to allow the time necessary to fulfill his new testing strategy, ECHA Secretariat considers that a reasonable time period for providing the required information in the form of an updated IUCLID dossier is 36 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant 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 testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, Section 8.7.2.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, 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 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 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://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[2] by Claudio Carlon, Head of Unit, Evaluation, E2

[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.