



**2019/2844(RSP)**

14.10.2019

# **DRAFT MOTION FOR A RESOLUTION**

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others)

(D063690/01 – 2019/2844(RSP))

**Committee on the Environment, Public Health and Food Safety**

Members responsible: Bas Eickhout, Maria Arena, Martin Hojsík

**European Parliament resolution on the draft Commission implementing decision partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others)  
(D063690/01 – 2019/2844(RSP))**

*The European Parliament,*

- having regard to the draft Commission implementing decision partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others) (D063690/01),
- 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<sup>1</sup> ('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) of the European Chemicals Agency<sup>2</sup>, 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<sup>3</sup>,
- having regard to the judgment of the General Court of 7 March 2019 in Case T-837/16<sup>4</sup>,
- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- having regard to Rule 112(2) and (3) of its Rules of Procedure,

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> Consolidated version of 9 December 2016 of the Opinion of the Committee for Risk Assessment (RAC) and Opinion of the Committee for Socio-economic Analysis (SEAC) on an Application for Authorisation for Chromium trioxide use: Functional Chrome Plating, ECHA/RAC/SEAC: Opinion N° AFA-O-0000006522-78-02/F. <https://echa.europa.eu/documents/10162/50002b75-2f4c-5010-81de-bcc01a8174fc>

<sup>3</sup> OJ L 55, 28.2.2011, p. 13.

<sup>4</sup> 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/document/document\\_print.jsf?docid=211428&text=&dir=&doclang=EN&part=1&occ=first&mode=lst&pageIndex=0&cid=1573675](http://curia.europa.eu/juris/document/document_print.jsf?docid=211428&text=&dir=&doclang=EN&part=1&occ=first&mode=lst&pageIndex=0&cid=1573675)

- A. whereas chromium trioxide was added to the candidate list of substances of very high concern under the REACH Regulation in 2010<sup>5</sup> 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<sup>6</sup> due to that classification, the high volumes that were in use, the high number of sites where it was used in the Union and the risk of significant exposure to workers<sup>7</sup>;
- C. whereas Cromomed S.A. and four other companies (the ‘Applicants’) have jointly submitted an application for authorisation in accordance with Article 62 of the REACH Regulation for the use of chromium trioxide in functional chrome plating for a broad array of applications, including general engineering and steel production<sup>8</sup>;
- D. whereas the Commission received the opinions of RAC and SEAC in December 2016; whereas the draft Commission implementing decision was only submitted to the REACH Committee at the end of August 2019;
- E. 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<sup>9</sup>, is to ensure a high level of protection of human health and the environment;
- F. 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;
- G. whereas RAC confirmed that it is not possible to determine a ‘derived no-effect level’ for the carcinogenic properties of chromium trioxide; whereas chromium trioxide qualifies therefore as a ‘non-threshold substance’, i.e. a substance for which it is not possible to estimate a ‘safe level of exposure’;
- H. whereas in the case of such ‘non-threshold substance’, the REACH Regulation considers that, by default, the risk cannot be considered ‘adequately controlled’ within the meaning of Article 60(2) of that Regulation, and in that case, an authorisation may only be granted if the conditions of Article 60(4) are fulfilled;
- I. whereas Article 60(4) of the REACH Regulation provides that an authorisation may only be granted if the applicant proves, *inter alia*, that, for each use applied for, there are no suitable alternative substances or technologies; whereas, according to Article 60(5) of that Regulation, when assessing whether suitable alternatives are available, the

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<sup>5</sup> <https://echa.europa.eu/documents/10162/6b11ec66-9d90-400a-a61a-90de9a0fd8b1>

<sup>6</sup> 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).

<sup>7</sup> [https://echa.europa.eu/documents/10162/13640/3rd\\_a\\_xiv\\_recommendation\\_20dec2011\\_en.pdf](https://echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf)

<sup>8</sup> Information on the application available at: <https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12473/term>

<sup>9</sup> 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.

Commission shall take into account all relevant aspects, including the technical and economic feasibility of alternatives for the applicant;

- J. whereas the analysis of alternatives presented by the Applicants is based on the work carried out by the Chromium Trioxide Authorisation Consortium (CTAC)<sup>10</sup>; whereas the uncertainties in the assessment by CTAC were one key reason for the European Parliament to object to the corresponding draft Commission implementing decision<sup>11</sup>;
- K. whereas the Applicants' analysis of alternatives is built on the premise that a technically feasible alternative can only be a 'like-for-like' substance<sup>12</sup>, i.e. a single substance or technology able to replace the substance of very high concern in all the different sectors and different applications in which it is used<sup>13</sup>;
- L. whereas such an approach, in an application for authorisation covering very different sectors and uses with very different performance requirements<sup>14</sup>, makes it "*impossible for a single alternative to comply with all of the requirements*", as explicitly recognised by SEAC<sup>15</sup>;
- M. whereas following such an approach unduly discriminates against alternatives that are available in certain sectors or for certain uses, amounts to giving the Applicants an unlawful derogation to their obligation to prove that there is no alternative for each use applied for, ignores the substitution objective enshrined in Article 55 of the REACH Regulation and does not encourage innovation;
- N. whereas SEAC stated that the analysis provided by the Applicants of whether technically suitable alternatives were available was not sufficiently thorough and lacked clear focus<sup>16</sup>; whereas SEAC stated that the Applicants fail to convincingly claim that

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<sup>10</sup> SEAC opinion, p. 30.

<sup>11</sup> 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) (Texts adopted, P8\_TA-PROV(2019)0316).

<sup>12</sup> SEAC opinion, p. 32, table 13.

<sup>13</sup> See Analysis of Alternatives on Functional chrome plating provided by the Applicants available at: <https://echa.europa.eu/documents/10162/ece8b65e-aec0-4da8-bf68-4962158a4952> p. 13-14: 'Several alternatives are being tested to substitute chromium trioxide. The challenge is to find a substitute which meets the requirements for all different types of products, and for the different uses of each specific application that at the same time is technically and economically feasible. Many alternatives are now qualified for individual applications when some of the functional chrome plating requirements are sufficient but none has all the key properties of functional chrome plating with an aqueous solution of chromium trioxide [...]'.

<sup>14</sup> Each sector (e.g. steel industry, general engineering industry) has different technical requirements: see SEAC opinion, p. 34, highlighting in yellow alternatives for which 'the parameters/assessment criteria fulfil some requirements for some but not all applications/sectors'.

<sup>15</sup> SEAC opinion, p. 36: 'Indeed, the applicants consider alternatives only to be promising when these satisfy cross-sectoral requirements of the aforementioned industry sectors (although the applicants' turnovers in these sectors are very limited), making it impossible for a single alternative to comply with all of the requirements' (own emphasis added).

<sup>16</sup> SEAC opinion, p. 35-36: 'In SEAC's view, the applicants have provided a generic assessment of the technical and economic feasibility of alternatives for different industry sectors ... without analysing in sufficient detail the substitutability of chromium trioxide for the use applied for. .... SEAC agrees with the applicants' conclusion that the alternatives assessed in the analysis of alternatives fail to provide some key functionalities. However, SEAC wishes to point out that the analysis of alternatives is not sufficiently thorough and lacks clear focus on the actual use of chromium trioxide by the applicants. The applicants presented some alternatives as promising and claimed that these be under investigation by the steel industry. However, the applicants neither

no alternatives for chrome-coating applications would be available, and moreover knew itself about existing alternatives that could be technically feasible for some of the uses applied for<sup>17</sup>; whereas SEAC affirmed that it would have needed more information to conclude on the economic feasibility of alternatives<sup>18</sup>;

- O. whereas this shows that the Applicants have not discharged the burden of proof, contrary to the requirements of the REACH Regulation, as confirmed by the General Court<sup>19</sup>;
- P. whereas SEAC nevertheless went on to state, following its own assumptions, that ‘alternatives, if and when technically feasible, are *unlikely* to be economically feasible’<sup>20</sup> (own emphasis added); whereas first, it is not for SEAC to fill gaps in the application with its own assumptions, and second, the term ‘unlikely’ shows that there are still uncertainties;
- Q. whereas SEAC’s opinion that alternatives are not technically and economically feasible is not consistent with its own findings and cannot be drawn in light of the shortcomings of the application;
- R. whereas the General Court made clear that ‘it is for the Commission alone to verify whether the conditions provided for in [Article 60(4) of the REACH Regulation] are fulfilled’,<sup>21</sup> that it is not bound by the opinions of SEAC or RAC, and that it must not follow their opinions if the reasoning therein is not ‘full, consistent and relevant’<sup>22</sup>;
- S. whereas the Commission, by endorsing SEAC’s inconsistent opinion in the draft Commission implementing decision<sup>23</sup>, did not fulfil its duties as set out by the General Court;
- T. whereas the draft Commission implementing decision in its recital 8 explicitly refers to the fact that “SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for some specific utilisations falling under the scope of the intended use”;
- U. whereas the General Court found that where, despite the presentation of evidence by the various actors involved in the authorisation procedure, there are still uncertainties with regard to the condition of unavailability of alternatives, it must be concluded that the

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presented further scrutiny of alternatives labelled as promising nor did they provide R&D plans in this regard. [...] In this sense, SEAC expresses reservations about the adequateness of the analysis for the scope of this application.’ (own emphasis added)

<sup>17</sup> SEAC opinion, p. 50: ‘[T]he applicants fail to convincingly support the claim that no alternatives for chrome-coating applications (in the applicants’ business sectors) would be available or would become available over the normal review period. SEAC is aware of alternative coating technologies that could already be or become technically feasible for specific parts coated by two of the five applicants’.

<sup>18</sup> SEAC opinion, p. 37, see in particular the conclusion of section 7.2.: ‘Nonetheless, more information about the share of parts that could be coated with a technically feasible alternative would have had to be provided in order for SEAC to conclude on the economic feasibility of such an alternative.’

<sup>19</sup> Judgment in Case T-837/16, paragraph 79.

<sup>20</sup> SEAC opinion, response to Question 7.2, p. 36.

<sup>21</sup> Judgment in Case T-837/16, paragraph 64.

<sup>22</sup> Judgment in Case T-837/16, paragraphs 66 and 68.

<sup>23</sup> Draft Commission implementing decision, paragraph 8.

- applicant has not met the burden of proof and therefore the authorisation cannot be granted to it<sup>24</sup>;
- V. whereas in light of the uncertainty referred to in recital 8, the draft Commission implementing decision is in breach of the judgment by the General Court;
- W. whereas the Commission attempts to justify its decision by affirming that the conditions – which it claims limit the scope of the uses authorised<sup>25</sup> - remedy the shortcomings of the application relating to the analysis of alternatives;
- X. whereas the adoption of conditions is legal and appropriate when they genuinely limit the scope of the authorisation by listing the specific uses that the Commission considered at the time of the authorisation as not having suitable alternatives;
- Y. whereas in this case, however, the Commission has left open the definition of the scope of the authorisation<sup>26</sup>, which indicates that it did not adopt a final decision on which uses did not have suitable alternatives at the date of the decision; that, on the contrary, by adopting those conditions, the Commission has delegated to the Applicants its exclusive power to make, on a case by case basis, the final evaluation and decision on the scope of the authorisation;
- Z. whereas the General Court considered such an approach to be unlawful<sup>27</sup>;
- AA. whereas, in addition, according to the General Court, if available information suggests that suitable alternatives are available in general, but these alternatives are not technically or economically feasible for the applicant, the applicant must provide a substitution plan for the authorisation to be lawfully granted<sup>28</sup>;
- BB. whereas, even though information on alternatives were available before the adoption of SEAC's opinion<sup>29</sup>, the Applicants, according to the opinion of SEAC, did not further

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<sup>24</sup> Judgment in Case T-837/16, paragraph 79.

<sup>25</sup> Article 1 of the draft Commission implementing decision : 'Authorised use' covers 'Use in functional chrome plating where any of the following key functionalities or properties is necessary for the intended use : wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, and effect on surface morphology'. It specifies for the avoidance of doubt that 'An authorisation for the use of chromium trioxide is not granted for functional chrome plating where none of the key functionalities listed in the first subparagraph is necessary'.

<sup>26</sup> i.e. leaving it to the Applicants to decide, and the enforcement authorities to assess, after the authorisation is adopted, whether any of the functionalities listed are 'necessary' for their use.

<sup>27</sup> Judgment in Case T-837/16, paragraph 83; see paragraph 97: 'Indeed, the statement that use of the lead chromates at issue in the present case is limited solely to those cases in which the performance of the compositions of substances containing those chromates is really necessary amounts to a declaration that a downstream user, whenever he identifies an alternative, should refrain from using the lead chromates at issue in the present case. However, such a declaration is a strong indication that, at the time of the adoption of the contested decision, the Commission itself did not consider that the examination of the condition relating to the lack of availability of alternatives had been completed'; see also paragraphs 86 and 98.

<sup>28</sup> Judgment in Case T-837/16, paragraph 76; in accordance with point (f) of Article 62(4) and point (c) of Article 60(4) of the REACH Regulation.

<sup>29</sup> SEAC opinion, p. 37: 'During the public consultation of other chromium trioxide applications SEAC has become aware of alternative coating technologies that could become feasible alternatives of some speciality parts'.

investigate them, nor did they offer more detailed plans to follow-up on R&D developments<sup>30</sup>;

- CC. whereas, the Commission proposes to grant the authorisation on the ground that the alternatives available in general are not technically or economically feasible for the Applicants, despite the fact that they have provided neither enough information on the economic feasibility, as noted by SEAC, nor a substitution plan, in breach of point (f) of Article 62(4) of the REACH Regulation;
- DD. whereas, according to Article 60(7) of the REACH Regulation, an authorisation shall only be granted if the application is made in conformity with the requirements of Article 62 thereof;
- EE. whereas the draft Commission implementing decision is in breach of the judgment of the General Court and of Article 60(4) and (7) of the REACH Regulation;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1907/2006;
  2. Calls on the Commission to withdraw its draft implementing decision and to submit a new draft granting the authorisation only for the uses specifically defined for which no suitable alternatives are available;
  3. Calls on the Commission to take swift decisions with regard to this application and others relating to the same substance in full compliance with the REACH Regulation;
  4. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

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<sup>30</sup> SEAC opinion p. 37 ‘Whilst the applicants mention that some alternatives are promising, and currently under investigation by the steel industry, they do not further investigate them; nor do they offer more detailed plans to follow up on R&D developments in this field’.