

23 MAY 1980

THE DIRECTOR, ARS, IS REQUESTING YOUR ASSISTANCE IN THE REVIEW OF THE PROPOSED USE OF OR SUGGESTED CROPPING OF AMENDMENT OF 12/17/79.

Re: WILSON, CHESTER, MA, LRD (78-769)

Re: Task 25, FLD, II (78-767) and 70X, LRD (78-769).

TO: Acting Chief, RCB

This amendment was suggested by CHESTER as a response to the deficiencies raised in our (the Wilson) review of 10/9/79 and transmitted to the petitioner via request letter (K. Taylor) of 11/5/79. These deficiencies will be restated below for ease of reference (using the numbering in our suggested review), followed by the petitioner's responses, our comments/conclusions thereon, and our recommendations.

Relatively so. Only a tentative conclusion can be drawn at this time in support of the emergency of the proposed 2 1/2% tolerance level of sugarcane. For further consideration, we will need to know:

- (1) The volume of material (H.C.) utilized in each of the field studies which have been submitted. If no "low volume" use (which the proposed directions specify) data is available, additional field studies (low volume type)—or revised directions for use to correspond with the available data—will need to be submitted.
- (2) That specific foreign countries are to be involved in this use and if any reliable data for that use is available from them. If no such data is available (which we presume to be the case), we will need written assurance that the climatic conditions and cultural practices in those countries are sufficiently similar to those in the sugarcane growing regions of the USA and Puerto Rico (for which some residue data have been provided) to warrant our consideration of the feasibility of translating the climatic data to a foreign use. Also, we will need written assurance that the proposed use directions specified in section B of this petition accurately reflect those which will appear on all the foreign labels for that use. Label article (with translations) should be submitted, if available.

70X OF
661
Dykes
pms

Pesticide's Residue, 35(1). The following are the volumes of carrier utilized in each of the residue locations; please add to Section L-1, Part B, pages 13-14:

- 1. Cuba, L-11 (248-012/104-0011)..... 15 G/A
- 2. Cuba, L-11 (248-012/104-0011) 15 G/A
- 3. Florida, Florida 20 G/A
- 4. Little Rock, Florida 20 G/A
- 5. Mexico, Mexico 14.5 G/A
- 6. St. Martinville, Louisiana 16.5 G/A
- 7. Mexico, Puerto Rico 20 G/A

We submit that these are all above the recommended use rates of 5-10 G/A.

In further support of our claim, we are submitting the results of 2 locations in Mexico at 10 G/A. These studies were conducted by the National Sugar Planters Association (NSA) under an agreement with Monsanto. These results show, even with the poor recoveries obtained, that at 10 G/A, results will not be deficient than those at higher G/A.

Since we have no studies at 5 to 9 G/A, we are assuming our label to recommend use of this product at 10 or more G/A.

Chemical/Conclusions, 35(1). In the two additional field studies from FL, A-1116 was applied over-the-top at 10 gal/A volume at application rates of 1 and 2 lb. acid equivalent/A (248-000 = 75% active ingredient; 248 acid equivalent), and the cane harvested 8-11, 20, and 29-34 days later. Residues of glyphosate and aminocyclophosphonic acid were analyzed for via GC methodology. At a 20-day fall and 1 lb ac/A rate (the most relevant conditions to the proposed use), residues of the metabolite were 0.65 ppm and of glyphosate per se were 0.05-0.06 ppm, apparently uncorrected for cane recoveries of 15-25 (percent) and 8-72% (metabolite). Residues in the residues prepared from 30-day fall cane (1 lb ac/A rate) were 0.5 ppm (metabolite) and 0.55-1.16 ppm (glyphosate); recoveries were 27-61% (percent) and 10-66% (metabolite).

It is our best judgment that these two additional studies do support the proposed tolerance levels for residues in both sugarcane (2 ppm) and molasses (20 ppm). The recovery data are unacceptably poor, but the methodology is noted for its variable recoveries (among other shortcomings) and has still been judged acceptable for enforcement purposes (see J. Corning memo of 1/6/77, 114 27150).

In view of the amended label text specifying use of the product in 10 or more gallons of water per acre, and the additional field study data discussed above, we consider this deficiency resolved.

Petitioner's Response, 12(2). No specific plans have been finalized into which countries we plan to market this product. Worldwide, sugarcane is grown in tropical or sub-tropical conditions. The crop has a 12-month growing season in all countries with the exception of Hawaii, where it is grown for 24 months before harvest. Cultural practices do not widely vary for any country. At this time, residue data are not available from any other country. Many countries, however, do require these data be conducted in that country. Should someone be made aware of any of these data which show the residue to be higher than those submitted to the agency, we would both not register in that country plus so inform the agency in the form of a request for higher tolerance.

We can assure the agency that the directions for use in all countries will essentially be the same as those proposed for use in the USA. In no case can we envision either the highest rate being exceeded or the minimum treatment-to-harvest interval being shortened.

Comments/Conclusions, 12(3). If, as the petitioner now claims, he does not yet know into which foreign countries he intends to market this product for the use proposed on sugarcane, his request for a tolerance for such a use would seem to be somewhat premature. No field data reflecting use in any foreign country to support the proposed tolerance has, as yet, been submitted to us; yet, the petitioner states that many countries do require residue data from studies conducted in their respective countries, presumably prior to permitting widespread commercial use of a product. We do not consider it unreasonable to expect that some such data should also be submitted for our consideration prior to expecting us to recommend for a tolerance for a foreign use.

We do not consider this deficiency resolved. For further consideration of the proposed foreign use of glyphosate on sugarcane, we will want to know what specific foreign countries are to be involved, a reiteration/reconfirmation of the specific proposed use pattern(s) for each country, and a representative amount of residue data from field studies conducted in the foreign countries in question via the proposed use(s) to demonstrate support of the proposed tolerance(s).

Deficiency 3b. We do not consider the setting of a food additive tolerance for the semi-processed commodity, raw sugar, to be appropriate. The appropriate related commodities to regulate are the r.a.c. sugarcane per se and the processed item, refined sugar. Since residues did not concentrate in refined sugar, no food additive tolerance is required therefor. A revised Section F deleting the proposed raw sugar tolerance is needed. (Note: this is consistent with our policy of regulating residues in refined oils, but not the crude oils from which they are derived).

Petitioner's Response, 3b. A revised Section F which, among other revisions (see deficiencies 3c and 4b), deletes the previously proposed food additive tolerance for residues in raw sugar is submitted as requested.

Comments/Conclusions, 3b. This deficiency is resolved.

Deficiency 3c. Concentration of residues does occur in sugarcane molasses. A 20 ppm food additive tolerance--based on a 10X concentration in the processing of raw cane to molasses--is presently proposed. A tolerance based on a 15X concentration factor would be more appropriate. A revised Section F will be needed. (In view of Conclusion 3a, we are not certain at this time what the ppm tolerance value for molasses should appropriately be. A level of 30 ppm appears likely, provided Conclusion 3a is satisfactorily resolved).

Petitioner's Response, 3c. A revised Section F which, among other revisions (see deficiencies 3b and 4b), raises the proposed food additive tolerance level for sugarcane molasses from 20 ppm to 30 ppm is submitted as suggested.

Comments/Conclusions, 3c. This deficiency is resolved.

Deficiency 4b. We classify the proposed use within 40 CFR 180.6(a)(2) with respect to the likelihood of secondary residues occurring in the kidney and liver of cattle, goats, hogs, horses, poultry, and sheep.

Contingent upon a 30 ppm food additive tolerance level proving acceptable for sugarcane molasses (see Conclusion 3c), we conclude that a 0.2 ppm tolerance will be needed for cattle kidney; levels of 0.1 ppm (presently established tolerance level) will suffice for the kidney of other animals and for the liver of all the aforesaid animals. however, we suggest that for administrative convenience and ease of enforcement, these tolerances be uniformly raised to 0.2 ppm for the kidney and liver

of cattle, goats, hogs, horses, poultry, and sheep. A revised Section F is needed. (Note: These conclusions will be subject to reconsideration if more than a 30 ppm food additive tolerance level proves appropriate for sugarcane molasses).

Petitioner's Response, 4b. A revised Section F which, among other revisions (see deficiencies 3b and 3c), proposes tolerances for the liver and kidney of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm is submitted as requested.

Comments/Conclusions, 4b. This deficiency is resolved.

Deficiency 5a. We require written assurance that adequate regulatory controls (legislation/enforcement) exist in each foreign country of intended use for the oversight of pesticide usage.

Deficiency 5b. We also require written assurance that the foreign labels for this use have been or will be registered with the appropriate regulatory authority in each country.

Petitioner's Response, 5a and 5b. It is beyond the scope of Monsanto to assure the agency that adequate regulatory controls exist in each of these countries. Before commercial introduction of this product in any country, Monsanto can assure the agency that all regulatory requirements of that country will be complied with. This will include proper preparation and filing of use directions as required.

Comments/Conclusions, 5a and 5b. As stated in Conclusion 3(a)(2), we reiterate the need for information as to which specific foreign countries will be involved in the proposed use. We herein also reiterate our need for assurance that each of those countries has some form of regulatory control over pesticide usage. We accept the petitioner's assurance that use directions will be filed, as required, in each country, but we request reconfirmation of the specifics of the proposed use pattern(s) for foreign usage. These deficiencies are not yet fully resolved.

Other Considerations

In our aforecited review we stated that:

"Since this is a foreign use only, as presently proposed, we are not concerned re residues in feed by-products which would not be exported, i.e., bagasse and forage/fodder. (Residue data indicates no concentration in bagasse; no information is provided on the forage/fodder).

"The petitioner should be advised, however, that if this use is subsequently extended to include the USA and/or its territories, either a label restriction precluding the feed use of sugarcane forage and fodder or residue data and a tolerance proposal therefor will be needed."

The petitioner was apprised of this eventuality via the aforesaid reject letter. As part of this current submission, the petitioner has brought to our attention their previously submitted (6/26/79 to P.M. 25, IL) not serviced to ILS until we inquired about a related matter on 4/11/80) label proposing domestic usage of their product, sodium sesqui salt of glyphosate in or on sugarcane and its processed fractions when this product is applied as a plant growth regulator. That label includes a restriction, "do not feed or forage treated sugarcane," thus alleviating our concerns on this issue. We note the label in question uses the trademark Tolaco Plant Growth Regulator to replace the 100-2000 code name which Monsanto inventories (6/24/79 cover letter transmitting the label) will no longer be used.

Although ILS was not made aware of it until 4/11/80 (telephone with P.M. 25, IL), long after our initial review of this petition, the petitioner has actually been requesting both foreign and domestic plant growth regulator usage for the sodium sesqui salt of glyphosate in or on sugarcane since 7/18/79 when a letter to that effect was sent by the petitioner to IL.

The proposed domestic usage is for foliar application of Tolaco[®] Plant Growth Regulator, a water-soluble powder containing 75% a.i. in the form of the sodium sesqui salt of L-(phosphonomethyl) glycine. The details in the formulation are not specified, but we believe them to be the same as for the previously proposed 100-2000 product; also, we think the only change is in the name of the formulated product. However, we request clarification of this; a Confidential Statement of Formula for this Tolaco[®] Plant Growth Regulator product should be submitted. (Note: the P.M. does not have this information in his files).

The Tolaco[®] formulation is to be applied to growing sugarcane with either airplane or helicopter aerial spray equipment at recommended rates (see below) in 10 or more gallons of water per acre. Directions for use are specified for IL, LA, TX, and HI. In IL, LA, and TX, apply 0.5-0.7 lbs of the product per acre 3-6 weeks before harvest of first ratoon cane only. In HI, apply 0.5-1.2 lbs. of the product per acre 4 to 10 weeks before harvest.

