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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Residue Chemistry Chapter for the Parathion Reregistration Eligibility Decision (RED) Document.
DP Barcode No.: D240986
Chemical No.: 057501
Reregistration Case No.: 0155

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist *Bonnie Cropp-Kohlligian*
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Health Effects Division [7509C]

THRU: *Alan P. Nielsen*
Alan P. Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division [7509C]

TO: Richard Griffin
Reregistration Branch II
Health Effects Division [7509C]

And

Arnold Layne/William Sproat
Reregistration Branch I
Special Review and Reregistration Division [7508W]

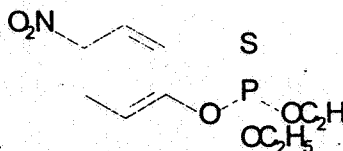
Attached is the Residue Chemistry Chapter for the Parathion RED document. This document was prepared by Dynamac Corporation under the supervision of HED and revised by the Branch to reflect Agency policies.

Attachment: Residue Chemistry Chapter for the Parathion RED Document.

cc: BLCKohlligian (RRB2), Parathion Reg. Std. File, Parathion SF, RF.
7509C:RRB2:BLCKohlligian:CM#2:Rm 804E:703-305-7462: 5/18/98.

1998

Parathion



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 057501; Case 0155

INTRODUCTION

Parathion [*O,O*-diethyl *O-p*-nitrophenyl thiophosphate] is an insecticide registered for use on alfalfa, barley, corn, cotton, rape seed, sorghum, soybean, sunflower, and wheat. Parathion is manufactured by Cheminova Agro A/S, the basic producer, under the trade name Ethyl Parathion. Parathion formulations registered by the basic producer for use on food/feed crops include three emulsifiable concentrate (EC) formulations. These products may be applied as broadcast foliar applications using only aerial equipment. Multiple Active Ingredient (MAI) formulations of parathion are registered in combination with methyl parathion.

REGULATORY BACKGROUND

Parathion is a List A reregistration chemical and was the subject of a Registration Standard dated 4/8/85, its associated Guidance Document dated 12/86, and a Reregistration Standard Update dated 8/17/93. A Data Call-In (DCI) Notice for parathion was also issued 3/14/96. These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Update was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of parathion.

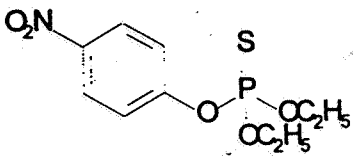
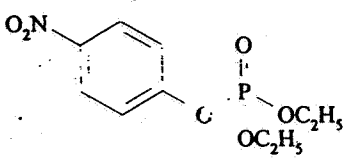
Due to the Agency's concern about worker exposure to parathion, the Agency and registrants of parathion products reached an agreement (*Federal Register Notices Vol. 56, No. 240 dated 11/13/91; and Vol. 57, No. 19 dated 1/29/92 and No. 34 dated 2/20/92*) under which uses of

parathion would be allowed only on the following food/feed crops: alfalfa, barley, canola, corn, cotton, sorghum, soybean, sunflower, and wheat. This agreement also required that label directions for parathion products be amended to allow only aerial applications by certified commercial applicators and only mechanical harvesting of treated crops; hand-harvesting of parathion-treated crops was to be prohibited.

Tolerances for residues of parathion or its methyl homolog (methyl parathion) in/on raw agricultural commodities (RACs) have been established under 40 CFR §180.121(a) and §180.319. No tolerances for residues of parathion have been established for animal commodities or processed food/feed commodities.

The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlhligian dated 5/21/98) has concluded that parathion residues of concern in plant commodities include parathion, its metabolite paraoxon [*O,O*-diethyl-*O-p*-nitrophenyl phosphate], and *p*-nitrophenol and that parathion residues of concern in animal commodities include parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon. The tolerance expression for plant and animal commodities may be based on parathion only. Parathion residues of concern to be included in the risk assessment for plant commodities will include parathion and paraoxon. Parathion residues of concern to be included in the risk assessment for animal commodities will include parathion, paraoxon, and 4-acetamidoparaoxon. Residues of *p*-nitrophenol resulting from the use of parathion do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The chemical names and structures of parathion, paraoxon, and 4-acetamidoparaoxon are depicted in Figure A.

Figure A. Chemical names and structures of parathion and its residues of concern in plant and animal commodities.

| Common Name/Chemical Name | Chemical Structure |
|--|--|
| <p>Parathion</p> <p><i>O,O</i>-diethyl-<i>O-p</i>-nitrophenyl thiophosphate</p> |  |
| <p>Paraoxon</p> <p><i>O,O</i>-diethyl-<i>O-p</i>-nitrophenyl phosphate</p> |  |

| Common Name/Chemical Name | Chemical Structure |
|--|--------------------|
| <p>4-Acetamidoparaoxon</p> <p><i>O,O</i>-diethyl-<i>O</i>-4-acetamidophenyl phosphate</p> | |

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 2/24/98 indicates that there are three parathion end-use products (EPs) with uses on food/feed crops registered to Cheminova Agro A/S. These EPs are presented below.

Parathion End-Use Products with Food/Feed Uses Registered to Cheminova Agro A/S.

| EPA Reg No. | Label Acceptance Date | Formulation Class | Product Name |
|-------------|--------------------------|----------------------|-------------------------------|
| 4787-15 | 12/96 | 4 lb/gal EC | PARATHION 4 EC |
| 4787-16 | 12/96 | 8 lb/gal EC | PARATHION 8 EC |
| 4787-19 * | 12/96 | 6 lb/gal EC | ETHYL-METHYL PARATHION 6-3 EC |

* This product is a MAI that also includes methyl parathion (3 lb/gal EC) in addition to the 6 lb ai/gal of parathion.

In accordance with an agreement between the Agency and the registrants of parathion products, uses of parathion are limited to the following feed/food crops: alfalfa, barley, canola, corn, cotton, sorghum, soybean, sunflower, and wheat. A review of the above end-use product labels and supporting residue data indicate that the following label amendments are required:

Use directions for wheat on all end-use product labels should be amended to specify a maximum of two applications per season at 0.75 lb ai/A/application at a minimum RTI of 14 days and a minimum PHI of 15 days.

Use directions for rape seed on all end-use product labels should be amended to specify a maximum of two applications per season at 0.5 lb ai/A/application at a minimum RTI of 7 days and a minimum PHI of 28 days. End-use product labels should be amended to allow use on the canola variety of rape only.

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Use directions for sorghum on all end-use product labels should be amended to specify: (i) use only on sorghum types grown for grain, (ii) a maximum of two applications per season at up to 1 lb ai/A/application, (iii) a 5-day minimum RTI, (iv) a 12-day PHI for forage and a 28-day PHI for grain and stover, and (v) a minimum spray volume of 5 gallons of water per acre.

