15 December 2016

(Presented at MSC-51)

Concerns: **Annex XV proposal for identification of 4-tert-butylphenol (PTBP) (EC No. 202-679-0) as a substance of very high concern under Article 57 (f) of the REACH Regulation**

Title: **Minority position of two MSC members who do not agree to the proposed identification of 4-tert-butylphenol (PTBP) (EC No. 202-679-0) as a substance of very high concern under Article 57 (f) of the REACH Regulation**

UK and CZ MSC members' minority opinion on proposal to identify 4-tert-butylphenol (EC Number: 202-679-0) as substance of very high concern (REACH Art 57(f) – ED environment)

We do not agree that 4-tert-butylphenol (PTBP) is an ENV EDC posing an "equivalent level of concern".

In the dossier the key supporting evidence is a study in Pike-perch and read across from other alkylphenols.

The only evidence of a relevant adverse apical effect linked to endocrine disruption for PTBP appears to be the virtually complete feminisation of a laboratory population of Pike-perch (*Sander lucioperca*) (Demska-Zakęś, 2005) at nominal concentrations of 100 µg/L [0.1 mg/L] and above. Taken at face value the results from this study would be sufficient for us to agree with SVHC identification on the basis of environmental endocrine disruption, since the (undefined) NOEC/EC10 suggests a highly potent effect (even though the substance is rapidly degradable). However, there are critical drawbacks that raise significant concerns regarding the reliability of this non-standard study and as such we cannot accept it as the key study. These are the lack of chemical analysis to confirm the exposure concentrations (especially as a semi-static exposure regime was used) and the inability to check any raw data (including original histological slides), which have not been released by the institution where the study was conducted. It is also not possible to check the species sensitivity from the positive control, 17β-estradiol, due to the high concentrations used. We had also raised an issue about the temperature used in the study, and whether this was suitable for the fish species. While this has been now been explained based on the text for the figures for the histology, we are uncomfortable that it is not possible to view the actual control histology images to support that conclusion.

As stated in the support document RAC concluded PTBP as aquatic chronic 1 due to the Krueger et al (2008) study. However we do not consider the adverse effects observed in that test for the endpoints where the NOEC <0.01 mg/l should be used for SVHC identification. Effects such as growth may not be due to an endocrine mode of action. The use of secondary sexual characteristics as definitive adverse effects for endocrine disruption are currently being discussed by the Endocrine Expert Group, but no decision has yet been reached. Therefore we do not think that they should be used at this point.

We therefore think that the case relies more heavily on the reliability of the read across from 4-tert-pentylphenol in particular. We agree that 4-tert-pentylphenol has endocrine disruptive properties in fish that give rise to a level of concern equivalent to PBT/vPvB and CMR substances .PTBP differs in structure by a single carbon atom, and the description of the physico-chemical and toxicokinetic data (in Annex I of the dossier) suggests that they will be of similar bioavailability to fish tissues. On balance, in the absence of more comprehensive studies on PTBP, it seems reasonable to assume that the substances are of similar long-term toxicity to fish. However, a key difference is that PTBP is rapidly degradable (see the recent Risk Assessment Committee opinion), which affects the overall level of environmental hazard it poses.

The adverse apical effect linked to endocrine disruption for 4-tert-pentylphenol (sex ratio) would trigger an Aquatic Chronic 2 classification when read across to PTBP (assuming equal potency). This is not the highest level of concern for chronic aquatic effects under existing EU law (i.e. the CLP Regulation), so we are not currently convinced that a substance should be identified as an SVHC on this basis. We think this is really a policy choice, and such a discussion has not yet been held.

The WHO definition is widely accepted for ED identification. However, Article 57(f) explicitly applies to substances that cause probable serious effects "scientific evidence of probable serious effects to the environment"). This is a step beyond the WHO definition, which does not have any specific regulatory context.

In PBT assessment, a chemical is of very high concern only if there is good evidence to show that it meets all three criteria (or is vPvB). A substance that meets two of the three criteria (e.g. P & T but not B) is still likely to be a high concern, but will not be prioritised as an SVHC. In other words, the level of concern is lower. We think this is an important distinction. On this basis we think it is not consistent to categorise all chemicals with endocrine disrupting properties, regardless of potency or degradability, as being of equivalent level of concern to PBT or vPvB (i.e. Article 57(d) and 57(e)).

We believe we should have criteria for environmental endocrine disruption that clearly highlight those substances that truly are of "very high" concern, recognising that some substances that can affect the endocrine system are a less serious concern. We believe that substances that are rapidly degradable should be considered a lower priority for the environment, unless they are highly toxic. The CLP Regulation provides an existing legal framework for this, especially as the aquatic criteria deal with adverse apical effects.

We therefore believe that persistence, as well as the potency of the adverse apical effect, are essential considerations for deciding whether a substance poses an equivalent level of environmental concern to CMR and PBT/vPvB substances. In other words, when a substance is being assessed for equivalent concern on environmental grounds, the factors considered under Article 57(d) and 57(e) are still relevant.

Overall, in our opinion there is not sufficient evidence to demonstrate that PTBP poses an equivalent level of concern, based on the current data.

UK & CZ MSC members 15 December 2016