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

APR 1 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3405 - Sethoxydim on Sugar Beet Tops
Evaluation of Analytical Methods and Residue Data
for Increasing the Existing Tolerance - Amendments
of March 10, 1987 and December 11, 1986
(No Accession Number, RCB No. 2038)

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TO: Robert J. Taylor, PM 25
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and

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THRU: Charles L. Trichilo, Chief
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At the request of Mrs. Susan Wayland, Deputy Director, Office of Pesticide Programs, this evaluation of the subject amendments is being expedited. Sugar beet tops are a major feed for cattle in California during certain times of the year. To allow feeding of tops in the State of California, BASF submitted by their amendment (letter) of March 10, 1987, revised Sections B and F. That submission is in response to our review of September 25, 1986 (PP#6F3405, V.F. Boyd Memorandum) and also our internal meeting of March 6, 1987. At that internal meeting RCB specifically pointed out what the petitioner had to do in order to meet RCB's recommendation for a 3.0 ppm tolerance with an expiration date on sugar beet tops. The Final Rule Document, submitted along with the subject amendments, does not mention an expiration date.

In the RCB memorandum of September 25, 1986, the following conclusions were presented as deficiencies.

(1b) A specific statement of preharvest interval (PHI) in number of days needs to be included in the Section B label for the purpose of controlling maximum sethoxydim residues in sugar beet tops.

(4b) Submitted residue data indicate that overtolerance residue levels could be expected in sugar beet tops from the present labeled use.

(4c) The residue data on hand are not adequate to support the proposed tolerance of 2 ppm sethoxydim residues in sugar beet tops. Therefore, additional residue data (to be generated in California or Arizona, Idaho, Michigan, and North Dakota or New Mexico)

reflective of maximum proposed rate and a minimum proposed PHI are necessary to establish a residue level for tolerance purposes.

NOTE TO PM: Petitioner should be copied on the detailed discussion of residue data in this review, especially the recommendation regarding additional residue field trials for data gathering.

(5) Since sugar beet tops are fed to livestock, an assessment of potential secondary residues in meat and milk will be required when a supportable residue tolerance is proposed.

In response to these deficiencies (March 10, 1987 amendment) the petitioner presents the following:

1. Revised Section B, which includes:

"Restrictions and Limitations for Sugar Beets":
"Sugar beet tops may be fed to livestock only in the states of CA, AZ and NM."

"If sugar beet tops are to be fed to livestock, do not make more than two (2) applications of Poast herbicide and do not make the last application closer than 100 days of harvest."

2. Revised Section F which includes a request: For a 40 CFR 180.412 amendment to increase the sethoxydim residue tolerance from 0.2 ppm to 3.0 ppm on sugar beet tops.

This response restricts the registration of sugar beet tops as a feed for livestock to California, Arizona, and New Mexico, which is supported by the residue data submitted from California (seven studies at label rate and around 100 days PHI). In addition, 1985 Residue Trial Data are presented (incompletely, by tables only) as an attachment to the current letter amendment (March 10, 1987). There is no storage information, the mode of application is missing, and no GLC chromatograms and raw data were submitted even though there were some deviation from the regulatory analytical procedure. These trial data include eight studies from California at label rate (0.5 + 0.5 lb ai/A) with PHI's of 54 to 93 days. All CA data, 15 residue studies (eight in this amendment and seven reported previously), report residue levels, resulting from the proposed label treatment, of 0.1 ppm to 1.75 ppm. The eight studies presented by summary in this March 10, 1987 amendment, only, can only be considered as ancillary data until complete trial conditions and raw analytical data are formally submitted and reviewed. However, from considering the previous submission, the California data are considered sufficient to support a tolerance of 3.0 ppm sethoxydim residue in sugar beets with no expectation that the tolerance level would be exceeded by the proposed use. That is why RCB indicated in the March 6, 1987 internal meeting that a tolerance with an expiration date was appropriate until residue problems in other areas of the country had been resolved.

An evaluation of potential secondary residues in meat and milk (Deficiency No. 5) will be done late in this review. For purposes of the revised Sections B and F it is considered that deficiencies 1b. and 4b. are satisfied.

