EUROPEAN CHEMICALS AGENCY

Helsinki, 04 July 2016

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For trimethoxy(methyl)silane, CAS No 1185-55-3 (EC No 214-685-0)

Addressees: Registrant(s)[1] of trimethoxy(methyl)silane

This decision is addressed to the Registrant(s) of the above substance with active registration pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by the Swedish Chemicals Agency as the Competent Authority of Sweden (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 27 June 2014, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Sweden has initiated substance evaluation for **trimethoxy(methyl)silane, CAS No 1185-55-3 (EC No 214-685-0)** based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Human health – sensitizer, exposure - wide dispersive use, consumer use and aggregated tonnage, trimethoxy(methyl)silane was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of Sweden was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concerns related to mutagenicity and derivation of DNELs.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 19 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA. By 27 June 2014 the Registrant(s) submitted update(s) of the registration dossier.

The evaluating MSCA considered the comments received from the Registrant(s) and the dossier updates. On the basis of this information section II was amended. The Statement of reasons (section III) was changed accordingly.

The pre-natal developmental toxicity test and extended one-generation reproductive toxicity study, which were initially intended to be requested in the present decision, were removed because they can be more appropriately addressed under dossier evaluation.

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

On 21 January 2016 the evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

By 22 February 2016 the evaluating MSCA received proposal(s) for amendment to the draft decision. The request to perform the Local lymph node assay, OECD 429 was removed from the decision based on the reasoning that available information is already sufficient to classify the substance as a skin sensitiser[2]. Consequently, the request for information on existing data on human skin sensitisation potential after exposure to the registered substance was also removed from the decision.

On 26 February 2016 ECHA invited the Registrant(s) to comment on the proposed amendment(s).

Referral to Member State Committee

On 7 March 2016 ECHA referred the draft decision to the Member State Committee.

By 29 March 2016, in accordance to Article 51(5), the Registrant(s) provided comments on the proposal for amendment. The Member State Committee took the comments into account and they are reflected in Section III, statement of reasons.

After discussion in the Member State Committee meeting on 25 – 29 April 2016, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 27 April 2016.

ECHA took the decision pursuant to Article 51(6) and Article 52 (2) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. **In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489. The comet assay shall be performed in rats via inhalation, as specified in Section III. DNA damage shall be assessed in lung and liver.**

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

2. **Further information to support the justification for the modified assessment factors used for derivation of the critical DNEL(s); and**

3. **Further information on exposure of consumers and professional users.**

[2] ECHA undersands that in their comments on the proposal for amendments the Registrant(s) stated that although they are of the opinion that the available data does not warrant for classifying the substance as a skin sensitizer, they agree with the proposal to remove the Local lymph node assay form the decision.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by exact date **11 October 2017** an update of the registration(s) containing the information required by this decision[3] including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1. In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489. The comet assay shall be performed in rats via inhalation. DNA damage shall be assessed in lung and liver

Concern

During the evaluation, the evaluating MSCA identified a further concern, i.e. a concern for mutagenic potential of trimethoxy(methyl)silane. The *in vitro* bacterial reverse mutation assay was negative. The positive results in a mammalian cell gene mutation assay ([redacted], 2002) indicate mutagenic potential of trimethoxy(methyl)silane. At concentrations causing a positive response in mutant frequency in the presence of S9 mix, relatively more small than large colonies were formed, which is indicative of a clastogenic mechanism of action. This is also in line with positive results of *in vitro* mammalian chromosome aberration test ([redacted] 2004). There is therefore concern from *in vitro* tests about potential to cause mutagenicity and *in vivo* study is necessary to clarify the concern.

The *in vivo* micronucleus assay (chromosome aberrations) according OECD Guideline 474 was provided and reported as negative. However, this study is considered not sufficient to clarify the concern related to potential of trimethoxy(methyl)silane to cause *in vivo* chromosomal aberrations. The reliability of the study is uncertain as no clear evidence that the substance has reached the target cells (bone marrow) has been provided. Although the Registrant(s) provided explanation that the clinical signs and mortality are the evidence of bioavailability of the substance and adequate exposure time, evaluation of bone marrow cell toxicity showed no signs of toxicity for the target cells at tested doses.

