



Brussels, 4.9.2015
C(2015) 6063 final

COMMISSION IMPLEMENTING DECISION

of 4.9.2015

**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 Nordenhamer Zinkhütte GmbH on 13 November 2013 in accordance with Article 62 of Regulation (EC) No 1907/2006, for the industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process.
- (3) On 22 October 2014 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 in Article 60(3)(a) of Regulation (EC) No 1907/2006 and 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 is appropriate and that the risk management measures and operational conditions as described in the application, provided they are applied in practice, are effective in limiting the risk.

¹ OJ L 396, 30.12.2006, p. 1.

² <http://echa.europa.eu/documents/10162/3aa8d418-275c-4732-ab80-80e8462a1be2>

- (5) In its opinion, the SEAC confirmed the applicant's conclusions that the overall benefits arising from the industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process outweigh the risks to human health or the environment arising from the use and that there are no suitable alternative substances or technologies in terms of their 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, are fully applied.
- (7) In its opinion, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. The recommended review period takes into account the lack of suitable alternatives in terms of their economic feasibility, while technically feasible alternatives are available, and the unlikelihood of technological change in the basic technology that would allow the applicant to switch to an alternative. The SEAC also considered the applicant's request for a 20-year review period based on an investment cycle of such length but at the same time took into account the RAC considerations for a shorter review period due to the need for improvements in the exposure assessment.
- (8) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 at twelve years.
- (9) In their opinions, the RAC and the SEAC did not recommend any additional risk management measures and operational conditions, nor additional monitoring arrangements compared to those described in the application. However, RAC recommended that a review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 should contain a more refined and thereby improved exposure assessment for both workers and man via the environment.
- (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 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.
- (11) 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 the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation³. The authorised use is identified by the following authorisation number:

[REACH/15/3/0]

Use: Industrial use of diarsenic trioxide to

³ <http://ec.europa.eu/DocsRoom/documents/7302/attachments/1/translations/en/renditions/native>

produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 May 2027.

Article 3

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

- (a) 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 the Member State.
- (b) When submitting the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 the holder of the authorisation shall provide a more refined and thereby improved exposure assessment for both workers and man via the environment.

Article 4

This Decision is addressed to Nordenhamer Zinkhütte GmbH, Johannastr. 1, 26954 Nordenham, Germany.

Done at Brussels, 4.9.2015

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

