EUROPEAN CHEMICALS AGENCY

Helsinki, 26.02.2014

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

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

For carbon tetrachloride, CAS No 56-23-5 (EC No 200-262-8)

Addressee: [redacted] registrant of carbon tetrachloride

The present decision is exclusively addressed to [redacted] and it contains information requests that are additional to the information requests included in the decision addressed to all concerned registrants of carbon tetrachloride.

Based on an evaluation by French Agency for Food, Environmental and Occupational Health Safety (ANSES) on behalf of the French Competent Authority (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 does not take into account any updates of the registration of the concerned registrant after 1 August 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

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

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of France has initiated substance evaluation for carbon tetrachloride, CAS No 56-23-5 (EC No 200-262-8) based on registration dossiers submitted by the addressees (concerned registrants) and prepared decisions in accordance with Article 46(1) of the REACH Regulation. The present decision is exclusively addressed to the registrant of [redacted] and it contains information requests that are additional to the information required in decision number in format SEV-D-000000XXX-XX-XX/F addressed to all registrants of carbon tetrachloride.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Human health/CMR; Exposure/High exposure for workers, high aggregated tonnage, carbon tetrachloride was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of France was appointed to carry out the evaluation.

Further information is required to clarify the abovementioned concerns. Therefore, draft decisions were prepared pursuant to Article 46(1) of the REACH Regulation to request

further information. The present draft decision was submitted to ECHA on 28 February 2013.

On 4 April 2013 ECHA sent the draft decision to the Registrants 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. The Registrants provided comments on the draft decision by the given timeline. Having taken the comments into account, the Competent Authority of France modified Section III of the draft decision.

In accordance with Article 52(1) of the REACH Regulation, on 1 August 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, MSCAs submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the concerned registrant of the proposals for amendment to the draft decision and invited it pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the MSCAs' proposals for amendment and amended the draft decision accordingly.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

On 7 October 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 4 to 8 November 2013, a unanimous agreement of the Member State Committee on the draft decision was reached on 7 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrant shall submit the following information:

- Further details of monitoring information already presented in the registration dossier. Detailed protocols, operational conditions, and description of tasks used to measure the exposure of workers, for all tasks and personal protective equipment worn during these tasks. The raw data of results and the analysis methods used to measurement shall also be submitted.
- Detailed specifications of the personal protection equipment shall be provided for each exposure scenario.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 26 May 2016 an update of the registration dossiers containing the information required by this decision.

At any time, the concerned registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on carbon tetrachloride and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

The exposure assessment of workers was to the largest extent based on measured data for inhalation. But no detailed information was available in the exposure estimation to validate the use of this study. Many RCRs are in the range of 0.5-1: according to R14- occupational exposure estimation guidance part 4.5, uncertainties have to be checked. Moreover, as some RCR with the proposed DNEL by registrant are close to 1, the use of a lower (FR-CA) DNEL would result to RCR superior to 1. In this context refinement of exposure scenarios are necessary.

Following an informal meeting with [redacted], additional data regarding occupational exposure were provided in September 2012: in particular details on tasks associated with a potential exposure of carbon tetrachloride, types of personal protective equipments, estimation of acute exposure values (95^{th} and 99^{th} percentiles according to measured exposure values). However raw data of results and analysis methods used to measure that substance were not provided. These data are necessary to assess the uncertainties and refine the exposure assessment, in order to perform a robust risk assessment.

In this context, following data are required: detailed protocols, operational conditions, and description of tasks for all measured exposure tasks and personal protective equipment worn during these tasks. The raw data of results and the analysis methods used to measurement have to be submitted.
Moreover, according to REACH Annex II detailed specifications of the personal protection equipment shall be provided for each exposure scenario. For skin protection, this included the type of material and its thickness, the typical or minimum breakthrough times of the glove material.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrant shall submit to ECHA an update of the registration dossiers containing the information required by this decision.

The following Registrant's comment has been considered: maximum RCR calculated with the inhalation data is 0.3. But as many combined RCRs are in the range of 0.5-1, some uncertainties have to be checked and as no detailed information in the exposure estimation is available, it is currently difficult to confirm the safe use of the substance. The necessity to have access to the full study is confirmed.

[redacted] proposes to provide the requested information concerning only its company, therefore the data about manufacture of substance.
[redacted]
According to Art. 46-2 of REACH regulation, the registrant shall submit all the information required. [redacted].

No amendments of the draft decision has been done.

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

[redacted]

Jukka Malm
Deputy Executive Director