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COMMISSION IMPLEMENTING DECISION

of 4.8.2017

granting an authorisation for a use of lead chromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Etienne Lacroix Tous Artifices SA)

(ONLY THE FRENCH 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) Lead chromate 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 28 November 2014, an application for authorisation was submitted by Etienne Lacroix Tous Artifices SA ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the industrial use of lead chromate in the manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection ('use applied for'). In order to align the wording of the use with the terminology of Regulation (EC) No 1907/2006, that use should be referred to as 'industrial use of lead chromate in the production of pyrotechnical delay devices contained into ammunition for naval self-protection'.
- (3) On 21 September 2015, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency² on the application.
- (4) In its opinion, the RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) neither for the carcinogenic (category 1B) properties nor for the reproductive toxicity (category 1A) properties of lead chromate and therefore, for both types of effect, that it 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 substances for which it is not possible to determine a threshold, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

¹ OJ L 396, 30.12.2006, p. 1.

² <http://echa.europa.eu/documents/10162/3c522aca-aa5a-4f6e-95d6-8b5b52482b53>

- (5) In its opinion, the RAC concurred with the applicant that for the current application it is not relevant to assess the risk to the general population that could potentially be exposed via the environment. However, as regards workers' exposure, the RAC considered that the operational conditions and risk management measures as described in the chemical safety report³, and in particular for those tasks involving the manual handling of the substance, are not appropriate and effective in limiting the risk to workers. Therefore, the RAC recommended the authorisation to be subject to additional conditions and monitoring arrangements.
- (6) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use 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.
- (7) Considering the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use applied for, provided that measures are implemented to improve the containment of the substance during operations involving its manual handling. Furthermore the applicant should conduct regular occupational exposure measurements relating to the use of lead chromate. The authorisation holder should use those measurements to review the effectiveness of the risk management measures and to take action, as appropriate.
- (8) 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 on one hand the importance of using the specific decoy launching system as a defence equipment for certain types of frigates and the related need of the continued use of lead chromate until the end-of-life of these frigates, the fact that the application concerns the depletion of an already existing stock of the substance, the very low quantities of lead chromate needed per annum for this particular use, which will cease with the end-of-life of the frigates, and the fact that no suitable alternative would be available before the end-of-life of the frigates. On the other hand, the review period takes into account the concerns of the RAC with regard to the lack of appropriateness and effectiveness of the risk management measures and operational conditions, as well as the uncertainties related to both the exposure and the socio-economic assessment.
- (9) However, given the applicant submitted its application for authorisation after the latest application date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and the sunset date set out in Annex XIV to that Regulation has already passed at the time of the adoption of this Decision, it is appropriate to set the starting point for the review period as from the adoption of this Decision.
- (10) In view of the RAC and the SEAC opinion, the Commission considers appropriate that, as regards the use of lead chromate applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at seven years as from the adoption of this Decision.
- (11) The language used for the description of the risk management measures and operational conditions included in the application for authorisation is different from the official language of the Member State where the use applied for takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the authorisation holders to submit,

³ <http://ec.europa.eu/DocsRoom/documents/14375/attachments/1/translations/en/renditions/native>

upon request, 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 the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect either the obligation of the authorisation holder 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 that Regulation 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 accordance with Article 4(1) of Directive 2004/37 of the European Parliament and of the Council⁴ or to prevent and reduce exposure in accordance with Article 5 of that Directive. Furthermore, this Decision is without prejudice to the application of the EU Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC⁵, Council Directive 98/24⁶, Directive 2004/37 of the European Parliament and of the Council⁷, Council Directive 92/85/EEC⁸ and Council Directive 94/33/EC⁹.
- (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 Council¹⁰ and Directive 2008/50/EC of the European Parliament and of the Council¹¹, 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 Council¹² and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹³. 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.

⁴ OJ L 158, 30.4.2004, p. 50.

⁵ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.06.1989, p. 1).

⁶ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 05.05.1998, p. 11).

⁷ 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, 30.04.2004).

⁸ Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/ 391 / EEC) (OJ L 348, 28.11.1992, p. 1).

⁹ Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

¹⁰ 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).

¹¹ 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).

¹² 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).

¹³ 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).

(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 lead chromate (EC No 231-846-0; CAS No 7758-97-6), 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/17/10/0	Industrial use of lead chromate in the production of pyrotechnical delay devices contained into ammunition for naval self-protection

Article 2

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

- (a) the authorisation holder shall implement appropriate technical measures to contain the substance at source. Full enclosure (such as glove boxes) with air extraction around the area where the tasks resulting in exposure are performed shall be used;
- (b) regular occupational measurements (with sampling done at least annually) relating to the use referred to in Article 1 shall be implemented. Those measurements shall:
 - (i) be based on relevant standard methodologies or protocols;
 - (ii) comprise personal inhalation exposure sampling (consisting of measurement of chromium and lead) and biomonitoring (consisting of measurement of lead);
 - (iii) be representative of the range of tasks with possible exposure to lead chromate and of the total number of workers that are potentially exposed;
- (c) the information gathered in the measurements referred to in point (b) shall be used to review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce workers' exposure to lead chromate;
- (d) the results of the measurements referred to in point (b) and a description of the effectiveness of improved technical measures referred to in point (a) and the outcomes of the review referred to in point (c) shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 3

As regards the authorised use of lead chromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 4 August 2024.

Article 4

The following monitoring arrangement shall apply:

- 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 referred to in Article 1, in an official language of that Member State.

Article 5

This Decision is addressed to Etienne Lacroix Tous Artifices SA, Route de Gaudiès, 09 270 Mazères, France.

Done at Brussels, 4.8.2017

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission