



**2020/2670(RSP)**

2.6.2020

# 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 under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd) for certain uses of chromium trioxide (D066992/01 – 2020/2670(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 under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd) for certain uses of chromium trioxide (D066992/01 – 2020/2670(RSP))**

*The European Parliament,*

- having regard to the draft Commission implementing decision partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd) for certain uses of chromium trioxide (D066992/01),
- 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 ('ECHA')<sup>2</sup>, pursuant to the second 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>,

---

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

<sup>2</sup> For use 1 (formulation of mixtures of chromium trioxide for functional chrome plating, functional chrome plating with decorative character and surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering ), RAC and SEAC opinions of 19 May 2017 available at:

<https://echa.europa.eu/documents/10162/5dab062f-8e37-9dae-40bd-25fa2ca625be>

For use 2 (functional chrome plating), RAC and SEAC opinions of 19 May 2017 available at:

<https://echa.europa.eu/documents/10162/c4fd2e61-4592-49e8-1e0b-34892be42ce7>

For use 4 (surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering), RAC and SEAC opinions of 19 May 2017 available at:

<https://echa.europa.eu/documents/10162/d05d7ddc-67af-b7db-3c5c-e95b2d3f8165>

Use 3 (functional chrome plating with decorative character) for which the applicant also submitted an application and RAC and SEAC adopted opinions on 19 May 2017 (available at: <https://echa.europa.eu/documents/10162/d198c14b-0eca-ef10-5444-33313c7742b0>) is not covered by the draft Commission implementing decision.

<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.

- having regard to Rule 112(2) and (3) of its Rules of Procedure,
  - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- 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 its classification as carcinogenic and mutagenic, the high volumes used, the high number of sites where it was used in the Union and the risk of significant exposure to workers<sup>7</sup>, 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 REACHLaw Ltd (the ‘Applicant’) acts as only representative of the Joint Stock Company ‘Novotroitsk Plant of Chromium Compounds’ (‘NPCC’), a Russian manufacturer of chromium trioxide;
  - E. whereas the Applicant submitted an application for authorisation for four uses of chromium trioxide (‘the NPCC application’); whereas the key documents provided as part of the NPCC application are the same as the ‘unmodified final version’ provided as part of the application<sup>8</sup> submitted by LANXESS Deutschland GmbH and six other companies jointly (‘the LANXESS application’) on behalf of a consortium of more than 150 companies, but whose exact membership is unknown;
  - F. whereas, the only non-confidential information provided by the Applicant in addition to the information contained in the LANXESS application is a half-page statement noting that it has engaged with its Union customers, all of them distributors only, with the objective of obtaining more detailed and use-specific data from them, their customers and the downstream supply chain in an attempt to improve the data basis, but that it only received a few filled questionnaires<sup>9</sup>; in other words, the Applicant failed to gather more detailed and use-specific data from its customers, which is the reason why it relies entirely on the unmodified final version of the LANXESS application;

<sup>5</sup> Decision of 14 December 2010 of the Executive Director of ECHA, ‘Inclusion of Substances of Very High Concern in the Candidate List’, ED/95/2010, available at: <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> Recommendation of the European Chemicals Agency (ECHA) of 20 December 2011 for the inclusion of substances in Annex XIV, available at: [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> See, for example for use 2, the “note to the reader” in the chemical safety report submitted by the Applicant, available at: <https://echa.europa.eu/documents/10162/7dd2ade6-bb47-4080-8124-a97335f9d2b8>

<sup>9</sup> Ibid.

- G. whereas the LANXESS application was manifestly not in line with the requirements of the REACH Regulation, as already brought to the Commission's attention in detail by Parliament in its resolution of 27 March 2019<sup>10</sup>;
- H. whereas it is evident that the NPCC application, being a copy of the LANXESS application, is equally deficient;
- I. whereas it is worrying to see that the draft Commission implementing decision fails to address the serious concerns raised by Parliament in its objection to the Commission draft implementing decision concerning the LANXESS application and that it proposes nevertheless to grant authorisation to NPCC through the Applicant;
- J. 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>11</sup>, is to ensure a high level of protection of human health and the environment;
- K. whereas, furthermore, pursuant 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;
- L. whereas RAC confirmed that it is not possible to determine a 'derived no-effect level' for the carcinogenic properties of chromium trioxide<sup>12</sup>, which is therefore considered as a 'non-threshold substance' for the purposes of point (a) of Article 60(3) of the REACH Regulation, i.e. a substance for which it is not possible to set a theoretical 'safe level of exposure';
- M. whereas Article 60(4) of the REACH Regulation provides that an authorisation to use a substance for which it is not possible to set a safe level of exposure 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;
- N. whereas point (d) of Article 62(4) of the REACH Regulation requires applicants to provide a chemical safety report in accordance with Annex I to that Regulation; whereas that report must include an estimation of the exposure levels, taking into account notably 'representative' exposure data, the quantity of the substance used for each identified use, the activities of workers related to the processes and the duration and frequency of their exposure to the substance<sup>13</sup>;
- O. whereas the Applicant envisages supplying up to 1 000 tonnes of chromium trioxide per year in the Union<sup>14</sup>, but failed to provide basic information, such as the information on

