

**List of Subjects**

Environmental Protection, Creosote, Pesticides and pests.

Dated: September 8, 2004.

**Frank Sanders,**

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

[FR Doc. 04-20798 Filed 9-14-04; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-2004-0223; FRL-7674-9]

**Acetamiprid; 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 identification (ID) number OPP-2004-0223, must be received on or before October 15, 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:**

Akiva Abramovitch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8328; e-mail address: [abramovitch.akiva@epa.gov](mailto:abramovitch.akiva@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if your rule stated "perform renovations of target housing for compensation. Target housing is defined (see §745.103) as any housing constructed prior to 1978". Potentially affected entities may include, but are not limited to:

- Industry (NAICS code 111)
- Crop production (NAICS code 112)
- Animal production, (NAICS code 311)
- Food 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. 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-2004-0223. 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 South 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 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 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-2004-0223. 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-2004-0223. 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-2004-0223.

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 South Bell St., Arlington, VA, Attention: Docket ID number OPP-2004-0223. 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: August 30, 2004.

**Donald R. Stubbs,**

*Acting 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 Nippon Soda Company, Ltd., 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.

### **Nippon Soda Company**

*PP 4F6833*

EPA has received a pesticide petition (PP 4F6833) from Nippon Soda Co., Ltd. c/o Nisso America Inc., 220 East 42nd

Street, Suite 3002, New York, NY, 10017. This petition proposes, pursuant to Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for the residues of acetamiprid in/on cucurbits, stone fruit, and tree nuts as given below. The proposed analytical method is by LC/MS/MS.

Pursuant to section 408(d)(2) of the FFDCA, as amended by the Food Quality Protection Act (FQPA), Nippon Soda Co., Ltd. has submitted the following summary of information, data and rationales in support of their pesticide petition and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. This summary was prepared by Nippon Soda Co., Ltd.; EPA is in the process of evaluating the petition and has not determined whether the data supports granting of the petition. EPA may have made minor edits to the summary for the purpose of clarity.

#### A. Residue Chemistry

1. *Plant metabolism.* The metabolism of acetamiprid in plants is well understood, having been investigated in eggplant, apples, cabbage, carrots, and cotton. Metabolism in plants primarily involves demethylation of the N-methyl group with subsequent hydrolysis of the acetamidine function to give the N-acetyl compound. This compound is then hydrolyzed to the corresponding amine followed by oxidation to the alcohol and acid. Conjugation of the alcohol with glucose is also significant. Degradation of the side chain without loss of the N-methyl group is seen in carrots since this is the major metabolic route in soil.

2. *Analytical method.* Based upon the metabolism of acetamiprid in plants and the toxicology of the parent and metabolites, quantification of the parent acetamiprid is sufficient to determine toxic residues. As a result a method has been developed which involves extraction of acetamiprid from crops with methanol, filtration, partitioning and cleanup, and analysis by LC/MS/MS methods. The limit of quantification (LOQ) for the method is 0.01 ppm and the method limit of detection (LOD) is 0.003-0.004 ppm for cucurbits, stone fruit, almond and pecan nutmeat. The LOQ and LOD for almond hulls is 0.02 ppm and 0.006 ppm, respectively.

3. *Magnitude of residues.* Magnitude of residue studies were conducted in cucumber, cantaloupe, and squash as the representative commodities for the cucurbit crop grouping. Trials were conducted in all of the major use areas for each of the crops as specified in the

Residue Chemistry Guidelines OPPTS 860.1500 with applications at the maximum label use rate for each crop. As a result of the field trials the following tolerance is proposed for the commodities in the cucurbit crop group: 0.5 ppm.

Magnitude of residue studies were conducted in peach, plum (fresh and dried), sweet cherry, and tart cherry as the representative commodities for the stone fruit crop grouping. Trials were conducted in all of the major use areas for each of the crops as specified in the Residue Chemistry Guidelines OPPTS 860.1500 with applications at the maximum label use rate for each crop. As a result of the field trials, the following tolerance is proposed for the commodities in the stone fruit crop group except plum, prune, fresh and dried: 1.2 ppm. The proposed tolerance for plum, prune, fresh and dried is 0.3 ppm.

