UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

DEC 6 1988

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP8F3646/FAP8H5558. Sethoxydim on Sugar Beet Roots. DEB Nos. 4091 and 4092. MRID Nos. 406391-01, 406391-02. Evaluation of Analytical Method and Residue Data Dated April 20, 1988

FROM: R. W. Cook, Chemist
Petition Tolerance Section I
Dietary Exposure Branch
Health Effects Division (TS-769C)

THRU: R. S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: R. J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch II - Herbicide, Fungicide and Antimicrobial Support
Health Effects Division (TS-769C)

The petitioner, BASF Corporation, Chemicals Division, is requesting an increase in the tolerance level for combined residues of 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in sugar beet roots from 0.1 to 0.5 ppm, and further an increase in tolerance levels in sugar beet molasses from 0.5 to 5.0 ppm. Currently, established tolerances for the above named compounds are 0.1 ppm in sugar beet roots, 3 ppm in sugar beet tops, and 0.5 ppm in sugar beet molasses.

Background

The original petition for tolerance for the subject chemical, hereafter called by its proposed common name sethoxydim, was PP3F2950, proposing 0.05 ppm in sugar beet roots and 0.2 ppm in sugar beet tops. Since the lower limit of detectability of the analytical method was 0.05 ppm for both parent and metabolites, it was concluded that 0.1 ppm was the more appropriate tolerance level. Sugar beet residue data and processing studies were discussed in several reviews (K. Arne, February 2, 1884; F.D. Griffith, April 4, 1984; K. Arne, April 5 and June 29, 1984). Based on these reviews, tolerances were established at 0.1 ppm in sugar beet roots, 0.2 ppm in sugar beet tops, and 0.5 ppm in sugar beet molasses.

Under amended labeling for EPA Registration No. 7969-58, field residue data showed residues up to 1.75 ppm in sugar beet tops. Since such values clearly indicated overtolerance situation, PP6F3405 proposed tolerances of 2 ppm and removal of the animal feeding restriction on sugar beet tops. Our deliberations of this petition (V. F. Boyd, September 25 1986; April 1, 1987; and September 3, 1987) concerned additional residue data, a specific PHI of 100 days, and finally a 3.0 ppm tolerance in sugar beet tops with deletion of the feeding restriction.

The current request decreases the specific PHI to 60 days, and proposes a tolerance level of 1 ppm in sugar beet roots.

Conclusions

1. The metabolism of sethoxydim in plants and animals is adequately understood. The residue of concern is the parent compound 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its 2-cyclohexen-1-one containing metabolites.

2. Adequate analytical methods are available in PAM II for enforcement purposes.

3. Residues of sethoxydim and its 2-cyclohexen-1-one metabolites in sugar beet roots are not likely to exceed the proposed 1 ppm tolerance level as a result of the proposed use (two applications of 0.5 lb ai/A and a minimum PHI of 60 days).

4. Previous sugar beet processing studies considered adequate for negligible type residue tolerances are not considered adequate for determining appropriate food additive tolerances in dried pulp, refined sugar, and sugar beet molasses. Sugar beet processing studies,

conducted at or near the proposed tolerance level, are needed.

5. We are unable to draw final conclusions on residues in meat, milk, poultry, and eggs, since we are unable to draw final conclusions on the adequacy of the proposed 5 ppm tolerance in molasses.

6. The proposed tolerance is incompatible with Canadian negligible residue type limit of 0.1 ppm. We foresee no resolution to such incompatibility.

Recommendation

We recommend against the establishment of the proposed tolerances for the reasons cited in Conclusion 4 and 5 above. The petitioner should resolve this deficiency by submitting adequate sugar beet processing studies conducted at or near the proposed tolerance level (previously submitted processing studies adequate at 0.1 ppm tolerance level are not adequate at the finite 1 ppm tolerance level).

## Detailed Considerations

### Manufacture and Formulation

The manufacture and formulation of Poast\ Herbicide are discussed in E. Zager memorandum of December 4, 1980 (PP0G2396, which see).

