

OPP-2004-0131. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

## II. What Action Is EPA Taking?

This document extends the comment period established in the **Federal Register** of May 7, 2004 (69 FR 25577) (FRL-7358-1), during which the registrant may withdraw the voluntary cancellation request. In that document, EPA issued a notice of receipt of request by a registrant to voluntarily cancel certain pesticide registrations. On May 20, 2004, EPA received a request from the USA Rice Federation for an extension of the time period to July 1, 2004, so that the USA Rice Federation may negotiate with the registrant, Bayer Crop Science, to withdraw its voluntary cancellation request. In light of the fact that the registrations will expire on July 1, 2004, the Agency will extend the comment period to June 21, 2004, not July 1, 2004. By extending to June 21, 2004, the Agency will be able to address timely received comments and requests for withdrawal before the expiration of the registrations on July 1, 2004. EPA is hereby extending the public comment period during which the registrant may withdraw the request to voluntarily cancel these pesticide registrations,

which was set to end on June 7, 2004, to June 21, 2004.

## III. What Is the Agency's Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Section 6(f)(1) further provides that the Administrator shall provide for a 30-day period in which the public may comment. For minor crops, this period shall be 180 days, except that the registrant may waive the 180-day comment period. In this case, Bayer CropScience waived the 180-day comment period.

### List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 2, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 04-12917 Filed 6-7-04; 12:03 pm]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0148; FRL-7360-2]

### Pymetrozine; Notice of Filing a Pesticide Petition To Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2004-0148, must be received on or before July 9, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2004-0148. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's

electronic public docket and and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are

mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

#### *C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2004-0148. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or

other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2004-0148. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2004-0148.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2004-0148. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public

docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. What Action Is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

**List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 24, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

**Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Syngenta Crop Protection, the pesticide's registrant, and submitted by the Interregional Research Project Number 4 (IR-4) and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

**Interregional Research Project Number 4**

*PP 2E6467*

EPA has received a pesticide petition (PP 2E6467) from the IR-4 Project, Project Centre for Minor Crop Pest Management, Rutgers, The State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 8920-3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerance for residues of the insecticide pymetrozine (1,2,4-triazin-3(2H)-one,4,5-dihydro-6-methyl-4-(3-pyridinylmethylene)amino in or on the raw agricultural commodity asparagus at 0.02 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

*A. Residue Chemistry*

1. *Plant metabolism.* The metabolism of pymetrozine in plants is understood for the purposes of the proposed tolerances. Studies in rice, tomatoes, cotton and potatoes gave similar results. The metabolic pathways have demonstrated that pymetrozine, per se, is the residue of concern for tolerance setting purposes.

2. *Analytical method.* Syngenta has submitted an analytical method (AG-643) for the determination of pymetrozine in crop substrates. The limit of detection (LOD) for the analytical method is 1.0 ng and the limit of quantification (LOQ) is 0.02 ppm.

Samples are extracted, purified with solid-phase and liquid-liquid partitions and analyzed by high performance liquid chromatography (HPLC). Analytical method has undergone independent laboratory validation. The pymetrozine Analytical Method AG-643 is proposed as the tolerance enforcement method. Syngenta has also submitted an analytical method (AG-647) for the determination of the major crop metabolite of pymetrozine, GS-23199. GS-23199 is considered a marker for metabolite residues. This metabolite is not proposed as part of the tolerance expression. Samples are extracted, purified with solid-phase and/or liquid-liquid partitions and analyzed by HPLC.

3. *Magnitude of residues.* Residue data were generated for pymetrozine for tolerance setting and dietary exposure estimates. Data were also generated for a major metabolite, GS-23199. Adequate residue trials were performed for pymetrozine on the uses proposed in this notice of filing.

