EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114294468-33-01/F Helsinki, 23 March 2015

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

For manganese dioxide, CAS No 1313-13-9 (EC No 215-202-6), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for manganese dioxide, CAS No 1313-13-9 (EC No 215-202-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number, [redacted] for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 12 June 2014, 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 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 7 October 2013.

On 22 November 2013 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 16 December 2013 ECHA received comments from the Registrant. On 18 February 2014 the Registrant updated his registration dossier (submission number [redacted]).

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

On 12 June 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 18 July 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, 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).

A unanimous agreement of the Member State Committee on the draft decision was reached on 1 September 2014 in a written procedure launched on 21 August 2014.

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

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)(vi) and/or (vii), 12(1)(e), 13 and Annexes X and XI 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:

> Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, inhalation 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. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

> 1. Revised DNELs for the workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks

or
A full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.) The results of the studies requested under section II.A. shall be taken into account when revising the DNELs.

Pursuant to Articles 10(a) (iii), 14(4),(6), Annex I 5.1 and 5.2 and Annex VI (3.5) of the REACH Regulation the Registrant shall submit the following information in the technical dossier as well as in the Chemical Safety Report (CSR):

2. Revised identification of consumer uses (SU [redacted], PC 9a/b) for [redacted] and the subsequent use of the [redacted] in private settings, a consumer exposure assessment within appropriate consumer exposure scenarios for the consumer use "coloring of [redacted] and the subsequent use of the clay in private settings" and description of the appropriate product integrated risk management measures for "[redacted] and the subsequent use of the [redacted] in private settings

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **30 September 2016.**

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 requirements.

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

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity study

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.

In the submission [redacted] on which the initial draft decision was based, the Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is "Study scientifically unjustified" based on the following arguments:
"*Inhalation:*
The particle size distribution test indicates that inhalation is a possible route of exposure . However, an investigation on the bioavailability of the registered substance in gastric and artificial lung fluid demonstrates the low bioavailability of the substance in both compartments (see [redacted], section 7.12). A literature review of available human and animal data on reproductive toxicity to manganese-based compounds showed equivocal

evidence of reproductive toxicity. The only reliable study on developmental toxicity via inhalation exposure (Lown et al (1984)) showed some evidence for affect on growth from pre-natal exposure of mice. However, the study only looked at one dose and therefore no dose-response relationship is available to prove that the result was not an anomaly. Furthermore, the concentration of MnO2 that the mice were exposed to is approximately 250 times higher than the IOELV proposed in this dossier for inhalation based on neurotoxicity of MnO2. STOT RE 2 is to be proposed for MnO2 and the risk mitigation required to protect against neurotoxicity will protect against any other unidentified adverse health effects. Therefore, taking all these factors into account, this test is not considered scientifically necessary in accordance with Annex XI, section 1.1.

Dermal:
The registered substance is very poorly water soluble (IUCLID section 4.8), hence minimal amount of the potential substance is made available for systemic absorption via the dermal route. Even if minimally available from exposure, the physiological properties of the registered substance do not indicate a significant rate of absorption through the skin. Furthermore, there were no systemic effects or any other evidence of absorption seen in the skin and eye irritation studies (IUCLID section 7.3) . Moreover, this is not the most likely route of systemic exposure. Therefore in accordance with Annex XI, section 1.1, this test is not considered necessary.

Oral:
MnO2 is mostly used in industrial settings where good industrial hygiene is employed. Outside these industrial settings, the registered substance is used by trained professionals. Exposure via the oral route is therefore implausible. In the highly unlikely event of any oral exposure occurs, a gastric simulation study (ref: [redacted] IUCLID section 7.12) indicates very low leaching of MnO2, and therefore of very limited bioavailability. In addition, MnO2 is to be proposed for classification as STOT RE2 (due to inhalation hazard) and therefore any risk mitigation to prevent inhalation would also prevent any possibility of muco-ciliary transport of inhaled particles back into the gastro-intestinal tract. Therefore in accordance with Annex XI section 1.1, this test is not considered necessary."

The Registrant has sought to waive the current information requirement on the basis of Annex XI, Section 1.1. governing the use of existing data. The justification of the adaptation given by the Registrant was the low bioavailability of the registered substance in the artificial lung and gastric fluid, the improbable oral exposure and the risk mitigation due to STOT RE2 classification. However, the general rules for adaptation of Annex XI, 1.1. deal with the use of existing data, not with adaptations based on low bioavailability or exposure considerations. In addition, if the Registrant meant to refer to the provisions of column 2 of section 8.7 of Annex IX –3rd bullet point, ECHA considered that the low bioavailability without proof of no systemic exposure would not fulfil this adaptation provision. Furthermore, there was no documentation of the claimed "no significant human exposure".

ECHA also noted that in the technical dossier (submission [redacted]) the Registrant has provided a study record for a supporting study (Lown et al. 1984) focusing on neurotoxicity in the pups exposed either *in utero* or via suckling through mothers (biological or fostered) to manganese dioxide and an abstract of a reliability 4 study (Massaro et al., 1980) focusing on the alterations in the behaviour of adult offspring of female mice exposed to manganese dioxide dust during gestation. However, these studies did not provide the information required by Annex IX, Section 8.7.2., because they were not specifically addressing the developmental toxicity, were not GLP-studies and were not done according to accepted guidelines. Nevertheless, they raised serious questions on the potential developmental toxicity of the registered substance (reduced neonatal activity scores and retarded offspring growth that persisted into adulthood, reduced weight for offspring of exposed dams,

affected balance and coordination by either gestational or postpartum exposure to manganese dioxide).

Therefore, the adaptation of the information requirement suggested by the Registrant could not be accepted and a request was made for a Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the inhalation route.

Following the draft decision, the Registrant submitted his comments in which he showed concern about the material requirements for the reproductive studies by inhalation. ECHA acknowledges that grinding the substance to increase its bioavailability may change the physical profile of the substance but is of the opinion that it will not significantly alter the chemical profile and change its identity.

ECHA considers that the Registrant's proposal to use results from MnCl2 relates solely to the provided 2-generation reproductive toxicity study with MnCl2, and is not a proposal to perform a pre-natal developmental toxicity study with MnCl2.

In the updated dossier the Registrant has provided a two-generation reproductive toxicity study (OECD 416), performed with an analogue substance, manganese chloride, to meet the information requirement for pre-natal developmental toxicity study. ECHA notes that the two-generation reproductive toxicity study does not adequately and reliably cover the key parameters of the pre-natal developmental toxicity study, e.g., skeletal and visceral examination of foetuses. ECHA considers that the finding of a similar number of implant sites and pups born in all groups does not remedy this defect. Hence this study fails to meet the requirement that there be adequate and reliable coverage of the key parameters addressed in the corresponding test method. Moreover, it would thereby be inadequate for the purpose of classification and labelling and/or risk assessment.

The Registrant argues that as an essential nutrient involved in bones formation which is poorly absorbed and under efficient homeostatic control, it is very unlikely that manganese dioxide will cause teratogenic effects, fact supported by the absence of abnormality in the litter's bones in the two generations study. The Registrant has provided a literature review on manganese compounds which showed equivocal evidence for reproductive toxicity. ECHA notes that the literature review does not contain any pre-natal developmental toxicity study neither on manganese dioxide nor on any other manganese salt. The Registrant argues that some of the parameters measured in the two-generation study (implant sites, pup numbers) provide sufficient reassurance for the pre-natal developmental toxicity endpoint. The Registrant also argues that the STOT RE sufficiently protecting for neurotoxicity, which is considered a more sensitive endpoint, will, by default, also protect for developmental toxicity. ECHA notes that each of these arguments, by itself, is not a valid adaptation neither in conformity with the provisions in Column II of REACH Annexes nor with those in Annex XI, and ECHA considers that, when considered together as a weight of evidence as described in Annex XI, 1.2, these arguments do not provide a sufficient weight of evidence from several independent sources leading to the assumption/ conclusion that the substance does not have a particular dangerous property, in this case for prenatal developmental toxicity.

The REACH Regulation requires this endpoint to be fulfilled with adequate information and the adaptation presented by the Registrant referring to a two generation study were not considered adequate to cover the pre-natal developmental toxicity endpoint.

The information available 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 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species. ECHA considers that testing with the rat or the rabbit as a first species is most appropriate.

According to the test method EU B.31/OECD 414, the test substance is usually administered orally. However, since the substance is:
- a manganese compound with very poor water solubility and with a very limited oral bioavailability,
- a powder in which approximately 80% of the particles are < 10 µm diameter (inhalable) and approximately 50% are less than 2.5 µm diameter (respirable),
ECHA considers that testing via the inhalation route is most appropriate.

