

**UK and CZ members' minority opinion on proposal to identify 3-benzylidene camphor (3-BC, EC 239-139-9) as substance of very high concern**

**(Art 57(f) – ED environment)**

The lack of a Commission definition of an endocrine disruptor for the environment means we are operating in a policy vacuum, and we have to be mindful that “case by case” decisions taken under REACH set precedents that may need to be taken into account for other legislation where consequences are perhaps more significant (e.g. PPPs, biocides). This is why we are uncomfortable with proposals being made before a definition has been agreed at EU policy level.

The WHO definition is widely accepted for ED identification. However, Article 57(f) explicitly applies to substances that cause probable serious effects. For us, this is a step beyond the WHO definition, which does not have any specific regulatory context. For example, for us a weak endocrine disruptor, or one that is rapidly degraded in the environment and non-bioaccumulative, is unlikely to cause a serious effect on a population of organisms.

We advocate the use of potency and fate parameters for the identification of environmental endocrine disruptors. This forms part of the hazard characterisation process and is consistent with hazard classification under the CLP Regulation. We think it is an essential requirement for distinguishing between chemicals that are truly of “very high concern” and those that might be toxic but are much less likely to cause problems. The PBT criteria apply a similar type of logic (i.e. there has to be a combination of properties to trigger an SVHC identification – if the criteria aren't all met, then the trigger doesn't come into play, but REACH still requires appropriate control).

In the absence of a definition, we have considered SVHC proposals to identify endocrine disruption for the environment on a case by case basis. We have agreed to previous proposals where there is:

- EITHER a mammalian reproductive effect with a plausible ED mechanism leading to a CLP classification, combined with indications of intrinsic potential for food chain contamination (i.e. persistence and/or a high level of bioaccumulation). We are open to the idea of specifying specific potency cut offs too.
- OR evidence of an adverse population-relevant apical effect (e.g. on fecundity) in a level 4/5 OECD conceptual framework aquatic study that can plausibly be linked to an ED mode of action, at a concentration that is consistent with an Aquatic Chronic 1 classification under CLP (since this takes account of both the NOEC/EC10 and degradation potential). It should really be the lead effect too.

The study of Kunz et al. (2006b) provides strong indications that 3-BC interacts with the endocrine system in fish. However, the only adverse apical end point investigated in this study (fecundity) may be unreliable because some of the replicates in the top two treatment groups clearly had problems spawning before

exposure began. One of the validity criteria in the OECD TG 229 is that fish must be actively spawning in all replicates prior to initiating chemical exposure, and this was not met. Since the factors causing reduced spawning before exposure are unknown, and it cannot be excluded that spawning behaviour for replicates in some of the other treatment groups may have been influenced in some way, the UK and CZ do not consider the study to be sufficiently reliable for SVHC identification purposes. A further concern is that losses of test substance between the 48-h renewal periods in the test are indicated to be between 70-80%. While measured concentrations are used to express the results of the study, it suggests some uncertainty in the levels of substance that the fish were exposure to.

We consider that further fish endocrine testing is warranted, with better concentration maintenance and improved statistical robustness so that a LOEC/NOEC for the apparent fecundity effect can be derived. Confidence in the value of the NOEC is important for us in the determination of a substance meeting 57f for endocrine disruption for the environment. This is because the NOEC for the adverse population-relevant apical effect (that is plausibly linked to an endocrine mode of action), such as fecundity, needs to occur at a concentration that is consistent with an Aquatic Chronic 1 classification under CLP. Although a NOEC is not apparent from the Kunz study, the uncertain reliability of the apical end point means this is not relevant in this test.

We express reservation that mammalian data being used as supporting evidence are not indicated as having being analysed in detail by the rapporteur. We think such an assessment is key if these data are to be used to support a conclusion which includes endocrine disruption in vertebrate wildlife.

Overall, in our opinion there is not sufficient evidence to demonstrate that 3-BC poses an equivalent level of concern, based on the current data.

UK & CZ members

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