*B. Toxicological Profile*

1. *Acute toxicity.* In general, pymetrozine has low acute toxicity being classified as Toxicity Category III for acute dermal and primary eye irritation studies and Toxicity Category IV for acute oral, acute inhalation and primary dermal studies. The oral lethal dose (LD)<sub>50</sub> in rats is >5,820 milligrams/kilogram (mg/kg) for males and females, combined. The rat dermal LD<sub>50</sub> is >2,000 mg/kg and the rat inhalation lethal concentration (LC)<sub>50</sub> is > 1.8 milligrams/liter (mg/L) air. Pymetrozine is a slight sensitizer in guinea pigs. End-use water-dispersible granule formulations of pymetrozine have similar low acute toxicity profiles.

2. *Genotoxicity.* Pymetrozine did not induce point mutations in bacteria (Ames assay in *Salmonella typhimurium* and *Escherichia coli*) or in cultured mammalian cells (Chinese hamster V79) and was not genotoxic in an *in vitro* unscheduled DNA synthesis assay in rat hepatocytes. Chromosome aberrations were not observed in an *in vitro* test using Chinese hamster ovary cells and there were no clastogenic or aneugenic effects on mouse bone marrow cells in an *in vivo* mouse micronucleus test. These studies show that pymetrozine is not mutagenic or genotoxic.

3. *Reproductive and developmental toxicity.* In a teratology study in rats, pymetrozine caused decreased body weights and food consumption in females given 100 and 300 mg/kg/day during gestation. This maternal toxicity was accompanied by fetal skeletal anomalies and variations consistent

with delayed ossification. The no observed adverse effect level (NOAEL) for maternal and fetal effects in rats was 30 mg/kg/day. In a rabbit teratology study, maternal death, reduced body weight gain and food consumption were observed at 125 mg/kg/day (highest dose tested). Embryo and fetotoxicity (abortion in one female and total resorptions in two females) accompanied maternal toxicity. Body weight and food consumption decreases, early resorptions and postimplantation losses were also observed in maternal rabbits given 75 mg/kg/day. There was an increased incidence of fetal skeletal anomalies and variations at these maternally toxic doses. The NOAEL for maternal and fetal effects in rabbits was 10 mg/kg/day. Pymetrozine is not teratogenic in rats or rabbits. In a 2-generation reproduction study in rats, parental body weights and food consumption were decreased, liver and spleen weights were reduced and histopathological changes in liver, spleen and pituitary were observed at approximately 110–440 mg/kg/day (highest dose tested). Liver hypertrophy was observed in a few parental males at approximately 10–40 mg/kg/day. Reproductive parameters were not affected by treatment with pymetrozine. The NOAEL for reproductive toxicity is approximately 110–440 mg/kg/day. The NOAEL for toxicity to adults and pups is approximately 1–4 mg/kg/day.

4. *Subchronic toxicity.* Pymetrozine was evaluated in 13-week subchronic toxicity studies in rats, dogs and mice. Liver, kidneys, thymus and spleen were identified as target organs. The NOAEL was 33 mg/kg/day in rats and 3 mg/kg/day in dogs. In mice, increased liver weights and microscopical changes in the liver were observed at all doses tested. The NOAEL in mice was <198 mg/kg/day. No dermal irritation or systemic toxicity occurred in a 28-day repeated dose dermal toxicity study with pymetrozine in rats given 1,000 mg/kg/day. Minimum direct dermal absorption (1.1%) of pymetrozine was detected in rats over a 21-hour period of dermal exposure. Maximum radioactivity left on or in the skin at the application site and considered for potential absorption was 11.9%.

5. *Chronic toxicity.* Based on chronic toxicity studies in the dog and rat, a reference dose (RfD) of 0.0057 mg/kg/day is proposed for pymetrozine. This RfD is based on a NOAEL of 0.57 mg/kg/day established in the chronic dog study and an uncertainty factor of 100 to account for interspecies extrapolation and interspecies variability. Minor changes in blood chemistry parameters,

including higher plasma cholesterol and phospholipid levels, were observed in the dog at the lowest observed adverse effect level (LOAEL) of 5.3 mg/kg/day. The NOAEL established in the rat chronic toxicity study was 3.7 mg/kg/day and was based on reduced body weight gain and food consumption, hematology and blood chemistry changes, liver pathology and biliary cysts.

The carcinogenic potential of pymetrozine has been evaluated in rats and mice. A liver tumor response was observed in male and female mice and female rats at high doses exceeding the maximum tolerated dose. These liver tumors correlated with reversible biochemical (induction of liver metabolizing enzymes) and morphological (hepatocyte and smooth endoplasmic reticulum proliferation) changes and a reversible saturation of metabolic processes. EPA has assigned a cancer classification of “likely” to pymetrozine and calculated a Q1\* value. However, Syngenta believes that the mechanism of action leading to liver tumors at maximum tolerated doses is a non-genotoxic threshold event and should be regulated as such.

6. *Animal metabolism.* The metabolism of pymetrozine in the rat is well understood. Metabolism involves oxidation of substituent groups of the triazine ring yielding ketones and carboxylic acids. Hydrolysis of the enamino bridge between rings results in products that are further metabolized. The metabolic pathways in animals and plants are similar.

7. *Metabolite toxicology.* The residue of concern for tolerance setting purposes is the parent compound. Metabolites of pymetrozine are considered to be of equal or lesser toxicity than the parent.

8. *Endocrine disruption.* Pymetrozine does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that pymetrozine has any effect on endocrine function in developmental and reproduction studies. Furthermore, histological investigation of endocrine organs in chronic dog, rat and mouse studies did not indicate that the endocrine system is targeted by pymetrozine.

#### C. Aggregate Exposure

1. *Dietary exposure.* Tier III acute, chronic and lifetime dietary exposure evaluations were made using the Dietary Exposure Evaluation Model (DEEM™), version 7.81 from Exponent. Empirically derived processing studies for cotton oil (0.62X), potato chips (1.00X), tomato

paste (0.57X) and tomato puree (0.21X) were used in these assessments. All consumption data for these assessments was taken from the USDA’s Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–1996 consumption database and the Supplemental CSFII children’s survey (1998) consumption database. These exposure assessments included all registered uses on cotton, pecans, hops, cucurbits, tuberous and corm vegetables, Brassica (cole) leafy vegetables, leafy vegetables, fruiting vegetables, and a pending new use on asparagus. Secondary residues in animal commodities were not included in the exposure assessment since no tolerance values exist for residues in meat and milk and a three-level dairy feeding study in lactating livestock showed no residues at any of the feeding levels. Additionally, the highest feeding level (10 ppm) used in this study was at least 10-fold higher than what would be expected in treated feed.

a. *Food.* For the purposes of assessing the potential dietary exposure, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed. These assessments utilized residue data from field trials where pymetrozine was applied at the maximum intended use rate and samples were harvested at the minimum pre-harvest interval (PHI) to obtain maximum residues. Percent of crop treated values were values were taken from the Biological and Economic Analysis Division’s (BEAD’s) latest pymetrozine estimate compiled on August 15, 2001.

i. *Chronic exposure.* The chronic reference dose (RfD) of pymetrozine is 0.0038 mg/kg bwt/day and is based on a NOAEL of 0.38 mg/kg bwt/day from a chronic feeding study in rats and a 100X uncertainty factor. No additional FQPA safety factor was applied. The pymetrozine Tier III chronic dietary exposure assessment was based upon field trial residue results. For the purpose of aggregate risk assessment, the exposure values were expressed in terms of margin of exposure (MOE), which was calculated by dividing the NOAEL by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the chronic reference dose (%RfD). Chronic exposure to the most exposed sub-population (children 1–2 years old) resulted in a MOE of 1,203 (1.1% of the chronic RfD of 0.0038 mg/kg bwt/day). Since the benchmark MOE for this assessment was 100 and the EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable

certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses of pymetrozine.

ii. *Acute exposure.* The aRfD for pymetrozine for all populations except females (13+ years old) is 0.42 mg/kg-bw/day and is based on a lowest observable adverse effect level (LOAEL) of 125 mg/kg/day from an acute neurotoxicity study in rats and a 300X uncertainty factor. The acute population adjusted-dose (aPAD) for females (13+ years old) is 0.10 mg/kg bwt/day and is based on a NOAEL of 10 mg/kg bwt/day from a rabbit developmental toxicity study and a 100X uncertainty factor. A Tier III probabilistic acute dietary analysis was conducted with a full distribution of residues for all registered commodities and asparagus. Each residue distribution was adjusted for percent of crop treated by adding zeroes to the distribution to account for the percent of crop not treated. Acute exposure to females (13–50 years old) resulted in a MOE of 123,640 (0.5% of the acute population adjusted dose (aPAD) of 0.10 mg/kg bwt/day). Acute exposure to the most exposed sub-population children 1–2 years old resulted in a MOE of 123,640 (0.2% of the acute RfD of 0.0038 mg/kg bwt/day). Since the benchmark MOE for this assessment was 300 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses of pymetrozine.

iii. *Lifetime exposure.* Lifetime risk to pymetrozine was evaluated by comparing exposure to a  $Q^*$  value of  $0.0119 \text{ (mg/kg bwt/day)}^{-1}$  based on male mouse liver benign hepatomas and/or carcinomas combined. Lifetime risk for the U.S. population was  $3.49 \times 10^{-7}$ . Since this value is below the EPA's lifetime risk limit of  $1.00 \times 10^{-6}$ , these results indicate that there is a reasonable certainty of no harm resulting from lifetime exposures through the consumption of pymetrozine-treated commodities.

b. *Drinking water.* Drinking water exposure to pymetrozine was evaluated based on the crop uses above with EPA's surface water Tier I model (Generic Expected Environmental Concentration (GENEEC)). Hops, with three applications at 0.1875 lb a.i./acre, gave the highest total application and this rate was; therefore, used in GENEEC to estimate the chronic, acute and lifetime estimated environmental concentrations (EECs) for drinking water.

1. *Acute exposure*—i. The acute EEC for pymetrozine was 4.27 ppb and the chronic EEC was 0.31 parts per billion (ppb.) The calculated acute DWLOC for the most sensitive sub-population children 1–2 years old was 4,190 ppb. Since acute EEC value of 4.27 ppb is less than the calculated acute DWLOC, these results indicate that there is a reasonable certainty of no harm resulting from acute drinking water exposures.

ii. *Chronic exposure.* The chronic EEC for pymetrozine was 0.031 ppb. The calculated chronic DWLOC for the most sensitive sub-population children 1–2 years old was 38 ppb. Since the chronic EEC of 0.31 ppb is below this value, these results indicate that there is a reasonable certainty of no harm resulting from chronic drinking water exposures.

iii. *Lifetime exposure.* Using a  $Q^*$  value of  $0.0119 \text{ mg/kg bwt/day}^{-1}$  and a chronic EEC of 0.31 ppb, the risk to a typical 70 kg adult drinking 2 liters of water per day would be at  $1.05 \times 10^{-7}$ .

2. *Non-dietary exposure.* Pymetrozine is registered on ornamentals and exposure could occur through post-application re-entry to treated plants. Syngenta believes that risks due to short-term, intermediate-term or chronic exposure are either not applicable or insignificant.

#### D. Cumulative Effects

EPA is also required to consider the potential for cumulative effects of pymetrozine and other substances that have a common mechanism of toxicity. Pymetrozine belongs to a chemical class known as pyridine azomethines and exhibits a unique mode of action. EPA consideration of a common mechanism of toxicity is not appropriate at this time since EPA does not have information to indicate that toxic effects produced by pymetrozine would be cumulative with those of any other chemical compounds; thus only the potential risks of pymetrozine are considered in this exposure assessment.

#### E. Safety Determination

1. *Acute risk.* Exposure to pymetrozine residues in food will occupy no more than 0.2% of the RfD of 0.42 mg/kg bwt/day for the most sensitive population subgroup children 1–2 years old. Residue values used for these dietary risk assessments were from field trials and incorporated percent of crop treated information in the residue distributions. Acute dietary exposure estimates were determined at the 99.9<sup>th</sup> percentile of acute exposure. Estimated concentrations of pymetrozine residues

in surface water and ground water were below the calculated acute drinking water level of comparison (DWLOC). Therefore, Syngenta does not expect acute aggregate risk to pymetrozine residues from food and water sources to exceed the level of concern for acute dietary exposure.

2. *Chronic risk.* Chronic dietary exposure to pymetrozine residues in food for the most sensitive population subgroup (children 1-2 years old) occupied 1.1% of the chronic RfD of 0.0038 mg/kg bwt/day. Residue values used for these dietary risk assessments were from field trials and incorporated percent of crop treated information, as indicated above. Estimated concentrations of pymetrozine residues in surface water and ground water were below the calculated chronic drinking water level of comparison (DWLOC). Syngenta believes that the chronic aggregate risk from pymetrozine residues in food and drinking water would therefore not be expected to exceed the EPA's level of concern.

3. *Lifetime risk.* The chronic lifetime dietary risk to pymetrozine residues in food for the U.S. population was  $3.49 \times 10^{-7}$ , which is below EPA's level of concern ( $1.0 \times 10^{-6}$ ). Residue values used for this lifetime risk assessment were from field trials and incorporated percent of crop treated information, as indicated above. The estimated concentrations of pymetrozine residues in surface water and ground water are lower than the calculated lifetime DWLOC. Therefore, Syngenta concludes that the aggregate lifetime risk from pymetrozine residues in food and drinking water sources would therefore not be expected to exceed EPA's level of concern for lifetime dietary exposure.

Syngenta has considered the potential aggregate exposure from food, water and non-occupational exposure routes and concluded that aggregate exposure is not expected to exceed 100% of the acute, chronic and lifetime reference doses. Therefore, Syngenta believes there is a reasonable certainty that no harm will result to infants and children from the aggregate exposures to pymetrozine.

#### F. International Tolerances

There are no established European Codex, Canadian, or Mexican maximum residue limits for pymetrozine. There are provisional MRLs in Germany for hops 10 ppm and potatoes 0.02 ppm. The European Union is currently evaluating a proposed tolerance of 5 ppm on hops. At this time, international

harmonization of residue levels is not an issue.

[FR Doc. 04-12703 Filed 6-8-04; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7671-8]

### Notice of Proposed Settlement Agreement Under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) as Amended, 42 U.S.C. 9606(a) and 9622(h), Agromac/Lockwood Superfund Site, Gering, NE, Docket No. CERCLA-07-2003-0302

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlement agreements, Lockwood Corporation and Agromac International, Inc., Agromac/Lockwood Superfund Site, Gering, Nebraska.

**SUMMARY:** Notice is hereby given that two proposed settlement agreements regarding the Lockwood Corporation and Agromac International, Inc. Superfund Site (Agromac/Lockwood), located in Gering, Nebraska, were signed by the United States Environmental Protection Agency (EPA) on December 17, 2003, and signed by the United States Department of Justice (DOJ) on May 1, 2004. Commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d).

**DATES:** EPA will receive written comments relating to these proposed settlement agreements until July 9, 2004.

**ADDRESSES:** Comments should be addressed to E. Jane Kloeckner, Senior Assistant Regional Counsel, United States Environmental Protection Agency, Region VII, 901 N. 5th Street, Kansas City, Kansas 66101 and should refer to: In the Matter of Agromac/Lockwood Superfund Site, Gering, Nebraska, Docket No. CERCLA-07-2003-0302. Comments may also be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to In re: Lockwood Corporation, D.J. Ref. 90-11-2-06925.

