11 December 2014

(Presented at MSC-39)

Concerns: **MSC opinions on the human health part of Annex XV proposals for identification of**

Bis(2-ethylhexyl) phthalate (DEHP) (EC No. 204-211-0)

Dibutyl phthalate (DBP) (EC No. 201-557-4)

Benzyl butyl phthalate (BBP) (EC No. 201-622-7)

Diisobutyl phthalate (DIBP) (EC No. 201-553-2)

as substances of very high concern under Article 57 (f) of the REACH Regulation

Title: **Minority position of four MSC members who do not agree to the proposed identification of above-listed substances as substances of very high concern for human health under Article 57 (f) of the REACH Regulation**

Justification of the ES, IT, UK and DE MSC members for the "no" votes on the Identification of the phthalates DEHP, DBP, DiBP and BBP as SVHC for the human health due to their endocrine activity.

Rationale:
The four phthalates have a harmonised classification as Repr. 1B on the evidence of adverse effects on the reproductive organs in rats and mice.

RAC made an extensive evaluation of the available information related to the hazard profile of the four phthalates during its opinion-making process for a Danish restriction proposal (ECHA/RAC/RES-O-0000001412-86-07/F). RAC concluded in 2012 that the four phthalates are not classified for any other human health endpoint than for reproductive toxicity, indicative of the latter endpoint being the most sensitive endpoint for the four phthalates. In particular, RAC recognised that multiple mechanisms may have occurred at the same time, leading to several effects that however all seem to follow from an anti-androgenic mode of action. The effects include early marker effects (e.g. on anogenital distance (AGD) and nipple retention), morphological and functional effects (e.g. on testes, epididymis, etc.). Although early marker effects may not be adverse per se, RAC concluded that in the case of the four phthalates all effects attributable to an anti-androgenic mode of action (be it functional or an early marker) are relevant endpoints, since they are so consistently observed in connection with each other in the available studies. Therefore, the most sensitive of these effects, resulting in the lowest No (or Lowest)-observed-Adverse-Effect Level (N(L)OAEL) was selected for each of the four phthalates for use in the establishment of Derived No-Effect Levels (DNELs).

It has been confirmed in 2013 by RAC (RAC/24/2013/08) that these effects are attributed to an anti-androgenic mode of action (MoA) being the most sensitive endpoint.

We therefore agree that the four phthalates have an endocrine activity. However, we do not support SVHC identification based on this MoA as it is not, in these cases, of an equivalent level of concern. The concern pointed out in the dossiers relies on decrease of sperm quality, Leydig cell tumors, cryptorchidism, reduced AGD, nipple retention, hypospadias and other reproductive malformations. All these effects have been considered in RAC conclusions in 2012 and 2013. It is therefore the same concern (i.e. effect) which has already been taken into account when the phthalates were included in the Candidate List (CL) due to their reprotoxic effects (in accordance with Art. 57c).