The necessity for further clarification of the potential to cause chromosomal aberrations *in vivo* remains. Thus, a further *in vivo* genotoxicity test shall be carried out to clarify this. The appropriate testing strategy should be considered based on the possible mechanisms involving gene mutations and/or chromosomal aberrations.

If the concern would be confirmed this would lead to improved risk management measures through classification of the substance for mutagenicity.

Alternative approaches

Positive results were obtained in both chromosome aberration and gene mutation studies on mammalian cells. However, the gene mutation study on mammalian cells shows results indicative of a clastogenic mechanism of action. Moreover, the available *in vitro* bacterial reverse mutation assays are negative. This dataset indicates that the main genotoxic mechanism is clastogenicity (numerical chromosome aberrations).

[3] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

The ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015), Chapter R.7a, section R.7.7.6.3 identifies that the following tests are options suitable to follow up on the positive results in *in vitro* tests showing chromosome aberrations and to address the concern for clastogenicity: the mammalian erythrocyte micronucleus test ("MN test", OECD TG 474), the mammalian bone marrow chromosomal aberration test ("CA test", OECD TG 475) or the *in vivo* mammalian alkaline comet assay (OECD TG 489). The MN test and CA test are able to detect chromosomal aberrations, whereas the comet assay is an indicator assay detecting putative DNA lesions and suitable to follow up both positive results for gene mutations and clastogenic effects. The transgenic rodent somatic and germ cell gene mutation assays ("TGR" OECD TG 488) and the *in vivo* mammalian alkaline comet assay are suitable to follow up a positive *in vitro* result showing gene mutation. Since in this case the concern is mainly on potential clastogenicity, the TGR is not considered to be an appropriate method. The comet assay is considered in this case to be the most appropriate method as it is suitable to follow up both positive results for gene mutations and clastogenic effects and can be used in different type of tissues.

In response to the draft decision the Registrant(s) agreed to perform the comet assay.

The comet assay shall be performed, using the test method: OECD 489 in rats via inhalation. DNA damage shall be assessed in lung and liver.

The reason for inhalation as a route of exposure:

- Inhalation is the relevant human exposure (beside the dermal exposure);
- Substance has rapid hydrolysis rate, that is pH dependent and testing with the inhalation exposure would allow investigation of effects from the parent substance, while the oral exposure would lead to rapid hydrolysis and exposure would be mostly to hydrolysis products.

The reasons for tissue selection are as follows:

- The lung was chosen due to exposure via inhalation as the initial site of contact with the body;
- Liver was chosen to study an effect on a tissue that is exposed to systemically available substances and it is a main site of metabolism. Moreover it is a slowly dividing tissue;

According to the strategy reflected in the legal text, if results of testing in somatic cells are positive, the potential for germ cell mutagenicity shall be considered.

Currently, the *in vivo* comet assay is not officially validated for the assessment of DNA damage in germ cells but only for the use in somatic cells. If the comet assay will be positive in somatic cells this will indicate the need to consider further investigation of germ cells mutagenicity, which will be done in the follow-up evaluation, pursuant to Article 46(3) of the REACH Regulation.

In the original draft decision the Registrant(s) were given the alternatives the comet assay and transgenic rodent (TGR) assay to address this concern. In response to the draft decision the Registrant(s) agreed to perform a comet assay.

Conclusion
Registrant(s) are required to perform a comet assay as specified in Section II, subject to the conditions presented in the Section III. Clarifying this concern has a potential impact on the risk management measures through classification of the substance for mutagenicity.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision: **In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489** as specified in Section II and III above.

The Registrant(s) are reminded that pursuant to Article 46(3) the evaluating MSCA may – after evaluation of the results from the test required above or any other new information – identify further information required to conclude on concerns raised during the evaluation. Such further requests could for example concern germ cell mutagenicity or carcinogenicity.

