Nufarm UK Limited
Crabtree Manorway North
Belvedere
Kent
DA17 6BQ

A H Marks and Company Limited
Wyke,
Bradford
W Yorkshire
BD12 9EJ

Environment Agency
UK Technical Advisory Group
Via e-mail to wfduktag@sniffer.org.uk

6th August 2007

Subject - Response to "**Proposals For Environmental Quality Standards For Annex VIII Substances** Document SR1 – 2007 UK TAG on the Water Framework Directive.

Dear Sir,

This document represents the response of A H Marks and Company Limited and Nufarm UK Limited, the current members of the "Mecoprop-P Task Force". Comments in this response specifically address the proposed revisions of the EQS values for Mecoprop defined on pages 68 and following of the consultative document.

The Task Force draws to the attention of the Authors that in UK agriculture, use of Mecoprop (racemic) has in recent years been superceded by Mecoprop-P (optically active isomer) which has had the effect of halving the use rate of the active ingredient. This has substantially reduced the environmental burden of the active.

The Task Force is concerned at the proposed EQS's. The basis of this concern is on the reliability of the individual data set used to derive the PNEC's.

In the consultative document (page 14 bullet point (d), The UK TAG writes that *"the regulatory standards should be based on adequate data in which there is sufficient confidence"*
The individual studies used to select the PNEC will be reviewed below, however there are some general points that should be considered.

Springborn Data
In the case of Mecoprop-P the Task Force does not consider that the studies used to set the PNEC are scientifically valid. The end points selected are from studies performed at the Springborn Laboratories Inc. in the early 1990's. The Task Force is convinced that these data are flawed. The attached review examines 21 studies from Springborn during this period, performed on a variety of Phenoxy herbicides. In most cases (19) studies

have been repeated in other laboratories and these results are presented. The laboratories performing these repeat studies are located in various countries in Europe and in the USA and the studies spanned a period of more than 15 years. In one case (MCPA, Selenastrum) the study has been repeated no fewer than 5 times in other laboratories. In the 19 studies from Springborn that were repeated in other labs, the result in the second laboratory was always towards reduced toxicity, in some cases the difference in the results was several orders of magnitude. Where there was more than one repeat the results were reasonably consistent, confirming the Springborn value as an outlier. Despite investigation at Springborn and elsewhere , no specific cause for this anomaly was discovered, As a result Springborn Laboratory stood by the results (and where it repeated the study itself and obtained different results it stood by those as well!). It seems unlikely that with such an extensive database, it is mere chance that the Springborn results always indicate the highest toxicity.
In the review of Mecoprop-P for Annex 1 inclusion under EC directive 91/414 the RMS (Denmark) accepted that the Springborn data was flawed and accepted alternative data to derive end points. These were endorsed at the ECCO meetings – which included UK representation. It is disappointing that this (publicly available) DAR seems not to have been reviewed for the current document

The Mecoprop-P Task force therefore asks the UK TAG to consider the more reliable data detailed in the discussion following.

Mode of action of the Phenoxy Herbicides
The mode of action of the phenoxy herbicides is well documented. Mecoprop-P, like the others, is a synthetic auxin, which in higher plants mimics the effects of natural plant auxins causing distorted growth, morphological changes and, in higher doses, death of the plant. They are not direct inhibitors of photosynthesis. The database of studies on single cell algae with the phenoxy herbicides indicates generally that the these organisms are not particularly susceptible to the phenoxy herbicides, and this is not surprising since there is no precedent for a “diffusion hormone” in a single cell plant. The aquatic macrophyte therefore forms a more likely model for detecting the herbicidal activity of phenoxy herbicides.

It should also be noted that in general the effect of Mecoprop-P on algae is reversible (ie it is phytostatic at least at moderate concentrations, rather than phytolethal (algicidal)). This was demonstrated in algae - Navicula pelliculosa (Jenkins 2007) and Skeletonema costatum (Burke 2007). Reversibility to the phytotoxicity of the structurally related herbicide MCPA was also shown with the macrophyte Lemna gibba (Jenkins 2006) where plants exposed to 4 mg/l MCPA acid (a value in excess of the EC_{50}) for 3 days were shown to exhibit rapid growth when placed in fresh media for 9 days.

Comments on the EA document “Proposed EQS for Water Framework Directive Annex VIII substances: Mecoprop” Science Report HOEP670085/SR19 (Feb 2007)

The above document forms the database of information on Mecoprop which is summarized and presented in SR1 2007. Having reviewed this document, the Task Force has some comments on aspects of this document:

1) The document puts a heavy reliance for physico-chemical and environmental fate properties on the Hazardous Substances Data Bank (HSDB) of the US National Library for Medicine. The Task Force is somewhat surprised and disappointed

that more emphasis is not put on the recently published DAR from the European pesticide review process. Data from the EU review process has been reviewed by experts and is accepted by European Member State regulatory authorities, including DEFRA, which made significant contribution to the document, and by organizations such as the European Food Standards Agency (EFSA). It would be of great benefit and clarity if we were working from the same peer reviewed database.

2) Some of the data cited in HOEP670085/SR19 comes from non primary sources and so the reliability of the data cannot be easily judged. This is reflected in the Kimlisch Code ranking of "4" for some of the PAN Pesticides Database entries. However there are entries in the database (e.g. on page 45, Hansveit 1988) where the study has apparently not been reviewed as it too is given a Kimlisch code of 4. The Task Force would like to point out that all studies which are reviewed in the DAR are available on request.
3) Data points used in HOEP670085/SR19 do not always appear to be correct. For example for bioconcentration (BCF) the document cites the HSDB. The entry for bioconcentration in the HSDB is given as an estimate (of 141) based only on a Log Kow value. The Task Force is disappointed that the EA has not used an EPA guideline study in bluegill sunfish which yields a BCF of 5.5. The study is cited in the EU DAR.
4) Tables 2.9 and 2.10 in HOEP670085/SR19 clearly show the difference in the results from Springborn (reports authored by Hoberg) and other laboratories. The values in the end point column demonstrates the large difference in numerical values.

The Task Force is willing to work with the Environment Agency in providing copies of reports and reviews which would improve the reliability of the information published in HOEP670085/SR19. Also any reports cited in this the communication (in particular the Springborn Paper) are available on request.

Signed for and on behalf of the Mecoprop-P Task Force

Andrew Bond
(Nufarm UK Limited)

Geoff Pigott
(A H Marks & Company Limited)

Appendix 1 – Individual discussion of the proposed aquatic end points (PNEC's)

Long term PNEC for Freshwater	
PNEC proposed 5.5μg/l (incorporating an Assessment Factor of 10) Based on a 5 day NOEC (120 hr) for Navicula pelliculosa of 55μg ai (0.055 mg/l) (Hoberg 92-10-4463) And the 120 day study for Selenastrum capricornutum where the NOEC was reported as 0.039 (Hoberg SLI 92-2-4113)	**SLI 92-10-4463** This is a flawed study. The cell density measurements indicate a lack of linear growth. The control culture shows a decrease in cell density between 24 and 48 hrs. The EC50 values calculated at the 72, 96 and 120 hours intervals do not show a dose related progression (the 72 hr time point is the lowest EC50 value) These results are not confirmed by the (guideline compliant) study of **Jenkins 2007** where the NOEC is reported as 10 mg/l The recovery of the algae has been demonstrated following exposure to 200 mg/l indicating that in a real event of a pulse high level of mecoprop-P in surface water caused by spillage or run off, the algae would rapidly reestablish following a decrease of water concentration. **SLI 92-2-4113** This is a flawed study. Here the EC50 values calculated at 48, 72, 96 and 120 hrs show that the material is less toxic with time (the EC50 at 120 hrs is > 2.8 as opposed to 1.4 at 48 hrs)
Task Force Proposal Based on Caley and Kelly 1999	There are 5 other (non Springborn) studies with these algae and a further 3 with the racemic product, performed at 6 different labs. Some demonstrate recovery. The most sensitive species is the macrophyte *Lemna.* This is expected from the known mode of action for mecoprop. In this study the NOEC was found to be 0.18 mg/l (expressed as mecoprop acid). We propose a PNEC of 18 μg/l (based on a 10 fold safety margin from the Lemna study NOEC).
Task Force PNEC Proposal	**PNEC 18 μg/l.**
Short term PNEC for Freshwater	
PNEC proposed 24μg/l (incorporating an Assessment Factor of 10) Uses the same data as above but applies a 10 fold assessment factor to the EC 50 rather than the NOEC	Effects on Biota Aquatic macrophytes are the most sensitive species, In the study of Caley and Kelly (1999) the EC_{50} was calculated to be 18.7mg/l (expressed as mecoprop-p acid). Applying a factor of 100 from the EC_{50} gives a value of 187(190)μg/l. It should be noted that experiments with the structurally-related phenoxy herbicide MCPA have shown that exposures at levels above the EC_{50} result in growth stasis, but the plants will recover in the absence of continued exposure, so the above value should be regarded as conservative.

Task Force PNEC Proposal	**PNEC 190 μg/l.**
Long term PNEC for Salt water	
PNEC proposed 0.3μg/l (incorporating an Assessment Factor of 10) Based on a 5 day LOEC (120 hr) for Skeletonema of 9μg ai (0.009 mg/l) (Hoberg 92-3-4170) applying a 3 fold factor to get from LOEC to NOEC	In the early *Skeletonema* study quoted growth declined steadily during the 120 hour study. This suggests medium deficiency. The reasons for discounting studies performed at this laboratory at that time are discussed in a separate document.
Task Force Proposal Based on Burke 2007 and Caley and Kelly 1999	A recent study (Burke 2006) has shown 47 mg/l to be a no effect level over 96 hours, thus confirming that marine algae are not especially sensitive to the effects of mecoprop-p. Given the above it is likely that macrophytes would be the most sensitive species and as there are no data on marine macrophytes the freshwater data are considered definitive. Thus, the PNEC should be derived in a similar manner to that for freshwater to give a value of 18 μg/l
Task Force PNEC Proposal	**PNEC 18 μg/l.**
Short term PNEC for Salt water	
PNEC proposed 1.7μg/l (incorporating an Assessment Factor of 10) The PNEC is calculated from the EC50 of the above study (quoted as 0.017 mg/l but in the report it is given as 0.018 mg/l)	The considerations are similar to those for long term assessment with freshwater values equally applicable. The PNEC is therefore 190 μg/l, based on results from Lemna.
Task Force PNEC Proposal	**PNEC 190 μg/l.**