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

CONFIDENTIAL

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

AUG 8 1990

MEMORANDUM

SUBJECT: PP#8F3607: Glufosinate-Ammonium (IGNITE) in or on Soybean Seed, Apples, Grapes, Field Corn (Grain, Forage, Fodder, and Silage), Nuts, and Almond Hulls. Amendment of 12/12/89. MRID Nos. 413231-01 through 413231-013. DEB No 6195.

FROM: Joel Garbus, Ph.D., Chemist
Tolerance Petition Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D, Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Joanne Miller, PM-23
Fungicide - Herbicide Branch
Registration Division (H7505C)

Hoechst-Celanese has petitioned for permanent tolerances for the herbicide glufosinate-ammonium (Ignite), monoammonium 2-amino-4-(hydroxymethylphosphinyl) butanoate, and its metabolite, 3-methylphosphinicopropionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid, in or on soybean seed, apples, grapes, field corn (grain, forage, fodder, and silage), and nuts at 0.05 ppm and in or on almond hulls at 0.50 ppm.

DEB in its review (J. Garbus, 5/23/89) identified deficiencies associated with Product Chemistry, Sections B and F, plant and animal metabolism, analytical methodology, and animal feeding studies. Hoechst-Celanese has responded by providing additional data and submitting revised Sections B and F.

Deficiencies Still Remaining

1. DEB recommends that the chemical name ammonium DL-homoalanine-4-yl (methyl phosphinate) be used in the proposed tolerance expression. A revised Section F should be submitted.

2. The revised label as submitted has not been corrected to remove the restriction on feeding treated corn forage and fodder. The petitioner should submit a revised Section B deleting the feeding restriction for treated corn forage and fodder.

3. The label as submitted does not reflect the changes that the petitioner states have been made in regard to the use of terbacil in tank-mixes. Terbacil is not registered for use on nuts other than pecans. The petitioner should submit a revised Section B with the use of terbacil on nuts restricted to pecans only.

4. DEB concludes that sufficient secondary residues in cattle kidney and liver and in poultry kidney tissues could occur from the pre-emergent use proposed in this request to require the proposal of tolerances for these commodities. The petitioner needs to propose tolerances at the limit of detection for milk, eggs, and meat and meat by-products of cattle goats, hogs, horses, and sheep, and livestock liver and kidney, including poultry. This will entail the submission of a revised Section F including tolerances for these commodities and of a proposed enforcement analytical methodology. The validation of the method by an independent laboratory and by the Agency will determine the limit of detection that will in turn determine the appropriate tolerance.

Recommendation

DEB continues to recommend against the proposed tolerances for glufosinate-ammonium in or on soybean seed, apples, grapes, field corn (grain, forage, fodder, and silage), and nuts at 0.05 ppm and in or on almond hulls at 0.50 ppm until these deficiencies cited above are resolved.

Note to PM: This chemical is a racemic mixture of which only the L isomer is an the active pesticide. Consequently the D isomer can be considered an impurity. The registered label should state only the concentration of the active L isomer. The appropriate branch of the Agency concerned with efficacy should verify that only the L isomer has pesticidal activity.

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Conclusions Manifesting Deficiencies

Below we shall restate all of the deficiencies as identified in our original review, give the petitioner's responses, and give our comments and conclusions.

Deficiency 1a.

> The registrant has not provided a Confidential Statement of Formulation (CSF) for technical glufosinate-ammonium. A CSF for technical glufosinate-ammonium is needed with certified limits based upon the results of the analyses of production batches. The CSF for technical glufosinate-ammonium must list all of the impurities that are present in the material at levels greater than 0.1%.

Response

Hoechst-Celanese has submitted a Confidential Statement of Formula (CSF) for technical glufosinate-ammonium. (See Confidential Appendix.)

Comment and Conclusion

Based upon Hoechst-Celanese's discussion of the formation of potential impurities and its analyses of five production lots for the components listed on the CSF, (See below.), the CSF for technical glufosinate-ammonium is satisfactory.

Deficiency 1b.

> Glufosinate is a substituted amino acid containing an asymmetric carbon atom. Hoechst's label states that the formulated material contains 1.67 lbs active per gallon. The petitioner should either inform the Agency whether both optically active isomers are active as herbicides or identify the active one. If only one isomer is herbicidally active, the label for the formulated product should express the content of the active material as pounds of the active isomer.

