

EIS No. 980264, Draft EIS, NOA, FL, Guana, Tolomato, Matanzas, Site Designation, National Estuarine Research Reserve, Management Plan, City of Jacksonville, St. Johns and Flagler Counties, FL, *Due*: August 31, 1998. *Contact*: Stephanie Thornton (301) 713-3125.

EIS No. 980265, Draft EIS, AFS, VT, Mount Snow/Haystack Resort, Expansion of Snowmaking Coverage and Development of Alternative Water Supplies, Special-Use-Permit and COE Section 404 Permit, Green Mountain National Forest, Manchester Ranger District, Windham County, VT, *Due*: August 31, 1998. *Contact*: Nancy Burt (802) 747-6742.

EIS No. 980266, Draft EIS, UAF, NM, University of New Mexico (UNM), Construction of the Enchanted Skies Park and Observatory on Horace Mesa near Grants, Cibola County, NM, *Due*: August 31, 1998. *Contact*: Julia Cantrell (210) 536-3515.

EIS No. 980268, Draft Supplement, AFS, AZ, Grand Canyon/Tusayan Growth Area Improvements, Updated Information on three New Alternatives, General Management Plan (GMP), Special-Use-Permit, Land Exchange Options, Approval and Licenses Issuance, Coconino County, AZ, *Due*: September 02, 1998. *Contact*: R. Dennis Lund (520) 635-8200.

Dated: July 14, 1998.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 98-19120 Filed 7-16-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[PF-820; FRL-6019-1]

BASF Corporation; Pesticide Tolerance Petition Filing

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 the docket control number PF-820, must be received on or before August 17, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of

Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Beth Edwards, Insecticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 206, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5400; e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of 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 section 408(d)(2); 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-820] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not

include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF-820) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: July 13, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing them in any way. 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.

BASF Corporation

PP 4E4411

EPA has received a pesticide petition (PP 4E4411) from BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.448 by establishing a tolerance for residues of hexythiazox [trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide] and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-

thiazolidine moiety (expressed as parts per million (ppm) of the parent compound), in or on the raw agricultural commodity dried hops. The proposed analytical method is gas chromatography using Nitrogen Phosphorous detection. 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 and animal metabolism.

BASF Corporation notes that metabolism in plants and animals is understood.

2. *Analytical method.* The proposed analytical method involves methanol extraction, clean-up by partition, and detection of residues by gc with npd.

3. *Magnitude of residues.* Nine residue trials were conducted in Bavaria Germany. The method of detection had a limit of detection of 0.05 ppm. After kiln drying, hops residues ranged from 0.61 to 1.53 ppm and averaged approximately 0.9 ppm.

B. Toxicological Profile

1. *Acute toxicity.* For the technical grade active ingredient:

Acute oral toxicity—Rat. LD₅₀ >5,000 milligram/kilograms (mg/kg) (Tox Category IV); *Acute Dermal Toxicity (rat)* LD₅₀ > 5,000 mg/kg (Tox Category III); *Acute Inhalation Toxicity (rat)* LC₅₀ > 2.0 mg/l (4 hrs) (Tox Category IV); *Primary Eye Irritation (rabbit)* - Hexythiazox is a mild ocular irritant (Tox Category III); *Primary Dermal irritation (rabbit)* - Hexythiazox is not a dermal irritant (Tox Category IV); *Dermal Sensitization (guinea pig)* - Hexythiazox is not a dermal sensitizer.

2. *Genotoxicity.* All mutagenicity tests were negative. *Ames Testing.* Negative (Accession No. 072941). *In vitro* cytogenicity (Chinese hamster ovary cells): Negative (MRID 00156894). *Rat primary hepatocyte unscheduled DNA synthesis assay* (MRID 00156893). *Mammalian cell forward gene mutation assay* (MRID 00155154).

3. *Reproductive and developmental toxicity—i. Developmental toxicity—Rat.* The maternal toxicity NOEL was determined to be 240 mg/kg/day. The fetotoxicity NOEL was 240 mg/kg/day, and the compound was not embryotoxic at the highest dose tested (HDT), 2,160 mg/kg/day (MRID 00147578).

ii. *Developmental toxicity—Rabbit.* No development or maternal toxicity

was observed at the HDT, 1,080 mg/kg/day (MRID 00146555).

iii. *Multi-generation reproduction—Rat.* The parental toxicity NOEL was determined to be 20 mg/kg/day. No reproductive effects were observed at 2,400 ppm (200 mg/kg/day), the HDT.

4. *Chronic toxicity.* The data submitted in support of this tolerance and other relevant material have been reviewed. The toxicological and metabolism data considered in support of this tolerance are discussed in detail in related documents published in the **Federal Registers** of April 26, 1989 (54 FR 17947), and February 21, 1996 (61 FR 6552) (FRL-5350-6).

5. *Chronic toxicity non-rodent—Dog and rodent—Rat.* The NOEL for chronic effects for hexythiazox is 2.5 mg/kg/day, based upon a 1-year dog study, and the RfD is 0.025 mg/kg/day (MRID 00146556, 00151359, and 00156895). A 2-year rat study showed a systemic NOEL of 430 ppm (21.5 mg/kg/day, MRID 00146559). No evidence of oncogenicity was observed in this study.

6. *Oncogenicity in the rodent—Mouse.* Hexythiazox produced an oncogenic effect in the livers of female mice (MRID 00147577, 00156896, 40328701, and 40328702) with a systemic NOEL of 250 ppm (37.5 mg/kg/day). The Agency has calculated an oncogenic potential of Q* = 0.039 (mg/kg/day)-1.

7. *Hormonal effects.* No specific hormonal effects testing has been conducted with hexythiazox, however, the compound was tested in two developmental bioassays and a multi-generation reproduction bioassay. No hormonal effects were noted in these relevant tests.

8. *Threshold effects.* A chronic dietary exposure/risk assessment has been performed for hexythiazox using the established reference dose (RfD) of 0.025 mg/kg-bwt/day. The RfD was based on a NOEL of 2.5 mg/kg/day from a 1-year dog feeding study.

9. *Non-threshold effects.* The Agency has classified hexythiazox as a class C (possible human) carcinogen based on a significantly increased incidence of hepatocellular carcinomas (p=0.028), and adenomas/carcinomas combined (p=0.024) in female mice at the HDT (1,500 ppm) when compared to the controls as well as a significantly increased (p> 0.001) incidence of preneo-plastic hepatic nodules in both males and females at the HDT (1,500 ppm). The decision supporting a Category C classification (rather than a Category B) was based primarily on the fact that only one species was affected (mouse), mutagenicity assays did not support upgrading to a B classification,

and structure-activity relationship of hexythiazox to other compounds supported a C classification. In classifying hexythiazox as a Category C carcinogen, the Agency concluded that a quantitative estimate of the carcinogenic potential for humans should be calculated because of the increased incidence of malignant liver tumors in the female mouse.

Thus, a Q* of 3.9×10^{-2} (mg/kg/day)-1 in human equivalents has been calculated. A full review of the data indicates that although hexythiazox is a carcinogen in mice, the risks would be extremely small from the proposed use on hops. Estimated dietary carcinogenic risk to the general population based on the highly conservative assumptions that all imported hops are treated with hexythiazox and would bear residues at the proposed tolerance level is estimated to be approximately 3×10^{-7} . In fact, the Agency estimated in 1993, that the most conservative estimate of the percentage of beer containing foreign grown hops (including imported beer and domestic beer brewed with imported hops) to be approximately 49%. In addition, the average residue seen in the residue studies supporting this tolerance was approximately 0.9 ppm. Incorporating this information into the risk calculation the estimated oncogenic risk from the proposed use is reduced to approximately 7×10^{-8} . Even this is an overestimation, as the calculations assume that the level of hexythiazox in finished beer is the same as the level in the dried hops. BASF has supplied information which demonstrates that finished beer brewed with hops containing an average level of 1.16 ppm results in hexythiazox levels of <0.05 ppm in the finished beer. Assuming a level of 0.05 ppm in beer produced from hops would further reduce the theoretical risk to approximately 4×10^{-9} .

A chronic dietary exposure/risk assessment has been performed for hexythiazox using a RfD of 0.025 mg/kg-bwt/day. The RfD was based on a NOEL of 2.5 mg/kg/day from a 1-year dog feeding study and a safety factor of 100. The endpoint effect of concern was hypertrophy of the adrenal cortex in both sexes, decreased red blood cell counts, hemoglobin content and hematocrit in males. The analysis was performed using tolerance level residues and 100% crop treated information. The exposure for established tolerances and the current proposal utilizes <1% of the RfD for the U.S. population.