Magnitude of residue studies were conducted in almonds and pecans as the representative commodities for the tree nut crop grouping. Trials were conducted in all of the major use areas for each of the crops as specified in the Residue Chemistry Guidelines OPPTS 860.1500 with applications at the maximum label use rate for each crop. As a result of the field trials, the following tolerance is proposed for the commodities in the tree nut crop group except almond hulls: 0.1 ppm. The proposed tolerance for almond hulls is 5.0 ppm.

#### B. Toxicological Profile

1. *Acute toxicity for technical acetamiprid.* The acute oral LD<sub>50</sub> for acetamiprid was 146 milligrams/kilogram (mg/kg) for female Sprague-Dawley rats and 217 for male rats. The acute dermal LD<sub>50</sub> for acetamiprid was greater than 2,000 mg/kg in rats. The acute 4-hour inhalation LC<sub>50</sub> for acetamiprid was greater than 1.15 milligrams/Liter (mg/L), the highest attainable concentration. Acetamiprid was not irritating to the eyes or skin and was not considered to be a sensitizing agent. The no observed effect level (NOEL) for acute neurotoxicity was 10 mg/kg and no evidence of neuropathy was noted.

*Acute toxicity for formulated acetamiprid 70WP.* The acute oral LD<sub>50</sub> for acetamiprid 70WP was 944 mg/kg for female Sprague-Dawley rats and 1,107 mg/kg for male rats. The acute dermal LD<sub>50</sub> for formulated acetamiprid was greater than 2,000 mg/kg in rats. The acute inhalation LC<sub>50</sub> (4-hour) for Acetamiprid 70WP was determined to be greater than 2.88 mg/L, the highest attainable concentration. Acetamiprid

70WP was concluded to be a mild eye irritant and slight skin irritant. There were no indications of skin sensitization for the formulated product.

2. *Genetic toxicity for technical acetamiprid.* Based on the weight of the evidence provided by a complete test battery, acetamiprid is neither mutagenic nor genotoxic. The compound was found to be devoid of mutagenic activity (with and without metabolic activation) in *Salmonella typhimurium* and *E. coli* (Ames assay). Acetamiprid was also not mutagenic in an *in vitro* mammalian cell gene mutation assay on Chinese hamster ovary (CHO) cells (HPRT locus, with and without metabolic activation). Acetamiprid did not induce unscheduled DNA synthesis (UDS) in either rat liver primary cell cultures or in mammalian liver cells *in vivo*. In an *in vitro* chromosomal aberration study using CHO cells, acetamiprid was positive when tested under metabolic activation at cytotoxic dose levels; no effect was detected without metabolic activation. Acetamiprid was non-clastogenic in an *in vivo* chromosomal aberration study in rat bone marrow. It also was negative in an *in vivo* mouse bone marrow micronucleus assay.

3. *Reproductive and developmental toxicity.* In the multi-generation rat reproduction study a NOEL of 100 ppm was established based on decreased body weight gains and a reproduction NOEL of 800 parts per million (ppm) highest dose tested (HDT) was established for reproductive performance and fertility. In the rat teratology study the developmental NOEL was 50 mg/kg/day (maternal NOEL of 16 mg/kg/day based on decreased body weight and food consumption) and in the rabbit teratology study the developmental NOEL was 30 mg/kg/day (maternal NOEL of 15 mg/kg/day based on decreased body weight and food consumption). In both the rat and rabbit studies there were no fetotoxic or teratogenic findings.

A developmental neurotoxicity study in rats with acetamiprid was conducted. The test article was administered orally by gavage to CrI:CD(SD)IGS BR rats once daily from gestation day 6 through lactation day 21 inclusive at dosage levels of 2.5, 10, and 45 mg/kg/day. One female in the 45 mg/kg/day group died during parturition on gestation day 23, following delivery of one pup. All other females survived to the scheduled necropsies. No adverse clinical signs were noted. F0 maternal toxicity was expressed at a dose level of 45 mg/kg/day by a single mortality and reductions in body weight gain and food

consumption. No maternal toxicity was exhibited at dose levels of 2.5 and 10 mg/kg/day. F<sub>1</sub> developmental toxicity was expressed at a dose level of 45 mg/kg/day by early postnatal mortality and reduced post-weaning body weights. No developmental toxicity was exhibited at dose levels of 2.5 and 10 mg/kg/day. Deficits in auditory startle response occurred in the 45 mg/kg/day group F<sub>1</sub> males and females without concomitant effects in other functional endpoints (FOB), neuropathology or brain morphometry. Based on the results of this study, the no observed adverse effect level (NOAEL) for maternal toxicity, developmental toxicity and developmental neurotoxicity is considered to be 10 mg/kg/day.

4. *Subchronic toxicity.* In the 3-month dog feeding study a NOEL of 800 parts per million (ppm) (32 mg/kg/day for both males and females) was established based on growth retardation and decreased food consumption.

In the 3-month rat feeding study a NOEL of 200 ppm (12.4 and 14.6 mg/kg/day respectively for male and female rats) was established based on liver cell hypertrophy at a dose of 800 ppm.

In the 3-month mouse feeding study a NOEL of 400 ppm (53.2 and 64.6 mg/kg/day respectively for male and female mice) was established based on increased liver/body weight ratio and decreased cholesterol in females at 800 ppm.

A 13-week dietary neurotoxicity study for acetamiprid established a NOEL of 200 ppm (14.8 and 16.3 mg/kg for male and female rats) based on reduced body weight and food consumption decreases at 800 ppm. There was no evidence of neurotoxicity.

A 21-day dermal study in rabbits at dose levels up to 1,000 mg/kg/day caused no systemic toxicity, dermal irritation or histomorphological lesions in either sex tested.

5. *Chronic toxicity.* In the 1-year dog study, the NOEL was established at 600 ppm (20 and 21 milligrams/kilogram/day (mg/kg/day) for male and female dogs, respectively) based on growth retardation and decreased food consumption at a dose of 1,500 ppm.

In the 18-month mouse study the NOEL was established at 130 ppm (20.3 and 25.2 mg/kg/day for male and female mice) based on growth retardation and hepatic toxicity at 400 ppm. In the 2-year rat study the NOEL was 160 ppm (7.1 and 8.8 mg/kg/day for male and female rats) based on growth retardation and hepatic toxicity. There were no indications of carcinogenicity in either the rat or mouse chronic studies.

6. *Animal metabolism.* The metabolism of acetamiprid is well

understood and the primary animal metabolite is IM-2-1.

7. *Metabolite toxicology.* Testing of IM-2-1 demonstrated that it is significantly less toxic than the parent acetamiprid and it is not being considered as part of the total toxic residue in plants, therefore, no tolerance is being requested by the registrant. The acute oral LD<sub>50</sub> of IM-2-1 is 2,543 mg/kg for male rats and 1,762 mg/kg for female rats.

8. *Endocrine disruption.* Acetamiprid does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproductive study in rats gave no indication that acetamiprid has any effects on endocrine function. The chronic feeding studies also did not show any long-term effects related to endocrine systems.

### C. Aggregate Exposure

1. *Dietary exposure.* Acute and chronic dietary analyses were conducted to estimate exposure to potential acetamiprid residues in or on the following crops: Cole crop group, citrus crop group, fruiting vegetable crop group, pome fruit crop group, grapes, leafy vegetables, canola oil, mustard seed, cotton, tuberous and corm vegetable crop group, cucurbit crop group, stone fruit crop group, and tree nut crop group using the DEEM™ FCID software. Exposure estimates to drinking water were made based on conservative tier 1 FIRST and SCIGROW modeling.

2. *Food.* The acute dietary exposure estimates at the 99.9<sup>th</sup> percentile for the U.S. population was calculated to be 6.2% of the acute reference dose (aRfD). The population subgroup with the highest exposure was children, 1–2 years old at 19.6% of the aRfD. The acute RfD was based on the NOEL of 10 mg/kg/day in the acute neurotoxicity study in rats. Chronic dietary exposure estimates from residues of acetamiprid and the animal metabolite for the U.S. population was 0.1% of the chronic population adjusted dose (cPAD). The subpopulation with the highest exposure was children 1–2 with 0.6% of the cPAD used. These values are based on projected percentages for percent of crop treated and field trial residues at maximum label rates and minimum pre-harvest interval (PHI) with no reduction factors for common washing, cooking, or preparation practices. These can be considered conservative values. The cPAD was based on the NOEL of 7.1 mg/kg/day in the chronic rat study and, an uncertainty factor of 100 to account for inter-species and intra-species

variations. In the final rule establishing tolerances for acetamiprid on canola and mustard, (September 3, 2003, 68 FR 52343; FRL-7324-1), EPA concluded that a data base uncertainty factor (e.g., FQPA factor) was not needed to account for the lack of a developmental neurotoxicity study with acetamiprid and that reliable data supported removing the additional safety factor (e.g., additional 3-fold or 3X) for the protection of infants and children. Since that time, an oral exposure developmental neurotoxicity study in the rat was conducted with acetamiprid and submitted to EPA. Based on the results of this and other developmental toxicology studies, the inclusion of an additional FQPA uncertainty factor is unwarranted.

3. *Drinking water.* EPA's draft Standard Operating Procedure (SOP) for incorporating estimates of drinking water exposure into aggregate risk assessments was used to perform the drinking water analysis for acetamiprid. This SOP utilizes a variety of tools to conduct drinking water assessments. These tools include water models such as SCI-GROW, first index reservoir screening tool (FIRST), PRZM/EXAMS, and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water. In the case of acetamiprid, monitoring data do not exist, therefore, FIRST and SCIGROW models were used to estimate acetamiprid residues in surface and ground water, respectively. The short-term were greater than 2,000 parts per billion (ppb) while the modeled drinking water estimated concentration (DWEC) was 17 ppb for surface water and 0.0008 ppb for ground water. The intermediate-term DWLOCs were also greater than 2,000 ppb while the modeled DWEC was 4 ppb for surface water and 0.0008 ppb for ground water. The modeled DWEC surface and ground water residues were less than the calculated DWLOCs for short-term and intermediate-term exposures for all adults and toddlers (1–2 years old).

4. *Non-dietary exposure.* A ready to use, dilute formulation of acetamiprid is registered for insect control on outdoor ornamentals, vegetables and fruit trees. Based on surrogate exposure data obtained from a carbaryl study, the homeowner MOE was calculated to exceed ten million. Postapplication exposure resulting from contact with acetamiprid treated foliage resulted in an MOE in excess of 500,000. Additionally a pending use allowing residential applications of formulated acetamiprid both indoors and outdoors resulted in short-term applicator

exposure MOEs of greater than 1,500 and short-term post-application exposure MOEs of greater than 2,000 for adult and toddler exposure scenarios. For intermediate-term post-application exposure following indoor applications, the MOEs for toddlers and adults were greater than 2,500. Short-term and intermediate-term aggregate exposure assessments were conducted using EPA's Draft Guidance for Performing Aggregate Exposure and Risk Assessments which suggests using the total MOE method for aggregating exposures. In the case of acetaminophen, an MOE greater than 100 provides a reasonable certainty that no harm will occur from the assessed uses. Using the total MOE method for aggregating exposures, adults had the lowest MOE estimates in the short-term aggregate assessment while toddlers had the lowest MOE estimates in the intermediate-term aggregate assessment. All short-term aggregate MOEs were greater than 900 and all intermediate-term aggregate MOEs were greater than 2,000. Therefore, there is reasonable certainty that no harm will result from aggregate (food, drinking water, and residential) exposure to acetaminophen residues.

