

do not need to file Initial Briefs in order to file Reply Briefs.

6. In authorizing the emergency transmission and delivery of electric capacity and energy, the Emergency Order limited the service provided by CSC for LIPA as follows:

[T]his order * * * shall be limited to requiring the transmission and delivery of such electric capacity and/or energy as is necessary in the judgment of the New York Independent System Operator to meet the supply and essential reserve margin needs of LIPA * * * and * * * prior to exercising its judgment as required by this order, the New York Independent System Operator must consult with ISO-New England, Inc. to ensure that the *scheduling* of such electric capacity and/or energy will not violate system *operating criteria* * * * (Emphasis added.)

7. The documents in the Referral indicate that "the day that DOE issued the [Emergency] Order, LIPA contacted the NYISO and remained in almost daily telephone and e-mail communication with NYISO to determine what those emergency operating and scheduling protocols would be." The documents further indicate that the "Implementation Protocol for Emergency Operation of the Cross Sound Cable" (Protocol for Emergency CSC Operation) was not made available to LIPA until NYISO sent a facsimile transmission to LIPA on September 23, 2002, one week before the Emergency Order expired.

8. To help the Commission understand the reasons for the delay in establishing the Protocol for Emergency CSC Operation as ordered by the Secretary, and to help the Commission ensure that such a delay does not occur again, NYISO and ISO-New England are hereby directed to answer the following questions on or before January 31, 2003:

A. Explain in detail why NYISO and ISO-New England did not establish the Protocol for Emergency CSC Operation within a week or less of the issuance of the Secretary's Emergency Order.

B. Explain in detail the processes followed and the reasons why it took 38 days to issue the Protocol for Emergency CSC Operation.

C. Explain whether the same processes would be used if the Secretary issued another emergency order. If not, what changes would be made?

D. The fourth paragraph of the Protocol for Emergency CSC Operation states:

All costs associated with energy provided pursuant to the [Emergency] Order and this Protocol shall be governed by the Emergency Transactions Agreement entered into between the NYISO and the New

England Power Pool on August 14, 2000.

(1) Identify and support all costs associated with providing energy under the Emergency Order including expenses associated with establishing the Protocol for Emergency CSC Operation.

(2) Provide a copy of the August 14 Emergency Transactions Agreement and the protocols used to support such agreement.

E. Is there a scheduling and operating protocol which will be used if another emergency order is issued or when the CSC is fully operational?

9. Any comments parties have with respect to the answers provided by the ISOs may be included in separate sections of the Initial or Reply Briefs.

The Commission Orders

(A) Procedures for Commission action on the Referral are hereby established as discussed in the body of this order.

(B) The NYISO and ISO-NE are hereby directed to submit responses, as discussed in the body of this order.

By the Commission.

Magalie R. Salas,
Secretary.

[FR Doc. 03-365 Filed 1-8-03; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7437-2]

EPA Public Meeting—Closing the Gap: Innovative Responses for Sustainable Water Infrastructure; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is hosting a one-day public forum to discuss water and wastewater infrastructure in the United States. EPA's goal is to bring together stakeholders, including those from business, government, and academia, to exchange information and views on management and sustainable financing of the nation's water and wastewater infrastructure. The meeting will be in Washington, DC, on January 31, 2003, starting at 9 a.m. This meeting is open to the public.

The forum will be composed primarily of two moderated expert panels who will offer their insights. At the forum, the audience will have an opportunity to provide questions to be discussed by the experts.

DATES: The meeting will begin at 9 a.m. on January 31, 2003.

ADDRESSES: The meeting will be held in the ballroom at the Marriott at Metro Center at 775 12th Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For more information on the location and agenda of this meeting, and general background information including related documents and reports on water and wastewater infrastructure needs, please see the Office of Water Web Page at <http://www.epa.gov/ow/> or contact the Safe Drinking Water Hotline, phone: (800) 426-4791 or (703) 285-1093. To assist in making arrangements for the number of attendees, please send an e-mail to closingthegap@cadmusgroup.com with the name, title, and organization of each person attending. Seating is limited to 300 people. If you need special accommodations at this meeting, including signing, you should contact Shawna Bergman at (202) 564-3641 by January 24, 2003, so that we can make appropriate arrangements.

Dated: January 3, 2003.

G. Tracy Mehan, III,
Assistant Administrator for Water.
[FR Doc. 03-392 Filed 1-8-03; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0340; FRL-7287-7]

Folpet; 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-2002-0340, must be received on or before February 10, 2003.