If the registrant chooses not to develop residue data on soybean forage, use directions for soybeans should be amended to prohibit the grazing or feeding of treated soybean forage to livestock.

A comprehensive summary of the registered food/feed use patterns of parathion, based on the end-use product labels registered to Cheminova Agro A/S, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of parathion is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of parathion food/feed uses are based on the use patterns registered by the basic producer, Cheminova Agro A/S. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on cotton, potato, and wheat metabolism studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) concluded that based on available plant metabolism data, parathion residues of concern in/on plant commodities are parathion, paraoxon, and *p*-nitrophenol. Parathion residues of concern to be included in the risk assessment for plant commodities based on cholinesterase inhibition will include parathion and paraoxon. The tolerance expression may be based on parathion only since detectable levels of paraoxon have not been found in/on commodities tested by FDA monitoring. Residues of *p*-nitrophenol resulting from the use of parathion do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its use as a fungicide on leather. Residues of parathion, paraoxon, and *p*-nitrophenol should be determined in/on plant samples collected from future plant magnitude of the residue studies.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based on acceptable ruminant and poultry metabolism studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) tentatively concluded that based on available animal metabolism data, parathion residues of concern in animal commodities are parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon. [Note: Livestock feeding studies remain outstanding.] Parathion residues of concern to be included in the risk assessment for animal commodities based on cholinesterase inhibition will include parathion, paraoxon, and 4-acetamidoparaoxon. As with plants, the tolerance expression may be based on parathion only. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for parathion but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its use as a fungicide on leather. Residues of parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon should be determined in meat, milk, poultry, and egg tissue samples from the required livestock feeding studies.

NOTE: Toxicology deems 4-acetamidoparaoxon of concern due to potential cholinesterase inhibition. However, if the registrant can demonstrate that 4-acetamidoparaoxon is much less toxic than parathion, feeding study data will not be needed for 4-acetamidoparaoxon and 4-acetamidoparaoxon residues in animal commodities will not need to be included in the risk assessment for parathion. 4-Acetamidoparaoxon will not be considered a residue of concern if the acute oral LD₅₀ is more than 200 mg/kg. If the acute oral LD₅₀ is less than 200 mg/kg, additional toxicological testing may be required.

OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of parathion as currently defined. The Pesticide Analytical Manual (PAM), Vol. II lists Methods I(a) and I(b) (PAM, Vol. I multiresidue methods for organophosphates), and (c) and I(d) for parathion.

The registrant has proposed a new enforcement method for plant commodities, which detects parathion and the metabolites paraoxon and *p*-nitrophenol. This method was described in the Parathion Update as the "acidic-extraction" method. In brief, residues in/on non-oily plant matrices are extracted by refluxing in acetone:0.1 N HCl or methanol:0.1 N HCl (80:20; v:v) for 1 hour, cooled, and filtered. Residues are then concentrated, partitioned into ethyl acetate, filtered, and reconcentrated. Residues in/on oily plant matrices are extracted with methanol:0.1 N HCl (80:20; v:v), concentrated, diluted with acetonitrile, and partitioned with hexane. Residues remaining in the acetonitrile extract are then concentrated, partitioned into ethyl acetate, dried over sodium sulfate, and reconcentrated. Residues of parathion and paraoxon in the

resulting ethyl acetate fractions are then determined by GC/flame photometric detection (FPD) in the phosphorus mode. The limits of quantitation are 0.04 ppm for parathion and 0.05 ppm for paraoxon.

The proposed enforcement method also includes procedures for determining *p*-nitrophenol. For the analysis of *p*-nitrophenol, residues in the ethyl acetate extract are concentrated, diluted with hexane, and cleaned-up on a Florisil column eluted with ethyl ether:hexane:methanol:acetic acid (49.5:49.4:1.0:0.1; v:v). Residues of *p*-nitrophenol are then concentrated to dryness, diluted with acetonitrile:0.1% acetic acid in water (45:55; v:v), and determined by HPLC analysis with UV detection (315 nm). The limit for *p*-nitrophenol is 0.02 ppm.

The above methods have been successfully validated using samples of representative plant commodities by both an independent laboratory and by the Agency (D. McNeilly, 11/3/93). The proposed method has also been successfully radiovalidated using samples from plant metabolism studies.

Residue data on crop plants and processed commodities have been collected using the above GC/FPD and HPLC methods with only minor modifications involving changes in solvents and cleanup procedures.

In conjunction with the ruminant and poultry feeding studies, the registrants must provide data validating the analytical method(s) used for determining parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon in meat, milk, poultry, and eggs.

If the feeding studies indicate that tolerances are necessary for residues in animal commodities, then an enforcement method will be required for determining the residues of parathion *per se* in animal commodities. The registrant has proposed GC/FPD enforcement methods (Leoni Methods II, IIa, and III) for residues in animal commodities; these methods have already been successfully radiovalidated using samples from the goat and hen metabolism studies (B. Cropp-Kohlligian, 3/12/97). If tolerances are required for residues in animal commodities, then the proposed enforcement methods must be validated by an independent laboratory, as per *PR Notice 96-1*, prior to being validated by the Agency.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that parathion is completely recovered using FDA Multiresidue Protocols D and E (PAM I Sections 232.4, 211.1, and 212.1). Paraoxon is completely recovered using FDA Protocol D (PAM I Section 232.4), but is not recovered using Protocol E (PAM I Sections 211.1 and 212.1).

OPPTS GLN 860.1380: Storage Stability Data

For purposes of reregistration, the requirements for supporting storage stability data are satisfied for all acceptable residue studies. Generally, residues of parathion and paraoxon are stable in most crop matrices for at least 2 years.

The available storage stability data indicate that residues of parathion and paraoxon are both stable at -20 C for up to 24 months in/on almonds, apples, beans (dry), clover, corn grain, cottonseeds, oranges, peppers, plums, spinach, strawberries, and sunflower seeds, and for up to 45.5 months in/on corn forage and fodder. Parathion is also stable in/on succulent beans stored at -20 C for up to 24 months; however, paraoxon was only stable for up to 6 months at -20 C and declined by ~30% after 24 months of storage. Parathion is also stable at -5 C in canola seed, oil, and processing waste for up to 14 months, and in canola meal for up to 6 months; residues of parathion in meal declined by ~25% after 14 months at -5 C. Residues of paraoxon are stable at -5 C in canola seed, oil, processing waste, and meal for up to 6 months, but declined by 20-35% in these matrices after 14 months of storage.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

For purposes of reregistration, the requirements for magnitude of the residue data in/on plants are fulfilled for the following crops/commodities: canola, corn, cottonseed, grain sorghum, soybean hay, soybean seed, and sunflower. Adequate field trial data depicting parathion residues of concern in/on these crops following applications made according to the maximum or proposed use patterns have been submitted. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Additional residue data are required on alfalfa RACs (forage and hay), aspirated grain fractions, barley RACs (grain, hay, and straw), cotton gin byproducts, soybean forage, and wheat RACs (grain, forage, hay, and straw).