Response

The petitioner has submitted a revised label on which the active ingredient is identified as Ammonium-DL-homoalanine-4-yl (methyl phosphinate). Although the L-isomer is the herbicidally active component, registration studies were conducted with the racemic mixture. Until it is feasible to manufacture the active isomer, the petitioner will continue to express the active as the DL racemate.

Comment and Conclusion

Identifying the active ingredient as the DL racemate of ammonium-homoalanine-4-yl (methyl phosphinate) on the CSF and on the label alleviates DEB's concerns regarding the recognition that the active ingredient possesses stereoisomerism. DEB recommends using this chemical name as the acceptable name until glufosinate has been accepted as an ANSI name. A revised Section F for the requested tolerances should also be submitted using ammonium-DL-homoalanine-4-yl (methyl phosphinate).

According to the petitioner glufosinate is a racemic mixture of which only the L isomer is an the active pesticide. Consequently the D isomer can be considered an impurity. The registered label should state only the concentration of the active L isomer. The appropriate branch of the Agency concerned with efficacy should verify that only the L isomer has pesticidal activity. As the DL mixture was used in TOX studies, unless TOX holds otherwise, the chemical expression of the racemic mixture should be part of the tolerance expression

The deficiency regarding the stereoisomeric form of the active ingredient can be considered resolved until the active isomer is enriched in formulations.

Deficiency 2.

> The registrant has not provided any discussion of the formation of impurities, although production lots of glufosinate-ammonium were analyzed for impurities (See below). It will be necessary for the registrant to provide a discussion of potential impurities in technical glufosinate-ammonium, following the product chemistry guidelines.

Response

The petitioner has submitted two reports entitled "Hoe 039866, Glufosinate-Ammonium Technical, Description of Starting Materials and Manufacturing Process" (Hoechst Report No. A39167) and "Hoe 039866, Glufosinate-Ammonium Technical, Discussion of the Formation of Impurities" (Hoechst Report No. A42093).

The description of the manufacturing process for glufosinate-ammonium given in the newly submitted report is complete and detailed. Included are the names and addresses of the suppliers of the starting materials and the technical specifications of these materials, including the nature and levels of impurities.

The second of the newly submitted reports contains a detailed discussion of the formation of possible impurities. The discussion considers possible impurities arising from reactions involving impurities in the starting materials, side reactions that are

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theoretically possible in the manufacturing process, and impurities resulting from the use of particular solvents. The discussion concludes that [redacted]

Comment and Conclusion

The information in the newly submitted report meets the guideline requirements for the pertinent sections of the Product Chemistry Guidelines.

This deficiency is resolved.

Deficiency 3.

For the analyses of production lots only [redacted] would be present. The potential formation of compounds related to and derived from the starting materials through side reactions is not discussed.

In the absence of an adequate discussion of impurities, we consider the analyses of production lots only for simple molecules as not meeting the product chemistry data requirements. It will be necessary for the petitioner to analyze an additional five production batches and identify all impurities which are present at levels greater than 0.1%

The descriptions of the analytical procedures for these analyses must include raw data, i.e., representative chromatograms, and validation data demonstrating accuracy and precision. The rationale for the determination of certified limits must be presented.

Response

The petitioner has submitted a report: Glufosinate-Ammonium Analysis of Five Typical Production Batches and Analytical Methods. The results of the analyses and descriptions of the analytical methods used are presented in the Confidential Appendix. The technical production material was examined for the impurities identified in the discussion of impurities.

Comment and Conclusion

The response to this deficiency is satisfactory. The deficiency is resolved.

Deficiency 4a.

The proposed label should clearly explain that the use of the term "post-emergent" refers to undesirable vegetation and not to crops.

Response

The petitioner has submitted a revised label in which the term "post-emergent herbicide" is no longer used to describe glufosinate-ammonium. The label now states that the product should be applied to weeds prior to the emergence of the crop.

Comment

This deficiency is resolved.

Deficiency 4b.

The proposed label should not carry a restriction on the feeding and grazing of treated corn forage as this conflicts with the request for a tolerance on corn forage and with Agency's policy regarding field corn forage and fodder feeding restrictions.

Response

The petitioner states that the inconsistency has been corrected.

Comment

The revised label as submitted has not been corrected to remove the restriction on feeding treated corn forage and fodder. The deficiency remains.

Deficiency 4c.

The herbicide terbacil (Sinbar) should be removed from the list of recommended herbicides for tank-mixes for use on grapes and nuts. Terbacil is not registered for use on grapes or nuts other than pecans. It is suggested for these uses on the proposed label.

