less than 12.5% of the cPAD for the total U.S. population and all the subpopulations. The greatest exposure occurred in infants and children. Exposure estimates for the acute dietary assessment were well under 100% of the acute population adjusted dose (aPAD) at the 99th percentile. The overall U.S. population and the highest exposed subpopulation (infants <1 year) utilized only 5.3% and less than 21%, respectively.

ii. *Drinking water.* There are no established maximum contaminant levels or health advisory levels for residues of BAS 670 H or its metabolites in drinking water. A tier 1 drinking water modeling assessment for BAS 670 H using the FIRST model (for surface water) and SCI-GROW (for ground water) produced estimated maximum concentrations of 0.22 parts per billion (ppb) (chronic) for surface water and 0.20 ppb for ground water. These estimated concentrations are less than a worst case calculated acceptable level of 3.95 ppb children chronic drinking water levels of concern (DWLOC) for residues in drinking water based on chronic aggregate exposure. Therefore, taking into account all uses and exposures one concludes, with reasonable certainty that residues of BAS 670 H in drinking water will not result in unacceptable levels of aggregate human health risk at this time.

2. *Non-dietary exposure.* There are no registered or proposed residential uses for BAS 670 H.

D. Cumulative Effects

At this time, there is no available information to indicate that BAS 670 H or its metabolites have a common mechanism of toxicity with other substances. Therefore, there is no reason to include this pesticide or its metabolites in a cumulative risk assessment. For the purposes of this tolerance action, EPA has not assumed that BAS 670 H and its metabolites have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Aggregate exposure to the overall U.S. population utilized only 8.7% of the aPAD and 12.7% of the cPAD, respectively. Therefore, no harm to the overall U.S. population would result from the use of BAS 670 H on field, sweet, or pop corn.

2. *Infants and children.* There is a complete toxicity base for BAS 670 H and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Taking into account the completeness of the data base, BASF Corporation concludes that the FQPA safety factor should be retained but reduced to 3X. This is based on the occurrence of kidney malformations in rabbits and skeletal variations in rabbits and rats, all occurring at doses, which caused either maternal tyrosine elevations or other evidence of maternal toxicity. The full toxicological data base that has been developed for BAS 670 H includes many additional mechanistic studies, revealing consistency and the mode of action of these effects. The kidney was a target organ in all repeated dose studies and these effects were caused by elevated tyrosine levels due to inhibition of the HPPD enzyme. Using the standard worst case exposure assumptions (residues at tolerance level and 100% crop treated), aggregate exposure to BAS 670 H from food and water will utilize 33% and less than 24% of the aPAD and cPAD, respectively for infants and children. EPA generally has no concern for exposures below 100% of the PAD because it represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. BASF Corporation concludes that there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to BAS 670 H residues with the approval of this tolerance petition.

F. International Tolerances

No maximum residue levels (MRLs) have been established for BAS 670 H by the CODEX Alimentarius Commission or in Mexico.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0177; FRL–7308–7]

Acetic Acid; Notice of Filing a Pesticide Petition to Establish an Exemption from the Requirements of 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–2003–0177, must be received on or before July 11, 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: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address:*benmhend.driss@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–2003–0177. 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 EPA's 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–2003–0177. 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–2003–0177. 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–2003–0177.

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–2003–0177. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or

CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: May 22, 2003.

Sheryl K. Reilly,

Acting Director, Biopesticides and Pollution Prevention 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 pesticide chemical residues or an explanation of why no such method is needed.

Eastman Chemical Company

PP 3F6516

EPA has received a pesticide petition (3F6516) from Eastman Chemical Company, P.O. Box 511, Kingsport, TN 37662 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide acetic acid. Pursuant to section 408(d)(2)(A)(i) of the FFDCA as amended, Eastman Chemical Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. The summary of the petition was prepared by the petitioner and represent 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.

It is the purpose of this petition to re-establish an exemption from the requirement of a tolerance for acetic acid when used as a grain and hay preservative on agricultural commodities such as alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay.

Acetic acid is currently exempt from the requirement of a tolerance when used as a catalyst under 40 CFR 180.1001(c). Previously, acetic acid was exempt from the requirement of a tolerance (40 CFR 180.1029), when used as a preservative on the above-mentioned commodities. This exemption was canceled, but only because the registrants at that time, did not wish to maintain the registration. Subsequent to the cancellation of the registrations, the tolerance exemption was revoked.

A. Residue Chemistry

There have been no analytical procedures conducted to ascertain residual acetic acid on treated commodities. The application rate for the preservation of grain and hay as per instructions, will result in concentrations of about 1% on hay and about 1.5% on grain. Additionally, acetic acid is generally recognized as safe (GRAS) under the Food and Drug Administration (FDA), 40 CFR 184.1005, for use in food when used in accordance with good manufacturing or feeding practice.

Since this request is for an exemption from the requirement of a tolerance, residual acetic acid on hay and grain will not pose a problem of exposure to humans or the environment especially since acetic acid is in the food chain and is naturally occurring in nature. Residuals at this low level are less than is found in vinegar used on foods.

B. Toxicological Profile

1. *Acute toxicity*. Acute oral at 4,960 milligrams/kilogram body weight (mg/kg) (bwt) (Category III). Acute dermal at 1,060 mg/kg bwt (Category II). Acute inhalation at 11.4 milligrams/Liter (mg/L) (Category III). Eye irritation, corrosive (Category I). Dermal irritation, corrosive (Category I). Mild irritant to guinea pigs at 20 mg/24 hours. (Category IV). Contact with concentrated acetic acid solutions may cause local damage to skin, eye, or mucosa.

2. *Genotoxicity*. Acetic acid and the sodium salt of acetic acid, provided negative results for mutagenicity assays in strains of *Salmonella typhimurium*.

3. *Reproductive and developmental toxicity*. In a teratogenicity study by the Food and Drug Research Laboratories, 5% acetic acid (apple cider vinegar), the administration of up to 1,600 mg/kg bwt, to pregnant mice for 10 consecutive days had no clear discernible effect on nidation or on maternal or fetal survival.

Additionally, similar acids to acetic acid, such as fumaric acid and citric acid, illicit no teratogenic or reproductive toxicity in rats or chick embryos. This is also true for propionic acid (or salts thereof) which is used in the same manner as proposed for acetic acid.

4. *Subchronic toxicity*. Waivers have been requested for the 90–day feeding, dermal and inhalation studies. The conditions of potential exposure requiring these studies are not triggered. Acetic acid is a food acid and is naturally occurring. Acetic acid is absorbed from the gastrointestinal tract and through the lungs and is readily, although not completely, oxidized in the organism. Acetic acid is proposed to be used as a hay and grain preservative at low concentrations, and for animal food only, and these low concentrations are lower than is found in commercially available vinegar (5% to 7%). Therefore, there would be no expected subchronic effects from the limited exposure expected to acetic acid, and the waivers should be granted.

5. *Chronic toxicity*. Waivers have been requested for chronic toxicity requirements for acetic acid. However, the results of two Russian studies reported the induction of hyperplasia in rats at 60 mg/kg bwt. This result is similar to induction of hyperplasia in rats by propionic acid in a 2–year study.

6. *Animal metabolism*. Acetic acid is a food acid and is naturally occurring. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Kreb's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria. Acetic acid is proposed to be used as a hay and grain preservative at low concentrations, and for animal food only. There are no expected adverse effects.

7. *Metabolite toxicity*. Acetic acid is a food acid and is naturally occurring in the environment as well as in plants and animals. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Kreb's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria.

C. Aggregate Exposure

1. *Dietary exposure*. Acetic acid is a food acid and is naturally occurring in plants and animals. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Kreb's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria.

Acetic acid is most commonly encountered by the human population in the form of vinegar, varying in concentration of acetic acid, from 4–7%. Acetic acid is considered generally recognized as safe (GRAS) by FDA when directly added to foods (20 CFR 184.1005). There are no reports in the literature of contact sensitization to vinegar.

Used in accord with instructions for the preservation of grain and hay, the concentration of acetic acid on the commodities used for animal food, will be less than 2%. Dietary exposure to acetic acid used in this application will therefore pose no threat to humans or the environment.

2. *Non-dietary exposure*. The only non-dietary exposure to acetic acid is the occupational exposure. Acetic acid end-use products are sprayed on grains and hay at application rates in ranges of less than 3% on the commodity, depending on the moisture content of the treated crop. Based on the use patterns, the potential for exposure of applicators and workers in the field being treated with acetic acid could be significant. However, applicators are generally confined in the cab of the tractor pulling the collecting systems to which the applicating sprays are attached. The hay or grain collected would contain less than 3% of the acetic acid and therefore subsequent exposure to the crop would cause no significant exposure to the acetic acid.

Certain protective clothing is recommended for acetic acid users due to eye and skin hazards associated with the handling of concentrated acetic acid and the use of such clothing and protective equipment is presented on the label.

D. Cumulative Effects

Acetic acid is used similarly as propionic acid, for the preservation of hay and grains. Under an aerobic conditions propionic acid acts as a carbon source for various microbes and is metabolized to acetic acid, methane, carbon dioxide, and water. For propionic acid, the metabolite of acetic acid poses no problems because acetic acid is also found in the food chain, is naturally occurring, and is applied in the same manner as propionic acid as a pesticide. For propionic acid all environmental fate data requirements are waived for the uses this petition requests for acetic acid. There should be no concern for cumulative effects for acetic acid as well.

E. Safety Determination

Human health assessment—i. *U.S. population*. Acetic acid is a normal component of metabolism in the human body and humans ordinarily consume acetic acid as vinegar, as a natural component of common foods, and as an added ingredient. Dietary exposure from pesticidal use would be very low.

ii. *Infants and children*. As noted above acetic acid is produced by the human body. Humans include infants and children as well as adults. For the same reasons as above, dietary exposure from pesticidal use would be of minimal concern.

F. Tolerance Exemptions for the Proposed Uses

The petitioner proposes that the use of acetic acid as a grain and hay preservative be granted an exemption from the requirement of a tolerance, as proposed below:

1. Post-harvest application of acetic acid, when used as a fungicide or preservative is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities: Alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut hay, peavine hay, rye grass, sorghum grain, soybean hay, sudan grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay.

2. Acetic acid is exempt from the requirement of a tolerance for residues in or on meat, and meat by-products: Cattle, sheep, hogs, goats, horses, and poultry, milk, and eggs when applied as a bactericide/fungicide to livestock drinking water, poultry litter, and storage areas for silage and grain.

3. Post-harvest application of acetic acid when used as a fungicide/preservative is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities: Cottonseed, peanuts, rice grain, and soybeans.

Noticeably, this tolerance exemption request re-establishes the same exemption criteria as was previously granted for acetic acid for this use.

G. International Tolerances

There are no known international tolerances for residues of acetic acid in food or animal feed.

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