Data are required depicting parathion residues of concern in/on alfalfa forage and hay harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.75 lb ai/A/application with a 7-day RTI. The registrant should refer to OPPTS GLN 860.1500 for information on location and number of field trials required.

Data are required depicting parathion residues of concern in/on aspirated grain fractions (grain dust) derived from grain of parathion treated field corn and grain sorghum. Adequate wheat grain dust data are available indicating that residues of parathion in/on wheat grain dust were 4.5x higher than in/on wheat grain. [Note: Aspirated grain fractions data from soybeans is not required since residues of parathion and paraoxon were below the LOQ (0.05 ppm) in/on soybeans treated with parathion at the 1x use rate.]

Data are required depicting parathion residues of concern in/on barley grain, hay and straw harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.75 lb ai/A/application with a 7-day RTI. The Agency has concurred (B. Cropp-Kohlligian, 9/12/96) that a total of ten tests on barley in regions representative of barley production will be sufficient.

Data are required depicting parathion residues of concern in/on cotton gin byproducts derived from cotton treated with an EC formulation of parathion at the maximum labeled rate and harvested 7 days after the final application using commercial equipment (stripper and mechanical picker). At least three field trials representing each type of harvesting (stripper and picker) are required.

Data are required depicting parathion residues of concern in/on soybean forage harvested 20 days following the last of two foliar applications of an EC formulation of parathion at 1x the maximum label use rate. Alternatively, the registrant may amend all end-use product labels to prohibit the grazing or feeding of treated soybean forage to livestock.

Additional data are required depicting parathion residues of concern in/on wheat grain, forage, hay, and straw harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.75 lb ai/A/application with a 14-day RTI. An additional seven wheat field trials conducted at the 1x rate are required to provide adequate geographic representation and an adequate number of samples for tolerance reassessment. These tests should be conducted in the following Regions: one test each in Regions 2, 4 and 7, two tests each in Regions 5 and 8.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for canola, corn, cottonseed, grain sorghum, and wheat. The available wheat grain processing data will be translated to the processed commodities of barley grain. The available cottonseed and grain sorghum processing studies indicate that residues of parathion do not concentrate in any cottonseed (meal, hulls, or oil) or grain sorghum (flour, grits or starch) processed fractions.

For canola, residues of parathion do not concentrate in canola meal, but concentrate by 1.5x in refined canola oil. Based upon this concentration factor and the current HAFT value of 0.13 ppm for residues of parathion in/on canola seed, a tolerance for residues of parathion in canola oil is not required.

For field corn grain, residues of parathion do not concentrate in corn meal, flour, grits or starch, but concentrate on average by ~3x in refined corn oil. Based upon this concentration factor and the current HAFT value of 0.0877 ppm for residues of parathion in/on field corn grain, a 0.3 ppm tolerance for residues of parathion in refined corn oil should be established.

For soybeans, data are required depicting the potential for concentration of parathion residues of concern in soybean hulls, meal and refined oil processed from seeds bearing detectable parathion residues. If no detectable residues are found in/on soybeans harvested from plants treated at a 5x exaggerated rate, a processing study will not be required.

For sunflower seed, data are available indicating that residues of parathion do not concentrate in sunflower meal, but no data are available on sunflower oil. Data are required depicting the potential for concentration of parathion residues of concern in oil processed from sunflower seeds bearing detectable parathion residues.

For wheat, the available wheat processing study indicates that residues of parathion do not concentrate in wheat flour, middlings, or shorts, but concentrate by 4.6x in wheat bran. Although additional wheat grain data are required, the current HAFT value of 0.84 ppm for residues of parathion in/on wheat grain and the concentration factor for wheat bran (4.6x) indicate that a tolerance of a least 4 ppm will be required for residues of parathion in wheat bran. The concentration factor for wheat bran (4.6x) will also be translated to barley bran.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are not fulfilled and remain outstanding. No tolerances have been established for parathion residues in animal commodities, although tolerances have been established on numerous animal feed items.

For the required feeding studies, ruminants and poultry should be dosed orally with parent only at 1x, 3x and 10x the maximum expected dietary burden for a minimum of 28 days or until residues plateau in milk and eggs if they have not done so by 28 days. Animals should be sacrificed within 24 hours of receiving the final dose. Milk and eggs should be collected throughout the study, and samples of muscle, fat, liver, and kidney (ruminants only) should be collected at sacrifice for analysis. Samples should be analyzed for residues of parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon. In addition, these studies must be supported by data depicting the storage stability of residues in animal commodities.

Based upon the established or reassessed tolerances for residues of parathion in/on animal feed items, the calculated maximum theoretical dietary burdens for livestock are presented below:

Calculation of maximum dietary burdens of livestock animals for parathion.

| Feed Commodity | % Dry Matter ^a | % Diet ^a | Tolerance (ppm) ^b | Dietary Contribution (ppm) ^c |
|---------------------|---------------------------|---------------------|------------------------------|---|
| Beef Cattle | | | | |
| alfalfa hay | 89 | 70 | 33 ^d | 26.0 |
| corn stover | 83 | 15 | 20 | 3.6 |
| sorghum grain | 86 | 15 | 2 | 0.3 |
| TOTAL BURDEN | | 100 | | 29.9 |
| Dairy Cattle | | | | |
| alfalfa hay | 89 | 60 | 33 ^d | 22.2 |
| corn stover | 89 | 15 | 25 | 3.6 |
| sorghum grain | 86 | 25 | 2 | 0.6 |
| TOTAL BURDEN | | 100 | | 26.4 |
| Poultry | | | | |
| sorghum grain | N/A | 80 | 2 | 1.6 |
| sunflower meal | N/A | 20 | 0.2 ^e | 0.04 |
| TOTAL BURDEN | | 100 | | 1.64 |
| Swine | | | | |
| sorghum grain | N/A | 90 | 2 | 1.8 |
| sunflower meal | N/A | 10 | 0.2 ^e | 0.02 |
| TOTAL BURDEN | | 100 | | 1.82 |

^a Table I (August 1996).

^b Current or reassessed tolerance from Table C.

^c Contribution = [tolerance / % DM (if cattle)] X % diet.

^d Anticipated residue estimate is based on data submitted for the use of an [redacted]

^e [redacted] on alfalfa [redacted]

^e Based on the 0.2 ppm tolerance for residues in/on sunflower seeds.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

Parathion is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Parathion is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

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OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

Confined rotational crop data are required. A confined rotational crop study has been submitted and is currently under review (DP Barcode D242254).

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops:

The need for limited field rotational crop studies and appropriate plantback intervals will be determined once data from the confined rotational crop study have been reviewed.