A Competent Authority (CA) submitted a proposal for amendment indicating an alternative substance to test, suggesting that the Registrant should conduct the study on an soluble inorganic manganese salt, such as the dichloride. Although finding the proposal "*plausible*" the Registrant argued that "*Considering the differences between the registered substance and a soluble inorganic manganese salt: valency, physicochemical properties, bioavailability and toxicokinetic behaviour, using a soluble inorganic salt could lead to excessive evaluation of the toxicity profile of the registered substance and hence an incorrect, misclassification.* " However, in his comments on the PfAs, the Registrant used the insolubility arguments and the CA opinion that "*the proposed PNDT study would only provide limited information on the potential of manganese dioxide to induce developmental toxicity*" to make a different point, i.e. to use the oral route instead of inhalation. This point however, is outside the scope, as the route of administration was not addressed by any of the proposals for amendment and ECHA still considers the inhalation route to be the most appropriate one.

Therefore, 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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the inhalation route.

Notes for consideration by the Registrant

Another CA submitted a proposal for amendment indicating that there was "*a supporting non-guideline developmental toxicity study in mice (rated Klimisch score 2 by the Registrant) is presented in the IUCLID file (Sanchez 1993). Such a study would normally not be acceptable to fulfil the standard information requirements of REACH since the subcutaneous administration route is used. However, in this case the test substance has shown systemic bioavailability (maternal death at highest dose and developmental effects up to 4 mg/kg bw/d). Consideration needs to be made by the registrant to evaluate whether the study may be acceptable for use for this endpoint (Based on evidence of developmental effects, this study may trigger a classification; currently this substance is not classified)*". In his comments to the CA proposal for amendment, the Registrant indicated that he agrees on the weaknesses of the Sanchez paper with regards to its application for regulatory compliance and its use to comply with the pre-natal developmental endpoint. ECHA considers based on the proposal for amendment, the Registrant should specifically evaluate if the adaptation possibility in Annex IX, Section 8.7, Column 2 may be fulfilled (the study needs not to be conducted if the substance is known to cause developmental toxicity, meeting the criteria for classification Category 1A or 1B, and the available data are adequate to support a robust risk assessment).

ECHA notes 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, 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, 8.7.2.

B. Information related to the chemical safety assessment and chemical safety report

1. Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

> Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.)

Annex I, 1.4.1 of the REACH Regulation requires DNELs to be established for the substance, reflecting the likely route(s), duration and frequency of exposure. The following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

A full justification shall be given specifying, inter alia, the choice of the information used, the routes of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid.

The ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8 provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1.
Firstly, ECHA notes that for the long-term DNELs for inhalation route systemic effects for

both workers and the general population, the Registrant is using the inhalation OEL (Occupational Exposure Limit Value). ECHA notes that Appendix R8-13 of the above-mentioned guidance document describes under which conditions EU or national OELs can be used instead of deriving a DNEL. According to those conditions, if the registrant is using a substance in a way that other human populations are exposed, the relevant DNELs should be derived. Therefore using an OEL (set for the working population) as a starting point for a DNEL derived for the general population is not appropriate and DNELs should be derived according to ECHA's Guidance R.8. for inhalation route for the general population.

Furthermore the use of an "assessment factor" (AF) of 2 for intra-species differences instead of 10 for general population is not according to the above ECHA Guidance. For the general population - systemic long term – inhalation route, the registrant should identify the dose descriptor and select the AF based on the species of that study. For intra-species differences an AF of 10 (general population) should be used and for exposure duration an appropriate AF based on the duration of that study must be selected.

Secondly, ECHA notes that for workers the inhalation OEL was used also as dermal DNEL. This is also against Appendix R-8.13 of the above Guidance which states that when the registrant is using a substance in a way that leads to other exposure routes than the exposure route on which the OEL is based, the relevant DNELs should be derived. Therefore using an inhalation OEL as dermal OEL is not appropriate and a worker dermal DNEL derived according to ECHA's Guidance R.8. should be provided.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. or are not fully justified. Consequently it is necessary to revise the DNELs or to provide a full justification for not using the recommended assessment factors..

The Registrant is given two options: the Registrant shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks.