These proposed settlement agreements may be examined or obtained in person or a copy requested by mail from the office of the United States Environmental Protection

Agency, Region VII, 901 N. 5th Street, Kansas City, KS 66101, (913) 551-7235. The Settlement Agreements may be examined at the Office of the United States Attorney, 1620 Dodge Street, Suite 1400, Omaha, NE 68102-1506. A copy may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing a request to Tonia Fleetwood, fax No. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy, please enclose a check in the amount of \$3.75 for the Bankruptcy Agreement, or \$19.50 for the Administrative Order (25 cents per page reproduction cost) payable to the U.S. Treasury.

**SUPPLEMENTARY INFORMATION:** These proposed settlements are intended to resolve the CERCLA liability of Lockwood Corporation, Debtor (Lockwood), and Agromac International, Inc. (Agromac) for response actions at the Agromac/Lockwood Site. This Site is located on Highway 92 East in Gering, Nebraska, and encompasses approximately 80 acres. It is generally in a commercial/agricultural area; however, a few residential homes are nearby.

Prior to acquisition by Agromac, the entire facility was owned by Lockwood, which manufactured and galvanized irrigation equipment and manufactured potato harvesting machines beginning in the early 1970s. In 1976, Agromac brought the facility and leased the irrigation manufacturing/galvanizing portion of the Block P Parcel to Powerhorse Lockwood Irrigation, Inc. (PLI), a defunct Nebraska corporation. During operations by Lockwood Corporation through 1984, Lockwood disposed of some hazardous wastes in a waste acid evaporation pond. In 1989, Lockwood obtained a RCRA Post Closure Permit from the State of Nebraska and a RCRA Corrective Action Permit from EPA, Region VII, which regulates the post-closure care of the evaporation pond and corrective action for six solid waste management units throughout the Agromac/Lockwood Site.

Agromac and Lockwood have been identified by EPA as eligible for a settlement based on their limited ability to pay for cleanup and reimburse response costs using EPA's Superfund Ability to Pay (ATP) Guidance. The Lockwood agreement is embodied in a Settlement under the United States Bankruptcy Court in Nebraska because Lockwood is under supervision of the US Bankruptcy Trustee due to its petition for liquidation under Chapter 7

of the US Bankruptcy Code. The Settlement Agreement is between the Lockwood Corporation Bankruptcy Trustee, Agromac International Inc., and the United States. The Agreement provides for (i) the hazardous waste management unit to be transferred from Lockwood to Agromac, and (ii) transfer of the remaining funds in the bankruptcy estate, net of \$52,000 in reimbursement of monitoring expenditures and fees, to an escrow account for use in cleaning up the property in accordance with the companion Administrative Order on Consent entered into between Agromac and the EPA. In return for the commitments by the Trustee, the United States grants Lockwood a covenant not to sue under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, and section 7003 of the Resource Conservation and Recovery Act, 42 U.S.C. 6973, relating to the Agromac/Lockwood Site.

The settlement with Agromac is pursuant to section 107 and 122 of CERCLA. The agreement provides for Agromac to pay \$65,000 to EPA and perform the final removal action at the Site. In addition, the Agromac settlement has certain re-openers for changed financial condition if Agromac sells real estate above its book value, in which case 40% of the excess proceeds will be paid to EPA. Agromac agrees to use all funds received in the Bankruptcy distribution from Lockwood to pay for the response actions. If the removal action costs less than Agromac received from the bankruptcy distribution, the remaining proceeds from the distribution will be paid to EPA. In return for the commitments by the Agromac, the United States grants Agromac a covenant not to sue under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, relating to the Agromac/Lockwood Site.

Dated: May 24, 2004.

**James B. Guilliford,**

*Regional Administrator, Region VII.*

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## FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 96-45; DA 04-1445]

### Parties are Invited to Comment on Petitions for Eligible Telecommunications Carrier Designations

**AGENCY:** Federal Communications Commission.