Response

The petitioner states that label has been revised to remove the use of terbacil on grapes and apples(sic) and to add a footnote that the use on nuts is restricted to pecans.

Comment

The label as submitted does not reflect the changes that the petitioner states have been made in this regard. The use on apples is permissible as there is an established tolerance for terbacil on apples. The use of terbacil on nuts is still suggested and a footnote restricting the application of this pesticide to pecans is lacking. The use on grapes has been removed from the label. A revised Section B should be submitted restricting the tank mix use of terbacil to pecans only. The deficiency remains.

Deficiency 5a.

> The proposed enforcement analytical method has not been validated by the Agency. The Analytical Chemistry Section has stated that before ACS can initiate their laboratory work deficiencies in the description of the proposed enforcement methodology must be addressed or resolved. These deficiencies have been brought to the attention of the petitioner.

Response

The petitioner responded to the problems pointed out by the Analytical Chemistry Section by submitting a revised analytical method.

Comment

The revised analytical method has been successfully validated by the Analytical Chemistry Section. (See J. Garbus memo 9/14/89.) This deficiency is resolved.

Deficiency 5b.

> If only one isomer is shown to be pesticidally active, the enforcement analytical method should be capable of determining the percentage of this isomer in residues.

Response

As active material is described in terms of the racemic mixture on the label and as residue levels and tolerances are expressed as levels of both isomers, it is sufficient to employ a method that determines both.

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Comment

DEB concludes that until the active isomer is enriched in pesticidal preparations the proposed methodology is adequate. This deficiency is resolved.

Deficiency 6.

Storage stability studies are described by the petitioner as preliminary. It will be necessary for the petitioner to provide evidence of storage stability of residues for the actual lengths of time and under the conditions that the treated agricultural commodities were stored.

Response

The petitioner has extended the storage time of commodities of the residue trials to encompass the actual time commodities were stored prior to analyses. The results are given in two Studies entitled:

Supplement to storage stability study in biological materials, (B0123/87, extending results to storage periods 18 and 24 months. (Hoechst Report No. A39283)

(Hoe 039866) Supplement to storage stability study in biological materials, (B0123/87, extending results to storage periods 18 and 24 months. (Hoechst Report No. A39283)

The following table summarizes the results:

Interval	Residue	Commodity	Recovery
0 Months	039866	Apples	65%
8 Months	039866	Apples	88%
18 Months	039866	Apples	67%
24 Months	039866	Apples	91%
0 Months	039866	Corn Grain	80%
8 Months	039866	Corn Grain	85%
18 Months	039866	Corn Grain	101%
24 Months	039866	Corn Grain	99%
0 Months	039866	Soybeans	78%
8 Months	039866	Soybeans	89%
18 Months	039866	Soybeans	60%
24 Months	039866	Soybeans	101%
0 Months	061517	Apples	85%
8 Months	061517	Apples	74%
18 Months	061517	Apples	87%
24 Months	061517	Apples	85%

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Interval	Residue	Commodity	Recovery
0 Months	061517	Corn Grain	95%
8 Months	061517	Corn Grain	89%
18 Months	061517	Corn Grain	123%
24 Months	061517	Corn Grain	75%
0 Months	061517	Soybeans	65%
8 Months	061517	Soybeans	84%
18 Months	061517	Soybeans	85%
24 Months	061517	Soybeans	97%

Comment

The petitioner has demonstrated the storage stability of residues over the interval of storage for commodities in residue trials. The deficiency is resolved

Deficiency 7a.

A complete description is needed of the plant metabolism study conducted with hydroponically grown lettuce.

Deficiency 7b.

Additional studies and discussions are needed to account for the unidentified radioactivity in the plant and animal metabolism studies. The petitioner should conduct studies to demonstrate that the unextractable radioactivity and the unidentifiable, extractable radioactivity does indeed represent incorporation into benign cellular components and not into bound components with potential residues of concern.

Deficiency 7c.

The nature of the residue in plants and animals is not understood. Pending receipt of the complete details of the lettuce study and of experiments demonstrating the incorporation of small metabolic fragments into natural plant and animal constituents, as a minimum we will consider the parent and its metabolite 3-phosphinicopropionic acid as the residue of concern.

Response

The petitioner has submitted a complete report of the metabolic study conducted with hydroponically grown lettuce: Hoe 039866 ^{14}C Absorption by Lettuce Plants from an Aqueous Solution. Identification of the Radioactive Substances in the Leaves. Report No. A21859 July 18, 1981.

In addition, the petitioner has submitted the results of a new study: Hoe 039866 ^{14}C Uptake, Metabolism, and Residue Determination in Corn Sown Three Days before Treatment of Soil and Grown Under Field Conditions. Determination of the Accountability of the Analytical Residue Method. Report A41451 May 31,1989

Also the petitioner has submitted a document summarizing 12 metabolic studies on plants: Reply to the EPA Dietary Exposure Branch Review Dated October 14, 1988 Hoe 039866 Nature of the Residue in Plants. Report A40566 January 10, 1989

The petitioner concludes that all studies indicate that only one metabolite, 3-methyl-phosphinicopropionic acid, is found in plant material after treatment of the soil with glufosinate-ammonium. In the new corn study, 40% of the recovered radioactivity was not accounted for by this metabolite but was found in natural plant constituents, 7% in protein, <5% in starch, and 30% in insoluble cellulose and lignin. The substrate for the incorporation of glufosinate-ammonium into natural constituents was demonstrated to be $^{14}CO_2$ arising from the soil metabolism of glufosinate-ammonium.

The petitioner has also submitted summaries of animal metabolism studies that point to the same conclusions, i.e., that the only metabolite of significance is 3-methyl-phosphinicopropionic acid and that unidentified radioactivity would be associated with animal cell constituents.

Comment

DEB had reviewed all of the plant metabolism studies in detail with the exception of the hydroponic lettuce study. DEB concluded that after the application of radiolabelled glufosinate to the nutrient medium (water or soil) in which lettuce, soybeans, corn, apples, and wheat were grown, only one labelled metabolite could be identified as a residue in plants, 3-methyl-phosphinicopropionic acid. Further metabolism results in short chain carbon moieties that can be incorporated into cellular constituents. The parent material was never found as a residue.

This postulated metabolic scheme is consistent with the results of all residue studies and with independent studies of the metabolism of glufosinate by microorganisms. However, the petitioner had not conclusively demonstrated that unextractable and unidentified extractable radioactivity is associated with natural plant constituents. DEB concluded that the petitioner should conduct studies to demonstrate this point. Report A41451 summarized above is the response to this request and demonstrates the presence of radioactivity derived from labelled glufosinate in native plant constituents.

It was shown that administered glufosinate and its metabolite are largely excreted and do not accumulate in any great degree in

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animal tissues. The greatest accumulation is these studies was 0.47% of the administered dose in the kidney of the goat sacrificed 8 hours after the last of 5 daily doses.

TLC analyses of extractable radioactivity demonstrated that the only identifiable components in feces, urine, milk, and tissues were the parent and its metabolite. It was assumed that the unidentifiable radioactivity arose from small C fragments and that it was associated with animal tissue components. The extremely low levels of incorporated radioactivity made identification difficult.

The animal metabolism of glufosinate-ammonium appears to be similar to that of plants. The residues of concern in animal tissues, milk, and eggs appear to be the parent and the metabolite 3-methyl-phosphinicopropionic acid.

DEB considers the petitioner's responses to these deficiencies as adequate. For the purposes of the present request, we will consider that the metabolism of glufosinate-ammonium by plants is understood and that the parent and its metabolite, 3-phosphinico-propionic acid, as the residue of concern.

These deficiencies are resolved.

Deficiency 8a.

Pending receipt of additional storage stability studies, DEB concludes that for all commodities except almond nutmeats, the results of the residue trials conducted under proposed label conditions indicate non-detectable residue of glufosinate-ammonium and its metabolite. With the exception of almond nutmeats, the residue data support the requested tolerances for the proposed uses.

Deficiency 8b.

The finding of finite residues in or on almond nutmeat in a residue trial conducted at label rates necessitates a tolerance of 0.10 ppm for this commodity alone with tolerances for each nut of the crop grouping. Alternatively the tolerance for the tree nut crop group could be raised to 0.1 ppm. The submission of a revised Section F will be required.

Response

The requested storage stability studies have been supplied (see above). A revised Section F has been submitted proposing a tolerance of 0.10 ppm for the tree nut crop group.

Comment

These deficiencies are resolved.

Deficiency 9a.

The petitioner will need to conduct feeding studies in ruminants and poultry according to the Residue Chemistry Guidelines to determine the level of residues in animal tissues, milk, and eggs.

Deficiency 9b.

The requirement for animal feeding studies will necessitate the development of analytical methods suitable for animal tissues.

Response

The petitioner has submitted two reports describing the experimental procedures and results of conventional feeding studies conducted with lactating cattle and with poultry. These studies were done in anticipation of a proposed use of glufosinate-ammonium as a pre-harvest desiccant. A methodology for the analysis of animal tissues for glufosinate-ammonium and its metabolite is also submitted.

The petitioner reiterates its position as stated in the original petition that these results also indicate that no detectable residues would result in animal tissues from the uses of glufosinate-ammonium proposed here. Therefore, the proposal of tolerances for animal racs and a methodology for animal tissues consequently are not needed.

Comment

Cattle Feeding Study

The petitioner's feeding study with lactating cattle was done at daily feeding levels of 4, 12, and 40 ppm in the diet. The material that was fed was a 3:1 mixture of parent and metabolite. The diet consisted of 87% corn silage, 10% hay, 2% corn grain, and 1% supplemental minerals, etc. Animals were maintained on this regime for 28 days, milked each day, and sacrificed either at 28 days or at 35 days. Tissues were kept frozen for 16 months pending the development of analytical techniques for glufosinate-ammonium in animal tissues (see below).

No residues of either parent or metabolite were detected in milk, muscle, or blood at any feeding level (4, 12, or 40 ppm). At the lowest feeding level (4 ppm) after 28 days the maximum residue levels found in milk and tissues were as follows:

Matrix	Parent 039866 (ppm)	Metabolite 061517 (ppm)
Milk	<0.02	<0.05
Muscle I	<0.05	<0.05
Muscle II	<0.05	<0.05
Liver	0.13	1.5
Kidney	<0.1	0.41
Fat	0.06	<0.05

Only three tissues demonstrated detectable levels of residue at a feeding level of 4 ppm, liver with a combined total residue of 1.63 ppm, kidney with about 0.5 ppm, and fat with about 0.06 ppm. At the higher feeding levels of 12 and 40 ppm, liver, kidney, and fat had detectable residues.

Matrix	Parent 039866 Max. Res (ppm)	Metabolite 061517 Max. Res. (ppm)
Liver		
3X (12 ppm)	<0.1	4.2
10x (40 ppm)	<0.1	10.7
Kidney		
3X (12 ppm)	<0.1	2.0
10x (40 ppm)	0.13	7.4
Fat		
3X (12 ppm)	<0.05	0.08
10x (40 ppm)	<0.05	0.16

The feeding levels in this study were 8 to 80 fold greater than the tolerances proposed in this petition. If we assume that the diet fed the animals in this study had been treated as proposed in this petition, the diet could have contained 0.045 ppm residues (90% corn forage and grain at the proposed tolerance of 0.05 ppm). If tissue residues are presumed to be proportionate to levels fed, under this feeding regime using the 4 ppm feeding level, liver tissue could contain 0.02 ppm (0.045/4.0 x 1.68 ppm) and kidney would contain 0.005 ppm (0.045/4.0 x 0.5 ppm). Similar results are obtained if we use the tissues residues found at the higher feeding levels. In all instances the calculated residues in liver and kidney are finite but below the reported limit of detection of the proposed analytical method for these matrices.

If we assume that cattle are fed a possible though improbable diet containing the greatest residue levels from the currently proposed uses (80% corn-20% almond hulls), the situation is the same. Such a diet could contain 0.14 ppm and would result in residues of 0.06 ppm in liver and 0.02 ppm in kidney. These are finite residues and

are still below the limit of detection of the proposed analytical method for these matrices.

Poultry Feeding Study

The petitioner's feeding study with laying hens was done at daily feeding levels of 4.5, 13.5, and 45 ppm in the diet. The material that was fed was a 3.5:1 mixture of parent and metabolite. The diet consisted of 42% corn grain, 20% wheat grain, 18% soybean meal, 6% alfalfa, and 13% supplemental minerals, etc. The hens were maintained on this regime for 28 days, eggs collected each day, and sacrificed either at 28 days or at 35 days. Tissues were kept frozen for 16 months pending the development of analytical techniques for glufosinate-ammonium in animal tissues (see below).

