United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substances (7508C)
EPA 738-R-05-005
June 15, 2006

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Ethephon

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Approved By:

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Date

Abstract

The Environmental Protection Agency (EPA) has concluded its tolerance reassessment for ethephon and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to ethephon. Therefore, the 45 tolerances established for residues of ethpehon are now considered reassessed as safe under section 408(q) of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA). EPA issued a Reregistration Eligibility Decision (RED) for ethephon in April 1995.

This Tolerance Reassessment Decision (TRED) document also considers dietary risk associated with three pending petitions:
1) The U.S. Department of Agriculture's Interregional Project No. 4 (IR-4) petition on behalf of the Agricultural Experiment Station of Hawaii requesting the establishment of a 0.5 ppm tolerance for residues of ethephon in or on the raw agricultural commodity (RAC) of coffee – there is currently an ethephon tolerance of 0.1 ppm for coffee bean;
2) BayerCrop Science Company's petition for an increased tolerance for residues of ethephon in or on cottonseed, establishment of a tolerance for ethephon on cotton gin byproducts and subsequent revisions to existing tolerances for meat and milk, and establishment of tolerances for poultry commodities; and
3) An IR-4 petition requesting establishment of a 1.0 ppm tolerance for residues of ethephon in or on filberts – IR-4 is proposing a new use of ethephon to promote earlier harvest in filbert production.

Although a TRED typically does not include an occupational assessment for new uses, it is included here for interested parties to see. These additional new/amended use tolerance petitions have not been approved and are pending the completion of an ecological assessment.

The Agency is issuing this TRED document for ethephon as announced in a Notice of Availability published in the ***Federal Register***. The Agency is providing a 60-day comment period for stakeholders to respond to this risk management decision. If substantive information is received during the comment period that indicates a need to reconsider the decisions presented in this document, EPA may modify these decisions as appropriate through an amendment.

I. Introduction

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision for Ethephon." This document is also known as a Tolerance Reassessment Eligibility Decision, or TRED. EPA issued a Reregistration Eligibility Decision (RED) in 1995. This TRED reassesses the tolerances associated with ethephon, to ensure the pesticide meets the standards of FQPA.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on the day before enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern, and that there is no common mechanism of toxicity with other pesticides, the tolerances are considered reassessed. Existing tolerances associated with ethephon must be reassessed in accordance with FFDCA, as amended by FQPA.

II. Background

Ethephon is a plant growth regulator. It is important to note that ethephon is an organophosphonate as opposed to an organophosphate. It is structurally different from and exhibits different physical/chemical properties than traditional organophosphate compounds. The toxicological profile of ethephon also differs from that of the organophosphate compounds. Ethephon is used to promote fruit ripening, abscission, flower induction, breaking of apical dominance (inhibition of the growth of lateral buds by the terminal bud of a shoot), and other plant responses. Ethephon is registered on a number of terrestrial food, feed, and nonfood crops, greenhouse nonfood crops, and outdoor plants, and 45 tolerances have been established for residues of ethephon in or on food commodities under 40 CFR §180.300.

Ethephon formulations include emulsifiable and soluble concentrates. Its use varies with plant species, chemical concentration, and time of application. Application is by broadcast to plant foliage by either ground or aerial equipment. Ethephon may also be applied by homeowners to select home garden vegetables (e.g., tomatoes) by using a hand sprayer. It is currently registered on a variety of fruit and vegetable crops, as well as tobacco, cotton, turf and other ornamentals. On average about 4.1 million pounds of ethephon are used annually on 1.7 million acres. The crops with highest percent crop treated are tart cherries (61%), grapes (40%), processed tomatoes (15%), and cotton (10%).

III. Risk Conclusions

The Agency has evaluated the toxicity and exposure databases for the pesticide active ingredient ethephon, and has conducted a human health risk assessment in support of the TRED for ethephon. EPA has evaluated the dietary, drinking water, and residential risks from the supported registered uses and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to ethephon. Therefore, the 45 tolerances established for residues of ethephon are now considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA.

