

Kędzierzyn-Koźle, Poland, 3rd February 2016

Dear Sirs,

Grupa Azoty ZAK S.A., on behalf of itself and of its customers, has prepared and timely submitted an authorisation application for DEHP to European Chemical Agency, therefore **Grupa Azoty ZAK S.A. customers may continue using DEHP after the *sunset date* - 21 February 2015 - until the decision by European Commission has been made.** *Sunset date* is set up for those companies who did not timely submit an authorisation application. However, until today Grupa Azoty ZAK S.A. has not received decision on authorisation for the DEHP uses described in its application.

In the end of September 2014 European Chemical Agency provided Grupa Azoty ZAK S.A. with draft decision (opinion of the Agency) which proposed a 4-year authorisation period for uses included in our application. According to the REACH Regulation, European Commission (EC) should draw up a draft authorisation decision within 3 months from receipt of Agency's opinion, but to this day, unfortunately, we have not received EC decision, even draft. The delay results from the fact that recently new information has appeared. It influences Commission's decision taken on phthalates, including DEHP. The main concern here, among others, is a suspicion on negative impact of DEHP on the human endocrine system. The reaction to those reports has been a recent of European Parliament calling the European Commission not to grant authorization for all uses of DEHP.

We are still waiting for a EC decision and we do not have any information when it might happen, because such situation was not foreseen by the REACH Regulation. We will keep you informed about subsequent actions taken by the Commission in this matter. We would like to ensure you once again that, in accordance with REACH Regulation, until the decision has been made by the European Commission, Grupa Azoty ZAK S.A. and its customers may continue using DEHP as previously.

We also remind that application submitted by Grupa Azoty ZAK S.A. covers the following uses:

- 1) Formulation of DEHP in compounds, dry-blends and Plastisol formulations.

<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1609/term>

2) Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, small household items (<10cm) that can be swallowed by children, clothing intended to be worn against the bare skin; also toys, cosmetics and food contact material (restricted under other EU regulation)].

<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1610/term>

The use of DEHP in medical devices (available in our product range as Oxoplast Medica®), is exempted from the authorization procedure and may be used without permission in "the immediate packaging of medicinal products covered under by Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC".

Kind regards,



Joanna Pokora

*Plenipotentiary of the Management Board for REACH
Manager of European Relations Branch Office*