Notes for consideration by the Registrant(s)

Registrant(s) may consider examining gonadal cells when conducting the comet assay (OECD TG 489), as it would optimise the use of animals. ECHA notes that a positive result in whole gonads is not necessarily reflective of germ cell damage since gonads contain a mixture of somatic and germ cells. However, such positive result would indicate that the substance and/or its metabolite(s) have reached the gonads and caused genotoxic effects. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

The Registrant(s) are reminded that according to Annex IX, Section 8.4., column 2 of the REACH Regulation, if positive results from an in vivo somatic cell study are available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. The need for germ cell mutagenicity investigation will be considered by the evaluating MSCA in the follow up to this decision.

In parallel to the substance evaluation of trimethoxy(methyl)silane, the evaluating MSCA is performing a substance evaluation of trimethoxyvinylsilane (CAS No 2768-02-73; EC No 220-449-8). As a result of that evaluation, the Registrant(s) of trimethoxyvinylsilane are also requested to perform an *in vivo* comet assay in rats via the inhalation route. The Registrant(s) of both substances have indicated they are members of the same group of substances. However, currently no read-across is proposed or justification provided in the registration dossiers. The addressees of this decision are invited to consider whether read-across between the substances could be justified and under such conditions perform only one in vivo Comet assay, avoiding unnecessary animal testing. It is however stressed that it is the Registrants' responsibility to justify the read-across, if proposed, and that the plausibility of the read-across based on the documentation provided by the Registrant(s) can only be assessed based on a-follow-up evaluation by the evaluating MSCA.

In their comments on the proposal for amendments the Registrant(s) disagreed to these "notes for consideration". ECHA therefore further clarifies that the points included in these notes (examination of the gonadal cells and read-across analysis) are not requested, but rather suggested and advised to be considered by the Registrant(s). Furthermore, in their comments on the proposal for amendments, the Registrant(s) mentioned that they intend to analyse also the bone marrow. ECHA points out that such addition is left to the discretion of the Registrant(s).

2. Further information to support the justification for the modified assessment factors used for derivation of the critical DNEL(s)

Concern
The concern is related to the risk characterization ratios (RCRs).

The risks of systemic toxicity for several use scenarios for workers and consumers have been assessed. The DNEL for systemic effects following single exposure via the dermal route is determined on the basis of results from the acute dermal toxicity study in rabbits ([redacted], 1963). The DNEL for systemic effects following single exposure via the inhalation route is determined based on results from the acute inhalation study in rats ([redacted], 2006). The long term exposure DNEL for systemic effects via the inhalation and dermal routes are determined on the basis of a 90-day inhalation study in rats ([redacted], 2008). The long term exposure DNEL for systemic effects via the oral route is determined on the basis of the 28 day oral rat study ([redacted], 2005). The RCR calculations were based on DNELs derived with the use of assessment factors (AF) for interspecies and intraspecies extrapolation lower than ECHA's guidance recommendation. Specifically, AF [redacted] instead of 2.5 was used for interspecies extrapolation. For intraspecies extrapolation AF [redacted] instead of 10 for general population and AF [redacted] instead of AF 5 for workers was used.

In response to the original draft decision the Registrant(s) changed the AFs used for derivation of the DNELs and updated the dossier accordingly. All interspecies AFs were changed to 2.5, according to the ECHA guidance. The intraspecies AFs were changed to 2.2 and 3.2 for the workers and the general population, respectively. The following justification for deviation from the guidance recommendation was provided: "The intraspecies assessment factor takes account for the variability in sensitivity between individuals. This AF also covers differences between ethnic and age groups. The default intraspecies factors are typically broken down into equal factors accounting for toxicodynamic and toxicokinetic differences, respectively. Accordingly, an interspecies factor of 10 is composed of two identical factors of $\sqrt{10} = 3.2$. Likewise, the default for workers (AF = 5) can be split into AFs of $\sqrt{5} = 2.2$. As discussed above, the conversion of siloxanes to silanols and their excretion proceeds without enzymatic involvement. Individual genetic dispositions are therefore without effect on these processes. As a result, the toxicokinetic components (3.2 and 2.2 for general population and workers, respectively) can be eliminated from the intraspecies AF."

It is noted that no *in vivo* toxicokinetics data are available for trimethoxy(methyl)silane to address the fate of the substance or its hydrolysis products following different routes of exposure. Trimethoxy(methyl)silane hydrolyses in water with a half-life of approximately 2.2 h at pH 7, generating methylsilanetriol. Based on Quantitative Structure-Property Relationship (QSPR) analysis it is predicted that upon inhalation (the most relevant route of exposure), trimethoxy(methyl)silane can be absorbed across the lungs and taken up to the systemic circulation. It can also be dissolved in the respiratory tract mucus and absorbed to the blood. These predictions are supported by inhalation studies where systemic toxicity is observed. The QSPR analysis also predicts that both the parent substance and the hydrolysis product are mainly eliminated via the kidney in the urine.

Elimination of the "toxicokinetics element", which leads to less conservative DNELs is not sufficiently supported, i.e. by data on absorption, distribution or excretion of the substance. Using these modified AFs results in higher DNEL values and brings the RCRs below 1 in some use scenarios. For example, for the consumer use of sealants:
Modified AF: Dermal DNEL (0,3 mg/kg bw/d) --> RCR=0,34
Default AF: Dermal DNEL (0,1 mg/kg bw/d) --> RCR=1

The request for information to support the use of modified AFs is considered suitable and necessary to obtain information that will allow clarifying whether there is a risk (RCRs above 1). If no adequate justifications for the use of modified AF is provided the default values shall be used. In such case the foreseen risk management measure would be adjustment of the use scenarios by the Registrant(s) to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified AFs, the evaluating MSCA will carry out the evaluation based on default AFs, which may result in identification of a risk.

In their comments to the proposal for amendments the Registrant(s) agreed with the proposal that the concern and the information requested should be further specified. The decision was amended accordingly.

Conclusion
The hydrolysis rate and absorption levels of trimethoxy(methyl)silane in the respiratory tract are not determined, neither are the patterns of distribution in the body or excretion rates. Because of the lack of this information it cannot be excluded that the toxicokinetics components, absorption, distribution and excretion can vary in the exposed population.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **further information to support the justification for the modified assessment factors used for derivation of the critical DNEL(s) for the registered substance subject to this decision.**

3. Further information on exposure of consumers and professional users

Concern
Assessment of exposure of professional users and consumers due to the use of products containing trimethoxy(methyl)silane has been reported in the registration. The methodology used and/or clarification provided is however considered not sufficient to conclude that the exposure assessment covers expected uses and that the risks are controlled.

As an example, for the estimation of exposure in scenario "Professional and consumer use of sealants" a modifying factor is used to the CONSEXPO modelled results. This factor is based on the comparison of the results from the experimental study simulating the use of sealant ([redacted] 2010) and CONSEXPO output with the input parameters reflecting the experimental study. Although it is likely that the result of tier 1 exposure model would overestimate the exposure, the use of the factor of 0.1 as presented is considered not well substantiated. This extrapolation from the modelled data to the real exposures based on a single study with conditions different from the real situation exposure is not considered adequate, specifically in the situation when the resulting RCRs are close to 1.

In response to the draft decision the Registrant(s) have updated the exposure estimations. The "correction factor" 0.1, derived from the monitoring study is removed. For estimation of the inhalation exposure, "mass transfer rate" (the velocity by which a compound is transferred between the product and air) is refined. The "mass transfer rate" has been set to 0.0013 m/min (ConsExpo default=3100 m/min), based on results from the study with simulated application of sealant containing trimethoxy(methyl)silane ([redacted] 2010). This refinement results in an estimated inhalation exposure mean event concentration for consumers' use of sealants of 1.6 mg/m^3. For workers the updated estimated exposures are 6.01 mg/m^3 (RCR=[redacted]) compared to 61.6 mg/m^3 (RCR=[redacted]) using the default values.