At 28 days the maximum residue levels found in eggs and tissues at this feeding level were as follows:

Matrix	Parent 039866 (ppm)	Metabolite 061517 (ppm)
Eggs		
1X (4.5 ppm)	<0.05	<0.05
3X (13.5 ppm)	<0.05	<0.05
10X (45 ppm)	0.07	<0.05
Muscle I		
1X (4.5 ppm)	<0.05	<0.05
3X (13.5 ppm)	<0.05	<0.05
10X (45 ppm)	<0.05	<0.05
Muscle II		
1X (4.5 ppm)	<0.05	<0.05
3X (13.5 ppm)	<0.05	<0.05
10X (45 ppm)	<0.05	<0.05
Liver		
1X (4.5 ppm)	<0.1	<0.1
3X (13.5 ppm)	<0.1	<0.1
10X (45 ppm)	<0.1	<0.1
Kidney		
1X (4.5 ppm)	<0.05	0.69
3X (13.5 ppm)	0.07	2.0
10X (45 ppm)	<0.05	7.8

Matrix	Parent 039866 (ppm)	Metabolite 061517 (ppm)
Fat		
1X (4.5 ppm)	<0.05	<0.05
3X (13.5 ppm)	<0.05	<0.05
10X (45 ppm)	<0.05	<0.05

Only one organ demonstrated detectable levels of residue, kidney with about 0.75 ppm at 4.5 ppm in the feed, 2.7 ppm at 13.5 ppm , and 7.8 ppm at 45 ppm. If poultry were to be fed diets derived from the commodities of this petition, the diet could have contained 0.03 ppm residues (42% corn grain and 18% soybean meal at the proposed tolerance of 0.05 ppm). If tissue residues are presumed to be proportionate to levels fed, under this feeding regime kidney tissue could contain 0.05 ppm (0.03/4.5 x 0.78 ppm). This is a finite residue but below the reported limit of detection of the proposed analytical method for this animal matrix.

If we assume that poultry are fed a possible diet containing the greatest residue levels from the currently proposed uses (70% corn grain-30% soybeans), the situation is the same. Such a diet could contain 0.05 ppm and would result in residues of 0.08 ppm in poultry kidney. This is a finite residue both still below the limit of detection of the proposed analytical method for residues in kidney.

Analytical Methods for Animal Matrices

The analytical methods used to determine residue levels of glufosinate-ammonium in animal matrices in general are similar to those used with plant materials. Water extracts of tissues are diluted with acetone to precipitate protein and, after centrifugation, subjected to anion ion-exchange chromatography. The formic acid eluant is derivitized with trimethyl orthoacetate and cleaned up on silica gel. Aliquots are subjected to gas chromatography and residues of glufosinate-ammonium and its metabolite quantified by a P sensitive flame detector.

Recoveries for glufosinate-ammonium and its metabolite from spiked animal tissues, milk, and eggs ranged from 62 to 124 percent. The practical limit of detection for milk is given as 0.02 ppm, for liver and kidney as 0.1 ppm and for other tissues and eggs as 0.05 ppm. However, no rationale can be discerned for arriving at these limits of detection.

Conclusion

In its reports of the feeding studies with cattle and poultry, the petitioner concludes that it would be necessary to propose tolerances for secondary residues of glufosinate-ammonium for cattle liver and kidney and for poultry kidney if glufosinate-

ammonium is used as a pre-harvest desiccant. However, the petitioner concludes that such tolerances are not needed for the proposed use as a pre-emergent herbicide.

DEB concludes that the proposed use of this petition leads to a 180.6(a)2 situation i.e., sufficient secondary residues in certain animal tissues could occur from the pre-emergent use to require the proposal of tolerances. Although the estimations of potential residues in animal tissues based upon the reported feeding studies are below the stated limits of detection for glufosinate-ammonium in kidney and liver, these calculated values are reasonably close to the stated practical limits of detection. Further, the rationale for arriving at the limits is not explained.

DEB concludes that the petition should propose tolerances for secondary residues at the purported limits of detection [0.02 ppm for milk. 0.05 ppm for eggs, 0.05 ppm for meat and meat by-products (except liver and kidney) of cattle, goats, hogs, horses and sheep, and 0.1 ppm for livestock liver and kidney, including poultry].

This will entail the submission of a revised Section F including tolerances for these commodities and submission of a proposed enforcement analytical methodology. The validation of the method by an independent laboratory and by the Agency will be required. The results of the independent validations will determine the limits of detection and consequently the tolerances that finally should be proposed.

cc with CBI: PM-23, PP8F3607, SF., RF., Reviewer, FOD/PIB(Furlow)
cc without CBI: circ.
RDI: PE:8/7/90:RDS:8/7/90
H7509C:DEB:JG:jg:CM:2:Rm:803:557-1405:8/8/90.

GLUFOSINATE

Page_____ is not included in this copy.

Pages 17 through 18 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

X___ Description of the product manufacturing process.

X___ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.