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Table A. Food/Feed Use Patterns Subject To Reregistration for Parathion (Case 0155).

| Site | Application Type Application Timing Application Equipment* | Formulation [EPA Reg. No.] | Max. Single Application Rate (lb ai/A/application) | Max. # Apps./season | Minimum Retreatment Interval (Days) | Use Limitations ^b |
|--|--|---------------------------------|--|------------------------|--|------------------------------|
| Alfalfa (not for use on alfalfa grown for seed) | | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] | 0.75 | 2 per cutting | 7 | A 15-day PHI/PGI is specified. Do not apply when crop or weed in treatment area are in bloom. | |
| | 8 lb/gal EC [4787-16] | 0.38 in CA and NV 0.50 | | | | |
| | 6 lb/gal EC [4787-19] | 0.38 in CA and NV | | | | |
| Barley | | | | | | |
| Broadcast foliar application Aerial equipment | 4 lb/gal EC [4787-15] | 0.75 | 6 | 7 | A 15-day PHI/PGI is specified. Do not apply more than 6 applications/season. | |
| | 8 lb/gal EC [4787-16] | 0.50 | | | | |
| | 6 lb/gal EC [4787-19] | 0.50 | | | | |
| Corn | | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] | 1.0 - field/pop 0.75 - sweet | 6 | 5 | A 12-day PHI/PGI is specified. Do not apply more than 6 applications/season. | |
| | 8 lb/gal EC [4787-16] | 0.75 | | | | |
| | 6 lb/gal EC [4787-19] | 0.38 | | | | |
| Cotton | | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] | 1.0 | 6 | 7 | A 7-day PHI is specified. Do not apply more than 6 applications/season. Labels for 4787-15 and -16 prohibit feeding of treated cotton trash within 15 days of application to dairy animals or animals being finished for slaughter. | |
| | 8 lb/gal EC [4787-16] | 1.2 | | | | |
| 6 lb/gal EC [4787-19] | | | | | | |

(continued; footnotes follow)

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Table A (continued).

| Site Application Type Application Timing Application Equipment * | Formulation [EPA Reg. No.] | Max. Single Application Rate (lb ai/A/application) | Max. # Apps./season | Minimum Retreatment Interval (Days) | Use Limitations ^b |
|--|---|--|---------------------|-------------------------------------|---|
| Rape seed (oilseed-producing varieties only, which include canola and crambe) | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] 8 lb/gal EC [4787-16] 6 lb/gal EC [4787-19] | 0.50 | NS | NS | A 28-day PHI is specified. Do not graze treated forage or feed treated forage or threshing waste to livestock. Apply in a minimum of 3 gal/A. |
| Sorghum | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] 8 lb/gal EC [4787-16] 6 lb/gal EC [4787-19] | 1.0 0.38 | 6 | 7 | A 12-day PHI/PGI is specified (21-day PHI/PGI for EPA Reg. No. 4787-19). Do not apply more than 6 applications/season. |
| Soybeans | | | | | |
| Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] 8 lb/gal EC [4787-16] 6 lb/gal EC [4787-19] | 0.75 0.80 0.38 | 2 | 7 | A 20-day PHI/PGI is specified. Do not apply more than 2 applications/season. |
| Sunflowers | | | | | |
| Broadcast foliar applications beginning at flowering Aerial equipment | 4 lb/gal EC [4787-15] 8 lb/gal EC [4787-16] 6 lb/gal EC [4787-19] | 0.50 1.0 0.66 | 3 | 5 | A 30-day PHI is specified. |

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Table A (continued).

| Site | Application Type Application Timing Application Equipment ^a | Formulation [EPA Reg. No.] | Max. Single Application Rate (lb ai/A/application) | Max. # Apps./season | Minimum Retreatment Interval (Days) | Use Limitations ^b |
|-------|--|-------------------------------|--|------------------------|---|---|
| Wheat | Broadcast foliar applications Aerial equipment | 4 lb/gal EC [4787-15] | 0.75 | 6 | 7 | A 15-day PHI/PGI is specified. Do not apply more than 6 applications/season. |
| | | 8 lb/gal EC [4787-16] | | | | |
| | | 6 lb/gal EC [4787-19] | 0.50 | | | |

^a The labels allow only aerial applications in a minimum application volume of 2 gal/A and prohibit applications through any type of irrigation system.

^b Labels specify a 3-day restricted entry interval (REI) for all crops except corn (6-day REI). The labels also specify that treated crops must be mechanically harvested; hand harvesting of treated crops is prohibited. Labels for the 4 and 8 lb/gal ECs bear the following rotational crop restriction: "Do not plant any food or feed crop in parathion treated soils other than those with registered parathion uses". No rotational crop restriction is listed on the label for the 6 lb/gal EC.

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Table B. Residue Chemistry Science Assessments for Reregistration of Parathion.

| GLN: Data Requirements | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References ¹ |
|---|----------------------------------|------------------------------------|--|
| 860.1200: Directions for Use | N/A | Yes ² | See Table A. |
| 860.1300: Plant Metabolism | N/A | No | GS00155001 GS00155002 00160331 40751601 40810901 41228601 41343701 41414101 41715401 42672401 |
| 860.1300: Animal Metabolism | N/A | No | 00057039 40288901 40288902 40623803 40784401 41397601 41398001 43107501 ³ 43196801 ³ |
| 860.1340: Residue Analytical Methods | | | |
| - Plant commodities | N/A | No | 00003724 00035332 00047726 00101098 00101100 00101118 00101122 00101127 GS00155004 42133601 42575701 ⁴ 42709101 43216201 ³ 43556001 ⁵ |
| - Animal commodities | N/A | Yes ⁶ | 00088048 00101106 00101107 44133201 ⁷ |
| 860.1360: Multiresidue Methods | N/A | No | |
| 860.1380: Storage Stability Data | N/A | No | 00101166 42161201 42544701 42666701 43685601 ⁸ |
| 860.1500: Crop Field Trials | | | |
| <u>Legume Vegetables (Succulent or Dried) Group</u> | | | |
| - Soybeans | 0.1 [§180.121(a)] | No ⁹ | 00101100 41344207 |
| <u>Foliage of Legume Vegetables Group</u> | | | |
| - Soybeans forage and hay | 1 (hay) [§180.121(a)] | Yes ¹⁰ | 00101100 41344207 |

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Table B (continued).

| GLN: Data Requirements | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References ¹ |
|---|----------------------------------|------------------------------------|--|
| <u>Cereal Grains Group</u> | | | |
| - Barley | 1 [§180.121(a)] | Yes ¹¹ | |
| - Corn | 1 [§180.121(a)] | No ¹² | 41717707 |
| - Sorghum | 0.1 (N) [§180.121(a)] | No ¹³ | 00101098 00101226 41412504 43546601 ¹⁴ [REDACTED] |
| - Wheat | 1 [§180.121(a)] | Yes ¹⁶ | 43239501 ³ 43511302 ⁵ [REDACTED] |
| <u>Forage Fodder and Straw of Cereal Grains</u> | | | |
| - Barley hay and straw | None | Yes ¹¹ | |
| - Corn forage and fodder | 1 (forage) [§180.121(a)] | No ¹⁷ | 41717707 |
| - Sorghum forage and fodder | 3 [§180.121(a)] | No ¹³ | 00058046 00061199 00101098 00101213 00101226 43546601 ¹⁴ [REDACTED] |
| - Wheat forage, hay and straw | None | Yes ¹⁶ | 00101114 43239501 ³ 43511302 ⁵ [REDACTED] |
| <u>Non-grass Animal Feeds</u> | | | |
| - Alfalfa (fresh) | 1.25 [§180.121(a)] | Yes ¹⁸ | 00035332 00047726 00061199 00101111 00101118 00101119 00101121 00101124 [REDACTED] |
| - Alfalfa hay | 5 [§180.121(a)] | Yes ¹⁸ | [REDACTED] |
| <u>Miscellaneous Commodities</u> | | | |
| - Aspirated grain fractions | None | Yes ¹⁹ | 43511301 ⁵ |

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Table B (continued).

| GLN: Data Requirements | Current Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References ¹ |
|---|----------------------------------|------------------------------------|--|
| - Cottonseed | 0.75 [§180.121(a)] | Yes ²⁰ | 00101122 00101226 41344210 |
| - Canola | 0.2 (rape seed) [§180.121(a)] | No | 00003724 42709102 43624201 ⁵ |
| - Sunflower seed | 0.2 [§180.121(a)] | No | 41596109 42077801 |
| 860.1520: Processed Food/Feed | | | |
| - Barley | None | No ²¹ | |
| - Corn (field) | None | No ²² | 41596102 |
| - Cottonseed | None | No | 41717703 |
| - Canola | None | No | 42709103 |
| - Sorghum | None | No | 41717705 |
| - Soybeans | None | Yes ²³ | |
| - Sunflower seed | None | Yes ²⁴ | 42077801 |
| - Wheat | None | No ²⁵ | 43511301 ⁵ |
| 860.1480: Meat, Milk, Poultry, and Eggs | None | Yes ²⁶ | 00088048 00101104 00101105 00101106 |
| 860.1400: Water Fish and Irrigated Crops | None | N/A | |
| 860.1460: Food Handling | None | N/A | |
| 860.1850: Confined Rotational Crops | N/A | Yes ²⁷ | |
| 860.1900: Field Rotational Crops | None | N/A ²⁷ | |

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1. Bolded references were reviewed in the Residue Chemistry Chapter of the Parathion Reregistration Standard dated 4/8/85, and *italicized* references were reviewed in the Residue Chemistry Chapter of the Parathion Reregistration Standard Update dated 8/17/93. All other references were reviewed as noted.
2. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to use directions on all end-use product labels. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use.
3. CB Nos. 13359, 13651, 14024; DP Barcodes D200095, D202635, D205594; S. Hummel; 12/20/94.
4. CBRS No. 11230, DP Barcode D186341, L. Cheng, 5/5/93.
5. DP Barcodes D212528,, D213012, and D215507; B. Cropp-Kohlligian; 5/27/98.

6. In conjunction with the ruminant and poultry feeding studies, data are required validating the analytical method(s) used for determining parathion, paraoxon, and 4-acetamidoparaoxon in meat, milk, poultry, and eggs.

If tolerance are required for residues in animal commodities, then the proposed GC/FPD enforcement methods (Leoni Methods II, IIa, and III) must be validated by an independent laboratory, as per *PR Notice 96-1*, prior to being validated by the Agency.

7. CBRS No. 17624, DP Barcode D230692, B. Cropp-Kohlligian, 3/12/97.
8. CB No. 15803, DP Barcode D216966, B. Cropp-Kohlligian, 9/24/97.
9. The available data are adequate and indicate that the currently established tolerance for residues of parathion in/on soybeans should be lowered from 0.1 ppm to 0.05 ppm.
10. The available residue data on soybean hay are adequate and support the established 1 ppm tolerance for residues of parathion in/on hay; however, no parathion residue data are available for soybean forage. Data are required depicting parathion residues of concern in/on soybean forage harvested 20 days following the last of two foliar applications of an EC formulation at 1x the maximum label use rate. Alternatively, the registrant may amend all end-use product labels to prohibit the grazing or feeding of treated soybean forage to livestock.
11. Data are required depicting parathion residues of concern in/on barley RACs (grain, hay and straw) harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.75 lb ai/A/application with a 7-day RTI. A total of ten tests are required in regions representative of barley production.
12. The available data are adequate and support establishing separate tolerances for residues of parathion in/on field corn grain and pop corn grain at 0.1 ppm and in/on sweet corn grain at 0.05 ppm.
13. The available data are adequate and indicate that: (i) the established tolerance for residues of parathion in/on sorghum grain should be increase from 0.1 ppm to 2 ppm, (ii) the established tolerance for residues of parathion in/on sorghum forage should be lowered from 3 ppm to 2 ppm, and (iii) the established tolerance for residues of parathion in/on fodder (stover) should be increased from 3 ppm to 13 ppm.
14. DP Barcode D216095, B. Cropp-Kohlligian, 5/21/98.

16. Additional data are required depicting parathion residues of concern in/on wheat RACs (grain, forage, hay, and straw) harvested 15 days following the last of two foliar applications of an EC formulation of parathion at 0.75 lb ai/A/application with a 14-day RTI. Seven additional field trials are required on wheat in the following geographic regions: one test each in Regions 2, 4 and 7, two tests each in Regions 5 and 8.
17. The available forage data are adequate and support increasing the currently established tolerance for residues of parathion in/on corn forage from 1 ppm to 8 ppm. Separate tolerances should be established for residues of parathion in/on sweet corn forage and field corn forage.

The available corn fodder data are adequate to support the establishment of separate tolerances for residues of parathion in/on field corn stover, pop corn stover, and sweet corn stover at 20 ppm.
18. There are no alfalfa field trial data reflecting the maximum use rate of parathion on alfalfa using the currently registered EC formulation. Alfalfa field trial data are required reflecting the maximum use rate of parathion on alfalfa. Tests must be conducted using an EC formulation of parathion. Residues of parathion, paraoxon, and *p*-nitrophenol should be determined in/on alfalfa forage and hay samples collected from these field trials. The registrant should refer to OPPTS GLN 860.1500 for information on location and number of field trials required.
19. Data are required depicting parathion residues of concern in/on aspirated grain fractions (grain dust) derived from grain of parathion treated field corn and grain sorghum. [Note: Aspirated grain fractions data from soybeans is not required since residues of parathion and paraoxon were below the LOQ (0.05 ppm) in/on soybeans treated with parathion at the 1x use rate.] Adequate wheat grain dust data are available indicating that residues of parathion in/on wheat grain dust were 4.5x higher than in/on wheat grain. Based on available wheat residue data, a tolerance of 4 ppm would be appropriate.
20. Data are required depicting parathion residues of concern in/on cotton gin-byproducts derived from cotton treated at the maximum labeled use rate and harvested 7 days after the final application using commercial equipment (stripper and mechanical picker). At least three field trials representing each type of harvesting (stripper and picker) are required.
21. Processing data from wheat grain will be translated to barley grain processed commodities. Once adequate barley grain data are available, a tolerance for residues of parathion in barley bran should be established using a concentration factor of 4.6x.
22. The available data are adequate and support the establishment of a tolerance for residues of parathion in refined corn oil at 0.3 ppm.
23. Data are required depicting the potential for concentration of parathion residues of concern in soybean hulls, meal and oil processed from seeds bearing detectable parathion residues. If no detectable residues are found in/on soybeans harvested from plants treated at a 5x exaggerated rate, a processing study will not be required.
24. Data are required depicting the potential for concentration of parathion residues of concern in sunflower oil processed from seeds bearing quantifiable parathion residues.
25. The available data are adequate and support the establishment of a tolerance for residues of parathion in wheat bran. Although additional wheat grain data are required, available data indicate that a tolerance of at least 4 ppm will be required.
26. Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are not fulfilled and remain outstanding. No tolerances have been established for parathion residues in animal commodities, although tolerances have been established on numerous animal feed items.

For the required feeding studies, ruminants and poultry should be dosed orally with parent only at 1x, 3x and

10x the maximum expected dietary burden for a minimum of 28 days or until residues plateau in milk and eggs if they have not done so by 28 days. Animals should be sacrificed within 24 hours of receiving the final dose. Milk and eggs should be collected throughout the study, and samples of muscle, fat, liver, and kidney (ruminants only) should be collected at sacrifice for analysis. Samples should be analyzed for residues of parathion, paraoxon, *p*-nitrophenol, and 4-acetamidoparaoxon. In addition, these studies must be supported by data depicting the storage stability of residues in animal commodities.

27. Confined rotational crop data are required to satisfy OPPTS GLN 860.1850. A confined rotational crop study has been submitted and is currently under review (DP Barcode D242254). The need for limited field rotational crop data to satisfy OPPTS GLN 860.1900 requirements will be determined once the confined rotational crop study has been reviewed.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of parathion are currently expressed in terms of parathion or its methyl homolog (methyl parathion) [40 CFR §180.121 (a) and §180.319]. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has determined that the tolerance expression for parathion residues of concern in/on plant commodities may be based on residues of parathion only. **Tolerances for parathion should be moved from 40 CFR §180.121(a) and listed under a separate 40 CFR §180.XXX (a) section. Under the new listing, tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) and §180.319 should be revoked.**

The tolerance definition for parathion residues should also be changed to read as follows:

Tolerances are established for the residues of parathion [*O,O*-diethyl-*O-p*-nitrophenyl thiophosphate] in/on the following raw agricultural commodities:

A summary of the parathion tolerance reassessment for commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat only are presented in Table C. Table C also includes modifications in commodity definitions where needed.

The appropriate tolerances for parathion residues in animal commodities will be determined once data are available from the outstanding livestock feeding studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has determined that the tolerance expression for parathion residues of concern in/on animal commodities, if tolerances are needed, may be based on residues of parathion only.

Tolerances Listed Under 40 CFR §180.121 (a):

Tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) and §180.319 should be revoked.

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for residues of parathion in/on field corn grain, pop corn grain, sweet corn (K+CWHR), field corn forage, sweet corn forage, undelinted cottonseed, grain sorghum grain, grain sorghum forage, grain sorghum stover, rape seed (canola seed), soybean seed, soybean hay, and sunflower seed. Additional residue data are required before existing tolerances can be

reassessed on the following commodities: alfalfa forage, alfalfa hay, barley grain, and wheat grain.

Based upon the current use patterns and the available residue data, the established tolerances for residues of parathion in/on cottonseed, rape seed (canola seed), soybean hay, and sunflower seed are adequate. The available residue data indicate that tolerances can be lowered on field corn grain (0.1 ppm), pop corn grain (0.1 ppm), sweet corn: K+CWHR (0.05 ppm), grain sorghum forage (2 ppm), and soybean seed (0.05 ppm). The available data also indicate that tolerances should be increased on field corn forage (8 ppm), sweet corn forage (8 ppm), grain sorghum grain (2 ppm), and grain sorghum stover (13 ppm).

Although residue data are incomplete for wheat grain, the available data indicate the established tolerance on wheat grain (1 ppm) may be adequate.

Although residue data are incomplete for alfalfa forage and hay, the available data indicate the established tolerances may need to be increased to 11 ppm and 33 ppm, respectively.

Tolerances Listed Under 40 CFR §180.319:

As there is no registered use for parathion on rye, the tolerance for parathion residues in/on rye should be revoked.

Tolerances Needed Under 40 CFR §180.XXX:

New tolerances are needed for residues of parathion in/on the following RACs: aspirated grain fractions, barley hay and straw, corn stover, cotton gin byproducts, soybean forage, and wheat forage, hay and straw. At the present time, sufficient data are only available to determine an appropriate tolerance for residues of parathion in/on corn stover (20 ppm). Additional residue data are required before appropriate tolerances can be determined for residues in/on the remaining commodities.

Although residue data are incomplete for wheat forage and straw, the available data indicate that tolerances of 1 and 10 ppm, respectively, may be necessary.

In addition, a tolerance of at least 4 ppm will be required for residues of parathion in/on aspirated grain fractions, based upon the 4.5x concentration factor and current HAFT value of 0.84 ppm for residues of parathion in/on wheat grain. However, this tolerance cannot be assessed until a complete set of wheat grain data are available, along with aspirated grain fraction data on field corn and grain sorghum.

Separate tolerances are also required for residues of parathion in the following processed food/feed items: barley bran, refined corn oil, and wheat bran. Refined corn oil is the only processed commodity for which there is sufficient data available to assess a tolerance (0.3 ppm).

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The wheat processing study indicates that residues of parathion concentrate by 4.6x in bran of wheat and barley (translated); however, additional field trial data on barley and wheat grain are required before tolerances for these commodities can be determined. No data are presently available depicting residues in/on barley grain.

In addition, requirements for processing studies on soybeans and sunflower seeds remain outstanding.

Table C. Tolerance Reassessment Summary for Parathion. [NOTE: Tolerances should only be established for RACs and, if necessary, processed commodities of alfalfa, barley, canola, corn, cotton, grain sorghum, soybean, sunflower, and wheat, in accordance with an agreement limiting the use of parathion to these crops. All other currently established tolerances for residues of parathion listed under 40 CFR §180.121 (a) and §180.319 should be revoked.]

