

Minority position statement by Frank Jensen (RAC) and Peter Hammer Sørensen (RAC) on:

The Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP 2b) (DH002058-60):

Use 2: *Industrial use in polymer processing by calendaring, 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).*

We only have problems with the opinion related to the exposure to the consumers. We can fully support the opinion concerning workers!

Our reasons for having a problem with the opinion concerning the consumers are given below:

1. It is written on page 11 that *"However, for the risk assessment, 90th percentile values are considered more relevant than average levels. Thus, the overall 90th percentile value for mothers and children was used for the risk assessment (no 90th percentile values were reported for the individual countries)."* This calculation requires individual measurements of each individual e.g. weight (bw) and age in order to calculate the correct 90th percentile. So if we don't have these numbers/results for the individual Member States there is a great risk of excess misinterpretation of data.
2. It is also stated on page 11, that *"Therefore RAC decided to take forward for risk assessment for consumers the same exposure values as chosen by the applicant:*

*Biomonitoring (DEMOCOPHES project, preliminary results, 90th percentile)
9 µg/kg/day (Adults)
10 µg/kg/day (Children)*

We haven't been able to find any reference to these values. The published Layman's Report does not mention these figures and they can't be reliably calculated from the figures in that report (see also above). This makes the calculations and assumptions non-transparent for the RAC.

3. On page 13 it is stated that *"As discussed in section 4, the data reported in the DEMOCOPHES layman's report indicates (up to roughly 1,7 times) higher average exposure levels in several European countries compared with the overall average for the 17 participating countries [..... and the following conclusions.....]*

Those "1,7 times" are questionable if they are based on the 50th percentile published in the layman's report – and not the 90th percentiles used which are not published. We cannot see it is possible to use the same extrapolation factor for the 50th and 90th percentiles. Again, in our opinion this needs individual datasets.

As we read the Laymann's report it is the averages that are shown in the table for the different countries; this indicates that the levels of DEHP in some of the individuals must be very high in those countries with the highest numbers.

Minority position statement by Lars Fock (SEAC) on:

The Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP 2b) (DH002058-60):

Use 1: *Formulation of DEHP in compounds, dry-blends and Plastisol formulations.*

Use 2: *Industrial use in polymer processing by calendaring, 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).*

I voted against the opinion, due to disagreement with the draft opinion (DO) on the conclusion on feasibility of alternatives (point 7.2) and the discussion on whether benefits exceeds the cost (point 8). Based on considerations seen from the downstream user's point of view the DO states that "as a whole, alternatives are not economically feasible". I find the argumentation for downstream users to be very weak and not based on updated and accurate information. DEHP is to a large extent already replaced by other plasticizers and no information is available indicating that for most downstream users suitable alternatives do not exist.

However, I agree that the three applicants do not have economic feasible alternatives to meet the demand of a majority of downstream users and therefore the cut off criterion laid down in Art. 60 (4) was not fulfilled, implying that an authorization could be issued if the benefits of an authorization exceeds the cost.

The other reason for the minority position was that the break even analysis carried out in the DO was not sufficiently justified and the conclusion did not address the uncertainty sufficiently. The analysis should be based on the cheapest economically feasible alternatives and not on the basket of all plasticizers used. Other plasticizers might have other technical and commercial benefits which are not taken into account. Furthermore, it is not documented that one of the major alternatives, DIDP, should be 60% more expensive than DEHP. Adjusted assumptions would bring the number of cases for breakeven below the number of maximum number of cases of male infertility. Furthermore, other anti-androgenic health effects, as mentioned in SEACs and RACs opinion on the Danish dossier, should be included in the overall conclusion on whether or not benefits exceed the cost.