EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 10.7.2019

granting an authorisation for certain uses of ammonium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (BAE Systems (Operations) Limited and others)

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

Whereas:

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

(2) On 18 March 2016, BAE Systems (Operations) Limited and Qioptiq Ltd ('the applicants') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the industrial use of ammonium dichromate in the process of manufacturing holographic combiners for diffractive head-up displays intended to be used in military aircrafts ('use 1'), and Display Technologies Limited submitted an application for authorisation for the industrial use of ammonium dichromate in the process of manufacturing cathode ray tubes (CRT) for head up displays intended to be used in military and civilian aircrafts ('use 2'). For the sake of consistency with the terminology of Regulation (EC) No 1907/2006, the term ‘manufacturing’ should be replaced by ‘producing’ in the description of both authorised uses.

(3) On 14 June 2017, 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[2] on the applications pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of ammonium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore

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

[2] https://echa.europa.eu/documents/10162/2dc48473-b77a-ebfc-c319-e340ac0c82c0 https://echa.europa.eu/documents/10162/5bd3b9d6-35cf-0e09-1cc0-f3642bce1b05

ammonium dichromate is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. Pursuant to Article 60(3)(a) of the same Regulation, its Article 60(2) does not apply to that substance, and therefore an authorisation may only be granted in accordance with Article 60(4) of that Regulation.

(5) In its opinion on use 1, RAC concluded that the risk management measures are appropriate and effective in limiting the risks in one of the sites where that use takes place. In its opinions, RAC also concluded that the risk management measures and operational conditions as described in the application for use 2 and at one of the sites for use 1 are not appropriate and effective in limiting the risk. Therefore, for both uses covered by the applications, RAC recommended the authorisation to be subject to conditions. The Commission, having evaluated RAC's assessment, concurs with RAC's conclusion and recommendation.

(6) In its opinions, SEAC concluded that the overall socio-economic benefits arising from the uses of ammonium dichromate covered by the applications outweigh the risk to human health arising from those uses and that there are no suitable alternative substances or technologies for the applicants. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of ammonium dichromate covered by the applications, provided that the risk management measures and operational conditions described in the applications and, in particular, in the chemical safety reports, as well as the conditions set out in this Decision, are fully applied.

(8) In its opinions, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years for use 1 and four years for use 2. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments. In particular, with regard to use 1, the Commission takes into account the fact that the applicants' past and continuous research and development activities had not led to the development of an alternative that could be implemented within shorter timelines, the time necessary for qualification and certification of any potential alternative to ensure compliance with the relevant performance and safety requirements under applicable airworthiness regulations, and the significant socio-economic benefits of continued use. With regard to use 2, the Commission takes into account the end-of-production cycle of the CRT technology, the need to service legacy customers, the time necessary for development, industrialisation and qualification of any potential alternative, the very low quantity of the substance applied for, and the significant socio-economic benefits of continued use.

(9) Therefore, it is appropriate to set a review period of twelve years for use 1 and of four years for use 2 from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(10) 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 uses take place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holders to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.

(11) This Decision does not affect the obligation of each authorisation holder to ensure that the use does not adversely affect human health or the environment having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect the obligation of each 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 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 accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council[3], or to prevent and reduce exposure in accordance with Article 5 of that Directive. This Decision does not affect the application of the Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7], and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

(12) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC[8] or 2010/75/EU[9] of the European Parliament and of the Council, or with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with other emission limit values or environmental quality standards under Union legislation, as those may include further or more onerous requirements.

(13) On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or, failing that, two years after the notification, unless the

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3 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).

4 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, 29.6.1989, p. 1).

5 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).

6 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

7 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, 5.5.1998, p. 11).

8 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).

9 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).

10 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).

11 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).

European Council, in agreement with the United Kingdom, unanimously decides to extend that period.

(14) This Decision is addressed to legal entities established in the United Kingdom. Unless otherwise provided for in a withdrawal agreement, this Decision can therefore only apply to those addressees until the Treaties cease to apply to the United Kingdom notwithstanding the end of the validity laid down in this Decision.

(15) 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 uses of ammonium dichromate (EC No 232-143-1; CAS No 7789-09-5):

Authorisation number	Authorisation holder	Authorised use
REACH/19/24/0	BAE Systems (Operations) Limited	Industrial use in the process of producing holographic combiners for diffractive head-up displays intended to be used in military aircrafts
REACH/19/24/1	Qioptiq Ltd.	
REACH/19/24/2	Display Technologies Limited	Industrial use in the process of producing cathode ray tubes for head up displays intended to be used in military and civilian aircrafts

The authorisation is granted subject to full application of the risk management measures and operational conditions described in the chemical safety reports[12], as well as the conditions set out in this Decision.