---

<sup>10</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(2019)0317).

<sup>11</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, para. 45.

<sup>12</sup> RAC and SEAC opinions of 19 May 2017, see e.g. opinions for use 2, p. 4.

<sup>13</sup> Section 5 of Annex I to the REACH Regulation, in particular Section 5.2.4.

<sup>14</sup> RAC and SEAC opinions of 19 May 2017, see e.g. opinions for use 2, p. 6.

the breakdown of tonnage according to the uses applied for, merely estimating that the proportionate breakdown is the same as in the LANXESS application<sup>15</sup>, which concerned 6 000 tonnes for use 2 and 900 tonnes for use 4<sup>16</sup>;

- P. whereas the Applicant stated that its supply chain would be identical to that covered by the LANXESS application, without however providing any figures on the number of downstream users concerned nor the number of workers exposed as a result of NPCC's imports, which in itself illustrates the non-conformity of the NPCC application; despite RAC and SEAC stating that it would not be possible to confirm that the supply chains were identical, they nevertheless based their opinions on that assumption<sup>17</sup>;
- Q. whereas based on the figures provided in the LANXESS application, the NPCC application potentially concerns a very large number of downstream users (more than 2 100 sites) active in a wide array of industry sectors ranging from automotives to hydraulics, from general engineering to printing, from sanitary to military, and from the food to steel sectors, with a high number of workers exposed (more than 32 000 workers) and a very high number of people estimated to be working and living in the near neighbourhood (21 million)<sup>18</sup>;
- R. whereas RAC had estimated that the granting of the authorisation based on the LANXESS application would lead to 30 statistical fatal cancer cases every year for the uses corresponding to the uses applied for in the NPCC application<sup>19</sup>;
- S. whereas the draft Commission implementing decision formally concerns three 'uses'; whereas according to SEAC, the use descriptions for uses 2 and 4 have an 'extremely broad scope'<sup>20</sup>; whereas this vitiates the risk assessment, the socio-economic assessment as well as the assessment of the availability of suitable alternatives;
- T. whereas for the LANXESS application, RAC noted, as regards each use applied for, the discrepancy between the total number of potential sites (up to 1 590), the number of members in the consortium (150+) and the measured exposure data (from 6 to 23 sites);
- U. whereas in other words, the data that were meant to be representative for a wide range of very different plating sites across the Union came from less than 2 % of the sites concerned, and only from a quarter or even less than a tenth of Member States<sup>21</sup>;

---

<sup>15</sup> RAC and SEAC opinions of 19 May 2017, see e.g. opinions for use 2, p. 12.

<sup>16</sup> RAC and SEAC opinions of 19 May 2017, see opinions for use 2, Annex 1, p. 28, and opinions for use 4, Annex 1, p. 42.

<sup>17</sup> RAC and SEAC opinions of 19 May 2017, see e.g. opinions for use 2, p. 7.

<sup>18</sup> RAC and SEAC opinions of 19 May 2017, see opinions for use 2, Annex 1, p. 42, and opinions for use 4, Annex 1, p. 55-56.

<sup>19</sup> Ibid

<sup>20</sup> RAC and SEAC opinions of 19 May 2017, see opinions for use 2, Annex 1, p. 36, and opinions for use 4, Annex 1, p. 59.

<sup>21</sup> Use 2: 1 590 sites in total, with measured exposure data from 23 sites in seven Member States (see RAC and SEAC opinions of 19 May 2017, Annex 1, p. 7-8); Use 4: 515 sites in total, with measured exposure data from 11 sites in two Member States (see RAC and SEAC opinions of 19 May 2017, Annex 1, p. 8-9.)

- V. whereas as a result RAC identified substantial uncertainties in the risk assessment relied on, raising serious concerns as to the representativeness and reliability of information provided on the exposure, *inter alia*, of workers<sup>22</sup>;
- W. whereas the failure to provide the necessary information regarding the exposure scenarios of workers is acknowledged in the draft Commission implementing decision<sup>23</sup>;
- X. whereas, instead of considering the NPCC application not to be ‘in conformity’ under Article 60(7) of the REACH Regulation, the draft Commission implementing decision simply requires that the Applicant provide the missing information<sup>24</sup> in its review report, which would come years after adoption of that draft decision<sup>25</sup>;
- Y. 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 has to be provided prior to authorisation 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;
- Z. whereas the General Court clearly stated that conditions attached to an authorisation, as provided for in Article 60(8) and (9) of the REACH Regulation, cannot be aimed at remedying any shortcomings in an application for authorisation or any deficiencies in the assessment incumbent on the Commission<sup>26</sup>;
- AA. whereas granting an authorisation based on the NPCC application despite the obvious lack of representativeness of the data in the chemical safety report provided defeats the purpose of an *ex ante* authorisation system that places the burden of proof on the applicant<sup>27</sup>;

---

<sup>22</sup> See RAC and SEAC opinions of 19 May 2017 for use 2, Annex 1, p. 24, and for use 4, Annex 1, p. 36: ‘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, considering that there is a wide variability between the chromium plating sites in relation to e.g. building layout, the scale and frequency of plating operations, level of the automation of the process, use of electrolysis, the size of the parts treated, and the availability of LEV [local exhaust ventilation], which affects the exposures and RMMs [risk management measures] needed to control the exposure.’ [own emphasis added].

<sup>23</sup> Recital 6 of the draft Commission implementing decision.

<sup>24</sup> Including, as detailed in Article 2 of the draft Commission implementing decision: ‘The authorisation holder shall develop specific exposure scenarios for representative processes, operations and individual tasks (including automatic versus manual systems and open versus closed systems and combinations thereof), describing risk management measures and operational conditions representative of all sites where the authorised uses take place, which are used to control worker exposure to chromium (VI) and its emissions to the environment, in each of the specific scenarios. The exposure scenarios shall contain information on the exposure levels resulting from the implementation of those risk management measures and operational conditions [...]’.

<sup>25</sup> Recital 20 and Article 7 of the draft Commission implementing decision.

<sup>26</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, paragraphs 82 and 83.

<sup>27</sup> See notably Article 1(3) of the REACH Regulation.

- BB. whereas, furthermore, the SEAC opinion highlighted significant uncertainties in the analysis of alternatives presented by the Applicant, which is also reflected in the draft Commission implementing decision<sup>28</sup>;
- CC. whereas a technical alternative is a substance capable of performing an equivalent function to the substance of very high concern, with a potentially lower but still acceptable level of performance, or changes in production, process or product that remove the need for the substance altogether<sup>29</sup>;
- DD. whereas according to the the analysis of alternatives in the LANXESS application alternatives are available for individual applications, but the challenge would be to find one single substitute fit for all purposes and all uses<sup>30</sup>;
- EE. whereas such a ‘one size fits all approach’, especially in an application for authorisation covering very different sectors and uses with very different performance requirements, unduly discriminates against alternatives that are available either in certain sectors or for certain uses, and, if followed, would give the Applicant an unlawful derogation from its obligation to prove that there is no alternative for each use applied for; whereas such an approach disregards the substitution objective provided for in Article 55 of the REACH Regulation and does not encourage innovation;
- FF. whereas the availability of suitable alternatives to functional chrome plating has been confirmed by a recent survey by the German Federal Institute for Occupational Safety and Health for various applications<sup>31</sup>;
- GG. whereas SEAC noted for both uses 2 and 4 ‘that the wide scope of the use applied for [...] includes technical applications for which suitable alternatives may already be available and implemented or will become so in short term’ but then concluded that the ‘related assessment performed by the applicant is too general to exclude these from the scope of the authorisation’<sup>32</sup>;
- HH. whereas as a consequence, no applications are excluded specifically from the scope of the authorisation;

<sup>28</sup> Recital 12 of the draft Commission implementing decision.

<sup>29</sup> Guidance on the preparation of an application for authorisation (OJ C 28, 28.1.2011, p. 1).

<sup>30</sup> Analysis of Alternatives, p. 11-12: ‘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 have all the key properties of functional chrome plating with an aqueous solution of chromium trioxide ...’,

<https://echa.europa.eu/documents/10162/70ae9192-4c86-4e68-9021-0a90f7b56444>

<sup>31</sup> Survey on technical and economic feasibility of the available alternatives for chromium trioxide on the market in hard/functional and decorative chrome plating, Federal Institute for Occupational Safety and Health, Germany, 2020, final paragraph of the abstract: ‘However, in this survey available alternatives were identified that are technically and economically feasible – sometimes in one or few uses only, but sometimes even in larger areas of application. Some of the alternatives are long-established technologies with known strengths and weaknesses. And there are developments underway that expand the fields of application and specifications of these processes.’, <https://www.baua.de/EN/Service/Publications/Report/Gd101.html>

<sup>32</sup> RAC and SEAC opinions of 19 May 2017 for both uses 2 and 4, p. 15.

- II. whereas the General Court has annulled an authorisation due to the Commission's failure to verify a sufficient quantity of substantial and verifiable information in order to conclude either that no suitable alternatives were 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 were only negligible<sup>33</sup>;
- JJ. whereas in this case, the uncertainties on the analysis of alternatives were far from negligible, as SEAC considered that the Applicant's approach with regard to existing alternatives was "not fully appropriate"<sup>34</sup>;
- KK. whereas the General Court has affirmed that it is the applicant who carries the burden of proving the lack of existing alternatives, and that when this burden of proof is not discharged 'he cannot be granted authorisation'; whereas in the same case, the General Court also noted that 'none of the stakeholders involved in the authorisation procedure or, moreover, ECHA or the Commission is required to prove the opposite of the condition relating to the absence of alternatives, that is to say that alternatives do exist'<sup>35</sup>;
- LL. whereas, considering the uncertainties highlighted by SEAC as to the availability of alternatives, the Commission is thus proposing to grant the authorisation on the basis of an *assumption* that there are no suitable alternatives for all the uses covered, not on the basis of significant and reliable evidence, and in a situation caused by the failure of the Applicant to discharge its burden of proof, contrary to the requirement as found by the General Court<sup>36</sup>;
- MM. whereas 'in order to ensure that the authorisation covers only those uses for which no suitable alternatives are available, the Commission considers it necessary to further specify the description of uses 2 and 4' with 'key functionalities', considering 'that the applicant has only discharged its burden of proof in demonstrating the absence of suitable alternatives as regards uses 2 and 4 only with regard to such limited scope of the uses'<sup>37</sup>;
- NN. whereas, firstly, what the Commission considers a limitation of scope *de facto* represents a complete list of all key functions for which chromium trioxide is used and therefore does not limit the scope of the authorisation in any way<sup>38</sup>;

---

<sup>33</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, paragraph 86.

<sup>34</sup> RAC and SEAC opinions of 19 May 2017 for use 2, Annex 1, p. 37: "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".

<sup>35</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 79.

<sup>36</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 86.

<sup>37</sup> Recitals 13 and 14 of the draft Commission implementing decision.

<sup>38</sup> Compare Article 1(1) of the draft Commission implementing decision with RAC and SEAC opinions of 19 May 2017 for use 2, Annex 1, p. 30, and for use 4, Annex 1, p. 44.



- OO. whereas the General Court has explicitly rejected a similar attempt of the Commission to grant authorisation while allegedly limiting the scope<sup>39</sup>;
- PP. whereas, secondly, the Commission draft implementing decision leaves it to the Applicant to decide subjectively, once the authorisation has been granted, whether using the substance is ‘necessary’ for those key functionalities, even though such an analysis is meant to be performed as a precondition for obtaining the authorisation;
- QQ. whereas the Commission is thus delegating to the Applicant its exclusive power to reach a conclusion concerning the analysis of alternatives, in breach of the provisions of the REACH Regulation, which require the Commission to take the final decision as to whether an applicant has successfully proven that there is no alternative for a given use , as recalled by the General Court<sup>40</sup>;
- RR. whereas, thirdly, the draft Commission implementing decision requires the missing information relevant to the analysis of alternatives to be provided by downstream users, by means of notifications made pursuant to Article 66(1) of the REACH Regulation, after the authorisation is granted<sup>41</sup>;
- SS. whereas such information was, however, necessary for the Commission to be able to reach a conclusion, in the first place, as to whether alternatives were available for each application covered; whereas this approach is also clearly incompatible with the judgment of the General Court<sup>42</sup>;
- TT. whereas the draft Commission implementing decision not only rewards laggards, but also discourages innovation and frontrunners that have invested in safer alternatives;
- UU. whereas the General Court held that in the event that suitable alternatives are available in general, but that such solutions are not technically or economically feasible for the applicant, an authorisation may be granted if the socio-economic benefits outweigh the

---

<sup>39</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 97: ‘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.’

<sup>40</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 64: ‘it is for the Commission alone to verify whether the conditions provided for in that provision [Article 60(4)] are fulfilled’ [own emphasis added]; see also para. 78.

<sup>41</sup> Article 5 of the draft Commission implementing decision requiring downstream users to provide in their notifications pursuant to Article 66(1) of the REACH Regulation: ‘an explanation of the key functionalities of chromium trioxide listed in Article 1(1) which are necessary for their use, including a justification why such key functionalities are necessary for that use.’

<sup>42</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 82: ‘it should be emphasised that, in principle, irrespective of their content, the conditions imposed in accordance with Article 60(8) and (9)(d) and (e) of Regulation No 1907/2006 cannot purport to remedy any shortcomings in an application for authorisation or in the analysis of alternatives submitted by an applicant for authorisation or any deficiencies in the Commission’s examination of the conditions provided for in Article 60(4) of Regulation No 1907/2006’.

risk to human health or the environment and the applicant presents a substitution plan within the meaning of point (c) of Article 60(4) of the REACH Regulation<sup>43</sup>;

- VV. whereas the Commission, however, did not request a substitution plan from the Applicant;
- WW. whereas a number of downstream users, covered by the draft Commission implementing decision, have already applied separately for authorisation; whereas RAC and SEAC have already issued their opinions on some of those applications; whereas some authorisations for downstream users have already been granted;
- XX. whereas, however, there may be specific applications amongst the very broad uses covered by the NPCC application for which downstream users did not make a separate application, but for which the conditions of Article 60(4) of the REACH Regulation may be fulfilled;
- YY. whereas Parliament, in its resolution of 27 March 2019, therefore considered it to be appropriate, exceptionally, to grant to such downstream users that have not made a separate application, and for which the necessary data are missing, the possibility to submit the missing data within a short deadline<sup>44</sup>;
- ZZ. whereas it is highly regrettable that the Commission did not follow that approach, but continues, in a manner that is contrary to the judgment of the General Court, to draft authorisations based on applications which lack sufficient evidence to prove that the conditions for authorisation under the REACH Regulation are met;
- AAA. whereas in summary, the Commission draft implementing decision is unlawful because:
- a. it is in breach of Article 60 of the REACH Regulation, as it is based on an application that does not comply with the requirements set out in that Article, because it lacks key information with regard to the uses applied for, in particular concerning related tonnages, operational conditions, exposure scenarios, risk management measures; and lacks a proper assessment of safer alternatives and a substitution plan, thus making it impossible to verify whether the conditions for an authorisation are met;
  - b. it seeks to remedy shortcomings by requiring downstream users to provide information, which is necessary to be provided in the application itself, after granting the authorisation, as part of a future review;
  - c. it illegally delegates to the Applicant the Commission's exclusive power to reach a conclusion on the availability of alternatives;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in the REACH Regulation;

---

<sup>43</sup> Judgment of the General Court of 7 March 2019, *Sweden v Commission*, T-837/16, ECLI:EU:T:2019:144, para. 75 and 76.

<sup>44</sup> See paragraph 3 of the resolution of 27 March 2019.

2. Calls on the Commission to withdraw its draft implementing decision and to submit a new draft to the committee;
3. Calls again on the Commission, exceptionally, to grant to downstream users whose use is covered by the NPCC application, but for which no separate application for authorisation has yet been made, the possibility to submit the missing data within a very short deadline, including a substitution plan where the applicant claims that alternatives that are available are not technically or economically feasible for it;
4. Calls on RAC and SEAC to swiftly assess the resulting complemented application, including a proper check that it includes all the necessary information specified in Article 62 of the REACH Regulation;
5. Calls on the Commission to swiftly come forward with a new draft in full compliance with the REACH Regulation;
6. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.