



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

R.F.
9/23/91

SEP 23 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sethoxydim (POAST®). Impact of Craven Analytical Data on Registrations: alfalfa, forage and hay; beans, dry, forage and hay; beans, succulent; Brassica leafy vegetables (cabbage, broccoli, cauliflower and mustard); cottonseed; flaxseed and straw; fruiting vegetables (tomato and pepper); grapes; lentils; peanuts and hull; peas, dry, forage and hay; peas, succulent; potatoes; soybeans; sugar beet tops; and sweet potatoes. DP Barcode: D165411. CB # 8461.

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THROUGH: Edward Zager, Chief *Edward Zager*
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BASF submitted information pertaining to sethoxydim residue chemistry data generated by Craven Labs. This information was submitted in response to allegations concerning the validity of Craven analyses. The Agency will not utilize data generated by Craven Labs to make regulatory decisions prior to the resolution of the issues involving these allegations.

Sethoxydim is a FIFRA 88 List B chemical. The Phase IV review was issued 2/25/91. The complete chemical name is 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one.

Residues of sethoxydim that are being regulated include the parent compound and its metabolites containing the 2-cyclohexene-1-one structure, and are expressed in terms of the parent compound [40CFR180.412].

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CONCLUSIONS

1. Sethoxydim residue data were generated by Craven Labs for alfalfa, hay; beans, dry, forage and hay; beans, succulent; Brassica leafy vegetables (cabbage, broccoli, cauliflower and mustard); cottonseed; flaxseed and straw; fruiting vegetables (tomato and pepper); grapes; lentils; peanuts and hull; peas, dry, forage and hay; peas, succulent; potatoes; soybeans and sugar beet tops. The bean and grape processing studies were also analyzed by Craven labs.

2. In the interim, there are non-Craven residue data to support the tolerances established on: alfalfa, hay and forage; beans, succulent and forage; dry and hay; Brassica leafy vegetable; cottonseed; flax seed and straw; fruiting vegetable; grapes; lentils; peanuts and hay; peas, succulent and forage; peas, dry and hay; raspberry; soybeans and hay; strawberry; sugar beet root and tops; and sweet potato.

3. For artichoke, no residue data other than those produced by Craven Labs are available and no crop residue data are translatable. No residue data are available to determine whether the 3 ppm tolerance is adequate.

4. Stability data for sethoxydim and its metabolites in soybean seed, tomato, apple, orange and potato under frozen storage were not generated by Craven Labs. Data from these crop matrices are adequate to profile the stability of sethoxydim and its metabolites in various crops.

RECOMMENDATION

CBRS recommends that a DCI be issued to replace residue chemistry data generated by Craven Labs Inc, as follows:

Magnitude of the residue studies reflecting the maximum use pattern using ground or aerial equipment or both are required as summarized in Table 1 on next page.

Bean and grape processing studies. Succulent beans and grapes bearing detectable residues of the parent and the regulated metabolites should be processed; residues in cannery waste (for beans), and raisin, juice, raisin waste and pomace, wet and dry (for grapes) need to be measured.

Table 1. Crop Field Trial Parameters for Each Commodity to be Tested Using EC Formulation

Commodity	Maximum			Minimum		Equip ²	States ³
	Rate lb ai/A ¹	Seasonal	No. of Appl	PHI days	Interva l days		
alfalfa (hay) ¹⁰	0.3-0.5	1.0	n/a	20	n/a ⁴	G,A	CA/ID/OR/WA, IA/MN/NE/WI NY/OH/PA
artichoke	0.94	1.88	2	7	21	G	CA
beans (succulent)	0.3-0.5	0.8	2 ⁵	15	n/a	G	NY/NJ, TN/NC/VA, CA, MI, FL
beans (dry)	0.3-0.5	0.8	2 ⁵	30	n/a	G	CA, ID, MI, CO, NE, ND
broccoli	0.3	0.6	2	30	21	G	CA, TX/AZ, OR
cabbage	0.3	0.6	2	30	21	G	NY, CA, FL, TX, WI, NJ, SC/NC GA/TK
mustard green	0.3	0.6	2	30	21	G	TX/AZ, HI/OR/IN, LA/GA/TR
cotton	0.5	1.5	3	40	21	G,A	TX, CA, AL/GA/SC, OK/AR/TR/MS
flax ⁶	0.3-0.5	0.8	2 ⁵	75	n/a	G	MI, ND, SD
peppers	0.3	0.9	3	20	21	G,A	CA, FL, TX, NC, NJ
tomatoes	0.3	0.9	3	20	21	G,A	CA, FL, IN, MI, SC/TN PA/OR, NJ (ground only)
grapes	0.5	1.0	2	50	n/a	G	CA, NY, WA, MI, NC
lentils	0.3-0.5	0.8	2 ⁵	50	21	G	translatable from dry peas
peanuts ⁷	0.3	0.5	2 ⁵	40	21	G,A	GA, TX, NC/VA
peas (succulent)	0.3-0.5	0.8	2 ⁵	15	n/a	G	CA, DE, ID, MN, WI, OR/WA
peas (dry)	0.3-0.5	0.8	2 ⁵	30	n/a	G	CA, DE, ID, MN, WI, OR/WA
potatoes ⁸	0.5	1.0	2	30	21	G	CA, FL, OR, WA, ID
raspberry	0.5	1.0	2	45	21	G	ID, OR/WA, ND, MN, WI, NE, CA, CO
soybeans ⁹	0.5	1.0	2	90	n/a	G,A	IN/IL, IA/NE, MO, MN TN, AR, MS/LA
strawberry ⁹	0.5	0.5	1	30		G	CA, FL, OR/WA, IN/MI, NY/OH/PA
sugar beet	0.5	1.0	2	100	21	G,A	CA, FL, OR/WA, IN/MI, NY/OH/PA, VA, RE, MI

¹ refers to single application rate, provided by BASF in the submission ² G = ground, A = aerial; broadcast or band application ³ if a slash appears between states then either site may be chosen ⁴ to be provided of proposed by the registrant (not listed in the LUIS report) ⁵ the last application should be 0.3 lb ai/A, except for peanuts (0.2 lb ai/A) ⁶ pending review of the residue data that were used to establish the Canadian tolerance and aerial versus ground data ⁷ pending resolution of the Huntington Lab analyses ⁸ trials for which Craven results have been verified by re-analyses need not be repeated ⁹ pending review of non-Craven data submitted in March 1991 ¹⁰ pending review of label amendment data to revise the PHI to 14 days in September 1991; seasonal maximum is 1 lb ai/A with no fixed number of applications (PP#3F2904 corresponding file)

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Detailed Considerations

Alfalfa (hay) (40 ppm; PHI=20 days for hay and 7 days for forage; 2 x 0.5 + 1 x 0.3 lb ai/A; ground and aerial)

Hay samples from field trials (CA, ID, MT, ND, SD, NE, KS, IL, IA, MI, WI, MN, PA, NY) conducted at 2 x 0.5 + 1 x 0.3 lb ai/A or 3 x 0.5 lb ai/A and PHI's of 15-23 days were analyzed by Craven. Non-Craven data reflected trials from CA, TX, WI or NY treated at 1 x 0.5 lb ai/A and PHI's of ca 20 days. BASF stated that the company will be submitting in September 1991 a label amendment requesting the PHI be revised to 14 days, and results of this study were analyzed by an independent laboratory which demonstrated good agreement between laboratories (Craven and non-Craven). Furthermore, a comparative study of POAST® and POAST® Plus on alfalfa is available on request showing good Craven and non-Craven correlation. BASF stated that the forage data were not analyzed by Craven.

Conclusion: The non-Craven residue data are adequate to support the alfalfa hay tolerance in the interim. However, the Craven data for alfalfa hay may need to be replaced in order to support the tolerance on alfalfa hay since the non-Craven data reflect less than the maximum use pattern. Bridging data (such as inter-laboratory and cross-formulation - POAST® and POAST® Plus) are not acceptable as supporting evidence. Pending review of the PHI amendment data, replacement residue data reflecting maximum label use pattern from alfalfa grown from CA/ID/OR/WA, IA/MN/NE/WI, NY/OH/PA are appropriate to support alfalfa tolerances. According to PP#3F2904 correspondence file, PHI's are 7 days for forage and 20 days for hay; seasonal maximum is 1 lb ai/A with no fixed number of applications. CBRS verified the alfalfa forage data were not analyzed by Craven (PP#3F2904, Second Amendment, 12/6/85, Report # PR-256, MRID # 00155129). List B Phase IV review required no additional residue data for alfalfa hay and forage.

Artichoke (3 ppm; PHI=7 days; 2 x 0.94 lb ai/A; ground only)

Samples from field trials conducted in CA were analyzed by Craven Labs (verification through PP#7E3549 and information provided in Phase III submission). No other data are available.

Conclusion: Since no residue data other than Craven data are available and no crop residue data are translatable to artichoke, the 3 ppm tolerance is not supported in the interim. No data are available to determine whether the 3 ppm tolerance is adequate. Artichoke trials conducted at the maximum use pattern (0.47 lb ai/A/treatment and 0.94 lb ai/A/season, PHI=7 days) in CA using ground equipment may be required. Phase IV review cited no residue data gap.

Beans (succulent and forage) (5 ppm; PHI=15 days; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

All U.S. trial samples (beans and forage using maximum use pattern) were analyzed by Craven. Non-Craven data included residue trials conducted in Campinas, Sp, Brazil, Nova Scotia, British Columbia, Canada using less than the maximum use pattern (1 x 0.8 lb ai/A with PHI's=44-68 days or 1 x 0.23-0.5 lb ai/A with PHI's=14-54 days). Canadian and Japanese tolerances were established based on non-Craven data. BASF stated that samples (number not known) of snap beans and lima beans had been re-analyzed and showed excellent agreement with Craven results. An aerial versus ground study on beans resulting from 1 x 0.5 lb ai/A and PHI=15 days is in progress.

Conclusion: Since all U.S. trials were analyzed by Craven, these data may need to be replaced in order to support the registration on succulent beans. The Canadian residue data discussed above are not adequate to support the bean tolerances since maximum use pattern was not used in these field trials. Residue trials conducted in NY/NJ, TN/NC/VA, CA, MI, FL are needed to replace the Craven data. In the interim, soybean residue data can be used to support the succulent bean tolerances. The bean processing study was analyzed by Craven labs according to Phase III submission (and verified in PP8F#3640/8H5557, MRID # 40611406) and may need to be replaced. Phase IV review did not discuss beans and peas residue data because these crops had been registered after the FIFRA 88 Phase II submission.

Beans (dry and hay) (20 ppm and 50 ppm; PHI=30 days; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

Craven analyzed samples from residue trials conducted at maximum use pattern in CA, ID, NE, ND, CO, MN, WI, NY for dry beans and in CA, ID, CO, ND, NE, MN, WI, MI for hay. BASF analyzed trials conducted in Canada (Ontario, Saskatoon, Saskatchewan) using 1 x 0.3-0.8 lb ai/A and PHI's=61-111 days. Canadian and Japanese tolerances were established based on independent lab data. An aerial versus ground study on beans (1 x 0.5 lb ai/A with 30 day PHI) is in progress.

Conclusion: The Canadian residue data are adequate to support the bean tolerances in the interim. However, additional field trials conducted in CA, ID, MI, CO, NE, ND are needed to replace the Craven data. Phase IV review did not discuss beans and peas residue data because these crops had been registered after the FIFRA 88 Phase II submission.

Brassica (5 ppm; PHI=30 days; 2 x 0.3 lb ai/A; ground only)

(cabbage)

All U.S. (CA, FL, NJ, MD, CT, MN, MI, NC, MA, MS and TX) residue samples were analyzed by Craven. Trials conducted in Sao Paulo, Brazil and Ontario, Canada were analyzed by BASF.

(broccoli)

All U.S. residue samples (CA, NJ, KS, TX) were analyzed by Craven; samples collected from Manitoba and Ontario of Canada were analyzed by BASF. An aerial versus ground study (CA, TX, OR) on broccoli is expected to be complete by early 1992. BASF also stated that a European (OECD) tolerance established based on non-Craven results.

(cauliflower)

Samples from trials conducted in MS and CA were analyzed by Craven. No other U.S. residue data are available. Non-Craven data were derived from trials conducted in Canada (New Brunswick, Ontario and Manitoba).

(mustard greens)

All residue samples (TX, MD, SC, KS) were analyzed by Craven.

Conclusion: The Brassica group tolerance is supportable in the interim based on the Canadian residue data (cabbage and cauliflower). Residue data used in support of U.S. crop group tolerance were all analyzed by Craven. These data may need to be replaced: additional cabbage field data from NY, CA, FL, TX, WI, NJ, SC/NC/GA/TN and mustard green field data from CA, TX/AZ, MI/OH/IN, FL, LA/GA/TN. Phase IV review cited additional mustard green field trials from CA and FL.

Cottonseed (5 ppm; PHI=40 days; 3 x 0.5 lb ai/A; ground and aerial)

Cotton samples harvested from field trials conducted in TX, OK, GA and AR by ground applications were analyzed in BASF laboratories. Residue data from ground and aerial applications made in CA, TN and LA were analyzed by Craven.

Conclusion: Residue data produced by BASF are adequate to support the cottonseed tolerance in the interim. CBRS notes that both the Craven and non-Craven data do not reflect maximum use pattern. The Phase IV review concluded that ground and aerial residue data reflecting maximum label use are needed from TX, CA, AL/GA/SC, and OK/AR/TN/MS.

The Phase IV review also concluded that the cottonseed processing study is adequate. The Phase III submission stated that the cotton processing study was performed jointly by BWC Chemicals Group and Texas A & M University, Oilseed Products Division. CBRS has verified that the processing results were not analyzed by Craven

(PP#2F2748/3H5392, Report # PR-210, MRID # 00110510 and Report # PR-211A, MRID # 00127281).

Flax (seed and straw) (5 ppm; PHI=75 days; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

Residue results on flax seeds and straw from SD, ND, MN using the maximum label use pattern (1 x 0.5 + 1 x 0.3 lb ai/A; PHI=75 days) were analyzed by Craven. Non-Craven data reflect less than the maximum use pattern (1 x 0.5 lb ai/A and PHI=75, 88 days). BASF stated that a Canadian tolerance was established based on non-Craven residue data. An aerial versus ground study on flax was submitted to EPA but was rejected due to a "technical question" (not related to the integrity of analytical method).

Conclusion: The non-Craven data are adequate to support the flax tolerances in the interim. If the non-Craven data discussed above were used to establish the Canadian tolerance, these data are not adequate because maximum use pattern was not used in these field trials. Pending review of the aerial versus ground flax data, additional residue data on flax seed and straw harvested from MN, ND, SD may be required. CBRS found that the flax processing study was analyzed by Craven labs (PP#6F3411, CR-25, MRID # 00159591). Soybean processing data can serve as surrogate data. Phase IV review cited no data gaps.

Fruiting vegetable (4 ppm; PHI=20 days; 3 x 0.3 lb ai/A; ground and aerial)

(peppers)

Only two residue samples resulting from less than maximum label rate in CA were analyzed by Craven. Trials (using ground equipment only) conducted in TX, MS, FL, NC, NJ, MI with maximum use pattern were analyzed by BASF.

(tomatoes)

Only two samples resulting from less than maximum label rate in CA were analyzed by Craven. Tomato residue trials (using ground equipment only) conducted in VA, NC, FL, TX, MN, MI with maximum use pattern were analyzed by BASF.

(eggplants)

One eggplant from SC was analyzed by Craven. However, eggplant residue data are not required for a crop group tolerance.

Conclusion: The non-Craven data are adequate to support the fruiting vegetable group tolerance in the interim. However, the Craven pepper and tomato data from CA may need to be replaced in order to support the fruiting vegetable crop group tolerance. Phase

IV review cited additional tomato residue data from PA/OH, NJ as a data gap; but concluded the tomato processing study to be adequate. Phase III submission stated the BASF AG, FRG analyzed the data. This information has been verified in PP#5F3284, Report # PR-261, MRID # 00148007.

Grapes (0.2 ppm; PHI=50 days; 2 x 0.5 lb ai/A; ground only)

According to the table attached to BASF's 3/12/91 letter, grape trials were conducted in WA, OH, CT, NY, NJ, MO and CA. All residue analyses were performed by Craven. BASF cited apple residue data which were not analyzed by Craven as supporting evidence in validating the Craven grape study.

Conclusion: Since apples and grapes are not in the same crop group, residue data are not translatable in support of the grape tolerance. However, the limited raspberry residue data are adequate to support the grape tolerance in the interim (see Raspberry below). Grape residue trials conducted in CA, NY, WA, MI, NC may be required. Since the grape processing study was analyzed by Craven labs (as stated in the Phase III submission and verified through PP#8F3660/8H5561, MRID # 40725802), a new processing study may be necessary. Tolerances on grapes and pome fruits were established after the FIFRA 88 Phase II submission. The Phase IV review commented that grape and pome fruits residue data would be reviewed in Phase V.

Lentils (30 ppm; PHI=50 day; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

Tolerance on lentils was established as a result of IR-4's request. Craven analyzed all the lentil trials conducted in the U.S. (WA and ID; see PP#8E3597, MRID # 40446501) whereas BASF analyzed the residue samples collected in Canada (Saskatoon and Alberta). BASF stated that an aerial versus ground study concerning the bean crop group would soon be completed and results from independent analyses would be used as supporting data.

Conclusion: Non-Craven dry pea residue data were generated in Canada (Manitoba and Saskatchwan) and are adequate to support the lentil tolerance in the interim. No non-Craven lentil data resulting from U.S. field trials are available. Use pattern of POAST on dry peas (40 ppm, 30 day PHI) is similar to lentils (30 ppm, 50 day PHI), but the dry pea residue data generated from trials conducted in the U.S. (WA, ID, MT and CA) were also analyzed by Craven. The data to be generated on dry peas (see below) are translatable to lentils. Provided adequate residue data are submitted on dry peas, no new data on lentils are necessary. Phase IV review cited no data gaps.

Peanuts and hulls (25 ppm; PHI=40 days; 1 x 0.3 + 1 x 0.2 lb ai/A; ground and aerial)

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Peanut seed data from OK, VA, NC, SC, GA with the maximum use pattern (1 x 0.3 + 1 x 0.2 lb ai/A, PHI=40 days) were analyzed by Craven. Residue data not analyzed by Craven included peanut meat and hull samples harvested in AL, GA, NC, TX, VA (analyses performed by Huntingdon Analytical Labs and BASF labs). No MRID # was assigned to the Huntingdon analyses. BASF stated that an Australian tolerance was established based on non-Craven data, and a POAST® and POAST® Plus comparative study on peanuts that was not analyzed by Craven supports Craven data.

For hulls non-Craven data included samples from AL, GA, NC, TX; Craven Labs analyzed trials from OK, TX, VA, NC, SC, GA.

Conclusion: The petition number PP#3F3254 referenced in BASF's submission is incorrect and should be PP#3F3234. The peanut tolerances were established in connection with PP#3F3234 but cited residue data submitted in PP#3F2950/3H5413. We could verify only the BASF peanut meat and hull data in PP#3F2950/3H5413 (as MRID # 00131857) and could not locate the Huntingdon Labs results. BASF needs to submit more information for the Huntingdon data. The BASF-analyzed peanut meat and hull data are adequate to support the established tolerances in the interim. Pending resolution on the Huntingdon data, replacement residue data may be required from GA, TX, NC/VA field trials using ground and aerial application equipment. The peanut processing study was jointly performed by BASF and the University of Texas. Phase IV review required peanut residue data from GA, TX, NC/VA resulting from aerial applications; the processing study was adequate.

Peas (succulent and forage) (10 ppm and 20 ppm; PHI=15 days; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

Craven labs analyzed residue samples from trials conducted in CA, OR, WA, MN, WI, MD, NY, NJ, IL for peas and in WI, MN, MI, NY, CT, WA, OR, CA, IL for forage reflecting maximum label use pattern. No non-Craven data are available for U.S. residue trials. Residue trials conducted in British Columbia, Canada used less than maximum label pattern. BASF stated that a Canadian tolerance was established on non-Craven data and an aerial versus ground study on beans (1 x 0.5 lb ai/A, PHI=15 days) is in progress.

Conclusion: Since all U.S. samples from trials were analyzed by Craven, these data may need to be replaced in order to support the registration on succulent beans. Residue trials conducted in CA, DE, ID, MN, WI, OR/WA are appropriate. In the interim, the soybean residue data can be used to support the succulent pea tolerances. Phase IV review did not discuss beans and peas residue data because these crops had been registered after the FIFRA 88 Phase II submission.

Peas (dry and hay) (40 ppm; PHI=30 days; 1 x 0.5 + 1 x 0.3 lb ai/A; ground only)

All samples from U.S. residue trials (peas and hay) were analyzed by Craven. Non-Craven pea residue trials were conducted in Manitoba, Saskatchewan, Canada and used less than the maximum use pattern. BASF stated that a Canadian tolerance was established on non-Craven data and an aerial versus ground study on beans (1 x 0.5 lb ai/A, PHI=30 days) is in progress.

Conclusion: The Canadian dry pea residue data are adequate to support the tolerance in the interim. Additional residue trials conducted in WA/OR, ID may be required. Phase IV review did not discuss beans and peas residue data because these crops had been registered after the FIFRA 88 Phase II submission.

Potatoes (4 ppm; PHI=30 days; 2 x 0.5 lb ai/A; ground and aerial)

All except one U.S. potato residue trials (CA, WA, ID, MN, MI, WI, ND, NY, NJ, ME, VA, GA) were analyzed by Craven. Non-Craven data included trials conducted in British Columbia, Ontario, New Brunswick, Manitoba of Canada (less than label maximum use pattern). BASF stated that selected samples from the Craven studies were re-analyzed by BASF for direct comparison which showed excellent agreement and are available for submission. Independent laboratories data that showed good agreement with Craven results were used to establish potato tolerances in Canada, Japan and Europe. BASF also cited sweet potato residue data (non-Craven) in support of Craven potato results and the potato processing study was not analyzed by Craven.

Conclusion: Sweet potato and potato are in the same crop group and sweet potato residue data (see below under sweet potato) are acceptable to support potato tolerance in the interim. Except for those samples from the Craven studies that are verified by re-analysis, all Craven-generated potato residue data are to be replaced. The potato processing study was conducted and analyzed by a WA state contractor and BASF at BASF Research Triangle Park, NC (CBRS verified this information in MRID # 4019502, PP#7F3529/7H5537); the study was deemed adequate in the Phase IV review. Phase IV review required potato residue trials to be conducted in ID, OR/WA, ND, MN, WI, ME, CA, CO using aerial equipment.

Raspberries (5 ppm; PHI=45 days; 2 x 0.5 lb ai/A; ground only)

Craven labs analyzed residue samples harvested from MI, OR, WA, CA. Non-Craven data included residue samples from NY, NJ (2 or 3 x 0.5 lb ai/A, 21-31 days).

Conclusion: The NY-NJ residue data are adequate to support the raspberry tolerance in the interim. Raspberry residue data from WA and OR may be required to support the established tolerance. We note that even though the raspberry tolerance was set at 5 ppm, residues resulting from 2 x 0.5 lb ai/A and PHI≤45 days were generally <0.1 ppm. Phase IV review cited no residue data gap.

Soybeans (10 ppm seed and hay; PHI=90 days; 2 x 0.5 lb ai/A and aerial)

Craven labs analyzed residue samples of soybean seed trials conducted in MN, SC, MS, IN, but all these trials were less than the maximum label use rate (1 x 0.2 or 1 x 0.3 or 1 x 0.2 lb ai/A). Non-Craven data on seeds were generated from trials conducted in NC, MI, MO, MS, IL, MN, GA, NJ (all at 2 x 0.5 and \leq 90 day PHI), Rio Grande do Sul State, Brazil and Canada. BASF stated that a comparative study of POAST® versus Plus on soybean which was analyzed by an independent lab showed agreement with Craven results.