C. Aggregate Exposure

1. *Dietary exposure.* The exposure for established tolerances and the current

proposal utilizes <1% of the RfD for the U.S. population. Non-nursing infants <1 represent the most exposed sub-population and the percent of the RfD consumed by this group is <3%. BASF has estimated the theoretical oncogenic risk for the currently registered uses of hexythiazox (apples and pears) to be approximately 1.5×10^{-6} . This risk number includes the very conservative assumptions that all apples and pears are treated with hexythiazox and that all resulting residues are at the tolerance level. In its recent FR Notice establishing the tolerance in apples the Agency recognized these conservative overestimations and concluded "in reality, the Agency knows that all apples would not be treated with this pesticide and expect that even apples receiving maximum treatment will have residues far below tolerance level. For example, in field trials conducted using application rates 10 times the label amount, residues in apples still did not exceed the tolerance level. Further, the maximum residue level (MRL) in apple juice would be expected to be less than 50% of the residue level in whole fruit. Based on an assessment of the cancer risks of the proposed use of hexythiazox, the Agency believes that the proposed use of hexythiazox on apples will pose an extremely small risk to humans." The current proposal will not increase the theoretical oncogenic risk significantly.

In addition, the Agency has concluded that based on the residue and feeding levels of spent hops "meat and milk tolerances are not required for this petition."

2. "Other" exposure. Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Since this tolerance is for an "imported use," BASF does not anticipate exposure to residues of hexythiazox in drinking water. BASF has not estimated non-occupational exposure for hexythiazox. Since the current registrations for hexythiazox in the United States are limited to commercial apple/pear production, the potential for non-occupational exposure to the general population is considered to be insignificant.

D. Cumulative Effects

BASF also considered the potential for cumulative effects of hexythiazox and other substances that have a common mechanism of toxicity. BASF is unaware of any conclusive data regarding the potential for hexythiazox to share a common mechanism for toxic effects with any other compound. In

dietary assessment, the food factor for hops is only 0.03%. Therefore, BASF concluded that any concern regarding a common mechanism of toxicity would be insignificant.

E. Safety Determination

1. *U.S. population.* Using the exposure assumptions described above, BASF concludes that aggregate exposure to hexythiazox will utilize approximately <1% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD. In addition the calculated theoretical oncogenic risk associated with this use is more than 100 times less than the Agency's general level of concern (1×10^{-6}).

Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of hexythiazox, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* The toxicity database includes both developmental and reproductive testing in which no significant concerns were identified. BASF therefore believes the established RfD of 0.025 mg/kg/day is the appropriate approach for assessing risk in children. Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of hexythiazox, including all anticipated dietary exposure and all other non-occupational exposures.

F. Other Considerations

The qualitative nature of the residues in plants and animals is adequately understood. There is a practical analytical method for detecting and measuring levels of hexythiazox in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances.

G. International Tolerances

A maximum residue level has not been established for hexythiazox by the Codex Alimentarius Commission.

[FR Doc. 98-19247 Filed 7-16-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6126-2]

Report on the Shrimp Virus Peer Review Workshop

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of a draft final report.

SUMMARY: This document announces the availability of a draft final report of a peer review and risk assessment workshop, sponsored by the U.S. Environmental Protection Agency (EPA), National Center for Environmental Assessment, on behalf of the Joint Subcommittee on Aquaculture (JSA), National Science and Technology Council, held January 7-8, 1998. The report entitled, "Report on the Shrimp Virus Peer Review and Risk Assessment Workshop: Developing a Qualitative Risk Assessment" (EPA/630/R-98/001A), was completed under contract to the EPA. It develops a qualitative ecological risk assessment describing the potential risks of nonindigenous pathogenic shrimp viruses on wild shrimp populations in U.S. coastal waters. Expert conclusions and recommendations contained in the report are currently undergoing an independent scientific review. The results of this independent review and the draft final report will be used as the basis for a risk management workshop on shrimp viruses scheduled for July 28-29, 1998 in New Orleans (see 63 FR 36895-36896 (July 8, 1998)).

DATES: The report will be available on or about July 24, 1998.

ADDRESSES: An electronic version of the draft final report will be accessible on the EPA National Center for Environmental Assessment home page at <http://www.epa.gov/ncea/>.

FOR FURTHER INFORMATION CONTACT: Dr. H. Kay Austin, U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment (8601D), 401 M Street, SW, Washington, DC 20460; telephone (202) 564-3328; fax: (202) 565-0066; e-mail austin.kay@epa.gov. For technical assistance contact Dr. Tom McIlwain, Chairperson of the JSA Shrimp Virus Work Group, National Marine Fisheries Service, 3209 Frederick Street, Pascagoula, MS 39567, (601) 762-4591.

SUPPLEMENTARY INFORMATION: Public concerns over the potential introduction and spread of nonindigenous pathogenic shrimp viruses to the wild shrimp fishery and shrimp aquaculture