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Certain uses of chromium trioxide

European Parliament resolution of 27 March 2019 on the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) (D060095/03 – 2019/2654(RSP))

The European Parliament,

– having regard to the draft Commission implementing decision granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others) (D060095/03),

– 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'), and 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 second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006,

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1 OJ L 396, 30.12.2006, p. 1.
2 Use 1: https://echa.europa.eu/documents/10162/a43a86ab-fcea-4e2b-87d1-78a26cde8f80
Use 2: https://echa.europa.eu/documents/10162/dc9ea416-266e-4f49-88cb-35576f574f4a
Use 3: https://echa.europa.eu/documents/10162/fab6fe18-3d69-483b-8618-f781d18d472e
Use 4: https://echa.europa.eu/documents/10162/0f5571f8-d3aa-4031-9454-843cd7f765a8
Use 5: https://echa.europa.eu/documents/10162/6ee57573-de19-43b5-9153-dad5d9de3c1e

– 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[1],

– having regard to the judgment of the General Court of 7 March 2019 in Case T-837/16[2],

– 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 chromium trioxide was added to the candidate list of substances of very high concern under the REACH Regulation in 2010[3] because of its classification as carcinogenic (category 1A) and mutagenic (category 1B);

B. whereas chromium trioxide was included in Annex XIV to the REACH Regulation in 2013[4] due to that classification, the high volumes currently in use, the high number of sites where it is used in the Union and the risk of significant exposure to workers[5], with a sunset date of 21 September 2017;

C. whereas companies willing to continue using chromium trioxide had to submit an application for authorisation by 21 March 2016;

D. whereas Lanxess and six other companies ('the Applicants') formed a consortium, with a membership of more than 150 companies, but whose exact membership is unknown, to submit a joint application[6];

E. whereas, having jointly submitted an application before the deadline of 21 March 2016, the Applicants and their downstream users were allowed to continue using chromium

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Use 6: https://echa.europa.eu/documents/10162/ab92f048-a4df-4d06-a538-1329f666727a

1 OJ L 55, 28.2.2011, p. 13.

2 Judgment of the General Court of 7 March 2019, *Sweden* v *Commission*, T-837/16, ECLI:EU:T:2019:144: http://curia.europa.eu/juris/documents.jsf?oqp=&for=&mat=or&lgrec=en&jge=&td=%3BALL&jur=C%2CT%2CF&num=T-837%252F16&page=1&dates=&pcs=Oor&lg=&pro=&nat=or&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&language=en&avg=&cid=2535071

3 https://echa.europa.eu/documents/10162/6b11ec66-9d90-400a-a61a-90de9a0fd8b1

4 Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 108, 18.4.2013, p. 1).

5 https://echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf

6 http://www.jonesdayreach.com/SubstancesDocuments/CTAC%20Press%20Release%20Conclusion%20plus%20Annex%20+%20Cons%20Agt+amendm.PDF

trioxide, pending the authorisation decision in application of Article 58 of the REACH Regulation, in respect of the uses applied for;

F. whereas the Commission received the opinions of the RAC and SEAC in September 2016; whereas the Commission's delay in drafting the decision de facto led to the continued use of chromium trioxide being tolerated for one and a half years after the sunset date;

G. whereas the primary objective of the REACH Regulation, in light of its recital 16, as interpreted by the Court of Justice of the European Union[1], is to ensure a high level of protection of human health and the environment;

H. whereas according to Article 55 and in light of recital 12 of the REACH Regulation, a central aim of authorisation is the substitution of substances of very high concern with safer alternative substances or technologies;

I. whereas the RAC confirmed that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide, which is therefore considered as a 'non-threshold substance' for the purposes of point (a) of Article 60(3) 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;

J. whereas the RAC has estimated that the granting of such an authorisation would lead to 50 statistical fatal cancer cases every year;

K. whereas Article 60(4) of the REACH Regulation provides that an authorisation to use a substance whose risks are not adequately controlled may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies;

L. whereas the application concerns the use of 20 000 tonnes of chromium trioxide per year;

M. whereas the application concerns a very large number of downstream users (more than 4 000 sites) active in industry sectors ranging from cosmetics to aerospace, from food packaging to automotive, and from sanitary to construction, with an unprecedented number of workers who are exposed (more than 100 000 workers);

N. whereas the application formally concerns six 'uses'; whereas those use descriptions are nevertheless so generic that they result in a very broad scope, or even an 'extremely broad scope'[2]; whereas this vitiates both the socio-economic assessment as well as the assessment of suitable alternatives;

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[1] Judgment of the Court of 7 July 2009, *S.P.C.M. SA and Others* v *Secretary of State for the Environment, Food and Rural Affairs*, C-558/07, ECLI:EU:C:2009:430, paragraph 45.

[2] See RAC/SEAC opinion on use 2, p. 25, or on use 5, p. 61.

O. whereas point (d) of Article 62(4) of the REACH Regulation requires the Applicants to provide a chemical safety report in accordance with Annex I; whereas this must include an exposure assessment[1];

P. whereas the RAC noted a major discrepancy between the scope of the application submitted and the information provided therein[2];

Q. whereas the RAC identified major gaps in the information provided by the Applicants regarding the exposure scenarios for workers[3];

R. whereas the failure of the Applicants to provide the necessary information regarding the exposure scenarios of workers was acknowledged in the draft Commission implementing decision[4];

S. whereas, instead of considering the application not to be in conformity under Article 60(7) of the REACH Regulation, the draft Commission implementing decision simply requires that the Applicants provide the missing data in their review report, years after adoption of this draft decision[5];

T. whereas the review report, in accordance with Article 61 of the REACH Regulation, is not intended to give companies additional time to fill gaps in information that had to be provided up front (since such information is key to the decision-making), but is meant to ensure that the information initially provided in the application is still up-to-date;

U. whereas the General Court clearly stated that conditions attached to an authorisation, within the meaning of Article 60(8) and (9) of the REACH Regulation, cannot aim at remedying the potential failures of or gaps in the application for authorisation[6];

V. whereas the SEAC opinion furthermore highlighted significant uncertainties in the analysis of alternatives presented by the Applicants, which were also reflected in the draft Commission implementing decision[1];

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[1] REACH, Annex I, section 5.1.

[2] 'RAC notes the discrepancy in each use applied for, [...] between a) the total number of potential sites which the applicant […] considers may be covered by this application (up to 1 590 sites as given in the SEA) [for use 2], b) the number of CTAC members (150+) and c) the measured exposure data provided (from 6 to 23 sites for uses 1 to 5)'.

[3] 'The greatest uncertainty arises from the lack of clear link between the OCs [operational conditions], RMMs [risk management measures] and exposure values for specific tasks and sites, which could justifiably represent the application. RAC sees this as a substantial weakness of the application' (RAC opinion on use 2, p. 12).

[4] 'RAC concluded that there are significant uncertainties regarding worker exposure due to limited availability of measured exposure data. It further concluded that a prevalent lack of contextual information has made it difficult to establish a link between the operational conditions and risk management measures described in the application and the claimed exposure levels for specific tasks and sites, thereby preventing RAC from further evaluation. Those uncertainties concern the reliability and representativeness of the exposure data and how it relates to the specific risk management measures in place', Draft decision, recital 7.

[5] Draft decision, recital 25 and Article 8.

[6] Judgment of the General Court of 7 March 2019, *Sweden* v *Commission*, ECLI:EU:T:2019:144, paragraphs 82 and 83.