Article 2

1. The authorisation bearing number REACH/19/24/1 shall be subject to the conditions set out in paragraphs 2 to 9.

2. Without undue delay, the authorisation holder shall select and implement risk management measures following the hierarchy of control principles with a view to limiting dermal and inhalation exposure of workers to ammonium dichromate.

3. The authorisation holder shall investigate the process containment, such as a glove box, or a local extraction ventilation, such as a fume cupboard for working

[12] Use 1 : http://ec.europa.eu/docsroom/documents/24106
Use 2: http://ec.europa.eu/docsroom/documents/24107

contributing scenarios 2.2, 2.3 and 2.4 in the relevant chemical safety report referred to in Article 1, document it and make it available, upon request, to the competent authority of the Member State.

4. The authorisation holder shall implement organisational measures such as training, relevant procedures and supervisions/inspections, in order to limit workers exposure to ammonium dichromate. The authorisation holder shall provide workers with annual training dedicated to the safe use of ammonium dichromate and to the use of PPE.

5. At the latest on 10 July 2020 the authorisation holder shall verify and demonstrate the appropriateness of personal protective equipment (PPE) for skin exposure, in particular gloves, for handling ammonium dichromate and shall document the outcomes and conclusions of that review, including the implementation of any additional risk management measures.

6. The authorisation holder shall conduct regular occupational exposure measurements of ammonium dichromate, personal and stationary, related to the use covered by the authorisation. Those measurements shall:

   (a) take place at least annually;

   (b) comprise both personal and static inhalation exposure sampling;

   (c) be based on relevant standard sampling and analytical methods ensuring a sufficiently low detection limit;

   (d) be representative of the range of all the tasks with possible exposure to ammonium dichromate, and for the total number of workers that are potentially exposed;

   (e) include contextual information about the tasks with possible exposure to chromium (VI), on the sampling time related to shifts, the tasks performed and PPE worn.

7. The authorisation holder shall annually perform biomonitoring of workers with possible exposure to ammonium dichromate by measuring chromium (VI) values in urine.

8. The authorisation holder shall use the information gathered in the measurements referred to in paragraphs 6 and 7 to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce, as appropriate, exposure of workers to ammonium dichromate.

9. The results of the measurements and the contextual information referred to in paragraphs 6 and 7, as well as the outcome and conclusions of the review and any actions taken in accordance with paragraph 8, shall be documented and included, together with the outcomes and conclusions of the review referred to in paragraph 5, in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, submitted to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The authorisation bearing number REACH/19/24/2 shall be subject to the conditions set out in paragraphs 2 to 11.

2. Without undue delay, the authorisation holder shall select and implement risk management measures following the hierarchy of control principles with a view to limiting dermal and inhalation exposure of workers, and shall further apply to the updated risk management measures and operational conditions set out in the Annex.

3. The authorisation holder shall investigate the process containment or the use of local extraction systems, such as a fume cupboard for all tasks which may result in exposure of workers to ammonium dichromate, in particular for working contributing scenarios 5, 6 and 7 in the relevant chemical safety report referred to in Article 1 and for the complementary working contributing scenario 'inverting of measuring cylinder - process step 4 (compl-1)' referred to in the Annex, shall document it and make it available to the competent authority of the Member State.

4. The authorisation holder shall re-arrange work organisation for working contributing scenarios 5 and 6 in the relevant chemical safety report referred to in Article 1 to prevent dermal exposure of the face.

5. The authorisation holder shall evaluate which tasks require the use of respiratory protection equipment (RPE) to prevent inhalation exposure and ensure that appropriate RPE is selected which provides adequate protection in all of the different possible exposure situations.

6. At the latest on 10 July 2020, the authorisation holder shall verify and demonstrate the appropriateness of PPE for skin exposure to ammonium dichromate, in particular gloves, for handling ammonium dichromate and shall document the outcomes and conclusions of that review, including the implementation of any additional risk management measures.

7. The authorisation holder shall provide workers with annual training on the safe use of ammonium dichromate and on the adequate use of PPE and RPE, if relevant.