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/Correct Commodity Definition |
|---|-------------------------|------------------------------|---|
| Tolerances listed under 40 CFR §180.121 (a): | | | |
| Alfalfa, (fresh) | 1.25 | TBD* | Available data indicate that the tolerance may need to be increased to 11 ppm; <i>Alfalfa, forage</i> |
| Alfalfa, (hay) | 5 | TBD | Available data indicate that the tolerance may need to be increased to 33 ppm; <i>Alfalfa, hay</i> |
| Barley | 1 | TBD | <i>Barley, grain</i> |
| Corn | 1 | 0.1 | The available residue data support lowering the tolerance; <i>Corn, field, grain</i> <i>Corn, pop, grain</i> |
| | | 0.05 | The available residue data support lowering the tolerance; <i>Corn, sweet: K+CWHR</i> |
| Corn, forage | 1 | 8 | Residue data indicate that the tolerance should be increased; <i>Corn, field, forage</i> <i>Corn, sweet, forage</i> |
| Cottonseed | 0.75 | 0.75 | <i>Cotton, undelinted seed</i> |
| Rape seed | 0.2 | 0.2 | <i>Canola, seed</i> |
| Sorghum | 0.1 | 2 | Available data indicate that the tolerance should be increased; <i>Sorghum, grain, grain</i> |
| Sorghum fodder | 3 | 13 | Available data indicate that the tolerance should be increased; <i>Sorghum, grain, stover</i> |
| Sorghum forage | 3 | 2 | Available data indicate that the tolerance should be decreased; <i>Sorghum, grain, forage</i> |
| Soybean | 0.1 | 0.05 | <i>Soybean, seed</i> |
| Soybean hay | 1.0 | 1 | <i>Soybean, hay</i> |
| Sunflower seed | 0.2 | 0.2 | <i>Sunflower, seed</i> |

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Table C (continued).

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/Correct Commodity Definition |
|---|-------------------------|------------------------------|--|
| Wheat | 1 | TBD | Although incomplete, the current data support the 1 ppm tolerance; <i>Wheat, grain</i> |
| Tolerances listed under 40 CFR §180.319: | | | |
| Rye | 0.5 | Revoke | Temporary tolerance no longer in effect. Not a registered use for parathion. |

Table C (continued).

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | Comment/Correct Commodity Definition |
|--|-------------------------|------------------------------|--|
| Tolerances needed under 40 CFR §180.XXX (a) | | | |
| Aspirated grain fractions | None | TBD | The available data on wheat support a tolerance of at least 4 ppm. |
| Barley, bran | None | TBD | To be based on 4.6x concentration factor observed for wheat bran and barley grain residue data. |
| Barley, hay | None | TBD | |
| Barley, straw | None | TBD | |
| Corn, oil, refined | None | 0.3 | |
| Corn, stover | None | 20 | Tolerance based upon available residue data on corn fodder; <i>Corn, field, stover</i> <i>Corn, pop, stover</i> <i>Corn, sweet stover</i> |
| Cotton gin byproducts | None | TBD | |
| Soybean, forage | None | TBD | |
| Wheat, forage | None | TBD | Although incomplete, the available data support a 1 ppm tolerance. |
| Wheat, bran | None | TBD | Available data indicate that at least a 4 ppm tolerance will be required. |
| Wheat, hay | None | TBD | |
| Wheat, straw | None | TBD | Although incomplete, the available data support a 10 ppm tolerance. |

TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

DIETARY EXPOSURE ASSESSMENT SUMMARY

For reregistration and risk assessment purposes, adequate plant metabolism data are available. Adequate field trial data for parathion residues of concern are available for all registered commodities, with the following exceptions: alfalfa RACs (forage and hay), aspirated grain fractions, barley RACs (grain, hay, and straw), cotton gin byproducts, soybean forage, and wheat RACs (grain, forage, hay, and straw). Adequate processing data for parathion residues of concern are available for all processed commodities except for soybean processed commodities

and sunflower seed oil. Based on available magnitude of the residue data, anticipated residue estimates (chronic/acute) for the combined residues of parathion and paraoxon in/on plant commodities are provided in the table below.

Chronic/acute anticipated residue (AR) estimates for the combined residues of parathion and paraoxon in/on plant commodities based on available magnitude of the residue data.

| Food Code | Food Name/Food Form | Anticipated Residues ^a |
|-----------|---------------------------|-----------------------------------|
| 270100A | Soybean-oil | 0.1 ppm ^b |
| 28023AA | Soybeans-unspecified | 0.1 ppm |
| 28023AB | Soybeans-mature,seeds dry | 0.1 ppm |
| 28023WA | Soybeans-flour, full fat | 0.1 ppm ^b |
| 28023WB | Soybeans-flour, low fat | 0.1 ppm ^b |
| 28023WC | Soybeans-flour, defatted | 0.1 ppm ^b |
| 24001AA | Barley | 0.88 ppm ^c |
| 15004AA | Corn-pop | 0.14 ppm ^d |
| 15005AA | Corn-sweet | 0.1 ppm |
| 24002EA | Corn,grain-endosperm | 0.14 ppm ^d |
| 24002HA | Corn,grain-bran | 0.14 ppm ^d |
| 24002SA | Corn sugar | 0.14 ppm ^d |
| 270020A | Corn,grain-oil | 0.42 ppm ^e |
| 24006AA | Sorghum | 2 ppm |
| 24007AA | Wheat-rough | 0.88 ppm |
| 24007GA | Wheat-germ | 0.88 ppm ^c |
| 24007HA | Wheat-bran | 4 ppm ^f |
| 24007WA | Wheat-flour | 0.35 ppm ^g |
| 270030A | Cottonseed-oil | 0.015 ppm ^h |
| 27003WA | Cottonseed-meal | 0.03 ppm ⁱ |
| 27017AA | Rape-seed | 0.18 ppm |
| 15018AA | Sunflower-seed | 0.25 ppm |
| 27010A | Sunflower-oil | 0.25 ppm ^j |

^a Unless otherwise specified, ARs are based on the HAFT value for the combined residues of parathion and paraoxon. Parathion and paraoxon residue levels from field trial data reported below the LOQ (0.05 ppm) were

