

# **Opinion of the SCP regarding the inclusion of Azimsulfuron in annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/AZIM/002-Final) - Opinion expressed by the SCP on 4 February 1999**

## **TERMS OF REFERENCE**

The draft Commission Directive proposing the inclusion of azimsulfuron in Annex 1 to Directive 91/414/EEC had been referred to the Scientific Committee on Plants for consultation with the following questions:

1. Are the male reproductive effects seen in the 2-generation rat study of relevance for health and the environment?
2. Having regard to the intrinsic aquatic ecotoxicological properties of azimsulfuron, the Committee is requested to evaluate the risk to the environment which could occur from its uses.

## **BACKGROUND**

The draft Commission Directive for the inclusion of azimsulfuron in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion. The Committee had been supplied with documentation comprising a dossier provided by du Pont de Nemours and Company, a monograph prepared by the Italian authorities, a review report prepared by the Commission services of the Directorate General for Agriculture and the Recommendations of the ECCO Peer Review Programme.

Azimsulfuron is a sulfonylurea herbicide used to control a wide range of monocotyledonous and dicotyledonous weeds in rice culture. It acts on sensitive species by inhibition of the enzyme acetolactate synthase which leads to the cessation of cell division. It is absorbed mainly through the leaves and to a lesser extent by the roots and is translocated in plants via the xylem and phloem. It is applied post-emergence at a maximum application rate of 25 g active substance / ha per growing season.

## **OPINION OF THE COMMITTEE**

The Committee would like to draw the Commission's attention to the fact that in preparing its opinion, it has been necessary to re-evaluate original studies in order to clarify inconsistencies between the monograph and the review report regarding important data. Particular attention is drawn to the difficulty in establishing the relevance of Italian field studies on the fate and distribution in paddy field water which were poorly reported in the documentation. The Committee is of the opinion that this situation does not contribute to the necessary transparency required of the evaluative procedure nor to the efficient use of resources. The effectiveness of the SCP's intervention is highly dependent it being supplied with high quality reliable documentation. Accordingly, the Committee requests that in future

it is supplied with documentation of an appropriate quality in order to discharge its responsibility.

### Question 1

#### **Are the male reproductive effects seen in the 2-generation rat study of relevance for health and the environment?**

It is the Committee's opinion that since the mammalian reproductive effects of azimsulfuron were first detectable at concentrations equal to or above those causing systemic toxicity, it is unlikely that reproductive effects would occur in man through use of this product, except when human exposure is so high so as to cause systemic toxicity.

In the two-generation reproduction in rats (1) the NOECs<sup>1</sup> for systemic toxicity were 125 ppm for F0 and F1 parents and 1000 ppm for F0 and F1 pups. NOECs for reproductive toxicity for F0 and F1 parents were 1000 ppm for both. There were no detectable effects on fertility or gestation indices, length of gestation, number of implantations or delivered pups in any treatment group. In the highest treatment (i.e., 8000 ppm) hypertrophy of the pancreas occurred and the mean number of epididymal sperm in F1 males was significantly lower than the control value, but there was no detectable effect on testes weight. In a separate study (2) examining testicular effects of azimsulfuron in rats, plasma estradiol levels were significantly depressed in a 30,000 ppm exposure group giving a NOAEL<sup>2</sup> estimated at 300 ppm. The NOAEL for estradiol depression was above the NOAEL which was based on pancreas weight, hypertrophy and the acinar cell labelling index.

Regarding the ecotoxicological significance of possible endocrine modulation, the applicant referred to two chronic studies performed on rainbow trout (3) that no evidence of possible endocrine modulation was found in these studies and therefore possible adverse effects on endocrine modulation do not appear to be relevant for azimsulfuron. The Committee is aware of ongoing international activities to develop a harmonised testing and assessment scheme regarding endocrine disruptive effects in the environment (i.e., the OECD EDTA working group, in conjunction with the US-EPA EDSTAC group). Although the Committee notes that the end-points measured in the two mentioned studies are not specific for determining endocrine modulation per se, it is of the opinion that endocrine modulation is very unlikely to occur with azimsulfuron in the environment.

### Question 2

#### **Having regard to the intrinsic aquatic ecotoxicological properties of azimsulfuron, the Committee is requested to evaluate the risk to the environment which could occur from its uses.**

The Committee accepts that azimsulfuron is likely to degrade under field conditions within 3 (DT<sub>50</sub><sup>3</sup>) to 10 (DT<sub>90</sub>) days. Partitioning into the sediment can be expected to be low. Initial concentrations in paddy water are expected to be 25 - 33 mg/l which will be reduced to approximately 10 mg/l after 5 days and 5 mg/l after 7 days, respectively (when water will be discharged into irrigation ditches and/or other surface waters). Those levels are close to or within the range of effect concentrations for algae (NOEC < 8.1 mg/l) and *Lemna* (NOEC 0.46 mg/l, with 14-day EC<sub>50</sub>'s<sup>4</sup> of 0.8 - 0.93 mg/l; but effects reversible after the end of the

exposure). The severity of effects to algae and mainly aquatic plants will therefore depend on (and be manageable by appropriate choice of)

the length of the holding period the dilution at the time of application and in the receiving water bodies.

It is suggested that risk management might take account of these factors.

With regard to terrestrial non-target plants, it can be concluded from efficacy screening data that there is a risk of phytotoxic effects from spray drift directly adjacent (1-2 m) to the treated paddies. Appropriate care needs to be taken to protect non-target plants and adjacent crops from spray drift or treated water.

## REFERENCES

( 1 ) Fujii, S., 1994. DPX-A8947: Teratogenicity Study in Rats. Generated by Institute of Environmental Toxicology. Submitted by E.I du Pont de Nemours and Company, Company file No.: IET 90-0039, July 25, 1994.

(2) Cook, J.C., 1994. DPX-A894-24: Mechanistic Studies for Pancreatic and Testicular Effects. Feeding Study in Rats. Generated and submitted by E.I du Pont de Nemours and Company. File No. HLR 167-95, April 24, 1994.

(3) Kreamer, G.C., 1994. Early life-stage toxicity of DPX-A8947-24 (technical) with Rainbow Trout, **Oncorhynchus mykiss. Generated and submitted by E.I. du Pont deNemors and Company, December, 1994.**

Kreamer, G.C., 1994. Flow-through, 28-day toxicity of DPX-A8947-24 (technical) with Rainbow Trout, **Oncorhynchus mykiss. Generated and submitted by E.I. du Pont deNemors and Company, December, 1994.**

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<sup>1</sup> No observed effect concentration

<sup>2</sup> No observed adverse effect level

<sup>3</sup> Disappearance time for 50/90% of compound

<sup>4</sup> Effective concentration 50%