



Brussels, 29.5.2015
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COMMISSION IMPLEMENTING DECISION

of 29.5.2015

**granting an authorisation for a use of diarsenic trioxide under Regulation (EC) No
1907/2006 of the European Parliament and of the Council**

(Text with EEA relevance)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Diarsenic trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was submitted by Yara France (“the applicant”) on 22 July 2014 in accordance with Article 62 of Regulation (EC) No 1907/2006, for the industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate from synthesis gas formed in the production of ammonia.
- (3) On 9 January 2015 the European Chemicals Agency sent to the Commission the opinions of the Committee for Risk Assessment (“RAC”) and the Committee for Socio-economic Analysis (“SEAC”)² pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion the RAC confirmed that it is not possible to determine a DNEL for the carcinogenicity (category 1A) properties of diarsenic trioxide and that it is a non-threshold substance. Therefore, it meets the criteria of Article 60(3)(a) of Regulation (EC) No 1907/2006 and the authorisation cannot be granted for the use of that substance according to the provisions in Article 60(2) of that Regulation. RAC confirmed that the exposure assessment in the application appears to be appropriate however the risk management measures and operational conditions as described in the

¹ OJ L 396, 30.12.2006, p. 1.

² <http://echa.europa.eu/documents/10162/271ba483-5615-40ef-83f2-b68ac073359c>

application need improvement in order to further limit the risk to workers exposed to diarsenic trioxide as well as to reduce the emissions to the environment.

- (5) In its opinion, the SEAC confirmed the applicant's conclusion that the overall benefits of the use of diarsenic trioxide applied for outweigh the risks to human health or the environment arising from that use and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant, both in accordance with the provisions in Article 60(4) of Regulation (EC) No 1907/2006.
- (6) It is therefore appropriate to authorise that use provided that the risk management measures and operational conditions described in the application, in particular in the chemical safety report, as well as the monitoring arrangements recommended in the opinions of RAC and SEAC are fully applied.
- (7) In its opinion, the SEAC recommended the time-limited review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twenty two months. The recommended review period takes into account the fact that the benefits from the continued use of the substance outweigh the risks to human health and the environment arising from that use, the lack of suitable alternatives in terms of their technical or economic feasibility to be implemented by the sunset date and the fact that the applicant has provided substitution planning activities for transition to an alternative within a period of twenty two months of the sunset date.
- (8) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 at twenty two months.
- (9) In its opinion, the RAC identified a need to improve the existing risk management measures in order to further reduce workplace exposure and releases to the environment and therefore recommended the authorisation to be subject to specific monitoring arrangements in addition to the risk management measures recommended in the chemical safety report. Furthermore, a review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 should contain information gathered on the basis of specific monitoring arrangements recommended in the opinions of RAC and SEAC.
- (10) In order to facilitate the enforcement of the decision, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, to the competent authority of the Member State where the use takes place a proof that the specific monitoring arrangements have been performed.
- (11) Furthermore, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, to the competent authority of the Member State where the use takes place a succinct summary of the risk management measures and operational conditions of the relevant parts of the chemical safety report submitted as part of the application in an official language of that Member State.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of diarsenic trioxide (EC No. 215-481-4, CAS No. 1327-53-

3), subject to full application of both the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation³, and the monitoring arrangements set out in Article 4 below. The authorised use is identified by the following authorisation number:

[REACH/15/1/0]

Use: The industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate from synthesis gas formed in the production of ammonia

Article 2

A maximum quantity of 5 tonnes per year of diarsenic trioxide newly added to the carbon dioxide removal unit shall not be exceeded.

Article 3

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 March 2017.

Article 4

The following monitoring arrangements referred to in Article 60(9)(f) shall apply:

- (a) The holder of the authorisation shall perform:
- measurements of the personal inhalation exposure for each of the tasks where exposure to arsenic can reasonably be anticipated;
 - biomonitoring for each of the tasks for which arsenic exposure can reasonably be anticipated, as well as yearly biomonitoring for workers on site who are not considered to be exposed to arsenic;
 - monthly measurements on arsenic emissions from the U202 stack and from the evaporator;
 - documentation and evaluation of the information gathered in the actions above and shall use this to improve the overall effectiveness of the risk management measures.

On request of the competent authority of the Member State where the authorised use takes place, the holder of the authorisation shall submit to that authority a documented proof of having performed the actions above.

- (b) On request of the competent authority of the Member State where the authorised use takes place, the holder of the authorisation shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in Article 1, in an official language of that Member State.
- (c) The information gathered on the basis of the specific monitoring arrangements listed in subparagraph (a) shall be used to support the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

³

<http://ec.europa.eu/DocsRoom/documents/8899/attachments/1/translations/en/renditions/native>

Article 5

This Decision is addressed to Yara France, Immeuble Opus 12, 77 Esplanade du Général de Gaulle CS 90047, 92914 Paris La Défense Cedex, France.

Done at Brussels, 29.5.2015

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