- calculated at the LOQ level (0.05 ppm) and resulted in AR residue levels higher than tolerance levels reported for soybeans, corn, and sunflower seed. Concentration/reduction factors used in AR calculations for processed commodities also include parathion and paraoxon residue levels. Except as specified for soybean processed commodities and sunflower oil, all default concentration factors inherent in the DRES analysis should be deactivated.
- b No soybean processing data are available; hence, any default concentration factors inherent in the DRES analysis for soybean processed commodities should be activated.
 - c The wheat grain HAFT value for residues of parathion and paraoxon has been translated to barley grain and wheat germ.
 - d The field corn grain HAFT value for residues of parathion and paraoxon has been translated to pop corn grain, corn grain-endosperm, corn grain-bran, and corn grain-sugar.
 - e Based on the HAFT value for residues of parathion and paraoxon in/on field corn grain (0.14 ppm) multiplied by the concentration factor for refined corn oil (3x).
 - f Based on the HAFT value for residues of parathion and paraoxon in/on wheat grain (0.88 ppm) multiplied by the concentration factor for wheat bran (4.6x).
 - g Based on the HAFT value for residues of parathion and paraoxon in/on wheat grain (0.88 ppm) multiplied by the reduction factor for wheat flour (0.4x).
 - h Based on the HAFT value for residues of parathion and paraoxon in/on cottonseed (0.75 ppm) multiplied by the reduction factor for refined cottonseed oil (0.02x).
 - i Based on the HAFT value for residues of parathion and paraoxon in/on cottonseed (0.75 ppm) multiplied by the reduction factor for cottonseed meal (0.04x).
 - j Processing data on sunflower seed oil is not available; hence, any default concentration factors inherent in the DRES analysis for sunflower seed oil should be activated.

For reregistration and risk assessment purposes, adequate animal metabolism data are available. Livestock feeding studies remain outstanding. Based on available goat and hen metabolism data, anticipated residue estimates for the combined residues of parathion, paraoxon, and 4-acetamidoparaoxon in/on animal commodities are provided in the table below. [Note: Residue of paraoxon were not detected in any sample collected from the goat metabolism studies.]

Chronic/acute anticipated residue (AR) estimates for the combined residues of parathion, paraoxon, and 4-acetamidoparaoxon in/on animal commodities based on available metabolism data.

| Animal Commodity | Anticipated Residue |
|------------------|--------------------------|
| Cattle liver | 0.8 ppm ^a |
| Cattle kidney | 0.5 ppm ^a |
| Cattle fat | 0.11 ppm ^a |
| Cattle muscle | 0.14 ppm ^b |
| Whole milk | 0.20 ppm ^a |
| Poultry liver | 0.002 ppm ^c |
| Poultry muscle | 0.003 ppm ^d |
| Poultry fat | 0.01 ppm ^d |
| Poultry skin | 0.006 ppm ^d |
| Whole egg | 0.00008 ppm ^c |

^a Anticipated residue estimates based on the highest combined residues of parathion and 4-acetamidoparaoxon found in goat liver (2.57 ppm), kidney (1.55 ppm), fat (0.36 ppm), and whole milk (0.73 ppm) samples collected from goats dosed with [¹⁴C]parathion for 5 consecutive days at 100 ppm (MRIDs 40288902, 40623803, and 41397601; memo by R. Perfetti dated 7/23/90). Maximum dietary burdens for beef cattle and dairy cattle are calculated at 29.9 ppm and 26.4 ppm, respectively.

^b Anticipated residue estimate based on the highest combined residues of parathion and 4-acetamidoparaoxon found in goat muscle (0.474 ppm) samples collected from goats dosed with [¹⁴C]parathion for 5 consecutive days at 100 ppm (MRID 43107501; memo by S. Hummel dated 12/20/94). Maximum dietary burden for beef cattle is calculated at 29.9 ppm.

^c Anticipated residue estimates based on the highest combined residues of parathion, paraoxon, and 4-acetamidoparaoxon found in hen liver (0.014 ppm) and whole egg (0.0007 ppm) samples collected from hens dosed with [¹⁴C]parathion for 5 consecutive days at 15 ppm (MRIDs 40288901, 40784401, and 41398001; memo by R. Perfetti dated 7/23/90). Maximum dietary burden for poultry is calculated at 1.64 ppm.

^d Anticipated residue estimates based on the highest combined residues of parathion, paraoxon, and 4-acetamidoparaoxon found in hen muscle (0.038 ppm), fat (0.143 ppm), and skin (0.089 ppm) samples collected from hens dosed with [¹⁴C]parathion for 6 consecutive days at 25.1 ppm (MRID 43196801; memo by S. Hummel dated 12/20/94). Maximum dietary burden for poultry is calculated at 1.64 ppm.

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CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for parathion residues in/on various fruit and vegetable commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex MRLs for parathion are currently expressed in terms of the parent. The U.S. tolerance definition will be compatible with Codex. A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for parathion and applicable U.S. tolerances.

| Codex | | | Reassessed U.S. Tolerance (ppm) | Recommendation and Comments |
|--|----------------|------|---------------------------------------|---|
| Commodity (As Defined) | MRL (mg/kg) | Step | | |
| Apricot | 1 | CXL | None | Not registered for this use in the U.S. |
| Citrus fruits | 1 | CXL | None | Not registered for this use in the U.S. |
| Fruits (except as otherwise listed) | 0.5 | CXL | None | Not registered for this use in the U.S. |
| Peach | 1 | CXL | None | Not registered for this use in the U.S. |
| Vegetables (except carrots) | 0.7 | CXL | None | Not registered for this use in the U.S. |

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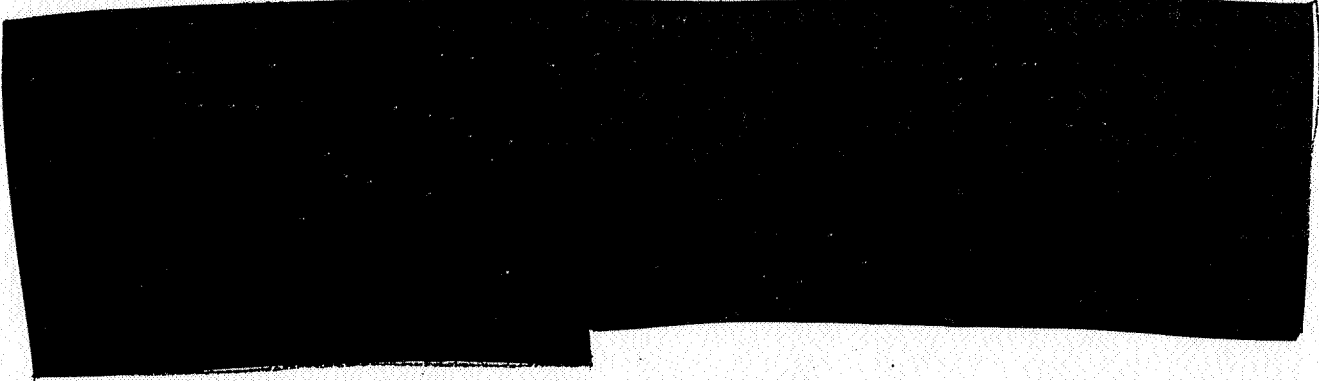
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