



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 5 1986

MEMORANDUM

SUBJECT: Request to Amend the Registration of Iprodione to
Include Tolerances on Rice, Rice Hulls, and Rice straw

TO: Lois Rossi, PM 21
Registration Division
(TS-767)

FROM: Margaret L. Jones *M. L. Jones 11/19/86*
Review Section III
Toxicology Branch, HED
(TS-769)

THROUGH: Marcia Van Gemert, Ph.D., Head *M. Van Gemert 11/20/86*
Review Section III
Toxicology Branch

and Theodore M. Farber, Ph.D., Chief
Toxicology Branch *T. M. Farber 11/21/86*

Compound: Iprodione; Rovral; Glycophene Tox. Chem No: 470A

Registration No: 178651, 178652 Tox. Project No: 2328

Petitioner: Rhone Poulenc

Accession No: N/A Petition No: 6F3443, 6H5507

Action Requested: Amend the registration of Iprodione to
include tolerances on rice, rice straw, and rice hulls.

Data Considered:

Reproduction in the rat (undated)
Chronic/oncogenicity in the mouse (3/6/78)
Subchronic dog (undated)
Developmental toxicity in the rabbit (12/12/85)

Data Currently Lacking on Iprodione: Toxicology data requirements
were published in the Federal Register (Vol.49 No.207, 10/24/84,
pp.42892 - 42893). According to these requirements, the
following data for the technical chemical are lacking:

Acute Dermal LD50

1/4

Dermal sensitization
Developmental Toxicity in a species other than the rabbit
General Metabolism

Actions Under Way to Obtain Missing Data: No known action is presently under way to obtain these data.

Published Tolerances for Iprodione: Tolerances exist for Iprodione in or on raw agricultural commodities as published in 40 CFR 180.399, 21 CFR 193.251 and 21 CFR 561.263.

Effect of Proposed Tolerances on Acceptable Daily Intake (ADI): The present request for tolerances of Iprodione in or on rice at 10.0 ppm was analyzed using the Toxicology Branch acceptable daily intake (ADI) program. The ADI program cannot analyse the effect of tolerances on rice hulls or rice straw as these are not human foods. The secondary residues expected to occur in meat and/or milk as a result of this additional use will be considered by Residue Chemistry Branch and Toxicology Branch will then analyse the impact on the acceptable daily intake.

The present analysis used the ADI based on the three generation reproduction study in rats with a no observed effects level (NOEL) of 500 ppm (25 mg/kg/day). The cumulative percent of the ADI used from the existing and proposed actions is 13.56 for the US population. (Please note the previous analysis using the Tolerance Assessment System (TAS) indicated a slightly higher percent ADI. The difference reflects slightly different consumption information for each raw agricultural commodity.)

Acceptable Daily Intake, Maximum Permissible Intake, and Theoretical Maximum Residue Contribution: The ADI is based on the results of the three generation reproduction study discussed above.

ADI = 0.25 mg/kg/day
MPI = 15 mg/day (60 kg)
TMRC = 0.034 mg/kg/day
NOEL = 500 ppm (25 mg/kg/day)
Safety Factor (SF) = 100

Recommendation: Toxicology Branch recommends acceptance of the proposed tolerances for Iprodione in or on rice at 10.0 ppm. If, as expected, this use results in added residues in meat and/or milk from the use of rice straw and rice hulls as feed, a revised petition should be submitted to the Agency reflecting the new levels in those commodities.

It is further recommended that steps be taken to obtain the currently lacking toxicity data on Iprodione.

No known regulatory actions are pending against the registration of Iprodione.

TOXICOLOGY BRANCH ADI PRINTOUT

Date: 11/13/86

Glycophene (Iprodione)

Caswell #470A

NOEL = 0.0000 mg/kg

ADI = 0.250000 mg/kg/day

CFR No. 180.399

LEL = 0.0000 mg/kg

Safety Factor = 100

Status: ADI NOT VERIFIED BY TOX ADI COMMITTEE OR AGENCY RFD COMMITTEE.
WHO last reviewed 1977.

RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

DRAFT

| CROP | TOLERANCE (PPM) | PETITION NUMBER | FOOD FACTOR | MG/DAY |
|----------------------------------|--------------------|--------------------|----------------|----------|
| 1 Almonds | 0.050 | | 0.03 | 0.000023 |
| 54 Eggs | 0.800 | | 2.77 | 0.033240 |
| 61 Garlic | 0.100 | | 0.03 | 0.000045 |
| 67 Grapes, not including raisins | 60.000 | | 0.45 | 0.405000 |
| 84 Lettuce | 15.000 | | 1.31 | 0.294750 |
| 90 Meat, red | 0.400 | | 10.81 | 0.064860 |
| 93 Milk and dairy products | 0.300 | | 28.62 | 0.128790 |
| 128 Poultry | 2.000 | | 2.94 | 0.088200 |
| 134 Raisins | 300.000 | | 0.04 | 0.180000 |
| 151 Stone fruits | 20.000 | | 1.25 | 0.375000 |
| 203 Kidney | 3.000 | | 0.03 | 0.001350 |
| 204 Kiwi fruit | 10.000 | | 0.03 | 0.004500 |
| 211 Liver | 3.000 | | 0.03 | 0.001350 |

TMRC

0.026285 mg/kg/day (60kg BW, 1.5kg diet)

%ADI

10.514050

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

| CROP | TOLERANCE (PPM) | PETITION NUMBER | FOOD FACTOR | MG/DAY |
|----------------------------|--------------------|--------------------|----------------|-------------|
| 1 Almonds | 0.250 | 5F3241 | 0.03 | 0.000112500 |
| 10 Beans, dry edible | 4.000 | 4F3150 | 0.31 | 0.018600000 |
| 11 Beans, lima | 2.000 | 4F3150 | 0.19 | 0.005700000 |
| 12 Beans, snap | 2.000 | 4F3150 | 0.98 | 0.029400000 |
| 17 Boysenberries | 15.000 | 4F3129 | 0.03 | 0.006750000 |
| 18 Blueberries | 15.000 | 5E3214 | 0.03 | 0.006750000 |
| 19 Broccoli | 25.000 | 6F3305 | 0.10 | 0.037500000 |
| 48 Currants | 15.000 | 5E3214 | 0.03 | 0.006750000 |
| 90 Meat, red | 0.200 | 4F3129 | 10.81 | 0.032430000 |
| 93 Milk and dairy products | 0.400 | 4F3129 | 28.62 | 0.171720000 |
| 105 Onions | 0.500 | 4F3111 | 0.83 | 0.006225000 |
| 115 Peanuts | 0.100 | 4G3037 | 0.36 | 0.000540000 |
| 115 Peanuts | 0.400 | 4F3129 | 0.36 | 0.002160000 |
| 127 Potatoes | 0.500 | 6F3366 | 5.43 | 0.040725000 |

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

| CROP | TOLERANCE (PPM) | PETITION NUMBER | FOOD FACTOR | MG/DAY |
|-----------------|--------------------|--------------------|----------------|-------------|
| 135 Raspberries | 15.000 | 5E3214 | 0.03 | 0.006750000 |
| 223 Ginseng | 4.000 | 6E3426 | 0.03 | 0.001800000 |

TMRC
0.032517 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.006800

RESIDUE CONTRIBUTION OF NEW (PENDING) TOLERANCES

| CROP | TOLERANCE (PPM) | PETITION NUMBER | FOOD FACTOR | MG/DAY |
|----------|--------------------|--------------------|----------------|-------------|
| 137 Rice | 10.000 | 6F3443 | 0.55 | 0.082500000 |

TMRC
0.033892 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.556800