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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2874. Oryzalin in or on wheat and barley.
Amendment of 12/15/83; Accession No. 072238.

FROM: M. Nelson, Chemist *mjn*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: R. Taylor, PM 25
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

This amendment was submitted in follow-up to the conference held 12/8/83 (see conference memo dated 12/16/83) on the subject petition, and pertains to the deficiencies raised in the 11/18/83 review (M. Nelson).

In this submission the petitioner has provided the following:

1. A revised Section B in which the following statements have been added to proposed labeling for Surflan® 75W (EPA Reg. No. 1471-96) and Surflan® A.S. (EPA Reg. No. 1471-112):

"When combining wheat or barley, the cutter bar should be adjusted to leave standing stubble at a height of at least eight (8) inches. Stubble reduces wind erosion and loss of soil moisture. During combining, cut straw should be chopped and spread evenly over the field as mulch. Straw is an important part of the stubblecrop no-till program and should not be removed from the field."

Additionally, the precaution statement has been amended to read: "Do not graze or feed treated forage, hay or straw to livestock. Do not remove straw from the field."

2. Comments from several authorities in the field re the disposition of wheat or barley straw in conjunction with stubblecrop, no-till crop culture.

The consensus of those comments is that the straw is routinely left in the field for mulch. The straw is not grazed. Baling is not commonly practiced, but could occasionally occur; baled straw is not used for feed, but for bedding.

3. A summary of the presentation made by the petitioner's representatives at the 12/8/83 conference.

The concept of stubblecropping (i.e., the no-till planting of a cash crop in the stubble of a previous cash crop) is described. The applicability of Surflan® usage in stubblecropping is explained. And, the potential market areas for the proposed use of this petition are discussed.

In an effort to convince the Agency (RCB) that a straw restriction (on the labeling) is practical for stubblecropping (specifically, the proposed use of this petition) and, in fact, is reflective of common practice, the petitioner sets forth the following argument:

"Straw mulch, left in the field following the harvest of winter wheat, is a valuable part of no-till doublecrop soybean production. The straw as a mulch provides an excellent culture for moisture retention at critical times of the year when rainfall may be scarce and erratic. Straw stubble helps to prevent soil erosion on rolling ground where many of the no-till doublecrop soybeans are grown. In the Del-Mar-Va area [one of the primary market areas], coarse soils are predominant and here the straw stubble is valued as protection from severe wind erosion. Many of the no-till doublecrop soybeans are raised in marginally productive areas. The straw mulch increases organic matter and soil nutrients. This improves productivity and increases the value of farmland.

"Finally, by not removing the straw from the field, the no-till doublecrop farmer realizes one of his major goals--fewer trips across the field, with a saving in fuel, labor, and soil compaction.

"Straw is an essential part of the no-till doublecrop system and it would be against the farmers' best interest to remove it from the field. We believe the straw restriction is practical for stubblecropping and is now the common practice."

4. A freezer storage stability study of oryzalin in wheat, wheat straw, and milled by-products [I-ODD-83-13].

Ground samples of untreated wheat grain, straw, and milled by-products (red dog, flour, shorts, bran, germ) were fortified with 0.05 ppm of oryzalin and stored at -20°C until assayed. Days in storage: 12-323. Percent recovery: 67-123.

Comments and Conclusions

In an effort to corroborate the comments provided in this amendment by the petitioner from several authorities in the field, we discussed the proposed usage with the USDA, ARS, Beltsville (Dr. Leland W. Briggie, Crop Science Staff, National Research Program Leader for Small Grains, 344-3713). Dr. Briggie was in agreement with those experts' claims re no-till stubblecrop culturing that wheat and barley straw is normally left in the field as mulch, not grazed, and in only ca 1% of the cases might it be baled for bedding purposes--which practice is under grower control and therefore should be amenable to restrictive labeling. He also confirmed that a stubblecrop doublecrop, no-till program for wheat and barley with soybeans is an increasingly popular and common practice, and that the petitioner's proposed use pattern seems reasonable to him within the context of that type program.

On the basis of the available information, we now can conclude that, for purposes of the proposed use of this petition, a labeling restriction for wheat and barley straw will be practical, and acceptable to us. The following straw-related deficiencies raised in our (M. Nelson) review of 11/18/83 are therefore no longer germane to this petition: 2b, 3a, and 5c, and are considered moot.