### Proposed Use

The petitioner does not submit full use directions for Poast Herbicide on sugar beets. The petitioner states that the only change, in the "Restriction and Limitation for Sugar Beets," is the addition of the statement "Do not apply Poast within 60 days of harvest to sugar beets."

### Nature of the Residue

The Branch has previously concluded (V. F. Boyd, PP6F3405, September 25, 1986) that the nature of the residue is adequately understood in plants and animals. The residue of concern is the parent compound and its 2-cyclohexen-1-one containing metabolites. Since the current action, changing the tolerance levels in sugar beet roots and molasses should have no effect on the metabolism of sethoxydim in plants or animals, we reiterate our previous conclusion.

### Analytical Method

The analytical method used for the submitted residue data is

BWC Method No. 30 B, originally submitted in PP3F2904. This is the PAM II, method I for sethoxydim. Adequate analytical methods are available for enforcement purposes.

Recovery of sethoxydim per se in sugar beet roots ranged from 80% to 108% at fortification levels of 0.05 to 10 ppm. Recovery of metabolites containing the 2-cyclonexen-1-one moiety (both hydroxylated and non-hydroxylated) ranged from 65 % at the same fortification levels. The analytical method is sensitive to 0.05 ppm and control values sin the field residue trials did not exceed this level.

Magnitude of the Residue (MRID #406391-01,406391-02)

The petitioner has submitted two reports of field residue trials of Poast Herbicide on sugar beets. One report "Magnitude of the Residue of Sethoxydim and Metabolites in Sugar Beet Roots" Report 87/5019 by Yvonne H. Single, dated January 1987, describes 17 field trials in 9 States conducted in 1985. The other report "Magnitude of the Residue of Sethoxydim and Metabolites in Sugar Beet Roots and Tops" Report 88/5024, dated December 1987 by David L. McAleese describes 14 trials in 5 States conducted in 1985 and 1986.

In Report 87/5019, trials in CA (8), MN, ND, MI, TX (2), CO, NE, ID, and OR, were treated with split applications of 0.5 + 0.5 lb ai/A at 60 (range 54-68) days and 90 (range 87-118) days PHI (the ID trial used a single application of 0.5 lb ai/A). All applications were made with ground equipment. The interval between planting and first application ranged from 22 to 105 days; the interval between first and second applications ranged from 6 to 94 days. The age of the plants at time of sampling ranged from 148 to 235 days. Only three sugar beet root samples showed residues over the limit of detection (0.05 ppm): 0.07, 0.20, and 0.28 ppm at the proposed 60-day PHI (range 57-59 days).

Interestingly, the 0.07 ppm value is derived from the one trial without the second 0.5 lb ai/A treatment. The other two samples came from sugar beet plants treated 43 days apart and harvested 59 days after the second application. The residue consisted of combined nonhydroxylated moieties; the hydroxylated moieties were <0.05 ppm. It is noted that the samples represent northern tier States, North Dakota and Idaho. No sugar beet tops were analyzed in this study.

In Report 88/5024, trials in CA, ND, MN, ID, and MT were treated with split applications of 0.5 + 0.5 lb ai/A at 60 days (range 36-77) and 90 days (range 86-104) PHI. The interval between planting and first application ranged from 21 to 120 days; the interval between first application and second application ranged from 9 to 175 days. The age of the plants at time of sampling ranged from 147 to 299 days. Nine of 38 and 0

of 38 samples of sugar beet roots showed residues >0.05 ppm of the nonhydroxylated moiety and the hydroxylated moiety, respectively. The maximum level detected in roots was 0.40 ppm. Roots with detectable residues showed <0.10 ppm at 90 days (range 77-91) PHI while at 60 days (range 56- 64) PHI were >0.10 to 0.40 ppm.

Sugar beet tops (not under consideration herein) showed nonhydroxylated moiety residues as high as 1.40 ppm, with 26 of 38 samples showing >0.05 ppm; and 5 of 38 sugar beet tops showing >0.05 to 0.12 ppm of the hydroxylated moiety.

Based upon the submitted residue data and in consideration of the previously submitted residue data, it is concluded that combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in the raw agricultural commodity sugar beet roots will not exceed the proposed 1.0 ppm tolerance level, based upon the use as proposed and a 60-day PHI.

Storage stability data for sethoxydin has been previously considered under PP3F2904 (J. Onley, 1/12/84; and F. D. Griffith, 4/4/84. memo of conference). We have previously concluded this data are adéquate (V. F. Boyd, PP673405, 9/25/86).

Processed Commodities

The processed commodities involved in sugar beet production are sugar, dried sugar beet pulp and sugar beet molasses. Under PP3F2950 (see memorandums of April 5 and June 29, 1984), two sugar beet processing studies were submitted. In both studies, sugar beets bearing residues less than the detection limit of 0.05 ppm for each of the nonhydroxylated and hydroxylated moieties were processed. Detectable (> 0.05 ppm) residues were found in molasses. Upon reexamination of the chromatograms, the petitioner was able to estimate residue levels in raw sugar beet roots at 0.02 ppm of each nonhydroxylated and hydroxylated residue. Thus, 0.02 + 0.02 ppm processed into 0.12 ppm, and 0.02 + 0.015 ppm processed into 0.17 ppm, calculating the concentration factor as 5X.

When these processing studies were conducted, we were contemplating a tolerance level of 0.1 ppm, comprised of <0.05 ppm nonhydroxylated and <0.05 ppm hydroxylated residue. We are now considering establishing a non-negligible tolerance level of 1 ppm. Therefore, we now consider the processing studies inadequate support for establishing food or feed additive tolerances in processed sugar beet fractions dry pulp, refined sugar, and molasses. The petitioner should conduct processing studies on sugar beet roots bearing residues as demonstrated in the submitted residue data.

Meat, Milk, Poultry, and Eggs

The animal feed items of concern are sugar beet tops, molasses, and dehydrated pulp. These materials are fed at levels of 10 to 30 percent to beef/dairy cattle and 0 to 15 percent to poultry or swine. If a tolerance of 5 ppm in molasses is established, the dietary burden would be 5 ppm x 20%= 1 ppm, much less than the dietary burden of 10 ppm in soybeans. However, in the absence of adequate processing data relevant to the proposed tolerance level of 1 ppm in sugar beet roots, it is not possible to draw final conclusions on the adequacy of the proposed 5 ppm tolerance in molasses.

International Residue Limits

There are no Codex proposals above Step 6, and there are no Mexican limits. The Canadian limit for sethoxydim per se is 0.1 ppm (a negligible type limit). The tolerance level proposed by the petitioner increases the current incompatibility; we foresee no resolution to this problem herein.

Attachment: IRLS (Codex)

cc:8F3648/8H5558, R.W. Cook, RF, Circ (7), PMSD/ISB
TS-769:TPSI:R.W. Cook:CM2:Rm 810:557-7324
RDI:R.S. Quick: 11/30/88:R.D. Schmitt:12/1/88
53495:I:Cook:C.Disk:KENCO:11/04/88:aw:VO:aw:EK:aw
KENCO Typing corrected by R. W. Cook 11/8/88:
corrected by vg 12/5/88

# INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Sethoxydim

CODEX NO. ____

CODEX STATUS:

☑ No Codex Proposal
Step 6 or above

Residue(if Step 8): ____

| Crop(s) | Limit (mg/kg) |
|---|---|

PROPOSED U.S. TOLERANCES:

Petition No. 8F3648/8H5338

RCB Reviewer RWJ Cook

Residue: Sethoxydim + 2-cyclohexene-1-one containing metabolites

| Crop(s) | Limit (mg/kg) |
|---|---|
| Sugarbeet roots | 1.0 |
| Sugarbeet molasses | 5.0 |

CANADIAN LIMITS:

☑ No Canadian limit

Residue: Sethoxydim

| Crop(s) | Limit (mg/kg) |
|---|---|
| Sugarbeets | 0.1* |

MEXICAN LIMITS:

☑ No Mexican limit

Residue: ____

| Crop(s) | Limit (mg/kg) |
|---|---|

* Negligible residue type limit

NOTES:

* Increases current 0.1 ppm on roots to 1.0 ppm; tops = no change @ 3.0 ppm



revised 1986

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