8. The authorisation holder shall conduct regular occupational exposure measurements of ammonium dichromate, personal and stationary, related to the use covered by the authorisation. Those measurements shall:

   (a) take place at least annually;

   (b) comprise both personal and static inhalation exposure sampling;

   (b) be based on relevant standard sampling and analytical methods ensuring a sufficiently low detection limit;

   (c) be representative of the range of all the tasks with possible exposure to ammonium dichromate, and of the total number of workers that are potentially exposed;

   (d) include contextual information about the tasks with possible exposure to chromium (VI), on the sampling time related to shifts, the tasks performed and PPE worn.

9. The authorisation holder shall annually perform biomonitoring of workers with possible exposure to ammonium dichromate by measuring chromium values in urine.

10. The authorisation holder shall use the information gathered in the measurements referred to in paragraphs 8 and 9 to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce exposure of workers to ammonium dichromate.

11. The results of the measurements and the contextual information referred to in paragraphs 8 and 9, as well as the outcome and conclusions of the review and any actions taken in accordance with paragraph 10, shall be documented and included, together with the outcomes and conclusions of the review referred to in paragraph 6, in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, submitted to the competent authority of the Member State where the authorised use takes place.

Article 4

1. If the use covered by authorisation number REACH/19/24/1 is relocated to the site where the use covered by authorisation number REACH/19/24/0 takes place, both authorisations shall be subject to the conditions set out in paragraphs 2 to 4.

2. The authorisation holders shall ensure that any changes to the production process shall include risk management measures to limit exposure to workers and humans via the environment to at least the levels described in the application for authorisation for use REACH/19/24/0 corresponding to exposure scenario 1 in the relevant chemical safety report referred to in Article 1 and preferably reduce them further.

3. In the production following the exposure scenario 2 in the relevant chemical safety report referred to in Article 1, the authorisation holders shall select and implement appropriate risk management measures that follow the hierarchy of control principles with a view to limiting the exposure.

4. The authorisation holders shall ensure that programmes of occupational exposure monitoring take duly into account any changes in the production process due to relocation and those in the risk management measures resulting from actions under paragraphs 2 and 3.

Article 5

1. As regards the authorisation bearing numbers REACH/19/24/0 and REACH/19/24/1, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2029.

   The authorisation shall cease to be valid on 21 September 2029 with respect to any holder of the authorisation who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 March 2028.

2. As regards the authorisation bearing the number REACH/19/24/2, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2021.

   The authorisation shall cease to be valid on 21 September 2021, unless a review report has been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 March 2020.

Article 6

1. The authorisation bearing number REACH/19/24/0 shall be subject to the monitoring arrangements set out in paragraphs 2 to 5.

2. The authorisation holder shall conduct regular occupational exposure measurements of ammonium dichromate, personal and stationary. Those measurements shall:

(a) take place at least annually;

(b) comprise both personal and static inhalation exposure sampling;

(c) be based on relevant standard sampling and analytical methods ensuring a sufficiently low detection limit;

(d) be representative of the range of all the tasks with possible exposure to ammonium dichromate, and of the total number of workers that are potentially exposed;

(e) include contextual information about the tasks with possible exposure to chromium (VI), on the sampling time related to shifts, the tasks performed and PPE worn.

3. The authorisation holder shall annually perform biomonitoring of workers with possible exposure to ammonium dichromate by measuring chromium values in urine.

4. The authorisation holder shall use the information gathered in the measurements referred to in paragraphs 2 and 3 to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce exposure of workers to ammonium dichromate.

5. The authorisation holder shall document the results of the measurements and the contextual information referred to in paragraphs 2 and 3, as well as the outcome and conclusions of the review and any actions taken in accordance with paragraph 4, include this information in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, shall submit it to the competent authority of the Member State where the authorised use takes place.

Article 8

The authorisation holders shall submit, upon request, to the competent authority of the Member State where the authorised use takes place a succinct summary of the applicable risk management measures and operational conditions described in the relevant chemical safety report in an official language of that Member State.

Article 9

This Decision is addressed to:

(1) BAE Systems (Operations) Limited, Airport Works, Marconi Way, ME1 2XX, Rochester, Kent, United Kingdom;

(2) Qioptiq Ltd., Glascoed Road, LL17 0LL, St. Asaph, Denbighshire, United Kingdom;

(3) Display Technologies Limited, Greenside Way, Middleton, M24 1SN, Manchester, United Kingdom.

Done at Brussels, 10.7.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

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For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION