The European phenolic resin industry, represented by the European Phenolic Resins Association (EPRA) welcomes the opportunity to comment on the submission made by the Swedish Chemicals Agency with respect to the harmonised classification and labelling of 4,4'-Bisphenol F (4,4' BPF, 4,4'-methylenediphenol, CAS 620-92-8, EC 210-658-2). The hazard class evaluated in the proposal for BPF is reproductive toxicity.

Although EPRA members do not use BPF as a starting material for resin manufacture, it is well known that BPF is generated as an oligomer during the phenol formaldehyde reaction process before being further polymerised during subsequent processes to manufacture articles across a range of industrial sectors for wider societal use. Currently, there is no registration of BPF according to the REACH Regulation. Nevertheless, EPRA is working closely with its Downstream Users to understand the hazard properties of BPF in phenolic resins. To this end, EPRA has commissioned a literature research conducted by the consultants DHI which concluded that the there is a lack of information on full lifecycle and reproduction toxicity studies on BPF.

EPRA understands that the Swedish classification proposal on reproductive toxicity is based on substance specific data retrieved from scientific studies in the open literature, a weight of evidence of substance specific data on BPF and supported by read-across from bisphenol A (BPA), a structural analogue to BPF which has a harmonised classification as Repr. 1B, 360F; STOT SE 3, H335; Eye Dam. 1, H318; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410.

EPRA would like to highlight the following key points:

- With respect to the Swedish assessment of adverse effects on sexual function and fertility, no key *in vivo* study has been identified relating to either male or female fertility that in itself demonstrates a reduced reproductive performance or other adverse effects of BPF. So, the effect on male and female fertility highly relies on read-across to BPA hypothesizing the same Mode of Action.

- It is to be noted that in Table 18 of the classification proposal, where data between BPF and BPA are compared, half of the studies are given Klimisch scores 'not assignable or not reliable'. It would be important to understand why studies with such low Klimisch score have been the considered for a classification of BPF.

In summary, no key *in vivo* study has been identified that indicates adverse effects in relation to male and female fertility of 4,4' BPF and the Swedish classification proposal is not based on stand-alone data from BPF but relies to a high degree on a weight of evidence from a series of studies and read-across from BPA. It is acknowledged that there is a significant lack of data for BPF, however, EPRA would like to highlight that a read-across approach for harmonised classification of BPF can be hampered by a bias in data selection and in the evaluation of data if a specific mode of action is suspected beforehand. Coupled with the lack of information on full lifecycle and reproduction toxicity studies, there is clearly some way to go before any regulatory conclusion can be reached on equivalence with BPA.

European Phenolic Resins Association (EPRA)

29th September 2023