Procedural and substantive flaws of the DEHP in PVC opinions[1]

Arkema (France), ZAK (Poland) and Deza (Czech Republic) have applied for authorisation of the continued use of diethylhexyl phthalate (DEHP), in plastic (polyvinyl chloride, PVC) articles to which European citizens are routinely exposed, such as flooring, upholstery, footwear and car seats. Vinyloop Ferrara, Stena Recycling and Plastic Planet have applied for authorisation of the use of DEHP in recycled soft PVC containing articles. DEHP is a substance of very high concern (SVHC).

The Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC) of the European Chemicals Agency (ECHA) finalised their opinions on these applications in October 2014.

Granting the authorisations applied for would not be in compliance with the provisions of Title VII of REACH, in particular Articles 60, 62 and 64 and would undermine the main objective of REACH to "encourage and, in certain cases, to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available" (preamble, recital 12).

This is all the more the case as the provisions of REACH are in general underpinned by the precautionary principle according to Article 1(3), whilst the importance of this principle for the authorisation of SVHC is emphasised by recital 69 of the preamble.

Hence, the deficiencies outlined hereafter need to be addressed by the Commission so that it can properly meet its obligations under Article 60(1).

In particular, it needs to be noted that:

1. **The uses applied for are multiple, broad and not sufficiently documented**: The applications were not made in conformity with the requirements of Article 62 (as required by Article 60(7)). Whilst REACH allows applications for several uses, these uses need to be well defined and exposures documented. Adequate control in accordance with Annex 1 can only be demonstrated for specific uses. However, the applicants provided such broad descriptions of uses which were not documented by corresponding exposure scenarios and exposure assessments that it is impossible to clearly understand the risks from the continued use of the substance. As a consequence, the scope of the authorisations applied for is so broad and unclear that they result in what are, in essence, requests for general authorisation for an

[1] ECHA/RAC/Opinion N° AFA-O-0000004275-75-12/D and ECHA/SEAC/Opinion N° AFA-O-0000004275-75-12/D; ECHA/RAC/Opinion N° AFA-O-0000004275-75-13/D and ECHA/SEAC/Opinion N° AFA-O-0000004275-75-13/D; ECHA/RAC/SEAC Opinion N°AFA-O-0000004151-87-16/D; ECHA/RAC/SEAC Opinion N° AFA-O-0000004151-87-17/D; ECHA/RAC/Opinion N° AFA-O-0000004280-84-12/D and ECHA/SEAC/Opinion N° AFA-O-0000004280-84-12/D; ECHA/RAC/Opinion N° AFA-O-0000004280-84-13/D and ECHA/SEAC/Opinion N° AFA-O-0000004280-84-13/D; as well as the opinions which are the subject-matter of case T-189/14, for which the opinions are not publicly available yet. Consultation numbers: 0002-02, 0003-02, 0004-02, 0008-01and 0008-02.

industrial sector rather than use-specific authorisations. This alone should have been a reason to reject the applications.

2. The RAC requested information from the applicants after the applications had already been deemed complete by ECHA's secretariat: The applications were not in conformity with the requirements of Article 62 which are referred to in Article 64(3). According to Article 64(3), each of the committees shall first check that the applications include all the information specified in Article 62 that is relevant to its remit. Article 64(3) allows additional information to be requested by the Committees only before they make a judgement on conformity of the application with the requirements of Article 62. Further information from the applicant can be requested only by the SEAC in relation to possible alternative substances or technologies. However, it was the RAC that requested information that it deemed important, much later, after the conformity check phase. Therefore, any information that was received by the RAC after that phase may not be taken into account for the final opinions or the Commission decisions.

3. The applications for DEHP were submitted under the "adequate control route", but adequate control was neither documented nor demonstrated: Authorisation is granted according to Article 60(2) under the "adequate control route" if the use of the substance is adequately controlled in accordance with Annex 1. In this case, adequate control was demonstrated in none of the applications, as the RAC identified remaining risks to workers. For this reason alone, the applications must be rejected.

4. The RAC set and used a reference derived no effect level (DNEL) for DEHP, a known endocrine disrupting chemical (EDC): By setting a reference DNEL, the RAC annulled one of the basic principles of REACH – that the burden of proof for the safety of a substance rests on the user of the substance.
Furthermore, the RAC acknowledges that the reprotoxicity of DEHP is mediated by an endocrine mode of action but claims that it is nevertheless appropriate to establish the reference DNEL because the substance has been identified according to Article 57(c) and not (f). Under Article 60(3), thresholds should only be established after due consideration of the science. Nonetheless, the RAC simply decided to set a threshold because DEHP was designated as a reproductive toxicant – without considering that it is mediated by an endocrine mode of action.

5. The applicants did not show that socio-economic benefits of using the substance outweigh the risks: The applicants submitted their applications for authorisation under the unfounded assumption that the risk to human health or the environment from the use of DEHP arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report. As a consequence, the applicants could not demonstrate that the socio-economic benefits of continued use outweigh the risk to human health or the environment arising from the use of the substance in the socio-economic analysis (SEA) they submitted as part of the applications. The applicants merely claimed that there was no risk whatsoever. Moreover, by carrying out its own 'worst case scenario' calculations, the SEAC also disregarded the applicable burden of proof. Therefore, the requirement of Article 60(4) that an authorisation may be granted only if the applicant shows that the socio-economic benefits outweigh the risk of the continued use was not met and the authorisation must be denied.

6. Alternatives that are technically and economically feasible for the uses applied were disregarded: The applicants did not demonstrate that there are no alternative substances or technologies that are economically and technically feasible for the uses applied for. As highlighted in the SEAC's opinion, the applicants, when providing their analysis of alternatives, discarded alternative materials, substances and techniques claiming that they cannot produce the alternatives, even though authorisation is sought for many downstream uses, not for manufacturing. Furthermore, DEHP has, to a large extent, already been replaced by other plasticisers and materials. During the public consultation, manufacturers of alternatives as well as downstream users applying these alternatives have provided overwhelming information which shows that readily available and technically and economically feasible alternatives do exist.

Nonetheless, the SEAC concluded that the alternatives are not economically feasible for the uses applied for. However, the applicants did not provide sufficient evidence that, by switching to an alternative, the users of the substance would not be able to have a profitable business, whereas ECHA's guidance on applications for authorisation reads that "[o]ne criterion for an alternative to be economically feasible is whether the net present value of the revenues minus costs is positive. In other words, the issue is that using the alternative should result in generating gross profit."

7. The public was denied the information necessary to contribute to the consultation on alternatives: The opportunity for third party input (according to Articles 64 (2) and (3)) was jeopardised by the lack of adequate access to relevant information. There was no possibility of constructive third party input because 70% of the documentation included in the raw PVC applications and 90% of that included in the recycled PVC applications was deemed confidential, including the whole of the chemical safety reports in some cases. Therefore, information essential for the submission of information on alternatives, such as the population exposed and import and manufacturing volumes, was not made available to third parties during the public consultation. Without the opportunity for third party input, the Commission would effectively not be able to comply with Article 60(4), second sentence, which stipulates that the authorisation decision shall be taken after consideration of all of stated elements, including third party contributions submitted under Article 64(2). Therefore, the applications should be rejected.