EUROPEAN
COMMISSION

Brussels, 8.2.2017
C(2017) 661 final

COMMISSION IMPLEMENTING DECISION

of 8.2.2017

granting an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Boliden Mineral AB)

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 8.2.2017

granting an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Boliden Mineral AB)

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Sodium dichromate is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 21 May 2015, Boliden Mineral AB ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

(3) On 29 February 2016, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency ('the Agency') on the application[2].

(4) In its opinion, the RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore that sodium dichromate is a non-threshold substance. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, Article 60(2) of that Regulation does not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

(5) In its opinion, the RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population. However, the RAC considered that due to

[1] OJ L 396, 30.12.2006, p. 1.

[2] http://echa.europa.eu/documents/10162/4d963558-d574-493f-9c35-778cde2461e8

the shortcomings in the exposure assessment, its reliability should be increased, in particular regarding the strategy of monitoring of exposure and number measurements of exposure.

(6) In its opinion, the RAC recommended the authorisation to be subject to additional conditions and monitoring arrangements. The authorisation holder should develop and implement a strategy for monitoring of occupational exposure, conduct regular occupational exposure measurements related to the authorised use of sodium dichromate and to include the results in the case of a review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006. The outcomes and conclusions of those monitoring measurements should also be submitted, upon request, to the competent authority of the Member State where the use takes place for enforcement purposes, in an official language of that Member State.

(7) In its opinion, the SEAC concluded that the socio-economic benefits arising from the use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores outweigh the risks to human health and the environment arising from that use and that there are no suitable alternative substances or technologies in terms of their economic feasibility for the applicant. The SEAC concluded that, while it could be technically possible to continue producing with one of the alternative substances under assessment, it had not sufficient information to evaluate whether additional research will render its implementation also economically feasible.

(8) Based on the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the use of sodium dichromate applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report[3] are fully applied.

(9) 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 seven years. The recommended review period takes into account that the benefits of continued use significantly outweigh the risks to human health or the environment but also the uncertainty with regard to the outcome and timeframe of planned R&D activities to find a feasible alternative due to insufficient information in this regard.

(10) Therefore, as regards the use of sodium dichromate applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(11) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.

(12) This Decision does not affect either the obligation of the holder of the authorisation to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 or the obligation of the employer to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible in

[3] http://ec.europa.eu/DocsRoom/documents/15925/attachments/1/translations/en/renditions/native

accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council[4], or to prevent and reduce exposure in accordance with Article 5 of that Directive.

(13) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directive 2010/75/EU of the European Parliament and of the Council[5] and Directive 2008/50/EC of the European Parliament and of the Council[6], as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council[7] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[8]. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.

(14) 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 sodium dichromate (EC No. 234-190-3, CAS No. 10588-01-9/7789-12-0) provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, as well as the conditions set out in Article 2 of this Decision are fully applied:

Authorisation number	Authorised use
REACH/17/4/0	Use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores

Article 2

The authorisation referred to in Article 1 shall be subject to the following condition:

– the authorisation holder shall develop and implement a programme for monitoring of occupational exposure to sodium dichromate to all workers potentially exposed at the

[4] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

[5] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)(OJ L 334, 17.12.2010, p. 17).

[6] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

[7] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

[8] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

site(s) and conduct regular occupational exposure measurements (with sampling done at least annually) related to the use referred to in Article 1.

Article 3

As regards the authorised use of sodium dichromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024.

Article 4

The following monitoring arrangements shall apply:

(a) the information gathered from the measurements referred to in Article 2 shall be used to regularly review the effectiveness of the risk management measures and operational conditions and to take action as appropriate;

(b) on request of the competent authority of the Member State where the use takes place, the authorisation holder shall submit to that authority the information obtained from the measurements referred to in Article 2, as well as documentation on the review of the effectiveness of the risk management measures and operational conditions, in an official language of that Member State;

(c) on request of the competent authority of the Member State where the authorised use takes place, the authorisation holder shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report, in an official language of that Member State;

(d) when submitting the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 concerning the use referred to in Article 1 of this Decision, the authorisation holder shall provide the results of the monitoring as described in Article 2 of this Decision as well as a report resulting from the review of the effectiveness of the risk management measures and operational conditions it is required to perform in accordance with point (a) of this Article.

Article 5

This Decision is addressed to Boliden Mineral AB, Rönnskärsverken, 932 81, Skelleftehamn, Sweden.

Done at Brussels, 8.2.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION