United Phosphorus Limited

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Monday 12th September 2011

Dear Standing Committee Members,

United Phosphorus Limited is the sole notifier supporting the active substance asulam for approval under Regulation (EC) No 1107/2009. Asulam will now be subject to the Appeal Committee procedure. On the basis of the existing dataset that has been submitted and evaluated by both the RMS and EFSA we are extremely confident that asulam meets the conditions for approval, particularly when compared with other substances that have been approved.

One of the issues of critical concern raised by EFSA is that there needed to be a further assessment of the toxicological properties of sulphanilamide in order to address the risk assessment for the consumer (ADI and ARfD). Sulphanilamide is both a plant and minor rat metabolite as well as an impurity of asulam synthesis. The lowest toxicological effect level for sulphanilamide reported in the public domain is 22 mg/kg/day. This value has been derived from a non-guideline developmental study conducted more than 70 years ago. Following a thorough review of this study, it is not clear where or how this value was derived, as the study reports a value of 1000 mg/kg/day.

Even when an extremely cautious approach is taken (with correction for oral absorption) the LOEL is approximately 30 times greater (647 mg/kg/day) than the value in the public domain. The lowest reported value for asulam is 36 mg/kg/day, which is approximately 18 times lower than 647 mg/kg/day for Sulphanilamide.

The widely reported LOEL value for sulphanilamide is clearly not associated with the study that has been referenced. It can be concluded that the public domain LOEL value should not be used to determine reference doses for the risk assessment of sulphanilamide.

United Phosphorus Limited is fully committed to supporting asulam and demonstrating that sulphanilamide does not pose an unacceptable risk to consumers. After careful consideration of the justification for conducting further studies on vertebrate animals, we have commissioned a limited set of toxicological studies as listed in appendix A. The results from these studies will be available by March 2012.

Products containing asulam have some very important niche use for which no other suitable chemical or non-chemical alternatives exist, particularly in relation to bracken control in upland areas of the UK.

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Consequently, uses of asulam-containing products have an important role not only in the production of certain edible crops but also for the purposes of maintaining biodiversity in upland areas. In addition asulam-containing products are used as an important conservation tool at certain archaeological sites, and other sites of particular scientific importance in order to protect rare plant and animal species.

Based on the available scientific data, we are confident that sulphanilamide poses no additional risk to consumers when comparing the risk against exposure to asulam. We anticipate that the additional studies that we have commissioned will confirm this situation. United Phosphorus Limited firmly believes asulam meets the conditions of Annex I inclusion.

Should you require any further information, please do not hesitate to contact me.

For and on behalf of United Phosphorus Limited,

B. Mistry

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APPENDIX A

On-going Toxicological Studies Conducted with Sulphanilamide

- Acute oral toxicity of Sulphanilamide in Rats (OECD 420)
- 28 day Repeat dose oral toxicity study in the Rat (OECD 407)
- Bacterial (Ames) reverse mutation test (OECD 471)
- In vitro chromosome aberration study in human lymphocytes (OECD 473)
- Mouse Lymphoma L5178Y TK Assay (OECD 476)