A. Toxicity of Ethephon

The toxicity database for ethephon is adequate for the selection of doses and endpoints for use in risk assessment. Ethephon (an organophosphonate) produces organophosphate-like signs of toxicity including salivation, lacrimation, urination and defecation. These toxic signs occur in experimental animals usually at high doses of exposure. The most sensitive indicator of exposure to ethephon is the inhibition of red blood cell and plasma cholinesterase which occurs at low levels of exposure and may not be accompanied by clinical signs of toxicity until a threshold level of exposure is reached. In developmental toxicity studies, ethephon caused developmental effects, only at doses greater than those which caused maternal toxicity. In a reproductive toxicity test, offspring effects occurred at similar doses to those causing parental toxicity. Ethephon did not produce oncogenic or delayed neurotoxic effects when tested on rats, mice and hens. Acute and subchronic exposure of rats to ethephon did not produce neurobehavioral or neuropathological effects. Ethephon is rapidly absorbed from the gut and eliminated in the urine with minimum metabolic transformation.

Ethephon exhibits low acute toxicity via the oral (Toxicity Category III), inhalation (Toxicity Category IV), and dermal (Toxicity Category III) routes of exposure. Ethephon is dermally corrosive and is a skin and eye irritant (Toxicity Category I) but not a dermal sensitizer.

Human studies have shown that humans may be more susceptible to the clinical toxicity of ethephon than experimental animals. For this reason, endpoints for risk assessment are based on a 28-day oral human clinical toxicity study in which adult human subjects were intentionally exposed to ethephon. These studies were reviewed by the independent Human Studies Review Board in April, 2006 which concurred with the Agency's conclusions regarding both the ethical and scientific conduct of these studies.

The selection of an acute RfD of 0.06 mg/kg/day from the 28-day human study was based upon cholinergic signs in humans of both sexes following daily bolus dosing (capsule) at the Lowest Observed Adverse Effect Level (LOAEL) of 1.8 mg/kg/day.

The same study is considered appropriate for selection of a chronic endpoint because metabolism studies in rats show ethephon is rapidly excreted in urine as the disodium salt of the parent compound, and through exhalation as ethylene, and is not retained in the body. Therefore, chronic exposures would not lead to accumulative effects and the short-term study selected would be appropriate for the chronic exposure.

B. Uncertainty and FQPA Safety Factor

The FFDCA, as amended by FQPA, directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post- natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrates that the resulting level of exposure would be safe for infants and children.

An uncertainty factor (UF) of 10X for intraspecies variation is adequate for this risk assessment. The conventional UF of 10X for interspecies extrapolation was not applied because the endpoint selected for the risk assessment was from a human study. An additional 3X factor is applied for the lack of a No Observed Adverse Effect Level (NOAEL) in the study used for endpoint selection. Therefore, an uncertainty factor of 30X was used to assess risk for the general population and all population subgroups.

The Agency concluded that no FQPA Safety Factor is necessary to protect the safety of infants and children in assessing ethephon exposure and risks because the toxicology database for ethephon contains acceptable guideline developmental and reproductive studies as well as acute and subchronic neurotoxicity studies. The Agency also concluded that there is no quantitative or qualitative evidence of increased susceptibility following in utero or postnatal exposure in any of the developmental or reproductive studies. The RfDs and toxicity endpoints established are protective of pre/postnatal toxicity following acute and chronic exposures.

There are no residual uncertainties identified in the exposure databases and the Agency's conservative assessments will not underestimate the potential exposure to infants and children resulting from the use of ethephon. Therefore, the FQPA Safety Factor is 1X.

The Agency's human health and drinking water findings for the pesticide ethephon are summarized in the following risk assessments: *Ethephon: HED Risk Assessment for Tolerance Reassessment Eligibility Decision D32866: PP#6F4743 Revised Use Tolerance for Cottonseed D284421: PP#0E6205 Revised Use Tolerance for Coffee D280690: PP#4E3865 New Use Tolerance for Filberts D327932 (May 10, 2006),* and *Tier II Drinking Water Exposure Assessment for Ethephon (March 27, 2006).* For further details, please refer to these risk assessments and other technical documents pertaining to the Ethephon TRED, which are available on the internet at http:/www.regulations.gov and in the public docket for viewing.

C. Dietary Risks from Food and Drinking Water

EPA conducted acute and chronic dietary exposure analyses using the Dietary Exposure Evaluation Model (DEEM^{TM}). The chronic dietary (food + water) analysis is highly conservative in the assumption that residues are present at tolerance levels. The acute analysis is more refined but still conservative in the use of field trial data as opposed to monitoring data as a basis for estimating residues for all commodities except apples and grapes. Actual residues as seen in monitoring data are generally much lower than residues reported in field trials because, unlike in field trial studies, not all crops are treated at the maximum rate, with the maximum number of

applications, nor are they harvested at the minimum post harvest interval. The use of field trial data, therefore, results in exposure estimates that are generally higher than if monitoring data were available. Both assessments are conservative in the assumption of 100% crop treated (CT) in the absence of CT information.

The screening-level surface water model, PRZM/EXAMS, and the screening-level groundwater model, SCIGROW (version 2.1), were run using the use pattern for turf to derive conservative estimated drinking water concentrations (EDWCs). This scenario represented the highest potential for drinking water contamination. The acute drinking water EDWC for ethephon in surface water is 169 ppb. The chronic drinking water EDWC for ethephon in surface water is 6.7 ppb. The peak and annual groundwater EDWCs for ethephon are $\leq$ 0.67 ppb.

The acute dietary exposure estimates (combined food + water), for existing and proposed uses for the U.S. population and all population subgroups occupy less than 100% of the acute Population Adjusted Dose (aPAD) for the general U.S. population and all population subgroups. The highest acute exposures at the 99.9th percentile were for children 1-2 years old at 77% of the aPAD.

The estimated chronic dietary exposure estimates (combined food + water) from existing and proposed uses are below the Agency's level of concern for the general population and all population subgroups and occupy less than 100% of the Chronic Population Adjusted Dose (cPAD). The highest estimated chronic exposures were for children 1-2 years old at 16% of the cPAD.

Acute and chronic dietary risks are below EPA's level of concern for the U.S. Population and all population subgroups. Therefore, no mitigation measures are necessary to address dietary risks from food and drinking water.

D. Residential Risks

Non-cancer risk estimates are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100X which includes 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10X for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of ethephon, the conventional UF of 10X for interspecies extrapolation was not applied because the endpoint selected for the risk assessment was from a human study. As detailed in the FQPA section above, a 10X for intraspecies variation and an additional 3X factor for the lack of a No Observed Adverse Effect Level (NOAEL) in the study used for endpoint selection were applied in the ethephon assessment. Therefore, an MOE $\geq$ 30 does not exceed EPA's level of concern.

Residential exposure to ethephon was assessed because there is potential exposure to non-occupational (residential) handlers during handling and application of ethephon. Exposure to residential handlers can occur when they mix, load, or apply liquids with a low pressure

handwand or with a backpack sprayer. Only short-term exposures are expected for residential handlers because ethephon is typically applied only once a year. The basic assumptions and surrogate exposure data used in the residential assessment were drawn from EPA's *Standard Operating Procedures for Residential Exposure Assessments*, (EPA, 1997).

For the residential risk assessment, the Agency selected the dose of 0.06 mg/kg/day from a 28-day human clinical toxicity study based upon cholinergic signs in humans of both sexes for both the oral and inhalation routes of exposure. Absorption via the inhalation route is considered to be equivalent to the oral route of exposure.

Residential use of ethephon is limited to outdoor ornamental plants and home garden vegetables. Based on the residential use pattern of ethephon and the toxicological endpoints of concern, only inhalation exposures were assessed (no endpoint appropriate for dermal risk assessment was identified in the ethephon toxicology database). For the residential handler exposure scenarios assessed (handwand and backpack sprayers), the MOEs were 20,000. These MOEs were greater than the target of 30 and therefore risks are below the Agency's level of concern.

Post application dermal exposures to adults and children were not assessed because reentry exposure is not anticipated based on residential use patterns and no dermal toxicological endpoint was identified, as noted above. Incidental ingestion of residue by toddlers via hand-to-mouth activity is also unlikely to occur and was not assessed. Additional label language was added to homeowner use-product labels following the 1995 RED to address potential risk associated with the corrosiveness of ethephon products. Therefore, the risks estimated for all of the residential exposure scenarios were below the Agency's level of concern and no mitigation measures are necessary to address residential risks.

E. Aggregate Risk

In accordance with FQPA, EPA must consider and aggregate pesticide exposures and risks from all potential sources including food, drinking water, and residential sources. In an aggregate assessment, exposures are combined and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD). When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. In general, exposures from various sources are aggregated only when the toxic effects for different routes of exposure are the same.

In the case of ethephon, an aggregate assessment was performed using high-end estimates of exposure and conservative assumptions. Further refinements would have been incorporated into the risk assessment if exposures of concern had been identified. Since the screening-level aggregate assessment did not show risks of concern, the Agency concludes with reasonable certainty that combined residues of ethephon from food, drinking water and residential exposures do result in an aggregate risk of concern to any population subgroup.

The aggregate risk assessment integrates the assessments conducted for dietary/drinking water and residential exposure. Since there is potential for concurrent exposure via the food, water and residential pathways, all routes of ethephon exposure have been considered. The short

term aggregate risk is the estimated risk associated with combined exposures from the following pathways: average food exposures, average drinking water exposures, and short term inhalation exposures. The exposures for these routes may be aggregated because EPA selected a common toxicity endpoint (clinical signs) via these routes. An aggregate short-term exposure assessment for children is not required because residential exposures to children are not expected as a result of home use of ethephon products. For short-term aggregate risk the MOE for combined exposure for adults is 1,800. Since the target MOE for short-term aggregate risk is 30, aggregate risk is below EPA's level of concern for ethephon.

IV. Regulatory Determinations

A. FQPA Assessment Supporting Tolerance Reassessment Decision

EPA has evaluated the dietary and residential risks from the supported registered uses of ethephon and has determined that there is a reasonable certainty that no harm to any population subgroup will result from exposure to ethephon. The acute dietary exposure estimates (food + water) for the U.S. population and all population subgroups are <100 % of the acute Population Adjusted Dose (aPAD) and are below the Agency's level of concern at the 99.9^{th} percentile of exposure. The highest estimated exposure was to children 1-2 years old at 77% of the aPAD. The chronic dietary exposure estimates (food + water) for the U.S. population are below the Agency's level of concern for the general U.S. population and all population subgroups. The highest estimated average chronic exposure occurred in children 1-2 years of age (16% of the cPAD). This assessment is considered conservative since field trial and tolerance level residues, and screening level water estimates were included in the dietary assessment. Therefore, the tolerances for ethephon established at 40 CFR §180.300 are now considered reassessed under Section 408 (q) of FFDCA.

EPA has determined that risk from exposure to ethephon is within its own "risk cup." In other words, EPA is able to conclude that the tolerances for ethephon meet the FQPA safety standards. In reaching this determination, the Agency has considered the available information on the potential sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, drinking water and residential uses. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to ethephon "fit" within the risk cup for this chemical.

B. Cumulative Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ethephon and any other substances, and ethephon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ethephon has a common mechanism of toxicity with other substances. It is important to note that ethephon is an organophosphonate as opposed to an organophosphate. It is structurally different from and exhibits different physical/chemical properties than traditional organophosphate compounds. The toxicological profile of ethephon also differs from that of the organophosphate compounds. EPA has therefore determined that ethephon does not share a common mechanism of toxicity with the organophosphate compounds and was not included in this cumulative assessment. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

C. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on ethephon, there was no estrogen or androgen, mediated toxicity. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, ethephon may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

D. Tolerance Reassessment Summary

Tolerances for residues of ethephon in/on food and feed commodities that are currently established or are proposed under 40 CFR §180.300(a) and (b) are summarized below. Tolerances are expressed in terms of ethephon *per se.*

Tolerance Reassessment Summary for Ethephon			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Tolerances listed under 40 CFR §180.300 (a)			
Apple	5.0	5.0	
Barley, bran	5.0	5.0	
Barley, grain	2.0	2.0	
Barley, pearled barley	5.0	Revoke	Tolerance for barley, grain will cover barley, pearled barley.
Barley, straw	10.0	10	
Blackberry	30.0	30	
Blueberry	20.0	20	
Cantaloupe	2.0	2.0	
Cattle, fat	0.1	0.02	Tolerance can be reduced.
Cattle, mbyp	0.1	Revoke	Separate tolerances for Cattle, meat byproducts, except kidney and Cattle, kidney need to be established.
Cattle, meat	0.1	0.02	Tolerance can be reduced.
Cherry	10	10	
Coffee, bean	0.1	0.50	Increase in tolerance required./ Coffee, green bean
Cottonseed	2	6.0	Increase in tolerance required./ *Cotton, undelinted seed*
Cranberry	5	Revoke	No registered uses exist.
Cucumber	0.1	Revoke	Registrant limiting use to cucumbers grown solely for seed.
Fig	5	To Be Determined	No registered uses exist.
Goat, fat	0.1	0.02	Tolerance can be reduced.
Goats, mbyp	0.1	Revoke	Separate tolerances for Goat, meat byproducts, except kidney and Goat, kidney need to be established.
Goat, meat	0.1	0.02	Tolerance can be reduced
Grape	2.0	2.0	
Hog, fat	0.1	0.02	Tolerance can be reduced
Hog, fat	0.1	0.02	Tolerance can be reduced
Hog, mbyp	0.1	Revoke	Separate tolerances for Hog, meat byproducts, except kidney and

Tolerance Reassessment Summary for Ethephon			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
			Hog, kidney need to be established.
Hog, meat	0.1	0.02	Tolerance can be reduced
Horse, fat	0.1	0.02	Tolerance can be reduced
Horse, mbyp	0.1	Revoke	Separate tolerances for Horse, meat byproducts, except kidney and Horse, kidney need to be established.
Horse, meat	0.1	0.02	Tolerance can be reduced.
Nut, macadamia	0.5	0.50	
Milk	0.1	0.01	Tolerance can be reduced.
Pepper	30	30	
Pineapple	2	2.0	
Pumpkin	0.1	Revoke	Use limited to pumpkins grown solely for seed.
Raisin	12	12	*Grape, raisin*
Sheep, fat	0.1	0.02	Tolerance can be reduced.
Sheep, mbyp	0.1	Revoke	Separate tolerances for *Sheep, meat* byproducts, except kidney and Sheep, kidney need to be established.
Sheep, meat	0.1	0.02	Tolerance can be reduced.
Sugarcane, molasses	1.5	1.5	
Tomato	2	2.0	
Walnut	0.5	0.50	
Wheat, bran	5.0	5.0	
Wheat, grain	2.0	2.0	
Wheat, milled fractions (exc. flour)	5.0	5.0	Wheat, milled byproducts
Wheat, straw	10.0	10	
Tolerances listed under 40 CFR §180.300(b)			
Sugarcane	0.1	0.10	Regional registration (HI only).
Tolerances to be proposed under 40 CFR §180.300 (a)			
Apple, juice	N/A	10	New tolerance needed.
Cotton, gin byproducts	None	180	New tolerance needed.
Filbert	None	0.80	New tolerance needed

