**Follow up to the European Parliament non-legislative resolution on the draft Commission implementing decision partially granting an authorisation for certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.)**

1. **Resolution tabled pursuant to Rule 106 of the European Parliament's Rules of procedure**
2. **Reference numbers:** 2019/2606 (RSP) / B8-0219/2019 / P8\_TA-PROV(2019)0316
3. **Date of adoption of the resolution:** 27 March 2019
4. **Competent Parliamentary Committee:** Committee on the 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 certain uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH) (Grupa Azoty Zakłady Azotowe Kędzierzyn S.A). The resolution considers that the draft Commission implementing decision exceeds the implementing powers conferred on the Commission by REACH, because according to the European Parliament´s view it does not respect the conditions set out in Article 60(4) and 60(7) of that regulation for granting an authorisation. Therefore, the European Parliament calls on the Commission to withdraw the draft implementing decision and to submit a new draft rejecting the authorisation.

1. **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 scientific assessment made by the European Chemicals Agency’s (‘the Agency’) Committee for Socio-economic Analysis (SEAC) and subsequently with the Commission’s conclusion 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 decision fails to take into account relevant information on the technical and economic feasibility of alternatives from the restriction procedure leading to the restriction of DEHP and other phthalates set out in Annex XVII to REACH (as amended by Commission Regulation (EU) 2018/2005-‘the restriction’). The main reasons for the SEAC concluding in its 2015 opinion on the authorisation application that alternatives are not economically feasible for the applicant’s downstream users were substitution costs and the likely economic impact on EU producers of articles, mainly due to pressure from cheaper imports. Considering that the restriction allows the continued import of exempted articles, and that prices of alternatives to DEHP are still higher than the price of DEHP, the Commission has determined that the circumstances have not substantially changed as regards the use of DEHP in the production of those articles, and that the conclusion that alternatives are not economically feasible for the applicant’s downstream users remains relevant and valid for that use. However, for articles prohibited by the restriction, as alternatives are technically feasible and imports of articles containing DEHP will be prohibited, it is no longer demonstrated that alternatives are not economically feasible. Therefore, the Commission concluded that an authorisation should be refused for that part of the use.

ii. The Commission rejects the claim that the draft decision should have taken into account the endocrine disrupting (ED) properties for human health and the environment of DEHP in the context of the socio-economic assessment under Article 60(4). In accordance with Article 62(4)(d) of REACH, and as confirmed by the case-law (General Court judgments in cases T-115/15[[1]](#footnote-1) and T-108/17[[2]](#footnote-2)), an application for authorisation only has to take into account the intrinsic properties listed in Annex XIV to REACH for the substance in question. The Agency is currently considering the inclusion of the additional ED properties of DEHP in that Annex. The recommendation to the Commission on the terms of such inclusion is expected in mid-2019. As long as ED properties are not included in Annex XIV, the risks resulting from them are not relevant for assessing whether the conditions for granting an authorisation are met. The Parliament’s resolution further considers that the authorisation for certain articles exempted from the restriction could represent an unacceptable risk to human health and the environment due to the ED properties of DEHP. The Commission considered that the Agency’s Risk Assessment Committee (RAC) assessed the information available at the time of preparation of the restriction and in the absence of an assessment of a threshold for the ED properties of DEHP, RAC concluded that the proposed ‘Derived No-Effect Level’ based on reprotoxic effects was sufficient to substantiate the restriction and took into account these properties in the uncertainty analysis. The Commission furthermore recalls that the European Parliament did not raise any objection during the scrutiny period of the regulatory procedure with scrutiny before the adoption of the restriction in December 2018.

iii. The Commission rejects the claim that the draft decision requires the applicant to submit in the review report missing data to remedy failures or gaps in the information provided to demonstrate that the risk was adequately controlled and not reduced to a level as low as technically and practically possible. The Commission highlights that the conditions imposed in the draft decision for the review report are not aimed at rendering the application compliant with the conditions of Article 60(4) and (7) of REACH.

The Commission recalls that Article 60(7) does not concern the material conditions for the grant of an authorisation and its aim is enabling the Commission to verify whether an application for authorisation is in conformity with the requirements of Article 62 from a formal point of view[[3]](#footnote-3).

In its opinion on this application for authorisation, in which adequate control of the risks had not been demonstrated, SEAC could nevertheless conclude on the socio-economic assessment on the basis of a break-even analysis. The Commission has no reason to conclude differently based on the scientific assessment made by RAC and SEAC of the application for authorisation, complemented with the additional information from the restriction procedure, including on the conclusion regarding the lack of suitable alternatives. However, in the light of the limited information submitted on workplace exposure, the draft decision requires that the review report contains relevant exposure information from representative downstream user workplaces, covering the life-cycle of the substance up to its incorporation into articles. Such information must include a description of operational conditions and risk management measures for workplaces and technologies and representative measurement data, including geographical location of downstream users and the type of users that allow a more precise evaluation of worker exposure to DEHP. Furthermore, updated information shall also be provided about the status of economic feasibility of alternatives. A shortened review period of 36 months from the date of adoption of the decision (compared to the SEAC recommendations of 4 years from the sunset date) is proposed, to allow a minimum time to the applicant to submit the required data on worker exposure and on analysis of alternatives, i.e. within 18 months from the adoption of the decision.

Finally, the Commission concludes that granting the authorisation will increase worker protection by improving the conditions at the workplace with immediate effect after the adoption of the decision. Furthermore, regardless of whether an authorisation is granted or not, soft PVC articles containing DEHP exempted from the restriction can continue to be imported from third countries. Not granting an authorisation would place EU producers of soft PVC articles derogated from the restriction in a competitive disadvantage vis-à-vis non-EU producers.

Based on the provided reasoning, the Commission cannot follow the objections raised in the European Parliament’s resolution and affirms that the draft decision is within the implementing powers conferred on the Commission in the REACH. Nevertheless, the Commission will consider whether the draft decision needs to be revised in the light of the recent judgments of the General Court in cases T-837/16 (*Swede*n v *Commission*) and T‑108/17 (*Client Earth* v *Commission*).

1. Judgment of the General Court of 11 May 2017, case T-115/15, *DEZA* v *ECHA*, upheld by judgment of the European Court of Justice of 23 January 2019, case C-419/17 P [↑](#footnote-ref-1)
2. Judgment of the General Court of 4 April 2019, case T-108/17, *Client Earth* v *European Commission* [↑](#footnote-ref-2)
3. Judgment of the General Court of 4 April 2019 in case T-108/17, *Client Earth* v *European Commission*, paragraphs 104 and 106 [↑](#footnote-ref-3)