For soybean-hay, all residue data were non-Craven. Trials conducted in MO, TX, NC, NJ, IL, MI, MN.

Conclusion: Non-Craven soybean data contained in 00100535 were verified through microfiche (Document Control 9/10/91). The samples were initially analyzed at BWC Chemists and later sent to BASF Residue Labs in Limburgerhof, Germany for blind analyses. No MRID # or source information was referred to the U.S. trials results performed by the Huntingdon Analytical. The soybean petition PP3F2509 did not contain the Huntingdon data. More information on the Huntingdon data is required. Pending review of the Huntingdon data, adequate residue data are available to support the current established tolerances. Soybean processing was not analyzed by Craven labs according to the Phase IV submission. Phase IV review concluded that the soybean processing study was adequate but required additional soybean residue trials to be conducted in IL, IA, MO, MN, TN, AR, MS/LA using aerial equipment.

Strawberry (5 ppm; PHI=30 days; 1 x 0.5 lb ai/A; ground only)

No tabulation of residue data was included. BASF stated that six Craven samples had been re-analyzed at BASF and confirmed Craven results. In addition, BASF requested to reduce the Phase IV new residue data (non-Craven) were received by EPA in March, 1991.

Conclusion: All strawberry residue data in PPF3383 were analyzed by Craven. In the interim, the raspberry residue data were analyzed to support the strawberry tolerance. Pending review of the recently submitted non-Craven data, residue trials to be conducted in CA, FL, OR/WA, IN/MI, NY/OH, LA may be required.

Sugarbeet tops (3 ppm; PHI=100 days; 2 x 0.5 lb ai/A; ground and aerial)

Craven labs analyzed field trials conducted in the following states: CA, OR, MI, ND, MN, CO, TX, NE, all treated with 2 x 0.5 lb ai/A and harvested at 60-104 days after application. Non-Craven trials included trials from MT, CA, MN, ID, also applied at 2 x 0.5 lb ai/A using aerial and ground equipment and harvested 68-104 days.

noted in the attachments of the 3/12/91 letter that sugarbeet roots were not analyzed by Craven. BASF also stated that a petition (PP#8F3646 & 8H5558) on sugarbeets, roots and tops, is pending to reduce the current PHI to 60 days.

Conclusion: The non-Craven data contained in MRID # 40639101 and 00155129 were verified in PP#8F3646 and are adequate to support the sugarbeet tolerances during the interim period. PP#8F3646 & 8H5558 is pending because of lack of adequate processing data but the Craven and non-Craven residue data were adequate to support the requested 60-day PHI (see R. Cook's 12/6/88 review). Additional residue data generated from sugarbeets grown in WA, NE, MI may be required. Phase IV review only required a new sugarbeet processing study.

Sweet potato (4 ppm; PHI=30 days SE or 60 days West; 1 x 0.5 lb ai/A SE or 2 x 0.5 lb ai/A West; ground only)

BASF stated that the tolerance is established but the label is pending (?). No Craven data were involved. Residue trials were conducted in NC, LA, CA and Campinas, Brazil.

Conclusion: According to PP#9E3789, MRID # 41188901, all residue samples were shipped to Japan and analyzed at the Nisso Odawara Research Center. No action is required. The sweet potato residue data can be used to support potato tolerance in the interim.

Frozen Storage Stability Data

Frozen storage stability data that were not generated by Craven Labs included those on soybean seed, tomato, apple, orange, and potato. Data for the parent compound and its metabolites in these crops are available for up to 36 months. Stability studies that were analyzed by Craven Labs concerned strawberries and a legume vegetable (snap beans). The non-Craven frozen stability data cover an adequate spectrum of crops and data on strawberries and snap beans are supplementary.

Conclusion: Data in soybean seed, tomato, apple, orange and potato are adequate to profile sethoxydim and its metabolites in various crops.

cc:Circ, RF, Craven Subj F, Cheng, Flood, Bagley
RDI:FSuhre:9/20/91:EZager:9/20/91
H7509C:CBII-RS:LCheng:CM#2:RM810:9/18/91:02:9/23/91

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