



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

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APR 15 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#9F2163 and FAP#9H5204. Glyphosate in water, fish and various crops. Amendment of 2/24/82.

From: R. B. Perfetti, Ph.D, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: Robert Taylor, Product Manager No. 25
Herbicide-Fungicide Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

This amendment is in response to our memo of 11/23/81 in which several deficiencies in the subject petition were outlined. The petitioners response to these deficiencies will be discussed in the order in which they appeared in the memo cited above.

Deficiency 1:

The major remaining questions (see conclusions 2, 3 and 9 in our memo of 9/24/80) with regard to this aquatic use involve the submission of an acceptable fish metabolism study and proposing an appropriate tolerance level in fish. The petitioner has informed us that this metabolism study is being performed. We await submission of this information.

Response to 1:

The petitioner has submitted an additional fish metabolism study. This study involved holding channel catfish in a static environment of ^{14}C -labeled glyphosate for 10 days

followed by a 10 day depuration period. The concentration of glyphosate in the water during the exposure period was ca. 0.95 ppm. After the 10 day exposure period 18 catfish were sampled and dissected into fillet and viscera. The remaining fish were sampled and dissected after the depuration period. Total radioactivity in fish fillet and viscera after 10 days of exposure was 0.126 ppm and 0.364 ppm respectively. This calculated to 0.225 ppm on a whole fish basis. After depuration, fish fillet contained 0.022 ppm of radioactive residues and the viscera showed 0.077 ppm which calculated to 0.05 ppm of radioactivity on a whole fish basis.

Samples of fish viscera and fillet (both exposed and depurated) were extracted with chloroform/water in a blender, centrifuged and the chloroform and aqueous solution were retained separately. Remaining solids were lyophilized and combusted. The aqueous solution was filtered and cleaned-up on both an anion and a cation exchange column. Fractions containing radioactivity were further identified via hplc and high voltage electrophoresis.

Fish viscera and fillet contained slightly more than 20% of unextractable activity after exposure. The amount of unextractable activity increased to approximately 50% in either sample type after depuration. In exposed fish fillet ca. 56% of the total radioactivity was identified as glyphosate with another ~2% found to be aminomethylphosphonic acid (AMPA). In viscera ~67% of the radioactive residue in these tissues was glyphosate and ~1% was identified as AMPA. This translates to approximately 75 and 92% of the extractable activity in exposed fish fillet and viscera respectively identified as glyphosate or its metabolite AMPA. For depurated fish essentially 30 and 40% of the total activity in fillet and viscera respectively were identified as parent compound and AMPA. In terms of water soluble extracts 53 and 70% of the extractable activity in fillet and viscera was identified as glyphosate with 7 and 6% identified as aminomethylphosphonic acid respectively.

Since approximately 60 and 70% of the total radioactive residue in fish fillet and viscera respectively were identified as glyphosate and aminomethylphosphonic acid we find this study minimally adequate to conclude that the nature of the residue in fish is adequately understood. The terminal residue of concern will consist of glyphosate and aminomethylphosphonic acid.

Based on both the "cold" and radiolabeled studies in fish it is our judgement that the 0.25 ppm tolerance level proposed for fish is acceptable.

Deficiency 2:

We request that the raw data for the Florida study involving direct application to non-moving waters be submitted for our files. This information was missing from the original petition.

Response to 2:

The petitioner has referenced pages in PP#6G1679 which he claims contains this raw data. We have rechecked this petition and find that the raw data for the Florida Study carried out on 10/16/75 in Fort Lauderdale, Fla. - 3 is not contained in that petition. The raw data we require is from the summary table found in volume 3 of 4, R.D.#220 dated 12/22/78, D II, Part 2, pp 60. We do not consider this deficiency resolved but we are not holding up these tolerances because this raw data has not been submitted. We request that the petitioner again be asked to submit this raw data in order to complete our files.

Deficiency 3:

The inert ingredient, [REDACTED] which is found in two of the new formulations proposed must be cleared under Section 180.1001 before any tolerances for this aquatic use can be established.

INERT INGREDIENT
INFORMATION DELETED

Response to 3:

The petitioner claims that this inert is already cleared. We have been informed by R. Taylor (Product Manager No. 25, RD) that the [redacted] has not to date been cleared under Section 180.1001. stop

We do not consider this deficiency resolved.

Recommendation

At such time as the inert ingredient the [redacted] is cleared under Section 180.1001 we recommend, TOX and EFB considerations permitting, that the proposed tolerances for combined residues of glyphosate and its metabolite aminomethylphosphonic acid in or on water (Food-additive tolerance) at 0.5 ppm, fish at 0.25 ppm and irrigated crops at 0.1 ppm be established.

It should be noted that we require that the rice paddy and estuarial treatment restrictions remain on the label until the shellfish residue studies using "non-aged" residues required previously are submitted and a tolerance for shellfish is established.

Finally, as per our discussion in Deficiency 2 above the petitioner should again be requested to submit the raw data for the Fort Lauderdale, Florida - 3 study carried out on 10/16/75 so that our files for glyphosate will be complete. The summary table for this study can be found in R.D.#220, Vol. 3 of 4, D II, Part 2, pp 60 dated 12/22/78.

TS-769:RCB:R.B.Perfetti:MCH:CM#2:RM810:X77324:4/15/82
cc: RF, Circu., R. B. Perfetti, Thompson, TOX, EEB,
EFB, FDA, PP#9F2163
RDI: Quick, 4/9/82; Schmitt, 4/9/82

INERT INGREDIENT
INFORMATION
DELETED