In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the DNELs derived for workers and for the general population provided in the chemical safety report by specifying how the following has been taken into account:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

Following the draft decision, the Registrant committed in his comments to draft decision to update the dossier with the requested information while pointing out that he still considers that "*the SCOEL IOELV is appropriate as it is protective against all health endpoints and is very stringent, hence should also be protective of the general population.*" However, ECHA noted that in the updated dossier no revision of the DNEL using ECHA's recommended assessment factors was done.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information:

Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation.

The results of the studies requested under section II.A. shall be taken into account when revising the DNELs.

2. *Pursuant to Articles 10(a) (iii), 14(4),(6), Annex I 5.1 and 5.2 and Annex VI (3.5) of the REACH Regulation the Registrant shall submit the following information in the technical dossier as well as in the Chemical Safety Report (CSR):*

> Revised identification of consumer uses ([redacted] PC 9a/b) for [redacted] and the subsequent use of the clay in private settings, a consumer exposure assessment within appropriate consumer exposure scenarios for the consumer use "coloring of clay and the subsequent use of the clay in private settings" and the description of the appropriate product integrated risk management measures for "coloring of clay and the subsequent use of the clay in private settings

Pursuant to Articles 10(a) (iii) and Annex VI (3.5) of the REACH Regulation the technical dossier should contain information on all the identified uses. However, there is no record of identified consumer uses - neither in the technical dossier nor in Chapter 2 of the CSR, although in Chapter 9 of the CSR the Registrant addressed the use of manganese dioxide as a pigment for "[redacted] and the subsequent use of the [redacted] in private settings" (p. 116 of the CSR and Table 48).

Manganese dioxide is classified according to CLP/GHS as STOT Rep Exp 2. According to Article 14(4) of the REACH Regulation the exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate), exposure estimation(s) and the risk characterization is a standard requirement.

The Registrant recorded in the CSR, that no information about operational conditions is available. For exposure assessment and risk characterization the Registrant has used exposure values coming from the RIVM fact sheets which do not reflect the conditions of use for [redacted]. Furthermore the Registrant recommended inappropriate communicated risk management measures (respiratory protection, ventilation) for consumers to control the risks (p.117 of the CSR: *"It is recommended that professional and leisure-time [redacted] wear respiratory protection when handling powders containing a high amount of manganese dioxide to minimise inhalation exposure. [redacted] have to wear RPE with ≥95% efficacy when [redacted]. Further, they have to ensure that the rooms they working in are well vented (≥80% reduction efficacy) and they have to wear gloves with a reduction efficacy of 90% when direct dermal contact with the substance is possible to avoid intensive dermal contact with the substance".* Without ventilation and the respiratory protection the Registrant indicates a health risk for consumers (p. 169 in Chapter 10 of the CSR). In the Table 121 from the CSR referring to the risk characterization for professional and consumer exposure the "activity type" is "Public domain". However, the term "public domain" is generally used within the modelling of exposure related to professional use. In this case on p. 169, the term is used in relation to PROC 4 which is only interpreted for industrial and professional use. Consumer exposures are not explicitly covered.

Finally, pursuant Article 14(6) "any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment". Communicated risk management measures like ventilation and respiratory protection are not appropriate for consumers to control the risks adequately. For this the ECHA Guidance

on information requirements and chemical safety assessment, Chapter R.13 points out: "Consumer instructions cannot be expected to be highly effective, unless consumer behavioral data suggest that a sufficient degree of implementation can be assumed. Therefore consumer RMMs that depend on instructions should as a general rule only be introduced when the use of such RMMs can be shown to be effective, necessary and well adhered to by consumers."

Taking into account all the arguments above it is concluded that the Registrant could not demonstrate the safe use of manganese dioxide for [redacted] by consumers. Therefore, a revised identification of consumer uses (SU [redacted], PC 9a/b) fo[redacted] and the subsequent use of the [redacted] in private settings, a consumer exposure assessment within appropriate consumer exposure scenarios for the consumer use "[redacted] and the subsequent use of the [redacted] in private settings" and the appropriate product integrated risk management measures for "[redacted] and the subsequent use of the [redacted] in private settings" are requested.

In his comments on the proposals for amendment from Germany related to consumer uses issues, the Registrant indicated that "*has since reviewed the respective consumer use and believes this was erroneously included in the original CSR submission and will be removed accordingly as part of the next registration update*".

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3 of the REACH Regulation. This request has been removed from the present decisoin, upon the dossier update. Therefore ECHA considers that a reasonable time period for providing the required information in the form of an updated registration, is 18 months from the date of the adoption of this decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by 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

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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