That leaves four other deficiencies to be discussed, each in turn. Deficiency 2a requested the petitioner revise the proposed label prohibition against the grazing or feeding of treated forage and straw to apply to forage and hay. The petitioner has submitted revised labeling that reads in part "Do not graze or feed treated forage, hay or straw to livestock." This satisfactorily resolves that deficiency.

Deficiency 2c noted that a single application to wheat and barley is implied, but not specified, and since the field study data reflect only a single application, we requested that it be clarified on the label that the intended use is for but a single application per crop. The petitioner does not address this deficiency in this amendment, and the proposed labeling does not contain the requested clarification. This deficiency still remains to be resolved.

Deficiency 5a noted the lack of storage stability data for oryzalin, and indicated the need for: (a) information as to the length and manner of storage of all the submitted wheat and barley field trial and processing samples prior to analysis; (b) frozen storage stability data for oryzalin residues in crops that encompasses a time frame similar to (a) above; and, (c) if other than parent is to be regulated, frozen stability data in crops for the metabolite(s) of concern.

The petitioner has submitted a freezer storage stability study of oryzalin in wheat, wheat straw, and milled by-products (red dog, flour, shorts, bran, germ). Control samples were fortified at a level of 0.05 ppm and stored at -20°C until assayed some 12-323 days later. Reported recoveries ranged 67-123%.

The petitioner has not provided the information requested in (a) re length and manner of storage of all the field trial studies. However, we do now have most of that information, including that for the milled by-products, typically reflecting storage on the order of a year or less. We feel this is adequate to allow us to conclude that (b) was of adequate duration to support the majority of the residue data in this

petition. As for (c), since metabolism questions in straw have become moot, the residue of concern is considered to be parent compound only for wheat and barley grains. We consider this deficiency resolved.

Deficiency 6 indicates the need for meat/milk/poultry/egg tolerances and a MTO of proposed enforcement methodology. Since straw considerations have now become moot in re this petition owing to our acceptance of restrictive labeling, only residues in wheat and barley grains need be considered in relation to the ^{14}C metabolism/feeding studies (steer, pig, hens) discussed in PP#2G2612 (R. Loranger review of 6/18/82). We have considered: (1) the low or non-detectable level of residue found in treated grains under proposed use conditions; (2) the percentage of the animal diet such grain might comprise; (3) the exaggerated levels of those feeding studies and the level of residue reported; (4) enforcement method sensitivities; and, (5) the fact that the data from those feeding studies was reported as total ^{14}C activity, and we have concluded that, for all practical purposes for this petition, a category studies 3 situation actually exists. We therefore withdraw our request for a proposal of meat/milk/poultry/egg tolerances in re this petition. [Such tolerances will be needed, however, to support other permanent tolerance requests reflecting "real" residues (e.g., alfalfa).] The need for a MTO at this time thus becomes moot. We note, however, for future reference that the petitioner indicates their preferred method of choice would be the HPLC procedure because in that procedure derivatization of oryzalin is not necessary prior to analysis. For purposes of this petition we consider deficiency #6 resolved.

Summary. Deficiencies 2a, 2b, 3a, 5a, 5c, and 6 from our (M. Nelson) review of 11/18/83 are now considered either resolved or moot for purposes of this petition. Deficiency 2c remains outstanding.

Conclusion 4b from the aforementioned review dovetails with Deficiency 6 and is considered moot for this petition.

Re Conclusion 5b, we can now conclude that the residue of concern in wheat and barley grains is oryzalin per se, and that the proposed tolerance level of 0.05 ppm is appropriate in conjunction with the proposed use.

Re Conclusion 5d, we reaffirm our earlier conclusion that food/feed additive tolerances for grain by-products are not needed in re this petition.

Recommendations

Provided the petitioner revises the label to specify only one application (Deficiency 2c of 11/18/83 review) to these crops, and provided toxicological considerations permit, we recommend for the establishment of the proposed tolerance of 0.05 ppm in/on wheat and barley grains.

The Codex sheet was attached to the 11/18/83 review.

cc: R.F., Circu, Reviewer, TOX, EEB, EAB, 3F2874/072238
FDA, Robert Thompson

RDI: R. Quick: 2/28/84; R. Schmitt: 2/28/84

TS-769: RCB:MN:mh:CM#2:RM810:X77324:2/28/84