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: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7740; e-mail address: giles-parker.cynthia@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 identification (ID) number OPP-2002-0340. 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. 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-2002-0340. 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-2002-0340. 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-2002-0340.

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-2002-0340. 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: January 2, 2003.

Debra Edwards,

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 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.

Makhteshim-Agan of North America Inc.

2E6512

EPA has received a pesticide petition (2E6512) from Makhteshim-Agan of North America Inc. (MANA), 551 Fifth Ave., Suite 1100 New York, NY 10176 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 folpet *N*-[(trichloromethyl)]thiophthalimide in or on the raw agricultural commodity hop at 120 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 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 of folpet in plants is adequately understood based on acceptable avocado, grape and wheat metabolism studies. The metabolism of folpet in livestock is adequately understood. Based on the results observed in the metabolism studies, secondary residues such as phthalimide and phthalic acid are not expected to be of toxicological concern. The residue of concern is folpet per se.

2. *Analytical method.* An adequate gas chromatography/electron capture detector (GC/ECD) analytical method is available for enforcing tolerances of folpet in or on plant commodities. The method of detection had a limit of detection (LOD) of 0.01 mg/kg (ppm) and a limit of quantitation (LOQ) of 0.02 milligrams/kilogram (mg/kg) (ppm) in dried hops.

3. *Magnitude of residues.* Five residue trials have been conducted in Bavaria, Germany during 1996 and 1997. The hops were treated up to 8 times per season at a rate of up to 4.3 kg active ingredients/hectare (a.i./ha) (up to 23 kg a.i./ha per season), considering a 14 day PHI. After kiln drying, the measured residues in hops ranged from 25 to 65 ppm. Folpet was not detectable in any of the processed hop commodities (LOD for spent hops = 0.01 ppm; beer = 0.003 ppm). The generated data support the requested tolerance.

B. Toxicological Profile

1. *Acute toxicity.* In studies using laboratory animals, in general folpet has been shown to be of low acute toxicity: The acute oral LD₅₀ and the acute dermal LD₅₀ in rats were greater than 5,000 mg/kg. The acute rat inhalation LC₅₀ (4-hour) was 0.48 mg/l. Folpet was irritating to the eyes of rabbits. It was not irritating to rabbit skin in a standard dermal irritation study but was a dermal sensitizer in a guinea pig maximization study. Based on these results, folpet is expected to be classified as TOXICITY CATEGORY IV for acute oral and dermal toxicity, and skin irritation, and as TOXICITY CATEGORY II for acute inhalation toxicity, and eye irritation.

2. *Genotoxicity.* Folpet was tested for genotoxic effects in several standard tests. Folpet is neither mutagenic nor genotoxic in mammals. In some of the *in vitro* studies mutagenic events were observed, such as gene mutations/DNA damage in bacteria and mammalian cells, chromosomal aberrations in mammalian cells and mitotic recombination in yeast. However, folpet does not present a genotoxic risk based on the fact that folpet degrades with a half-life of 0.97 seconds *in vivo*. This fast detoxification effectively eliminates systemic exposure to folpet or thiophosgene.

3. *Reproductive and developmental toxicity.* In an oral developmental study with New Zealand rabbits, the maternal and developmental no observed adverse effect level (NOAEL) was 10 mg/kg/day based on decreased food consumption, increased number of fetuses and litters with hydrocephalus and associated skull malformations at the lowest observed adverse effect level (LOAEL) of 20 mg/kg/day. In the rat developmental study the developmental no observed effect level (NOEL) was 60 mg/kg and the lowest observed effect level (LOEL) was 360 mg/kg.

A two-generation reproductive study in rats produced a parental NOEL of 34.5 mg/kg/day. There was a marginal decrease in the body weight of the F₁ offspring at birth and during lactation

but no other changes in physical, functional, or behavioral endpoints were observed. The NOEL in the F₂ of 40 mg/kg/day was based on decreased body weight gain and decreased fertility of the males. The LOEL in this study was 180 mg/kg.

For both developmental and reproductive bioassays, the effects elicited by folpet are considered secondary to its primary effect: irritancy of the gastrointestinal tract. Folpet is absent in the systemic circulation and its initial ring degradate, phthalimide, has been shown not to be a developmental toxin.

