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COMMISSION IMPLEMENTING DECISION

of 13.5.2024

refusing an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ilario Ormezzano Sai S.r.l. for certain uses of sodium dichromate

(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) Sodium dichromate is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.
- (2) On 21 March 2016, Ilario Ormezzano Sai Spa² ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of sodium dichromate. The uses for which authorisation was sought are the repackaging of sodium dichromate to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings ('use 1') and the use as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings ('use 2').
- (3) The European Chemicals Agency ('the Agency') sent the opinions on the application for authorisation for use 1³ and use 2⁴ adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission⁵ pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 15 May 2017, the Commission received the opinions.

¹ OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>.

² Ilario Ormezzano Sai Spa subsequently changed its corporate name to Ilario Ormezzano Sai S.r.l.

³ <https://echa.europa.eu/documents/10162/a643ea5d-e60f-0612-598f-9457b90fb194>.

⁴ <https://echa.europa.eu/documents/10162/e681a734-ed81-3bd6-36fc-177b09e5f165>.

⁵

- (4) On 29 November 2018, the European Parliament adopted a resolution⁶ concerning the draft Commission Decision granting an authorisation for certain uses of sodium dichromate to Ilario Ormezzano Sai S.r.l. In that Resolution, the Commission was called upon to refuse the authorisation, mainly due to the uncertainties concerning the assessment of alternatives. The Commission took note of that resolution.
- (5) The judgment of the General Court of 7 March 2019 in Case T-837/16⁷, *Sweden v. Commission*, provided the interpretation of Article 60(4) and (5) and Article 62(4), point (f), of Regulation (EC) No 1907/2006 as regards suitability of alternatives and the requirement to provide a substitution plan. On 22 April 2020, the Commission therefore sent a request to the applicant to complement the information provided in the application for use 2 accordingly, by submitting a substitution plan.
- (6) On 24 September 2020, the applicant submitted to the Agency a substitution plan. On 28 July 2021, the Commission received from the Agency an addendum to the Agency's opinion adopted by SEAC on use 2⁸.
- (7) In its opinions on uses 1 and 2, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic properties of sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium dichromate is a substance 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(2) of Regulation (EC) No 1907/2006 does not apply to sodium dichromate and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.
- (8) In its opinions on uses 1 and 2, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to members of the general population who could potentially be exposed to Cr(VI) via the environment, posed by the uses of sodium dichromate. However, RAC concluded that those measures are not appropriate and effective in limiting the risk to workers. RAC therefore recommended imposing additional conditions and monitoring arrangements.
- (9) For an alternative to be suitable it needs to 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, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.
- (10) An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible. Certain potential alternatives may provide the functionality, but at some loss of 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

⁶ European Parliament resolution of 29 November 2018 on the draft Commission implementing decision granting an authorisation for certain uses of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Ilario Ormezzano Sai S.R.L.) (D058762/01 – 2018/2929(RSP)) (OJ C 363, 28.10.2020, p. 98).

⁷ Judgment of the General Court of 7 March 2019, *Sweden v. Commission*, T-837/16, ECLI:EU:T:2019:144, paragraphs 75 and 76.

⁸ <https://echa.europa.eu/documents/10162/b2b2655a-c39e-c70a-8253-250a9eeeab7d>.

technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

- (11) Similarly, an alternative the use of which does not lead to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use for which an authorisation is sought should be considered economically feasible.
- (12) In its opinion on use 1, SEAC noted that sodium dichromate had no separate function at the repackaging stage and therefore relied on the analysis of the alternatives for use 2. Therefore, SEAC concluded that there were no suitable alternative substances or technologies available before the sunset date. Having evaluated SEAC's assessment, the Commission agrees that the analysis of alternatives for use 1 needs to rely on the analysis carried out for use 2.
- (13) In its opinion on use 2, SEAC concluded that there were no suitable alternatives available for the applicant by the sunset date while noting a number of uncertainties in the analysis. On technical feasibility, SEAC noted that at least two groups of alternatives are available in the Union but are most likely not technically feasible. However, SEAC highlighted that a number of uncertainties still remained, and in particular, that the applicant's claims that the alternatives do not provide the required performance as regards colour characteristics and crease/stretch resistance were too general and did not relate to specific alternatives.
- (14) After evaluating SEAC's assessment and all relevant information available, the Commission does not agree with SEAC's conclusion that there are no suitable alternative substances or technologies for the applicant. The Commission considers that the initial application had several serious shortcomings and contained a high level of uncertainty, clearly reflected in the SEAC conclusion. In particular, the Commission highlights SEAC's remarks on the justification on technical feasibility of the alternatives, showing a lack of depth and completeness, as well as making the information difficult to assess by SEAC. Although the applicant addressed some of those uncertainties during the opinion making process, the remaining uncertainties are still of such magnitude that the Commission cannot consider them negligible. The Commission therefore considers that the applicant has not discharged its burden of proof in demonstrating the absence of suitable alternatives as regards use 2, and consequently also as regards use 1.
- (15) As the applicant failed to fulfil one of the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is not necessary to assess the fulfilment of the other condition, namely that socio-economic benefits outweigh the risk to human health arising from the use of the substance.
- (16) It is therefore appropriate to refuse the authorisation for the uses of sodium dichromate described in the application.
- (17) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information.
- (18) The measures provided for in this Decision is 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 refused in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of sodium dichromate (EC No 234-190-3; CAS No 10588-01-9 (anhydrous); CAS No 7789-12-0 (dihydrate)):

- (a) repackaging to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings;
- (b) use as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings.

Article 2

This Decision is addressed to Ilario Ormezzano Sai S.r.l., Via Cavour 120, 13894, Gaglianico, Biella, Italy.

Done at Brussels, 13.5.2024

For the Commission
Thierry BRETON
Member of the Commission