For estimation of the dermal exposure, the diffusion coefficient (rate of the transfer of a substance through a medium to the surface) was refined. The diffusion coefficient 0.001cm^2/min is used in the refined estimations. The Registrant(s) have estimated this diffusion coefficient for trimethoxy(methyl)silane in a sealant product based on (1) the silane has a slow diffusion through a viscose medium and (2) crosslinking reaction of the reactive silane with the polymer matrix in the product makes its diffusion slower. Nonetheless, the Registrant(s) state that it may be necessary to measure the diffusion coefficient of representative silanes through polymer matrices to further support the setting of the diffusion coefficient. The ConsExpo modelled estimates for dermal load estimates are decreased from 15 mg/cm^2 to 0.1 mg/cm^2 for consumer use of sealants, consequent to this refinement.

It is noted that the refinements to the ConsExpo modelled exposure calculation of trimethoxy(methyl)silane lead to substantial reductions in the estimated exposure values, but experimental evidence to support these refinements and the accuracy of the estimates is limited. Refinement of the inhalation exposure is based on the simulation study that covers one use condition ([redacted] 2010). In this study measurement of the air concentrations of trimethoxy(methyl)silane was ended before the levels had reached a plateau. For estimation of the dermal exposure, there is no data supporting the used diffusion coefficient.

The refinements to the exposure estimates impact the risk management measures as these lead to a ten times decrease in the RCR values. As the current values for consumer use in sealants range from 0,1 to 0,3, RCRs will be above 1,0 without the refinements. Moreover, this might be an underestimation since the DNELs used to calculate the RCRs are derived using assessment factors lower than the default (without the toxicokinetics element).

Furthermore, for the calculation of exposure in scenarios "Professional and consumer use of coatings" and "Professional and consumer use of sealants" using CONSEXPO the "typical concentration" of the substance in the product(s) is used. The evaluating MSCA noted that those concentrations do not reflect maximum nominal concentrations as reported for some of the market products.

In response to the draft decision the Registrant(s) state that "studies are available that support crosslinking of the substance occurring between formulation and end use of sealant products. Hence, it is considered that the substance undergoes some initial reactions during and after the sealant product is formulated; therefore, the amount of substance added to the formulation is not the same as the amount in the product at the point of use."

The exposure scenario should cover the use of sealants by professionals and consumers for products containing trimethoxy(methyl)silane up to 2.5% by weight (the concentration added initially to the formulation). A concentration of 0.6% of trimethoxy(methyl)silane in the product has been used for the exposure assessments. In the updated CSR the Registrant(s) refer to supporting studies ([redacted], 2013, [redacted] 2010). The evaluating MSCA notes that in this study the percentage of the free trimethoxyvinylsilane, measured by head space chromatography, is reduced in a sealant product, compared to the initial amount in the formulation.

The request for information to support the use of modified parameters in modelled exposure estimates is considered suitable and necessary to obtain information that will allow to clarify whether there is a risk (RCRs above 1). If no adequate justifications for the use of modified parameters is provided the default values shall be used. In such case the foreseen risk management measure would be adjustment of the use scenarios by the Registrant(s) to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified parameters, the evaluating MSCA will carry out the evaluation based on the default values, which may result identification of a risk.

Conclusion
Further information on exposure estimation including support for the refined parameters, measured exposure data for representative and specific scenarios or estimated data from suitable models is needed to justify the accuracy of the exposure assessment and the RCRs.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the **further information specified above on exposure of consumers and professional users of the products containing** the registered substance subject to this decision.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing .

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrant(s) to perform the studies on behalf of all of them.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 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 the ECHA's internet page at http://echa.europa.eu/regulations/appeals . The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[4] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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

References