



Brussels, 17.3.2022
C(2022) 1514 final

COMMISSION IMPLEMENTING DECISION

of 17.3.2022

refusing an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to DCL Corporation (NL) B.V. OR for certain uses of lead sulfochromate yellow and of lead chromate molybdate sulfate red

(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) Lead sulfochromate yellow and lead chromate molybdate sulfate red are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement in Article 56(1)(a) of that Regulation.
- (2) On 19 November 2013, DCC Maastricht BV², acting as only representative, ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for the placing on the market of lead sulfochromate yellow and lead chromate molybdate sulphate red, for six uses. The uses for which authorisation was sought are the same for both substances: the distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use ('use 1'); the industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.) ('use 2'); the professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking ('use 3'); the distribution and mixing of pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use ('use 4'); the industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use ('use 5'); and the professional use of solid or liquid colour premixes and precompounds containing pigment in the application of hot melt road marking ('use 6').
- (3) On 2 January 2015, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-

¹ OJ L 396, 30.12.2006, p. 1.

² DCC Maastricht BV subsequently changed its name to DCL Corporation (NL) B.V. OR.

economic Analysis (SEAC) of the European Chemicals Agency³ and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

- (4) On 7 September 2016, the Commission adopted Implementing Decision C(2016) 5644 final⁴ granting an authorisation for all uses applied for, for both substances. Decision C(2016) 5644 final, subject to an application for annulment under Article 263 of the Treaty on the Functioning of the European Union in case T-837/16, was annulled by the General Court in the judgment of 7 March 2019. The annulment was confirmed by the judgment of 25 February 2021 of the Court of Justice in the appeal case C-389/19 P⁵, which maintained the effects of Decision C(2016) 5644 final until a new Commission Implementing Decision on the application for authorisation is adopted. Therefore, the Commission adopts this Decision on the application for authorisation, the effects of which replace the effects of Decision C(2016) 5644 final as of the date of the notification of this Decision to the applicant.
- (5) According to Article 2(2) of Decision C(2016) 5644 final, the review period expired on 21 May 2019 as regards uses 3 and 6 of both substances. Since the applicant has not submitted a review report for those uses, the provision authorising those uses has expired and, consequently, those uses are not allowed. Therefore, uses 3 and 6 are not included in this Decision.
- (6) RAC concluded in its opinions that it is not possible to determine a derived no-effect level (DNEL) for either the carcinogenic (category 1B) properties or the reproductive toxic (category 1A) properties of lead sulfochromate yellow and lead chromate molybdate sulfate red in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore lead sulfochromate yellow and lead chromate molybdate sulfate red are substances for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60, paragraph 2, of Regulation (EC) No 1907/2006 does not apply to those substances and an authorisation may therefore only be granted with respect to those substances under paragraph 4 of that Article.
- (7) In its opinions on uses 1, 2, 4 and 5, RAC concluded that the risk management measures and operational conditions described in the application are appropriate to limit the risk to human health, provided that they are adhered to. Nevertheless, RAC considered that some of the factors for the effectiveness of respiratory protective equipment and personal protection equipment might not be achieved in practice and

³ - For lead sulfochromate yellow:
<https://echa.europa.eu/documents/10162/2b1ed281-8904-41b6-9297-a5a56c903fc6>
<https://echa.europa.eu/documents/10162/55f79321-687b-41af-b486-fc19e40fb263>
<https://echa.europa.eu/documents/10162/ad1b0af9-01c4-4ec0-9200-16e39ad2211c>
<https://echa.europa.eu/documents/10162/a133ba7f-abb1-4a5d-8e2e-e8b225e4c4c0>
<https://echa.europa.eu/documents/10162/2178e745-4b2d-44d5-9b39-4fbcacd67b26>
<https://echa.europa.eu/documents/10162/a559b759-0037-4803-8825-0f5f75d95a54>

- For Lead chromate molybdate sulphate red:
<https://echa.europa.eu/documents/10162/87f426a0-374f-4d1d-999f-8dcea782492c>
<https://echa.europa.eu/documents/10162/ab72b524-ffbd-495a-a7c6-7781f9293ee3>
<https://echa.europa.eu/documents/10162/a8824e48-32ea-4be4-be5c-38acca58e757>
<https://echa.europa.eu/documents/10162/b07280b5-5453-460a-9811-38bb616ab57e>
<https://echa.europa.eu/documents/10162/f7e355bf-6fd1-42dc-8d9e-03e949738012>
<https://echa.europa.eu/documents/10162/c07e1bfc-9105-4113-b20b-038bc7e931e1>

⁴ Commission Implementing Decision C(2016) 5644 of 7 September 2016 granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulfate red under Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

⁵ Judgement of 25 February 2021, *Commission v Sweden*, C-389/19 P, EU:C:2021:131.

had reservations about the intensity of use and overreliance on such equipment as reported in the application. For those reasons, and to ensure the effectiveness of those measures, RAC recommended as condition to carry out biomonitoring programmes on exposure of the employees, as well as air emission monitoring programmes. Having evaluated RAC assessment, the Commission agrees with that conclusion and recommendation.

- (8) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide some functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying an additional effort which is reasonable, taking into account the circumstances of the case.
- (9) In its opinions, SEAC concluded that there are no suitable alternative substances or technologies as regards uses 1, 2, 4, and 5 applied for. After re-evaluating SEAC's assessment and all relevant information available, the Commission notes that there was evidence casting serious doubts on that conclusion. In particular, according to detailed submissions in the public consultation by other producers of certain paints and their customers, it seems that there are alternative substances on the market used by other operators and accepted by their customers for the same uses as those applied for. Moreover, lead sulfochromate yellow and lead chromate molybdate sulfate red have been phased out since decades in certain Member States, with operators in those Member States having successfully managed to switch to safer alternatives providing the required functionalities for the uses applied for. The Commission acknowledges that those major uncertainties on the availability of suitable alternatives, which cannot be clarified based on the data submitted by the applicant, were neither addressed in SEAC's assessment and conclusion, nor properly explained by the applicant in its responses.
- (10) Therefore, the Commission does not agree with SEAC's conclusion that there are no suitable alternative substances or technologies and, given the persisting major uncertainties, considers that the applicant has not discharged its burden of proof in demonstrating the absence of suitable alternatives as regards uses 1, 2, 4, 5 for which the authorisation was sought.
- (11) As a consequence, considering that the applicant failed to fulfil one of the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, namely to demonstrate that there are no suitable alternative substances or technologies, it is unnecessary to assess the other condition that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substances.
- (12) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to refuse the authorisation for uses 1, 2, 4, 5 of lead sulfochromate yellow and lead chromate molybdate sulfate red applied for.

- (13) The Commission has based its assessment on the relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby refused in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of lead sulfochromate yellow (EC No 215-693-7, CAS No 1344-37-2) and lead chromate molybdate sulfate red (EC No 235-759-9, CAS No 12656-85-8):

- distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use;
- industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.);
- distribution and mixing of pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use;
- industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use.

Article 2

This Decision is addressed to DCL Corporation (NL) B.V. OR, Sortieweg 39, 6219 NT Maastricht, Netherlands.

Done at Brussels, 17.3.2022

For the Commission

Thierry BRETON

Member of the Commission

