

Follow up to the European Parliament non-legislative resolution on Objection pursuant to Rule 112: partially granting an authorisation for a use of chromium trioxide (Cromomed S.A. and others)

- 1. Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of procedure**
- 2. Reference numbers:** 2019/2844 (RSP) / B9-0151/2019 / P9_TA-PROV(2019)0046
- 3. Date of adoption of the resolution:** 24 October 2019
- 4. Competent Parliamentary Committee:** Environment, Public Health and Food safety (ENVI)
- 5. Brief analysis/assessment of the resolution and requests made in it:**

The European Parliament resolution objects to a draft Commission implementing decision partially granting an authorisation for the use of chromium trioxide in functional chrome plating to the company Cromomed and four other applicants under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('draft decision'). The resolution calls on the Commission to withdraw the draft decision and to submit a new draft decision granting the authorisation only for the uses specifically defined for which no suitable alternatives are available.

6. Response to requests and overview of action taken, or intended to be taken, by the Commission:

The draft decision in question is to be adopted in accordance with the examination procedure under Article 5 of Regulation (EU) No 182/2011. The Commission recalls that, in accordance with Article 11 of that regulation, the scope of the right of scrutiny of the European Parliament and of the Council is limited to the question whether the draft implementing act exceeds the implementing powers provided for in the basic act (in this case the Regulation (EC) No 1907/2006 (REACH)).

When preparing the draft implementing decision, the Commission acted within the implementing powers conferred on it by Article 64(8) of REACH, and it respected all the requirements set out in that regulation, notably Article 60, paragraphs (4), (5), (7) and (8). The fact that the Parliament does not agree with the assessment made by the European Chemicals Agency's ('the Agency') Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) and subsequently with the Commission's own assessment and conclusions goes beyond the scope of the right of scrutiny of the European Parliament with regard to draft implementing acts.

Nevertheless, the Commission takes note of the position of the Parliament and therefore would like to explain its position on the concerns expressed in the resolution.

- i. The Commission rejects the claim that the draft Commission implementing decision proposing the authorisation is in breach of Article 60(4) of REACH due to uncertainties regarding the assessment of alternatives for the use applied for, also in the light of the interpretation provided by the General Court Judgment in case T-837/16 ("the judgment").

In particular, the resolution criticises the uncertainties identified in SEAC's assessment of the alternatives. The Commission recalls that uncertainties are inherent to any scientific assessment and they are relevant for the decision-making only when their nature or magnitude may affect the overall scientific conclusion. In this case, SEAC could still conclude on the non-suitability of alternatives for the applicants in spite of the uncertainties identified. The Commission concurs with SEAC's reasoning and conclusion that there are no suitable alternative substances or technologies available that would satisfy key technical requirements of all the business sectors relevant for the applicants.

There were no submissions during the public consultation bringing evidence on suitable alternatives. Nevertheless, based on available information from other chromium trioxide applications and given the broad scope of the use covered by this application, SEAC could not exclude the technical feasibility of alternatives for some specific utilisations falling under the scope of the use. Notwithstanding this uncertainty, SEAC recognised that since all of the applicants are Small and Medium-Sized Enterprises (SMEs), it is likely that it is economically unfeasible for them to switch to alternatives that have only a limited range of applicability and that this would require a significant investment.

In order to address this uncertainty, the Commission proposed to limit the scope of the authorisation to the use where any of the following key functionalities or properties are necessary for the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, and effect on surface morphology. This limitation of the scope ensures that the authorisation is only granted for utilisations for which the applicant has provided sufficient evidence that no alternatives are available, and excludes potential interpretations that also other utilisations could be covered. In other words, it is a partial authorisation limiting the scope of the use to utilisations for which the sufficient evidence has been provided. Moreover, even if there were remaining doubts, SEAC's opinion is sufficiently clear to conclude by sufficient weight of evidence, based on the best scientific data available that any technically feasible alternative within the scope of the use would not be economically feasible for the applicant.

- ii. The resolution claims that in the light of the interpretation provided by the judgment, the Commission should have concluded that there are suitable alternatives in general for the use applied for. In that case, an authorisation could only be granted if the alternatives are not technically or economically feasible for the applicant and if he submits a substitution plan.

In this regard, in addition to taking into account the SEAC opinion, the Commission reviewed the application and the supporting evidence, as well as other information available (e.g. information from other similar uses/ cases) in the light of the criteria provided by the judgment to identify suitable alternatives in general. According to these criteria, a 'suitable' alternative must be safer, available not only *in abstracto* or in laboratory or exceptional conditions, and it must be technically and economically feasible in the EU. Moreover, the alternative must be available from the point of view of production capacities of the substance or feasibility of the technology, and fulfil legal and factual requirements for putting it into circulation.

Based on the SEAC opinion and the review of the above information against the criteria identified by the General Court, the Commission concluded that for the limited scope of the use proposed to be authorised (i.e. as limited in the Commission decision

through the key functionalities and properties) there are no suitable alternatives in general and that there is no evidence that would cast doubts on this conclusion. Therefore, there is no obligation for the applicants to submit a substitution plan. This conclusion is in line with the conclusion on other applications for authorisation for the use of chromium trioxide for functional chrome plating adopted after the General Court Judgment.

- iii. The Commission also rejects the claim that the draft Commission implementing decision proposing the partial authorisation is in breach of Article 60(7) of REACH due to the lack of conformity of the application with the requirements set out in Article 62 of that Regulation.

The Commission recalls that Article 60(7) of REACH does not concern the material conditions for the granting of an authorisation, but is limited to enabling the Commission to verify whether an application for authorisation is in conformity with the requirements of Article 62 from a formal point of view¹.

The Commission considers that the information provided by the applicants is in conformity with the requirements of Article 62 and, as explained under point (i), that information is exhaustive and sufficient for assessing whether the applicant has discharged its burden of proof on the absence of suitable alternatives.

Based on the above, the Commission cannot follow the objections raised in the European Parliament's resolution and affirms that the draft implementing decision is within the implementing powers conferred on the Commission under REACH and in full compliance with the REACH Regulation.

¹ Judgment of the General Court of 4 April 2019 in case T-108/17, Client Earth v European Commission, paragraphs 104 and 106