#### D. Cumulative Effects

A determination has not been made that acetaminophen has a common mechanism of toxicity with other substances. Acetaminophen does not appear to produce a common toxic metabolite with other substances. A cumulative risk assessment was therefore not performed for this analysis.

#### E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above and, based on the completeness and reliability of the toxicity data, it is concluded, that aggregate exposure from the existing and proposed uses of acetaminophen will utilize at most 6.2% of the acute reference dose (aRfD) at the 99.9 percentile of exposure and 0.1% of the chronic population adjusted dose (cPAD) for the U.S. population. These percentages are likely to be much less, as more realistic exposure data and models are developed. EPA generally has no concern for exposures below 100% of the aRfD and cPAD. Drinking water levels of comparison (DWLOCs) based on these exposure estimates are much greater than conservative estimated concentrations, and would be expected to be well below the 100% level, if they occur at all. Existing and pending uses allowing residential applications of acetaminophen both

indoors and outdoors resulted in short-term applicator exposure MOEs of greater than 1,500 and short-term post-application exposure MOEs of greater than 2,000 for adult and toddler exposure scenarios. For intermediate-term post-application exposure following indoor applications, the MOEs for adults and toddlers were greater than 2,500. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to acetaminophen.

2. *Infants and children.* In multi-generation reproduction and teratology studies, no adverse effects on reproduction were observed in either rats or rabbits. In the long term feeding studies in rats and mice there was no evidence of carcinogenicity. Acetaminophen was not mutagenic under the conditions of testing. There is no indication of developmental neurotoxicity associated with acetaminophen. Using the conservative assumptions described in the exposure section above, the percent of the acute reference dose (aRfD) that will be used is 19.6% for children 1–2 years old (the most highly exposed sub-group) at the 99.9 percentile of exposure and 0.6% of the chronic population adjusted dose (cPAD). As in the adult situation, drinking water levels of comparison are much higher than the worst case drinking water estimated concentrations and would be expected to use well below 100% of the RfD, if they occur at all. MOEs resulting from post-application exposure to acetaminophen in residential areas are greater than 2,000. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of acetaminophen.

#### F. International Tolerances

Acetaminophen is registered for use on food crops in several countries outside the United States.

[FR Doc. 04–20680 Filed 9–14–04; 8:45 am]

**BILLING CODE 6560–50–S**

## DEPARTMENT OF ENERGY

### Office of Fossil Energy; National Petroleum Council

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting.

This notice announces a meeting of the National Petroleum Council. Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that notice of these meetings be announced in the **Federal Register**.

**DATES:** Thursday, September 30, 2004, 9 a.m.–12 p.m.

**ADDRESSES:** The Westin Embassy Row Hotel, 2100 Massachusetts Ave., NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** James Slutz, U.S. Department of Energy, Office of Fossil Energy, Washington, DC 20585. Phone: 202–586–5600.

**SUPPLEMENTARY INFORMATION:** *Purpose of the Committee:* To provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and gas or the oil and gas industry.

#### *Tentative Agenda:*

- Call to Order and Introductory Remarks
- Remarks by the Honorable E. Spencer Abraham, Secretary of Energy
- Consideration of the Council's Response to the Secretary's Request for Advice on Petroleum Refining and Inventory Matters
  - Administrative Matters
  - Discussion of Any Other Business Properly Brought Before the National Petroleum Council
  - Adjourn

*Public Participation:* The meeting is open to the public. The chairperson of the Council is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement to the Council will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact James Slutz at the address or telephone number listed above. Request must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda.

*Transcripts:* Available for public review and copying at the Public Reading Room, Room 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on September 10, 2004.

**Rachel Samuel,**

*Deputy Advisory Committee, Management Officer.*

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