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

NOV 17 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

623A

MEMORANDUM

DATE: November 13, 1981

SUBJECT: Oryzalin; Request for tolerance at 0.05 ppm on Peas
PP#9E2219, Amendment of 9/9/80, from IR-4, Rutgers
University, New Brunswich, New Jersey

FROM: R. Bruce Jaeger, Section Head
Toxicology Branch/HED (TS-769)

TO: Mr. Donald Stubbs
ERS/PCB/RD (TS-767C)

Please note Toxicology Branch's previous consideration with respect to Oryzalin on peas, memorandum attached (10/19/81).

Attachment (2)

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

10/19/81

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE:

SUBJECT: Proposed Rule - Tolerance for Oryzalin on Sweet Potatoes and Peas (PP#8E2075/9E2219)

FROM: Robert B. Jaeger, Section Head RBJ; 10/19/81
Review Section #1
Toxicology Branch/HED (TS-769)

TO: Douglas Campt, Director
Registration Division (TS-767)

THRU: William L. Burnam, Acting Chief WLB
Toxicology Branch/HED (TS-769)

John W. Melone, Acting Director Anne Barton
Hazard Evaluation Division (TS-769)

Toxicology Branch has responded previously to the Proposed Rule for Oryzalin on Sweet Potatoes and Peas (Toxicology Branch memo, same subject, M.L. Quaife, 9/1/81). As noted, Toxicology Branch did not support the proposed use. Subsequent to that memo, Toxicology Branch met with representatives of Eli-Lilly and discussed at great length the teratogenic potential of Oryzalin. We are of the opinion that this issue will be resolved shortly and are optimistic that it will be favorable. We are presently awaiting test results (teratogenic study in rabbits) and a full medical investigation (conducted by Eli-Lilly) to resolve this deficiency.

Furthermore, the question of oncogenicity is still unresolved with demonstrated positive response in the rat. The mouse oncogenicity study has recently been reviewed (Quaife 10/7/81) and it was concluded that the NOEL is 500 ppm (with regard to chronic feeding effects) and negative for oncogenicity in the mouse at up to and including 3650 ppm (highest level fed).

Toxicology Branch is hopeful that a statistical evaluation of the rat oncogenicity study and subsequent risk assessment can be completed as soon as possible, and thereby determine a VSD (virtually safe dose).

The record of correspondence from RCB (Errico, 9/5/80; Nelson, 9/7/78, Errico, 12/6/79) clearly indicate that "the residue of concern is the parent compound, Oryzalin", and that there were NDR (< 0.01 ppm) of Oryzalin in any of the sweet potatoe samples analyzed, nor in the pea pod or pea seed samples analyzed. RCB further concluded that there will be no problem of secondary residues in meat, milk, poultry and eggs from the proposed uses.

Toxicology Branch is still of the opinion that the oncogenic potential of Oryzalin needs to be resolved. However, in consideration of the nature of the residue (NDR at < 0.01 ppm) and that the registration for Oryzalin is conditional upon satisfactory resolution of the oncogenic potential, Toxicology Branch supports the proposed use on sweet potatoes and peas.

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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DATE: SEP 1 1981

SUBJECT: Oryzalin, PP's 8E2075 and 9E2219, comment on proposed Federal Register (FR) Document on by TB/HED.
CASWELL No. 623A

PP No. 8E2075 and
PP No. 9E2219

IR-4
Rutgers University
New Brunswick, N.J.

FROM: Mary L. Quaife, Ph.D. MLQ, 9/1/81
Review Section #1
Toxicology Branch/HED (TS-769)

TO: Mr. Donald Stubbs
ERS/PCB/RD (TS-767C)

THRU: Mr. William Burnam, Acting Chief
Toxicology Branch/HED (TS-769)

TB/HED is asked to concur, non-concur, or comment on a FR document which would establish tolerances for oryzalin on peas and sweet potatoes, each at 0.05 ppm.

A memo from TB which recommends for a tolerance on peas is not included. TB agrees with that in PP 9E2219 of 12/5/79 (included) from Dr. L. Anderson which disapproves of granting one on peas, pending evaluation of missing studies on oryzalin, and does not endorse those in PP 8E2075 of 6/2/78 and 11/6/78 (by Mr. D. Ritter) which approve of a tolerance on sweet potatoes (included, also).

Oryzalin is an oncogen in the rat and has potential problems with respect to teratogenicity (cf. TB reviews on record). Pending final evaluation of the chronic/oncogenicity studies, an allowable daily intake for human beings cannot be calculated. Pending resolution of the question of its possible teratogenicity, oryzalin cannot be evaluated properly with respect to human toxicity.

TB/HED does not concur with establishment of the proposed tolerances.

RECEIVED 9-9-81

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