4. *Subchronic toxicity.* In a 90-day feeding study in rats, the NOEL was established at 3,000 ppm and the LOEL was 10,000 ppm. Noted effects were decreased brain weight and decreased total blood protein including albumin.

In a subchronic dermal toxicity study, folpet was applied to rats at dose levels of 0, 1, 10, and 30 mg/kg body weight for 6 hours per day, 5 days a week, for a total of 21 days over a period of 30 days. All folpet treated rats developed pronounced dermal irritation in a dose-related manner. Systemic toxicity based on decreased body weight gain was observed at 10 and 30 mg/kg dose levels, but without clearly separating this effect to the severe skin damage.

5. *Chronic toxicity.* A 2-year feeding chronic toxicity/carcinogenicity study in rats was conducted with folpet at dietary concentrations of 0, 200, 800, or 3,200 ppm. For chronic toxicity, the NOAEL was 200 ppm (9 mg/kg/day) and the LOAEL was 800 ppm (35 mg/kg) based on hyperkeratosis/acanthosis and ulceration/erosion of the non-glandular stomach in males and females. No evidence of carcinogenicity was observed in this study.

A 2-year feeding chronic toxicity/carcinogenicity study in CD-1 mice showed a statistically significant, dose-related increase in the incidence of duodenal adenocarcinomas with an increase of about 50% at the highest dose tested (1,429 mg/kg/day). A similar response was seen in a chronic feeding study with B6C3F1 mice at the highest dose tested (HDT) of 1,000 mg/kg.

In previous assessments, the Agency has concluded that folpet is a Group B2 carcinogen, based on the increased incidences of duodenal adenomas and carcinomas in males and females of two strains of mice.

6. *Animal metabolism.* Results from the livestock and rat metabolism studies showed that orally administered folpet was rapidly absorbed, hydrolyzed and metabolized, followed by rapid elimination, predominantly via the urine. The major fecal degradate was

phthalamic acid, while phthalic acid was a minor degradate. Most of the applied dose was excreted within 24 hours.

7. *Metabolite toxicology.* There are no folpet metabolites identified in plant or animal commodities, which require regulation.

8. *Endocrine disruption.* The standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. There is no evidence which suggests that folpet is an endocrine disrupter. The existing studies are generally considered to be sufficient to detect any endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure.* Potential dietary exposures from food under the existing tolerances for domestic uses (avocados) and imported commodities (apples, cranberries, cucumbers, grapes, lettuce, melons, onions, strawberries, and tomatoes), were estimated using the Dietary Exposure Evaluation Model (DEEM) for acute and chronic exposure based on the U.S. Department of Agriculture's (USDA) 1989–1992 individual consumption data. Residue data were based on field trials and percent crop information along with processing factors from submitted studies. No data from USDA's Pesticide Data Program (PDP) were available for folpet.

i. *Food.* Acute dietary exposure was compared to the acute population adjusted dose (aPAD), which utilizes 25.3% for females (15–50 years) at the 99th percentile, the only population group of concern for the acute Reference Dose (aRfD = 0.03 mg/kg/day, using the NOAEL of 10 mg/kg from the rabbit study, and the FQPA safety factor of 3X).

The results of the chronic (non-cancer) dietary analysis indicate that the chronic Population Adjusted Dose (cPAD) was below 1% for the U.S. population and its most sensitive subgroups based on a cRfD of 0.09 mg/kg/day.

Concerning the dietary cancer risk, the Agency's calculated upper bound risk was 9.8×10^{-8} , based on a Q* of 0.00186 mg/kg/day⁻¹, using field trial data, processing factors and percent crop treated information. This risk level is far less than EPA's level of concern of 1×10^{-6} .

Based on USDA's consumption data not more than 0.0022% of the U.S. population diet is constituted of hops

(Federal Register of June 1, 2000, Vol. 65, No 106, p. 35069–35090, Table 10; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food). Furthermore, USDA's import statistics show that not more than 38% of beer consumed in the USA is imported and/or contains imported hops, which translates into a diet contribution from imported hops of not more than 0.0007%. For the purposes of this risk assessment, it was also demonstrated in brewing studies using hops treated with folpet at maximum label rates (range of residues: 25 to 65 ppm) and exaggerated hopping rates (0.002% or up to 2 g per liter wort) that no folpet residues could be measured in the finished beer (LOD = 0.003 ppm). Hopping rates in beer production are usually less than 0.001% in brew water (wort). Even considering that trace amounts of folpet would enter the brewing process, it will be rapidly hydrolyzed and completely degraded by the end of the beer brewing.