Relative to deficiency 4c. we quote from the Detailed Considerations, Residue data pages 7 and 8, memorandum of V.F. Boyd, September 25, 1986, PP#6F3405: "Residue data generated in CO, MN, ND, and MI reflect the use of only 2 1/2 pints (0.5 lb ai/A) of Poast per season. Therefore, four additional field trials reflecting the maximum rate of application per growing season and a shorter PHI of approximately 100 days are recommended in the following locations: 1 in CA or AZ; 1 in ID; 1 in MI; and 1 in ND or MN. All field trials should employ application by ground. The studies in MI and ND or MN should also

employ application by air. All field trials should employ harvest for analysis at a PHI approximately 100 days after last application."

Only tables of residue data from trials in 1985 performed in Minnesota, North Dakota, Michigan, Texas (2), Colorado, Nebraska, Idaho, and Ontario are presented in the present March 10, 1987 amendment. The PHI's are all less than 100 days (56-98 days) and all applications, with exception of Idaho, are at label rate. The residues range from < 0.1 ppm to 2.5 ppm of sethoxydim residues in sugar beet tops. These data appear to show some correlation between PHI and amount of residue with the higher level of 2.5 ppm in tops harvested at 68 days after second application. However, no indication of application method (aerial and/or ground), raw data, storage conditions, and GLC chromatograms were submitted. When these data are presented in detail as a part of a complete submission of residue data for Poast on sugar beets, these trial data might suffice for the studies as requested in the RCB review above, and a 3.0 ppm on sugar beet tops could be established without restricted registration.

Since the tolerance is being requested with a restricted geographic limitation as discussed at our March 6, 1987 internal meeting, it is recommended that the tolerance be stated as a tolerance with an expiration date. Sugar beets are a major crop and reflect a major use. Sugar beets are also used as a major feed item. These criteria prevent the issue of a permanent geographic restriction under the Agency Minor Use Policy. However, it now appears according to the "Final Rule" document as presented on March 17, 1987, the consideration has now focused on a permanent tolerance instead of a tolerance with an expiration date as was discussed at our March 6, 1987 internal meeting. To insure that no misconception results from this proposed action it would now seem appropriate to allow the petitioner to properly substantiate in a revised Section D the 1985 residue data to relieve the temporary label restriction against feeding sugar beet tops.

Deficiency 5 states that an assessment of potential secondary residues in meat and milk will be required when a supportable residue tolerance is proposed. The proposed tolerance of 3.0 ppm in sugar beet tops would result in < 15.0 ppm sethoxydim residues being fed to cattle. Some suggested feed rations might contain:

Flax meal	25%	x 7 ppm	=	1.75
Alfalfa hay	50%	x 20 ppm	=	10.00
Sugar beet tops	25%	x 3 ppm	=	0.75
		TOTAL		12.50 ppm

or

Flax meal	10%	x 7 ppm	=	0.70
Alfalfa hay	65%	x 20 ppm	=	13.00
Sugar beet tops	25%	x 3 ppm	=	0.75
		TOTAL		14.45 ppm

The established meat and milk tolerances of:

meat, byproducts and fat - 0.2 ppm
milk - 0.05 ppm

were produced by the feeding of sethoxydim residues at 50 ppm. It is concluded that a proposed tolerance of 3.0 ppm in sugar beets would not be expected to exceed the established meat and milk tolerances as a secondary residue source.

It is considered that Deficiency 5 is satisfied.

Recommendations

1. For a tolerance with an expiration date, RCB will recommend that a 3.0 ppm sethoxydim tolerance be established on sugar beet tops if EAB and TOX considerations permit.

2. For a permanent tolerance, the petitioner will need to provide sample storage information, the mode of application(s) and other field trial information, GLC chromatograms, and raw data in order to substantiate the 1985 residue data. If these residue data are substantiated, then a revised Section B should be proposed without any geographical label restrictions.

cc: R.F., Circu., V.F. Boyd, EAB, EEB, PMSD/ISB, FDA, PP#6F3405
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