

PMSD/ISB

DIETARY EXPOSURE BRANCH, HED

DATA REVIEW QUICK FORM

OCT 6 1988

Date: \_\_\_\_\_

MEMORANDUM

SUBJECT: Petition Review for Establishment  
of Tolerance(s).  
Evaluation of Analytical Method(s)  
and Residue Data.

FROM: Maxie Jo Nelson, Chemist  
Tolerance Petition Section I  
Dietary Exposure Branch  
Health Effects Division, TS-769C

mjn

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

RMP

TO: Robert J. Taylor PM 25  
Registration Division, TS-767C

and

Toxicology Branch - HFA Support  
Health Effects Division, TS-769C

1. Petition No(s): 8F3660/8H5561
2. DEB No(s): 4355, 4356 HED# 8-1192A
3. MRID No(s): 407258-00 thru -02
4. Pesticide(s): Sethoxydim (Poast®)
5. Tolerance Proposal (RACs & Levels):  
grapes @ 1 ppm dried grape pomace @ 30 ppm  
raisins @ 5 ppm raisin waste @ 5 ppm
6. Petitioner: BASF Corporation

7. Tolerance Expression: parent plus metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent)

8. Established Pesticide Tolerances: 40 CFR 180.

§180.412 - §180.413

The PESTICIDE CHEMICAL NEWS GUIDE

| PPM                                                                                                                                          | CROP                              | PPM     | CROP                        | PPM   | CROP                          |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------|-----------------------------|-------|-------------------------------|
| <p>2-[1-(ETHOXYIMINO)BUTYL]-5-[2-(ETHYLTHIO)PROPYL]-3-HYDROXY-2-CYCLOHEXENE-1-ONE AND METABOLITES<br/>40 CFR 180.412; 185.2800; 186.2800</p> |                                   |         |                             |       |                               |
| 40                                                                                                                                           | Alfalfa Forage                    | 0.2     | Hogs, Fat                   | 0.2   | Poultry, Meat                 |
| 40                                                                                                                                           | Alfalfa, Hay                      | 0.2     | Hogs, MBYP                  | 5     | Raspberries                   |
| 3 (R)                                                                                                                                        | Artichokes (California)           | 0.2     | Hogs, Meat                  | 5     | Strawberries                  |
| 0.2                                                                                                                                          | Cattle, Fat                       | 0.2     | Horses, Fat                 | 0.2   | Sheep, Fat                    |
| 0.2                                                                                                                                          | Cattle, MBYP                      | 0.2     | Horses, MBYP                | 0.2   | Sheep, MBYP                   |
| 0.2                                                                                                                                          | Cattle, Meat                      | 0.2     | Horses, Meat                | 0.2   | Sheep, Meat                   |
| 5                                                                                                                                            | Cottonseed                        | 0.05(N) | Milk                        | 10    | Soybean Hay                   |
| 15 FA                                                                                                                                        | Cottonseed Soapstock              | 5       | Peanut Hulls                | 10    | Soybeans                      |
| 0.5                                                                                                                                          | Eggs                              | 25      | Peanuts                     | 0.5FA | Sugar Beets, Molasses         |
| 5                                                                                                                                            | Flaxseed                          | 75 FA   | Peanut Soapstock            | 0.1   | Sugar Beets, Roots            |
| 7 FA                                                                                                                                         | Flaxseed Meal                     | 8 FA    | Potato Flakes               | 3     | Sugar Beets, Tops             |
| 2                                                                                                                                            | Flax Straw                        | 8 FA    | Potato Granules             | 20 FA | Sunflower Meal                |
| 4                                                                                                                                            | Fruiting Vegetables               | 4       | Potatoes                    | 7     | Sunflower Seeds               |
| 0.2                                                                                                                                          | Goats, Fat                        | 8 FA    | Potato Waste (Processed)    | 24 FA | Tomato Products, Concentrated |
| 0.2                                                                                                                                          | Goats, MBYP                       | 0.2     | Wet or Dry                  | 12 FA | Tomato Pomace, Dried          |
| 0.2                                                                                                                                          | Goats, Meat                       | 0.2     | Poultry, Fat                |       |                               |
|                                                                                                                                              |                                   | 0.2     | Poultry, MBYP               |       |                               |
| <p>Administrative Guidelines: None<br/>Tolerances Pending:</p>                                                                               |                                   |         |                             |       |                               |
| 15                                                                                                                                           | Beans, Dry 7/20/88                | 1       | Celery 6/22/88              | 40    | Peas, Dry 7/20/88             |
| 40                                                                                                                                           | Beans, Forage 7/20/88             | 0.5     | Citrus Fruit 3/30/88        | 40    | Peas, Forage 7/20/88          |
| 40                                                                                                                                           | Beans, Hay 7/20/88                | 1.5FA   | Citrus Molasses 3/30/88     | 40    | Peas, Hay 7/20/88             |
| 15                                                                                                                                           | Beans, Succulent 7/20/88          | 1.5FA   | Citrus Pulp, Dry 3/30/88    | 40    | Peas, Succulent 7/20/88       |
| 4                                                                                                                                            | Blueberries 3/30/88               | 2       | Cucurbit Vegetables 6/22/88 | 0.8   | Pomace, Dry 5/25/88           |
| 5                                                                                                                                            | Brassica Leafy Vegetables 6/22/88 | 1       | Lettuce, Head 6/22/88       | 0.2   | Pome Fruits 5/25/88           |
|                                                                                                                                              |                                   | 2       | Lettuce, Leaf 6/22/88       | 4     | Spinach 6/22/88               |

11. Is Pesticide a Registration Standard Chemical? (Yes/No) No

If yes, date Guidance Document issued: N/A

12. Letter(s) of Authorization (if applicable): N/A

13. Formulation(s): Poast® Herbicide, EPA Reg. No. 7969-58, an emulsifiable concentrate containing 1.53 lbs ai/gal.

14. Inerts Status: Under RD purview.

15. Manufacturing Process: Discussed in 12/4/80 review, E. Zager, PP# 062396. Technical product is ≥ 95% pure. Impurities are not expected to pose a residue problem.

16. Proposed Use(s): For post-emergent control of annual and perennial weeds, apply 1.5-2.5 pts (0.3-0.5 lbs ai)/A/application as a broadcast spray using 5-20 gpa spray volume. Always add 2 pts/A of oil concentrate. May be used for spot treatments @ 1-1.5% Poast plus oil concentrate (= 0.15-0.22 lb ai/10 gal. spray). Rate depends on weed height and species. Repeat applications are allowed. Do not apply >7.5 pts Poast/A/season. Do not apply within 14 days of harvest. Apply by ground equipment only. Thorough coverage of grass foliage is essential.
17. Plant Metabolism Data on: soybeans (PP# 0G2396 and 3F2904); alfalfa (PP# 3F2904); sugarbeets (PP# 3F2950); tomatoes (PP# 5F3284).
18. Plant Residues Comprised of: parent plus metabolites (including the sulfoxide, MSO, and sulfone, MSO<sub>2</sub>) containing the 2-cyclohexen-1-one moiety
19. Plant Metabolism Data Translatable Here: #17
20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition is is not adequately defined.  
The Residue of Concern is: parent sethoxydim plus its metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent)

21. Animal Metabolism Data on: rats (PP# 0G2396), lactating goats (PP# 0G2396 and 3F2904), and laying hens (PP# 3F2904).
22. Animal Residues Comprised of: similar to plants; parent and its several metabolites containing the 2-cyclohexen-1-one moiety. In goats, sethoxydim may also be demethylated to form an analogous series of "nor" metabolites (ref. PP# 3F2904).
23. Animal Metabolism Data Applicable Here: # 21.
24. Nature of Animal Metabolism Data (is) is not adequately defined.  
The Residue of Concern is: parent sethoxydim plus metabolites containing the 2-cyclohexen-1-one moiety (calculated as parent).
25. Analytical Method(s) (Give Reference and/or Brief Description)  
Method 30 G (ref. PP# 3F2904) - grapes, juice, wet pomace.  
Method 30 H (ref. PP# 3F2904) - raisins, raisin waste, dry pomace.  
Both Methods are sulfur-specific FPD GLC and only slightly modified (in clean-up) vs PAM II, Method I procedure (which is Method 30).  
Raisins, raisin waste, and dry pomace were rehydrated prior to solvent extraction.  
Residue is measured as two separate peaks: one of dimethyl ester (DME) derivatives, the other of hydroxy-DME derivatives.)  
Representative chromatograms were submitted.

26. Has there been a Method Trial? (Yes, No) Yes, of Method 30.  
 If yes, provide details: PP# 2F2670 - soybeans, milk, liver.  
For details, see K. Kinsler memo, 4/1/83. PMV was successful.

If no, is a Method Trial needed? N/A.

27. Residues Determined by Method(s): parent and regulable metabolites  
as the dimethyl ester (DME) and OH-DME derivatives of pentane-dioic  
acids. (Two separate GLC peaks, one for each.)

28. Method Validation (RACs/"spike chemical"/fortification level(s)/  
 recovery range/average recovery):

|            | Spike       | Recov. Parent | Recov. MSO | Recov. 5OH-MSO <sub>2</sub> |
|------------|-------------|---------------|------------|-----------------------------|
| grapes     | 0.05-5 ppm  | 88-95%        | 84-110%    | 76-90%                      |
| juice      | 0.05, 2.5 " | —             | 86, 96%    | 76, 84%                     |
| wet pomace | 0.05, 5 "   | —             | 84-96%     | 76-84%                      |
| dry "      | 0.1-10 "    | —             | 84-100%    | 77-97%                      |
| raisins    | 0.1-20 "    | —             | 80-110%    | 76-93%                      |
| " waste    | 0.1-20 "    | —             | 84-97%     | 78-97%                      |

29. Method Validation (limit of detection and/or sensitivity in ppm):

Parent: <0.05 ppm

Metabolite(s) (specify): (MSO, 5OH-MSO<sub>2</sub>) <0.05 ppm in  
grapes, juice, wet pomace; <0.1 ppm, dry pomace, raisins, raisin waste.

30. Method Validation (state crops and control values reported):

grapes, juice, wet pomace <0.05 ppm (from DME), <0.05 ppm (from DME-OH)  
dry pomace, raisins, raisin waste <0.1-0.21 ppm (from DME), <0.1  
ppm from DME-OH.

31. Adequate Analytical Method(s) (are) are not Available for Enforcement Purposes.

These Method(s) are located: PAM II, Method I

32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols (I) (II) (III) IV (circle, as applicable).

Additional multiresidue test information for parent compound that is needed: None; Protocol IV is N/A.

[MRID# 403098-01; PP# 6F3452.]

33. PAM I Multiresidue Methods Data are available for metabolite(s) tested via Protocols (I) (II) (III) IV (circle, as applicable).

Additional multiresidue test information for metabolite(s) that

is needed: None; see #32. Testing of metabolites was with MSO and 5-OH-MSO<sub>2</sub>.

34. Residue Data (RAC(s) and Processed Commodities)

Data from 14 field trials were submitted, only 5 of which (all CA) closely approximate the maximum proposed use of 0.5 lb ai x 3 applications, 14-day PHI. The maximum residues reported in grapes from those 5 trials were 0.47 ppm (from DME) and <0.05 ppm (from DME-OH), for a total combined residue of <0.52 ppm. Storage time = 16-37 months.

4X rate data (14-day PHI) are also available from 2 of those 5 trials; the total combined residue ranged <0.10 to <2.05 ppm for grapes.

Data from the other field trials (9) reflect longer PHIs (30-151 days) and only 1-2 applications, generally at the 0.5 lb ai/A rate. These data can not be meaningfully extrapolated to the proposed use.

→ We conclude inadequate residue data are available to support the proposed use and to allow a determination of the appropriate tolerance level for grapes (and, therefore, byproducts as well) to be made.

→ 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 USA grape growing areas. The additional studies should include WA, NY, and MI.

Grape processing trials are discussed under #47.

35. Frozen Storage Stability Data (are) are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): Ref. discussion, pp 7-8, 5/18/88 review, M. Flood, PP#8F3606. Studies are available on several crops, including strawberries up to 60 months (recovery of weathered residues @ 60 months was 89% from DME and 74% from DME-OH).

36. Regional Registration is (is not) involved.

If yes, list States in which use is sought: N/A

If yes, indicate/explain (see 51 FR 11341, 4/2/86 - Policy on Minor Uses) if a bona fide "Minor Use" is involved: N/A

- (37.) Geographic Representation is (is not) adequate. If no, list RAC(s) and States from which additional data are needed: Proposed use pattern is not supported by geographically representative studies. Additional studies representing the major growing areas (per Ag. Stat.) need to be submitted. Include WA, NY, MI.

- (38.) Residues will not exceed proposed tolerance(s) on (commodities) a decision on the appropriate level(s) for tolerances is deferred pending receipt/review of additional studies (see #34).  
but may exceed proposed tolerance(s) on (commodities) \_\_\_\_\_

39. Livestock Feeding Studies on (species): lactating dairy cows and goats and laying hens (PP#DG2396, 3F2904).

40. Animal Feeding Levels: goats, up to 300 ppm; cows up to 50 ppm; hens, up to 250 ppm. (Ref. 5/18/88 review, PP#8F3606, for discussion.)

41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s)  
dry pomace @ 30 ppm  
Levels (proposed tolerance level x percent in diet): 9 ppm  
in beef cattle; 6 ppm in dairy cattle/goats; 6 ppm in  
hogs; 6 ppm in horses; 9 ppm in sheep; 1.5 ppm in  
poultry.

(42.) Livestock Tolerances are Adequate in (species) judgment deferred  
until appropriate tolerance levels for the commodities of  
but not adequate in this petition can be determined.  
(Note: #44).

43. Livestock Tolerances Need to be Established: Yes (No) If yes,  
species/levels: Already established; see #8.

44. Other Comments: Poultry and egg tolerances are based on ~12.5  
ppm ingestion level, and meat and milk tolerances on ~50 ppm.  
(Ref. 5/18/88 review, PP#8F3606.) Tolerances are established and  
pending on a number of animal feed items.

→ (45.) Other Considerations: Both wet and dry grape pomace show a  
concentration of residues vis-a-vis the RAC (see #47). Section F  
should be revised to propose the pomace tolerance in terms of  
"pomace (wet and dry)" at 30X the level of the RAC.

46. Additional Information Needed: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

47. Residue Data (continued): Grapes from 2 CA field trials (treated with 0.5 or 2.0 lb ai x 3 applications, 14-day PHI) were used in grape processing. Samples were stored frozen 18-31 months prior to analysis. Residues in the grapes ranged up to 2.0 ppm (ppm parent as DME; NDR of DME-OH).

Concentration factors reported were:

|            |            |         |           |
|------------|------------|---------|-----------|
| juice      | 0.6-1.2 X  | raisins | 3.2-3.6 X |
| wet pomace | 1.0-3.1 X  | " waste | 1.4-4.0 X |
| dry pomace | 5.5-28.3 X |         |           |

Based on these data we concur that the tolerance level for raisins and raisin waste should be 5X that of the RAC; that no food additive tolerance is needed for juice; and that the pomace tolerance should be at 30X the RAC. Re pomace, see #45.

48. RECOMMENDATIONS: Negative, for the reasons cited in #34, 37, 38, 42, and 45. For further consideration the petitioner needs to submit the additional field trials requested and a revised Section F.

49. Other Comments Under Recommendations:

50. Compatibility with Codex Tolerances? (Explain) N/A; see Attachment. There are no IRL's established for a sethoxydim/grape use.

ATTACHMENT(S): (1) International Residue Limits Status Sheet  
(2)

cc: RF, Circ, Reviewer, PP# 8F3660, PMSD/ISB.

Approved: RSQuick RML 10/6/88; RDSchmitt RML 10/6/88.

INTERNATIONAL RESIDUE LIMIT STATUS

*1. 4/12/83*

CHEMICAL Sethoxydim

CODEX NO. \_\_\_\_\_

CODEX STATUS:

☒ No Codex Proposal  
Step 6 or above

Residue(if Step 8): \_\_\_\_\_

| <u>Crop(s)</u> | <u>Limit</u><br><u>(mg/kg)</u> |
|----------------|--------------------------------|
|----------------|--------------------------------|

PROPOSED U.S. TOLERANCES:

Petition No. 8F3660

RCB Reviewer Nelson

Residue: parent plus metabolites  
w/ 2-cyclohexen-1-one moiety

| <u>Crop(s)</u> | <u>Limit</u><br><u>(mg/kg)</u> |
|----------------|--------------------------------|
|----------------|--------------------------------|

|                  |    |
|------------------|----|
| grapes           | 1  |
| raisins          | 5  |
| raisin waste     | 5  |
| dry grape pomace | 30 |

CANADIAN LIMITS:

☒ No Canadian limit *(on grapes)*

Residue: \_\_\_\_\_

| <u>Crop(s)</u> | <u>Limit</u><br><u>(mg/kg)</u> |
|----------------|--------------------------------|
|----------------|--------------------------------|

MEXICAN LIMITS:

☒ No Mexican limit

Residue: \_\_\_\_\_

| <u>Crop(s)</u> | <u>Limit</u><br><u>(mg/kg)</u> |
|----------------|--------------------------------|
|----------------|--------------------------------|

NOTES: