iii. *Aggregate exposure (diet + water).* The estimated chronic aggregate exposure of imazethapyr from potential residues in food and water are summarized in Table 3 as follows. Imazethapyr is not registered for residential use and therefore residential exposure was not considered.

TABLE 3. — ESTIMATED CHRONIC AGGREGATE EXPOSURE FROM THE USE OF IMAZETHAPYR

Population Subgroup	Chronic Food Exposure (mg/kg/day)	Chronic Drinking Water Exposure[1] (mg/kg/day)	Aggregate Exposure[2] (mg/kg/day)	Aggregate %cPAD
U.S. Population	0.000476	0.003600	0.004076	0.16
Infants (< 1 year old)	0.000693	0.012600	0.013293	0.53
Children (1-6 years old)	0.000937	0.012600	0.013537	0.54
Females (13-49 years old)	0.000379	0.004000	0.004379	0.18
Adults (20-49 years old)	0.000424	0.003600	0.004024	0.16

[1] Aggregate Exposure = Food Exposure + Drinking Water Exposure
[2] Drinking Water Exposure (mg/kg/day) = [Drinking Water Concentration (µg/L) * Water Consumed (L/day)/ Body weight (kg)]/1,000

The assessment results indicate the aggregate exposure of imazethapyr from potential residues in food and drinking water will not exceed the U.S. EPA's level of concern (100% of PAD). The percent chronic PAD was <1% for all subpopulations. Additional refinements such as the use of anticipated residues and predicted percent crop treated would further reduce the estimated chronic dietary exposure and %cPAD. Overall, considering a ''worst-case'' scenario, we can conclude with reasonable certainty that no harm will occur from chronic aggregate exposure of imazethapyr residues from the current crops, including the higher proposed tolerance values.

2. *Non-dietary exposure* . Imazethapyr products are not currently registered for requested to be registered for residential use; therefore the estimate of residential exposure is not relevant to this tolerance petition.

D. Cumulative Effects

Imazethapyr is a member of the imidazolinone class of herbicides. Other compounds of this class are registered for use in the United States However, the herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxyacid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the low toxicity of the imidazolinone compounds in animals. We are aware of no information to indicate or suggest that imazethapyr has any toxic effects on mammals that would be cumulative with those of any other chemical. Therefore, for the purposes of this tolerance petition no assumption has been made with regard to cumulative exposure with other compounds having a common mode of action.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated the aggregate exposure to imazethapyr will utilize less than 1% of the cPAD for the U.S. population and all subpopulations, respectively.

2. *Infants and children.* All subpopulations based on age were considered. Infants and children remained below 1% of the aggregate cPAD for food and water. BASF, considering a worst-case situation, concludes with reasonable certainty that no harm will result to infants or children from aggregate exposure to imazethapyr residues.

No additional FQPA safety factor(s) are considered to be appropriate for imazethapyr. There is a complete toxicity database for imazethapyr and the exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the toxicology data and conclusions, a FQPA safety factor of 1X appears to be appropriate for imazethapyr.

F. International Tolerances

There are no Codex maximum residue levels established or proposed for residues of imazethapyr on rice.

[FR Doc. 05–12444 Filed 6–28–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0033; FRL–7718–8]

Paraquat Dichloride; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Potection 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 identification (ID) number OPP–2005–0033, must be received on or before July 29, 2005.

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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703) 305–5697; e-mail address: *tompkins.jim@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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. 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. 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–2005–0033. 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, 1801 S. Bell St., 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. 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 toward 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 in 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–2005–0033. 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, Attention: Docket ID Number OPP–2005–0033. 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–2005–0033.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0033. 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 a 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: June 10, 2005.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner 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.

Syngenta Crop Protection, Inc.

PP 2F6433 , 3E 6763, 1E 6332, 1E 6319, 1E 6223

EPA has received pesticide petitions (2F6433, 3E6763, 1E6332, 1E6319, and 1E6223) from Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300 and Interregional Research Project#4 (IR4), 681 US Highway #1 South, New Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of paraquat dichloride in or on the raw agricultural commodities: cotton, seed at 5.0 parts per million (ppm); cotton gin byproducts at 82.0 ppm; soybean, seed at 0.70 ppm; soybean, forage at 0.40 ppm; soybean, hay at 6.0 ppm; soybean, aspirated grain fractions at 60.0 ppm; wheat, grain at 1.5 ppm; wheat, forage at 0.40 ppm; wheat, hay at 3.0 ppm; wheat, straw at 40.0 ppm; wheat, aspirated grain fractions at 65.0 ppm; barley, hay at 3.0 ppm; vegetable, brassica leafy, group at 0.05 ppm; fruit, pome, group at 0.05 ppm; fruit, stone, group at 0.05 ppm; berry group at 0.05 ppm; animal feed, nongrass, group at 5.0 ppm; vegetable, legume, edible-podded, subgroup at 0.05 ppm; pea and bean, succulent, shelled, subgroup at 0.05 ppm; pea and bean, dried, shelled, except soybean, subgroup at 0.3 ppm; grape at 0.05 ppm; cranberry at 0.05 ppm; barley, straw at 1.0 ppm; beet, sugar, tops at 0.05 ppm; sorghum, forage at 0.1 ppm; hops, cone, dry at 0.5 ppm; cattle, kidney at 0.3 ppm; goat, kidney at 0.3 ppm; hog, kidney at 0.3 ppm; horse, kidney at 0.3 ppm; sheep, kidney at 0.3 ppm; vegetable, fruiting, group at 0.05 ppm; vegetable, cucurbit, group at 0.05 ppm; nut, tree, group at 0.05 ppm; ginger at 0.1 ppm, okra at 0.05 ppm, tanier at 0.05 ppm, and onion (dry bulb) at 0.1 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residue in plants is adequately understood based on studies depicting the metabolism of paraquat

dichloride in carrots and lettuce following preemergence treatments and in potatoes and soybeans following desiccant treatment. The residue of concern in plants is the parent, paraquat dichloride; the current tolerance expression for plant commodities, as defined in 40 CFR 180.205(a) and (b).

2. *Analytical method.* An adequate analytical method (spectrometric method) has been accepted and published in The Pesticide Analytical Manual (PAM Vol. II) for the enforcement of tolerances in plant commodities.

3. *Magnitude of residues*—i. *Cotton.* As required under reregistration, residue studies (MRID No. 44432402) were conducted to determine the levels of paraquat cation on ginned cotton seed and cotton byproducts. Twelve residue field trials were conducted during 1995 in the United States. This data reflects a use pattern of a total of 3 lbs ai/A per season as preemergence; followed by two post-directed applications with shielded/hooded sprayers; followed by three broadcast defoliation/desiccation applications. Paraquat dichloride residues in cotton seed ranged from <0.05 to 4.6 mg/kg. These data support a cotton seed tolerance of 5.0 ppm and a gin byproducts tolerance of 82.0 ppm with a 3 day PHI.

ii. *Wheat.* As required under reregistration, residue studies (MRID No. 44965703) were conducted to determine levels of paraquat cation in or on wheat grain, forage, hay, straw, and aspirated grain fractions. Twenty-two residue trials were conducted on wheat (nine on spring wheat and thirteen on winter wheat) during 1997 and 1998. This data reflects a use pattern (preemergence/broadcast, prior to heading/spot spray and three days before grain and straw harvest/broadcast for a total of 1.75 lbs. ai/A. The range of paraquat dichloride residues was: wheat grain (0.06 to 1.1 ppm), wheat forage (<0.050 to 0.29 ppm), wheat hay (<0.050 to 2.8 ppm), wheat straw (4.0 to 40 ppm), and aspirated grain fractions (40 to 61 ppm). These data support a revised tolerance for grain of 1.5 ppm, forage of 0.4 ppm, hay of 3.0 ppm, straw of 40 ppm, and aspirated grain fractions of 65 ppm.

iii. *Soybean.* As required under reregistration, residue studies (MRID No. 44965702) were conducted to determine levels of paraquat cation on soybean seed, forage, hay, and aspirated grain fractions (MRID No. 44965701). Twenty-two field residue studies were conducted on soybeans during 1997 and 1998. The aspirated grain fractions study was conducted during 1995 at 12X the label rate two days prior to harvest. The 1997–1998 data reflects a use pattern (preemergence, directed spray, spot spray, and three days before harvest for a total seasonal rate of 2.9 lbs. ai/A. The range of paraquat dichloride residues was: soybean seed (<0.05 to 0.69 ppm), soybean hay (<0.05 to 5.65 ppm), soybean forage (<0.05to 0.38 ppm), and aspirated grain fractions (57 ppm based on calculations presented in MRID No. 44965701). These data support a revised tolerance for soybean seed at 0.7 ppm, hay at 6.0 ppm, forage at 0.4 ppm and aspirated grain fractions at 60 ppm.

iv. *Ginger.* As required under reregistration, residue studies, residue studies were conducted to determine levels of paraquat cation on ginger. Data was collected from three field studies in Hawaii. All samples from these studies showed residues less than 0.1 ppm.

v. *Okra.* As required under reregistration, residue studies were conducted to determine levels of paraquat cation on okra. Trials were conducted in South Carolina, Tennessee and Texas. No quatifiable residues were found in any of the samples.

vi. *Onion (dry bulb).* There is an established tolerance for pre-plant and preemergence applications of paraquat dichloride. Several states appealed to IR4 to request a tolerance for post-directed applications in onion (dry bulb). Field trials were conducted in New York, Texas, Ohio, Washington, California and Colorado. No quatifiable residues were observed in any of the samples.

vii. *Tanier.* As required under reregistration, residue studies were conducted to determine levels of paraquat cation on tanier. There is an existing tolerance for tanier for Puerto Rico only. Data was collected from one field trial in Florida. No quantifiable residues were observed in any of the samples.

The 1997 Paraquat Dichloride Reregistration Eligibility Decision (RED) indicates that crop group tolerances will be established and indicates the tolerance levels (0.05 ppm) for vegetable, brassica leafy, group; fruit, pome group; fruit, stone, group; and berry group. These are based on existing tolerances. New grape (0.05 ppm) and cranberry (0.05 ppm) tolerances are proposed as they were part of the small fruit group which is being changed to berry group. The request for animal feed, nongrass, group tolerance is also based on statements in the RED to group alfalfa, clover, and birdsfoot trefoil existing tolerances (these are based on broadcast preemergence uses). The RED indicates that tolerances should be raised for forage (75 ppm) and hay (210 ppm). These tolerances are not being proposed as they appear to be based on harvest aid uses in clover and birdsfoot trefoil which are not relevant as only the broadcast preemergence uses are desired in these crops. The field residue data for preemergence broadcast uses in alfalfa, clover and birdsfoot trefoil supports the existing tolerance of 5 ppm. The only harvest aid use for crops in this group is for use on alfalfa grown for seed which has a grazing and feeding prohibition.

Proposed tolerance for barley, straw (1.0 ppm) is a new tolerance indicated in the RED assessment. Proposed individual (miscellaneous) tolerance changes based on the RED assessment include beet, sugar, tops (0.05 ppm); sorghum, forage (0.1ppm); and hops, cone, dry (0.5 ppm). The proposed increased tolerances for kidney are to harmonize U. S. tolerances with Codex Maximum Residue Levels (MRL's) as discussed in the RED. Proposed tolerances for vegetable, fruiting, group; vegetable, cucurbit, group, and nut, tree, group update the crop group nomenclature only. They are based on existing crop group tolerances. The proposed tolerances for Crop Subgroups 6A, 6B, and 6C (Peas and Beans) are not discussed in the RED and result from a new tolerance (peas, dry) granted in Sept. 1991. The use pattern for Group 6C is for a harvest aid application while 6A and 6B are for preplant/preemergence application.

Tolerances discussed in the RED which are not being requested include: grape, juice (the processing factor is 1.0 so the tolerance is the same as grape), raisin (processing factor is 1.0), pineapple, process residue (the processing factor is 0.6), sugarcane molasses (processing factor is 0.1 for refined molasses) and corn, field, flour (processing factor is 1.0, discussed in the Sept. 1991 FR Notice).

Animal feed, grass, group will not be requested. Syngenta Crop Protection, Inc. is voluntarily removing animal feed, grass (pasture and range) uses from the label except for grasses grown for seed and ''juniper leaf moisture reduction or desiccation prior to prescribed burning of pastures'' which have a feeding/grazing prohibition.

B. Toxicological Profile

1. *Acute toxicity.* Acute toxicity studies conducted with the 45.6% paraquat dichloride technical concentrate give the following results: oral LD_{50} in the rat of 344 mg/kg (males) and 283 mg/kg (females) (Category II); dermal LD_{50} in the rat of >2,000 mg/kg for males and females (Category III); the primary eye irritation study showed

corneal involvement with clearing in 17 days (Category II) ; and dermal irritation of slight erythema and edema at 72 hours (Category IV). Paraquat dichloride is not a dermal sensitizer. Acute inhalation studies conducted to EPA guideline with aerosolized sprays result in LC_{50} of 0.6 to 1.4 µg paraquat cation/L (Category I). However, since paraquat dichloride has no measurable vapor pressure, and hydraulic spray droplets are too large to be respired, inhalation exposure is not a concern in practice.

2. *Genotoxicity*. Paraquat dichloride was not mutagenic in the Ames test using *Salmonella typhimurium* strains TA1535, TA1538, TA98, and TA100; the chromosomal aberrations in the bone marrow test system; or in the dominant lethal mutagenicity study with CD–1 mice. Additionally, paraquat dichloride was negative for unscheduled DNA synthesis in rat hepatocyctes *in vitro* and *in vivo.* Paraquat dichloride was weakly positive in the mouse lymphoma cell assay only in the presence of metabolic activation. Paraquat dichloride was weakly positive in mammalian cells (lymphocytes) and positive in the sister chromatid exchange (SCE) assay in Chinese hamster lung fibroblasts. Paraquat dichloride is nonmutagenic.

3.*Reproductive and developmental toxicity*. A three-generation reproduction study in rats fed diets containing 0, 25, 75, and 150 ppm (0, 1.25, 3.75, or 7.5 mg of paraquat cation/kg/day, respectively) showed no effect on body weight gain, food consumption and utilization, fertility and length of gestation of the F0, F1, and F2 parents at any dose. The no observed effect level (NOEL) and lowest observed effect level (LOEL) for systemic toxicity are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/day), respectively, expressed as paraquat cation, based on high mortality due to lung damage (alveolar histiocytes). The NOEL for reproductive toxicity is less than or equal to 150 ppm [7.5 mg/kg/day; highest dose tested (HDT)] expressed as paraquat cation, as there were no reproductive effects.

Two developmental toxicity studies were conducted in rats given gavage doses of 0, 1, 5, and 10 mg/kg/day and 0, 1, 3, and 8 mg/kg/day, respectively, expressed as paraquat cation. In the first study, the NOEL for maternal toxicity was 1 mg/kg/day based on clinical signs of toxicity and decreased body weight gain at 5 mg/kg/day (the LOEL). The NOEL for developmental toxicity was set at 5 mg/kg/day based on delayed ossification of the forelimb and hindlimb digits. In the second study, the maternal and developmental NOEL is 8 mg/kg/day (HDT) as there were no effects observed at any dose level even though the animals were examined more carefully in the manus and pes assessment. Based on both studies the overall NOEL for maternal and developmental toxicity is at least 3 mg/kg/day.

The developmental toxicity studies were conducted in mice given gavage doses of 0, 1, 5, and 10 mg/kg/day and 0, 7.5, 15, or 25 mg/kg/day paraquat ion, respectively. In the first study the NOEL and LOEL for maternal toxicity are 5 mg/kg/day and 10 mg/kg/day, respectively, based on reductions in body weight gain and death (range-finding study). The NOEL and LOEL for developmental toxicity are 5 mg/kg/day and 10 ma/kg/day, respectively, based on an increased number of litters and fetuses with partial ossification of the 4thsternebrae at 10 mg/kg/day (HDT). Both the maternal and developmental NOELs are at 15 mg/kg/day in the second study. The maternal LOEL of 25 mg paraquat cation/kg/day is based on death, decreases in body weight and body weight gain, and mean fetal weights, retarded ossification and other skeletal effects. The developmental/maternal NOEL should be based on the second study and is 15 mg/kg/day. Paraquat dichloride is not a developmental toxin.

4. *Subchronic toxicity.*A 90 day feeding study in dogs fed doses of 0, 7, 20, 60, or 120 ppm with a NOEL of 20 ppm (equivalent to 0.56 mg paraquat cation/kg/d for males and 0.71 mg paraquat cation/kg/d for females) based on lung effects such as alveolitis and alveolar collaps seen at the LOEL of 60 ppm.

A 21 day dermal toxicity study in which rabbits were exposed dermally to doses of 0, 1.5, 3.4, 7.8, or 17.9 mg/kg/day resulted in a NOEL of 1.15 mg paraquat cation/kg.day and a LOEL of 2.6 mg paraquat cation/kg/day based on dermal irritation.

A 21 day inhalation toxicity study in rats that were exposed to respirable aerosols of paraquat at doses of 0, 0.01, 0.1, 0.5, and 1.0 q/L with a NOEL of 0.01 ug paraquat cation/L and a LOEL of 0.10 µg paraqut cation/L based on histopathological changes to the epithelium of the larynx and nasal discharge.

5.*Chronic toxicity*. In a 12–month feeding study, dogs were fed dose levels of 0, 15, 30, or 50 ppm, expressed as paraquat cation. These levels corresponded to 0, 0.45, 0.93, or 1.51 mg of paraquat cation/kg/day, respectively, in male dogs or 0, 0.48, 1.00, or 1.58 mg of paraquat cation/kg/day, respectively for female dogs. There was a dose-related increase in the severity and extent of chronic pneumonitis in the mid-dose and high-dose male and female dogs. This effect was also noted in the low-dose male group, but was minimal when compared with the male controls. The systemic NOEL is 15 ppm (0.45 mg/kg/day for males and 0.48 mg/kg/day for females, expressed as paraquat cation). The systemic LOEL is 30 ppm (0.93 mg/kg/day for males and 1.00 mg/kg/day for females, expressed as paraquat cation).

In a 2–year chronic feeding/carcinogenicity study, rats were fed doses of paraquat dichloride at 0, 25, 75, or 150 ppm which corresponds to 0, 1.25, 3.75, or 7.5 mg of paraquat cation/kg/day. Paraquat dichloride enhanced the development of ocular lesions in all of the treated groups. The predominant lesions detected opthamoscopically were lenticular opacities and cataracts. At test week 103, dose-related statistically significant ($P<0.001$) increases in the incidence of ocular lesions were observed only in the mid-dose and high-dose male and female groups. Based on these findings, the NOEL (approximate) and the LOEL for systemic toxicity, for both sexes, are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/day), respectively. In this study, there was uncertain evidence of carcinogenicity (squamous cell carcinomas in the head region; ears, nasal cavity, oral cavity, and skin) in males at 7.5 mg/kg/day (HDT) with a systemic NOEL of 1.25 mg/kg/day. Upon submission of additional data to EPA, the incidence of pulmonary adenomas and carcinomas was well within historical ranges and it was determined that paraquat dichloride was not carcinogenic in the lungs and head region of the rat.

In another 2–year chronic feeding/carcinogenicity study, rats were dosed at 0, 6, 30, 100 or 300 ppm, expressed as paraquat dichloride (nominal concentrations), equivalent to 0, 0.25, 1.26, 4.15, or 12.25 mg/kg/day, respectively (males) and 0, 0.30, 1.5, 5.12, or 15.29 mg/kg/day respectively (females), expressed as paraquat dichloride. The incidence of ocular changes was low and not caused by paraquat dichloride in this study. The systemic NOEL is 100 ppm of paraquat dichloride (4.15 and 5.12 mg/kg/day, for males and females, respectively); or 3.0 mg/kg/day (males) and 3.7 mg/kg/day (females), expressed as paraquat cation. The systemic LOEL is 300 ppm of paraquat dichloride (12.25 and 15.29 mg/kg/day, for males and females, respectively); or 9.0 mg/kg/day (males) and 11.2 mg/kg/day (females), expressed as paraquat cation. There were no

evidence of carcinogenicity in this study even at the highest dose tested.

In a two year chronic feeding/oncogenicity study, SPF Swiss derived mice were fed paraquat dichloride at dose levels of 0, 12.5, 37.5, or 100/125 ppm, expressed as cation. Because no toxic signs appeared after 35 weeks of dosing, the 100 ppm level was increased to 125 ppm at week 36. There were no carcinogenic effects observed in this study. The systemic NOEL for both sexes is 12.5 ppm (1.87 mg/kg/day) and the systemic LOEL is 37.5 ppm (5.6 mg/kg/day), each expressed as paraquat cation based on renal tubular degeneration in males and weight loss and decreased food intake in females. Paraquat dichloride is classified Category E of carcinogenicity (no evidence of carcinogenicity in animal studies).

6. *Animal metabolism*. The qualitative nature of the residue in animals is adequately understood based on the combined studies conducted with ruminants (goats and cows), swine, and poultry. The residue of concern in eggs, milk, and poultry and livestock tissue is the parent, paraquat dichloride.

7. *Metabolite toxicology*. The nature of the residues in plants and animals is adequately understood. The residue of concern in eggs, milk, poultry, livestock, and in crops is the parent, paraquat dichloride.

8. *Endocrine disruption*. There is no evidence of endocrine effects in the database supporting registration of paraquat dichloride.

C. Aggregate Exposure

1. *Dietary exposure*. Syngenta Crop Protection, Inc. has estimated aggregate exposure based on all proposed and established tolerances.

2. *Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed (i.e., pesticide petition PP#2F6433).

i. *Acute exposure*. The paraquat dichloride acute dietary exposure assessment utilized the Dietary Exposure Evaluation Model (DEEM™, version 7.76) and the USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII Children's Survey (1998) consumption database. The acute reference dose (aRfD) for paraquat dichloride is 0.0042 mg/kg-bw/day for females 13–50 years of age and 0.0125 mg/kg-bw/day for children and the U.S. population. The aRfD is based on a reproduction study in rats with a no observable adverse effect level (NOAEL) of 1.25 mg/kg-bw/day and an uncertainty factor of 100X. An additional FQPA safety factor of 3X was applied for females between the ages of 13 and 50 years due to a data gap for a prenatal developmental study conducted in a non-rodent species. The paraquat dichloride Tier II acute dietary exposure assessment was based upon established and proposed tolerances for paraquat dichloride. The maximum percent crop treated (%CT) values that were described in the most recent EPA exposure assessment for paraquat dichloride (published in the **Federal Register**) of September 21, 2001 (66 FR 48593)(FRL-6799-2) were used for all currently registered crops. One-hundred percent crop treated was assumed for all proposed crops. It should be noted that the most recent EPA acute exposure assessment for paraquat dichloride was based on a probabilistic Monte Carlo analysis using tolerance residue values. The current Syngenta acute assessment was performed deterministically using tolerance residue values. 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 no observable adverse effect level (NOAEL) by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the acute reference dose (%aRfD). Acute exposure to the U.S. population resulted in a MOE of 377 (26.47% of the aRfD of 0.0125 mg/kg-bw/day). The most exposed sub-population was females (13–19 years, not pregnant or nursing) with a MOE of 712 (41.78% of the aRfD of 0.0042 mg/kg-bw/day). Since the benchmark MOE for females (13–50 years of age) 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 paraquat dichloride.

ii. *Chronic exposure*. The paraquat dichloride chronic dietary exposure assessment utilized the Dietary Exposure Evaluation Model (DEEM™, version 7.76) and the USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII Children's Survey (1998) consumption database. The chronic reference dose (cRfD) for paraquat dichloride is 0.0045 mg/kg-bw/day and is based on a one-year feeding study in dogs with a NOAEL of 0.45 mg/kg-bw/day and an uncertainly factor of 100X. No additional FQPA safety factor was applied. The paraquat dichloride Tier II chronic dietary exposure assessment was based upon established and proposed tolerances for paraquat dichloride. The average percent crop treated (%CT) values that were described in the most recent EPA exposure assessment for paraquat dichloride published in the **Federal Register** of September 21, 2001, were used for all currently registered crops. For the proposed crops, it was assumed that 100 percent of these crops were treated. For the purpose of aggregate risk assessment, the exposure values were expressed in terms of MOE and as a percent of the reference dose (%RfD). Chronic exposure to the U.S. population resulted in a MOE of 1,475 (6.8% of the cRfD of 0.0045 mg/kg-bw/day). The most exposed sub-population was children (1–6 years old) with a MOE of 507 (19.7% of the cRfD). Since the benchmark MOE for this assessment was 100 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 paraquat dichloride.

1. *Drinking water*. To estimate total aggregate exposure to a pesticide from food, drinking water and residential uses, the Agency calculates the drinking water level of comparison (DWLOCs) which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water would not result in unacceptable levels of aggregate human health risk. The calculated DWLOC for acute exposure to paraquat dichloride in surface and ground water was 74 ppb for the most exposed sub-population (females 13–19 years, not pregnant or nursing). The calculated DWLOC for chronic exposure to paraquat dichloride in surface and ground water was 36 ppb for the most exposed sub-population (children 1–6 years). Based on the comparison to the EECs for surface and ground water, the estimated environmental concentrations of paraquat dichloride in surface and ground water are below the DWLOC based upon food exposures; therefore, the EPA should not have a drinking water concern for paraquat dichloride.

2. *Non-dietary exposure*. Paraquat dichloride is not registered for use on any sites that would result in residential exposure.

D. Cumulative Effects

Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The EPA does not have, at this time, available data to determine whether paraquat dichloride has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, the EPA has not assumed that paraquat dichloride has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*—i. *Acute risk.* The acute dietary exposure analysis (food only) showed that exposure from all established and proposed paraquat dichloride tolerances would be 26.5% of the aRfD for the general U.S. population.

ii. *Chronic risk.* The chronic dietary exposure analysis (food only) showed that exposure from all established and proposed paraquat dichloride tolerances would be 6.8% of the cRfD for the general U.S. population.

2. *Females 13–50 years of age— Acute risk.* The acute dietary exposure analysis (food only) showed that exposure from all established and proposed paraquat dichloride tolerances would be 41.8% of the aRfD for the most exposed sub-population (females 13–19, not pregnant or nursing).

3. *Infants and children*—i. *Acute risk.* The acute dietary exposure analysis (food only) showed that exposure from all established and proposed paraquat dichloride tolerances would be 38.3% of the aRfD for the next most exposed sub-population (children 1–6 years).

ii. *Chronic risk.* The chronic dietary exposure analysis (food only) showed that exposure from established and proposed paraquat dichloride tolerances would be 19.7% of the cRfD for the most exposed sub-population (children 1–6 years). The next most exposed sub-population was non-nursing infants with an exposure of 12.7% of the cRfD. There is no indication of quantitative or qualitative increased susceptibility of rats or mice to *in utero* and/or prenatal/postnatal exposure to paraquat dichloride. The EPA has determined that a developmental neurotoxicity study is not required. Infants and children are not expected to show any particular sensitivity to paraquat dichloride.

Syngenta has considered the potential aggregate exposure from food and water and concluded that aggregate exposure is not expected to exceed 100% of the acute or chronic reference dose and that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to paraquat dichloride.

F. International Tolerances

Compatibility between U.S. tolerances and Codex Maximum Residue Levels (MRLs) exist for eggs, milk, ruminant tissues, passion fruit, sunflower seed and vegetables including beans (succulent), brassica (cole) leafy vegetables group, carrots, cassava, corn (sweet), cucurbits, fruiting vegetables, lettuce, onions (dry bulb and green), peas (succulent), pigeon peas, turnips (roots and tops), and yams. Incompatibilities of U.S. tolerances and Codex MRLs on the following raw plant commodities remain because of differences in agricultural practices: Cottonseed, dry hops, dry peas/beans, maize, olives, potatoes, rice, sorghum, soybeans and wheat. No questions of compatibility exists with respect to commodities where no Codex MRLs have been established but United States tolerances exist or where Codex MRLs have been established but U.S. tolerances do not exist.

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BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget

June 16, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 29, 2005. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Leslie F. Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., DC 20554 or via the Internet to *Leslie.Smith@fcc.gov*, and/or to Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov*. If you would like to obtain or view a copy of this new information collection, you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Leslie F. Smith at (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Commission has requested approval of these information collections under the emergency processing provisions of the PRA by July 1, 2005.

OMB Control Number: 3060–XXXX.

Title: Federal Communications Commission Proposes Collection of Location Information, Provision of Notice and Reporting on Interconnected voice over Internet Protocol (VoIP) E911 Compliance.

Type of Review: Emergency.

Form Number: N/A.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, Local or Tribal Governments; and Individuals or households.

Number of Respondents: 100.

Estimated Time per Response: 0.09 hours–16 hours.

Frequency of Response: Recordkeeping; on occasion, annual,