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Authorisation for certain uses of sodium dichromate

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))

The European Parliament,

– having regard to 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),

– 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] ('the REACH Regulation'), in particular Article 64(8) thereof,

– having regard to the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)[2], pursuant to the third subparagraph of Article 64(5) of the REACH Regulation,

– having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[3],

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1 OJ L 396, 30.12.2006, p. 1.

2 Opinion on Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings (EC No 234-190-3);
Opinion on 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 (EC No 234-190-3).

3 OJ L 55, 28.2.2011, p. 13.

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

– having regard to Rule 106(2) and (3) of its Rules of Procedure,

A. whereas sodium dichromate is included in Annex XIV to the REACH Regulation because of three intrinsic properties: carcinogenicity, mutagenicity and reproductive toxicity (category 1B); whereas sodium dichromate was added to the REACH Regulation candidate list in 2008[1], because of its classification as carcinogenic, mutagenic and toxic for reproduction (category 1B) according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2];

B. whereas the molecular entity that drives the carcinogenicity of sodium dichromate is the chromium (VI) containing ion, which is released when sodium dichromate solubilises and dissociates; whereas chromium (VI) causes lung tumours in humans and animals by the inhalation route and tumours of the gastrointestinal tract in animals by the oral route;

C. whereas already in 1997 in the framework of Council Regulation (EEC) No 793/93[3], sodium dichromate was identified as a priority substance for evaluation in accordance with Commission Regulation (EC) No 143/97[4]; whereas in 2008 the Commission issued a recommendation to reduce the risk from exposure to sodium dichromate[5];

D. whereas Ilario Ormezzano Sai S.R.L (the Applicant) submitted an application for authorisation to use sodium dichromate in the dyeing of wool; whereas the application is described in the opinions of the RAC and the SEAC as an ‘upstream’ application; whereas the Applicant is the supplier of sodium dichromate to 11 downstream users that either manufacture the dyes or are dyers themselves;

E. whereas the purpose of the REACH Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of the hazards posed by substances, and the free circulation of substances on the internal market, while enhancing competitiveness and innovation; whereas the primary objective of the REACH Regulation is the first of those three objectives, in

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1 European Chemicals Agency Decision by the Executive Director of 28 October 2008 on the inclusion of substances of very high concern in the candidate list.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

3 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).

4 Commission Regulation (EC) No 143/97 of 27 January 1997 concerning the third list of priority substances as foreseen under Council Regulation (EEC) No 793/93 (OJ L 25, 28.1.1997, p. 13).

5 Commission Recommendation of 30 May 2008 on risk reduction measures for the substances sodium chromate, sodium dichromate and 2,2′,6,6′-tetrabromo-4,4′-isopropylidenediphenol (tetrabromobisphenol A) (OJ L 158, 18.6.2008, p. 62).

light of Recital (16) in the preamble to the Regulation, as interpreted by the Court of Justice[1];

F. whereas the REACH Regulation does not provide for a special authorisation regime for so-called 'upstream applications'; whereas any applicant for authorisation, whatever their role or level in the supply chain, must provide the information listed in Article 62 of the REACH Regulation;

G. whereas RAC confirmed that it is not possible to determine a derived no-effect level for the carcinogenic properties of sodium dichromate and sodium dichromate is therefore considered as a 'non-threshold substance' for the purposes of Article 60(3)(a) of the REACH Regulation; whereas this means that a theoretical 'safe level of exposure' to this substance cannot be set and used as a benchmark to assess whether the risk of using it is adequately controlled;

H. whereas Recital (70) of the REACH Regulation states 'for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects';

I. whereas RAC concluded that the operational conditions and risk management measures described in the application were not appropriate and effective in limiting the risk[2];

J. whereas Article 55 of the REACH Regulation provides that the substitution of substances of very high concern with safer alternative substances or technologies is a central aim of the authorisation chapter;

K. whereas Article 64(4) of the REACH Regulation provides that the mandate of SEAC is to assess the 'availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application […] and any third party contributions submitted under paragraph 2 of this Article';

L. whereas Article 62(4)(e) of the REACH Regulation requires the applicant for authorisation to provide 'an analysis of alternatives considering their risks and the technical and economic feasibility of substitution';

M. whereas Article 60(4) of the REACH Regulation provides that an authorisation to use a substance whose risks are not adequately controlled can only be granted if there are no suitable alternative substances or technologies;

N. whereas SEAC noted many deficiencies in the application for authorisation regarding the analysis of alternatives; whereas the Applicant, according to SEAC, failed to address key issues to the extent that this 'hinder[ed] the Committee's assessment of

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1 Case C-558/07, *S.P.C.M. SA and Others* v *Secretary of State for the Environment, Food and Rural Affairs*, ECLI:EU:C:2009:430, § 45.