Label restrictions include: Do not apply to any crops other than sugarcane. Do not apply to sugarcane to be harvested for seed purposes. Do not feed or forage treated sugarcane. Do not rotate crops other than corn (all), soybeans, small grains, forage grasses, beans (edible), cotton, or sorghum for one year following application.

The available residue data to support the proposed domestic usage consists of the 7 field studies (TX, LA, 2HI, 2 FL, PR) previously submitted with this petition (see review of M. Nelson, 10/9/79; four of those studies--TX, LA, 2HI--had also been earlier submitted with PF# 6G2060, see M. Nelson review of 9/22/78 thereon), plus the 2 additional studies from HI (see Conclusion 3a(1) for discussion thereof). There is also processing study data available in conjunction with various of the field studies.

Recommendations

Based on the field study and processing data, we conclude there is adequate information available to recommend in favor of the proposed tolerances for combined residues of the sodium sesqui salt of glyphosate and its aminomethylphosphonic acid metabolite in or on sugarcane (2 ppm) and sugarcane molasses (30 ppm), resulting from domestic usage as a plant growth regulator, and for the raising to 0.2 ppm of the existing tolerance on liver and kidney of cattle, goats, hogs, horses, poultry, and sheep. Our favorable recommendation is contingent upon its being confirmed that the Polaco[®] formulation contains cleared inerts (a Confidential Statement of Formula for this product should be submitted), and upon toxicological considerations permitting.

We would not favor the proposed foreign usage at this time for the reasons discussed in Conclusions 3a(2) and 5a, above. For further consideration of such a foreign usage, the following should be submitted:

1. A listing of the specific foreign countries where the product will be used on sugarcane;
2. A reconfirmation of the proposed use pattern(s) for each country;
3. A limited but representative number of field studies from those foreign countries which reflect proposed use conditions; and,

4. Assurance that those countries have regulatory oversight of pesticide usage.

Note to P.M.: If/when these tolerances are established, some manipulation of the phraseology used in the present regulations (40 CFR 180.364; 21 CFR 193.235, 561.253) will be necessitated. There are, presently, established permanent tolerances on sugarcane (0.1 ppm) and sugarcane molasses (2 ppm) from a herbicidal usage of glyphosate, isopropylamine salt. These tolerances will be supplanted by the higher tolerances (if/when established) for sugarcane (2 ppm) and sugarcane molasses (30 ppm) of this petition. However, these higher tolerances are from plant regulator use of the sodium sesqui salt of glyphosate. Thus, it will need to be clearly indicated in the text of each section (180.364; 193.235, 561.253), as applicable, that the sugarcane and sugarcane molasses tolerances--unlike the other commodities having established tolerances within those sections--are for combined residues of glyphosate and its aminomethylphosphonic acid metabolite resulting from application of glyphosate isopropylamine salt for herbicidal purposes and/or the sodium sesqui salt for plant growth regulator purposes. These same considerations will also apply to the liver and kidney tolerance which will need to be raised from its present 0.1 ppm to 0.2 ppm to cover the higher residues resulting from the plant regulator use on sugarcane of the sodium sesqui salt.

Nelson

INTERNATIONAL SPECIAL LIMIT STATUS

CHEMICAL CYPERMETHRIN 42

PETITION NO. 42122/885190

CDA No. 2010

CODE STATUS

REGIONS V. L. TOLERANCES

 to Code Regional
 101 & 01 above

Residue (at 0.1%)

Residue: glycolate and
acetate/ethyl/propyl ester

(101/01) Limit (ppm)

(101/01) Tol. (ppm)

ppm

sugarcane 2

liver and kidney
of cattle, goats,
hogs, swine,
poultry, sheep

corn 20 (FAT)

CANADIAN LIMIT

MEXICAN TOLERANCE

Residue

Residue

Code Limit (ppm)

Code Tolerance (ppm)

None 1/

None

Notes: 1/ These are "glycolate" negligible residue limits
in other countries at 0.1 ppm