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

JUN 17 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 16, 1981

SUBJECT: PP#9E2145; Gibberellins A_3, A_4 and A_7 on all Raw Agricultural Commodities. Request for an exemption.
CASWELL#467 Accession#099780[illegible]2

FROM: William S. Woodrow, Ph.D WSW 6/16/81
Toxicology Branch, HED (TS-769) WSW for LDC 6/16/81

TO: Minor Crops Officer
Registration Division (TS-767) H for WJB

Petitioner: Dr. G.M. Markle
IR-4 Project Associate
Coordinator
Cook College, P.O. Box 231
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Action Requested:

Drs. G.M. Markle and Dr. R.H. Kupelian on behalf of the IR-4 Technical Committee request an exemption from the need for tolerances for residues of Gibberellins A_3, A_4 and A_7 on all Raw Agricultural Commodities.

Residue Chemistry Branch Considerations

Residue Chemistry Branch recommended against the proposed exemption of Gibberellins A_3, A_4 and A_7 on all RAC's (See May 28, 1981 memo, R. Perfetti) due to lack of information RCB previously requested regarding application rates, times of application, levels of Gibberellins occurring naturally in crops, adequate analytical methods for identifying and quantifying Gibberellins, and limited residue data.

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Toxicology Branch Recommendations:

1. The request for exemption of Gibberellic acid (Gibberellins) A_3, A_4 and A_7 from the requirement of tolerances on all Raw Agricultural Commodities is not toxicologically supported at the present time.

   The petitioner based his request for exemption of Gibberellins from the requirement of tolerances on RAC's on the following items:

   1) Gibberellins have been used for approximately 20 years; apparently without affecting human health;

   2) Gibberellins are natural plant growth regulators that are associated with plants and RAC's;

   3) A tolerance of 0.15 ppm for Gibberellin A_3 has been established for a number of RAC's. A combined tolerance of 0.5 ppm has been established for Gibberellins A_4 and A_7 in or on apples; and,

   4) The petitioner further states that the Draft Subpart M Guidelines for Registering Biorational Pesticides in th U.S., September 29, 1980 exclude biochemical pesticides from the requirement of a tolerance when:

      a. Toxicology data developed using Tier 1 testing in accordance with Sections 163.153-10 through 18 indicate that Tier 11 testing is not required; and,

      b. The rate of biochemical pesticide application is equal to or less than 20 grams of active ingredient per acre.

   A record of the Gibberellin toxicity data on hand for Gibberellins considered as conventional pesticides is listed in the attached memos (D. Ritter, February 2, 1976, and W.E. Parkin, August 4, 1972).

   The following toxicity tests would be required for compliance with Draft Subpart M (September 29, 1980) Biochemical Biorational Guidelines, Tier 1:

      a. A battery of short-term mutagenicity tests; and,

      b. A battery of cellular immune response studies.

Since the recommended Gibberellin application rates for 9 of 29 registered Gibberellin tolerances (attached list) exceeds 20 grams a.i. per acre; Gibberellins as a class of similar compounds clearly do not fit the application rate limit criterion for biochemical pesticides cited above in the proposed Subpart M Guidelines.

The 20 grams per acre a.i. limit for biochemical biorationals as well as finalized specific criteria for defining such chemicals may be subject to change in the near future as a result of the Agency's response to public comment upon publication of the Subpart M Guidelines in the Federal Register.

Until such time as final agreement concerning biochemical biorational pesticide applicatiomn rate registration exclusion limits and definition criteria for these chemicals are available, the Agency must defer consideration of Gibberellins for exemption from the requirement of tolerances on Raw Agricultural Commodities.

2. No new toxicology data were submitted.

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TABLE 1. AMOUNTS OF GIBBERELLINS APPLIED TO VARIOUS CROPS

CROP	CONCENTRATION OF OF ACTIVE INGREDIENTS IN SPRAY	DOSAGE RATE: Grams of Gibberellins Applied per Acre
Grapes:		
Seedless	10 - 15 ppm	3 - 8.5
"	5 - 20 ppm	3 - 12
"	20 - 40 ppm	8 - 48
"	20 - 50 ppm	16 - 40
Raisin	2.5 - 10 ppm	0.75 - 6
Black Corinth	2.5 - 20 ppm	1 - 8
Wine varieties	1 - 40 ppm	0.4 - 16
Blueberries	200 ppm	210
Oranges	5 - 20 ppm	10 - 40
Tangelos	5 - 15 ppm	10 - 30
Lemons	10 ppm	20
Prunes	50 ppm	40 - 60
Cherries:		
Sour	10 - 25 ppm	8 - 30
Sweet	7.5 - 10 ppm	15 - 24
Artichokes	25 ppm	5
Celery	5 - 12.5 ppm	5 - 10
Rhubarb	250 - 500 ppm	0.03 grams per plant
Sugarcane	1000 - 3000 ppm	28 - 84
Hops	10 ppm	6
Lettuce	10 ppm	0.4 - 4
Seed Potatoes	0.5 - 1	Approx. 1
Seed treatments:		
Cotton		1.5
Beans		1.5
Oats		1.5
Rye		1.5
Wheat		1.5
Peas		1.5
Soybeans		1.5
Pears*	10 - 25 ppm	30 - 40
Grapefruit*	10 - 30 ppm	30 - 50
Limes*	10 ppm	20
Apples	23 ppm	9.5 - 19

* Use proposed but not yet registered.