2 Opinion on Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings (EC No 234-190-3), p. 19, Question 6.

technical feasibility', and some aspects as important as the economic feasibility of alternatives were only 'briefly discussed' by the Applicant[1];

O. whereas the main argument used by the Applicant to conclude that no alternatives were suitable was that the customers (i.e. manufacturers/retailers of clothes) would not accept the quality of the colouring of the textile when dyed with an alternative;

P. whereas, however, the alleged requirements of the customers were not supported by any evidence, and it is not clear whether the reference to 'customers' preference' was made in full knowledge of the risks of sodium dichromate[2];

Q. whereas in addition, SEAC has noted, despite further inquiries with the Applicant, that 'whether an alternative product will ultimately be accepted by the customers of their downstream users still remains somewhat subjective and uncertain'[3], SEAC noted in its conclusion: 'After welcome clarifications by the Applicant, the Committee still finds a number of uncertainties in the analysis';

R. whereas despite these gaps and uncertainties in the application, SEAC still concluded that no suitable alternatives were available, simply making a general statement that these uncertainties 'are inherent to this kind of use (discussions on product quality can be marred by the subjectivity of fashion trends and consumer aesthetic tastes)'[4];

S. whereas, in this context, the SEAC opinion shows that the Applicant has not provided a comprehensive analysis of alternatives available on the market to substitute the use of sodium dichromate for the uses applied for, but fails to draw the adequate conclusions;

T. whereas such an outcome cannot be reconciled with the fact that alternatives are known to have been available for many years[5], that leading fashion brands are contributors to the ZDHC Roadmap to Zero Programme, which does not allow the use of chromium (VI) in textile manufacturing[6], and that individual textile companies have explicit policies that do not allow the use of chromium (VI) (e.g. H&M)[7], including companies in high-end fashion markets (Armani[8] and Lanificio Ermenegildo Zegna[9]);

U. whereas Gruppo Colle and Ormezzano have been the only applicants for authorisation under the REACH Regulation for chrome dyes;

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1 Opinion on Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings (EC No 234-190-3), pp. 24-25.

2 Applicant's analysis of alternative available at: https://echa.europa.eu/documents/10162/88b2f393-17cf-465e-95eb-ba07282ba400

3 Opinion on Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings (EC No 234-190-3), p. 24.

4 Opinion on Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings (EC No 234-190-3), p. 26.

5 See https://marketplace.chemsec.org/Alternative/LANASOL-CE-pioneering-replacement-of-chrome-dyes-since-20-years-44

6 See: https://www.roadmaptozero.com/mrsl_online/

7 See H&M Group Chemical Restrictions 2018 Manufacturing Restricted Substances List (MRSL).

8 See Armani's Restricted Substances List Version 9 - Effective as of the Season SS 18.

9 See Huntsman presentation entitled 'Turning risks into opportunities - How to dye wool sustainably' (p. 18).

V. whereas the REACH Regulation places the burden of proof on the applicant for authorisation to show that the conditions for granting an authorisation are fulfilled; whereas SEAC has a duty to provide 'scientific advice founded on the principles of excellence, transparency and independence', which 'is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'[1];

W. whereas it is not clear why, despite the deficiencies or uncertainties identified regarding the analysis of alternatives, SEAC concluded that sufficient information was available to reach a conclusion on the suitability of the alternatives; whereas it is also not clear why claims of subjective preferences were not rejected despite the absence of detailed objective and verifiable evidence, and why those claims were not assessed against best market practice;

X. whereas it is not acceptable to tolerate potentially numerous cases of infertility, cancer and mutagenic effects, despite the availability of alternatives to sodium chromate, on the basis of an assumption that manufacturers of clothes would not accept alternatives due to their subjective 'taste';

Y. whereas such an interpretation of the notion of alternatives and the level of proof required from the applicant is neither in line with the objective to replace substances of very high concern with alternatives, nor with the primary objective of the REACH Regulation to ensure a high level of protection of human health and the environment;

Z. whereas the Commission is aware of the availability of suitable alternatives, thanks in particular to information provided during the public consultation and trilogue[2] organised by the European Chemicals Agency in the context of the Gruppo Colle case[3];

AA. whereas it is not appropriate for the Commission to ignore critical information showing the availability of suitable alternatives from this parallel case;

AB. whereas Article 61(2)(b) of the REACH Regulation empowers the Commission to review an authorisation at any time if 'new information on possible substitutes become available';

AC. whereas the granting of an authorisation for the use of a non-threshold substance for applications for which alternatives are clearly known to be available is not in accordance with the conditions set out in the provisions of the REACH Regulation, and would unduly reward laggards and set a dangerous precedent for future authorisation decisions under the REACH Regulation;

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1 Judgment of the Court of First Instance (Third Chamber) of 11 September 2002, *Pfizer Animal Health SA* v *Council of the European Union*, Case T-13/99, ECLI:EU:T:2002:209.

2 As explained in RAC and SEAC Opinion in the Gruppo Colle case: Use of sodium dichromate as mordant in wool dyeing (EC No 234-190-3) (p. 21 referring to two alternatives: Lanasol and Realan).

3 ECHA Adopted opinions and previous consultations on applications for authorisation - Gruppo Colle.S.r.l. - Use of Sodium dichromate as mordant in wool dyeing (EC No 234-190-3).

1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1907/2006, by not respecting the conditions set by that Regulation for granting an authorisation;

2. Calls on the Commission to withdraw its draft implementing decision and to submit a new draft rejecting the application for authorisation for certain uses of sodium dichromate (Ilario Ormezzano Sai S.R.L.);

3. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.