W. whereas, in light of Article 55 and Article 60(4) of the REACH Regulation, an applicant must prove that there are no suitable alternative substances or technologies for the uses for which it has applied;

X. whereas suitable alternatives have been shown to be available for many of the applications that are covered by the uses to be authorised[2];

Y. whereas the General Court reminded the Commission that, in order to legally grant an authorisation under Article 60(4) of the REACH Regulation, it has to verify a sufficient amount of substantial and verifiable information in order to conclude either that no suitable alternatives are available for any of the uses covered in the application or that, at the date of the adoption of the authorisation, the remaining uncertainties on the lack of available alternatives are only negligible[3];

Z. whereas in this case, the uncertainties on the analysis of alternatives were far from negligible[4];

AA. whereas the fact that the 'uses' for which the Applicants decided to apply are very broad cannot legitimately justify an incomplete analysis of alternatives;

AB. whereas Article 62 of the REACH Regulation does not provide for any information waiver for companies applying together as a consortium;

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[1] 'Due to the very broad scope of the intended uses, the SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications that are covered by the description of the uses applied for', Draft decision, recital 14.

[2] Alternatives related to applications 2 to 5:
– PVD CROMATIPIC plasma coating, see https://marketplace.chemsec.org/Alternative/Eco-friendly-chrome-plating-based-on-nanotechnologies-94
– EHLA process, see https://marketplace.chemsec.org/Alternative/Effective-Protection-against-Wear-Corrosion-with-the-EHLA-Process--185
– TripleHard, see https://marketplace.chemsec.org/Alternative/TripleHard-REACH-compliant-hard-chrome-is-the-best-in-the-market-96
– Hexigone Inhibitors, see https://marketplace.chemsec.org/Alternative/Chrome-and-Zinc-free-Corrosion-Inhibitor-for-Coatings-Highly-Effective-Drop-In-Replacement-of-Hexavalent-Chromate--95
– SUPERCHROME PVD COATING, see https://marketplace.chemsec.org/Alternative/SUPERCHROME-PVD-COATING-a-green-alternative-to-hexavalent-chrome-plating-10
– Oerlikon Balzers ePD, see https://marketplace.chemsec.org/Alternative/Oerlikon-Balzers-ePD-Reach-compliant-Chrome-look-for-plastic-parts-on-a-new-level-69

[3] Judgment of the General Court of 7 March 2019, *Sweden* v *Commission*, ECLI:EU:T:2019:144, paragraph 86.

[4] 'According to the applicant, applications where substitution is already possible are not covered by the application anyhow. The applicant does, however, not specify such applications or their related technical requirements. SEAC finds the applicant's approach to resolve this issue not fully appropriate and emphasises the need for the applicant to demonstrate more concretely that substitution has taken place where indeed already feasible. This could have been achieved by undertaking a more precise and use-specific assessment of alternatives', SEAC opinion on use 2, p. 25.

AC. whereas the authorisation proposed by the Commission is therefore in breach of Article 60(7) and (4) of the REACH Regulation;

AD. whereas, moreover, a number of downstream users covered by the draft Commission implementing decision have already applied separately for authorisation; whereas the RAC and SEAC have already issued their opinion on some of these applications; whereas some authorisations for downstream users have already been granted;

AE. whereas, however, there may be specific applications among the very broad uses of the joint application by the Applicants for which downstream users did not make a separate request for authorisation, but for which the conditions of Article 60(4) of the REACH Regulation may be fulfilled;

AF. whereas such applications may be in important areas;

AG. whereas it would therefore be appropriate, exceptionally, to give a chance to such downstream users that have not yet made a specific application to submit a separate application within a short deadline;

1. Calls on the Commission to withdraw its draft implementing decision and to submit a new draft;

2. Calls on the Commission to carefully assess whether any authorisations can be granted in full compliance with the REACH Regulation for specific, well-defined uses covered by the application submitted by the Applicants;

3. Calls on the Commission to grant, exceptionally, to downstream users whose use is covered by the application by the Applicants, but for which no separate application for authorisation has yet been made, and for which the relevant data is missing, the possibility to submit the missing data within a short deadline;

4. Calls on the RAC and SEAC to assess swiftly those subsequently completed applications, including a proper check that those applications have included all the necessary information specified in Article 62 of the REACH Regulation;

5. Calls on the Commission to take swift decisions with regard to those applications in full compliance with the REACH Regulation;

6. Calls on the RAC and SEAC to no longer accept applications that do not include the information to be provided pursuant to Article 62 of the REACH Regulation;

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