Tolerance Reassessment Summary for Ethephon			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Egg	None	0.002	New tolerance needed.
Cattle, kidney	None	1.0	New tolerance needed.
Cattle, meat byproducts, except kidney	None	0.20	New tolerance needed.
Goat, kidney	None	1.0	New tolerance needed.
Goat, meat byproducts, except kidney	None	0.20	New tolerance needed.
Hog, kidney	None	1.0	New tolerance needed.
Hog, meat byproducts, except kidney	None	0.20	New tolerance needed.
Horse, kidney	None	1.0	New tolerance needed.
Horse, meat byproducts, except kidney	None	0.20	New tolerance needed
Sheep, kidney	None	1.0	New tolerance needed.
Sheep, meat byproducts, except kidney	None	0.20	New tolerance needed.
Poultry, fat	None	0.02	New tolerance needed.
Poultry, liver	None	0.05	New tolerance needed.
Poultry, meat	None	0.01	New tolerance needed.
Poultry, meat byproducts, except liver	None	0.01	New tolerance needed. A previous memo (D280983, 5/7/02, T. Morton) incorrectly stated the registrant proposed a tolerance for Poultry, meat byproducts, except kidney.
Wheat, germ	None	5.0	New tolerance needed.
Wheat, shorts	None	5.0	New tolerance needed.

Codex Harmonization

Several maximum residue limits (MRLs) for ethephon have been established by Codex. Both Codex and the U.S. regulate ethephon *per se*. The Codex MRLs, applicable U.S. tolerances, and recommendations for harmonizing U.S. tolerances with Codex MRLs are presented below. Recommendations for compatibility are based on conclusions following reassessment of U.S. tolerances.

Codex MRLs and Applicable U.S. Tolerances.

Commodity	MRL (mg/kg)	U.S. Tolerance (ppm)	Recommendation
Apple	5	5.0	Compatibility exists
Barley	1	2.0	Residue data reflecting the U.S. use pattern support a 2.0 ppm tolerance
Barley straw and fodder, dry	5	10	Residue data reflecting the U.S. use pattern support a 10 ppm tolerance
Blueberries	20	20	Compatibility exists
Cantaloupe	1	2.0	Residue data reflecting the U.S. use pattern support a 2.0 ppm tolerance
Cherries	10	10	Compatibility exists
Chicken eggs	0.2	0.002	Proposed
Cottonseed	2	6.0	Originally compatibile; but the U.S. needs to increase the level.
Dried Grapes (=currants, raisins and sultanas)	5	12	Residue data reflecting the U.S. use pattern support a 12 ppm tolerance
Edible offal of cattle, goats, horses, pigs & pigs	0.2	0.02	Proposed
Figs, Dried or dried and candied	10	TBD[a]	No U.S. registered uses
Grapes	1	2.0	Residue data reflecting the U.S. use pattern support a 2.0 ppm tolerance
Hazelnuts	0.2	none	
Meat of cattle, goats, horses, pigs, & sheep	0.1	0.02	
Milk of cattle, goats and sheep	0.05	0.01	Reduced from 0.1 ppm
Peppers	5	30	Residue data reflecting the U.S. use pattern support a 30 ppm tolerance
Pineapples	2	2.0	Compatibility exists
Poultry meat	0.1	0.01	Proposed
Poultry, Edible offal of	0.2	0.01	Proposed
Rye	1	none	
Rye straw and fodder, dry	5	none	
Tomatoes	2	2.0	Compatibility exists
Walnuts	0.5	0.50	Compatibility exists
Wheat	1	2.0	Residue data reflecting the U.S. use pattern support a 2.0 ppm tolerance
Wheat straw and fodder, dry	5	10	Residue data reflecting the U.S. use pattern support a 10 ppm tolerance

a) TBD -Prior to revocation, the Agency will determine whether, due to import considerations, the tolerance should be retained or raised to be compatible with the Codex MRL.

V. Data Requirements

Product Chemistry Data Requirements

All pertinent data requirements are satisfied except for the Bayer CropScience formulation intermediate (F1). These data are not expected to change the regulatory conclusions for ethephon described in this document. The required data for the TRED are as follows:

- 830.7050 – Ultraviolet/visible Absorption
- 830.6313 – Stability to Normal and Elevated Temperatures, Metals and Metal Ions (stability)

The registrant should submit the above required data and either certify that the suppliers of beginning materials and manufacturing process for the ethephon manufacturing use products have not changed since the last comprehensive product review, or submit an updated product chemistry data package.