In view of this information and assumptions, the resulting dietary risk contribution via imported hops is negligible, even if 100% of the imported hops would be treated with folpet at maximum label rates.

ii. *Drinking water.* The potential for folpet to leach into groundwater or contaminate surface water is very limited considering that folpet is currently only registered for the use on avocados in two counties in Florida. Based on the available information, the predicted residues in drinking water do not indicate an unacceptable contribution to acute or chronic dietary exposure at this time. Since the proposed petition does not add any new uses or exposures to it, contribution of any folpet residues in drinking water to the total dietary intake is negligible.

2. *Non-dietary exposure.* Not applicable.

D. Cumulative Effects

There is a common mechanism of toxicity that folpet shares with captan with regard to its carcinogenicity in the mouse. Folpet and captan share the common metabolite, thiophosgene, which contributes to the irritancy of the duodenum in mice along with the parent compounds, leading (at dose levels above the established threshold and for administration with sufficient time) to adenomas. Thiophosgene reacts not only with thiol groups, as does folpet and captan, but also with a variety of other functional groups. This instability results in its rapid loss. The cumulative effect of captan and folpet oral exposure is of theoretical interest only, as the threshold for irritancy in the

mouse duodenum is above 60 mg/kg/day (captan) or 50 mg/kg/day (folpet). If the mouse test system reflected human susceptibility, a 70 kg individual would need to consume more than 3.5 grams folpet plus captan in order to approach the NOEL of 50 mg/kg/day. Given the expected residue levels of folpet and those of captan, this is not possible.

E. Safety Determination

1. *U.S. population.* Using the exposure assumptions described above, MANA concludes that the total dietary exposure to folpet is acceptable. According to import information statistics from the USDA and under the conservative (worst-case) dietary exposure assumption described above, not more than 0.0022% of the U.S. population diet is constituted of hops, which means not more than 0.0007% can potentially be contributed to imported hops. Based on these insignificant dietary contributions, MANA considers the potential folpet residue contribution negligible, concluding that the most sensitive population group of concern are still females (15–50 years) with an aPAD of 25% and a cPAD of <1%. There is generally no concern for exposures below 100% of the PAD since it represents the level at or below which no appreciable risks to human health is posed. The upper bound calculated dietary cancer risk was 9.8×10^{-8} , based on a Q^* of 0.00186 mg/kg/day⁻¹, which is far less than EPA's level of concern of 1×10^{-6} .

Thus, there is reasonable certainty that no harm will result to the U.S. population in general or to any of its subgroups of concern from aggregate exposure to folpet residues in or on imported hops.

2. *Infants and children.* Data from rat and rabbit development toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from pre-natal and post-natal exposure to the pesticide.

FFDCA Section 408 provides that the Agency may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity or incompleteness of the database. However, the toxicology database for folpet regarding potential pre- and post-natal effects in offspring is complete

according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns.

EPA assigned an FQPA safety factor of 3x in the 1999 Reregistration Eligibility Decision (RED). This was based on the apparent hydrocephaly seen in New Zealand rabbits. Subsequently, additional data were provided to the Agency that showed folpet does not induce hydrocephaly. The Agency agreed with the assessment contained in the submitted document and rescinded its request for a new rabbit study. The Agency has not, as of yet, removed the FQPA 3x safety factor. A FQPA safety factor of 1x would be also consistent with that of captan. The appropriate acute Reference Dose (aRfD) for folpet, calculated with a FQPA safety factor of 1x, would be 0.01 mg/kg/day. This aRfD should be used in future assessments concerning the potential risks to infants and children. However, for the purpose of this assessment, MANA used the existing aRfD of 0.03 mg/kg/day, as it was done in the 1999 RED.

MANA concludes that there is a reasonable certainty that no harm will result to infants and children from the anticipated dietary exposure to residues of folpet and considering that the proposed import tolerance does not affect foods and beverages legally consumed by children and infants.

F. International Tolerances

Germany has established an MRL (maximum residue limit) of 120 ppm for residues of folpet in dried hops. No CODEX MRL for hops exists.

[FR Doc. 03–389 Filed 1–8–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7437–1]

Proposed CERCLA Section 122(h)(1) Administrative Agreement for Recovery of Response Costs for the City Chemical Corporation Site, Hudson County, Jersey City, NJ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency ("EPA"), Region II, of a