Informal discussion of the path of the Ag aquatic PNEC and the related SSD model

(Key points of teleconference between Mark Crane and Mark Raffray, 10 November 2008*)*

1. The draft Hazard Assessment for Ag prepared for the UK Environment Agency (EA) by WCA (Pete Simpson) was discussed. Note: This document was included in the WCA project proposal for Ag recently circulated via Caroline. The assessment applies a tentative Species Sensitivity Distribution (SSD) assessment to derive an aquatic long-term PNEC for Ag (currently ~11 ng/L), based on an Assessment Factor of 5.

2. Mark Crane remains reasonably optimistic that an aquatic PNEC for Ag approaching 20 ng/L can be established. This is based on an expectation that a less conservative AF can be applied, i.e. an AF of 3. Negotiation between WCA and the regulators on this point is planned.

3. WCA still consider that the most sensitive indicator species is fish, and that the NOEC of 0.08 mcg/L established by the Morgan et al. (2005) study is the key driving data in that respect.

4. An important forthcoming discussion is a peer review group meeting organised between EA, their expert reviewers and WCA scheduled 4 December 2008. The SSD will be discussed in depth at that meeting. The PMC algal study endpoint (EC10) would make a useful contribution to the total dataset being considered. Though not discussed with Mark Crane, early indications are that the outcome of our algal study is not adverse in terms its EC10 value.

5. In terms of REACH registration/CSA, it will be necessary to connect the UK EA efforts with ECHA and other competent authorities. Checking the likely acceptability of the SSD path and AF can be achieved at this stage because the UK Competent Authority representative (Steve Dungey) can be approached via WCA.

6. A BLM approach is a possible fall back strategy if SSD does not provide a satisfactory outcome. In summary this would take place via assessments of the influence of pH, dissolved organic carbon, and building a dataset commencing with Daphnia, then algae etc. This approach has been taken by several NFM groups, e.g. for Mn and Cu. Cost would be high – certainly hundred of thousand EU range, and the program would be lengthy. Parametrics (the WCA partner in the US) is a possible contractor, and there are others in Europe. Prior to any such program – and to evaluate whether it is really required – PMC would need to have a good understanding of environmental concentration (PEC) in member production facilities and downstream use. A combination of published field data on Ag PEC, sector information (e.g. photographic industry), member input, and EUSES default factors could be utilised.

<u>Proposed near-term actions</u>

- As per prior agreement between PMC and EA, the algal study data should be provided.
- The EC10 summary and if possible the preliminary algal study report (ahead of Quality Assurance checking) should be transferred to WCA ahead of the 4 Dec 2008, for their awareness and so that informal input can be given at the EA meeting.
- The status of the SSD discussion needs to be checked on a regular basis by PMC. If a reasonable amount of extra study data would definitely improve the AF, then PMC can consider whether it would be worthwhile to initiate this work or buy the data if it exists already (e.g. from Biocidal Product dossier data holders).
- In line with the tiered strategy agreed at the last TAP/WG meeting in September, and in case a BLM approach ultimately becomes necessary, PMC should commence building an Ag PEC dataset (see point 6 above).