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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

24 AUG 1993

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: RfD Report of Tebuconazole (Folicur)
Triazolyalalanine residues in crops treated with
tebuconazole (and other triazole fungicides)

CASRN. 107534-96-3
EPA Chem. Code: 128997
Caswell No. 463P

From: Alberto Protzel
Toxicology Branch II
Health Effects Division (H7509C)

Alberto Protzel 7/14/93

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TO: Benjamin Chambliss, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

Concern for triazole-derived residues from DPX-H6573 (also known as Nustar^R) was indicated in a 1/3/90 memorandum from W.J. Hazel (HED) to R.D. Schmitt (HED). At that time, levels of up to ≤ 0.9 ppm for triazolyalalanine and up to ≤ 0.14 ppm for triazole were found for various RACs and/or their processed products and the HED Metabolism Committee was requested to address the issue. Consensus was reached [8/21/90 Memorandum from W.J. Hazel (HED) to S. Lewis (RD) and R. Engler (HED)] that triazole-containing compounds derived from DPX-H6573 (Nustar^R) are not of concern due to their natural occurrence and/or their low toxicity and/or their indistinguishability from background.

Subsequently, in the case of tebuconazole, TB-II was asked to comment on the toxicological significance of possible levels of triazolyalalanine of up to 6.66 ppm and 40 ppm that could be present with tolerance levels of tebuconazole in wheat seeds and barley grain, respectively (Memorandum from A. Protzel to R.D. Schmitt dated 4/10/91).



Upon examination of the existing toxicological database on triazolyalanine (Memorandum from A. Protzel to R.D. Schmitt dated 4/10/91) a tentative RfD-like value of 0.2 mg/kg/day was calculated for triazolyalanine, based on a dog subchronic NOEL of 8000 ppm and an uncertainty factor of 1000. Based on the above RfD-like value it was concluded that, at the time, the observed levels of triazolyalanine did not appear to pose toxicological concern for diets comprising of up to 50% wheat and 10% barley seeds.

More recently, the HED/RfD Committee was asked to comment on whether the assessment of toxicological significance for triazolyalanine and its congener plant residues derived from tebuconazole should be done on an individual basis using the above RfD-like approach or whether the triazoles should be included in the tolerance expression for the parent compound. It should be emphasized that triazolyalanine is a common plant metabolite for several, if not all, triazole fungicides. Furthermore, the tolerance expression for almost all triazole fungicides is based on the parent compounds and all triazole-moiety containing metabolites.

The HED/RfD Committee met on April 8, 1993 to address the issue and concluded that the above RfD-like approach should not be used at this time. Whether the triazolyl residues should be included with the tolerance expression of the parent compound awaits an examination by the HED/Metabolism Committee.

A. Individual in Attendance

1. Peer Review Committee Members and Associates (Signature indicates concurrence with the peer review unless otherwise stated).

William Burnam

Reto Engler

Marcia Van Gemert

Karl Baetcke

Henry Spencer

William Sette

Roger Gardner

James Rowe

George Ghali

Rick Whiting

Wm L Burnam
Reto Engler
Marcia Van Gemert
Karl Baetcke
Henry Spencer
William Sette
Roger Gardner
James Rowe
George Ghali
Rick Whiting

2. Scientific Reviewer(s) (Committee or non-committee members responsible for data presentation; signatures indicate technical accuracy of panel report).

Alberto Protzel

James Rowe

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James Rowe

3. Others:

Kerry Dearfield and Michael Metzger of the Health Effects Division as observers

CC: Penny Fenner-Crisp
Richard Schmitt
Kerry Dearfield
Marcia Van Gemert
James Rowe
Alberto Protzel
Rick Whiting
James Kariya
Michael Metzger
Edward Zager