PMSD/133

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

MAY 4 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3660/FAP#8H5561. Sethoxydim in or on Grapes and Grape By-Products.
Amendment of January 23, 1989.
DEB#: 5119, 5120 HED#: 9-1079 MRID#: None

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: R. Taylor/V. Walters, PM Team 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch, FHA Support
Health Effects Division (H7509C)

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR DEB

A further revised Section F is needed.

CONCLUSIONS

1. BASF has submitted revised (1/23/89) supplemental labeling for use of Poast® herbicide (EPA Reg. No. 7969-58) on grapes (originally proposed as a total nte 1.5 lbs ai/A/season, 14-day PHI; now revised to a total nte **1.0** lb ai/A/season, **50**-day PHI) to support the proposed tolerance of 1.0 ppm on grapes.

2. Residue results from 11 trials in 7 states (5 CA, CT, NY, OH, MO ,WA, NJ) on 8 varieties of grapes are now pertinent to the proposed revised use pattern for Poast® on grapes. DEB now concludes adequate field trial data and geographic and varietal representation exist for the proposed use of Poast® on grapes (in conjunction with the revised supplemental labeling). **This deficiency is resolved.**

3. DEB also concludes those field trial data demonstrate the proposed tolerance level of 1.0 ppm for the combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent) in or on grapes is now higher than is necessary in conjunction with the proposed supplemental labeling. **DEB recommends the proposed tolerance level for grapes be lowered to 0.2 ppm. A further revised Section F is requested.**

4. We reaffirm our earlier conclusion that the appropriate level for setting the requested food/feed additive tolerances on raisins and raisin waste is at 5X that of grapes; on grape pomace (wet and dry) at 30X that of grapes; and, that no food additive tolerance is needed for grape juice. **DEB requests a further revised Section F lowering the proposed tolerance levels on grape by-products to: raisins, 1.0 ppm; raisin waste, 1.0 ppm; and grape pomace (wet and dry), 6.0 ppm.**

5. A revised (1/23/89) Section F has been submitted which proposes the tolerance for grape pomace in terms of "grape pomace (wet and dry)". **This deficiency is resolved.**

6. **Conditional** upon receipt of the requested further revised Section F, DEB can conclude the established animal commodity tolerances for combined residues of sethoxydim and metabolites will be adequate to cover any secondary residues arising as a result of the proposed use on grapes.

RECOMMENDATION

Contingent upon receipt/evaluation of the requested further revised Section F (see Conclusions 3 and 4 above), and toxicological considerations permitting, DEB recommends in favor of the establishment of the following tolerances for the combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent):

grapes - 0.2 ppm	**raisin waste - 1.0 ppm**
raisins - 1.0 ppm	**grape pomace (wet and dry) - 6.0 ppm**

DETAILED CONSIDERATIONS

BACKGROUND

By transmittal letter dated 1/23/89, the petitioner (BASF Corporation) has submitted its response to the three deficiencies cited by the Agency's letter (R. J. Taylor, PM 25) of 1/11/89. Those deficiencies were raised by DEB in its earlier review (M. Nelson, 10/6/88) of this petition.

For the reader's convenience, those deficiencies are restated below (using the same wording/numbering of the Agency's 1/11/89 letter to the petitioner), followed by the petitioner's response, and our comments/conclusions.

DEB DEFICIENCY #3:

"Inadequate residue data are available to support the proposed use and allow a determination of the appropriate tolerance level for grapes (and, therefore, by-products as well) to be made."

DEB DEFICIENCY #4:

"Additional field trials with grapes need to be conducted. Those trials should reflect the proposed use pattern, various varieties of grapes, and adequate geographic representation of the major U.S. grape growing areas (per Ag. Stats.). Include the states of WA, NY, and MI."

BASF RESPONSE TO DEFICIENCIES #3 AND #4:

~~BASF~~ proposes the maximum use conditions (originally proposed as a total of 1.5 lbs ai/A/season; preharvest interval, 14 days) be changed to a total of **1.0** lb ai/A/season; preharvest interval, **50** days to support the proposed tolerance of 1.0 ppm for residues of sethoxydim [and metabolites] in/on grapes.

Revised supplemental labeling (dated 1/23/89) for use of Poast® herbicide on grapes which contains this preharvest interval increase (page 10) and total lbs ai/A/season decrease (pages 7, 8, and 10) is submitted as part of this amendment.

DEB COMMENTS/CONCLUSIONS RE DEFICIENCIES #3 AND #4:

As part of this amendment, BASF has also submitted a Table 1 (incorporated into this review) which summarizes the residue trials for Poast® on grapes pertinent to the proposed revised supplemental labeling.

Table 1
Sethoxydim Residues in Grapes(a)
Applicable to Two Applications
of 0.5 lb ai/A PHI 50 days
Proposed Tolerance - 1.0 ppm

RCN	Test Site	Variety	Application Rate (lb ai/A)	PHI	Sethoxydim DME (ppm)	Equivalents DME-OH (ppm)
3329	Greenfield, CA	Zinfandel	3 X 0.5	20	<0.05	<0.05
3330	Greenfield, CA	White Reisling	3 X 0.5	17	<0.05	<0.05
3333	Stonington, CT	Gamay Noir	2 X 0.5	49	<0.05	<0.05
3334	Riverside, NY	Yates	2 X 0.5	49	0.06	<0.05
3336	Wooster, OH	Aurore	2 X 0.5	41	<0.05	<0.05
3337	Mountain Grove, MO	Catawba	2 X 1.0(b)	46	0.07	~~<0.12~~ <0.05
3338	Prosser, WA	Concord	2 X 0.5	30	<0.05	<0.05
3570B	Hope, NJ	Concord	2 X 0.5	42	0.11	~~<0.16~~ <0.05
4181	Reedley, CA	Thompson Seedless	3 X 0.5	19	<0.05	<0.05
5315	Dinuba, CA	Thompson Seedless	3 X 0.5	14	<0.05 - 0.14(d)	<0.05
5315	Dinuba, CA	Thompson Seedless	3 X 2.0(c)	14	<0.05 - 0.29(d)	<0.05
5316	Fresno, CA	Thompson Seedless	3 X 0.5	14	0.47	<0.05
5316	Fresno, CA	Thompson Seedless	3 X 2.0(c)	14	2.0	<0.05

(a) Data from BASF 87/5056 (MRID No. 40725801)

(b) 2 X rate

(c) 4 X rate

(d) Data from 6 seperate samplings

As shown by that Table, with the proposed PHI increased to 50 days, and the total lbs ai/A/season decreased to nte 1.0 lb ai/A/season, the data originally submitted (MRID# 407258-01) provide residue results from 11 trials in 7 states (5 CA, CT, NY, OH, MO, WA, NJ) on 8 varieties of grapes which can be utilized to support the petitioner's tolerance request on grapes.

Accordingly, DEB now concludes that adequate field trial data and geographic and varietal representation exist for the use of Poast® on grapes (in conjunction with the proposed supplemental labeling). **This deficiency is resolved.**

However, DEB also concludes those field trial data (see Table 1) demonstrate the requested tolerance level of 1.0 ppm for the combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent) in or on grapes is now higher than is necessary in conjunction with the proposed supplemental labeling. **DEB recommends the proposed tolerance level for grapes be lowered to 0.2 ppm. A further revised Section F is requested.**

We reiterate our previous conclusion (10/6/88 review) that the appropriate levels for setting the requested food/feed additive tolerances on raisins and raisin waste is at 5X that of grapes; on grape pomace (wet and dry), at 30X that of grapes; and, that no food additive tolerance is needed for grape juice (MRID# 407258-02).

Accordingly, **DEB requests a further revised Section F lowering the proposed tolerance levels on grape by-products to: raisins, 1.0 ppm; raisin waste, 1.0 ppm; and grape pomace (wet and dry), 6.0 ppm.**

DEB DEFICIENCY #6:

"Both wet and dry grape pomace show a concentration of residues. The Section F should be revised to propose the tolerance in terms of 'grape pomace (wet and dry)', at 30X the level of the RAC."

BASF RESPONSE TO DEFICIENCY #6:

A revised (1/23/89) Section F is submitted, incorporating the requested change of terminology to "grape pomace (wet and dry)". The level proposed remains at 30X that of grapes per se.

DEB COMMENTS/CONCLUSION RE DEFICIENCY #6:

This deficiency is resolved.

OTHER CONSIDERATIONS

In the Agency's 1/11/89 letter to the petitioner, it is also stated that, "Judgment on the adequacy of livestock tolerances will await submission of requested data." **Conditional** upon receipt of the requested further revised Section F, DEB can conclude that the established animal commodity tolerances for combined residues of sethoxydim and metabolites will be adequate to cover any secondary residues arising as a result of the proposed use on grapes. [For a summary discussion of the available feeding study data, refer to the M. Flood review of 5/18/88, PP#8F3606/FAP#8H5553 (Sethoxydim/citrus).]

An updated International Residue Limits status sheet will be appended to our next review, following receipt of the requested further revised Section F.

cc: Reviewer (M. Nelson), Reading File, Circulation (7), PP# 8F3660/FAP#8H5561, ISB/PMSD (E. Eldredge), R. Schmitt.

H7509C:DEB:Reviewer(MJN):CM#2:Rm810:557-7423:typist(mjn):
3660SETH.GRP:5/3/89.
RDI:SectionHead:RSQuick:5/3/89:ActingBranchSeniorScientist:
RALoranger:5/3/89.